

# Evaluation of Directly Observed Short Course Treatment (DOTS) Program in Kerbala province in Iraq between 2005 and 2017

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**Objective** To study the outcomes of treatment among the patients put on DOTS in Kerbala governorate since the initiation of DOTS strategy in October 2000.

**Methods** All quarterly reports were collected in addition to the annual reports to estimate the outcome indices of DOTS in the governorate. Discussion with experts working for decades in TB control programs revealed some defect in determining these indices.

**Results** Between 1988 and 2017 there was a total of 8665 TB patients. Pulmonary TB patients formed 62% and extra-pulmonary TB formed 38%. Gender distribution showed male predilection (60.3%) and a mean age of patients was  $41.88 \pm 19.74$  year and one half of the patients were above 44 year of age, but the most frequent age group was 25–34 years. Positive smear case detection rates were below the WHO planned goals ranging from 11.5% and 29.1%. The total reported deaths during the study period were 78 deaths. Defaulters were 97 patients at a rate of 2.39, while treatment failure cases amounted to 33 patients (a rate of 0.81%). Drug sensitivity test was introduced to country in 2010 and was done only in Baghdad till the introduction of Genexpert MTB/RIF test in January 2014 and a total of 72 patients were MDR cases.

**Conclusions** The success in DOTS in Kerbala is similar to the results in Iraq and in most developing countries and approaching the WHO set goals. However, the case detection rates were behind. Some defect areas need further support to prevent failure and aid TB control.

**Keywords** case detection rate, directly observed treatment short-course, Kerbala, smear-positive and -negative, extra-pulmonary tuberculosis

## Introduction

Tuberculosis (TB) is one of the most ancient diseases of mankind, as molecular evidence go back to over 17,000 years or perhaps for several million years.<sup>1</sup> According to World Health Organization (WHO), TB is a worldwide pandemic and is considered as the main infectious killing diseases worldwide and is just second to HIV in incidence. TB incidence has fallen by an average of 1.5% per year since 2000 and is now 18% lower than the level of 2000.<sup>2</sup>

The “STOP TB” strategy was planned to eliminate TB as a public health problem from the world by 2050.<sup>3</sup> In addition the sustainable development goals for 2030 adopted by the United Nations in 2015, put one of the targets ‘to end the global TB epidemic.’<sup>2</sup> The WHO End TB Strategy calls for 90% reduction in TB deaths and 80% reduction in the TB incidence rate by 2030, compared with 2015.<sup>2</sup>

In 2015, there were an estimated 10.4 million new (incident) TB cases worldwide, however, globally there was a 4.3 million gap between incident and notified case.<sup>2</sup> The rate of decline in TB incidence remained at only 1.5% from 2014 to 2015. This rate is below the goal of 4–5% annual decline by 2020 to reach the first milestones of the End TB Strategy.<sup>2</sup>

For mortality, there were an estimated 1.4 million TB deaths in 2015, and an additional 0.4 million deaths resulting from TB disease among people living with HIV. Over 95% of TB deaths occur in low- and middle-income countries.<sup>4</sup> This number of TB deaths fell by 22% between 2000 and 2015, however, TB remained one of the top 10 causes of death worldwide in 2015.<sup>2</sup> Many of these live in the world’s poorest, most vulnerable communities or are among marginalized populations such as migrant workers, refugees and internally displaced persons, prisoners, indigenous peoples, ethnic minorities, and drug users. The social impact of TB is great,

as it renders these poor patients debilitated, emaciated and unable to work and is associated with loss of appetite leading to under-nutrition which will further aggravate symptoms and leads to a vicious circle ending in suffering and death. Here, it is important to consider that most patients are in their main productive age groups and mostly males who represent the single family ‘money earner’ especially in poor societies.

