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RESEARCH ARTICLE

Process Evaluation of Quality in the Diagnosis and Treatment of Tuberculosis in Public Health Facilies of Southwes Ethiopia: Cross Sectional Study

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ABSTRACT

Background: Even though Ethiopia has implemented the Directly Observed Treatment Short (DOTS) service for a long time, the national targets of Tuberculosis (TB) control were not achieved yet. Like the country wide, the Kersa district shares the same problem, and also TB control program have never been evaluated in this district.

Methods: Process evaluation was conducted based on Donabedian's structure-process-outcome model of health care quality. Facility based cross-sectional study design was employed. Four, tuberculosis directly observed short course therapy providing health centers were selected. Medical records of TB suspects and patients were reviewed. Ongoing laboratory practice and patient provider interaction was observed.

Results: The resources recommended by national tuberculosis control program for diagnosis and treatment were available, except a shortage of paediatric dose of TB drug and Acid Fast Bacilli (AFB) reagents. Only 64.8% of TB suspects received sputum smear laboratory examination, and 52.7% of TB patients received the right doses of treatment.

Conclusion: The shortage of drugs and reagents and, low uptake of microscopic AFB examination service was the main constraints of service. Adequate and continuous resource supply and regular and continuous monitoring of diagnosis and treatment process should be considered. *J Microbiol Infect Dis 2016;6(4): 156-162*

Key words: Quality, evaluation, program, Tuberculosis

INTRODUCTION

Tuberculosis is a major global health problem. Each year, there are around 9 million new cases of TB, and close to 2 million people die from the disease. Globally there are 22 high-burden countries that account for about 80% of the world's TB cases and Ethiopia stands 7th of them [1-3].

Global efforts to control TB were strengthened in 1991, when a World Health Assembly Resolution recognized TB as a major global public health problem. Two targets, 70% of the TB case detection rate and 85% of the TB treatment cure rate were established as the part of this resolution. These two targets were embedded within the Directly Observed Treatment Short Courses (DOTS) strategy launched by World Health Organization (WHO) in 1994, and subsequently endorsed by the WHO stop TB Strategy in 2006 [3].

Despite widespread acceptance of the principles of DOTS, most developing countries have failed to achieve the global targets. Currently TB case notification and treatment success rates were 46% and 84%, respectively [1,4]. In addition to this the quality and population coverage of DOTS are still low in most countries in general and in Ethiopia specifically. The TB laboratory service network is poor and also there were insufficient resources and shortage of trained staff to provide essential service [3-5].

The effort of TB control began in Ethiopia in the early 1960s with the establishment of TB centers and sanatoriums in three major urban areas of the country. Now a day Ethiopia has adopted the global targets of TB control. Though TB control program run for such a long time in Ethiopia, it is the leading cause of morbidity, the third cause of hospital admission next to deliveries and malaria. The incidence of all forms and smear positive TB stand at 341 and 152 per 100,000 populations, respectively. The prevalence and mortality of all forms of TB is estimated to be 546 and 73 per 100,000 popula-

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tions respectively. In the year 2006/7 Ethiopia registered 129,743 cases of TB [3].

Jimma zone in general and Kersa district, particularly shares the same problems. According to zonal health department report, the case detection rate of the zone was 24.4% and 31.7% for smear positive and all form of TB respectively. In the same year the district annual report shows that, smear positive pulmonary TB case detection was low and even far below the zonal performance, which is 15.4% [6, 7].

In addition to this poor achievement, TB control program has never been evaluated before at Kersa District; hence the aim of this study is to evaluate the quality of diagnosis and treatment of TB.

METHODS

Study area and period

The study was conducted at Kersa district from June to July, 2014. Kersa is one of the 17 districts in the Jimma zone and located at 22km to the south-eastern part of Jimma town and 357 km from the capital city of the country, Addis Ababa. Jimma is located in the south-western part of the country. The district has 35 Kebeles (the lowest administrative unit) and has 188,268 total population. It is 1600 to 2400m high above sea level with relatively hot tempearature, ranges from 24°c to 28°c.

Study design

Facility based cross-sectional study design was conducted in four purposely selected health centers for their implementation of DOTS program.

Conceptual frame of evaluation

Donabedian's structure -process-outcome model of health care quality was employed as a framework for the study [9] (Fig 2).

