DIVISION OF ACUTE DISEASE PREVENTION EMERGENCY RESPONSE AND ENVIRONMENTAL HEALTH **BUREAU OF IMMUNIZATION AND TUBERCULOSIS** 

# Iowa Tuberculosis Control Program 2014 Annual Report







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## FOREWORD

TB remains a major health problem globally, in the U.S. and in lowa, killing an estimated 1.3 million people annually. Despite this grim statistic, TB morbidity rates are declining in the U.S. and around the world. In lowa, TB case rates remain relatively stable due to the influx of immigrants and refugees from areas of the world where TB is prevalent. Vigilance is required to properly treat and cure patients to prevent treatment relapse, treatment failure or the development of acquired drug resistant TB. Declines in funding, misdiagnosis and challenging clinical case management still plague TB Control efforts in the United States.

## **PURPOSE AND OVERVIEW**

The purpose of this report is to provide a summary of Tuberculosis (TB) in Iowa and the activities and achievements of the TB Control Program and our partners during the 2014 calendar year. This report provides Iowa-specific TB rates, funding sources, and program-specific data, often in ten-year time lines to more accurately reflect trends.

Previous reports included TB control efforts by the World Health Organization and the Centers for Disease Control and Prevention. Reports paid tribute to the role TB disease played in the history of man including historical TB treatments, myths, and bygone TB control practices. The 2014 Report does not include these overviews. Please refer to previous reports for this information.

The annual report serves as an informational resource for stakeholders, local partners, policy makers and others interested in Iowa's TB Control efforts. The report is available for download on the TB Control Program Web page <u>http://www.idph.state.ia.us/ImmTB/TB.aspx?prog=Tb&pg=Tb</u> <u>Home.</u>

## IOWA'S TB CONTROL PROGRAM

The TB Program is comprised of two full time employees: the Program Manager and the TB Nurse Consultant. The program provides direct oversight of cases afflicted with latent tuberculosis infection (LTBI) and TB disease from admission to discharge in the TB Control Program. This includes consultation with physicians, nurses, local public health agencies (LPHAs) and other healthcare providers regarding TB transmission, pathogenesis, treatment, signs and symptoms, infection control practices, and contact investigations.

The purpose and scope of responsibilities is defined by the core functions of the TB Control Program which include:

- Disease consultation and education
- Investigation of active or suspect TB cases
- Case management of LTBI and active TB cases
- Administration of Iowa's TB Medication Program
- Data management and analysis
- Administration and finance

# THE DIFFERENCE BETWEEN LATENT TB INFECTION AND TB DISEASE:

FROM CDC'S DIVISION OF TB ELIMINATION

## WHAT IS TB?

Tuberculosis (TB) is a disease caused by a germ called *Mycobacterium tuberculosis* that is spread from person to person through the air.



TB usually affects the lungs, but it can also affect other parts of the body, such as the brain, the kidneys, or the spine. When a person with infectious TB coughs or sneezes, droplet nuclei containing *M. tuberculosis* are expelled into the air. If another person inhales air containing these droplet nuclei, he or she may become infected. However, not everyone infected with TB bacteria becomes sick. As a result, two TBrelated conditions exist: latent TB infection and TB disease.

## WHAT IS LATENT TB INFECTION?

Persons with latent TB infection do not feel sick and do not have any symptoms. They are infected with M. tuberculosis, but do not have TB disease. The only sign of TB infection is a positive reaction to the tuberculin skin test or TB blood test. **Persons with latent TB infection are not infectious and cannot spread TB infection to others.** 

## **LTBI Characteristics**

- Usually has a skin test or blood test result indicating TB infection
- Has a normal chest x-ray and a negative sputum test
- Has TB bacteria in his/her body that are alive, but inactive
- Does not feel sick
- Cannot spread TB bacteria to others
- Needs treatment for latent TB infection to prevent TB disease; however, if exposed and infected by a person with multidrug-resistant TB (MDR TB) or extensively drug-resistant TB (XDR TB), preventive treatment may not be an option

Without treatment, about 5 to 10% of infected persons will develop TB disease at some time in their lives. About half of those people who develop TB will do so within the first two years of infection. For persons whose immune systems are weak, especially those with HIV infection, the risk of developing TB disease is considerably higher than for persons with normal immune systems.