Two main problems are faced in TB control, the infectivity in spite of mild symptoms and compliance with a long troublesome therapy. A patient with TB can infect up to 15 other people through close contact over the course of a year.<sup>3</sup> For this case detection rate (CDR) is a key element in TB control and is a major deficit in most national control problem in developing countries.<sup>5–7</sup> New molecular techniques were added to improve CDR which depended on direct sputum slide examination and culture; such as GeneXpert MTB/RIF. This test was introduced in Kerbala/Iraq in January 2014 and had increased CDR.<sup>8–10</sup>

When TB is detected the patient needs a 6-month treatment that involves taking several pills two to three times a week and can be associated with side-effects. For this reason, it is difficult to ensure compliance, especially since the symptoms of the disease often disappears after the first few weeks of therapy. Fundamental dangerous problems result from incomplete treatment: failure, recurrence and multiple drug resistant forms of TB.<sup>7</sup>

The WHO declared TB as a global emergency in 1993, and directly-observed treatment, short-course (DOTS) was the internationally accepted strategy to combat TB epidemic. It has been adopted in most countries around the world with great proved positive impact on disease control.<sup>7,11–17</sup>

Many previous studies tried to evaluate the efficiency of DOTS in a retrospective comparative study between DOTS and self-administered treatment in Southern India analyzed 150 case record files of patients with pulmonary TB. The treatment outcome in DOTS group was cured 70.7%, treatment completed 1.3%, failure 5.3%, deaths 10.7%, defaulters 8%, and transferred out 4% whereas in self-administered treatment group, cure was seen in 68% and 4% completed the treatment, 1.3% had treatment failure, and 26.7% were lost to follow up. However, the treatment success rate was similar (72%) in both groups.<sup>18</sup> Another study in Northeastern Nigeria collected the quarterly reports between 2003 and 2012 and reported a total of 31 198 new TB cases of all types. Two fifths of these were smear-positive pulmonary TB and 33.8% and 26.2% for smear-negative pulmonary TB and extra-pulmonary TB cases, respectively. An average CDR of 19.1% and treatment success rate of 85.5% for smear-positive pulmonary TB were reported.<sup>12</sup> A prospective study followed 302 TB patients in Aligarh District, Uttar Pradesh/India in 2012/2013 and found that males formed 72.2% of the sample and were mostly in the age group of 15–30 years. More than one half (53%) resided in urban areas; 63.6% were literate; and 45% had a high standard of living index (SLI). Treatment outcome was significantly associated with age group, literacy status, and SLI ( $P < 0.05$ ). On logistic regression, the 31–45 years age group, literacy, and high SLI were found to be significantly associated with good treatment outcome.<sup>13</sup>

The WHO Eastern Mediterranean Region accounted for only 7% of the estimated global TB cases in 2016, while most cases occurred in East Asia Region (45%) and the African Region (25%). The annual incident TB cases relative to population size (the incidence rate) varied widely among countries in 2016, from under 10 per 100,000 population in most high-income countries to 150–300 in most of the 30 high TB burden countries.<sup>4</sup>

High fertility remains a continuous phenomenon in Iraq with a total fertility rate of 4.3, where population almost tripled between 1970 (10 million) and 2010 and estimates that by 2030, it will have quadrupled to almost 50 million.<sup>19</sup> The country is still recovering from long period of wars, sanction, conflict, and political turmoil that affect all the infrastructure foundations in the country. Historically speaking, TB remained as a major killer in Iraq in the previous century and with moderate to high burden.<sup>7</sup> The annual incidence of TB showed an increase from 90.8 per 100,000 in 1980 to 125.6 per 100,000 in the 1990s,<sup>20</sup> as a result of the economic sanction imposed on the country after Kuwait invasion. In 2011, 9248 cases of tuberculosis were reported, with a notification rate of 28 cases per 100,000 population. As a result of deteriorating socioeconomic conditions during the past decade, the incidence of tuberculosis has been on the rise.<sup>19</sup> The WHO estimated incidence rate is decreasing from 167 to 43 per 100,000 population between 2002 and 2015.<sup>7,19,21</sup>

