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Mohammed AlKhalawi   April 23, 2013

**Evaluation of Tuberculosis Public Health Surveillance,
Al-Madinah Province, Kingdom of Saudi Arabia, 2012**

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ABSTRACT

Objective: To evaluate the quality of the data, the sensitivity of the surveillance, and the completeness of identification and investigation of patient's contacts for the tuberculosis (TB) surveillance program in Al-Madinah province. The surveillance program is responsible for data collection, analysis, feedback, as well as the implementation of actions and has a significant role in controlling and eliminating the disease.

Methods: The study covered the TB surveillance program in Al-Madinah province in 2011. First, we reviewed all the notifications, treatment cards, and register books, as well as monthly and quarterly reports, for completeness and accuracy of data. Then, we searched for the missed cases that were not reported. Finally, we reviewed all the patients' contacts' reports to assess the degree of completion of identification and investigation.

Results: The results revealed high completeness rates for demographic and disease data and low completeness rates for the test result fields. The sputum smear and chest x-ray fields were 80% complete. Furthermore, the tuberculin test field was left blank in 108 cases (46% completeness). Moreover, the sputum culture field was completed only in 63 reports (31.5% completeness). The lowest completeness was seen in the HIV test result field, where only 50 cases (25%) were completed. The contact identification and investigation showed that 42 smear-positive cases' contacts were not identified. Out of the 448 contacts identified, only 301 (67%) of them were investigated. The review of hospital records and lab registers showed that 244 cases were not reported, in spite of the fact that 213 of them (87.3%) were confirmed by labs.

Conclusion: The results indicated that the rates of completeness for the different notification report fields varied; the lab result and HIV test fields had the lowest rates of completion. Also, over half of patients' contacts were not identified or investigated, and there were a significant number of unreported cases, most of which were laboratory confirmed. Finally, we found a number of discrepancies between the treatment cards, logbooks and the reported data.

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Introduction

1.1 Disease Importance

Tuberculosis (TB) is a significant global health problem. Among infectious diseases, TB is the second leading cause of death globally and the single most infectious killer among youth and adults (1). TB is also a leading cause of death among women (2). Annually, millions of people all over the world are infected with *Mycobacterium tuberculosis* (Mtb), the bacterium that causes TB. Not all TB cases are identified, and some identified are not treated. Untreated active TB patients can infect 10 – 15 persons annually (3). So, there are 1.4 million deaths annually even though the available short course drugs can treat 90% of them. Among patients who have died, half a million are women, and 64,000 of them are children (4).

Multiple factors (e.g., international travel, migrations, tourism, and commerce) play a role in the global spread of TB. Within countries, crowded living conditions, poverty, and contact with an infected person are the most significant risk factors affecting the spread of the disease. The TB picture is even worse when an individual is co-infected with Human Immunodeficiency Virus (HIV) or has developed a drug resistance. According to the World Health Organization (WHO), ⅓ of HIV patients are infected with TB, which is the major cause of death among them (1).

In 2011, ¼ of the deaths among HIV patients were due to TB. Furthermore, drug resistance to TB that is caused by bacteria that do not respond to first line treatment (MDR-TB) is growing. In some cases, severe resistance to second line treatment (XDR-TB) may also occur (4).

1.2 Global Pandemic

TB is still considered highly important on the international public health agenda. Currently, ⅓ of the world's population is infected with Mtb (1). In 2011, WHO estimated the number of new TB cases to be 8.7 million (1). There were 1.4 million deaths and more than 10 million orphans as a result of TB. However, the estimated number of new cases has decreased annually, which means a decrease in the global burden of TB. Between 1990 and 2011, the death rate dropped by 41% (1). At least 95% of deaths occurred in low and middle-income countries. In 2011, there were 430,000 deaths due to HIV and TB combinations, and there were 1.1 million new TB-HIV cases, most of which were in Africa. About 310,000 cases of MDR-TB were reported in the same period, and 9% of them were XDR-TB (4).

1.3 Regional Pandemic

TB in the Mediterranean Region is in a state of improvement. In 2011, the prevalence of TB was 1,000,000 patients. In addition to 660,000 new cases, there were 9,000 TB and HIV co-infections. In total, there were 99,000 deaths due to TB in the region in 2011. In addition, there were 10,000 estimated new cases of MDR-TB (4). There has been a decrease in the prevalence and mortality rate (5). The notification rate has increased, while the estimated incidence rate has decreased, indicating an improvement in case identification and diagnosis (4).

Among countries in the Middle East, the Kingdom of Saudi Arabia (KSA) does not have the highest TB burden, yet it faces real challenges in controlling and preventing TB due to its huge number of pilgrims and migrant workers (6). In 2011, there were 6,200 cases there, of which 4,900 were new. In the same period, there were 1,100 deaths due to TB. In addition, there were 110 cases of TB and HIV co-infections. According to WHO, only 80% of cases were detected, and most of the new cases were smear-positive, which is the most contagious type. The

WHO estimates that MDR-TB comprises 1.8% of all of TB cases. In contrast to the Mediterranean Region as a whole, the prevalence and mortality rates in KSA over the last ten years were almost unchanged (7).

1.4 Disease Impact

TB affects not only the patient's health, but also his quality of life, family, community and government (8, 9). TB patients have a heavy burden: most cases occur in their most productive years of life, and after contracting the disease they become weak and unable to work. Patients' families must deal with the serious issues of caretaking and the possibility that the infection might be passed to them. The direct costs of the treatments and the indirect costs of absence from work are an economic burden on the government. While the health impact of the disease can be described by the incidence, prevalence and mortality rate, the economic impact cannot be described exactly and directly. The WHO estimated the annual spending on TB in low and middle-income countries to be $8 billion (10). In fact, some studies estimate that TB is the greatest economic burden of any in the societies where it is prevalent (11).

1.5 Problem

KSA, like many countries in the world, has a TB public health surveillance (PHS) program. It is responsible for data collection, analysis, and feedback, as well as the implementation of actions. The quality of data in a TB PHS program is critical. More accurate and complete data increase the usefulness of information. High detection rates and accurate and complete data help health officials understand the trend of the disease and its characteristics, in addition to the disease burden. The identification of new TB cases among patient contacts is one of the key steps in preventing TB's spread. A strong PHS system helps decision makers establish and evaluate different interventions to control the disease. Furthermore, it assures

appropriate medical therapy and follow-up. Beyond that, the data can be used to make

comparisons between different regions and other countries.

