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Susan L. Spieldenner Date

EFFECTIVENESS OF PROVIDING A WRITTEN REFERRAL TO NEWLY ARRIVING IMMIGRANTS AT FIRST PORT OF ENTRY ON THE COMPLETION OF U.S. TB EVALUATIONS

BY

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Abstract

EFFECTIVENESS OF PROVIDING A WRITTEN REFERRAL TO NEWLY ARRIVING IMMIGRANTS AT FIRST PORT OF ENTRY ON THE COMPLETION OF U.S. TB EVALUATIONS

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Tuberculosis (TB) remains one of the most serious infectious diseases worldwide and continues to pose a significant public health concern in the U.S. Of the 11,545 cases of TB disease reported in the U.S. in 2009, 60% were among foreign-born residents. Over the past 15 years, the percentage of TB cases in the U.S. among foreign-born individuals has doubled. A two-step process is used in the U.S. to reduce the likelihood that immigrants seeking permanent residence arrive with TB, an overseas pre-immigration examination, and a U.S.-based post-immigration TB evaluation for individuals considered at risk for active TB disease and given a classification for TB during their overseas screening. In 2005, 53% of immigrants with a TB classification completed their U.S. examination. Incomplete U.S. examinations represent missed opportunities for early detection and treatment of TB disease and latent TB infection. This retrospective cohort study of 398 Filipino immigrants arriving at Detroit Metropolitan Airport (DTW) with a TB classification between December 2006 and August 2007 examines whether or not the written referral used at DTW and verbal instructions given upon U.S. entry increase the likelihood of U.S. TB evaluation completion. Of the 398 cohort immigrants, 212 (53%) completed a U.S. TB evaluation. This proportion is the same as seen in other studies. Almost no difference was found in the proportion of immigrants completing a U.S. TB evaluation between those individuals that received a written referral and those that did not ($p = .97$). Results did not support use of the referral as written and used at DTW as an effective method for increasing U.S. examination completion rates. Lack of effectiveness of the referral in this study does not however, support not providing a referral upon U.S entry. Recommendations made from this study include completing an analysis of referral methods currently used by other CDC Quarantine Stations to facilitate completion of U.S.-based TB evaluations (particularly Chicago and Honolulu), improving the current referral form used at DTW, a review of information provided to immigrants prior to departure for the U.S, and exploring the use of incentives for both public health agencies and arriving immigrants.

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Chapter I: Introduction

Introduction and Rationale

Tuberculosis (TB), despite advances in detection, identification, and treatment remains one of the most serious infectious diseases worldwide. The World Health Organization (WHO) reported 9.4 million new cases of TB and 1.7 million deaths as a result of TB in 2009 and that more than 2 billion people in the world are infected with TB.[1, 2] The incidence of TB varies from country to country as well as within countries with the highest rates occurring primarily in South-East Asia and Africa.

TB also continues to remain a significant public health concern in the United States (U.S.). In 2009, 11,545 cases of TB disease were reported in the U.S. While the number of reported cases of TB has decreased over time, including those individuals born outside the U.S., one major trend has been an increasing proportion of TB cases among foreign-born residents. Over the past 15 years, the percentage of TB cases among foreign-born individuals has doubled from 29% in 1993 to 59% in 2009.[3]

In 2008, 1,107,125 immigrants to the U.S were granted permanent residence. By country of origin; Mexico contributed the most with 189,989 (17.2%) immigrants, China was second with 80,271 (7.3%), India third with 63,352 (5.7%), the Philippines fourth with 54,030 (4.9%) and Vietnam seventh with 31,497 (2.8%).[4] The incidence of TB disease reported in 2008 for each of those five countries was 20, 97, 168, 285, and 200 per 100,000 population, respectively.[1] In comparison, the U.S. incidence of TB disease reported for 2007 was 4.4 per 100,000 population.[5] In 2008, the five most common countries of birth among foreign-born individuals reported with TB disease in the U.S.

were Mexico (23%), the Philippines (11%), Viet Nam (8%), India (8%) and China (5%), accounting for over one half of all foreign-born cases.[6]

Problem Statement

The U.S. employs a pre-arrival health screening policy for individuals seeking permanent resident status to reduce the likelihood of immigrants arriving with TB disease. Immigrants required to undergo overseas medical screening by physicians contracted by the U.S. Department of State (DOS) include: immigrants (individuals applying for permanent residence), refugees, those applying for V or K (fiancé) visas, and those applying for temporary visas if there is reason to suspect that an inadmissible health-related condition, including TB, exists. Approximately 400 overseas physicians (panel physicians) are selected by the DOS consular offices to perform these medical examinations. Upon arrival in the U.S., immigrants considered at risk for TB disease are required to complete another examination within 30 days.

The Centers for Disease Control and Prevention (CDC), Division of Global Migration and Quarantine (DGMQ) provides guidance for overseas medical screenings through the use of Technical Instructions (TIs), which define the elements that comprise a complete health screening for TB. Under the 1991 TIs, individuals over the age of 14 years are required to undergo a medical examination for signs and symptoms of TB and receive a chest x-ray (CXR). If the CXR results suggest that active TB is likely, sputum specimens are obtained and examined by microscopy for acid-fast bacilli (AFB). Such immigrants are given a TB classification as follows and are allowed to travel if no bacteria are seen:

- Class B1 TB, clinically active, not infectious. An abnormal chest x-ray or series of chest x-rays suggestive of current pulmonary TB and sputum smear examinations for AFB that are negative on three consecutive days.
- Class B2 TB, not clinically active. An abnormal chest x-ray or series of chest x-rays suggestive of TB not clinically active (e.g., fibrosis, scarring, pleural thickening, diaphragmatic tenting, blunting of costophrenic angles).
- Class B3, consistent with TB old or healed. An abnormal chest x-ray or series of chest x-rays where the only abnormality is calcified hilar lymph node, calcified primary complex, or calcified granuloma.

If bacteria are seen in at least one sputum smear under microscopy, a Class A TB, infectious diagnosis is given and the immigrant can only travel once treatment for TB is started and they are considered no longer infectious but prior to completion of therapy. The presence or absence of AFB by sputum smear microcopy is considered an indication of infectiousness. The ability to detect TB using the methods proscribed in the 1991 TIs (CXR and sputum smear microscopy) is limited since culture is not included.[7]

In 2005, 8125[8] (2.1%) of the 384,071[9] immigrants and refugees who entered the U.S. received classifications for TB, of whom only 53% had documentation indicating completion of their follow-up U.S. TB evaluation. Evidence of the inadequacy of the system in preventing a significant number of immigrants and refugees from entering the U.S. with infectious TB disease included the identification of infectious TB disease among 48 newly arriving individuals who were found to have sputum smears positive for AFB during their U.S. TB evaluation.[8] Assuming no significant difference between the two groups (those who completed their U.S. TB evaluation and those who did not) in

2005, an additional 43 individuals with infectious TB were not promptly diagnosed upon their U.S. arrival. Therefore, for a one-year period, more than 23 per 100,000 immigrants and refugees potentially had undetected infectious TB on arrival.

New TIs were released in 2007 and revised in 2009 that included a number of added measures intended to further reduce the likelihood that immigrants will arrive in the U.S. with undetected TB disease.[10] Children immigrating from countries for which the WHO-estimated incident rate of TB is $\geq$ 20 cases per 100,000 population are given a tuberculin skin test (TST) or an interferon gamma release assay (IGRA) followed by CXR and sputum specimen collection if the TST result is $\geq$ 10mm induration or the IGRA is positive. Cultures are obtained on all sputum specimens and individuals beginning treatment for TB must complete therapy prior to travel. Immigrants who are contacts to individuals with TB disease (have shared the same enclosed air space) are given a TST or IGRA followed by CXR and sputum specimen collection if the TST result is $\geq$ 5mm or the IGRA is positive. The length of time that results of TB screening examinations are valid for travel has been reduced from 12 months to 6 months for immigrants with no TB classification or Class B2 TB or Class B3 TB, if negative for HIV infection. For individuals with Class B1 TB, Pulmonary or Class B1, Extrapulmonary or who have HIV infection, validity of screening results has been reduced from 6 months to 3 months. The TB Classifications for immigrants in the 2007 TIs were revised as follows:

- Class A TB, pulmonary (must complete treatment for TB prior to travel unless a waiver is granted)

- Applicants who have sputum smears that are positive for AFB microscopy, unless non-tuberculosis mycobacterial disease is diagnosed
- Applicants who have negative sputum smears but cultures positive for TB

- Class B1 TB, pulmonary
  - Completed treatment, applicants who are diagnosed with pulmonary TB and successfully complete directly observed therapy (DOT) prior to immigration
  - No treatment, applicants who have medical history, physical exam, HIV or CXR results suggestive of pulmonary TB but have negative AFB sputum smears and cultures and are not diagnosed with TB or can wait to have TB treatment started after immigration
- Class B1 TB, extrapulmonary
  - Applicants with evidence of extrapulmonary TB
- Class B2 TB, latent TB infection (LTBI) evaluation
  - Children age 2 to 14 years of age (with no known TB exposure) who have a positive IGRA or a TST ($\geq$ 10mm induration) who are not HIV positive (if tested), have no clinical findings of TB, and have a normal CXR
  - Contacts of all ages to an individual with TB disease who have a positive IGRA or a TST ($\geq$ 5mm induration) who have no clinical findings of TB, and have a normal CXR

- Class B3 TB*, contact evaluation - applicants who are a recent contact of a known TB case
    - All contacts who travel <8 weeks after contact ends
    - All contacts who have a positive IGRA or a TST of ≥5 mm induration

A phased implementation of the new protocol began in March of 2007 in Thailand with refugee populations seeking permanent U.S. resettlement and then in October, for all immigrants coming from the Philippines and Mexico. As of October, 2010, 28 countries worldwide were using the revised 2007/2009 TIs when screening for TB for all immigrants and refugees and an additional six countries for refugee populations only; all other countries continue to use the 1991 protocol. Following implementation of the 2007 TIs, analysis of data for immigrants arriving in California from Mexico, Viet Nam and the Philippines indicate that while the diagnosis of TB disease within the first six months of arrival has been reduced, a timely U.S. TB evaluation for those at risk of TB disease remains important. A study completed by the California Department of Public Health Tuberculosis Control Branch compares the proportion of immigrants diagnosed with TB disease within the first 6 months of arrival to California one year prior to and one year following implementation of the 2007 TIs.[11] While the results indicate a reduction in the diagnosis of TB disease from 4.2% to 1.5%, a total of 22 cases of TB disease were identified between October 1, 2007 and September 30, 2008 following implementation of the 2007 TIs. The site of disease for all cases was pulmonary. Immigrants from the Philippines represented the largest portion of the cohort (78%) and the greatest number of cases, n=17.

* Immigrants who are contacts may receive more than one classification.

Under both the 1991 and the 2007/2009 TIs, those individuals given a classification for TB in their overseas medical screening are required to complete a second examination upon arrival in the U.S. To facilitate the completion of the U.S. TB evaluations for immigrants arriving with a classification for TB, the CDC DGMQ provides state and local public health departments with overseas medical screening results and locating information for the immigrant or refugee. Despite notification, the U.S. TB evaluation for new entrants is frequently not completed. Reasons for this are likely numerous but from the immigrants' perspective may include: 1) the lack of knowledge of the importance of completing the evaluation, 2) the lack of knowledge of how to arrange an evaluation, and/or 3) fears that evaluation results will negatively influence resettlement. Reasons related to local health departments may include lack of resources, competing disease control priorities and/or failure to return U.S. TB evaluation forms to CDC DGMQ. Local health departments are encouraged to, although are not required to, complete U.S. TB evaluations on recently arrived immigrants with a TB classification. Incomplete U.S. TB evaluations for new entrants creates the potential for delayed identification of infectious TB cases and subsequent spread of disease within the U.S as well as lost opportunities to treat individuals with latent TB infection (LTBI) who may be at risk of developing TB at a later date.

Evaluations of the TB screening of recently arrived immigrants with a TB classification have shown that the U.S. TB examination identifies more cases of TB disease than traditional contact investigations and is an important strategy in early case detection and treatment.[12, 13] An additional potential benefit to screening is the identification and treatment of individuals with LTBI. The Institutes of Medicine's

(IOM) 2000 report on TB, "Ending the Neglect: The Elimination of Tuberculosis in the United States" emphasized the importance of TB screening and treatment for individuals at risk of LTBI in moving towards the elimination of TB.[14] In regards to individuals from countries experiencing high TB rates, the committee's recommendation was that "tuberculin skin testing be required as part of the medical evaluation for immigrant visa applicants from countries with high rates of tuberculosis" and that **"**when indicated, [immigrants should] complete an approved course of treatment for latent infection before receiving a permanent residency card (informally called a "green card")". Approximately one person in ten with LTBI will go on to develop TB disease at some time during their life and for those individuals with HIV or other immunosuppressive diseases the proportion is higher.[2] While this recommendation has not been fully implemented, the evaluation of immigrants referred to local health departments with a TB classification takes advantage of an existing system to identify and treat individuals with TB disease or LTBI.

TB cases identified through immigrant and refugee screening when compared with cases found through passive screening methods are generally earlier in the disease process, less ill, are hospitalized for fewer days, and are less likely to be infectious.[12, 15, 16] Studies of the cost-effectiveness of TB evaluation and treatment of newly arrived immigrants in the U.S. and Canada, while few, have shown that early case identification and successful treatment of individuals with LTBI can potentially reduce domestic disease transmission and deaths caused by TB, prevent future cases of TB disease and LTBI, and provide cost savings.[15, 16]

The expanded screening modalities of the new 2007/2009 TIs cannot guarantee that immigrants and refugees will not arrive with TB disease. U.S.-based TB evaluations of individuals with an overseas TB classification remain an important activity for controlling TB. There is, however, little evidence regarding which strategies improve the completion rate for those U.S. TB evaluations. One study done in Santa Clara County, California looked at the effectiveness of interventions used to encourage recently arrived immigrants with a TB classification to present for TB screening. The Santa Clara County TB Control Program evaluated the progressive use of letters, telephone calls, and home visits and found that these methods were relatively low in cost and that 96% (235 of 244 recent arrivals) responded to the interventions. During the length of this study, Santa Clara County identified 16 (5.7% of arrivals with a TB classification) individuals with active TB disease, of who 13 had reported for screening after receiving a letter, telephone call or home visit.[17]

Currently, three of the 20 U.S. CDC DGMQ Quarantine Stations (Chicago, Detroit and Honolulu) provide a personal referral to newly arriving immigrants upon U.S. entry, although each of these referrals is slightly different, by either making appointments at a TB control program or by giving the immigrants instructions to call their State health department upon arrival at their U.S. residence. In Chicago, an appointment is made at a TB control program for all immigrants residing within the borders of Chicago or the telephone number for a local TB control program is provided to those going to suburban Cook County (near Chicago). The Honolulu Quarantine Station makes an appointment at the State TB Control Program for all individuals immigrating to Hawaii. At the Detroit Quarantine Station, written referrals to the State health department with jurisdiction over

the immigrant's new home are provided by quarantine staff for most immigrants arriving from Monday through Friday during regular hours of operation. However, no published studies have been found that have looked at the benefit of the use of a written referral at time of U.S. arrival.

Theoretical Framework

Evaluating public health activities designed to decrease the occurrence of infectious disease and incorporating the knowledge gained through these efforts is a key strategy to ensuring successful population health outcomes and wise use of limited resources. In 1999, CDC recommended that public health programs "conduct routine, practical evaluations that provide information for management and improve program effectiveness."[18] Utilization focused evaluation emphasizes the use of evaluation findings by potential stakeholders.[19] The stakeholders in this study are immigrants seeking permanent U.S. residence, local and state TB control programs, the CDC DGMQ and the CDC Division of TB Elimination (DTBE).