The implementation of DOTS in Iraq was started in October 2000 as pilot project in Al Sader district in Baghdad and it was expanded in 2004 to include all the governorates.<sup>7</sup> However, great difficulties and obstacles faced the program implementation.<sup>7,21</sup> Many previous studies tried to evaluate the efficiency of DOTS in Iraq, but most of these studies lack the sound methodology. In 1998 Ameen conducted a study to evaluate the early pilot project where DOTS was implemented in Al-Sader district in Baghdad. Treatment success rate of

pulmonary TB was 82%, treatment failure 4.4%, defaulter rate 6% and death rate 1.2%.<sup>22</sup> Later on, many published studies tried to evaluate DOTS program in Iraq,<sup>7,19,21</sup> and in different Iraqi governorates: Al-Sader district in Baghdad,<sup>6</sup> Najaf,<sup>23,24</sup> Babylon,<sup>25</sup> Dywania,<sup>26</sup> Misan,<sup>27</sup> Basrah,<sup>28</sup> Salah-Eldeen,<sup>29</sup> Baqoba,<sup>30</sup> and Anbar.<sup>31</sup> Most studies reported failure to reach WHO set target for case detection while cure success and conversion rates of smear-positive cases were approached.

A national plan was signed with the WHO and it included in its sixth strategic goal an objective of 'Accelerating implementation of the Stop TB Strategy through expanding and enhancing implantation of the DOTS strategy, strengthening capacity of the national tuberculosis program and other partners, improving surveillance and supporting operational and epidemiological research.'<sup>19</sup>

## Materials and Methods

Ethical approval to examine patients' case files was given by Kerbala Health Directorate and the ethical committee in Kerbala Medical College. The study was descriptive and this entailed retrospective study of case files and record of positive TB cases at the respiratory diseases consultation clinic and Districts Health Sectors in Kerbala governorate and review of national reports.

Evaluation indices included the CDRs, sputum conversion rates, cure rate, treatment success rate, default rates and contact tracing during the study period between 2005 and 2017. The quarterly reports which reflect previous 9 months treatment outcomes were reviewed in addition to the annual reports to estimate the outcome indices of DOTS in the governorate. Data were analyzed using SPSS-20 software. Deep interrogation and discussion with experts working in TB control programs in the governorate for decades revealed the main obstacles in TB control.

## Results

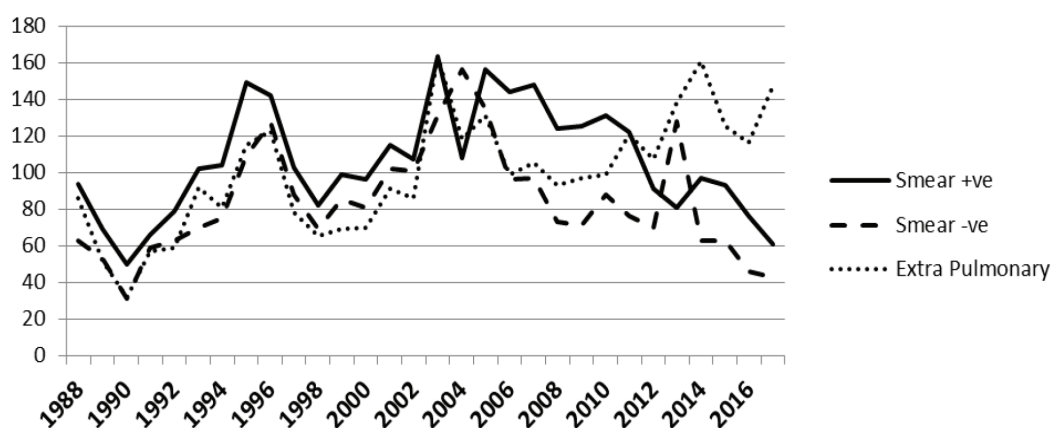
Revision of total TB cases in Kerbala governorate by type for the last 30 years between 1988 and 2017 showed a total of 8665 patients with smear-positive pulmonary TB forming 36.7%, and smear-negative pulmonary TB forming 29.9%, while extra-pulmonary TB forming 34.4%. The mean annual incidence of total TB cases was 288.8 case per year including: 105.9 case of smear-positive pulmonary TB was, 83.7 case of smear-negative pulmonary TB and 99.2 case extra-pulmonary TB. The median endemic index increased from 69 patients in the first 5 years to 104, 99,148, and 124 in following periods but decreased to 81 in the last 5 years (Table 1 and Fig. 1).

