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Screening of Tuberculosis at Health Centers in Khairpur District of Sindh

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ABSTRACT

A retrospective cross-sectional study was conducted to evaluate treatment outcomes among 951 tuberculosis (TB) cases treated at 12 tuberculosis (TB) treatment facilities in Sindh's district of Khairpur. Secondary data analysis was conducted on tuberculosis (TB) patients registered at various health units in Sindh's Khairpur district. Additionally, 165 individuals were interviewed, including hospital administrators and managers, tuberculosis-infected individuals, individuals with an incomplete tuberculosis diagnosis, and confirmed tuberculosis patients, to ascertain patients' satisfaction with the services provided at these TB treatment facilities during their treatment. It was determined that there was only one TB Desk Aid in nine Basic Medical Units (BMUs), but none in the remaining BMUs. Only seven BMUs had consistently used the tuberculosis suspect register. None of these facilities offered microscopy services. As per the overview reactions regarding the interaction qualities, 75 percent of attendees had been made aware that they could just transmit tuberculosis to others, and 58.8 percent of participants were informed about preventative measures to limit tuberculosis spread. 71 percent of participants were told to return to the treatment center for TB services, 76.4 percent were told that TB is treatable, 68.5 percent were told about the adverse effects of TB medications, and 69.7 percent were able to recognize the signs that TB medications should be stopped. 66.1 percent, on the other hand, were completely ignorant of the link between HIV and tuberculosis. Ninety percent of those who took part were not advised to get an HIV test. According to the study's findings, success rates were two to three times lower than those recommended by the World Health Organization, indicating inadequate services. In the district of Khairpur, there is no method for hospital Directly Observed Treatment Short-course (DOTs) linkage, resulting in poor identification and referral of suspicious cases to laboratories with microscopy facilities. The success rate of tuberculosis treatment has been found to be lower than the recommended level. It was concluded that these tuberculosis treatment centers only meet the WHO's 85 percent target.

Keywords: TB, TB care quality, and TB treatment in Pakistan

Introduction

Tuberculosis (TB) is a curable contagious illness caused by the bacteria Mycobacterium tuberculosis. It is the major cause of mortality from a curable infectious disease, particularly in low- and middle-income countries(Atkinson & Mabey, 2019).It might not even contribute

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to the occurrence of severe physical consequences, as well as to the occurrence of certain potentially fatal complications. Additionally, tuberculosis is considered to be a highly disruptive contagious disease that is likely to affect an increasing number of people around the world, including both males and females(Lee, 2015).

According to a World Health Organization (WHO) report published in 2007, Mycobacterium tuberculosis has been found in one-third of the worldwide people, and it was found to be associated with a higher chance of evolving into infection (Unies et al., 2010).Despite the fact that the performance of national programs working for tuberculosis control indicates that tuberculosis treatment is successful in most cases around the world.

It is required to make more concerted efforts to improve tuberculosis effluent quality in order to reduce disease incidence, as a range of factors can affect the chance of treatment success, including co-infection with a number of other disorders. Drug-resistant (MDR) (WHO, 2010) and thoroughly drug-resistant (XDR) (Tovar et al., 2016), tuberculosis, as well as co-infection with HIV(Pawlowski, Jansson, Sköld, Rottenberg, & Källenius, 2012), poverty, and tuberculosis,(Benatar & Upshur, 2010) are all significant challenges to tuberculosis control, especially in low- and middle countries(Tola, Tol, Shojaeizadeh, & Garmaroudi, 2015).

Based on the current World Health Organization, whereas South-East Asia contributes to 46.5 percent of the world's tuberculosis hardship, (“Global Tuberculosis Report 2019. Geneva: World Health... - Google Scholar,” n.d.), Pakistan is ranked fifth among areas with a high liability for multidrug-resistant tuberculosis (MDR-TB), (Javaid, Shaheen, Shafqat, Khan, & Ahmad, 2017),and 4th among countries with the largest rate of MDR-TB in the world(“National Tuberculosis Control Strategic Plan—Vision... - Google Scholar,” n.d.).

In Pakistan, tuberculosis is the ninth leading cause of death after heart disease and cancer.The number of cases of pulmonary tuberculosis that were reported as drug-resistant tuberculosis in Pakistan reached 14,000 by the end of 2016. Of these, approximately 4.2 percent were incident cases, and 16 percent were retreatment cases, both of which were reported as MDR-TB. Despite these difficulties, the success rate for drug-susceptible tuberculosis treatment was 91 percent in 2015(Ahmad, Mokaddas, & Al-Mutairi, 2018).