Of special concern are persons infected by someone with extensively drug-resistant TB (XDR TB) who later develops TB disease; these persons will have XDR TB, not regular TB disease.

## WHAT IS TB DISEASE?

In some people, TB bacteria overcome the defenses of the immune system and begin to multiply, resulting in the progression from latent TB infection to TB disease. Some people develop TB disease soon after infection, while others develop TB disease later when their immune system becomes weak. The general symptoms of TB disease include:

- Unexplained weight loss
- Loss of appetite
- Night sweats
- Fever
- Fatigue
- Chills

The symptoms of TB of the lungs include:

- Coughing for 3 weeks or longer
- Hemoptysis (coughing up blood)
- Chest pain

Other symptoms depend on the part of the body that is affected. **Persons with TB disease are considered infectious and may spread TB bacteria to others.** If TB disease is suspected, persons should be referred for a complete medical evaluation. If it is determined that a person has TB disease, therapy is given to treat it. TB disease is a serious condition and can lead to death if not treated.

### **TB Disease Characteristics**

- Usually has a skin test or blood test result indicating TB infection
- May have an abnormal chest x-ray, or positive sputum smear or culture
- Has TB bacteria in his/her body
- Usually feels sick and may have symptoms such as coughing, fever, and weight loss
- May spread TB bacteria to others
- Needs medication to treat TB disease

## **TB MORBIDITY AND TRENDS IN IOWA**

The number of TB cases in Iowa, as in the rest of the U.S., has significantly declined since the discovery of antibiotics that kill the TB bacilli. Despite drugs that can cure TB disease, TB remains a significant public health issue in Iowa and the rest of the country. The 2014 TB case rate for Iowa is 1.75 cases per 100,000 persons. This is significantly lower than the 2014 national average of 3.0 cases per 100,000 persons. Iowa owes its low TB case rate in part to proficient contact investigations, healthcare providers observance of treatment guidelines, adherence to DOT for active disease cases and the provision of medication for LTBI to approximately a thousand Iowan's annually.

During the last decade, Iowa averaged greater than 1,200 LTBI and 46 TB disease cases each year. Figure 1 illustrates the average number of cases in Iowa each year by decade, dating back to 1930. Note that Iowa averaged 757 cases of TB disease each year during the decade of the 1940s. During this decade, scientist first discovered antibiotics that could treat TB, culminating with the discovery of other antibiotics in the 50's and 60's that led to doctors curing patients of TB. The discovery and use of these antibiotics ultimately led to the sharp decline of TB cases and subsequently, the number of persons with LTBI. Persons with untreated LTBI represent the reservoir of future TB cases.



Figure 1: Average Number of TB Cases in Iowa Each Year - by Decade.

In 2014, Iowa reported 54 cases of active TB disease. Since 2005, Iowa has averaged 46 cases of TB each year. (Figure 2: Number of TB cases 2005 - 2014). Although case rates are declining, many cases have existing co-morbidities that make TB treatment considerably more complex and require extensive care, including the use of second line drugs. Treatment with second line drugs is complicated and expensive, requiring expert consultation and extended treatment durations.



Figure 2: Number of Iowa TB Cases per Year 2005-2014

Counties with larger population centers such as Polk, Black Hawk and Johnson report the majority of TB cases. However, as Figure 3 illustrates, many (52/99) Iowa counties reported TB cases during calendar years 2005 - 2014.



Figure 3: Iowa Counties with TB Cases 2005 - 2014

## LTBI AND TB DISEASE TREATMENT

The program prioritizes the detection and treatment of persons with LTBI to prevent future cases of TB disease. Figure 4 illustrates that the Program issues greater than 1,200 LTBI prescriptions on average each year to Iowan's diagnosed with LTBI. Left untreated, 5-10% of persons with LTBI will develop TB disease. The only way to eliminate TB disease is to treat and cure all persons diagnosed with LTBI.