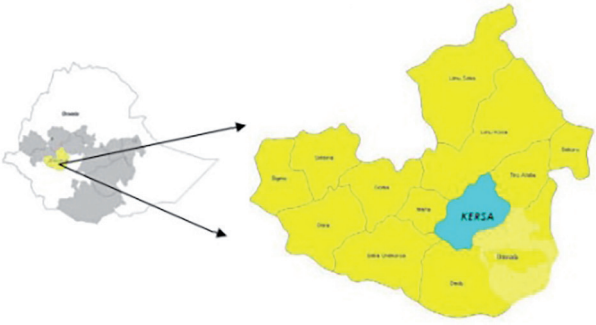

Figure 1. Map of Kersa district, southwest Ethiopia [8]

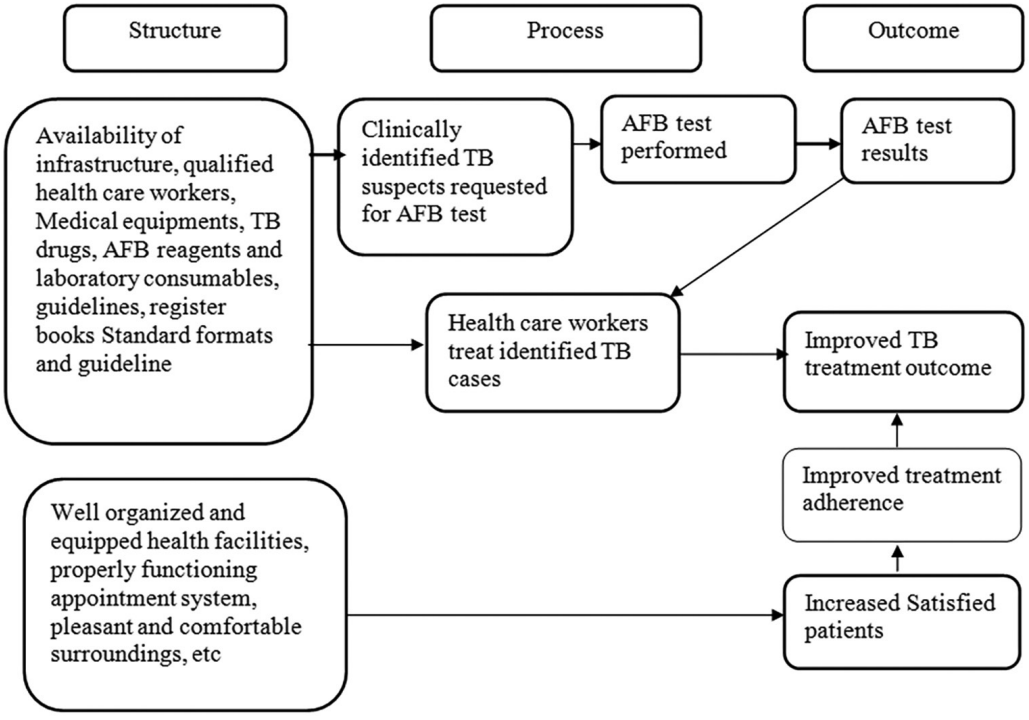

Figure 2. Conceptual framework of diagnosis and treatment of tuberculosis at Kersa District, 2014.

Sampling techiniques

Four HCs were selected purposely based on the DOTS service provision. Medical records (individual patient folders and TB unit register) registered from October 2013 to September 2014 were reviewed. TB unit registers were reviewed in all HCs and patient folders reviewed in three HCs.

Patient folders were reviewed to assess whether TB suspects were requested for and got sputum smear AFB test and the test positivity rate. TB unit register was also reviewed to assess a cohort of TB patients and variables like age, sex, TB type, drug regimen, date treatment started, treatment follow-up, follow-up sputum result and treatment outcomes were collected.

Inventory was conducted to assess the availability of resources for diagnosis and treatment. Finally ongoing laboratory diagnosis and patient-provider interaction was observed to evaluate the service quality in practice.

Focus and approach of evaluation

The primary purpose of this evaluation was to produce information that would guide the program improvement. Therefore the formative evaluation approach was used. The formative evaluation approach is a type of evaluation performed during the entire planning process and program execution to answer evaluation questions important to modify an intervention.