According to the European Region of the International Union for Tuberculosis and Lung Disease (IUATLD), TB prevention efforts in all nations comprise the techniques of

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medication, procedure, diagnosis, and follow-upIt is the Global Health Organization's (WHO) standard criteria for obtaining tuberculosis clinical outcomes in countries with a relatively large incidence of the disease that are used. These methods include 06 categories. Those are therapy accomplished (successfully treated), failure (therapy interrupted), transmitted out (converted out), and mortality for the analysis of therapeutic efficacy in countries with a high incidence of the disease. Aside from that, the World Health Organization recommends that thorough monitoring be carried out of the outcome of treatment in order to determine the efficiency and efficacy of tuberculosis prevention strategies(Bao, Du, & Lu, 2007).

In Pakistan, the prevalence of pulmonary tuberculosis cases is 144 cases per 100,000 people, indicating that treatment adherence is low and dropout rates are high in the country. Previous studies have also identified inadequacies in the quality of services provided to patients, which is concerning(Coghlan et al., 2015).As previously stated in according to the Census Tuberculosis Monitoring System, services are insufficient in relation to the World Health Organization's tuberculosis management system. As a consequence, the present study attempted to assess the entire performance of health care staff and equipment, as well as the overall leadership effectiveness of patients diagnosed in all main tuberculosis management programs, including public and private, in the Sindh district of Khairpur.

Methodology

In order to examine treatment outcomes among patients, a qualitative cross-sectional study was performed with cases from 12 tuberculosis treatment centers in Sindh's district of Khairpur. Secondary data analysis was performed on a patient population who had all been examined by the research teams and were enrolled as active TB sufferers in the health units of Sindh's Khairpur district. The sufferers were all registered tuberculosis patients in the healthcare facilities of Sindh's Khairpur district and had all been examined by the researchers. The National TB Control Program's registry was used to identify newly diagnosed tuberculosis cases in the Khairpur district, and secondary data was collected from all public and private basic tuberculosis management centers in the district, including those that were not affiliated with the government. Over the course of the study's duration, which ran from July 1, 2016, to September 30, 2016, information about the participants was gathered.

In addition, 165 people were interviewed, including hospital in charge people and managers, TB infected people, people with an incomplete TB diagnosis, and confirmed tuberculosis

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patients, to assess the patients' satisfaction with the services provided at these TB treatment facilities during their treatment. The research was carried out in the Khairpur area of Northern Sindh's Sukkur division. For the retrospective assessment of treatment results, the study included all TB diagnostic facilities, Health Units, Hospitals, and Health Centers that provided TB treatment services. All in charge professionals and managers, TB infected individuals, individuals with incomplete TB diagnoses, and confirmed tuberculosis patients were interviewed for the quality evaluation. The healthcare workers were chosen based on their knowledge of TB facilities and treatment options.

Sampling

The sample size was calculated with the help of the Open Epi Software. According to the National Tuberculosis Prevention and Control Report (2016), a sample size of 246 was used in our analysis in order to have an 80 percent capability to predict a relative cure rate of 80 percent for tuberculosis in Sindh province with a 5-percent standard deviation. An overall total of 951 patients were sampled to reduce the possibility of error and to reduce the amount of data that was missing.To select cases, a universe sampling technique was used, so all registered tuberculosis patients from July 1, 2016, to September 30, 2016 (n=951) were included in the survey.A non-probability purposive sample technique was employed to select persons for the quality assessment. Using the same Open Epi software, a sample of 165 was calculated for the quality assessment.

Criteria for Evaluation

As indicated in the Donabedian paradigm, the quality predictors were a) structure, b) process, and c) outcomes. The framework provides an evaluation mechanism that allows researchers to investigate health services in terms of Structure, Process, and Outcome(ROURKE, 1957) in a methodical manner. Staff characteristics, health-care characteristics, organizationalissues, and professional competency were used to evaluate the process, whereas the framework, on the other hand, was evaluated through patient-provider contact and HIV testing of tuberculosis patients. In order to identify the results, the disease detection accuracy, likelihood of success, and defaulter rate of government health facilities in Sindh were investigated. Statistics from Sindh's national tuberculosis control program were used to determine the outcomes.