The detailed information was available for the period between 2005 and 2017, where a total of 2514 pulmonary TB patients (62%) and 1514 extra-pulmonary tuberculosis patients (38%) were reported making a total of 4055 patients (Table 2). Male were affected more than females where males formed 60.3% of total TB patients, with a male to female ratio of 1.52:1.

The data obtained for age distribution were for the period between 2009 and 2017 where ENRS program was run. TB patients mean age was  $41.88 \pm 19.74$  year and the most frequent age group was 25–34 years and about one half (45.8%) of the patients were above 44 years of age (Fig. 2). On comparing the proportion of age groups distribution of sputum

**Table 1. The distribution of total tuberculosis patients by type in Kerbala governorate between 1988 and 2017 (n = 8665)**

Year	Smear-positive	Smear-negative	Extra-Pulmonary	Total	Median endemic index
1988	94	63	86	243	69
1989	69	53	52	174	
1990	50	31	32	113	
1991	66	59	57	182	
1992	79	63	59	201	104
1993	102	70	92	264	
1994	104	75	81	260	
1995	149	109	115	373	
1996	142	127	123	392	
1997	103	88	78	269	99
1998	82	69	65	216	
1999	99	85	69	253	
2000	96	81	70	247	
2001	115	102	91	308	
2002	107	101	86	294	148
2003	163	131	163	457	
2004	108	156	118	382	
2005	156	135	131	422	
2006	144	96	99	339	
2007	148	97	105	350	124
2008	124	73	93	290	
2009	125	71	97	293	
2010	131	88	99	318	
2011	122	76	121	319	
2012	91	70	107	268	81
2013	81	128	138	347	
2014	97	63	161	321	
2015	93	63	125	281	
2016	76	46	116	238	
2017	61	43	147	251	
Total	3177 (36.66%)	2512 (28.99%)	2976 (34.35%)	8665 (100%)	



**Fig. 1 The distribution of total tuberculosis patients by type in Kerbala governorate between 1988 and 2017 (n = 8665).**

Table 2. The indices for DOTS evaluation among tuberculosis patients in Kerbala governorate between 2005 and 2017 (n = 4055)

Year	Positive sputum smear	Negative sputum smear	Extra-pulmonary TB	Total TB cases	Pulmonary TB Incidence per 100,000	Recurrent TB cases	Estimated TB cases	Post smear case detection rate	Total cases case detection rate
2005	156	135	131	422	34.4	9	560	27.9	75.4
2006	144	96	99	339	27.4	6	510	28.2	66.5
2007	148	97	105	350	27.0	15	509	29.1	68.8
2008	124	73	93	290	21.0	7	500	24.8	58.0
2009	131	71	97	299	20.8	6	500	26.2	59.8
2010	131	88	99	318	21.8	11	500	26.2	63.6
2011	122	76	121	319	19.2	3	500	24.4	63.8
2012	91	70	107	268	15.1	9	456	20.0	58.8
2013	81	128	138	347	19.0	7	495	16.4	70.1
2014	97	63	161	321	14.1	11	517	18.8	62.1
2015	93	63	125	281	13.4	11	500	18.6	56.2
2016	84	48	118	250	11.0	12	520	16.2	48.0
2017	61	43	147	251	8.4	12	529	11.5	50.0
Total	1463	1051	1541	4055	0.0281	119	6596	22.2	61.5