The framework for this study is also built on the premise of evidence-based clinical practice or medicine (EBM). The two fundamental principles of EBM are that "evidence alone is never sufficient to make clinical decisions" and that a "hierarchy of evidence should guide clinical decision making."[20]

The outcome of interest in this study is the impact of providing a written referral and verbal instruction on the completion of U.S. TB evaluations. Figure 1 shows the conceptual diagram for the relationship between recently arrived immigrants, the receipt of the referral used at Detroit Metropolitan Airport (DTW) and completion of U.S.-based TB evaluations. An individual's decision and/or ability to complete their U.S. TB

evaluation may be affected by several covariates; type of TB classification, sex, age, marital status, arrival with a household member that also has a TB classification, current treatment for TB or a history of TB treatment. Potential confounders include varying local and state health department policies and/or resources devoted to immigrant TB evaluations, distance of an immigrant's residence from the clinic, clinic hours and available transportation, loss of data at a number of steps in the information transfer process, data entry errors or the provision of inaccurate immigrant locating information to local and/or state health departments.

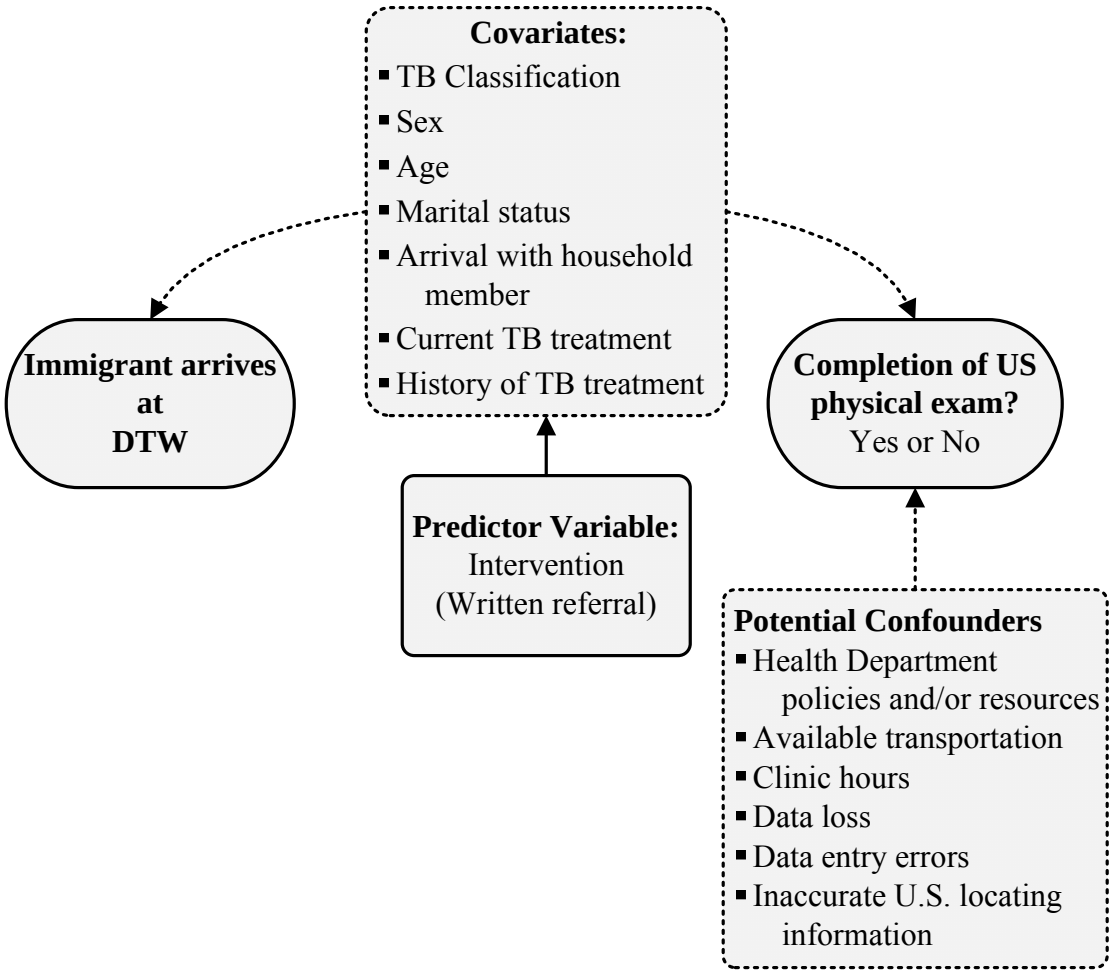


Figure 1. Conceptual Model for Study

Purpose Statement

The purpose of this study is to determine if providing the written referral used at the Detroit Quarantine Station to immigrants identified with a TB classification during their overseas medical examinations at time of U.S. arrival will increase the likelihood that U.S. TB evaluations will be completed. This study will focus on newly arriving immigrants from the Philippines (the most frequent country of origin for immigrants entering through the Detroit Metropolitan Airport), which in 2008 reported 285 TB cases per 100,000 population.[1]

Research Question

Question: Does providing newly arriving Filipino immigrants with the written referral used at the Detroit Quarantine Station containing 1) the telephone number for the State public health department with jurisdiction over their new residence and 2) instructions to call upon arrival at their residence, increase the likelihood that the immigrant will make and keep an appointment with the public health department responsible for providing their U.S. TB evaluation?

Null hypothesis: The completion rate for U.S. TB evaluations between immigrants receiving the written referral used at the Detroit Quarantine Station upon U.S. entry will not increase significantly compared with immigrants who did not receive a referral.

Significance Statement

The global TB incidence and an increasingly mobile world population have a significant and growing impact on U.S. TB control efforts. The percentage of U.S. foreign-born TB cases has been rising for over a decade: in 2009, 13 states reported $\geq$

70% of individuals diagnosed with TB were foreign-born.[3] While only a portion of the disease burden among foreign-born residents is a result of recently arrived immigrants seeking permanent residence, it is a portion for which a system of TB screening is in place and efforts to improve the quality of those overseas screenings are ongoing. Equally important is the handoff between panel physicians performing the overseas TB screening and the follow-up evaluations performed by U.S. State and local public health. An answer to the question proposed by this study would hopefully provide evidence to support expanding the use, terminating the use, or developing others methods of a referral system for immigrants on arrival who are at risk for TB. Improving the completion rate for U.S. TB evaluations would potentially lead to earlier identification of individuals with TB disease, which would in turn reduce the severity of an individual's disease, the transmission to others in their family and community, and prevent future cases of TB.

Definition of Terms

Abbreviations

AFB	Acid fast bacilli
ATS	American Thoracic Society
CBP	Customs and Border Protection, a part of the U.S. Department of Homeland Security
CDC	Centers for Disease Control and Prevention
CXR	Chest x-ray
DTBE	CDC Division of Tuberculosis Elimination
DGMQ	CDC Division of Global Migration and Quarantine
DOS	U.S. Department of State
DOT	Directly Observed Therapy
DTW	Detroit Metropolitan Airport, Detroit, Michigan
EBM	Evidence-based medicine
EDN	Electronic Disease Notification system
IGRA	Interferon gamma release assay
IOM	Institute of Medicine
LTBI	Latent TB Infection
NTCA	National Tuberculosis Controllers Association (NTCA)
TIs	Technical Instructions
TB	Tuberculosis
TST	Tuberculin skin test
WHO	World Health Organization

Definitions

Alien – The term "alien" in this document means any person not a citizen or national of the United States.[21]

Directly Observed Therapy – A health care provider or public health worker observes (watches) an individual with TB swallow their medication.

Foreign-born – A person born outside the U.S.

Immigrant – A foreign-born individual seeking permanent residence in the U.S. who does not qualify as refugee or asylum seeker.

Interferon gamma release assay (IGRA) - Blood test that measures a component of cell-mediated immunity reactivity to *M. tuberculosis* in fresh whole blood.

Latent TB infection (LTBI) – Some persons who inhale TB bacteria are not able to immediately clear them from their lungs and become infected. The bacteria multiply for a period of time but are eventually contained by the person's immune system. Persons with LTBI are not sick, are not contagious, and cannot spread TB to others. In general, one in ten persons with LTBI will go on to develop TB disease sometime during their life.

Overseas medical evaluation/screening – An examination performed by a panel physician and required for all persons seeking permanent U.S. residence.

Panel physician – An overseas physician selected by the Department of State (DOS) consular offices to perform medical examinations of persons seeking permanent U.S. residence.

Technical Instructions (TIs) – The instructions developed by the CDC Division of Global Migration and Quarantine for overseas panel physicians to provide guidance on the requirements for medical evaluations given to persons seeking permanent U.S. residence.

TB classification – Classifications defined in the TIs and assigned by overseas panel physician to persons at risk for TB which includes:

From the 1991 TIs:

- Class A TB, infectious. An abnormal chest x-ray or series of chest x-rays suggestive of current pulmonary TB and one or more positive sputum smear examinations for acid-fast bacilli.
- Class B1 TB, clinically active, not infectious. An abnormal chest x-ray or series of chest x-rays suggestive of current pulmonary TB and sputum smear examinations for acid-fast bacilli that are negative on 3 consecutive days.
- Class B2 TB, not clinically active. An abnormal chest x-ray or series of chest x-rays suggestive of TB not clinically active (e.g., fibrosis, scarring, pleural thickening, diaphragmatic tenting, blunting of costophrenic angles).
- Class B3, consistent with old or healed TB. An abnormal chest x-ray or series of chest x-rays where the only abnormality is calcified hilar lymph node, calcified primary complex, or calcified granuloma.

From the 2007 TIs (revised in 2009):

- Class A TB, Pulmonary (must complete treatment for TB prior to travel unless a waiver is granted)
  - Applicants who have sputum smears that are positive for AFB microscopy unless non-tuberculosis mycobacterial disease is diagnosed
  - Applicants who have negative sputum smears but positive cultures for TB bacteria
- Class B1 TB, Pulmonary
  - Completed treatment, applicants who are diagnosed with pulmonary TB and successfully complete directly observed therapy (DOT) prior to immigration
  - No treatment, applicants who have medical history, physical exam, HIV-infection, or CXR results suggestive of pulmonary TB but have negative AFB sputum smears and cultures and are not diagnosed with TB or can wait to have TB treatment started after immigration
- Class B1 TB, Extrapulmonary - Applicants with evidence of extrapulmonary TB

- Class B2 TB, LTBI Evaluation
  - Children age 2 to 14 years of age who have a TST of ≥ 10mm induration who are not HIV positive (if tested), have no clinical findings of TB, and have a normal CXR
  - Contacts of any age who have a TST of ≥ 5mm induration who are not HIV positive, have no clinical findings of TB, and have a normal CXR
- Class B3 TB, Contact Evaluation - Applicants who are a recent contact of a known TB case but no signs or symptoms of TB

TB disease – A condition caused when a TB infection is not contained by a person's immune system and progresses to cause clinical signs or symptoms of disease. TB can attack any part of the body but disease is most commonly found in the lungs. TB disease of the lungs or throat can be infectious while TB confined to other parts of the body, except in rare circumstances, is not. Some persons with TB disease are identified early in the course of the illness before signs and symptoms generally associated with TB are present but other signs of illness are present.

U.S. TB evaluation/screening – A health examination generally performed by local public health departments for arriving immigrants or refugees with a classification for TB assigned by the overseas panel physician. Screenings include a review of the immigrant's health history in regards to TB, their current health status and possibly a tuberculin skin test, a CXR, and collection of sputum for microscopic examination.

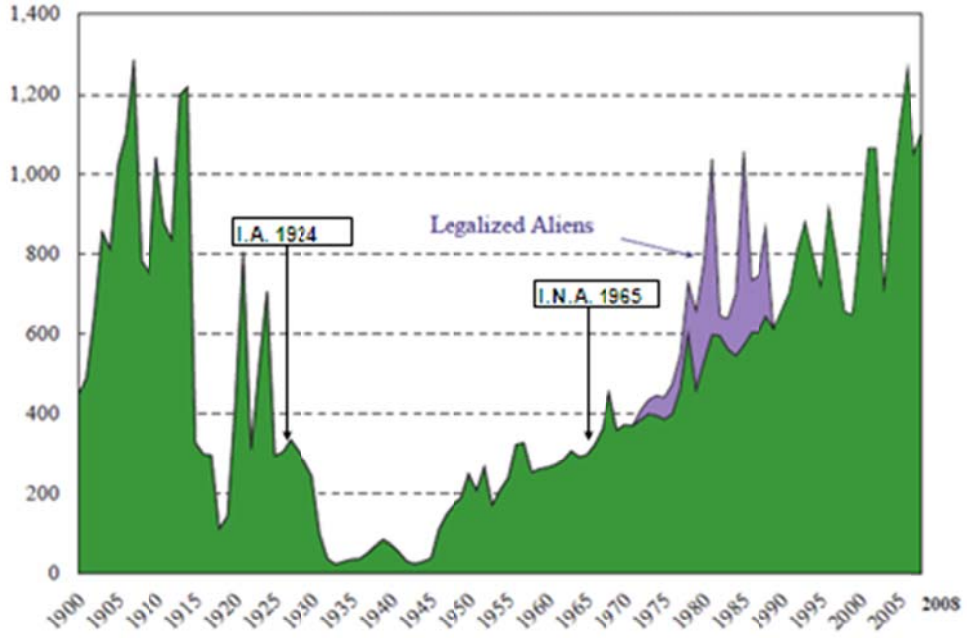
Chapter II: Review of the Literature

Introduction

Importation of TB has been a major U.S. public health concern for over a century and was first addressed on a national level in 1891 with legislation that sought to restrict entrance for individuals suffering from "a loathsome or a dangerous contagious disease".[22] Prior to 1890, immigration was regulated by individual states. Federal screening for inadmissible conditions by the physicians of the U.S. Marine Hospital Service began on January 1, 1982 at Ellis Island, New York City; the port of entry for approximately 70% of arriving immigrants.[23] Between 1891 and 1930, federal immigration laws turned away approximately a half million (roughly 2%) of the 25 million immigrants inspected by the U.S. Marine Hospital Service (renamed the U.S. Public Health Service in 1912).[24]

National law regarding immigration has changed over time; two of the most significant for TB control have been the Immigration Act of 1924 (the Johnson-Reed Act) passed following World War I and the Immigration and Nationality Act of 1965. The Immigration Act of 1924, an exclusionary policy, initially capped the number of arriving immigrants to 150,000 per year, limited the number of persons of each nationality to two percent of the 1890 census with a preference for migrants from Northern and Western Europe while completely eliminating migration from Asia. It dramatically slowed immigration, established the visa system, and transferred medical examinations for those seeking permanent residence to overseas.[25] The national quota system was eventually eliminated by the Immigration and Nationality Act of 1965, which set the founding strategies for the nation's current permanent immigration policy

including: “reunification of families, the admission of immigrants with needed skills, protection of refugees and diversity of admission by country of origin”.[26] Today, permanent immigration is limited to 675,000 individuals annually, although some categories are allowed to exceed this limit. In 2008, 1.1 million individuals were granted permanent U.S. residence, the greatest number since the early 1900’s (Figure 1).



Source: *Statistical Yearbook of Immigration*, U.S. Department of Homeland Security, Office of Immigration Statistics, multiple fiscal years. Aliens legalizing through the Immigration Reform and Control Act of 1986 are depicted by year of arrival rather than year of adjustment.