Figure 4: Number of LTBI cases each year from 2005 – 2014

The length of LTBI treatment (up to nine months) coupled with a lack of public health resources, results in patients having to complete LTBI treatment on their own accord, just like with other illnesses. Significantly shorter treatment regimens paired with public health monitoring is the only method that will achieve TB elimination.

Figure 5 represents the percentage of patients who completed treatment from 2004 - 2013. During this period,

all patients with infectious TB completed treatment. Patient's not completing treatment had extrapulmonary TB, were not infectious and did not represent a public health risk.



Figure 5: Percentage of Iowa TB Cases who Complete Therapy 2004-2013

It is very important that people who have TB disease finish the medicine, taking the drugs exactly as prescribed. If they stop taking the drugs too soon, they can become sick again; if they do not take the drugs correctly, the TB bacteria that are still alive may become resistant to those drugs. TB that is resistant to drugs is harder and more expensive to treat.

# DIRECTLY OBSERVED THERAPY (DOT)

DOT is a strategy used by public health officials to assure patients with TB disease are correctly treated and cured. DOT is the standard of care for all patients afflicted with TB disease. The Centers for Disease Control and Prevention (CDC), Infectious Diseases Society of America (IDS), World Health Organization (WHO), and the American Thoracic Society (ATS) recommend healthcare providers implement DOT on each case of TB disease. With DOT, a designated healthcare worker watches a patient swallow each dose of TB medication. Without DOT, many patients do not take their medication properly, resulting in disease relapse, treatment failure and development of drug resistance, including multidrug-resistant TB (MDR-TB).

In 2001, the Iowa TB Control Program began providing DOT incentive funds to increase the proportion of TB patients who receive DOT. Since implementation of incentive funding, DOT rates have risen 40% in Iowa. During this time-period, virtually all pulmonary (infectious) cases of TB have had the benefit of DOT. Clinical benefits of DOT include significant reduction in disease relapse, treatment failure and development of multidrug-resistant TB (MDR-TB).

# **COUNTRY OF ORIGIN DATA**

The proportion of reported TB cases in non-U.S. born persons has increased significantly in the past two decades. In 1995 for example, non-U.S. born persons accounted for 38% of reported TB cases in Iowa. From 2005 - 2014, non-U.S. born persons accounted for 68% of reported TB cases in Iowa. Non-U.S. born persons account for only four percent of the Iowa population, highlighting the disparity. The decreasing numbers of U.S. born cases are due in part to effective TB control practices in this country.





In many parts of the developing world, TB is still widespread and remains a leading cause of death. Immigration of people from these countries to the United States illustrates what happens in one part of the world, directly impacts other parts of the world. Effective targeted testing programs for newly arriving refugees, immigrants, and students play a major role to identify and treat these populations.

From 2005 - 2014, 314 individuals, emigrating from 48 countries (excludes U.S.) developed TB disease after their arrival to Iowa (Figure 8). India and Mexico account for 30% of the TB morbidity in Iowa during this time period. As the map illustrates, TB anywhere is TB everywhere. Approximately 95% of all patients with active TB disease live in the developing world, where 99% of all TB deaths occur. TB is a good example of the global nature of public health. It is important to implement consistent and aggressive public health measures to halt TB disease, which left untreated, kills half of its victims.

## TB Cases By Country of Origin Iowa: 2005 - 2014



Figure 7: Country of Origin by Global Representation: Iowa 2005-2014

In Iowa, eight countries, led by India and Mexico, account for 198/314 (63%) non U.S. born TB cases from 2005 – 2014 (figure 8). Forty other countries complete the TB morbidity, further illustrating the global burden of TB.