1.6 Significance

TB remains an important disease requiring more attention and effort to control and

eliminate in KSA. The quality of data that is collected by the PHS program is critical. High

quality data is especially key since it is used to determine the distribution of the disease and

preventive actions. Moreover, increasing the detection rate and implementing measures that

prevent the transmission to contacts are critical steps to achieving WHO goals and MDGs. To

date, no study has ever been done in KSA to evaluate the TB PHS program.

Literature review

2.1 Kingdom of Saudi Arabia

KSA is the largest country in the Arabian Peninsula, and one of the most important countries in the Middle East. KSA occupies approximately 80% of the Arabian Peninsula with a total area of 2,150,000 sq. km (830,000 sq. miles) (12). It is bordered by the Red Sea in the west, and in the east by the Arabian Gulf, the United Arab Emirates, Qatar, and Bahrain. In the north, it is bordered by Jordan, Iraq and Kuwait and in the south by Yemen and Oman. In 2011, the estimated population of KSA was 28,376,355; more than 68% were Saudis (19,405,685) and the rest were foreign residents (13). KSA is divided into 13 provinces, each with a number of governorates. The capital city, which is located in the central region, is Riyadh.

Due to the discovery of oil in the 1920s and the resulting industrial growth, KSA has become a rapidly developing country. All of the country's sectors have demand for labor in different positions. Currently, more than 30% of the residents are immigrants with their families, distributed all over the country. Most of the immigrants are from poor, TB endemic countries (e.g., Asia, Southeast Asia, Africa).

Makkah and Al-Madinah are two important cities in the KSA that are holy for Muslims all over the world. The cities attract millions of visitors yearly performing Hajj, which is the fifth pillar of Islam. It is a pilgrimage to the holy city of Makkah performed from the eighth to the twelfth day of Dhul-hijaa, which is the twelfth month of the Hejre calendar and must be undertaken at least once by all Muslims who can afford to do it physically and financially. In addition, pilgrims can perform Omrah, a pilgrimage that can occur any time of the year. Hajj is the largest mass gathering in the world (14).

The province of Al-Madinah is located in the north of Holy Makkah. Since it is the second holiest city in Islam, most pilgrims tend to visit it; it is the place where prophet Mohammed emigrated and lived, and pilgrims come to pray in his mosque. The province contains eight governorates and its capital city is called Al-Madinah (15). The total population of the province is 1,777,933 and approximately 30% of them are foreign residents (13).

One of the most important ministries in KSA is the Ministry of Health (MOH). The MOH is responsible for the treatment and prevention services of all diseases all over the country through its directorates of health affairs that are present in each province. Also, it is responsible for planning and managing different health programs. In 2010, total health expenses in KSA were $8,245,000, which was 6.5% of governmental budget and came to $345 expenditure per capita. The health system is divided into three levels: primary, secondary and tertiary. Primary health care refers to health care workers who represent the first line for treating all patients and preventing diseases in the community. Usually, primary care is provided by family physicians in primary health care centers that are distributed in each district all over the country, even in villages. Generally, any case that requires advanced care is referred to a hospital. The second level of care in KSA is secondary care that is delivered by specialists and health professionals in the general hospitals. Currently, each city in the Kingdom contains one hospital or more to offer health care to the community. Tertiary care is provided through specialized hospitals or centers that give advanced health care to patients. Multiple centers are present now in different cities. One of the biggest advantages of the KSA health system is that all of the treatment and preventive services provided by the MOH are available for free to all KSA citizens and non-KSA governmental employees. Also, the treatment of contagious diseases and some specific prevention services, like immunizations, are free for every one, including non-citizens (16).

The MOH is responsible for the majority of health treatment and preventive services in KSA. Other health providers in the government and the private sector play a role in the treatment and preventive services. In the governmental sector non-MOH divisions (i.e., National Guard Health Affairs, Army Forces Medical Services) provide their services to their employees and their dependents. All health providers offer services at primary, secondary, and tertiary levels.

In each province, the MOH directorate of health affairs is responsible for implementing and supervising the health programs, treatment, and preventive services. Under each directorate is deputy of public health and multiple hospitals. In each city, there are a number of sectors, and under each sector, there are multiple primary health care centers. The MOH manages > 244 hospitals with a capacity of 33,277 beds. MOH also manages 2,037 primary health care centers (PHCs). Other governmental agencies manage 39 hospitals with a capacity of 10,822 beds. The private sectors manage 125 hospitals with a capacity of 11,833 beds and 1,950 dispensaries and clinics distributed in most cites. Moreover, more than 25,800 physicians, 63,300 nurses, 1,650 pharmacists, 32,360 allied health personal, and 26,000 personnel work in the MOH.

Although the KSA exerts much effort and spends a lot of money on TB, the MOH still faces big challenges to prevent and control TB due to large numbers of pilgrims and immigrant workers who come during the year. Annually, more than 3.16 million people from all over the world perform Hajj and more than 5.6 million people, excluding the residents in the country, perform Omrah (13) (17). The number of pilgrims has increased annually (8% in 2012). Furthermore, the immigrant workers and their families number more than nine million people; most of them are from endemic TB countries (e.g., India, Pakistan, Bangladesh, Indonesia) (13).

2.2 TB

TB is an infectious disease caused by Mtb. The bacteria are transmitted from an infected patient to a healthy person through the air after coughing, talking and sneezing. One of the significant issues related to TB is that not all infected persons develop the disease. In the cases of latent TB infections (LTBI), the infected people do not have symptoms or feel sick. Moreover, those people cannot transmit the disease to others unless Mtb becomes active and they become diseased. Patients with active TB are able to spread the disease to their contacts. Most TB cases are pulmonary; however, in some cases it can be extra-pulmonary and affect the kidney, spine, brain or lymph nodes. People with TB complain of a number of symptoms including cough, hemoptysis, chest pain, night sweating, fever, weakness, weight loss and lack of appetite (18).

Infected people differ in their response to TB since they differ in their immune systems. Some develop the disease within weeks while others become sick years later. Usually, 10% of LTBI become infected if they don't undergo treatment. The risk of disease is high in people with weak immune systems (i.e., AIDS patients, diabetes mellitus patients and substance abusers). Furthermore, those who come into close contact with an infected person, immigrants to high TB rate areas, the homeless, injection drug users and medical staff who take care of TB patients are at high risk for developing TB (18).

While a positive tuberculin skin test (TST) or positive TB blood test can determine whether or not a person has been infected with TB virus, it does not indicate whether the person has a LTBI or TB. Other tests, such as a chest x-ray and a sputum smear and culture, can be used to clarify the condition. Usually, a diagnosis of TB is made based on a medical history, physical examination, tests for TB infection and a chest x-ray (18).