Figure 2. Annual Legal Permanent Admissions and Status Adjustments, * 1900 – 2008

The literature review for this study includes the following topics:

- Public health and tuberculosis
- Current epidemiology of TB among U.S. foreign-born persons and U.S. TB control strategies
- Impact and effectiveness of immigrant health screenings
- Acceptability of TB screening among immigrants

- Methods used to improve completion of immigrant health screenings

The sources cited in this chapter were found using an electronic search of current articles (keywords: tuberculosis, immigrant screening, TB screening) from 1965 to 2010 through Ovid, PubMed, the Cochrane Library and review of relevant websites and texts.

Public Health and Tuberculosis

The role of public health in TB control has expanded over time to incorporate new tools and resources as they have become available. Prior to 1944 and the first use of streptomycin by Dr. Selman Waksman,[27] there was no effective biomedical treatment for TB; the tools of public health were limited primarily to environmental interventions, such as disinfection of living quarters and instructions on the disposal of sputum. Richard J. Coker in "Chaos to Coercion"[28] reviewed the increasing role of public health in TB control in New York City from the late 1900s through the mid 1990s and noted that as effective medication was discovered, the focus of public health began to shift from the societal nature of the disease and disinfection or other cleanliness measures to a more individualistic perspective. In 1991 in response to the rising numbers of TB cases reported beginning in the mid 1980s, the CDC DGMQ in cooperation with U.S. DOS issued revised TIs for overseas medical examinations.

Revisions of the TIs over time are an example of the increasing use of available technology and evidence based methods in the diagnosis and treatment of TB. The first evaluation of the 1991 TIs highlighted the need to improve diagnostic treatment methods. One study looked at the overseas screening program in Viet Nam and found that of 1179 adult applicants (between October 1998 – October 1999) with abnormal CXR, 82 (7%) were AFB smear positive (restricted from travel), while 183 (15.5%), were AFB smear

negative but TB culture positive (allowed to travel).[7] Using cultures (2007 TIs) as opposed to smear only (1991 TIs), twice as many individuals were diagnosed with active TB. A comparison of the 2007 (revised 2009) and 1991 TIs shows an expanded use of TB culture results, drug susceptibility testing, TST for contacts to individuals diagnosed with active TB disease and the use of DOT.[10, 29, 30] Three external evaluations of U.S. bound immigrant and refugee screening programs have been completed since implementation of the 2007 TIs. At the Damak International Organization for Migration (IOM) refugee camp in Nepal in August, 2009, reviewers found overall that the 2007 TIs had been well implemented and were effective in identifying individuals with active TB disease who would not have been diagnosed prior to travel using only the 1991 TIs methods. Of the immigrants identified with potentially infectious active TB disease between December 3, 2007 and July 15, 2009, 73% (94 of 129) were sputum smear negative and culture positive and would have been allowed to travel under the 1991 TIs.[31]

The two-step process employed in the U.S. for screening individuals at risk for TB disease that are seeking permanent resident status, an overseas pre-immigration examination and a follow-up post-immigration TB evaluation, is a well-established TB control strategy. However, the U.S. TB evaluation for new entrants, important in identifying individuals with active TB disease and reducing domestic TB transmission, is frequently not completed. Furthermore, while the overseas screening has limited value in determining the presence of LTBI, the follow-up U.S. TB evaluation provides an opportunity to identify and offer preventive TB treatment to individuals.

Current Epidemiology of TB among U.S. Foreign-born Persons and U.S. TB Control Strategies

Over one half of U.S. reported TB disease cases since 1992 have been among foreign-born residents.[3] The four essential strategies for U.S. TB control[32] are:

- Identification and treatment of individuals with active TB disease
- Identification, evaluation and treatment of individuals in contact with persons with active TB disease
- Targeting testing and preventive treatment of individuals at increased risk for LTBI
- Identification of settings in which a high risk for TB transmission exists and application of effective infection-control measures

The first, second and fourth priorities focus on halting recent transmission within the U.S. and the third on preventing future cases of TB disease from occurring. A study by Bennett et al. (2008)[33] determined that the estimated overall LTBI prevalence among U.S. foreign-born persons in 1999-2000 was 18.7%, over 10 times greater than the U.S. born prevalence of 1.8%. While the study was based on just 7,386 individuals participating in the National Health and Nutrition Examination Survey (NHANES), a complex cluster sampling design was used to create a nationally representative sample of the U.S. civilian, non-institutionalized population. Bennett found that only 19.5% of foreign-born study participants determined to have LTBI had been previously diagnosed with LTBI or TB and only 11.6% had received treatment for LTBI or TB.

Addressing LTBI among the U.S. foreign-born population in addition to stopping recent transmission has been identified as a pressing need in TB control for some time.

The 2000 IOM Report, "Ending Neglect: The Elimination of Tuberculosis in the United States", recommended utilizing existing systems for identifying foreign-born individuals during their highest risk for active TB, the first five years in the U.S., and providing treatment for LTBI when appropriate.[14] A relatively recent study by Cain et al. (2007)[34] that focused on TB elimination among foreign-born individuals found that the average TB rate for those in the U.S. less than one year was 121/100,000 population. This study looked at the 10 countries that had contributed the greatest number of U.S. TB cases in 2004. For 9 of the 10 countries, individuals in the U.S. for less than or equal to one year had between 1.2 and 4.3 times the rate of TB disease compared with the rate of their country of origin, implying the advantage of active surveillance opportunities that post-immigration U.S. TB evaluations can provide.

A study by Walter et al. (2007)[35] conducted at the San Francisco Department of Public Health questioned the adequacy of current guidelines for targeted testing and treatment of LTBI in preventing active TB disease. The cohort was 223 active TB cases reported over a two year period in 2002-2003. The study found that 62% of these cases were not preventable (had no indication for testing or negative test results) but also highlighted missed opportunities for testing, identification, and treatment of the remaining 38%.

While current guidelines and corresponding public health practice may not ensure attaining the Healthy People 2010 goal of TB reduction (1 case/100,000 population),[36] these guidelines do provide a framework for prioritizing the use of limited TB control resources. Making use of current systems such as the two-step process for evaluating newly arrived immigrants seeking permanent U.S. settlement is an efficient method for

identifying those that would benefit from treatment for LTBI and potentially preventing future cases of active TB.

Impact and Effectiveness of Immigrant Health Screenings

Post-arrival health screenings for newly arrived immigrants can be effective in identifying individuals with active TB. In four California studies, the percentage of immigrants and refugees found to have active TB disease when screened ranged from 3.5% to 7%.[12, 13, 17, 37] In the three county-based studies (San Diego, San Francisco and Santa Clara), the results are likely to be a fairly accurate representation of the actual number of individuals with active TB disease among newly arrived immigrants as the percentage of U. S. examinations completed was relatively high, 87%, 80.4% and 97.2%, respectively. Individuals with active TB disease found through screening were generally less likely to be highly infectious (smear-positive) and to be identified sooner after arrival; factors that can minimize TB transmission in the U.S.[12, 13] Authors of all four studies concluded that medical evaluation of immigrants and refugees resulted in a relatively high yield in detecting cases of active TB disease. They recommended making this activity a priority for TB control programs while also noting that post-migration examination was not successful in finding the majority of recent arrivals with TB disease (those for which screening is not required or who are without documentation) as only a portion of all foreign-born individuals at risk for TB complete pre-immigration health screening (those requesting legal permanent residence).

Other industrialized nations have had similar experiences with TB screening of newly arrived immigrants from high-risk countries. The Netherlands employs post-migration screening for all individuals arriving from high-risk countries that intend to

stay longer than 3 months. In a retrospective study of newly arriving persons (living in the Netherlands less than 30 months) over six years, 55% of individuals with active TB disease were identified through screening and 45% through passive case detection (individuals presenting with symptoms).[38] Those identified through screening had a shorter duration of symptoms between onset and diagnosis and early identification through screening was credited with reducing the infectious period by an estimated 33%. Another Dutch study (S. Verver, D. van Soolingen and M.W. Borgdorff, 2002) using genotyping and looking at TB transmission among immigrants from high-risk countries, found that source cases identified through screening had fewer secondary cases than cases who presented for treatment (found through passive surveillance).[39] The authors acknowledged some limitations of the study including the possibility of transmission in the immigrant's home country resulting in reactivation of TB disease identified later and mistaken as recent transmission in the Netherlands, and problems with accurate recording of duration of stay in patient's medical records. Australia, like the U.S., uses pre-departure and post-arrival screenings for immigrants from high-risk countries for TB. In the 10 years between 1984 and 1994, nearly 30% of TB cases reported among refugees within 1 year of arriving in New South Wales were identified as a result of screening.[40] Furthermore, 45.5% of newly arriving persons had a positive ($\geq$10mm) TST.

Post-migration health screening also provides the opportunity to identify those individuals in whom preventive therapy for LTBI would be of benefit. National recommendations, for priority populations and subpopulations for targeted testing and treatment of LTBI, include legal immigrants with Class B1 or B2 TB notification status, recently arrived refugees and foreign-born persons from high incidence TB countries who

have resided in the U.S. for less than 5 years.[32] The time between U.S. arrival and beginning preventive treatment for LTBI can be shortened by taking advantage of post-arrival health screenings.[41] A retrospective chart review study by K. Page et al. in Prince George County, Maryland over five years (1999-2004) found that while the majority of patients recommended for LTBI treatment did receive therapy within 5 years of arrival (84%), foreign-born individuals who were not referred for LTBI treatment through immigration screening were less likely to receive treatment within 5 years of arrival in the U.S (adjusted odds ratio 251.7 [range 78.4-808.2]).

Domestic follow-up of newly arrived immigrants can be a cost effective strategy in reducing transmission by earlier identification of individuals with active TB disease, reducing deaths caused by TB, and preventing future cases through early initiation of treatment for LTBI.[15, 16, 42] A complex modeling of costs associated with domestic follow-up of immigrants arriving with a B Classification was completed by T.Porco et al. based on incremental cost data in 2004.[15] While the study is built on a number of assumptions associated with TB occurrence and transmission over 20 years among a cohort of 1000 B-notification immigrants arriving in California, most of them are relatively conservative, resulting in a likely under-estimation of future costs saved by completion of U.S. screening. The results of this study showed that with approximately 3700 newly arriving persons with B-notifications annually in California, domestic follow-up for one year would prevent approximately 6 to 26 cases of active TB disease with a cost savings of $67,000 to $170,000. This study did not consider the costs to immigrants or society of lost wages, lost productivity, and time seeking health care.

There is not complete consensus on the benefits and cost-effectiveness of post-immigration screening of individuals from high-risk TB countries. There have also been concerns expressed regarding the acceptance of TB screening by immigrants and whether or not the practice is ethical. Following their cost-effectiveness study in Montreal, Quebec in 2000, K. Dasgupta and D. Menzies completed a review of English language publications prior to December 2003 to evaluate the cost effectiveness and impact of CXR screening programs on identifying individuals with active TB disease among those seeking permanent residence.[43] This study looked at only the cost comparison of CXR, sputum microscopy and culture, PCR amplification, TST, and cell-mediated immune tests in relation to identification of a case of active TB disease. It did not assess long term gains from reduced transmission or cases averted. The authors concluded that TB screening with CXR was not highly cost effective, but that the inclusion of TST would be somewhat more cost effective and that ideally long-term TB control strategies would include global investments to reduce TB in high-incidence countries.

Acceptability of TB Screening to Immigrants

To ensure that the public health TB control strategy of screening newly arrived persons seeking permanent residence is effective, it is also important to look at TB screening from the immigrant's point of view. A small qualitative study conducted in London, England addressed whether or not TB screening is acceptable to immigrants.[44] The authors stated that "acceptability is an essential but neglected ethical prerequisite of screening programmes…". Study results found that the "overwhelming majority of informants welcomed screening [only 4 of 53 individuals interviewed declined TB screening] and felt reassured by the process". While this study had significant

limitations, the number of participants was small, and they were already actively engaged in seeking health care, it did capture responses verbatim. An older study done in Los Angeles, California in 1993 used a survey of 313 patients with active TB disease to determine factors associated with delays in seeking health care.[45] Of the respondents, over two thirds were immigrants and most (85%) had arrived in the U.S. as adults. Of the 255 (71%) who responded to questions regarding immigration status, 48 (20%) reported having no immigrant documents. Only 1 in 10 reported participation in a TB screening program. Overall, 80% of those interviewed sought care within 60 days of symptom onset but many reported language difficulties. One in 10 said that language problems had been a factor in not seeking health care earlier. While the study did examine fears associated with seeking care, it did not address other possible barriers to accessing health care, such as knowledge of the health care system, transportation, and cost.

Immigration necessarily entails some measure of stress. In their article on "Migration, Refugees, and Health Risks", authors Carballo and Nerukar examine a range of health issues that can be associated with immigration, including communicable and non-communicable diseases, work-related injuries and psychosocial problems.[46] The article is a general overview of the challenges faced by immigrants in their new homes and calls for more focused attention on post-migration health policy. The authors note that while each immigrant's circumstance is unique, many are moving as a result of the "push of poverty" rather than the "pull of better living conditions" and are bringing with them health profiles and beliefs related to health care from their country of origin.

Methods used to Increase Completion of Immigrant Health Screenings

Only one study was identified that looked specifically at the effectiveness of interventions used to encourage immigrants with a TB Classification to present for TB screening. This study conducted by Catlos et al. looked at all newly arriving persons to Santa Clara County, California with a TB Classification of A, B1 or B2 between October 1, 1995 and June 30, 1996 to determine the cost and effectiveness of the different methods used to encourage completion of TB screening.[17] The County used progressive methods, first a letter, then telephone calls and finally home visits to encourage completion of the U.S. examination for TB. Over the nine months of the study, 323 immigrants with a TB Classification arrived and stayed in Santa Clara County, 79 (24.5%) presented for TB screening before a letter was sent, 213 (65.9%) presented after receiving a letter, 17 (5.2%) presented after receiving telephone calls, and 5 (1.5%) presented after receiving home visits. Use of letters were the most cost effective method ($9.90 per exam completed). During the study, 16 individuals (5.7% of arrivers) were diagnosed with active TB disease. Furthermore, preventive treatment was recommended for 171 individuals diagnosed with LTBI.

In addition, a Canadian study, while not an evaluation of methods for encouraging recent immigrants to present for TB screening, did note that of 792 recent immigrants who were sent referral letters, 654 (83%) attended an initial medical visit.[47] Both of these studies demonstrate that written referrals can be an effective method for encouraging recently arrived immigrants to complete TB screening.

Summary

Immigration to the U.S. by persons arriving with active TB disease or LTBI is certainly not a new public health issue. Federal, State and local governments have worked to minimize the importation of TB disease and transmission using the means available at the time since 1891. Current trends in the U.S. epidemiology of TB clearly reflect both the impact of the ongoing global TB epidemic and the effect of increasing numbers of persons arriving from TB high-burden countries. Even though early external evaluations of the improvements in overseas screening provided by implementation of the 2007/2009 revised TIs are very positive, domestic screening of individuals identified as being at risk for TB is likely to continue to be an effective strategy in the early identification of persons with active TB disease and an opportunity to identify and provide preventive treatment for LTBI. The Santa Clara County Health Department demonstrated that interventions designed to assist newly arriving persons in completing their U.S. TB evaluations can be highly effective. The study by Porco et al. provided evidence that domestic follow-up of immigrants with a TB Classification is a cost effective TB control activity. Although the Brewin et al. study was small and conducted in the United Kingdom, it demonstrated that the majority of recent immigrants felt TB screening was highly valued activity.