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Information gathering

The data for this study came from the TB Hospital Khairpur, the Regional Health Center ThariMirwah, the TH Kotdiji, the Regional Health Center Hingorja, the Regional Health Center Pir-Jo-Goth, the Regional Health Center Ranipur, the Regional Health Center Faiz Ganj, the Regional Health Center Garhi Mori, the Regional Health Center Choundiko, the Regional Health Center SobhoDero, and the PPM Project. The secondary data was collected using the NTP protocol. In addition, information was gathered from laboratories to determine how many people had been hospitalised with tuberculosis. Interviews with the staff in charge of the administration of the facilities, as well as TB patients who were being cured and/or visiting the clinic at the time of the survey, were conducted to obtain primary data on the overall service quality at these health units in Khairpur.

Data Analysis

Prior to transferring the data to SPSS version 20 for statistical analysis, the collected data was cleaned in Microsoft Excel 2010. The variables in the data that were not present were not taken into consideration. The results of univariate analysis were used to determine the upper and lower limits, percentages, and frequencies of treatment quality. Because of the need to extract effective statistical outcomes to obtain better results, the decision to use SPSS version 20 was made. In order to determine the study's power, a reliability analysis was carried out, and the Cronbach's Alpha value was 0.993, signifying that the data had greater power.

Protocols were resolved and associated to create a collection of structures that can be used to measure the quality of the services in order to assess their effectiveness. In the course of supposed visits to tuberculosis treatment centers, semi-structured interviews were conducted. The goal of these interviews was to learn about patients' people's perception of the services provided to them, and recommendations from the World Health Organization, the National Tuberculosis Program, and the International Standards for Tuberculosis Patients (ISTC) were used to assess overall service quality. The difference between expected and actual performance was used to determine the overall quality of the tuberculosis prevention and treatment program. Because this is the first survey to be conducted in the Sindh district of Khairpur, the results of the study were used to identify areas that needed to be improved.

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Ethical considerations

Whatever research project must take into account ethical considerations in order to avoid the possibility of moral ambiguity. It was our intention to use secondary data in order to obtain written approval from the ethical review committee, and we have requested permission from the appropriate authorities. As a result, the Shaheed Zulfiqar Ali Bhutto Institute of Science and Technology's Ethics Review Committee obtained informed consent before the study could begin. Upon receiving ethical approval, data was obtained from the National Toxicology Program's headquarters. As a result, the study adhered to all ethical standards to ensure that it was effective and that the results were retrievable after completion.

RESULTS

The retrospective survey comprised 951 cases of tuberculosis, and 165 semi-structured interviews were conducted to assess the quality of treatments given at 9 TB treatment facilities inSindh's Khairpur area. The outcomes are defined in terms of how they relate to each of the performance indicators listed in Table 2.

Structural Efficiency

Table 2 provides a comprehensive breakdown of the distribution of structural features within the Khairpur district. TB Desk assistance is available to 75% of the BMUs that were selected, according to the results of the study. As with BMUs in general, only 58 percent of BMUs maintain a consistent TB suspect registry. The data also revealed that 10 of the 12 BMUs have a TB survey question request form, whereas two BMUs do not have such a form. Sputum mugs and microscopic services were utilized by all of the BMUs to a 100 percent degree. Furthermore, 91.66% of BMUs had no strategy in place to identify cough patients, which is an alarmingly high number. According to the statistical analysis, there was no statistically significant relationship between the structural and process variables and the research outcomes. In total, 35.30 percent of the attempts were successful, with only 14 percent of the attempts being observed by the authorities. However, while the default rate, also known as the failure rate, is 0.42 percent, it indicates that structural and process factors are available. However, significant changes are required in order to achieve better results.

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Process Efficiency

The responses to the process characteristics are listed in Table 3. Seventy-five percent of the participants were advised that they would spread tuberculosis to others, and 58.8% were told about the preventive steps to prevent the spread of tuberculosis. Seventy-one percent requested to return to the facility for TB treatment, and 76.4 percent were told that TB can be treated, 68.5 percent were told about the negative effects of TB treatments, and 69.7% understood how to quit taking TB medications. However, 66.1 percent were unaware of the link between HIV and tuberculosis. Ninety percent of those who took part in the study were not recommended to get an HIV test. Table 3 shows the nature of the responses.

