



RESEARCH ARTICLE

EFFECTS OF SHORT TERM TUBERCULOSIS TREATMENT UNDER DIRECT SUPERVISION
ON THE PERFORMANCE INDICATOR OF NATIONAL TUBERCULOSIS CONTROL
PROGRAMME, GAZAN, 1438 H

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ABSTRACT

Tuberculosis is still a health problem of global concern, WHO estimates that there is two millions deaths annually and eight millions new cases of TB and encourages all countries to adopt all strategies to control TB and Directly Observed Therapy Short Term (DOTS) is one of these strategies. Therefore, the kingdom of Saudi Arabia adopted the implementation of DOTS in 2000 at facility level and then at community level in 2013. This is a descriptive study aims at identifying the effect of DOTS implementation at community level on the national tuberculosis program indicators. The main question of the study is that: what is the effect of CBDOTS on the national TB program performance indicators? The data were collected with two well-constructed and pre tested questionnaires with well-trained data collectors. Moreover, it includes all the registered patients in national tuberculosis registry in 2011 and 2014 and all the health workers in the program. It is found that there is no statistical significant difference between the program indicators before and after the implementation of directly observed therapy short term at community level, and there are many administrative factors affecting the program performance such as the absence of policies, procedures and strategic planning. The study recommends the upgrading of the policies, procedures and the strategy to cope with the global movement towards TB elimination, updating and expanding of the laboratory net for TB diagnosis, implementing the quality measures especially in laboratory services and ensuring all the financial resources for the strategy implementation.

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INTRODUCTION

On March 24, 1882, Dr. Robert Koch announced the discovery of *Mycobacterium tuberculosis*, the bacteria that cause tuberculosis (TB) (www.cdc.gov/tb/worldtbd/day/history.htm). Tuberculosis considered as one of the reemerging diseases with high prevalence rates. World Health Organization (WHO) considers TB as a global public health emergency and endorsed short term direct observed treatment strategy (DOTS) in 1995.

It is built on observing and monitoring the patients (WHO Global Report 2016; Prado et al., 2011), the supervisor of patient follow-up during the treatment period may be a nominated health worker that take advantage of a family member or a trained volunteer, community based direct observed treatment (CBDOT) has been adopted in many countries with the aim of reducing workload on health facilities; especially in high-burden countries (Nardell and Dharmadhikari, 2010). KSA adopted this strategy in 2000 and established an implementation at the hospital level by admitting the patients for two months receive treatment as in patient and continue for the coming four months at health

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center level (KSA Ministry of Health Report 2000). DOTS strategy strengthened public sector tuberculosis programs to tackle a large burden of the disease. The Stop TB Strategy, built on DOTS, helped to begin addressing drug resistant tuberculosis and HIV-associated tuberculosis while promoting research to develop new tools (WHO, End TB Strategy 2015). The Sustainable Development Goals (SDGs) for 2030 was adopted by the United Nations in 2015. One of its targets is to end the global TB epidemic. Gazan Province has been selected for the application as a first phase in 2013 in order to be assessing experience in preparation for distribution to other areas if it is successful. Therefore, ten field teams had been selected for this purpose; each team consists of doctor, nurse, and Epidemiology, in addition to a technician supervises both patients' treatment and screening of contacts and following them until cured indoors instead of admission in health facilities.

MATERIALS AND METHODS

This is cross sectional study conducted in Gazan Province. It is one of the smallest (11,670 km²) administrative areas of the Kingdom, located in the south-western tip of the country with a coastal boundary 260 km along the Red Sea and a 120 km border with the Republic of Yemen. The Yemeni border was finally and officially ratified following disputed 1934 boundaries in June 2000 as part of the Jeddah Treaty (1927). The present study aims at identifying the impact of the implementation of DOTS in community (CBDOT) on the national tuberculosis program performance indicators, detecting the administrative, financial and technical constrains facing the program, and the means of overcoming these constrains. It included all registered TB cases in national TB registers in 2013- 2014 and all health workers were included in the study. The study main question is that: what is the effect of CBDOTS on the national TB program performance indicators? The data were collected with two well-constructed and pre tested questionnaires with well-trained data collectors. There are four study dimensions: administrative, financial, technical, and constrains that affect the national TB program and tools to overcome all constrain affect the national TB program performance.