There has been little inquiry into the best methods for improving the completion rate of U.S. immigrant post-arrival TB screening. This study seeks to determine the effectiveness of providing a referral immediately upon arrival to the U.S. in encouraging immigrants to contact the public health resource responsible for TB control and prevention activities for their new residence. If effective, providing an intervention upon

arrival would assist both immigrants by making follow-up easier and local public health departments as less effort would be required to ensure follow-up.

Chapter III: Methods

Introduction

This study evaluates the effectiveness of providing the written referral used at Detroit Metropolitan Airport, Detroit, Michigan (DTW) (Appendix 1) and verbal instructions to newly arrived immigrants, whose first port of entry was DTW, identified as being at risk for TB disease during their pre-immigration medical screening on increasing the successful completion of U.S. TB evaluations. DTW was chosen as only three U.S. Quarantine Stations provide referrals to newly arrived immigrants (Chicago, Honolulu and DTW) and of these only DTW provides referrals regardless of location of U.S. residence.

Population and Sample

The population in this study is all newly arrived immigrants to the U.S. classified as B1 or B2 for TB during their overseas medical screening. The subjects (sample population) are immigrants whose first port of U.S. entry is the DTW between December 2006 and August 2007 (nine months). Immigrants arriving at DTW during this time frame were primarily from the Philippines (>90% for December 2006 – February 2007, unpublished data) and received their overseas medical screening per the 1991 TIs. This study does not include refugees or asylees as the support systems in place for these groups are more substantial than those for immigrants. Refugees generally have a sponsor who, upon arrival, can assist in making appointments and/or providing transportation to appointments. Immigrants arriving with incomplete or outdated overseas medical examinations were also excluded. These individuals must complete a medical screening performed by a U.S. Civil Surgeon in order to gain permanent legal

U.S. entry. To reduce the potential effect of country of origin on the outcome measure, completion of U.S. TB evaluation, study subjects were limited to those whose country of origin is the Philippines.

Assignment to the two groups in the study (those who received a written referral and those who did not), was determined by date and time of arrival at DTW. The DTW Quarantine Station was open for operation from 8:00 am to 5:00 pm Eastern Standard Time (EST), Monday through Friday excluding holidays during the time frame for this study. Those immigrants arriving on evening flights, weekends, holidays, or when the three quarantine staff members were otherwise engaged, became the group not receiving a referral. While the study sample is a convenience sample, there is no reason to assume that immigrants arriving on weekends, evenings or holidays were significantly different than those arriving during quarantine station hours of operation.

The inclusion criteria for this study were:

- Newly arriving Filipino immigrants of all ages at DTW between December 2006 and August 2007 with a B1 or B2 TB classification

The exclusion criteria for this study were:

- Refugees or asylum seekers
- Immigrants arriving at DTW from countries other than the Philippines
- Immigrants arriving with incomplete or outdated overseas medical examinations
- Immigrants for whom the presence or absence of receipt of referral was not documented by Quarantine staff on the immigration packet "face sheet"

Sample size calculations were based on an expected U.S. TB evaluation completion rate of 55% previously noted from unpublished 2005 CDC DGMQ data8 and a precision of $\pm$ 5%. The following formula was used to determine the sample size:[48]

$$n = Z^2 * \frac{P\,(1-P)}{d^2}$$

n = sample size
Z = 1.96 or the score Z corresponding to 95% degree of confidence desired to confirm that any change detected is not random
P = 55% the estimated rate of U.S. TB evaluations completed
d = 5% absolute precision

A minimum sample size of 380 that can detect a change of at least 5% was calculated with the above formula.

Research Design

This study is a retrospective (observational) cohort study comparing the rate of completion of a U.S. TB evaluation for newly arrived immigrants with either a B1 or B2 TB classification for those immigrants who receive a written referral with those who do not. This study will also examine the possible independent variables of an immigrant's TB classification, sex, age, marital status, arrival with a household member that also has a TB classification, current TB treatment at time of arrival, history of treatment for TB and state of U.S. residence on the completion of the dependent variable, U.S. TB evaluation.

Procedures

Overseas medical examination and U.S. TB evaluation information are routinely gathered by CDC DGMQ. Immigrants hand-carry sealed immigration packets that contain required immigration information including overseas medical examination forms (Appendix 2, 3, and 4). Upon arrival, the information packets were submitted to Custom and Border Protection (CBP) officers as part of the U.S. entry process. When an

immigrant arrived with a TB classification and Quarantine Station staff were available, CBP officers notified the Station. Overseas medical examination forms for immigrants arriving when Quarantine Station staff were not available were collected by CBP officers and forwarded to the Station.

Immigrants were not granted permanent U.S. entry without complete and current medical screening information. If this information was incomplete or outdated (travel occurred more than 6 months from the dated of the overseas examination), the immigrant was granted provisional U.S. entry, was informed that a completed U.S.-based examination by a Civil Surgeon within 30 days was required for permanent entrance and was provided with the location of Civil Surgeons near their U.S. place of residence.

At DTW, for immigrants arriving Monday through Friday from 8:00 am to 5:00 pm, standard written referrals encouraging completion of their U.S. TB evaluation were routinely provided by one of the three staff members at the station: the Medical Officer, Officer in Charge or Quarantine Public Health Officer. For this study, whether or not a referral was provided was noted on the "face sheet" of the immigration information packet. Although the station has responsibility for public health events at the international border 24-hours a day/seven day a week, during the time frame for this study, the station was not staffed to provide on-site immigrant processing after 5:00 pm or on weekends or holidays. Overseas medical examination information for all individuals arriving at DTW with a TB classification was photo-copied by the Detroit Quarantine Station and sent to the Chicago Quarantine Station for electronic data entry into a CDC DGMQ data base. A copy was then forwarded to the state health department TB control program with jurisdiction over the immigrant's U.S. residence.

Following the completion of a U.S. TB evaluation, the results were entered into a standard data collection form (Appendix 5 – CDC form 75.17), provided by CDC DGMQ, by local public health TB control programs. The form was sent to the State TB control program with jurisdiction over the immigrant's U.S. residence then forwarded to the CDC DGMQ where it was entered into an electronic data base. In the event that an immigrant did not report for their TB evaluation, the form contains instructions to the local health department to check a "no show" box and then forward the form to the State health department. The goal is to have a returned form for each immigrant whether a U.S. TB evaluation is completed or not.

Instrument

The written referral used by the Detroit Quarantine Station at the time of this study was a one page English language form instructing immigrants with a TB classification to contact the State health department TB control program at their new U.S. residence (Appendix A). The telephone number for the State TB control program was hand written at the top of the referral. Quarantine Station staff reviewed the instructions with the immigrant. In the event that an immigrant might show for their U.S. TB evaluation before copies of their overseas medical examination forms had been forwarded to either the State or local health department with jurisdiction over their U.S. residence, immigrants were provided with a copy of these forms along with the written referral.

Data analysis

Statistically significant differences in the demographic and social categorical covariates between the two study groups, those that received a written referral, and those

that did not, was analyzed using Pearson's chi-square test. Fisher's exact test was used in the event of cell size less than five. Median values for the continuous variable, age, were compared using the Wilcoxon rank sum test.

The CDC 75.17 form does not have a field to capture whether or not a TB evaluation has been completed. An algorithm was created to determine whether or not an immigrant's TB evaluation had been considered done. (Table 1)

Table 1. Algorithm for Determining if a U.S. TB Evaluation was Completed Using Answers from Returned CDC Form 75.17

Form Questions	Possible Answers	TB Evaluation Done*	
		Yes	*No*
A. Direct smear (in U.S.)	Positive	✓	
	Negative	✓	
	Not Done		✓
B. X-ray (in U.S.)	Normal	✓	
	Abnormal	✓	
	Not done		✓
C. X-ray (abroad)	Normal		✓
	Abnormal		✓
	Not done		✓
	Not available		✓
D. Presumptive diagnosis	Pulmonary TB – active	✓	
	Pulmonary TB – not active	✓	
	Pulmonary TB – activity undetermined	✓	
	Non-TB abnormality	✓	
	No abnormality	✓	
E. Has patient received chemotherapy prophylaxis in the past?	Yes		✓
	No		✓
	Unknown		✓
F. Are you prescribing chemotherapy or prophylaxis?	Yes	✓	
	No	✓	
Date of evaluation	Present with one or more "yes" column answer(s)	✓	

* A U.S. TB evaluation was considered done if CDC Form 75.17 contained any one of the answers checked in the above "Evaluation Done – Yes" column with or without the presence of a valid "Date of Evaluation". Presence of a Date of Evaluation alone was not sufficient to consider the evaluation complete.

If the CDC 75.17 contained any one of the designated answers, an evaluation was considered complete. Presence of a valid TB evaluation date in the absence of an answer to any one of the key questions was not sufficient to consider an evaluation done. The primary result of interest, impact of receiving a written referral on completion of a U.S. TB evaluation, was determined using Pearson's chi-square test.

Multiple factors may have affected completion of the U.S. TB evaluation including those specific to the immigrant, such as lack of knowledge of the importance of completing the examination, lack of knowledge of how to arrange an evaluation, fears that evaluation results will negatively influence resettlement, change of U.S. address prior to completing the evaluation, age, sex, marital status, arrival to the U.S. with a household member that also has a TB classification, accuracy of the immigrant's U.S. telephone number provided at U.S. entry, legibility of the State telephone number provided on the referral, availability of transportation to clinic appointments, experiences related to past treatment for TB, current treatment for TB, TB among a family member, or language barriers.

Factors not intrinsic to the immigrant may have included distance from the immigrants U.S. residence to the health department clinic, clinic hours of operation, immigrant TB evaluation policies and/or resources of state and local health departments. Those factors for which data were available were compared for significant differences between those immigrants that completed a U.S. TB evaluation and those that did not. U.S. state of residence, for states receiving 20 or more study group members was examined as a proxy for potential differences in TB prevention and control policies and/or resources. Criteria for being categorized as arriving with a household member that

also had a TB classification included the same arrival date, the same U.S. state residence and either a sequential immigrant identification number or completing the overseas physical examination within one week of each other. This definition of household member is relatively specific and likely provides an underestimation of the number of immigrants arriving with household members who also had a TB classification however, with no other data to identify familiar or household member status, it is probably the most accurate definition possible. A p-value <0.05 was considered statistically significant. Analysis was performed using SAS software, version 9.2 (SAS Institute).

Limitations and delimitations

Data collection for this study was subject to loss at various points in the process including:

- Upon arrival to the U.S.
  - Immigrants arriving with missing or expired overseas medical examination information forms (Appendix 2, 3, and 4) were excluded from the study. Although it is unlikely that immigrants with missing records will differ from immigrants whose incoming paperwork is complete, loss of these individuals to the study may potentially influence the results.
  - Receipt of referral may not have been noted on a new entrant's immigration packet "face sheet" by Quarantine Station staff. Immigrants with a missing referral status were not included in the study. Again, it is unlikely that immigrants without documentation of whether or not they received a referral differ from those with documentation but is another potential source of information loss.

- Overseas medical information collected by CBP officers when Quarantine staff were not available may not have been forwarded to the Quarantine station. For this study, it is possible that more Filipino immigrants may have arrived between December 2006 and August 2007. It is unlikely that these immigrants would differ significantly from other for whom information had been forwarded but it would have increased the number of immigrants in the non-referral group.
- Contact information regarding U.S. residence or U.S. telephone number may have been incorrect. Lack of accurate locating information may have impeded local or state health department efforts to follow-up with arriving immigrants. In addition, immigrants may have relocated within the U.S. soon after arrival, prior to completing their U.S. TB evaluation. This study does not include information on whether or not local or state health departments were able to contact study participants.
- There was no standardized method in this study for determining English language competency and/or an immigrants ability to understand the written referral used or handwritten information. While the English language competency of study participants was not evaluated, it is again unlikely that those receiving a referral differed in their ability to understand written and spoken English from those that did not.

- During completion of U.S. TB evaluation
  - U.S. TB evaluation information may have been incomplete or recorded incorrectly. While the CDC 75.17 form contains a check box (field) to note

that an immigrant did not report for their TB evaluation, it does not have a field noting whether or not a TB evaluation was completed. Evaluation completion was determined with an algorithm based on the presence or absence of information in other key fields. (Table 1)

- If the immigrant was seen by a private provider, the TB evaluation may have been done but the form (CDC 75.17) may not have been completed and/or returned to the local or state health department
- If the immigrant was seen by a local health department, the TB evaluation may have been done but the form (CDC 75.17) may not have been completed and/or forwarded to the state health department
- The TB evaluation form may not have been forwarded from the state health department to CDC DGMQ for data entry
- The TB evaluation form may have been forwarded at any point along the line but lost in the mail

- During data entry at CDC DGMQ
  - Data entry errors could have occurred, particularly in recording the unique identification number, would make matching the two sources of data, the overseas examination results and the U.S. TB evaluation difficult

In addition to data loss, the policies of state and local health departments may have influenced whether or not a U.S. TB evaluation was done. State and local health jurisdictions vary greatly as to policy and resources available for locating and completing U.S. TB evaluations for immigrants arriving with a TB classification. For arriving immigrants under the jurisdiction of health departments that devote more resources to

locating individuals and completing exams, the intervention may have been incorrectly credited for increasing the U.S. TB evaluation completion rate. For this reason, State of residence was an independent variable.

Lastly, the scope of this study was limited to Filipino immigrants arriving at DTW for the nine months between December 2006 and August 2007. The immigrant population whose first port of entry was DTW was primarily from the Philippines and is only a small fraction of those individuals seeking permanent U.S. residence (although a large proportion of foreign-born TB cases); as such, they are unlikely to be representative of all arriving immigrants.

Chapter IV: Results

Introduction

This chapter presents descriptive statistics and comparisons between two groups of Filipino immigrants with a B1 or B2 TB classification, those that received and those that did not receive the written referral used at the Detroit Quarantine Station and verbal instructions at their first port of entry, to examine the effectiveness of providing a referral on the successful completion of their U.S. TB evaluations.

Findings

Study Cohort

Between December 2006 and August 2007, 451 immigrants arrived at DTW with a B1 or B2 TB classification. The majority, 410 (90.9%) were from the Philippines. Thirty-eight immigrants were from one of 12 other countries representing Africa, Asia, Southeast Asia, Central and Eastern Europe. The records for three additional immigrants lacked a U.S. arrival date. Corresponding records were found for 402 of the remaining 410 immigrants in the CDC DGMQ database. Receipt of a referral was not noted for four of these individuals. The remaining 398 newly arrived Filipino immigrants with overseas medical examination information, known referral status, and corresponding information in the CDC DGMQ database were the cohort used in this analysis (Figure 3).