1.1. Outcome Achievement

The number of patients in various BMUs in the Khairpur District who received, were treated, failed, or died is used to assess the significance of the results. A total of 334 (35%) cases were cured at the Khairpur TB Hospitals; 574 (60.7%) treatment cases were accomplished; 14 (1.5%) deaths were reported, while 04 (0.4%) were treatment failures, 15 (1.5%) were lost to follow-up, and 05 (0.5%) were not reviewed at all 12 BMUs. Table 4 lists the details for each facility.

1.2. Overall quality

Table 5 provides in-depth information on overall quality performance. Each center's performance was evaluated based on the process and structural features that were accessible. The standard guidelines described in Table 1 were used to score these features. Based on process and structure features, all of the scores were added together to give a cumulative score, which means that the greater the score, the lower the quality. The lowest performing facilities were TH Kotdigi and RHC Ranipur, followed by RHC Garhi Mori. HIV screening of all TB patients was one of the most degraded performance factors.

Discussion

The current study used data from 12 basic medical facilities providing TB treatment medical services in the district to estimate the relative level of performance of services, medication, and management facilities for clinically diagnosed patients admitted in the district of Khairpur, Sindh, Pakistan. For the purpose of evaluating the quality of services, treatment,

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and management, the characteristics of healthcare systems were considered in terms of their structure, procedure, and efficiency, as the global public health Issue Organization and the Donabedian framework of Design, Procedure, and Outcome(ROURKE, 1957).

The current study discovered that the prevalence of physical characteristics in the Khairpur area of Sindh, Pakistan, is below the World Health Organization's approved criteria. It was determined that over two-thirds (75%) of the selected BMUs have TB desk assistance, yet only half of these institutions routinely register TB suspect cases. Additionally, the findings indicate that ten out of twelve BMUs have a tuberculosis request form. However, two BMUs did not have one. Sputum mugs and microscope examinations were available at all BMUs. Similarly, 92% of BMUs lacked a method for identifying coughing patients.

Additionally, it was noticed that the provision of TB desks falls short of the norm for tuberculosis treatment. Similarly, the suspect registry lacked an accurate record of finished tuberculosis treatments. Additionally, the study discovered that staff and healthcare features have no correlation with improved results, and that these poor case detection rates are associated with ineffective staff and/or healthcare features. The findings of this study corroborate those of Chimbindi, N., et al., who assessed patient satisfaction with therapy and quality in KwaZulu-Natal, South Africa, and established that treatment quality is dependent on health care staff attitudes, adequate patient facilities, and effective communication between patients and staff (Chimbindi, Bärnighausen, & Newell, 2014).

A similar study conducted in China found that communication breakdowns, particularly amongst health care professionals in patient services, were associated with unsatisfactory outcomes(Liang et al., 2012).Similarly, the current study's findings corroborate the underlying justifications for impoverished treatment outcomes in tuberculosis patients in Indonesia, where a lack of communication between patients and healthcare providers was identified as a significant predictor of poor treatment outcomes in tuberculosis patients. Additionally, in Indonesia, inadequate explanations, and harsh behavior on the part of health personnel had a detrimental effect on the success rate of tuberculosis treatment, (Widjanarko, Gompelman, Dijkers, & van der Werf, 2009), but the findings of this study did not demonstrate similar characteristics.

Although the staff of TB treatment facilities in our study received training, this trained workforce was diverted by the Health Department to other vertical programs and shift duties,

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whereas frequent transfers and relocations of trained DOTS staff from one facility to another harmed the program's overall coverage. Additionally, organizational challenges and personnel competency contributed to delays in the number of tests completed on each patient. Furthermore, tuberculosis patients' follow-up testing and HIV screening are insufficient. The current study indicated that the facility's services are substandard and do not adhere to World Health Organization guidelines, as the investigation demonstrated a low referral rate of all cough patients to laboratories for tuberculosis testing.

