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Evaluation of Tuberculosis Underreporting to National Tuberculosis Program (NTBP) based on data from laboratories in Tehran and NTBP

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Abstract

Background: According to the Global tuberculosis (TB) Report 2014, released by World Health Organization (WHO), difference between estimated number of TB patients and the number of patients who are registered by the National Tuberculosis Programs (NTBP) is about 3 million annually in the world. In the current study, we investigated the level of under-reporting of TB cases between labs with poor collaboration background with NTBP in Tehran.

Methods: In the context of TB, this is an inventory study that evaluating the level of under-reporting of TB cases. To do inventory study, first, after selecting laboratories based on poor collaboration background with NTBP and developing patient's list we matched the patient's list with the MoHME's database then, patients that were not recorded in NTBP's list were identified, and those with available telephone numbers were called.

Results: Out of 23 selected labs, 10 (5 private, 5 public (other than PHC)) had individuals with positive results. 71.6% of all samples are tested in public labs. Out of 23633 performed tests, 1396 individuals were positive. The under-reporting was, 62.5% and 39% in public and private laboratories, respectively.

Conclusion: Public and private sector laboratories will be able to significantly reduce their failure to report if they comply with the recommended requirements and standards of the NTBP in their Processes and software for registering patient information.

Keywords: Tuberculosis, National Tuberculosis Programs (NTBP), Underreporting, Inventory study

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Introduction

Tuberculosis (TB) is the 10th leading cause of death around the globe. In 2015, the incident of TB was about 10.4 million. Out of which, 1.8 were dead, 95% of deaths were in low-and-middle income countries (1). In 2015, its global incidence rate was 142 in 100 000 populations. The East Mediterranean Region (EMRO) of the World Health

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↑What is "already known" in this topic:
Difference between estimated number of TB patients and the number of patients who are registered, is about 3 million annually. The WHO mentioned the following reasons as the potential causes of this difference: {1} lack of access to health-care services, {2} people may have access to health-care services but the disease is not diagnosed, {3} patients may be diagnosed but are not registered.

→What this article adds:
Due to the lack of an integrated electronic health information system between laboratories, insurance organization and the Ministry of Health, the comprehensive fight against Tuberculosis has been challenged (patients may be diagnosed but are not registered). This study Proved the third reason and identified the processes that need to be improved to address the third cause that the WHO has mentioned.

Organization (WHO) with 670 000 infected persons and incidence rate of 109 per 100 000 populations accounted for 6 to 7% of the global burden of TB in 2013 (2). During 2010 to 2015, the success rate of TB treatment in the EMRO was about 88% (3). In 2015, the incidence rate of TB in the Islamic Republic (IR) of Iran, as a member of the EMRO, was 13 per each 100 000 populations and success rate of treatment was about 87% (4). According to WHO's report in 2015, the program for diagnosis, treatment and prevention of TB saved 43 million lives and since 1990, its mortality rate reduced by 47% (5).

However, based on the WHO's report in 2014, the difference between the estimated number of TB patients and the number of patients who are registered by the National Tuberculosis Programs (NTBP) is about 3 million annually. This statistical difference has been repeated during the past seven years. The WHO mentioned the following reasons as the potential causes of this difference: {1} lack of access to health-care services, {2} people may have access to health-care services but the disease is not diagnosed, {3} patients may be diagnosed but are not registered. Poor registration systems, lack and/or inadequate relationship with private physicians, hospitals and laboratories, and lack of mandatory reporting could be possible reasons for the latter. Some these 3 million hidden patients will die, some will survive and contaminate healthy people. 75% of this difference is related to 12 countries. World Bank has estimated that each dollar investment on TB will result to 30-dollar return (USA $). According to the latest estimates, only one out of every four patients with drug-resistant TB is detected (6). During the past two decades, two main strategies were employed to fight TB. First, diagnosis and treatment of TB using DOTS or Directly Observed Treatment Short course, from 1990s to 2005. Second, the Stop TB Strategy, since 2006 up to now. The Stop TB Strategy was developed as a mean to achieve Millennium Development Goals. The Sustainable Development Goals (SDGs) also considered TB.