Indicators sellection

The Indicators were setted based on (National Tuberculosis Program) NTP guideline. The selected indicators were again reviewed by stakeholders of the program (health workers at HCs and head of District health office,) for their local relevance. Finally each indicator was judged based on the preset judgment matrix.

Data analysis

Data analysis was conducted with SPSS 16.0. Descriptive statistics was computed and the findings were presented in figure, mean, proportion.

Ethics statement

Ethical approval for the study was obtained from the Ethical Committee of Jimma University. After a full explanation of the objectives of the study, written informed consent was obtained from the volunteers.

RESULTS

Availability of resources

Anti-TB drugs, except paediatric dose and AFB staining reagents were available at all health centers. In each health center there were one functional microscopy and weighing scale. One of health centers was equipped with solar microscopy for the absence of electricity.

There were two service providers in one of health centers and the rest have one provider who has received in-service trainings on TB treatment. One of health centers has two health officers and the rest each health center has only one. Similar to this there were two laboratory technicians in one and the rest each has only one. Except in Kusay Beru health center, where AFB examination service was not provided, all laboratory technicians in the rest health centers have received in-service training on AFB microscopic examination.

In all HCs there were no specimen reception and AFB examination rooms, and no TB treatment room in two HCs. In all health centers, there were information, education and communication materials in different language; Afan Oromo, Amharic and English, posted in waiting areas and different service points. TB suspects screening procedures were posted in an outpatient department room in all health centers, but national TB guideline was available in two health centers only which also have a separate TB treatment unit. There was TB treatment algorithm in all health centers, whether it has separated unit for TB treatment or not. In all health centers, there were standard tools for recording and reporting of TB.

Diagnosis

Three hundred eighty four individual patient folders which have TB suggestive patient history in clinical diagnosis were reviewed to make sure that whether TB suspects were requested for AFB examination service or not. Of these 182 (47.4%) reviewed at Serbo HC, 103 (26.8%) at Bulbul HC and 99 (25.8%) at Bala Wajo HC). The age of all patients was 15 years and above, the mean age was 36.8 with a standard deviation of 16.14. One hundred eighty three (47.7%) of patients were males and 201 (52.3%) were females.

AFB examination was requested for only 249 (64.8%) of 384 TB suspects. The test result of 21 (8.4%) AFB requested patients was not recorded in both integrated individual folders and even in the

laboratory AFB register, so in this study they were considered as not had received AFB examination service. Therefore AFB examination was provided to only 228 (59.4%) of 384 TB suspects, and only 10 (4.4%) of which were smear positive.

The test result of 21 (8.4%) patients was not recorded in individual patient folders, so in this study they were considered as not had received AFB examination service. Therefore AFB performed only in 228 (59.4%) of TB suspects and of which only 10 (4.4%) were smear positive.

Health care providers, heads of health centers and TB program pinpoint workers mentioned that the reason for not requesting, and performing a sputum smear examination was the negligence of care providers during diagnosis. One of heads of health centers said, *"If the clinicians are alert to screen TB suspects accordingly, the procedure is very easy to do so and nothing but their negligence made them to miss it."*

Treatment

From TB unit register 49 (31.8%) were smear positive Pulmonary Tuberculosis (PTB), 36 (23.4%) smear negative PTB and 69 (44.8%) were Extra Pulmonary Tuberculosis (EPTB). Except 10 smear positive cases the rest were diagnosed in nearby hospital (Jimma specialized hospital) and started treatment in study HCs.

Seventy three (47.4%) were males and 81 (52.6%) were females. Twenty one of patients aged below five years, and the majority of patients, 133 were in age category of 15-45 years.

Except one, all patients had finished intensive phase of treatment. While 31 (64.6%) of 48 smears positive PTB patients were Cured (a patient whose sputum smear was positive at the beginning of the treatment but was negative in the last month of treatment and on at least one previous occasion), 14 (29.2%) completed TB treatment (patient who completed treatment but who does not have a negative sputum smear result in the last month of treatment and on at least one previous occasion) , one patient died in the midst of intensive phase, one has defaulted the treatment and the result of one was not recorded. Therefore, in general the treatment success rate (a sum of cured and completed treatments) was 93.8%.