In some countries, the Bacille Calmette-Guérin (BCG) vaccine is given to infants and small children to prevent them from acquiring tuberculosis meningitis and miliary disease. However, the vaccine does not prevent all types of TB. When someone does contract TB, several drugs in various regimens can treat it. Depending on the situation, the treatment period varies from 6-9 months. To help patients take their medication and prevent resistance due to noncompliance, a directly observed therapy (DOT) strategy has been established, in which the patients take their medication in front of health care workers (HCW) daily (18).

In some cases, Mtb can develop drug resistance. Drug resistance develops when a patient does not complete the full course of treatment or does not take the medication regularly. This also occurs when the doctor prescribes the wrong treatment, the wrong dose or the wrong duration. Furthermore, the contacts of DRTB patients and those who have come from DRTB areas are prone to DRTB. If the organism resists isoniazid and rifampin, it called multidrug-resistant TB (MDR TB). If it resists isonized, rifampin, any fluoroquinolone, and at least one of three injectable second-line drugs (i.e., amikacin, kanamycin, or capreomycin), it is call extensively drug-resistant TB (XDR TB) (18).

2.3 Surveillance

Public health surveillance (PHS) is the "ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health action to reduce morbidity and mortality and to improve health"(19). Usually, the data that are disseminated by PHS can be used for describing disease situations, burdens, trends and detecting outbreaks early. Also, the data can be used to improve health systems by defining and ordering priorities, helping decision makers plan and implement new health programs as well as evaluate

existing programs. Furthermore, the data can help in resource allocation, evaluation of public policy, and formulation of new research hypotheses (19).

Although surveillance previously focused on major epidemics and infectious diseases, it currently encompasses non-communicable diseases, risk factors, health-related behavior and health-related events. Due to the different purposes of surveillance programs, their reporting systems differ. The two main types of surveillance are active and passive surveillance. In passive surveillance, health providers routinely report the data of patients with specified diseases to the health coordinator. On the other hand, in active surveillance, the health coordinator contacts the providers and asks for reports. While active surveillance is used for epidemics and suspected outbreaks, passive surveillance is used to report routine notifiable diseases. Passive surveillance is simple, cheap and not burdensome to the health coordinator. However, most passive surveillance reports are incomplete and some cases are not reported or the reporting is delayed, so they cannot detect outbreaks. Active surveillance assures complete reporting, but it is expensive and burdensome to the coordinator and health workers (20).

Better PHS will help the MOH improve the quality of services. Accurate data will assist decision makers in planning and ordering priorities. Timely data will support early outbreak detection and response. Also, the effectiveness of each intervention will improve and the cost will decrease (21). To improve PHS, it is essential to evaluate it regularly to ensure that the disease is monitored efficiently and effectively. Different PHS attributes can be assessed depending on the purpose of the program and the aim of the evaluation. Completeness of reporting, the sensitivity and specificity of the program, the simplicity, the timeliness of reports, and the data quality are the most important evaluated characteristics. The evaluation methods should highlight the substantial features since the PHS programs differ in their purposes,

objectives, methods and target populations (19). After each evaluation, the recommendations should be adopted to improve the quality, efficiency and usefulness of the program.

2.4 PHS in KSA

In KSA, there are multiple PHS programs to keep track of different health issues. These programs cover different communicable, non-communicable, and vaccine-preventable diseases. Different approaches, reporting forms and required timeframes for reporting are used depending on the goals of the program and the significance of the disease under surveillance. Currently, there are 36 notified infectious diseases in KSA (e.g., measles, mumps and poliomyelitis). Also, there are PHS programs for non-communicable diseases (NCD) like diabetes mellitus, hypertension and respiratory diseases. Furthermore, vaccine preventable diseases like poliomyelitis and hepatitis B are also under surveillance.

Since 1984, all HIV cases have been reported to the coordinators of the HIV surveillance program. Usually, the cases are detected after examinations due to clinical suspicion, screening of active cases' contacts, premarital screening, and migrants' pre-employment examinations. Also, the active surveillance of target groups like prisoners and drug users leads to the identification of some cases. All hospitals and clinics are required to report all HIV positive cases to the regional program coordinators. After that, the patients are referred to tertiary care centers and provided with needed treatments and investigations. At the same time, the regional program coordinators assign a unique code to each patient and report all cases to the head of the program in the MOH. The head of the program releases an annual report to concerned officials but not to the public (22).

A PHS program was established to keep track of vaccine-preventable diseases (VPD). The benefits of this surveillance are that it assists in estimating the disease burden, identifying

and controlling outbreaks, and providing data to decision makers for use in deciding which polices and intervention to implement. PHS encompasses but is not limited to poliomyelitis, diphtheria, pertussis, tetanus, measles, mumps, rubella, hepatitis B and meningitis (23).

Measles is another infectious disease that is notifiable by law in KSA. All suspected cases in primary health centers (PHC) are reported to the regional coordinator immediately (within 24 hours) and referred to hospitals to confirm the diagnosis and treatment. After lab confirmation, the case is reported to the regional coordinator as a confirmed case. At that time, active PHS starts in order to detect additional cases among the contacts of the case and to vaccinate the contacts. For each new case detected during active PHS, similar investigations are done among the contacts to detect cases and vaccinate them until no new cases are detected. All the confirmed cases are reported regularly to the head of the program in the MOH. The coordinator of the program collects, analyzes and interprets the data to decide what action should be taken. Also, he or she monitors the program activities and evaluates the outcome and impact of each intervention (24) (25).

2.6 TB Reporting in Different Countries

Nowadays, all the developed countries and some developing countries have their own TB surveillance programs because it is important to control and eliminate the disease as well as reach the WHO goals and MDGs. The different characteristics of existing programs depend on the disease situation and country's economic capacity. The differences lead to variations in the efficiency and usefulness of the programs. Here, three programs in Canada, Australia and Hungary will be described. Most PHS programs in developed countries share characteristics such as the use of an automated program for notification, the review and examination of data to ensure high quality data, and the reporting by labs of positive cases. Also, these programs

include supporting surveillance focused on target groups, in addition to continuous evaluation and process improvement.

The Canadian Tuberculosis Reporting System (CTBRS) is the national Canadian surveillance system that covers all provinces and territories. All clinically diagnosed and laboratory confirmed cases are reported to CTBRS, both new and relapsed cases. After that, the data is validated by comparing the paper-based or electronic reports with the original data sources. Then, the data is entered to a standalone computer to be added to TB dataset. All the disease data, as well as HIV status, lab results and treatment outcomes are added to the dataset. Then, the advanced dataset automatically produces a specific standardized analysis including tables and graphs. Later, the annual report is disseminated to public health officials, healthcare professionals, researchers and the media. Also, the data is shared with WHO and other health organizations concerned with TB. The surveillance has highly accurate data due to Canada's universal insurance and required reporting. In addition, another two national surveillance systems assist the CTBRS. The first one is laboratory-based and sends lab results on an ongoing basis to LCDC (Laboratory Center for Disease Control). The second one is aimed at the inmates and staff in federal correctional facilities in Canada. The unique feature of this system is that it monitors one of the most important target populations (26).