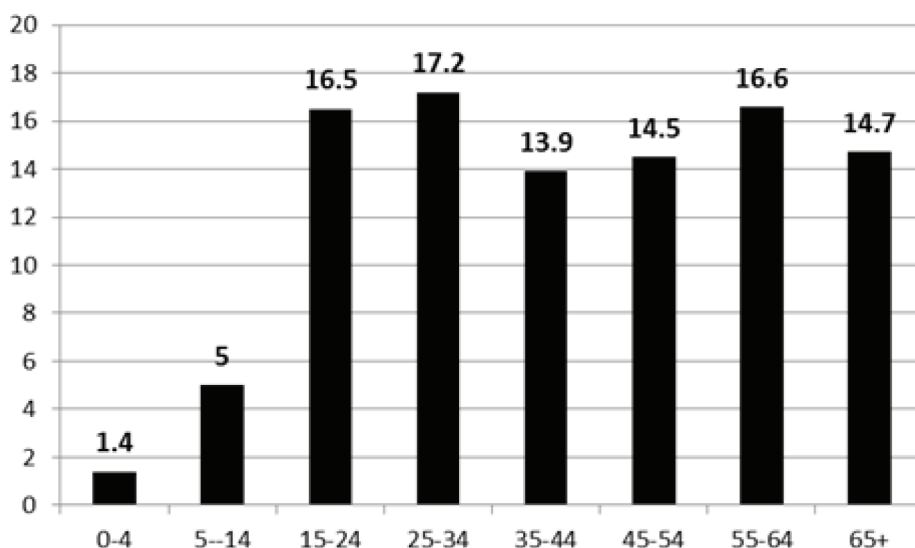


Fig. 2 The age distribution of total tuberculosis patients by in Kerbala governorate between 2009 and 2017 (n = 2456).

smear-positive tuberculosis patients in Kerbala governorate with available national TB patients age distribution showed almost similar distribution except the lower proportion those between 5 and 14 years of age in Kerbala governorate (Fig. 2).

The indices for DOTS evaluation showed that a total of 4055 patients were diagnosed with TB in the 13 years study period with a total CDR of 61.5% and the annual cases ranged between 250 and 422 patients.

Positive smear CDR ranged between 11.5% in 2017 and 29.1% in 2007; and were below the goals set by the WHO, with a mean total rate of 22.2%. Similarly, the total TB CDRs were below the goals and ranged between 50.0% in 2017 and 75.4% in 2005, with a mean total rate of 65.7% (Table 2).

A total of 78 deaths were registered during the study period which forms 0.02% of the total TB cases or an annual rate of six deaths per year. There was 119 recurrent TB and these formed 7.72% of the total pulmonary TB. Case detection rate ranged between 48% and 77% with a total of 59.3% (Table 3).

Those who interrupted their treatment were 97 patients at a rate of 2.39 of total TB patients, while the total treatment failure cases were 33 patients (a rate of 0.81%). Before 2010, drug sensitivity test depended on TB culture which was conducted in Baghdad while thereafter Genexpert MTB/RIF test introduced to country and was done only in Baghdad and introduced to the governorate in 2014. The results mentioned prior to this date were for tests performed outside the country with a total of 72 MDR patients. These were sent to Baghdad to receive the second line treatment. Case detection rate among contacts was 0.31% (60 positive cases among 19322 contacts, Tables 2 and 4).

On calculating the smear-positive CDR per 100,000 population the rates ranged between 5.0 and 19.8 per 100,000 population while the rates for smear-positive and new cases CDR were slightly higher (Table 3).

Great significant differences between the geographical districts in the governorate were found, ranging between

7.12 per 10,000 population in Hussainia district and 42.2 in Kerbala centre districts. These might be related to socioeconomic reasons or the difference in the high number of visitors to the holy shrines in the city center, keeping in mind that reported TB cases were for inhabitants (Table 5 and Fig. 3).

The cure conversion rate for TB is calculated after 9 month course for each quarter of a year. High sputum conversion rates (83–100%) were found in all quarterly reports and these rates and were consistent with the national rates (Fig. 4). The results for the next 2 years were comparable and high and the rates were all comparable to the high national rates.

Logistic regression model for data between 2009 and 2017 showed that the main significant predictors were age, gender,

and type of referral. For defaulters, the 95% odds ratio was 9.9 for age group 55 years compared with young patients or above and 9.2 for females compared with males.

## Discussion

The main defect appeared from this study was the low CDR which was previously reported in Iraq and most other developing countries. Similar low CDRs were reported by studies in Baghdad,<sup>6</sup> Najaf,<sup>23</sup> Salah-Eldeen/Tikirit – north of Baghdad,<sup>29</sup> Babylon governorate – central part in Iraq,<sup>25</sup> and in Missan governorate (South of Iraq).<sup>32</sup> Low CDR was found in Sudan,<sup>5</sup> Iran,<sup>16</sup> Cameroon,<sup>14</sup> India,<sup>1,33</sup> and most developing countries.<sup>4</sup> Active educational plan needs to be started to increase awareness of public and private physicians about TB to reach the goals for CDR.<sup>8,27,34</sup> Similar rates were reported in other developing countries, such as Sudan where all rates were lagging behind WHO goals.<sup>5</sup> A prospective study followed 302 TB patients in Aligarh District; Uttar Pradesh/India in 2012/2013 reported that the treatment outcome was significantly associated with age group and literacy and economic status.<sup>13</sup>