Figure 8: Iowa TB Cases by Country of Origin 2005-2014

## **SITE OF DISEASE**

The lungs are the most common site for TB disease, but any organ or body site may be involved. TB of the pleura (lining of the lungs) and lymph nodes is the most commonly occurring form of extrapulmonary tuberculosis. In Iowa, pulmonary cases accounted for 68% of the total cases during the last ten years (Figure 9). Patients with either pulmonary (lungs) or laryngeal (throat) TB are usually infectious.



Figure 9: Iowa TB Cases by Site of Disease 2005-2014

## **CONTACT INVESTIGATIONS**

All infectious cases require a contact investigation by a LPHA to identify contacts who:

- Have LTBI so treatment for LTBI can be given and active disease can be prevented.
- Have TB disease so they may be treated and further transmission can be stopped.

TB Contact Investigations, Iowa 2004-2013
Cases for investigation: 249
Number of contacts identified: 4,904
Number of contacts who completed evaluation: 4,210 (86%)
Number of LTBI identified: 822 (20%)
Number of TB cases identified: 25 (<1%)
Figure 10: Contact Investigation Data

Figure 10: Contact Investigation Data

Each infectious TB case in the United States has 10 contacts identified on average per CDC. Approximately, 20 - 30% of all contacts have LTBI, and 1% has TB disease. Of those contacts that ultimately will have TB disease, approximately half acquire disease in the first year after exposure. For this reason, contact investigations constitute a crucial prevention strategy.

LPHAs in Iowa are responsible for conducting investigations of infectious TB. Public Health agencies work closely with other agencies (e.g., Community Health Centers, private providers, labs etc.) to ensure the prompt reporting of suspected TB cases. A major challenge for LPHAs is the time involved to complete contact investigations. In order to be considered "evaluated", contacts to infectious TB cases must complete all TB testing, often requiring two TB tests. Persons with positive tests require a medical evaluation to include a chest x-ray to rule out active TB. LPHAs spend considerable amounts of resources in their efforts to complete the evaluation of contacts exposed to infectious TB.

The TB Control Program Manager and TB Nurse Consultant provide consultation to LPHAs on each infectious case of TB. Consultation consists of:

- When to initiate a contact investigation
- Assigning priorities to contacts
- Diagnostic and public health evaluation of contacts
- When to expand a contact investigation, and
- Data management of contact investigations

Contact investigations are timely, costly and consume limited resources from local, state and federal assets. "Contact investigations typically require hundreds of interdependent decisions, the majority of which are made on the basis of incomplete data, and dozens of time consuming interventions."<sup>1</sup> For these reasons, consultation and collaboration among LPHAs and the TB Program is vital to the diagnostic and public health evaluation of contacts.

<sup>&</sup>lt;sup>1</sup> Guidelines for the Investigation of Contacts of Persons with Infectious TB – Recommendations from the National TB Controllers Association and CDC.

## **TB CONTROL PROGRAM FUNDING**

In 2014, the TB Control Program received funds from the federal TB Cooperative Grant and state funds totaling \$519,034. Federal funds comprise 76% of the total budget while state funds comprise 24% of the program finances (Figure 11).

Funding Source 2014	
Federal TB Cooperative Grant	\$391,920
State Prescription Services	\$70,670
State TB	\$56,444
Total	\$519,034

Figure 11: 2014 total program funds

Program expenditures are divided into three main categories: **program infrastructure** (staff salary and operating expenses), **contracts** (including incentive funding for LPHAs to conduct directly observed therapy, pharmacy for prescription services and the State Hygienic lab), and **TB medications**. The funding distributions for these three categories are illustrated in Figure 12.



Figure 12: 2014 total program funds by funding source

Figure 13 illustrates how the TB Program disperses available contractual funds. LPHAs receive incentive funding for DOT and medical evaluation services. Funds for pharmacy services support the distribution of free antibiotics for all lowans with LTBI or TB disease. Funds for the State Hygienic Lab support rapid identification of TB, smear, culture and drug sensitivity testing.