The National Notifiable Disease Surveillance System (NNDSS), which was established in 1990 under the Communicable Diseases Network Australia (CDNA), manages the communicable disease reporting system in Australia. All 65 notifiable diseases are electronically reported daily or several times a week to NNDSS. All medical practitioners and laboratories are required to report TB cases to state and territory health authorities. After that, the states and territory health authorities send demographic, disease, and reporter data to the NNDSS. Each

reported case is assigned a unique number with no personal details identified in order to ensure confidentiality. Also, data of drug susceptibility of bacteriologically confirmed cases is collected, analyzed and reported. Due to the effective TB screening program, high standard of health care and multi-disciplinary TB services, almost all TB cases are reported. Furthermore, all the data received were examined for completeness and accuracy to assure high data quality. Any invalid or missed data are returned for review and correction. Moreover, there is a continuous process to improve the surveillance (27).

Another example of TB surveillance is in Hungary. There, all suspected cases are referred to district chest clinics to confirm the diagnosis. The patients are hospitalized in the regional respiratory institutes if the diagnosis is confirmed while the contacts are examined and treated in the district chest clinics. During the initial phase of treatment, patients are monitored clinically and bacteriologically. After that, patients are discharged and referred back to district chest clinics to complete the full course of treatment as outpatients. Until patients are fully cured, the district chest clinics follow up with them, provide them with medications, and perform the important tests. All physicians and hospitals are required to report new cases as well as reactivated cases to regional respiratory medicine institutes. Also, all initial and follow up TB results (i.e., smear, culture, and drug susceptibility) are reported by laboratories to the NTSC. The regional respiratory medicine institutes send the data to the district chest clinics and the NTSC. The district chest clinics enter the data into their local dataset and send monthly updates to the NTSC. The data include demographic information, disease status, lab results, results of contact investigations and risk factors (28).

2.7 TB Surveillance Program in KSA

The National Tuberculosis Control Committee in KSA was established in 1992 to implement a TB control program throughout the country. They launched PHS and created a manual of procedures and guidelines. Nowadays, any suspected TB cases are identified in the hospitals, clinics and primary health care centers. Specialists in the hospitals confirm the diagnosis and prescribe the treatment. After that, the specialists monitor most of the patients, or if that is too difficult, family doctors from the closest primary health care centers monitor them. Those with pulmonary and sputum smear positive results are admitted to the hospitals for two months.

Usually, cases are confirmed by lab results, which include sputum smear microscopy, mycobacterial culture, radiography and histopathology. PHS starts at the point when doctors suspect that a patient has symptoms of TB. At that time, the doctors register the patient in the suspected logbook and refer him to the closest hospital for confirmation. If the case is confirmed, it is reported to the TB coordinator or infection control section in the hospital. After that, the hospital coordinator will notify the regional coordinator. The coordinator will send the public health team from the nearest primary care center to visit the patient to identify and investigate his contacts. Later on, the regional coordinator will give the patient a unique number and inform the hospital coordinator of the number to label the patient's treatment card. After that, the hospital coordinator sends all the patient lab results and treatment outcomes to the regional coordinator. The coordinator monitors the patient's treatment plan, test results and treatment outcome. Also, the coordinator monitors the defaulted cases and persuades them to complete their treatment. Regional coordinators submit a monthly report of the new and relapsed cases as well as the lab results and treatment outcomes to the central unit (6, 29, 30).

2.8 Evaluation of PHS

To improve PHS, it is essential to evaluate the program regularly to ensure that the disease is monitored efficiently and effectively. This evaluation process should be tailored to the purpose of the program. Globally, different PHS systems are evaluated for different purposes. In this section, we will present some evaluation studies conducted in different countries for different purposes. After that, we will present some evaluation studies in KSA.

Boehmer, *et* al. conducted a study to evaluate the Colorado Electronic Disease Reporting System. The inpatient hospital discharge data during the period of the study were used to evaluate the completeness, data quality, and timeliness of eight notifiable diseases. The study showed different sensitivity and timeliness among the diseases. The greatest sensitivity (more than 90%) and timeliness (more than 75%) rates were seen in shigellosis, salmonellosis, and Neisseria meningitides. Legionellosis, pertussis, and West Nile virus infection showed medium sensitivity and timeliness. Hepatitis A showed lowest sensitivity at 67% and timeliness at 25%. Researchers concluded that the hospital discharge data and medical records could be used to evaluate the notifiable PHS system (31).

In Brazil, leprosy PHS was evaluated between 2001and 2007 to determine its quality. Researchers found that the program structure was simple and easily operated. Furthermore, the program presented complete and valid data, which leads to high quality data. Also, the program successfully described the socio-demographic distribution and clinical classification of the disease. The evaluators found that the positive predictive value (PPV) was high; the sensitivity was unknown because there was no other system recording the leprosy data in Brazil. Furthermore, most of the cases were reported, received treatment and were discharged from the

system in timely manner. Finally, the researchers concluded the evaluation by proving the usefulness of the surveillance program and offered recommendations to improve it (32).

Another PHS evaluation study was conducted on the Enhanced Tuberculosis Surveillance (ETS) program to measure its sensitivity and estimate underreporting in TB among children in the United Kingdom. The reporting scheme of the British Pediatric Surveillance Unit (BPSU) was matched with ETS to evaluate it. Researchers estimated 557 cases in the study period. Among estimated cases, 40% of them were reported to both BPSU and ETS. In addition, 18% of cases were reported to BPSU and 42% of cases were reported only to ETS. They found most of underreported cases were in children < five years of age. Researchers concluded that there was substantial under-reporting of cases, especially children < five years of age. Also, ETS missed 20% of cases, but the program can still be used to provide an idea of the extent of the disease (though not its actual burden). Finally, a lot of effort must be made to increase pediatric cases reported to ETS (33).