On the other hand, a high cure and sputum conversion rates were reached with low MDR rates in almost all the study period of one decade and a half and this was the good news concluded from this study (Fig. 5). Almost similar high success rates (>75%) were reported in an earlier study in Najaf governorate–central part of Iraq.<sup>23</sup>

Previously reported drug resistance TB (MDR-TB) among new cases in Iraq was 3%, and among retreatment cases it was 38%.<sup>19</sup> The drug resistant rate in this study was <2% and the reason for such low rate is for including data for the period before drug sensitivity test.<sup>8,9</sup> MDR is a significant problem resulting from incomplete therapy and patient non-compliance.<sup>7,8,23,35</sup> A study among 42 MDR TB patients attending TB center in Baghdad in the last 3 months in 2012 found that 19% of the patients had a history of default from treatment.<sup>10</sup>

The main age group affected was those between 15 and 44 years of age and this finding was similar to most reviewed studies in Iraq.<sup>7,8,21,25</sup> Productive age groups are the mostly

Table 3. The case detection rate (CDR) per 100,000 population among tuberculosis patients in Kerbala governorate between 2005 and 2017 (n = 4055)

Year	Population	New S+	CDR/100,000	New & S+/CDR
2003	720,000	126	17.5	18.0
2004	750,000	108	14.4	14.0
2005	787,072	156	19.8	20.0
2006	852,000	144	16.9	17.0
2007	887,858	148	16.7	17.0
2008	924,000	124	13.5	14.0
2009	961,638	125	13.0	13.0
2010	960,000	131	13.6	14.0
2011	1,000,000	122	12.2	12.0
2012	1,037,537	91	9.0	9.0
2013	1,122,400	81	7.2	7.0
2014	1,151,152	97	8.4	8.0
2015	1,180,539	93	7.9	8.0
2016	1,237,347	84	7.0	7.2
2017	1,283,122	61	5.0	5.2
Total	14,854,665	1691	11.5	11.8

Table 4. The indices for DOTS evaluation among tuberculosis patients in Kerbala governorate between 2005 and 2017 (n = 4055)

Year	Total contact examined	Discovered positive cases among contacts	Deaths	Death rate	Interrupted treatment cases	Interrupted treatment rate	Treatment failure cases	Treatment failure rate	Drug resistant cases
2005	2155	9	7	1.66	21	4.98	2	0.47	1
2006	1389	6	4	1.18	21	6.19	1	0.29	1
2007	1742	6	10	2.86	21	6.00	2	0.57	1
2008	1485	4	6	2.07	5	1.72	1	0.34	1
2009	1405	7	6	2.01	6	2.01	2	0.67	2
2010	1414	3	3	0.94	11	3.46	4	1.26	2
2011	1618	4	3	0.94	6	1.88	2	0.63	2
2012	1440	3	6	2.24	4	1.49	0	0.00	2
2013	1345	5	15	4.32	2	0.58	1	0.29	2
2014	1427	4	0	0.00	0	0.00	15	4.67	2
2015	1502	3	8	2.85	0	0.00	0	0.00	1
2016	1200	3	5	2.00	0	0.00	1	0.40	3
2017	1200	3	5	1.99	0	0.00	2	0.80	3
Total	19322	60	78	1.92	97	2.39	33	0.81	72



Table 5. The distribution of tuberculosis cases among the different geographical districts in Kerbala governorate between 2005 and 2014