Statistical Analysis

Many statistical procedures were used to analyze the data. Frequencies, and percentage are made for the result mean, in addition, standard deviation, P value, chi², ANOVA test were also used to determine the differences in the study population responses.

RESULTS

This study included 451 patients registered in national TB program, in addition to all health workers in the program. All results and information come from the national TB registry check list and questionnaire with health worker in the program. Thus, all variables were coded, P value was considered (0,05), and SPSS program was used to manage the data and the results. The results were formulated as follows:

- The number of cases registered in the National Tuberculosis Registry was (233) before the implementation of (CBDOTS) and (218) after implementation. The number of registered cases

revealed clearly that despite the efforts made in the program, it was not reflected in the incidence rates, as is the case at the level of the country according to the statistical report for the year 2015 and the study is consistent with the study of Elquraini (Elquraini and Elmagdi, 2010).

- The main reason behinds the re planning in controlling TB in the kingdom is to be in line with the end TB strategy goals of the 2015; since Global Strategy for TB Care is considered to be one of fundamental issues (Elhadooog, 2010).
- The distribution of patients according to nationality revealed that there is a number of Saudis among the patients (336); represents 74.5%. Non-Saudis represents (115; 25.5%) and they were mainly from Ethiopia (6.2%), and Yemen (6%). Male patients represent about 66.7% and the rest were females; representing 33.3%.
- Most of the patients were concentrated in the productive age group between 15 and 45 years, and most of the registered patients were in the unemployed category and are the poorest and vulnerable group similar to study conduct in Netherlands (Martien W. Borgdorff *et al.*, 2001).
- The pulmonary tuberculosis patients represent 355 (78.7%) %; and about (57.4%) of them were found positive sputum smear.

As shown in the above Table, there are no statistically significant differences between the two strategies in the treatment outcomes before and after implementation of (CBDOTS). This finding rejects the first hypothesis of the study that: *there are differences with statistical significance in the performance indicators between the strategy of treatment in the community (CBDOTS) and the strategy of treatment in health facilities (HDOTS)*. It is clear from Table 1 above that in the treatment failure [OR (95%CI) 0.55(0.09-3.06) and P value 0.496], the mortality rate [95% CI (0.31-3.97) and P value 0.859], the cure rate before and after the strategy were applied to [OR (95%CI) 1.17 (0.56-2.48), and P value 0.672]. This result was consistent with several studies in this aspect such as the one conducted in Tanzania by Wandwalo, *et al.* (2004), (Wandwalo *et al.*, 2004; Elmahalli and Abdel-Aziz, 2004). It also differs from the study conduct in Nigeria (Adewole *et al.*, 2015). The second part of study presents the results of the questionnaire filled with health workers in TB program. It includes the demographic characteristics of the health, moreover, both workers and variables were coded according *Likert Scale* to five score (strongly agree- agree – neutral – disagree –strongly dis agree), and P value is determined less than (0.05).

The result was as follows

There were (66) employees in the national tuberculosis Programme most of them aged ranged between 35-44 years at 57.2%, males represent 49, at 74.2, and the proportion of physicians was 27.3%, nursing was 33.3% and epidemiologists was only 34.8%. It is clear from the above Table that, in the administrative constrains; more than 50% of the employees agreed upon the lack of policies and procedures and the absence of strategic planning (Mean 4.5 and 4.15) were the largest. In addition, the administrative constrains facing the program, from their point of view, have been statistically significant and have (P value 0.003-0.009).