A study was conducted in Taiwan to assess the completeness and timeliness of the TB notification system. Researchers compared the reported cases to those who were taking two or more anti-TB medications during the same period. They determined timeliness by calculating the treatment start date and the date of notification. The study showed that 96.3% of cases were reported. From the reported cases, 81.8% were reported within the required time (7 days from treatment) while the rest of the reports were delayed. Most of the notification fields were 100% completed (i.e., patients' name, sex, birthday, address, reporting health care facilities, medical chart number, name of reporting doctors, and date of diagnosis). Only 0.04% had no information on the site of the disease and 2.7% had no information on the smear examinations. Researchers

concluded that only a small proportion of cases were not reported, but an essential proportion were reported late (34).

A different study was conducted in the United States to assess TB case reporting in the military. Different data sources (i.e., hospitalization, laboratory, and pharmacy) were compared to military TB records. To estimate the completeness and under-reporting, capture-recapture methods were used. The study showed under reporting of cases, which leads to an underestimation of TB burden. However, under reporting was similar to that of the civilian TB surveillance program. They concluded that including other data sources like hospitalization and pharmacy records would decrease under-reporting. However, it may lead to false-positive cases (35).

2.10 Evaluation of PHS in KSA

Childhood immunization programs are important interventions to prevent, control and eliminate different diseases. Programs are incomplete without a proper PHS that identifies and records vaccine preventable diseases. The evaluation of such programs is essential to ensure their efficiency and effectiveness. Ibrahim and Albar conducted a cross-sectional study to evaluate the vaccine preventable disease program in Jeddah and assess health workers' knowledge. The study showed that 42.4% of health facilities did not have access to the official standard case definition because they didn't have the surveillance manual. On other hand, a full 60.6% of facilities filled out the clinical registration reports correctly and completely. Even so, only ⅓ of reports from health facilities matched the clinical register. Moreover, only 27.3% of participating health facilities reported the correct number of cases during the study period, while only 27.3% of health facilities submitted reports on time. The study showed that two-thirds of

health workers involved in reporting received training, while almost half (46.6%) had a poor knowledge of surveillance (23).

The KSA National Cancer Registry (NCR) is a population-based registry for all cases of cancer throughout the country. Al-Zahrani, *et* al. conducted a study to estimate the number of missed cases and assess reporting validity. The medical records, pathology reports and death certificates were compared to estimate the missed cases. The study showed that there were 384 missed cases. Furthermore, the ascertainment rates of the medical records, pathology reports and death certificates were 51%, 53% and 17%, respectively. The aggregated registry ascertainment rate was 68%. Moreover, the major percentage discrepancies in data were in the fields of "stage of disease" (44%) and "histology code and behavior" (25.6%). The variables "laterality" (95%), "primary site code" (90%) and "basis of diagnosis" (85%) showed the highest percentage agreements. In addition, the agreement of tumor description (site, histology and stag) was 57%. They concluded that essential developments are required to improve the completeness and quality of the data (36).

Because a notification system is an essential step in the control and prevention of communicable diseases, Bakarman and Al-Raddadi conducted a study to evaluate the reporting system's quality and quantity. The study evaluated the required communicable diseases reports from hospitals and health centers that should be sent even if there are no disease cases to report. The study showed that 19% of the hospitals and health centers did not report their cases and that the remaining hospitals and centers did not send their reports on a regular basis. Only 74% of the expected reports were received and 11.5% of them were late. The administrative data in the reports (e.g., hospital name, week number, official sign and doctor name) were almost complete (92.5% - 99%). The personal data (e.g., patient name, age, sex, nationality and address) had a

range of completeness starting from 100% for age, sex and nationality, 80% for telephone number, 76.5% for patient name (three names) and 20% for address. The disease data had the lowest completeness percentage: only 13% for the mode of infection and 29% for previous vaccination. The researchers concluded that the usefulness of the reports was diminished due to incomplete, absent or incorrect data (37).

Manuscript Introduction

Tuberculosis (TB) is a significant global health problem. Among infectious diseases, TB is the second leading cause of death globally and the single most infectious killer among youth and adults (2). Currently, ⅓ of the world's population is infected with *Mycobacterium tuberculosis* (4). Not all TB cases are identified; and some that are identified are not treated. Untreated active TB patients can infect 10 – 15 additional persons annually (3).

The Kingdom of Saudi Arabia (KSA) does not have high TB burden, yet it faces real challenges in controlling and preventing TB due to its huge number of pilgrims and migrant workers. In 2011, there were 6,200 total cases in KSA, of which 4,900 were incident cases. In the same period, there were 1,100 deaths due to TB. In addition, there were 110 cases of TB and HIV co-infections. According to WHO, 80% of TB cases were detected, and most of the new cases were smear-positive, the most contagious type. WHO estimated that MDR-TB comprised 1.8% of all of TB cases. The prevalence and mortality rates in the last ten years were almost unchanged (7).

TB remains a significant disease that needs more attention and efforts in order to be controlled and eliminated. KSA, like many countries in the world, has a TB surveillance program, which is responsible for data collection, analysis, and feedback, as well as the implementation of actions.

The quality of data that are collected by surveillance is a critical attribute. More accurate and complete data increases the usefulness and utilization of information. High detection rates with accurate and complete data help health officials understand trends of diseases in a country and their characteristics, in addition to the disease burden. The identification of new TB cases among contacts is one of the key steps in prevention. A strong surveillance system helps

decision makers establish and evaluate different interventions for prevention and control. Further, it assures appropriate medical therapy and follow-up. Beyond that, data can be used to make comparisons between regions, as well as other countries.

The National Tuberculosis Control Committee in KSA was established in 1992 to implement a program throughout the country. They launched the PHS and created a manual. Nowadays, any suspected TB cases are identified in the hospitals, clinics, and primary health care centers (PHC). Specialists in hospitals confirm the diagnosis and prescribe treatment. After that, specialists monitor most of the patients, or if that is too difficult, family doctors from the closest PHC monitor them. Those with pulmonary and sputum smear positive results are admitted to the hospitals for two months. Usually, cases are confirmed by lab results, which include sputum smear microscopy, mycobacterial culture, radiography and histopathology.

PHS starts at the point when doctors suspect that a patient has symptoms of TB. At that time, the doctors register the patient in the suspected logbook and refer him to the closest hospital for confirmation. If the case is confirmed, it is reported to the TB coordinator or infection control section in the hospital. After that, the hospital coordinator will notify the regional coordinator. The coordinator will send the public health team from the nearest primary care center to visit the patient to identify and investigate his contacts. Later on, the regional coordinator will give the patient a unique number and inform the hospital coordinator of the number to label the patient's treatment card. After that, the hospital coordinator sends all the patient lab results and treatment outcomes to the regional coordinator. The coordinator monitors the patient's treatment plan, test results and treatment outcome. Also, the coordinator monitors the defaulted cases and persuades them to complete their treatment. Monthly, regional

coordinators submit a report of the new and relapsed cases as well as the lab results and treatment outcomes to the central unit (6, 29, 30).