Year	Kerbala center	Kerbala center (%)	Hindia	Hindia (%)	Hussainia	Hussainia (%)	Hurr*	Hurr (%)
2005	306	72.51	77	18.25	39	9.24		
2006	255	73.91	48	13.91	42	12.17		
2007	247	67.67	84	23.01	34	9.32		
2008	231	77.78	38	12.79	28	9.43		
2009	159	52.13	65	21.31	24	7.87	57	18.69
2010	157	47.72	59	17.93	40	12.16	73	22.19
2011	157	48.76	62	19.25	33	10.25	70	21.74
2012	139	50.18	44	15.88	20	7.22	74	26.71
2013	152	42.94	70	19.77	41	11.58	91	25.71
2014	154	46.39	77	23.19	32	9.64	69	20.78
2015	159	54.5	55	34.59	26	16.35	52	32.70
2016	122	48.8	56	22.40	21	8.40	51	20.40
2017	118	45.0	63	24.0	18	7.0	64	24.02
Total	2356	56.73	798	19.22	398	9.58	601	14.47

\*Hurr district was part of Kerbala centre till 2009.

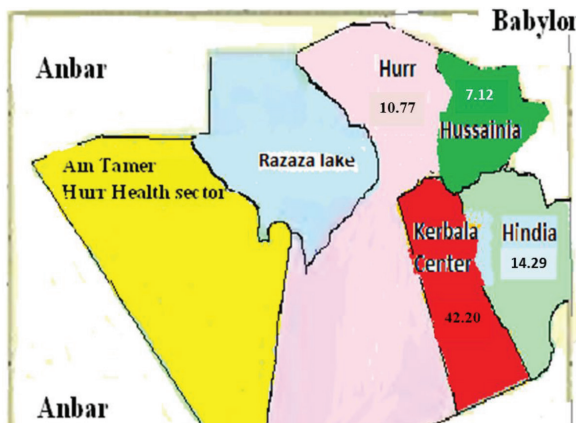


Fig. 3 The geographical distribution of all tuberculosis patients in Kerbala districts between 2005 and 2017.

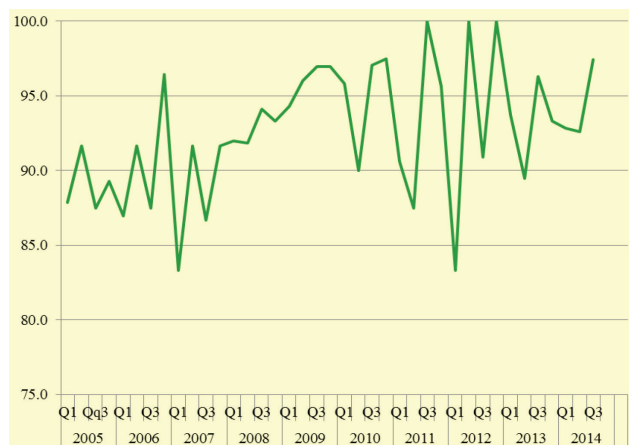


Fig. 4 The quarterly cure rates of TB cases in Kerbala from 2005 to 2015.

affected age group in most mentioned Iraqi studies, however the male proportion was lower than the global ratio,<sup>2</sup> but was similar to most Iraqi studies which report a decreasing male to

female ratio in recent years mostly due social factors-lower social stigma.<sup>6,21</sup>

A very low mortality rates were found in this study and these figures are believed to be far below the actual figures due to poor registration and loss of patients follow up.

The TB annual mortality rates in Iraq according to the annual statistical reports of the Ministry of Health ranged around 4–5% of total TB cases.

The main obstacles facing DOTS implementation are related to the social and political domains that affect TB incidence in Iraq. Detailed shortcomings included inadequate and improperly distributed DOTS administrative units, absence of program decentralization, proper training of working personals, provision of financial support for families of TB patients and provision of logistics for needed logistic for the program.

Most important obstacles reported by experts working in TB control center were those difficulties in diagnosing tuberculosis which is still a global problem especially among children; poor patients' compliance; the high proposed governorate inhabitants' number used to calculate the goals and other socioeconomic factors related to the political changes in the country.

## Conclusion

The results of DOTS monitoring in Kerbala showed very good sputum conversion and cure rate and were consistent with the national rates and the rates in most developing countries. Open discussion with experts working in TB control programs in the governorate for decades marked some essential defects and weakness that need to be corrected urgently to ensure better tuberculosis. The obstacles are mainly facing case detection and patients' compliance to complete the DOTS course.

## Conflict of Interest

None. ■

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