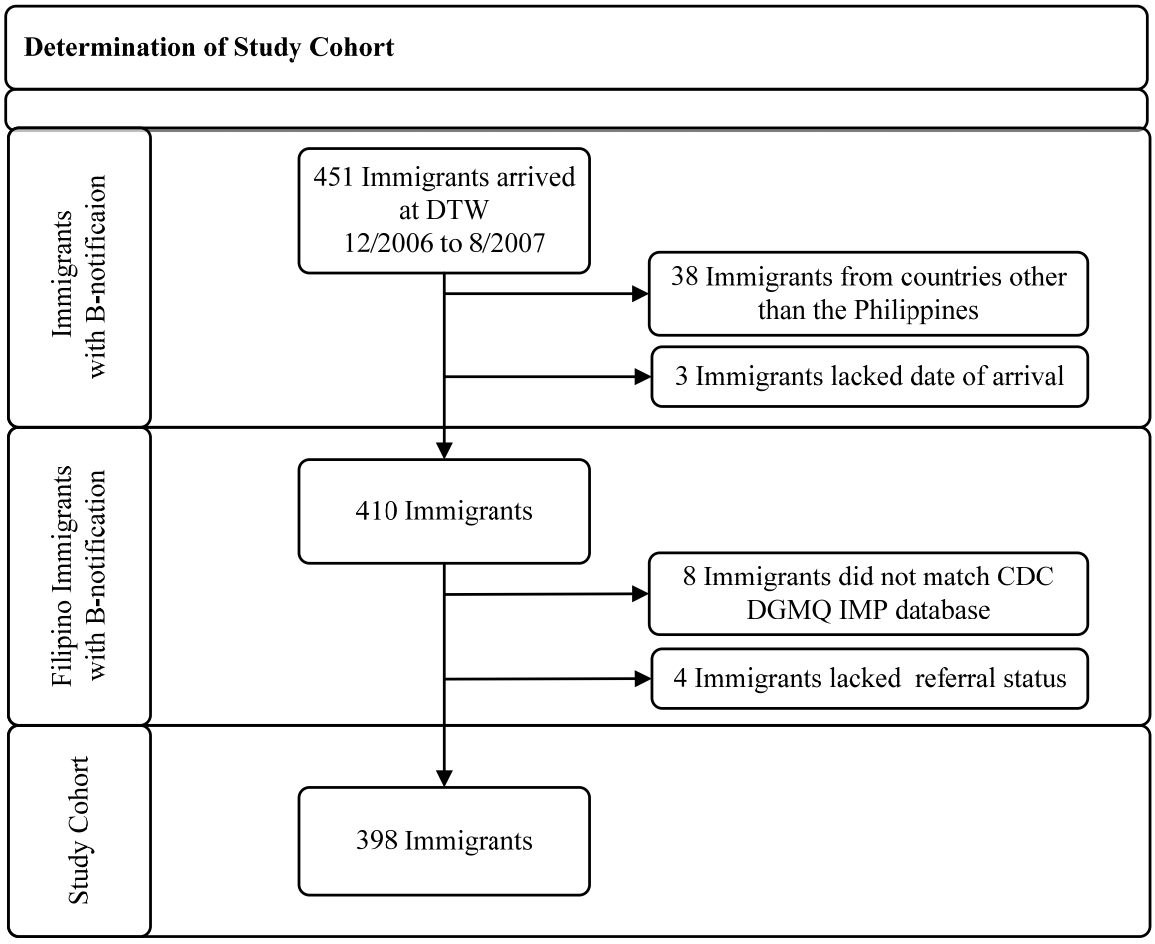


Figure 3. Immigrants Arriving at Detroit Metropolitan Airport, Detroit, Michigan (DTW) with a B1 or B2 TB Classification between December, 2006 and August, 2007

Study Cohort Demographic and Social Characteristics

The average age of the of the study cohort members was 55 years. Slightly more than half were female (61%), married (59%), and two-thirds (68%) had a B1 TB classification as opposed to a B2 TB classification. Forty-two (11%) immigrants arrived with a household member that also had a TB classification. Overseas medical records for 158 (40%) immigrants indicated previous treatment for TB and 11 (3%) individuals were under treatment at the time of U.S. arrival. No statistically significant differences

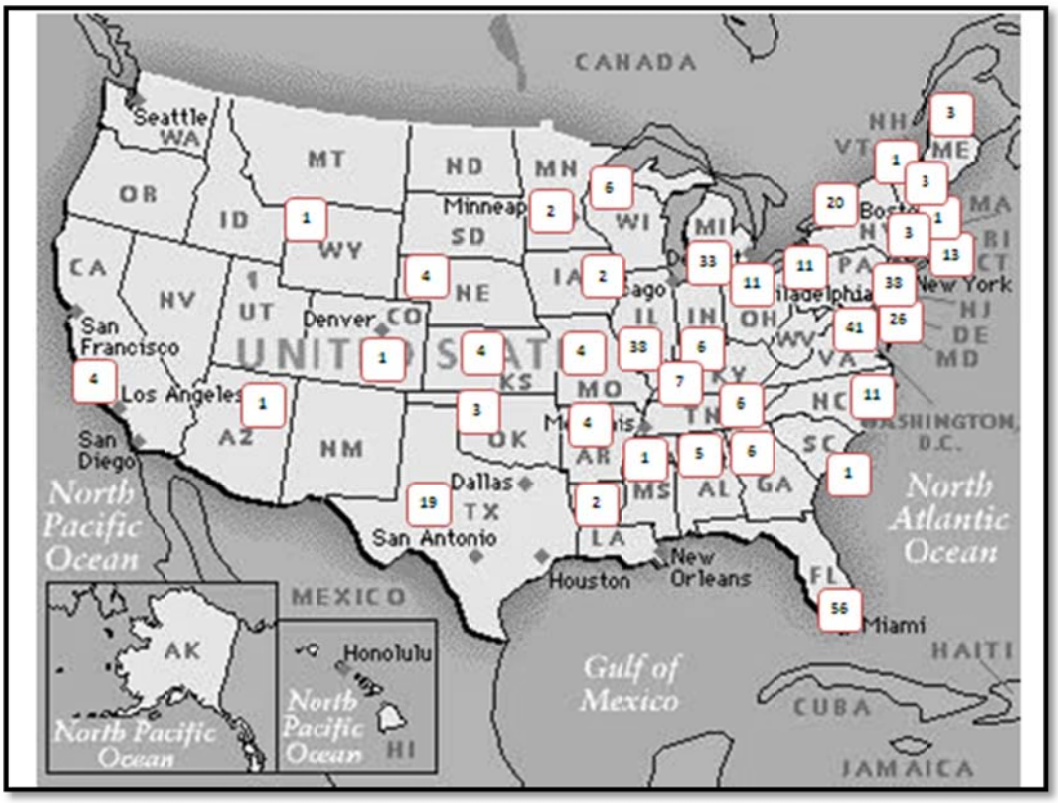
were noted between those arriving immigrants who received a referral and those who did not. (Table 2)

Table 2. Demographics and Social Characteristics of Study Cohort by Referral Group

Characteristic	Referral Yes		Referral No			
	n (250)	*%*	*n (148)*	*%*	$\chi^2(1)$	*p*
TB Classification						
Class B1	166	66	104	70	0.64	.42
Class B2	84	34	44	30	0.64	.42
Gender						
Female	152	61	90	61	0.00	.99
Age upon arrival (years)						
0-4 years	0		0			
5-14 years	2	< 1	1	< 1		
15-24 years	15	6	10	7		
25-44 years	49	20	37	25		
45-64 years	86	34	50	34		
65+ years	98	39	50	34		
Median (IQR)	61	(42-69)	58	(39-69)		.24
Marital Status						
Married	144	58	91	62	0.58	.44
Arrival with household member	26	10	16	11	0.02	.89
TB Treatment						
Current treatment	5	2	6	4	1.46	.11
History of treatment	97	39	61	41	0.23	.63

Abbreviations: IQR, interquartile range
p-value for mean age generated using Wilcoxon rank sum test, for current treatment using Fisher's exact test and all others using Pearson's chi-square.

U.S. destination locations included 37 states with most immigrants relocating to states in the eastern half of the country. Seven states: Florida, Virginia, Illinois, New Jersey, Michigan, Maryland and New York, received 20 or more immigrants each, and combined represented just over 60% of the study cohort. (Figure 4)



Thirty-seven states were designated as the U.S. state of residence for this study's cohort of arriving immigrants to the Detroit Metropolitan Airport, Detroit, Michigan. Of these, seven states; Florida, Illinois, Maryland, Michigan, New Jersey, New York and Virginia received 20 or more immigrants.

Figure 4. U.S. Residence for Study Cohort (n = 398)

The number of immigrants arriving each month was relatively consistent for six of the nine months included in the study, ranging between 11% and 13% of the total study cohort. The exceptions were January, which saw slightly more arrivals (15%) and April and August which saw fewer, 5% and 7%, respectively.

Effects of the Intervention on the Number of U.S. TB Evaluations Completed

Nearly 63% of arriving immigrants (250 of 398) received a written referral and verbal instructions encouraging them to complete their U.S. TB evaluation upon arrival at DTW. TB evaluation records (CDC 75.17 form) for 229 (58%) immigrants contained

either information in at least one field or were checked indicating that the immigrant had failed to report; 16 immigrants failed to report for their evaluation, 14 of 15 immigrants without a valid TB evaluation date were determined to have completed their evaluation using the study algorithm (Table 1) and 198 had both information in at least one key field and a valid evaluation date. One immigrant with a valid evaluation date was considered not evaluated as all other key form fields were blank. U.S. TB evaluation information was not available for 169 (42%) individuals in the study cohort and these also were considered to have not completed a U.S. TB evaluation. (Figure 5)

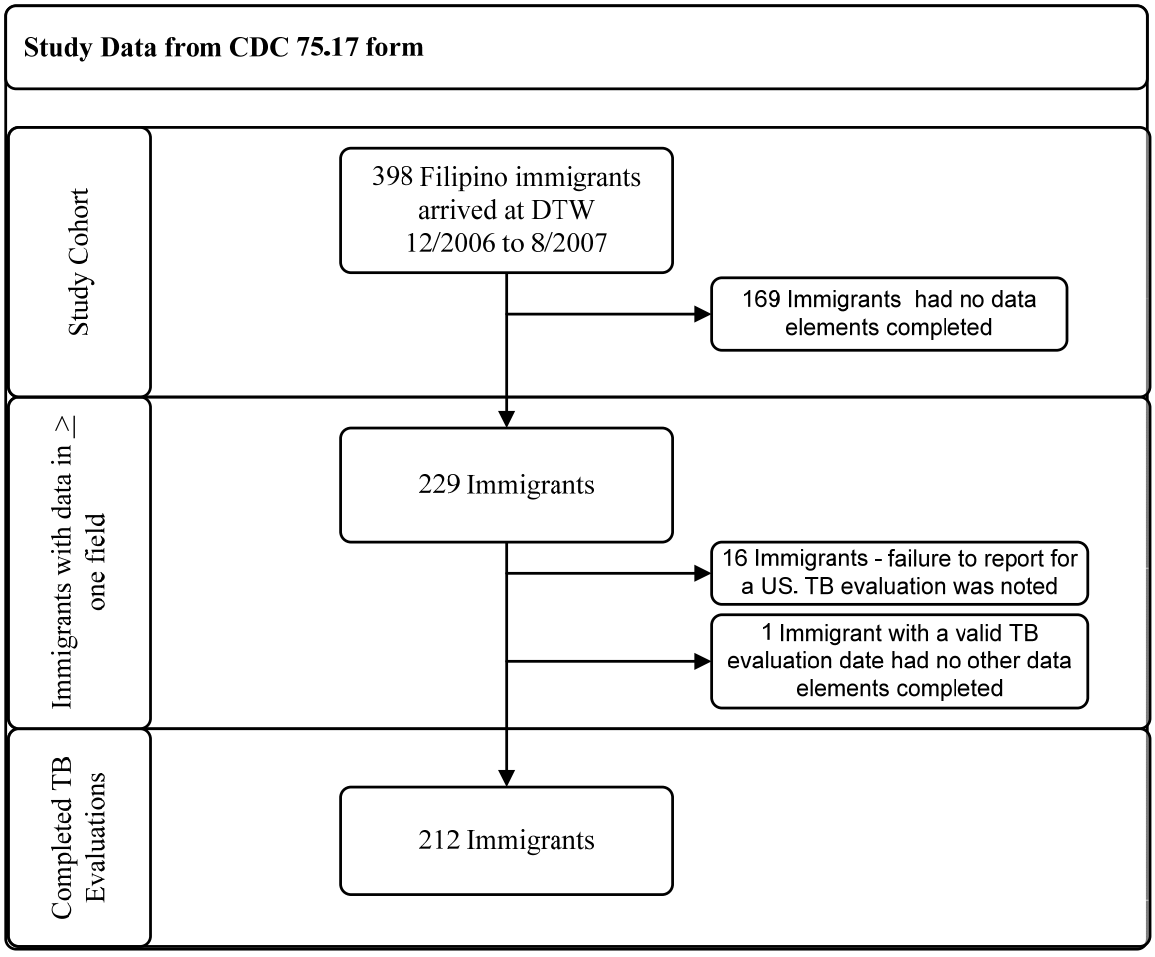


Figure 5. Completed U.S. TB Evaluations among Cohort

Of the 398 immigrants in this study, 212 (53%) completed their U.S. TB evaluation. Almost no difference was found in the proportion of immigrants completing a U.S. TB evaluation between those individuals that received a written referral and those that did not (p = .97). (Table 3)

Table 3. Study Cohort Completion of U.S. TB Evaluation by Referral Status

U.S. TB Evaluation	Referral Yes		Referral No			
	n (250)	*%*	*n (148)*	*%*	$\chi^2(1)$	*p*
Completed	133	53	79	53	.0012	.97
Not Completed	117	47	69	47	.0012	.97

p-value generated using Pearson's chi-square.

Regarding the possible independent variables TB classification, age, sex, marital status, arrival with a household member who also had a TB classification, current treatment for TB and history of prior TB treatment, only TB classification had a statistically significant association with completing a U.S. TB evaluation (p = .01). (Table 4)

Table 4. Demographics and Social Characteristics of Study Cohort by U.S. TB Evaluations Completed

Characteristic	Evaluation Completed					
	Yes		No			
	n (212)	*%*	*n (186)*	*%*	$\chi^2(1)$	*p*
Class B1	132	62	138	74	6.46	.01
Class B2	80	38	48	26	6.46	.01
Female	127	60	115	62	0.15	.69
Median age (IQR)	60	(44-69)	60	(35-69)		.47
Married	130	61	105	56	0.97	.32
Arrival with household member	23	11	19	10	0.83	.83
Current treatment	5	2	6	4	3.07	.05
History of treatment	79	37	79	42	1.12	.28

Abbreviations: IQR, interquartile range

p-value for mean age generated using Wilcoxon rank sum test, for current treatment using Fisher's exact test and all others using Pearson's chi-square.

Immigrants with a B2 TB classification were 1.3 times more likely to complete their U.S. TB evaluation (63%) than those with a B1 classification (49%). There was however, no statistically significant difference in completing a U.S. TB evaluation among immigrants with a B1 classification ($p = .77$) or a B2 classification ($p = .85$) as a group between those that received a referral and those that did not. While it appears that there may have been a negative association in completing their U.S. TB evaluation for immigrants receiving treatment for TB at U.S. arrival, the numbers are too small to draw a valid conclusion. Furthermore, although not significant, immigrants with no history of TB treatment were slightly more likely to complete a U.S. TB evaluation (55%) than those with a history of TB treatment (50%).