The SDG 3.3 is to eradicate TB by 2030. The global strategy to stop TB was adopted by the WHO in 2014 as part of the goal to eradicate TP pandemic by 2030. TB related goals of SDGs are already met in IR Iran. In SDGs, the goal on TB has been linked with the goal on Universal Health Coverage, so that by 2020 no family should face catastrophic health expenditures because of TB disease. 3 main pillars of the strategy to eradicate TB are {1} a program that is patient-centered and integrated; {2} highlighted policies and supportive systems; and {3}increasing research activities and innovation (7).

Status of TB in Tehran (capital of Iran)

Iran's capital, Tehran, with a population over 13 million, is a constant referral base for patients from around the country and the region. In Tehran, availability, accessibility, acceptability, and quality of TB treatments is well established, there are more than 19 smear microscopy, 2 culture laboratories in addition to one regional laboratory which are certified by the Supranational Reference Laboratory Network SRLN (and we know them as PHC TB lab network which provide free of charge services). In addition to the PHC TB lab network, there are a large number of private and public TB laboratories in the province of Tehran. Maximally, by a 20 minutes' travel people have access to a valid center for TB diagnosis and treatment. For people's poor financial conditions there are centers in PHC-network that provide free services. These centers actively follow patients with TB diagnosis.

Under-reporting and under-diagnosis are among important issues that are mentioned in WHO's 2015 report on TB, so that the difference between data sources, such as insurance organizations, and National TB Registration Systems, indicates a highlight gap(5). In this study, reporting and registration rates of TB patients in laboratories in I.R. Iran are investigated.

Methods

What is an inventory study and why is it important?

In the context of TB, an inventory study was done to assessing the level of under-reporting of TB cases. TB inventory studies compare the number of cases meeting standard case definitions recorded in all or a sample of public and private health facilities with the records of cases notified to local and national authorities. The comparison is done through a process called record-linkage (8).

Inventory studies can help to identify (and certify) countries in which TB incidence can already be measured directly from surveillance data. In other countries, they can be used to improve estimates of TB incidence by quantifying levels of under-reporting. Measuring levels of under-reporting can also help to identify ways in which surveillance systems need to be strengthened to progress towards the ultimate goal of measuring the number of cases directly from notification data (8).

Selecting laboratories and developing patient's list

First, after consultation with the Department of Tuberculosis, laboratories which have doubtful reporting system but are known in public and private sector for TB diagnosis were identified in Tehran. Based on Department of Communicable Diseases of MoHME, weak reporting is defined as irregular, discontinuous, and incomplete report during past years. Three types of diagnostic tests were selected as criteria, sputum smear, cultures, and PCR. Also, two PHC TB lab network were included in the study to compare their underreporting with selected laboratories.

Data about patients with positive tests, including full name, father's name, gender, national code, residential address, telephone number, name of the laboratory, nationality, type of laboratory (public, private and PHC laboratory), for the period of March 2014 to September 2014, were obtained from selected labs. Patients with positive results were recorded. Also, the number of samples with negative results were collected.

Matching collected data with MoHME's database

After developing the list of patients with positive results in selected laboratories, obtained data were compared with NTBP's database, for the period of March 2013 to December 2014. Because the authors were not able to deter-

mine whether patients were new cases (incidence) or prevalence, a longer time period was chosen to search NTBP's database. During this time period, 20 903 TB patients were registered all around the country. Then, patients that were not recorded in NTBP's list were identified, and those with available telephone numbers were called. Questions were only asked from patients and, if she or he was not alive, first relatives were asked. During the study, confidentiality was the author's first priority.

Ethical considerations

The current study has received its ethical code from Tehran University of Medical Sciences and MoHME. The authors have done their best to meet the confidentiality and anonymity of participants.