To improve PHS, it is essential to evaluate it regularly to ensure that the disease is monitored efficiently and effectively. Different PHS attributes can be assessed depending on the purpose of the program and the aim of the evaluation. The evaluation methods should highlight the substantial features since the PHS programs differ in their purposes, objectives, methods and target populations (19). After each evaluation, the recommendations should be adopted to improve the quality, efficiency and usefulness of the program.

Methods

This study was conducted in KSA during the summer of 2012. The study covered the TB PHS in Al-Madinah province in 2011. Evaluation was based on all new TB cases diagnosed between Jan 1, 2011, and Dec 31, 2011. The missed cases were identified by comparing all of the cases that were reported to the coordinator with all of the cases registered in the labs and hospitals. Register books from the three laboratories in Al-Madinah were reviewed and all confirmed positive cases in the same period were compared with reported cases to identify the ones that were missed. The admission reports and patient diagnoses in hospitals records were compared with reported cases. The register books in the infectious control departments or public health departments were reviewed and compared to reported cases. Because the system does not require reporting of any cases that are only in the country temporarily, Hajj- and Omrah-labeled cases were excluded.

All notifications sent from any health facilities to the regional coordinator were examined to assess external completeness. Patient demographic data, contact information, signs and symptoms of the disease, past history, disease data, lab results, HIV test result and reporter data were reviewed (Table 1).

Due to the highly infectious nature of TB, all the contact investigations were reviewed. The TB program requires investigation of pulmonary TB patients and their contacts with positive sputum smears. Two steps are associated with contact investigation: first, the epidemiologist in the next primary health center identifies the contacts and then those contacts are tested. To describe the quality (internal completeness) of data, monthly reports sent to the national coordinator were compared with patient treatment cards. We compared the lab results, disease

data, treatment plan and outcome between the monthly reports sent to the MOH and the

coordinator's register books.

Results

Demographic data were mostly complete (i.e., internal completeness) (Table 2), ranging from 91.5% - 100%; the lowest internal completeness was the identification (ID) field. The ID field was missing in 17 case records (91.5% internal completeness). There were three missing entries in the gender field (98.5% complete); one missing entry in age (99.5% complete); and the name and nationality fields were 100% complete. The disease section showed the highest rate of completeness, with 97.5% for sign and symptoms and 94% for past history. Patient classification and treatment plan show 94.5% completeness. Also, the site of the disease showed 91% completeness.

Test results showed the lowest completeness rates; sputum smear and chest x-ray fields were 80% complete. As to sputum smear test reporting, 37 reports (18.5%) had a blank field, while 3 reports (1.5%) labeled it "not done". The chest x-ray field was left blank in 36 reports (18%) and labeled "not done" in five reports (2.5%). Furthermore, there were 108 missing fields in the category of tuberculin test (46% completeness): 90 of them (83%) were left blank, and 18 (17%) were labeled "not done". The sputum culture field was completed in only 63 reports (31.5%); the remaining were either left blank (110 or 80.3%) or labeled "not done" (27 or 19.7%). The poorest internal completeness was seen in HIV test results. Only 50 reports (25%) had the field completed, while 130 of them (86.7%) were left blank and 20 (13.2%) were labeled "not done."

Administrative data and contact information completeness ranged from 79.5% to 95.5%. Doctor's name or signature showed 79.5% completeness. The hospital name field was

completed in 84.5% of the reports and contact information showed 89.5% completeness rate. Also, the admission data were completed in 95.5% of the reports.

The contact identification and investigation showed that 80 case contacts were identified and the remaining 120 were not identified (Figure 1). Those cases with identified contacts had a total of 448 contacts with a median number of 5 contacts per patient. Among the patients whose contacts were identified, 60 patients' contacts (a total of 301 contacts) were investigated, while the rest (20 patients with the total of 147 contacts) were not. The 120 cases whose contacts were not identified were distributed as such: 42 cases (35%) were smear positive, 75 cases (62.5%) were smear negative and 3 cases (2.5%) were extra-pulmonary. There were 9 cases labeled as "no contacts."

The review and comparison of the hospital records and lab registers with reported cases showed there were 244 confirmed cases that were not reported to the coordinator (Figure 2). Among the non-reported cases, 213 cases (87.3%) were confirmed as TB positive by labs. The remaining 31 cases (12.7%) were uncovered via hospital admission records.

There were 145 patient treatment cards available out of 200 (Table 3). After reviewing 12 key characteristics (a total of 1,740), we found discrepancies in 200 (11.5%) instances. Furthermore, the comparison of the results between the register book and monthly reports was done in 200 reports for all fields except the result field were the available data is available only for 94 fields. The comparison showed that there were 8 (8.5%) discrepancies in the test result field, 16 (8%) discrepancies in the x-ray field, 11 (5.5%) discrepancies in the sputum smear field, and 6 (3%) discrepancies in the fields of treatment plan and site of the disease.

Discussion

The purpose of the PHS program is to provide information that helps public health workers and decisions makers manage the disease and take appropriate actions. The ideal PHS system should have the following characteristics to obtain the maximum benefit: the data should be accurate and complete and sent within the appropriate time frame; the program should include all cases that occur and use a case definition and consistent lab protocols; the data should be analyzed and the feedback sent to those concerned; the decisions and implementation should be based on data; and it should be easy to adapt (38).

The reporting of TB cases is required in KSA. The presence of high quality data is a critical requirement of the program. More accurate and complete data will increase the usefulness and utilization of information. High detection rates and accurate and complete data help health officials understand the trends of the disease in the country and its characteristics, as well as the burden. Moreover, the identification of new cases among patient contacts is one of the key steps in preventing its spread. A strong PHS system helps the decision makers establish and evaluate different interventions to control the disease. Furthermore, it assures appropriate medical treatment and follow-ups with patients. Moreover, the data can be used to make comparisons between different regions and other countries (35).

5.1 Underreporting

In this evaluation, underreporting of cases was found. In addition to 200 reported cases, we found 244 cases that had not been reported. Most of the underreported cases were confirmed by laboratory testing (87.3%). Laboratories are fundamental components of TB PHS programs (19). Laboratory results will confirm the diagnosis and guide the treatment and contact

investigation. Although data sent by laboratories does not contain clinical information, one study found that the reporting improved after starting mandatory laboratory reporting (39).

Because the MOH cannot follow unreported cases, these patients have a higher risk of mortality and developing MDR-TB or even XDR-TB. Also, the patient contacts will not be screened for the disease, which will lead them to be at high risk of morbidity and mortality, especially if they have risk factors. Furthermore, under-notification will lead to an underestimation of the disease burden, limiting the ability to plan for the appropriate prevention and control strategies.