Figure 13: 2014 total funds distribution

## **CONTRACT SERVICES**

#### **STATE HYGIENIC LAB**

The TB Control Program contracts with the State Hygienic Lab (SHL) through the Tuberculosis Elimination Cooperative Agreement. In 2014, the TB Control Program contract amount with SHL was \$72,042 as demonstrated in figure 13. This agreement allows SHL to be the primary source for public health submission of suspect TB patient's specimens (typically sputum) for evaluation. The goal of SHL is to provide objective information within 24 - 48 hours of specimen receipt for smear and TB NAAT (rapid detection of MTB complex as well as rifampin drug resistance). SHL works with CDC to transfer clinical specimens of patients for whom second line drug testing is necessary. Additionally, SHL coordinates genetic testing of all culture positive MTB specimens with CDC to allow genetic linking of cases nationwide. The ability to rapidly and accurately detect drug resistance in *Mvcobacterium tuberculosis* Complex (MTBC) clinical isolates is critical for the appropriate treatment of patients suffering from TB and the effectiveness of the TB Control program.

SHL also is one of the few labs in the state that performs Interferon-Gamma Release Assays (IGRAs). IGRAs are wholeblood tests that can aid in diagnosing TB infection. SHL offers two IGRAs that have been approved by the U.S. Food and Drug Administration (FDA) and are commercially available in the U.S: QuantiFERON TB Gold In-Tube test (QFT-GIT); and T-SPOT® TB test (T-Spot). IGRAs are of particular use to LPHAs in the course of a contact investigation to an infectious TB patient. In a contact investigation, IGRAS are offered to Iowa citizens free of charge through the SHL.

## **PHARMACY SERVICES**

The TB Program contracts with NJL Pharmacy of Pleasant Hill, lowa to dispense TB medications for both LTBI and active TB disease patients. In 2014, the TB Control Program spent \$64,620 on TB medications for Iowa citizens (Figure 12). The contract for pharmacy services is \$34,500 as demonstrated in Figure 13.

#### LOCAL PUBLIC HEALTH AGENCIES

Iowa is unique in its ability and desire to provide incentive funding for LPHA's who provide directly observed therapy (DOT) to active pulmonary patients in their county. DOT is a standard of care for TB in which patients are observed to ingest each dose of anti-tuberculosis medications, to maximize the likelihood of completion of therapy. Programs utilizing DOT as the central element in a comprehensive, patient-centered approach to case management (enhanced DOT) have higher rates of treatment completion than less intensive strategies.

The CDC, American Thoracic Society (ATS) and Infectious Disease Society of America (IDSA) all recommend healthcare providers implement DOT on each active case of TB. Eligibility of LPHAs for DOT incentive funding may vary by funding cycle due to funding availability and the number of TB cases; but generally, all infectious (pulmonary and laryngeal), pleural, HIV positive, and childhood cases of TB disease are eligible. In 2014, the Iowa TB Control Program spent \$49,764 on contracts with LPHAs for DOT services as shown in Figure 13.

## CONCLUSION

The TB Program's vision is lowans living in communities free of TB disease. TB disease is both preventable and curable if treated early in the disease process. Iowa health care providers are at the forefront of this vision when they 'think TB' and diagnose TB early, which not only leads to an early cure, but stops transmission to others. Local public health agencies ensure the cure with the time intensive practice of directly observed therapy, watching their patients swallow each dose of medication. This proven TB control strategy ensures not only the cure, but prevents the development of acquired drug resistant TB, treatment relapse, treatment failure and death. These public health stewards stop further transmission by identifying and treating exposed contacts to infectious TB.

The fact remains that untreated, TB disease still kills 50% of its victims and is easily transmitted. Left unchecked, TB spreads through communities with cost measured in dollars and lives. The medical case management of TB is often complicated. Adherence to treatment guidelines is paramount to curing TB. The TB Control Program is dedicated to eradicating TB in lowa by ensuring each patient with LTBI or TB disease receives the best care available. The history of TB is as long as the history of mankind. This history has taught us many lessons, both through failures and successes. It is a lesson that needs constant vigilance in order to advance to the final eradication of an ancient disease that is believed to have killed more humans throughout history than all other disease combined.