In this research, system performance was significantly better than organizational performance, as evidenced by a significant number (71%) of patients being informed that their illness was transmissible and more than half receiving enough information about precautionary steps to reduce infection spread. In general, the process performance indicators in this study were favorable, except for knowledge and guidance regarding the relationship between tuberculosis and HIV, as well as the suggestions for HIV testing. Due to the increased risk of getting tuberculosis in HIV-positive patients, failure to educate them about the possibility of developing opportunistic and other co-infections has a detrimental effect on success rates. It is generally established that HIV co-infection with tuberculosis reduces the likelihood of good treatment results as compared to HIV-negative patients(Ali, Mavundla, Fantu, & Awoke, 2016).

The efficiency of TB treatment centers in our study painted a bleak picture of treatment results for tuberculosis patients in Sindh, with only a third (35%) of registered patients being totally cured of the disease, even though 60% finished the treatment regimen. These findings are worrisome because almost 42% of those who underwent treatment failed to be entirely cured of the condition. These results may indicate drug resistance, and the gaps in the DOT services given at some of these hospitals are disturbing. In particular, a relatively low cure rate (21 percent) at one of the largest TB treatment institutions is concerning. Measures should be taken to improve the success rate, as our results reveal a very low rate of treatment success, while the World Health Organization recommends an 85 percent success rate for treatment (Varma et al., 2009; Jordan & Davis, 2010). Although the mortality and loss of follow-up rates for tuberculosis patients are extremely low (less than 2%), the cure rate is extremely low, indicating some significant disparities in the treatment regimen(Karyadi et al., 2002).

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Conclusions:

No mechanism of hospital Directly Observed Treatment Short-course (DOTs) linkage in hospitals is being observed in district Khairpur resulting in inadequate identification and referral of suspected cases to the laboratories where microscopy services are available. The success rate of TB treatment was found to be below the recommended value. The WHO set a target for the treatment success which around 85%.

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Conflict of interest

Authors declare no conflict of interest.

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Table 1: Measuring/Evaluating Khairpur district health facility quality versus these indicators.

Estimated performance metrics for health-care facilities	**Current level of performance**	**Information source**	**Rating based on performance**
Indicators/guidelines for structural performance			
To arrive at a diagnosis, two sputum samples are required.	Two microscopic blades should be done for all suspected	Results for 3Q 2016 revised laboratory registers	1 = 81–100% = good 2 = 70–80% = fair
The medical center has a system for tracking missing and missing patients.	1 = Yes 2 = No	Surveyed facility directors, in-charges, and tuberculosis focus individuals	3 =<70% = poor 1 = good 2 = poor
Output standards/metrics			
Coverages provided by DOTS	Identification and notification of incidents	Assessed data of Quarter 3 2016	1=>80%=good 2=less than 80%= poor
Healed	Percent of participants deemed recovered	Assessed data of Quarter 3 2016	1 = 85–100% = good 2 = less than 85% = poor
Deficiency in therapy	Probability of failure reported	Assessed data of Quarter 3 2016	1 = 0 patients = good 2 = 1 or >patients = poor
levanter	proportion of violators	Assessed data of Quarter 3 2016	1 = 0 patients = good 2 = 1 or >patients = fair

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			3 = 8 and >patients = poor
Passed away	Proportion of died persons	Assessed data of Quarter 3 2016	1 = 0 = good 2= 1–5 patients = fair 3 = 5and>patients= poor

Table 2 depicts the list of structural and organizational parameters for TB care and diagnosis in Khairpur district healthcare institutions.

Structural and Organizational Characteristics	N	%
TB Desk aid		
Yes	9	75.00
No	3	25.00
TB Suspect register used consistently		
Yes	7	58.00
No	5	42.00
TB Request form		
Yes	10	83.33
No	2	16.66
sputum mugs		
Yes	12	100.00
No	-	-
Microscope services		
Yes	12	100.00
No	-	-
System of identifying cough patient		
Yes	1*	8.33
No	11	91.66

Table 3 Interviews Results on TB Treatment and Management process features in Khairpur District healthcare facilities.