The average U.S. TB evaluation completion rate for states receiving 20 or more immigrants was very similar to that of the study cohort (53%) however, individually, the rate varied widely from 0% in Virginia to 88% in Maryland. (Figure 6)

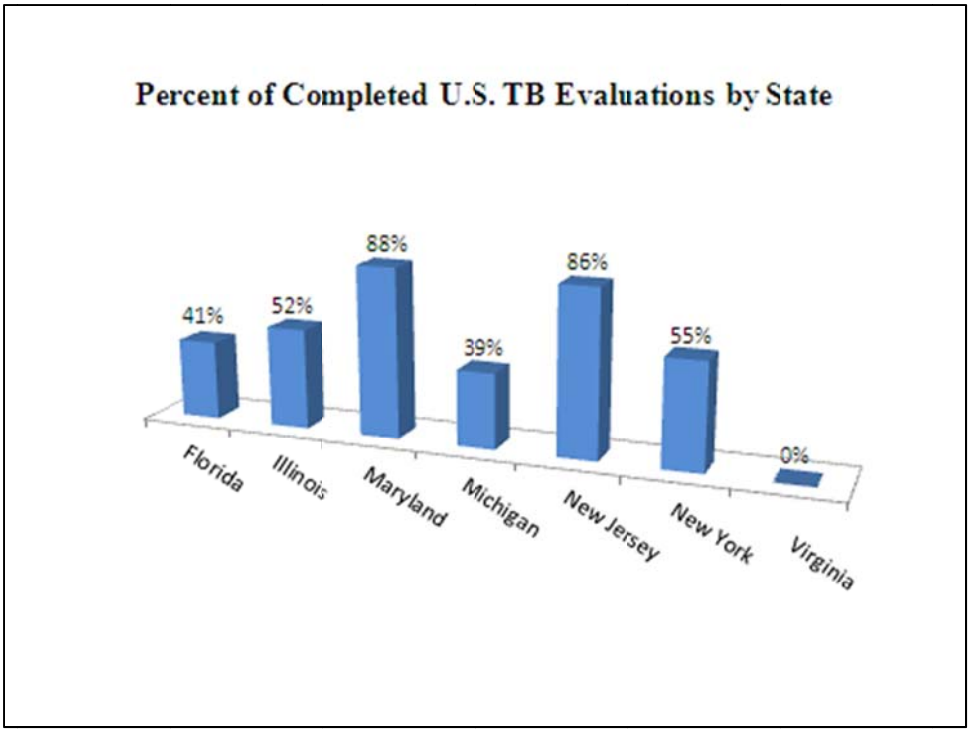


Figure 6. U.S. TB Evaluations Completed for the Seven States Receiving 20 or More Immigrant Arrivers with a TB Classification

Other Findings

Six immigrants (2.8%) were diagnosed with active TB disease during their U.S TB evaluation. Of these, five (four with a B1 and one with a B2 TB classification) had sputum smear negative pulmonary disease and one individual (with a B1 TB classification) had extrapulmonary disease. (Table 5)

Table 5. Characteristics and Demographics of Arriving Immigrants Diagnosed with Active TB Disease during Completion of U.S. TB Evaluation

Characteristic	Active TB Diagnosis		
	Pulmonary	Extra pulmonary	
	n (5)	*n (1)*	*Total*
Class B1	4	1	5
Class B2	1		1
Smear positive	0	N/A	0
Female	2	1	3
Median age (range)			55 (20 – 67)
Referral	3	1	4
Married	2	1	3
Arrival with household member	0	1	1
Current treatment	1	0	1
History of treatment	3	1	4

Abbreviations: N/A, not applicable

Although all of the immigrants with pulmonary TB were sputum smear negative, they still may have been infectious.[49] Four of the six had received TB treatment in the past, and one was currently on treatment at U.S. arrival.

Length of time from arrival to completion of U.S. TB evaluation within one year was also examined to determine if receipt of a referral was associated with a shorter time interval. Of the 212 immigrants that completed their U.S. TB evaluation, 198 had a recorded date in the U.S. TB evaluation date field, indicating evaluation completion. Of these, six individuals had an invalid U.S. TB evaluation date; four individuals had evaluation dates that preceded their entry date and two had evaluation dates that were the same as their U.S. arrival date, despite the need to travel from Detroit, Michigan to their states of residence (Ohio and Tennessee). Four additional immigrants were excluded as they reported for their U.S. TB evaluation over one year after U.S. arrival. The average

length of time between arrival at DTW and completing a U.S. TB evaluation for the remaining 188 immigrants was 65 days (median 42 days) regardless of referral status. No significant difference was found between those immigrants who received a referral and those who did not using a chi-square test on the dichotomous variable for TB evaluations completed within 30 days and those completed between 31 and 365 days after U.S. entry ($p = .49$). The verbal instructions that accompanied the written referral encouraged immigrants to complete their TB evaluations within one month. Furthermore, no significant difference was found using time intervals of within 60 and over 60 days ($p = .80$) or within 90 and over 90 days ($p = .53$). (Table 6)

Table 6. Comparison of the Time Interval to Completion of U.S. TB Evaluation within One Year U.S. Entry by Referral Status

Time Interval	Referral Yes		Referral No			
	n (116)	*%*	*n (72)*	*%*	$\chi^2(1)$	*p*
Within 30 days	41	35	22	31	0.46	.49
Within 60 days	72	62	46	64	0.06	.80
Within 90 days	89	77	58	81	0.38	.54

P-value generated using Pearson's chi-square.

Summary

Just 53% of the study cohort completed their U.S. TB evaluation; similar to results noted two years earlier.[8] The U.S. TB evaluation completion rate for immigrants receiving the written referral used at the Detroit Quarantine Station upon U.S. entry at the time of this study was not significantly increased compared with immigrants who did not receive a referral. Furthermore, of the factors identified as possible independent variables (TB classification, age, sex, marital status, arrival with a household member that also had a TB classification, history of TB treatment and current TB treatment), only TB classification was associated with a significant difference in whether or not a U.S. TB

evaluation was done; with immigrants with a B2 classification more frequently completing. When immigrants with a B1 classification or a B2 classification as a group were examined separately, those that had received a referral were no more likely to complete their U.S. TB evaluation than those that did not. The time interval between arrival at DTW and U.S. TB evaluation completion also was not affected by receipt of a referral.

Chapter V: Conclusions, Implications and Recommendations

Introduction

Tuberculosis continues to pose a significant public health concern in the U.S. with an increasing percentage of total cases diagnosed each year among foreign-born residents.[3] While foreign-born persons seeking permanent legal residence make up only a small percentage of all foreign-born arrivals to the U.S. at risk for TB, this population is readily identifiable and public health systems are already in place to provide post-immigration medical evaluation and treatment.

The addition of culture, drug susceptibility testing, TST or IGRA for close contacts and children, and required treatment completion for active TB cases prior to travel are significant improvements in the 2007/2009 TIs but cannot guarantee that immigrants and refugees will not arrive with active TB disease.[10, 11] TB screening of recently arrived foreign-born individuals has proven to be an effective method for finding and treating persons with active TB disease and remains an important U.S.-based activity for controlling TB.[12, 13, 17, 37] Despite this, only slightly more than half of recent arrivers nation-wide with either a B1 or B2 classification for TB complete a U.S. TB evaluation.[8] The results of this study however, may provide useful information for improving strategies to increase the successful completion of post-migration TB evaluations.

Summary of Study

This was a retrospective cohort study of 398 Filipino immigrants determined to be at increased risk for TB during their overseas medical screening who arrived at DTW (first port of U.S. entry) for the 9 months between December 2006 and August 2007. The research question was whether or not the written referral used at the Detroit Quarantine

Station and verbal instructions given upon U.S. entry would effectively increase the likelihood that a U.S.-based TB evaluation would be completed.

The results of this study did not support the use of the current written referral and verbal instructions as an effective method for increasing the likelihood that immigrants would complete their U.S. TB evaluation. Slightly more than half (53%) of U.S. TB evaluations were completed by this cohort. There was no significant difference in the rate of U.S. evaluations completed between those immigrants that received the written referral and those that did not. Furthermore, the length of time between U.S. arrival and completion of U.S. TB evaluation was not significantly shorter for immigrants receiving a referral. While study findings did not support the use of the current referral tool and was limited to just one port of entry and a single country of origin, results may be useful in planning or revising public health interventions for other immigrant populations seeking permanent U.S. residence.

Two additional study findings of possible public health interest were incomplete U.S. physical TB evaluations recorded for immigrants being treated for TB at time of U.S. arrival (8 of 11) and the significant disproportion of U.S. evaluations completed between individuals classified as B2 over those classified as B1. While the number of newly arrived immigrants under current treatment was quite small (11) and policy changes in the 2007/2009 TIs would prevent travel prior to TB treatment completion, this remains an important sub-population to target for continuity of care for those countries that have not yet adopted the new TIs. Individuals in this study cohort received overseas screening under the 1991 TIs. The disproportion of completed U.S. TB evaluations between immigrants classified as B2 over those classified as B1 may not be relevant for

the same reasons as more countries adopt the 2007 TIs. However, periodic assessment of this variable could be useful as it may indicate the need to address local public health policies regarding post-migration TB follow-up, or differences as a group in knowledge and beliefs between immigrants classified as B1 or B2. Individuals with a B1 classification under the 1991 TIs are considered at higher risk for active TB disease and targeting this group first for TB evaluation would be a more effective disease control activity.

Conclusion

The results of this study are important in showing that the proportion of U.S. TB evaluations among immigrants seeking permanent residence in the U.S. has not improved from prior studies and that the referral as written was not effective. Lack of success in this instance does not however, support the practice of not providing a referral upon U.S entry. While somewhat dated, results of the study performed by the Santa Clara County TB Control Program on the effectiveness of post-immigration contact in the form of letters, telephone calls and home visits on U.S. TB evaluation completion (96% completed) were impressive.[17] Other CDC DGMQ Quarantine Stations such as Chicago and Honolulu where follow-up appointments are made for arriving immigrants by Quarantine Station staff are likely to have a significant impact on the percentage of successful U.S. TB evaluations completed.

Much could be done to develop a better tool for referring newly arrived immigrants seeking permanent U.S. residence to their local TB control programs to complete an evaluation. In written format, the referral could be made more attractive to draw greater attention to the instructions or to be better remembered. Most immigrants

arriving at DTW had been in flight for 12 hours or more and were likely tired and anxious upon U.S entry. The referral process as performed in the busy international arrival area of DTW was not a part of this study and could also be improved. Other methods of referral such as telephone reminders or text messages could be explored. Input from newly arrived immigrants in the form of structured focus group discussions would be useful in improving both the referral and the referral process.

One of the greatest challenges to interpreting the results of this study was the lack of information regarding the U.S. TB evaluation for 42% (169 of 398) of the study cohort. Without the returned evaluation form (CDC 75.17), it was assumed that an evaluation did not occur which may or may not have been true. This lack of returned forms may have meant some were lost in transit. If this group was misclassified, the results may have been more significant for showing an impact of the referral letter. CDC DGMQ's development and implementation of the Electronic Disease Notification (EDN) beginning in 2006, which is replacing the paper-based system employed during the time frame for this study, may improve data collection of the evaluation form.

Implications

Recently arrived immigrants seeking permanent residence continue to present an important public health opportunity for identifying new cases of active TB disease, reducing the spread of TB with the U.S. and preventing future cases through LTBI treatment of those individuals most at-risk for developing active TB disease. Ongoing improvements in the CDC DGMQ TIs provides a potential forum to enhance the handoff of care between overseas panel physicians performing TB screening and their counterparts in the U.S. The results of this study, while not supportive of the referral

method examined, do highlight the need to improve the completion rate of post-migration TB evaluations for those immigrants identified as being at-risk for TB during their overseas screening. Few studies have attempted to determine the relative effectiveness of public health methods used to encourage recently arrived immigrants to complete their U.S. TB evaluations. Additional exploration of the effectiveness of current strategies for completing U.S. post-migration TB evaluations is needed to take advantage of contemporary TB control knowledge and public health systems already in place to identify and treat individuals with TB disease or LTBI.

Recommendations

Identifying Other Best Practice Methods

There are several areas of recommendation to be made from this study. The first is to determine what currently works well by completing an analysis of the methods used by other CDC DGMQ Quarantine Stations to facilitate completion of U.S.-based TB evaluations. In Chicago and Honolulu, a post-migration TB evaluation appointment is made by Quarantine Station staff for immigrants settling within the city of Chicago or the State of Hawaii, respectively. In addition, the Chicago Quarantine Station staff provide immigrants who will be residing in Suburban Cook County with the telephone number of their local public health department. The completion rates of these three locations should be compared with this study and others in the literature. If proven successful, these more extensive, individually tailored methods could be adopted by other Quarantine Stations.

Improving the Referral

The current referral form could be improved. The information presented could be made more accessible by incorporating adult learning strategies, by being more visually

appealing and more memorable, by being more relevant, practical with a clearly stated goal. The form in this study was plain-text, single-spaced and lacked easy to follow steps for completing a U.S. TB evaluation. It provided arriving immigrants with only a hand written telephone number to the State public health department having jurisdiction over their U.S. residence. As local public health departments are generally responsibility for post-immigration TB follow-up, the form could be improved by providing a local telephone number, a contact person and possibly directions for finding the health department. Conducting focus groups comprised of recently arrived immigrants to evaluate referral content, better ways of presenting the information and to improve the likelihood that the form would be looked at again once an arriver has reached their new residence could provide insightful and useful feedback. Other perhaps more cost effective methods of referral could be explored, such as text message, e-mail or leaving a telephone voice message. Furthermore, the accuracy of the State (and local) public health department numbers that were given was not determined by this study and periodic validation should be a part of the daily function of the DGMQ Quarantine Stations.

In addition, the English language comprehension levels necessary to understand the current referral form may have been problematic. The referral could be improved by providing a form in the immigrant's native language or in clear, jargon free, grade level appropriate language for English readers.

Improving the Referral Process

During this study, referrals were provided in a small area close to the CBP officer booths prior to luggage pickup, clearing customs and making connecting flights or continuing on by ground transportation. Finding a quieter location, assisting in

determining the time between flights or providing some direction to making connections might improve the process. Although each airport setting is unique, again, suggestions provided by focus groups of recently arrived immigrants could be used to improve how referrals are given.

Addressing the U.S. TB Evaluation during Overseas Screening

A review of the information provided to immigrants prior to travel may be useful. Clear, consistent messages regarding the importance of completing the required U.S. post-migration TB evaluation within 30 days of arrival could potentially increase policy adherence. In addition, a structured conversation at this time may provide immigrants with the opportunity to ask questions and receive answers in their native language that would help to increase their understanding of TB, the U.S. approach to TB control, and reduce their concerns regarding post-immigration diagnosis of TB on U.S. residence status. If more time is spent by the overseas Panel physician on explaining the process, the newly arriving immigrants may more clearly understand the importance of the U.S. post-migration TB evaluation.

Providing Incentives

Finally, the use of incentives for both TB control programs and arriving immigrants could be explored. In the U.S., states, territories and select big cities have been provided funding for TB prevention and control activities through cooperative agreements since 1992.[50] Since 2007, cooperative agreement funding amounts have been determined in part by a multi-variable based formula developed by the CDC Division of Tuberculosis Elimination (DTBE) in collaboration with the National Tuberculosis Controllers Association (NTCA). The formula is based on 5-year average epidemiologic

surveillance information. Between 2007, when the formula was first used and 2010, when the formula was revised, it included a variable for the number of arriving immigrants with A, B1 or B2 classification. The variable was removed from the revised 2010 formula as EDN was being implemented.[51] Inclusion could be re-considered for a variable representing the number of post-migration TB evaluations completed for individuals arriving with a B1 or B2 classification. Cooperative agreement recipients would then have a financial incentive to complete U.S. TB evaluations.

Use of incentives and enablers has long been recognized as an important strategy in completing TB treatment and contact investigations.[32, 52] Expansion of this successful public health strategy to arriving immigrants could also be explored.

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Appendix 1: Referral Form Used at Detroit Metropolitan Airport, Detroit, Michigan (DTW)

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
PUBLIC HEALTH SERVICE
CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)

ALIEN: (Name, Address, and Alien Number)

YOUR CHEST X-RAY SHOWS FINDINGS WHICH NEED TO BE CHECKED.