Results

Out of 23 selected labs, 10 (5 Private, 5 Public (other than PHC)) had individuals with positive results. Each lab had its own registration system. The time period of reporting to NTBP was also varying, from monthly reporting to every six months. To estimate the reporting rate, collected data were compared with NTBP's database. Among 1396 registered individuals with positive results (TB patients), 854 were male (61.2 percent), and 542 females (38.8 percent). For 959 patients, nationality was mentioned, 148 (about 15 percent) were not Iranian. Almost all of the foreigners were from Afghanistan (except for one patient from Azerbaijan, one from Iraq, and origin of three of them only was only mentioned as 'foreigner').

As Table 1 shows, 71.6% of all samples are tested in public labs. Also, out of 23633 performed tests, 1396 were positive (TB patient), which 82% of them were in public labs, (Fig. 1).

62.5%, and 39% of cases were not found in public and private laboratories, respectively (Fig. 2). One of the laboratories with 100% match had the best performance, and one of the laboratories had the poorest performance with 35% match.

Out of 813 TB cases who were not registered in the NTBP, 618 of them had registered telephone number. Those with telephone number were followed through TB office of the MoHME. Out of 618 TB patients with registered telephone number, 284 pateitnes answered the phone and 334 patients did not (reasons were: the number was

Table 1. Public and private providers from provided services and their contribution in diagnosing TB patients

	Private	Public	Total
Number of tests	6717(28.4%)	16916(71.6%)	23633(100%)
Number of diagnosed patients	252(18.1%)	1144(81.9%)	1396(100%)

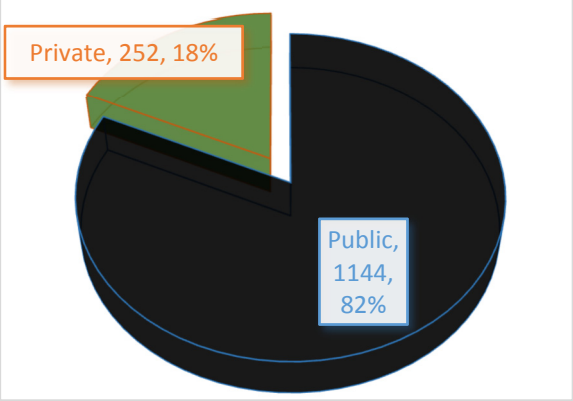

Fig. 1. Share of each section in diagnosed patients

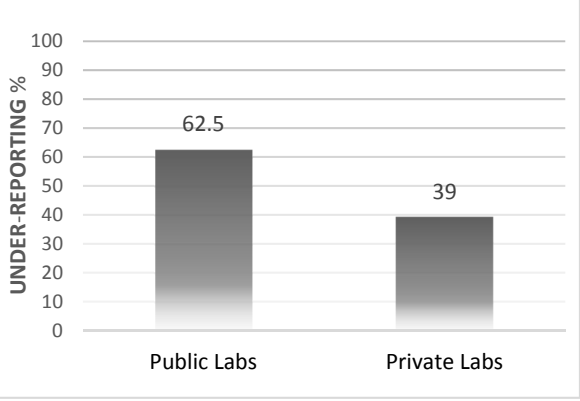

Fig. 2. Comparing Reporting Rate in each section (These values cannot be generalized to the whole system & belong to the labs with poor collaboration background with NTBP)

Table 2. Status of TB positive patients (who that were not found in the NTBP) tracked using telephone calls

Laboratory		Private	Public
The number of calls has been made		43	575
No response*		20	314
Responsiveness		23	261
The number of deaths before diagnosis		2	13
The number of deaths during treatment		2	40
The number of deaths after discharge		-	18
Where treatment has been received	Public hospital	3	101
	Outside of Tehran (private clinic)	8	50
	Discontinuation (remaining in the test phase)	8	3
	Defined centers for treatment	2	100
The place where the drug was taken	Special centers have been set	-	161
	Private pharmacies	-	91
Treatment less than 6 months		-	196
Treatment more than 6 months		-	50

* The number was not available, the phone was turned off on 3 times call, wrong phone number, the phone line was sold to another customer, etc.

not available, the phone was turned off on 3 times call, wrong phone number, the phone line was sold to another customer, etc.) (Table 2). In compliance with patient rights, a series of questions about the treatment place, the place where medicines were bought or taken, and diseases status were asked. If the patient was dead, questions were asked from relatives, whether the patient died before diagnosis or during treatment or after discharge (Table 2). If the patient was dead, due to the sensitivity of the issue and in order to avoid creating any concern for the raltives, detailed information was not obtained, where applied.