According to care providers' response, the reasons for such high success rate were: treatment service has never been interrupted at any particular time, the number of patients was small to follow up and patients have good awareness regarding the consequence of treatment interruption. In addition to these, there was good provider- patient interaction, which could strengthen the treatment compliance. The reason for the relatively low cure rate was, some patients could not produce appropriate sputum for follow up AFB test at 2nd, 5th and 6th months of treatment started.

The weight of the patients was used to determine the dose of the drug. The weight of all patients under intensive phase of treatment was recorded at the beginning of treatment. One hundred twenty one (91%) of 133 patients received the right dose of the drug under intensive phase. Eight patients received under the recommended doses and four patients received above the recommended dose. The weight of 110 patients were measured at the beginning of continuation phase (end of intensive phase), and the rest 23 patients were not. Of those 110 patients, 58 (52.7%) received the right dose, 47 (42.7%) received below and five (4.5%) patients received above the recommended dose. All patients received the right regimen under both phases of treatment.

One hundred six (62.3%) of 153 intensive phase patients received TB drugs infront of care providers for the NTP recommended 56 days, while the rest for less than 56((Mean=43). Fifty (32.7%) of 153 continuation phase patients visited health centers in regular interval of one month to receive TB drugs and the remaining 67.3% patients missed at least one monthly appointment.

AFB Follow-up examination status of smear positive TB patients was checked from the TB unit register review. Forty eight smear positive PTB patients finished both intensive and continuation phase of treatment and their sputum follow up test were performed**.** From total 48 smear positive PTB patients, 87.5%, 56.2% and 37.5% have gotten smear follow up test at the end of the 2nd, 5th and 6th months of treatment, respectively.

Laboratory practice observation

During study period AFB examination was requested to 12 patients. Each patient submitted three specimens (spot - morning - spot) as per NTP guideline recommendation, thus total number of specimens submitted were 36. Laboratory practice was observed from specimen collection to recording and reporting of AFB result using structured observation guide.

Laboratory technicians instructed all patients to produce the suitable sputum specimen. For all 36 specimens new sputum container and new frosted slides were used. All specimens were stained as per NTP recomendation (AFB staining procedures) but carbon fuchsine and methyline blue were not filtered propely.

Time taken to examine each slide was from 1 to 5 minutes and the mean time interval was 3.2 minutes. All technicians stored AFB slides, negative and positive slides for each run of slides in separate boxes for the external quality control purpose.

Laboratory technicians described that though they stored AFB slides for external quality assurance, they have never sent to regional laboratory. The TB focal person at the district is responsible to collect and take AFB slides from the diagnostic units for regional laboratory. However, the district TB focal person did not even supervised each health center in the last six months prior to the study period. Provider - patient interaction observation

Twenty patients were observed while taking anti- TB drug in front of providers. There was no barrier of communication concerning the language, all of patients and providers were using Afan Oromo. After greeting their clients, providers took the patient cards and tick on the TB unit register; then gave them the drug. Patients swallow drug in front of the providers. Eight out of 20 (40%) observed patients were treated by the providers not assigned to TB treatment, and treatment monitoring chart of 5 (25%) patients were not filled in the TB register during treatment.

DISCUSSION

All selected health centers have been providing TB treatment, but one of which did not have AFB examination service due to the absence of electricity. This mean there were only three diagnostic units for 188,268 populations of the district. The diagnostic unit (microscopic AFB examination) to population ratio is 1:62,756. This is lower than the WHO recommendation for developing countries, which is 1:50,000 [10].

All health centers have at least one nurse who has received in-service training on TB care, however, in one of health centers there was no full time assigned TB treatment provider. Therefore, in three of four health centers (75%) TB care was provided by trained TB focal persons, which is better when compared with the study finding at Tigray where only in 57% by trained TB focal person [11]. Based on the study finding of health workforce crisis in TB control of 22 high burden countries, there was the shortage of staffs at district health facility level in two countries and 14 at central level. However; the same study revealed that there was no apparent association between reported staff numbers and the country's TB burden or current case detection rates [12].

From TB register review the cure rate of smear positive PTB was 64.6% and treatment success rate was 98%. When compared with the study finding at south India, the present study revealed relatively low cure rate and high treatment success rate, which were 84.2% and 83.4% respectively [13]. The treatment success rate is also far better than the national target (85%) for treatment success [3].