PLEASE FOLLOW THE INSTRUCTIONS
IN THE PARAGRAPH CHECKED (X):

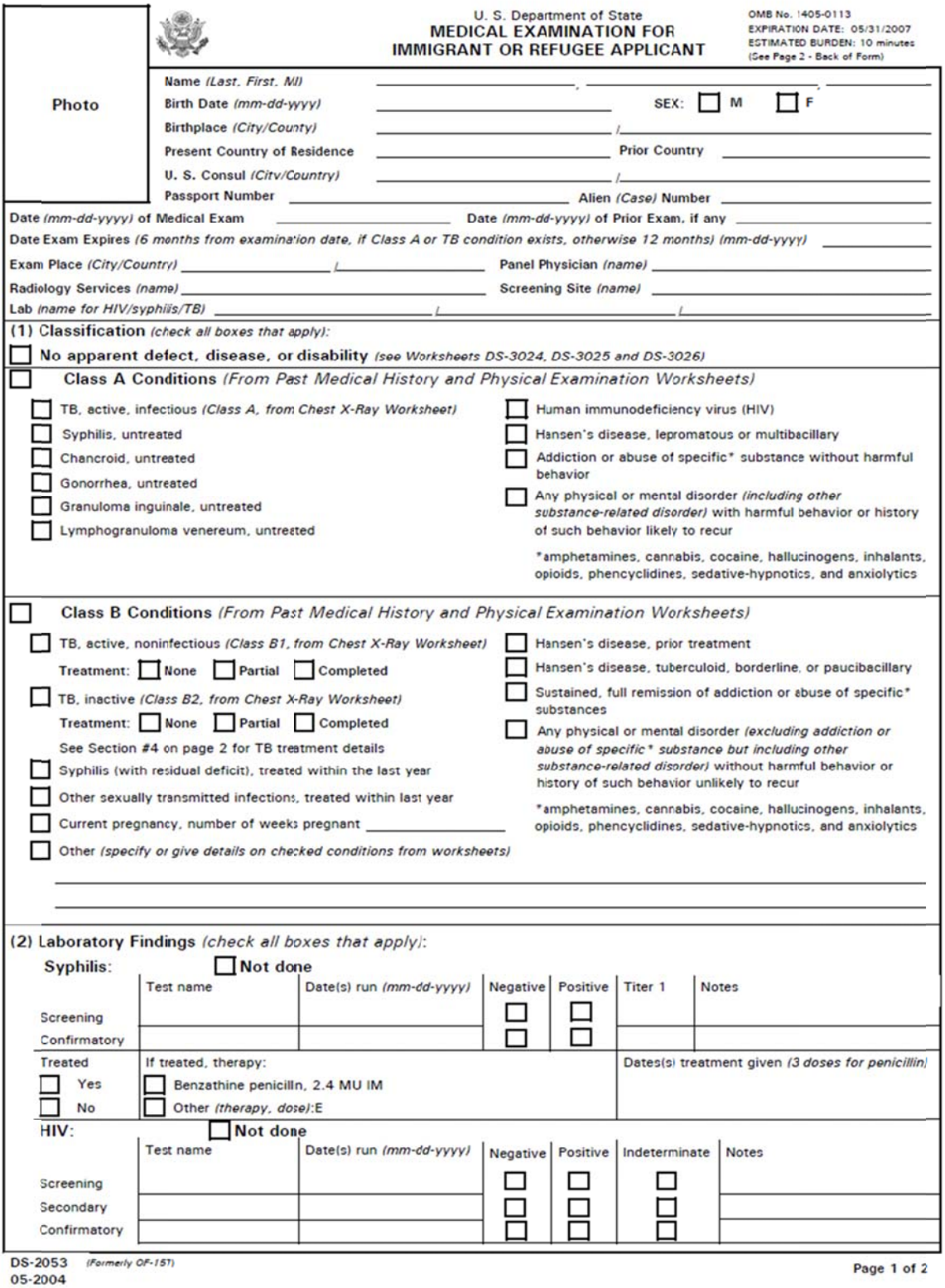
( ) You entered the United States with an approved waiver of excludability for Class A tuberculosis. Your medical records indicate that you were required to obtain the signature of a physician or health facility official in the United States who agreed to provide any treatment or observation necessary for the proper management of your tuberculosis condition. You should go directly to that physician or facility. The physician or health facility will be notified of your arrival.
You should present this form and your X-rays when you report for an evaluation.

Note:
If you are entering the United States as a refugee with an approved waiver of excludability for Class A tuberculosis, you may have been required to obtain the signature of a physician or health facility official in the United States. Therefore, you should telephone the health department in your area of resettlement as soon as possible after arrival at your destination. Please ask your sponsor for assistance. The health department will be notified of your arrival.
You should present this form and your X-rays when you report for an evaluation.

( ) You entered the United States with Class B1 or Class B2 tuberculosis. You are requested to telephone the health department in your area of resettlement as soon as possible after arrival at your destination. If you are entering the United States as a refugee you should ask your sponsor for assistance. The health department will be notified of your arrival.
You should present this form and your X-rays when you report for an evaluation.

Quarantine Officer _____ Date _____

Appendix 2: Overseas Medical Examination Form DS2053



U. S. Department of State
MEDICAL EXAMINATION FOR IMMIGRANT OR REFUGEE APPLICANT

OMB No. 1405-0113
EXPIRATION DATE: 05/31/2007
ESTIMATED BURDEN: 10 minutes
(See Page 2 - Back of Form)

Photo

Name *(Last, First, MI)* _____, _____, _____
Birth Date *(mm-dd-yyyy)* _____ SEX: ☐ M ☐ F
Birthplace *(City/County)* _____ / _____
Present Country of Residence _____ Prior Country _____
U. S. Consul *(City/Country)* _____ / _____
Passport Number _____ Alien *(Case)* Number _____

Date *(mm-dd-yyyy)* of Medical Exam _____ Date *(mm-dd-yyyy)* of Prior Exam, if any _____
Date Exam Expires *(6 months from examination date, if Class A or TB condition exists, otherwise 12 months) (mm-dd-yyyy)* _____
Exam Place *(City/Country)* _____ / _____ Panel Physician *(name)* _____
Radiology Services *(name)* _____ Screening Site *(name)* _____
Lab *(name for HIV/syphilis/TB)* _____ / _____ / _____

(1) Classification *(check all boxes that apply):*

☐ **No apparent defect, disease, or disability** *(see Worksheets DS-3024, DS-3025 and DS-3026)*

☐ **Class A Conditions** *(From Past Medical History and Physical Examination Worksheets)*

- ☐ TB, active, infectious *(Class A, from Chest X-Ray Worksheet)*
- ☐ Syphilis, untreated
- ☐ Chancroid, untreated
- ☐ Gonorrhea, untreated
- ☐ Granuloma inguinale, untreated
- ☐ Lymphogranuloma venereum, untreated
- ☐ Human immunodeficiency virus (HIV)
- ☐ Hansen's disease, lepromatous or multibacillary
- ☐ Addiction or abuse of specific* substance without harmful behavior
- ☐ Any physical or mental disorder *(including other substance-related disorder)* with harmful behavior or history of such behavior likely to recur

*amphetamines, cannabis, cocaine, hallucinogens, inhalants, opioids, phencyclidines, sedative-hypnotics, and anxiolytics

☐ **Class B Conditions** *(From Past Medical History and Physical Examination Worksheets)*

- ☐ TB, active, noninfectious *(Class B1, from Chest X-Ray Worksheet)*
  Treatment: ☐ None ☐ Partial ☐ Completed
- ☐ TB, inactive *(Class B2, from Chest X-Ray Worksheet)*
  Treatment: ☐ None ☐ Partial ☐ Completed
  See Section #4 on page 2 for TB treatment details
- ☐ Syphilis (with residual deficit), treated within the last year
- ☐ Other sexually transmitted infections, treated within last year
- ☐ Current pregnancy, number of weeks pregnant _____
- ☐ Other *(specify or give details on checked conditions from worksheets)*
- ☐ Hansen's disease, prior treatment
- ☐ Hansen's disease, tuberculoid, borderline, or paucibacillary
- ☐ Sustained, full remission of addiction or abuse of specific* substances
- ☐ Any physical or mental disorder *(excluding addiction or abuse of specific* substance but including other substance-related disorder)* without harmful behavior or history of such behavior unlikely to recur

*amphetamines, cannabis, cocaine, hallucinogens, inhalants, opioids, phencyclidines, sedative-hypnotics, and anxiolytics

_____
_____

(2) Laboratory Findings *(check all boxes that apply):*

Syphilis: ☐ **Not done**

	Test name	Date(s) run *(mm-dd-yyyy)*	Negative	Positive	Titer 1	Notes
Screening			☐	☐		
Confirmatory			☐	☐		

Treated	If treated, therapy:	Dates(s) treatment given *(3 doses for penicillin)*
☐ Yes	☐ Benzathine penicillin, 2.4 MU IM	
☐ No	☐ Other *(therapy, dose)*:E	

HIV: ☐ **Not done**

	Test name	Date(s) run *(mm-dd-yyyy)*	Negative	Positive	Indeterminate	Notes
Screening			☐	☐	☐	
Secondary			☐	☐	☐	
Confirmatory			☐	☐	☐	

DS-2053 *(Formerly OF-157)*
05-2004

Page 1 of 2

(3) **Immunizations** *(See Vaccination Form, check all boxes that apply)* **Not required for refugee applicants.**

☐ Vaccine history complete

☐ Vaccine history incomplete, requesting waiver *(indicate type below)*

☐ Incomplete vaccine history, no waiver requested

☐ Blanket waiver ☐ Individual waiver

I certify that I understand the purpose of the medical examination and I authorize the required tests to be completed.

Applicant Signature	Panel Physician Signature	Date *(mm-dd-yyyy)*

(4) Tuberculosis Treatment Regimen

(Fill out if applicant has taken in the past, or is now taking TB medication. If drug doses or dates not known or not available, mark "unknown".)

☐ Check if therapy currently prescribed (if current, don't mark "End Date")

Medication	Dose/Interval (i.e. mg/day)	Start Date *(mm-dd-yyyy)*	End Date *(mm-dd-yyyy)*
☐ Isonaizid (INH)			
☐ Rifampin			
☐ Pyrazinamide			
☐ Ethambutol			
☐ Streptomycin			
☐ Other, specify			

Applicant's weight (kg) _____

Remarks _____

PAPERWORK REDUCTION ACT AND PRIVACY ACT NOTICES

Public reporting burden for this collection of information is estimated to average 10 minutes per response, including time required for searching existing data sources, gathering the necessary data, providing the information required, and reviewing the final collection. Persons are not required to provide this information in the absence of a valid OMB approval number. Send comments on the accuracy of this estimate of the burden and recommendations for reducing it to: U.S. Department of State (A/RPS/DIR) Washington, DC 20520.

We ask for information on this form, in the case of applicants for immigrant visas, to determine medical eligibility under INA Sections 212(a) and 221(d), and, in the case of refugees, as required under INA Section 412(b)(4) and (5). If an immigrant visa is issued or refugee status granted, you will convey this form to U.S. Department of Homeland Security (DHS) for disclosure to the Centers for Disease Control and Prevention and to the U.S. Public Health Service. Failure to provide this information may delay or prevent the processing of your case. If an immigrant visa is not issued or refugee status is not granted, this form

Appendix 3: Overseas Medical Examination Form DS3024

U.S. Department of State

CHEST X-RAY AND CLASSIFICATION WORKSHEET

OMB No. 1405-0113
EXPIRATION DATE: 01/31/2004
ESTIMATED BURDEN: 45 minutes
(See Page 2 - Back of Form)

For Use with DS-2053 Complete Sections 1 through 5, As Applicable

Name *(Last, First, MI)*		Age
Birth Date *(mm-dd-yyyy)*	Passport Number	Alien (Case) Number

1. Chest X-Ray Needed *(mark all that apply)*

- ☐ History of tuberculosis *(TB)* disease
- ☐ Contact with TB patient
- ☐ TB signs or symptoms
- ☐ Adult *(with or without any of the other)*

(If child does not have any of the above, stop here)

2. Chest X-Ray Findings **Date Chest X-Ray taken** *(mm-dd-yyyy)* _____

- ☐ Normal findings
- ☐ Abnormal finding *(indicate findings and interpretation, checking all that apply, and any other in table below*

☐ **Can suggest ACTIVE TB** *(Need smears)*	☐ **Can suggest INACTIVE TB** *(Need smears if symptomatic)*	☐ **OTHER X-ray findings**
☐ Infiltrate or consolidation	☐ Discrete fibrotic scar or linear opacity	☐ **Follow-up needed**
☐ Any cavitary lesion	☐ Discrete nodule*(s)* without calcification	☐ Musculoskeletal
☐ Nodule with poorly defined margins *(such as tuberculoma)*	☐ Discrete fibrotic scar with volume loss or retraction	☐ Cardiac
☐ Pleural effusion	☐ Discrete nodule*(s)* with volume loss or retraction	☐ Pulmonary
☐ Hilar/Mediastinal adenopathy	☐ Other *(such as bronchiectasis)*	☐ Other
☐ Linear, interstitial markings		☐ **No follow-up needed for** Pleural thickening, diaphragmatic tenting, blunting costophrenic angle, solitary calcified nodule or granuloma or minor musculoskeletal or cardiac finding
☐ Other *(such as miliary findings)*		

Remarks

_____

_____

_____

3. Sputum Smears

☐ **No, applicant has no signs or symptoms of TB and :**

- ☐ X-ray suggests INACTIVE TB, this is a **Class B2/TB**
- ☐ OTHER X-ray findings suggest follow-up needed after arrival, this is **B Other**
- ☐ OTHER X-ray findings suggest **no followup needed,** this is **No Class**
- ☐ X-ray Normal, this is **No Class**

☐ **Yes, applicant has** *(mark all that apply)*:

- ☐ Signs or symptoms of TB present, See Section 1
- ☐ X-ray suggests ACTIVE TB, See Section 2

and smear results are:

Positive	Negative	Dates obtained *(mm/dd/yyyy)*
☐	☐	_____
☐	☐	_____
☐	☐	_____

Sputum smear results and X-ray findings:
At least one smear result POSITIVE and

☐ Any chest X-ray finding, this is **Class A/TB**
(Normal or Abnormal findings)

Three smear results NEGATIVE and

☐ X-ray Normal with

- ☐ Signs of symptoms resolved, this is **No Class**
- ☐ Signs or symptoms suggest follow-up needed after arrival, this is **B Other**

☐ X-ray suggests ACTIVE or INACTIVE TB, this is **Class B1/TB**

☐ OTHER X-ray findings suggest follow-up needed after arrival, this is **Class B Other**

4. ☐ **No Class** ☐ **Class A/TB** ☐ **Class B1/TB** ☐ **Class B2/TB** ☐ **Class B Other: follow-up needed**

5. Follow-up Needed After Arrival ☐ No ☐ Yes If Yes, for ☐ Not TB condition ☐ TB condition.

*(If yes, specify condition below **and** on DS-2053; include additional tests, and therapy used with start and stop dates and any changes)*