Table 1. The distribution of treatment outcome

Treatment outcome (n=254)	DOTS		OR (95%CI)	P. value
	Before	After		
Total Recruited	134	120		
Default	2	0		
Treatment Failure	4	2	0.55(0.09-3.06)	0.496
Deported	7	7	1.12(0.38-3.30)	0.883
Died	5	5	1.12(0.31-3.97)	0.859
Cured	116	106	1.17(0.56-2.48)	0.672

Table 2. Participants views on the of Administrative constrains

Statement	strongly agree	agree	Neutral	Disagree	Strongly disagree	Mean	SD	(Chi ²)	P value
deficiency of policy and procedure	15 (22.7%)	14 (21.2%)	9 (13.6%)	12 (18.2%)	15 (22.7%)	4.5	1.168	9.5	0.009
absence of strategic planning	12 (18.2%)	26 (39.4%)	4 (6.1%)	15 (22.7%)	9 (13.6%)	4.15	1.463	13.769	0.003
unclear structure	8 (12.1%)	26 (39.4%)	4 (6.1%)	12 (18.2%)	16 (24.2%)	3.38	1.557	0.846	0.838
no communication system	2 (3.0%)	11 (16.7%)	16 (24.2)	27 (40.9%)	10 (15.2%)	2.31	0.751	2	0.368
weak electronic management	3 (4.5%)	12 (18.2%)	21 (31.8)	21 (31.8)	9 (13.6%)	2.52	0.154	25.667	0.758

Table 3. Participants' views on the of financial constrains

Financial constrains	strongly agree	agree	Neutral	disagree	Strongly disagree	Mean	SD	(² Chi)	P value
Interrupted incentives	48 (72.7%)	13 (19.7%)	2 (3.0%)	2(3.0%)	1 (1.5%)	4.69	1.109	9.308	0.002
No nutritional program for patients	46 (69.7%)	18 (27.3 %)	1 (1.5%)	1 (1.5%)	1 (7.7%)	4.54	1.127	11.231	0.004
No budget for health education	33 (50.0%)	20 (30.3%)	7 (10.6%)	2 (3.0%)	4 (6.1%)	4.08	1.441	2.923	0.232
No budget for the program	39 (59.1%)	22 (33.3%)	1 (1.5%)	3 (4.5%)	1 (1.5%)	4.69	1.109	9.308	0.002
Old transport vehicles	16 (24.2)	9 (13.6%)	9 (13.6%)	22 (33.3%)	10 (15.2%)	2.15	1.281	5.077	0.279

Table 4. Participants' views on the of technical constrains

Technical constrains	Strongly agree	Agree	Neutral	Dis agree	Strongly dis agree	Mean	SD	(² Chi)	P value
Weak case notification	33.3	10 (15.2%)	8 (12.1%)	23 (34.8%)	3 (4.5%)	4.31	1.316	13.769	0.003
Deficiency in laboratories in the region	57.6	22 (33.3%)	5 (7.6%)	1 (1.5%)	0 (0.0%)	4.85	0.555	9.308	0.002
Difficulties in management of MDR case in the region	42.4	21 (31.8%)	15 (22.7%)	2 (3.0%)	0 (0.0%)	4.77	0.599	15.585	0
Weak early case detection in centers	27.3	13 (19.7%)	14 (21.2%)	16 (24.2%)	3 (4.5%)	3	1.414	2.462	0.292
Weak training in contact investigation	16.7	8 (12.1%)	17 (25.8%)	27 (40.9%)	3 (4.5%)	3.15	1.214	6.385	0.094
Unavailability of regular treatment	21.2	8 (12.1%)	4 (6.1%)	22 (33.3%)	18 (27.3 %)	3.62	1.66	3.308	0.347
Unavailability of tuberculin test	31.8	10 (15.2%)	2 (3.0%)	32 (48.5%)	1 (1.5%)	3.5	1.121	15.385	0
Difficulties in management of MDR case in the region	48.5	26 (39.4%)	5 (7.6%)	3 (4.5%)	0 (0.0%)	4.32	0.81	39.59	0.002
Unavailability of sputum test in some center	63.6	17 (25.8%)	6 (9.1%)	1 (1.5%)	0 (0.0%)	4.62	0.768	11.231	0.004
Isolation rooms are not adequate	28.8	30 (45.5%)	10 (15.2%)	4 (6.1%)	2 (3.0%)	3.31	1.377	2.923	0