From the TB register review 5.8% of patients under intensive phase received below the recommended dose and 2.9% above the recommended dose. Similarly, 40.6% patients under the continuation phase of treatment received below the recommended dose and 4.7% above the recommended dose. In addition to this 21 children received the adult dose of drug due to the absence of paediatric dose in all health centers. This contrasts the national TB control guideline as well as WHO standards; and also could cause drug side effect called hepatotoxicity [1,3,14].

Treatment adherence rate was 62.3% for intensive phase patients and 32.7% for continuation phase. This is the better adherence rate when compared with the study finding in Tigray region where only 5% of patients received observed treatment for recommended 56 days of intensive phase and only 16% attended health facilities on monthly basis to collect TB drug [11].

However, this finding contrasts the recommendation of both national TB treatment guideline and WHO standards of all intensive phase patients must take TB treatment on daily basis, followed by 4 months of self-administered treatment with a monthly visit to health facility to receive the drugs [3,6].

From total 48 smear positive PTB patients, 87.5%, 56.2% and 37.5% have gotten smear follow up test at the end of the 2nd ,5th and 6th months of treatment, respectively. This contrasts the national TB control program, which recommends that all sputum-positive patients on TB treatment must have one sputum specimen follow test at the end of 2nd, 5th and 6th month [3]. At the end of 2nd month

87.5% patients had received sputum follow- up test, which was lower than the study finding at Burkina Faso, 92.1% [15].

Only 64.8% of patients with persistent cough for two or more weeks were ordered for AFB. However; the national TB control program guideline and WHO standards recommended 100% of such patients should have AFB examination [3].

The heads of health centers and Woreda health office TB program pinpoint workers stated that the negligence of care providers to screen suspects was the main reasons for tuberculosis poor diagnosis. The similar finding at China underlined that the failure of physicians to recognize TB symptoms and being not very alert to TB-related symptoms were reasons that the experts described for the purpose of poor diagnosis [16].

Smear positive case detection rate was 4.4%, this contrasts the recommended smear positive case detection rate for developing countries, that is 10% [10]; and also relatively lower than the study finding at Tanzania, where it was 6.1% [17]. It is also too far lower than the study finding in India where 27 % [18], southern nations, nationality and people region where it was 25% [19] and Rwanda, where, 17.3% of TB suspects were smear positive [20].

Limited access or utilization of health facilities, insufficient clinical suspicion and referral of TB suspects for diagnosis, inadequate use or functioning of smear microscopy services were some of the reasons for low smear positive case detection [10]. Similarly, low availability of TB diagnosis units, low requesting of TB suspects for AFB examination and absence of laboratory quality control system were the contributing factors for low smear positive case detection.

There was poor supervision system in all health centers. All health centers have never been supervised by a district TB focal person within six months, prior to study period. However, national tuberculosis controls guideline and WHO recommends planned and regular supervision of TB program. According to NTP guideline district TB focal person should supervise health facilities once per month [3].

The structural aspect (availability) of service was fair; the process aspect (compliance) was poor and the outcome of the service (TB treatment outcome) was good. This finding was against the conceptual framework of the service. However, the structure-process-outcome model is only a servant, not a master. It should be remembered that the relations postulated to exist between adjacent pairs in the structure-process-outcome model are not certainties.

In conclusion, the overall quality of the service was fair. However, there were certain constraints in the provision of quality TB care. Shortage of paediatric TB drugs and AFB reagents and absence of separated TB units in two of health centers were some of the constraints from structural aspects of quality. Likewise, prescribing an incorrect dose of drug, low treatment adherence rate for both phases, not requesting all TB suspects for AFB examination and poor supervision trends were some of the constraints from process aspects of quality.

The intention of this study was to inform program coordinators, service providers and all those concerned about the success and the failure of the TB prevention and control program for better improvement. In addition to this, it will serve as the baseline of the next investigation regarding the quality of TB prevention and control program.

Table 1. Summary dimensions of quality in the diagnosis and treatment of tuberculosis at Kersa district, 2013.

Dimension	Expected (%)	Observed (%)	No. of indicators	Weigh	Result	Judgment
Availability	100%	77.5%	10	40%	31%	Fair
Compliance	100%	69.6%	10	40%	27.8%	Poor
Treatmentoutcome	100%	90%	3	20%	18%	Good
Overall quality of the service			23	100%	77%	Fair

Competing interests

The authors have no competing interests.

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Declaration of Conflicting Interests: The authors declare that they have no conflict of interest.

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