Different reasons could lead to underreporting: doctors may not know that notification is required or might notify only severe cases; they may not know the notification procedure (whom to notify and how) or how to fill out the reports; they may not have the report forms; or, they may not understand the importance of reporting and its implications. In addition, doctors may have time constraints that prevent them from reporting. In some cases, lack of laboratory conformation may lead to underreporting (40).

5.2 Completeness of Data

In the TB PHS program, most of the demographic, disease and treatment data were complete. However, the test result data had a much lower completeness rate. We noticed two different actions: either it was left blank or it was marked "not done." Accurate data are essential in the PHS system. Complete data will give precise information about disease trends, characteristics and affected persons. With correct data, the potential risk factors can be examined and modified. Also, it helps program managers and decision makers implement interventions and evaluate them. The high incidence of incomplete test results data may be due to lack of knowledge about how to fill out the reports. Also, it may be due not knowing the

importance of each data field. The absence of feedback may relate to the doctors thinking that this is just information collected and saved without being analyzed or used. Also, it may be due to lack of lab results or the doctors not being able to match the lab result with the right patients.

5.3 Contact Investigation

Only smear positive pulmonary TB patients can transmit the disease to contacts. As a result, the PHS program requires only contacts of smear positive pulmonary TB patients be identified and investigated (41). Among 200 reported cases, we found 122 pulmonary and smear positive, while the remaining 78 cases were either pulmonary and smear negative or extra-pulmonary TB. Among the 122 pulmonary and smear positive TB patients, 80 patients' contacts were identified. Among the identified 448 contacts, 301 (67%) were investigated and the rest 147 (33%) were not.

In the United States, the average number of contacts per patient is 10 (41). In KSA, these data are not routinely gathered. The average number of identified contacts was 5 per patient. We also found 42 positive sputum pulmonary patients whose contacts were not identified, and 20 patients whose 147 contacts were identified but not investigated. So, we estimated the number of infected non-investigated contacts to be 210 (42 patients with an estimated five contacts each), plus 147 known non-investigated contacts, for a total of 357.

One of the essential steps that helps control and eliminate TB is breaking down the disease's infection chain by contact tracing. Undiagnosed patients infect their contacts; new patients will infect their contacts. As a result, the disease remains endemic. Different studies have shown contacts tracing and investigation to be an effective TB control strategy (42-45).

Many reasons can lead to neglecting the contact investigation, for instance, weak communication between the coordinator and the health care center nearest to the patient's home

responsible for doing the investigation. Also, the person assigned to investigate a contact may be extremely busy or not know the importance of the investigation and its benefits.

5.4 Identification

One of the challenges that we faced when collecting the data was the lack of consistence in the recording of names. When the staff wrote names in Arabic, especially non-Saudi names, different spellings were used. Currently, the surveillance program assigns each patient a unique number that identifies the case. However, these numbers weren't used on lab results and reporting forms. This led to duplication and the inability to match the lab results with the cases.

Recommendations

6.1 Implementation of Automated Notification and Reporting

The KSA TB program depends on paper-based notifications and monthly reports. Paper-based reporting is slow and incomplete (46). Rapid and complete reporting is required to control and prevent TB. Different studies show that electronic reporting is more brisk and complete (46-49). Electronic reporting should include healthcare providers and laboratories. Because laboratories don't report detailed patient data, the need for electronic medical reports is great. Such a system would reduce the amount of incomplete data and delays in reporting that result from the paper-based reporting. Also, it would improve the availability of detailed information from laboratories notification (46). This system would also reduce the administrative time necessary for filling out paperwork.

6.2 Mandatory Lab and Suspected Cases Reporting

Because laboratories identified most of the missed cases, it is essential to implement mandatory laboratory reports. Also, all suspected cases should be reported to the coordinator even before lab confirmation. By providing a brief summery of suspected cases, the coordinator can follow up on the cases through the hospitals and labs looking for either confirmation or an incorrect diagnosis. In addition, s/he can investigate the contacts early and prevent possible transmissions. As a result, the rate of underreported cases would be reduced (50).

6.3 Investigation of the Contacts

Identification and investigation of contacts is one of the most productive methods of detecting new cases at an early stage and preventing new transmissions. To improve this process, different strategies for the method of detection and evaluation should be used.

Improving the communication between different health providers, especially in primary care

centers, will facilitate progress (50).

Accurate data is one of the key factors in a successful surveillance. The lack of

consistency in the recording of names is a major problem in TB surveillance; there is not a

systematic way of recording names (i.e., first and last name, first and middle name only) nor are

there standard spellings of non-citizens' names. Furthermore, the absence of an ID number in

the lab results may lead to duplication or inability to match the lab results with the cases. The

requirement of writing the ID number and the three names of the patients exactly as they are

written on the patient's ID card would prevent errors and duplication, help match all the patient

papers and, at the very least, lessen the time wasted by the coordinator trying to match them.

Other strategies include targeting doctors with a specific outreach program and a

continuous training program intended to raise their awareness and increase their response level.

Also, revising the manual of the national TB control program, which contains disease

information, reporting guidelines and control recommendations, would increase awareness and

improve the notification rates. Periodic feedback from headquarters to regional coordinators and

the dissemination of progress reports would increase the confidence of the providers in the

program. In addition, periodic evaluation of health providers' knowledge and attitudes regarding

the program would help detect any weaknesses in the process. Finally, the program should be

evaluated periodically to improve its quality and achieve optimum disease control.

Further study is needed to evaluate the time between diagnosis and notification, health

care workers' knowledge and practice in reporting TB cases, and the reasons for their not

investigating all the patients' contacts.

There were limitations that prevented the evaluation of more characteristics of the program. First, all data were handwritten, which took a long time to read and evaluate. Second, the lab registrations were unclear and did not contain the whole names. Third, the treatment cards of some patients were not on hand at the coordinators. Fourth, there were no other records systems of TB patients, so we could not apply the capture-recapture method. Finally, there were no electronic records of the inpatients in the hospitals, so we could not find the missed admitted cases.

In conclusion, the study showed that the rates of completeness for the different notification report fields varied; the lab results and HIV test fields had the lowest rates of completion. Also, over half of patients' contacts were not identified or investigated, and there were a significant number of unreported cases, most of which were laboratory confirmed. Finally, we found a number of discrepancies between the treatment cards, logbooks and the reported data.