Remarks

_____

_____

_____

DS-3024
01-2001

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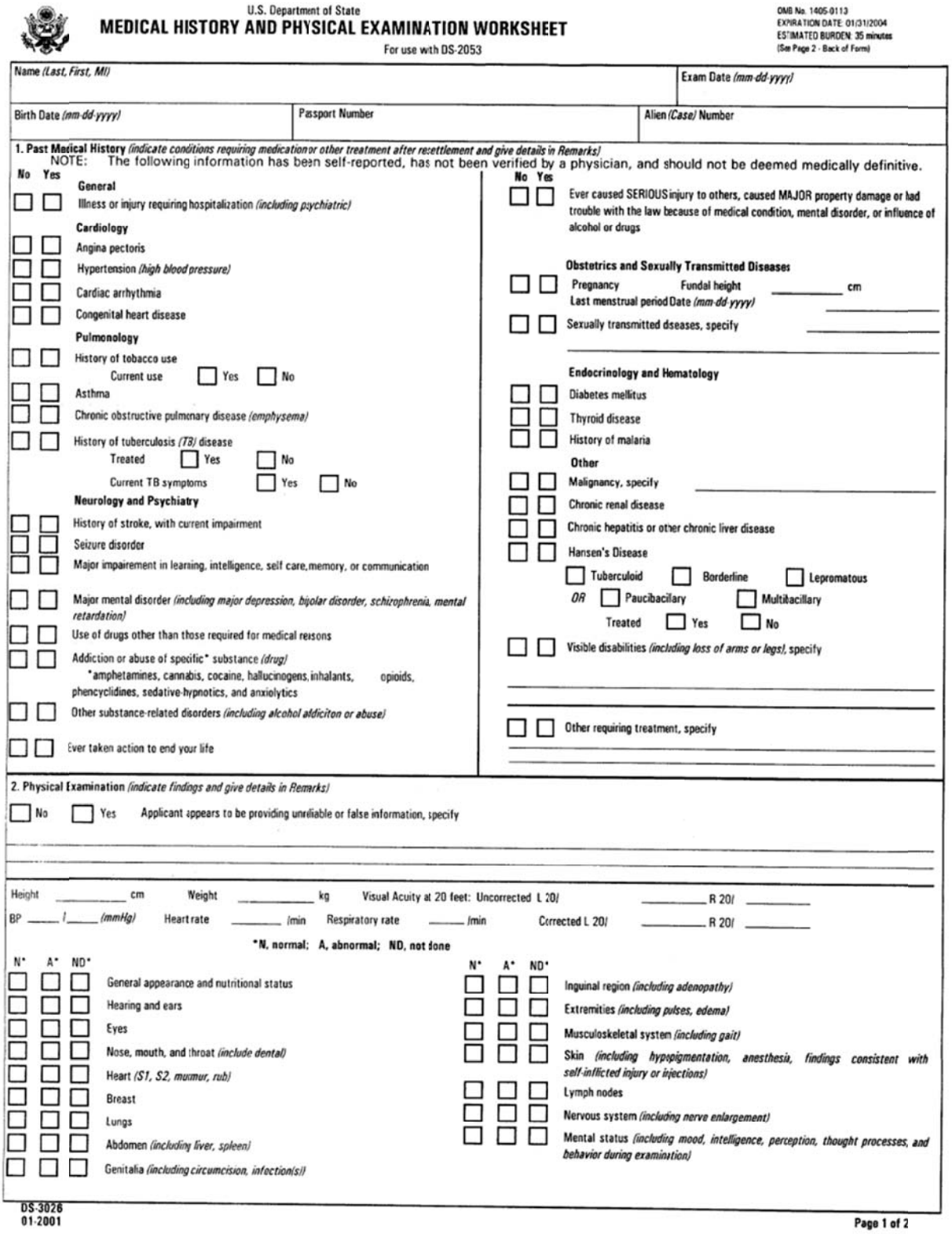
PAPERWORK REDUCTION ACT AND PRIVACY ACT NOTICES

Public reporting burden for this collection of information is estimated to average 45 minutes per response, including time required for searching existing data sources, gathering the necessary data, providing the information required, and reviewing the final collection. Persons are not required to provide this information in the absence of a valid OMB approval number. Send comments on the accuracy of this estimate of the burden and recommendations for reducing it to: Department of State (A/RPS/DIR) Washington, DC 20520-1849.

We ask for information on this form, in the case of applicants for immigrant visas, to determine medical eligibility under INA Sections 212(a) and 221(d), and, in the case of refugees, as required under INA Section 412(b)(4) and (5). If an immigrant visa is issued or refugee status granted, you will convey this form to the INS for disclosure to the Center for Disease Control and the US Public Health Service. Failure to provide this information may delay or prevent the processing of your case. If an immigrant visa is not issued or refugee status is not granted, this form will be treated as confidential under INA Section 222(f).

Appendix 4: Overseas Medical Screening Form DS3026



U.S. Department of State

MEDICAL HISTORY AND PHYSICAL EXAMINATION WORKSHEET

For use with DS-2053

OMB No. 1405-0113
EXPIRATION DATE: 01/31/2004
ESTIMATED BURDEN: 35 minutes
(See Page 2 - Back of Form)

Name *(Last, First, MI)* | Exam Date *(mm-dd-yyyy)*

Birth Date *(mm-dd-yyyy)* | Passport Number | Alien *(Case)* Number

1. Past Medical History *(indicate conditions requiring medication or other treatment after resettlement and give details in Remarks)*

NOTE: The following information has been self-reported, has not been verified by a physician, and should not be deemed medically definitive.

No Yes

General
- Illness or injury requiring hospitalization *(including psychiatric)*

Cardiology
- Angina pectoris
- Hypertension *(high blood pressure)*
- Cardiac arrhythmia
- Congenital heart disease

Pulmonology
- History of tobacco use — Current use ☐ Yes ☐ No
- Asthma
- Chronic obstructive pulmonary disease *(emphysema)*
- History of tuberculosis *(TB)* disease — Treated ☐ Yes ☐ No; Current TB symptoms ☐ Yes ☐ No

Neurology and Psychiatry
- History of stroke, with current impairment
- Seizure disorder
- Major impairement in learning, intelligence, self care, memory, or communication
- Major mental disorder *(including major depression, bipolar disorder, schizophrenia, mental retardation)*
- Use of drugs other than those required for medical reasons
- Addiction or abuse of specific* substance *(drug)*
  *amphetamines, cannabis, cocaine, hallucinogens, inhalants, opioids, phencyclidines, sedative-hypnotics, and anxiolytics
- Other substance-related disorders *(including alcohol addiction or abuse)*
- Ever taken action to end your life
- Ever caused SERIOUS injury to others, caused MAJOR property damage or had trouble with the law because of medical condition, mental disorder, or influence of alcohol or drugs

Obstetrics and Sexually Transmitted Diseases
- Pregnancy Fundal height _____ cm
  Last menstrual period Date *(mm-dd-yyyy)* _____
- Sexually transmitted diseases, specify _____

Endocrinology and Hematology
- Diabetes mellitus
- Thyroid disease
- History of malaria

Other
- Malignancy, specify _____
- Chronic renal disease
- Chronic hepatitis or other chronic liver disease
- Hansen's Disease
  ☐ Tuberculoid ☐ Borderline ☐ Lepromatous
  OR ☐ Paucibacillary ☐ Multibacillary
  Treated ☐ Yes ☐ No
- Visible disabilities *(including loss of arms or legs)*, specify
- Other requiring treatment, specify

2. Physical Examination *(indicate findings and give details in Remarks)*

☐ No ☐ Yes Applicant appears to be providing unreliable or false information, specify

Height _____ cm Weight _____ kg Visual Acuity at 20 feet: Uncorrected L 20/ _____ R 20/ _____

BP ____ / ____ *(mmHg)* Heart rate _____ /min Respiratory rate _____ /min Corrected L 20/ _____ R 20/ _____

***N, normal; A, abnormal; ND, not done**

N*	A*	ND*		N*	A*	ND*	
☐	☐	☐	General appearance and nutritional status	☐	☐	☐	Inguinal region *(including adenopathy)*
☐	☐	☐	Hearing and ears	☐	☐	☐	Extremities *(including pulses, edema)*
☐	☐	☐	Eyes	☐	☐	☐	Musculoskeletal system *(including gait)*
☐	☐	☐	Nose, mouth, and throat *(include dental)*	☐	☐	☐	Skin *(including hypopigmentation, anesthesia, findings consistent with self-inflicted injury or injections)*
☐	☐	☐	Heart *(S1, S2, murmur, rub)*	☐	☐	☐	Lymph nodes
☐	☐	☐	Breast	☐	☐	☐	Nervous system *(including nerve enlargement)*
☐	☐	☐	Lungs	☐	☐	☐	Mental status *(including mood, intelligence, perception, thought processes, and behavior during examination)*
☐	☐	☐	Abdomen *(including liver, spleen)*				
☐	☐	☐	Genitalia *(including circumcision, infection(s))*				

DS-3026
01-2001

Page 1 of 2

3. Additional Testing Needed Prior to Approving Medical Clearance

No	Yes	
☐	☐	Physical examination or laberatory results contradict nedical history
☐	☐	Referral prior to departure If yes, provide results _____
☐	☐	Referral prior to departure If yes, provide results _____

4. Follow-up Needed After Arrival

☐ No ☐ Yes, within 1 week ☐ Yes, within 1 month ☐ Yes, within 6 months

☐ For continuing medication, list type, dose, and frequency _____

☐ For continuing other treatment, specify _____

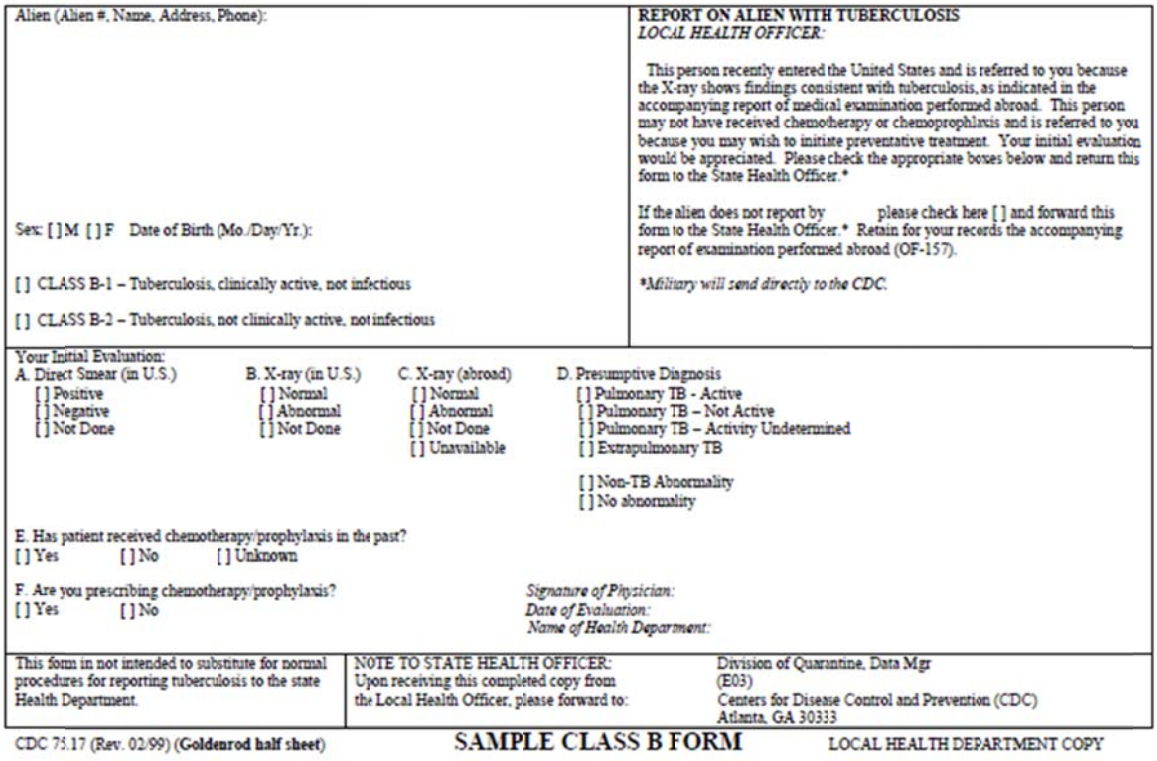
5. Remarks *(describe any abnormal history, abnormal findings, and resulting interventions)*

PAPERWORK REDUCTION ACT AND PRIVACY ACT NOTICES

Public reporting burden for this collection of information is estimated to average 35 minutes per response, including time required for searching existing data sources, gathering the necessary data, providing the information required, and reviewing the final collection. Persons are not required to provide this information in the absence of a valid OMB approval number. Send comments on the accuracy of this estimate of the burden and recommendations for reducing it to: Department of State (A/RPS/DIR) Washington, DC 20520-1849.

We ask for information on this form, in the case of applicants for immigrant visas, to determine medical eligibility under INA Sections 212(a) and 221(d), and, in the case of refugees, as recuired under INA Section 412(b)(4) and (5). If an immigrant visa is issued or refugee status granted, you will convey this form to the INS for disclosure to the Center for Disease Control and the US Public Health Service. Failure to provide this information may delay or prevent the processing of your case. If an immigrant visa is not issued or refugee status is not granted, this form will be treated as confidential under INA Section 222(f).

Appendix 5: CDC Form 75.17



Alien (Alien #, Name, Address, Phone):

Sex: [ ] M [ ] F Date of Birth (Mo./Day/Yr.):

[ ] CLASS B-1 – Tuberculosis, clinically active, not infectious

[ ] CLASS B-2 – Tuberculosis, not clinically active, not infectious

REPORT ON ALIEN WITH TUBERCULOSIS
LOCAL HEALTH OFFICER:

This person recently entered the United States and is referred to you because the X-ray shows findings consistent with tuberculosis, as indicated in the accompanying report of medical examination performed abroad. This person may not have received chemotherapy or chemoprophlaxis and is referred to you because you may wish to initiate preventative treatment. Your initial evaluation would be appreciated. Please check the appropriate boxes below and return this form to the State Health Officer.*

If the alien does not report by please check here [ ] and forward this form to the State Health Officer.* Retain for your records the accompanying report of examination performed abroad (OF-157).

**Military will send directly to the CDC.*

Your Initial Evaluation:

A. Direct Smear (in U.S.)
[ ] Positive
[ ] Negative
[ ] Not Done

B. X-ray (in U.S.)
[ ] Normal
[ ] Abnormal
[ ] Not Done

C. X-ray (abroad)
[ ] Normal
[ ] Abnormal
[ ] Not Done
[ ] Unavailable

D. Presumptive Diagnosis
[ ] Pulmonary TB - Active
[ ] Pulmonary TB – Not Active
[ ] Pulmonary TB – Activity Undetermined
[ ] Extrapulmonary TB
[ ] Non-TB Abnormality
[ ] No abnormality

E. Has patient received chemotherapy/prophylaxis in the past?
[ ] Yes [ ] No [ ] Unknown

F. Are you prescribing chemotherapy/prophylaxis?
[ ] Yes [ ] No

Signature of Physician:
Date of Evaluation:
Name of Health Department:

This form in not intended to substitute for normal procedures for reporting tuberculosis to the state Health Department.

NOTE TO STATE HEALTH OFFICER:
Upon receiving this completed copy from the Local Health Officer, please forward to:

Division of Quarantine, Data Mgr
(E03)
Centers for Disease Control and Prevention (CDC)
Atlanta, GA 30333

CDC 75.17 (Rev. 02/99) (**Goldenrod half sheet**) **SAMPLE CLASS B FORM** LOCAL HEALTH DEPARTMENT COPY

The CDC 75.17 is completed by private medical providers or local public health departments upon completion of the U.S. physical examination. It is then sent to the responsible state health department and forwarded to CDC DGMQ.