All of the recorded deaths were not due to TB, and various reasons were mentioned. In all cases that were passed, the authors failed to ask the main cause of death because of the grieving of the family. In 8 cases the treatment was not continued. 104 patients continued their treatment at public hospitals. 58 cases continued their treatment in the private sector, mostly not reported.

Two PHC TB lab network were also examined for under-reporting. This labs used the same Registration and Reporting policy. All cases in the PHC TB lab network were registered in the NTBP database.

Discussion

The incidence and prevalence of TB are usually higher in men so that in some countries, the incidence rate in men is twice than women (9, 10). In 2014, about 9.6 million TB patients were recorded, out of which 5.4 and 3.2 million (59.2%) were male and female, respectively, and one million were children (5). According to MoHME's report 12.8% of TB patients in Iran are foreigners (11). In 2014, 83% of TB patients in New York, USA, were foreigners (totally 198 patients were registered) (12). In the current study, 15% of patients were foreigners. In 2015, about one million refugees migrated to European countries, most of them were from Iraq, Afghanistan, and Syria. Studies show that the extent of this migration can change the Epidemic of TB (13). Iran, also, is surrounded by this threat. Afghanistan and Pakistan, on the eastern border of Iran, are two countries with high rates of TB incidence. Iraq, on the western border, is experiencing high levels of conflicts. The United Nation High Commission for Refugees reported that in 2015, about one million refugees entered Iran through legal ways, that most of them were from Afghanistan(14). Hence, improving health indicators in neighboring countries and promoting border health policies and the implementation of health diplomacy can be one of the options ahead.

Registration and reporting TB patients is a part of the program for control and care TB patients. Comprehensive relationships between physician, pharmacies, laboratories, and NTBP definitely have an obvious role in controlling TB. China after the establishment of an electronic system for reporting communicable diseases in 2004 experienced a dramatic increase in the number of reported patients (15). South Korea established an online system for reporting TB in 2000; its main aim was to calculate incidence and prevalence, but an investigation in 2006 showed that only 67.6% of patients who were diagnosed and treated in private sector were reported, while all patients in public sector were reported. In 2008, in addition to NTBP data, national health insurance data also were used for registration of TB patients. Through comparing these two data sources, it was revealed that 11.5 and 6.7% of patients in 2012 and 2013 were underreported to NTBP. Underreporting and/or no reporting was higher in private hospitals than public ones (5). The reporting rate of TB patients in Massachusetts, Puerto Rico, and Nassau County was 81, 86 and 65%, respectively (16). Another study in Greece showed that underreporting is about 80%. In other word, the incidence of TB in Greece is five times higher than the current one (17).

According to WHO's report on TB in 2015, 37% of 9.6 million estimate TB patients either are not diagnosed or not reported (5). In the current study, underreporting varied in different sectors, so that almost all patients who were visited/tested in PHC-network were reported. Underreporting in the public sector was 62.5%, it was mainly because of the lack of auto reporting system and also did not have professional staff who are skilled for reporting to NTBP. In the private sector, underreporting was 39%. In total, underreporting was 57.5%.This percentage was determined for laboratories with the worst reporting background in Tehran province and certainly cannot be generalized to the whole system or country. In small cities with a little workload, as well as in laboratories with a good cooperation background, the situation is different.

In follow-up of patients who were not registered in NTBP, it was found that some of them were receiving their medicines from private pharmacies (although all of them were based on medical doctor prescriptions). It shows that their healthcare providers were not aware of NTBP's and MoHME's policies about free distribution of TB medicines through PHC-network. Sensitivity of registration and reporting cannot be investigated through dividing centers into public, and private, because the highest level of reporting and simultaneously the lowest level of reporting belonged to public centers. With regard to the different charges for the sputum smear and cultures in public and private centers in Iran (two times more in private centers), most of the people prefer to go to the public centers, with the highest reputation. While 69% of tests are performed in public center, 80% of cases were diagnosed in public centers, which implies that high risk individuals were referred to these centers (public).