Interview outcome about process characteristics	N	%
Source of information about TB services		
Referred by health worker	112	67.9
Referred by somebody who ever used	20	12.1
Other	33	20.0

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Informed that you would transmit TB to others							
	Yes					118	71.5
	No					47	28.5
Informed when you stop spreading TB to others							
	Yes					97	58.8
	No					68	41.2
Informed when next to comeback for TB services							
	Yes					118	71.5
	No					47	28.5
Informed that TB is cured							
	Yes					126	76.4
	No					39	23.6
Informed about side effects of TB drugs							
	Yes					113	68.5
	No					52	31.5
Aware of all the signs to stop TB medication							
	Yes					115	69.7
	No					50	30.3
Informed about sputum follow-up tests at given points							
	Yes					113	68.5
	No					52	31.5
Informed about the link between HIV and TB							
	Yes					56	33.9
	No					109	66.1
Advised to take an HIV test							
	Yes					16	9.7
	No					149	90.3
HW explained how to collect the sample							
	Yes					165	100
	No					0	0
HWs explained things in a way you understand							
	Yes					120	72.7
	No					45	27.3
You received all the necessary information you need to know							
	Yes					118	71.5
	No					47	28.5
Had enough time to discuss problems with HWs							
	Yes					120	72.7
	No					45	27.3
Opinion about attitude of staff at the health facility							
	Very Good					92	55.8
	Good					51	30.9
	Fair					22	13.3

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	*: TB hospital Khairpur, **:TB Hospital Gambat and RHC Sobhodero, ***:RHC Hingorja , RHC Ranipur and RHC Choundiko, ****: RHC Hingorja , RHC Ranipur, RHC Choundiko, RHC sobhodero and PPM project

Table 4shows the outcomes of tuberculosis treatment at Khairpur district outpatient clinics.

Name of BMU's	Number of Cases registered	TB patient type	Cured	Treatment Completed	Treatment Failed	Died	Lost to follow up	Not Evaluated	Total
TB Hospital Khairpur	372	All cases consolidated	81	280	1	2	7	1	372
RHC ThariMirwah	74		45	28	0	0	0	1	74
TH Kotdiji	39		11	22	2	2	1	1	39
RHC Hingorja	28		19	9	0	0	0	0	28
RHC Pir-Jo-Goth	63		37	23	0	2	1	0	63
RHC Ranipur	20		9	7	0	2	2	0	20
RHC Faiz Ganj	48		20	25	0	2	1	0	48
RHC Garhi Mori	14		8	3	1	1	0	1	14
TB Hospital Gambat	103		45	57	0	1	0	0	103
RHC Choundiko	12		5	6	0	0	1	0	12
RHC SobhoDero	13		5	8	0	0	0	0	13
PPM Project	160		49	106	0	2	2	1	160
Total	946		334	574	4	14	15	5	946

TH: Taluka Hospital
RHC: Rural Health Center
PPM: Public Private Mix

Table 5 shows the results of a performance evaluation of TB care public hospitals in the Khairpur district.

		General Quality Assessment of TB Care facilities of Khairpur District											**Total score**
s. no.	**Name of BMU**	**A**	**B**	**C**	**D**	**E**	**F**	**G**	**H**	**I**	**J**	**K**	
1	TB Hospital Khairpur	1	1	1	2	2	1	1	2	2	2	2	17
2	RHC ThariMirwah	1	1	1	2	2	0	2	1	1	1	1	13
3	TH Kotdiji	2	2	1	2	2	0	2	2	2	2	2	19
4	RHC Hingorja	2	1	1	2	2	0	2	1	1	1	1	14
5	RHC Pir-Jo-Goth	1	1	1	2	2	0	2	1	1	2	2	15
6	RHC Ranipur	2	2	1	2	2	0	2	2	1	2	3	19
7	RHC Faiz Ganj	1	1	1	2	2	0	2	2	1	2	2	16
8	RHC Garhi Mori	2	2	1	2	2	0	2	2	2	2	1	18
9	TB Hospital Gambat	1	1	1	2	2	0	2	1	1	2	1	14

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10	RHC Choundiko	1	1	1	2	2	0	2	2	1	1	3	16
11	RHC SobhoDero	2	1	1	2	2	0	2	1	1	1	1	14
12	PPM Project Bridge	1	1	1	2	1	1	2	2	1	2	2	16
	Total	17	15	12	24	23	2	23	19	15	20	21	

Note: Patients have been given time to wait for the lab findings. B: It is now time to receive anti-TB medication. C: Each suspect has two smear tests. Every suspect is subjected to a D: HIV test. E: Last patient tracking system, F: Every member of the staff contributes to the detection of tuberculosis cases (hospital Dots Linkages), H: Cure rate, G: TB DOTS coverage I: the total number of treatment failures, J: the number of patients who died K: the number of patients who were lost to follow-up.