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Appendix A

Table1. Data reviewed from the notification report, 2011, Saudi Arabia, Al-Madinah province

| Category	Issue
Demographic data	Name
	Nationality
	Age
	Gender
	ID
Contact information	Patient telephone number
Disease data	Sign and symptoms
	Past history
	Site of the disease
	Patient's classification (new, relapse, transfer, failure or treatment after default)
	Treatment plan
Investigation results	Sputum smear
	Tuberculin test
	Chest x-ray
	Sputum culture
	HIV test
Admission date	Admission date
Reporter data	Hospital name
	Doctor name or signature

Appendix B

Table 2. Completeness Rate of Different Categories on TB notification Forms, 2011, Saudi Arabia, Al-Madinah Province

| Category	Issue	Missed	Label it (not done)	Completeness rate
	Name	Zero	-	100%
	Nationality	Zero	-	100%
Demographic data	Age	1	-	99.5%
	Gender	3	-	98.5%
	ID	17	-	91.5%
Contact information	Patient telephone number	21		89.5%
	Sign and symptoms	5	-	97.5%
	Patient's classification	11	-	94.5%
Disease data	Treatment plan	11	-	94.5%
	Past history	12	-	94%
	Site of the disease	18	-	91%
	Sputum smear	37 (92.5%)	3 (7.5%)	80%
	Chest x-ray	36 (87.8%)	5 (12.2%)	79.5%
Investigation result	Tuberculin test	90 (83.3%)	18 (16.7%)	46%
	Sputum culture	110 (80.3%)	27 (19.7%)	31.5%
	HIV test	130 (86.7%)	20 (13.3%)	25%
	Admission date	9	-	95.5%
	Hospital name	31	-	84.5%
	Doctor name or signature	41	-	79.5%

Appendix C

Figure 1. The Identification and Investigation of the Contacts in 2011, Saudi Arabia, Al-Madinah Province
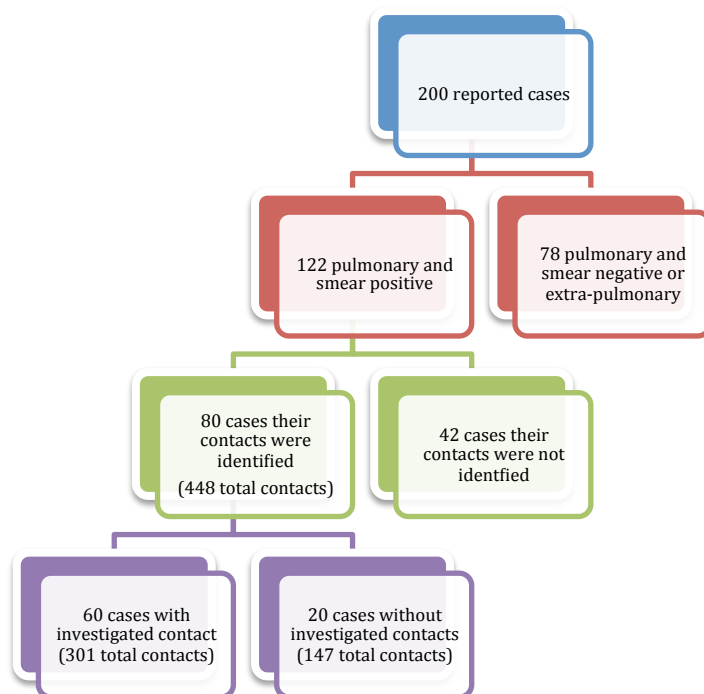
Appendix D

Figure 2. The Distribution of Missed Cases in 2011, Saudi Arabia, Al-Madinah Province

Distribution of missed cases in 2011, Almadinah province
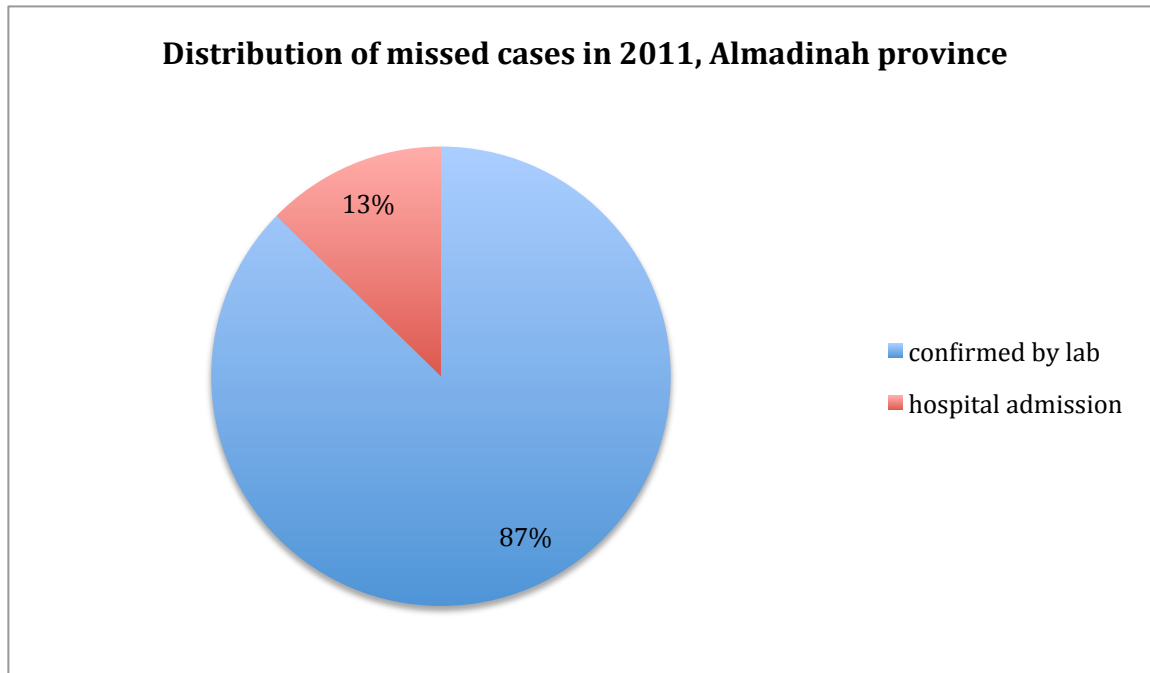
Appendix E

Table 3. Discrepancies between register book and monthly reports, 2011, Saudi Arabia, Al-Madinah Province

Field	Discrepancies
Result of treatment*	8 (8.5%)
X-ray	16 (8%)
Sputum smear	11 (5.5%)
Treatment plan	6 (3%)
TB code	5 (2.5%)

* The results in the report that was sent to Ministry Of Health were available for only 94 patients. The rest were not sent until after I collected the data.