Table 5. Health care worker views on the means to overcome the main obstacles

Means to overcome the main obstacles	mean	SD	(Chi2)	p value	order
Provision of financial resources	4.85	0.4	82.74	0	Second
Expansion of laboratories services	4.89	0.31	40.97	0	First
Provision of tuberculin test	4.79	0.45	68.27	0	Fifth
Issuing of standard operation procedures	4.7	0.63	99.58	0	Seventh
Support for health education system	4.74	0.54	62.82	0	Sixth
Attention to patient nutrition	4.79	0.41	21.88	0	Fifth
Provision of MDR drug	4.88	0.33	37.88	0	Third
Improving culture	4.83	0.38	29.33	0	Fourth
Application of early detection system	4.59	0.77	79.63	0	Eighth

Table 6. ANOVA of study participants views according to job title

Domains	Job title	Mean	SD	F. Value	P. value
Administrative Obstacles	Doctors	2.62	0.77	0.774	0.513
	Nurses	2.93	1.12		
	Epi tech	2.98	1.20		
	Lab tech	3.53	1.15		
Financial Barriers	Doctors	2.90	1.07	0.311	0.817
	Nurses	4.21	0.60		
	Epi tech	4.21	0.61		
	Lab tech	4.06	0.68		
Solutions Strategies	Doctors	4.27	0.23	3.214	0.029*
	Nurses	4.16	0.61		
	Epi tech	4.86	0.26		
	Lab tech	4.65	0.43		
Technical barriers	Doctors	4.90	0.31	0.414	0.744
	Nurses	4.41	0.53		
	Epi tech	4.78	0.37		
	Lab tech	3.51	0.60		

Table 7. Least Significant Difference (LSD) of the participants views according to Job title – Strategic Solutions Domain

(I) Occupation	(J) Occupation	Mean Difference (I-J)	P. Value	95% Confidence Interval	
				Lower Bound	Upper Bound
Doctors	Nurse	.21156	.065	-.0133-	.4364
	Epi tech	-.04198-	.716	-.2718-	.1879
	Lab tech	.45062*	.045	.0094	.8918
Nurses	Doctor	-.21156-	.065	-.4364-	.0133
	Epi tech	-.25354*	.024	-.4721-	-.0350-
	Lab tech	.23906	.276	-.1963-	.6745
Epi tech	Doctor	.04198	.716	-.1879-	.2718
	Nurse	.25354*	.024	.0350	.4721
	Lab tech	.49259*	.028	.0546	.9306
Lab tech	Doctor	-.45062*	.045	-.8918-	-.0094-
	Nurse	-.23906-	.276	-.6745-	.1963
	Epi tech	-.49259*	.028	-.9306-	-.0546-

This confirms the hypothesis of the study of *the existence of a relationship between the administrative factors and the performance of the national tuberculosis control program, and the development of strategic plans to achieve the vision and objectives of the program with a statistically significance methods*. On the other hands, the study shows that the existence of clear policies and procedures in the implementation of the strategy has a high impact on the performance of the program. More than (45.4%) of all employees found that the appropriate means of communication and electronic management did not constitute an impediment to the work of the program and were not statistically significant P value 0.368. Regards to financial constraints, more than 92% of employees agreed on that the biggest financial constrains for the program performance was the interruption of incentives for employees at Mean (4.69) and P value (0.002) followed by the lack of a special budget for the program with an average Mean (4.69) P value (0.002). This is consistent with the study hypothesis that: *(there is a relationship with a significant effect between the financial factors and the performance of the national program to control tuberculosis)*, elements of the short-term treatment strategy, the government commitment to program support and confirmed by the End TB Strategy (Global Strategy for Prevention, Cure and Control of TB after 2015), and the need for political commitment to adequate resources for tuberculosis care and prevention.