It should be noted that patients' information registration based on the time of treatment in hospitals and the time of diagnosis in laboratories was separate and different. Therefore some patients who were diagnosed in the lab might provide different information during treatment for various reasons. Some of the reasons may be as follow:

- Using other people's insurance book, because of lack of insurance (Iranian health insurance companies cover different services with different prices)
- Temporary residence, and therefore different addresses
- Stigma, fear from the irrational view of relatives, neighborhoods, and employers
- Foreigner patients may be illegal immigrants and fear to provide their residential address or may have not a

fixed place for living
- Initial shock resulted from a positive result
- Using fake names in the diagnosis phase
- Using the address of relatives who are living near the laboratory
- Using the address of another individuals

Also, the following reasons can be mentioned for the incomplete recording of patients' information:
- Samples which have been sent from other healthcare center usually are not checked for full record of information
- Laboratories consider the name, family name and a phone number as sufficient information
- Patients are not willing to provide information

With regard to what mentioned above, there is a possibility for registering a patient in the laboratory but not reporting her or him to NTBP, because different information are registered at the diagnosis phase. Some patients, also, are not totally reported. In this case, using multiple data sources and 'each patient one health code system can be a helpful way to address this issue (Using health insurance data can also be helpful in Iran's NTBP). But, before its implementation, all health insurance companies must employ EHRs. Almost all issues that were mentioned as problems are intra-sectoral, such as national health book, software for registering patient at diagnosis level (laboratories), and illegal migrants with TB diagnosis.

For homogeneity of recorded information at the diagnosis level, WHO has provided a framework that includes information such as Age or age group, Sex, Year of registration, Bacteriological results, History of previous treatment, and Anatomical site of disease. For case-based systems, a patient identifier Homogeneity of information also increase the credibility of obtained results. By employing WHO's framework NTBP programs will be able to categorize data based on regions, provinces, urban or rural, age group, mortality, comorbidities (such as TB and HIV/AIDS)(18)– currently NTBP's database in Iran can be Provide these categories. The WHO's framework is based on the assumption that the entered data are valid, and, if the patients do not provide correct information, problems still will exist. Employing EHRs can provide a solution. Based on the collected information, AZMON, TREND, and SYSTEM were the most common software that laboratories are using. Investigating these softwares revealed that MoHME's recommendations are not used. Then, using the MoHME's recommendations in future updates for these softwares will be helpful.

Iran's fifth developed plan (2012-16) emphasized on employing EHRs. EHR is the main requirement of providing innovative healthcare services and can be considered as the backbone of the health system. In this regard, since the beginning of 2016, integrated system of "SIB" –a Persian word that means apple- was implemented, that by the beginning of 2017 more than 42 million Iranians were registered. Using this information system can be helpful to reduce the number of unregistered TB patients.

At the end, given the 3 million difference between what is mentioned in WHO's report on TB in 2014, it can be said that a part of this difference in countries with required diagnostic and therapeutic centers is due to lack of integrated health information system, which results in unintended elimination of some diagnosed patients. The WHO report in 2015 noted that improving TB's care systems have resulted in increasing the total number of TB patients(5). Although registration and reporting the diagnosed patients is weak, it can be a hidden strength in fighting with TB. While some patients are not registered in NTBP, they have access to diagnostic and therapeutic services that they need.

Conclusion

As a result of Collaborating with NTBP and fulfilling their standards with a 100% compliance, PHC laboratories have represented the best condition in terms of reporting cases. Public and private sector laboratories will be able to significantly reduce their failure to report if they comply with the recommended requirements and standards of the NTBP in their Processes and software for registering patient information. It should be noted that the cooperation between insurance companies and designers of software and national health electronic records will have a significant impact on this reduction.

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Conflict of Interests

The authors declare that they have no competing interests.

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