A response of the study population to the technical constrains questions were as follows:

- Firstly, the workers stated that the shortage in the laboratory network is the most important technical factor with the Mean (4.85) and P value (0.002).

- Secondly: The workers also totally reported that the difficulty of treating drug-resistant patients was an obstacle to program performance, with the Mean (4.77) and P value (0.000).
- Thirdly: the workers stated the availability of sputum examination; in health centers and hospitals same as culture and sensitivity test on a regular basis (4.62, 4.32) and P value (0.002). And (0.004) is very important points.

The above mentioned results are consistent with study hypothesis that: *there is a relationship between the technical factors and the performance of the national tuberculosis control program*. Studies show that one of the most important elements of the success of the DOTS strategy is early diagnosis and case detection by microscopy of the sputum smear which should be technically feasible anywhere. Significant progress has been made in establishing a scientific consensus on ensuring the quality of the sputum examination and is still not available in all facilities. It necessitates consideration of the expansion of the laboratory network within the region and attention to quality standards. The study also shows the importance of the diagnosis and treatment of drug-resistant TB cases, which started to threaten many countries in the world. There has recently been a large-scale outbreak of drug-resistant TB even in countries that are supposed to adopt WHO recommendations. The misuse of type 2 drugs has contributed to this outbreak. According to the health workers, the most important means of overcoming the special factors influencing the programme's performance were the expansion of the laboratory network and the availability of sputum tests, as well as the availability of the programme budget and the provision of drug-resistant treatment.

It becomes apparent from Table 6 that there was no variation in the opinions of the workers with respect to the factors determining the performance of the TB programme except for the means to overcome the influencing factors where it was (F value 3.214, P value 0.029. The LSD test shows the disparity in the opinions of the employees that the difference was between the doctors and the lab technician P value and (0.045).

Reconditions

The study recommends that:

1. The policies, procedures and objectives of the national tuberculosis control program should be updated in line with the objectives of the end-of-tuberculosis strategy (Global Strategy for Prevention, Cure and Control of TB after 2015).
2. Developing a program to eliminate latent TB as a means of expanding the examination and treatment of the most vulnerable groups and establishing a register of registration, reporting and epidemiological surveillance should be one of priorities.
3. Expanding the network of qualified laboratories in hospitals and health centers capable of diagnosing tuberculosis should be accounted for.
4. Applying quality standards in the laboratory for diagnosis of tuberculosis, and the establishment of a central unit on quality control should be started soon.
5. Providing a special budget for the needs of the program to maintain continuous quality of performance should be focused on.
6. The program, policies and procedures should be adopted and strict control of their application correctly so as to prevent the emergence of strains resistant to drugs.
7. Studies and researches should be conducted to identify the existence of drug resistant strains.
8. Training and capacity-building of human resources should be considered.
9. The strategy in terms of cost and method of implementation to be consistent with the objectives of the program should be reviewed.
10. The implementation of strategy in the Kingdom is costly with no clear impact in TB program performance indicators, which make the need for evaluation of CBDOTS implementation is mandatory task.

Conclusion

The study concluded that:

- There are no statistically significant differences between the two strategies in treatment outcome.
- There are administrative factors affecting the performance of the program employees, the most important ones are: lack of policies and procedures, and the absence of strategic planning.
- The financial factors affecting the performance of the program are many. The most important of which is the absence of a budget for the program and the

interruption of incentives for workers, as well as the technical factors affecting the performance of the program.

- The study showed that there are important technical factors affecting the performance of the program, the most important of which are: (lack of laboratory network, difficulty in treating drug resistant cases, and lack of tests in health centers and hospitals).

Challenges

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