Evaluation of an Education Intervention for Immigration Applicants with B1 or B2 Tuberculosis Classifications

Gen-IC

Information Collection for Evaluation of Education, Communication, and Training (ECT) Activities for Mobile Populations

OMB No. 0920-0932

Expiration Date: 05/31/2021

Submitted on: January 14, 2021

Statement A

Contact:
Nancy Khalil, J.D.
MS H16-5
Centers for Disease Control and Prevention
1600 Clifton Road NE
Atlanta, Georgia 30329-4027
Phone: (770) 488-2070
Email: kuj2@cdc.gov

Table of Content

s

- **Goal of the study:** The goal of the generic information collection request is to increase immigrant arrivals' post-arrival follow-up at TB control programs, that is, to increase the percentage of new arrivals who are clinically evaluated at a local health department within 30 days of arrival.
- **Intended use of the resulting data:** Intended use of the resulting information is to confirm whether the educational program worked as expected, to support the decision to continue implementing the educational program at the Mexican panel physician sites, and to inform communication, training and/or education activities across DGMQ.
- **Methods to be used to collect:** The information collection will have a mixed-method design and will be conducted in two phases. The first phase includes a data collection at two panel physician sites among Mexican immigrant applicants with a B1/B2 classification to assess whether intervention successfully enhances attitudes, knowledge and intentions for following up at US health departments among participants who receive the intervention. This data collection is the focus of this OMB submission. The second phase of this project includes retrieval of TB follow-up worksheet data via the Electronic Disease Notification (EDN) system to compare follow-up rates for time periods when only the standard health education was administered to time periods when only the enhanced education was administered.
- **The subpopulation to be studied:** The populations covered under this generic include potential immigrants to the US as well as pregnant women and children, who will not be screened out of interviews. The project will not involve refugees.
- **How data will be analyzed:** Data will be analyzed using R. For the first phase it will follow a typical protocol for a non-equivalent groups design. For the second phase, a chi-square test will be performed for independence and calculate an odds ratio. Additionally, to adjust for possible confounding with reporting jurisdiction, a logistic regression will be performed to calculate adjusted odds ratio.

A.1. Circumstances Making the Collection of Information Necessary

In 2017, there were 9,105 active Tuberculosis (TB) cases reported in the United States (US). In addition, approximately 13 million people living in the United States have a latent TB infection (LTBI). More than 80% of TB cases in the United States developed from the reactivation of LTBI, and in 2017, 70% of all TB-disease patients in the United States were born outside of the nation. Foreign-born people are most likely to develop TB disease within the first year that they arrive in the United States. A 2012 study found that, although immigrants and refugees only accounted for 0.2% of foreign-born, documented people in the United States, they accounted for an estimated 41.6% of all TB cases. The TB burden in the United States disproportionately impacts newly arrived immigrants and refugees.

Immigrant visa applicants living overseas and seeking entry into the United States (US) undergo a health exam as authorized by the Immigration and Naturalization Act and 42 CFR part 34 and described by the Centers for Disease Control and Prevention's (CDC) Tuberculosis (TB) Technical Instructions for Panel Physicians (TI). The TIs are promulgated by CDC's Division of Global Migration and Quarantine (DGMQ). Exams are carried out by panel physicians, and upon completion, issuance of visas is conducted by the Department of State's consular sections. The TIs focus on medical aspects of the

examinations and do not specifically require education of applicants about the medical conditions identified in the examination, nor does it specifically mention the recommended follow-up at the local health department once the applicant is admitted into the United States.

According to the most recent TIs published in 2018, applicants who have signs and symptoms, physical exam or chest x-ray findings suggestive of TB disease, or have known HIV infection, but have negative AFB sputum smears and cultures and are not diagnosed with TB disease receive a B1 Pulmonary classification from the panel physicians. Applicants who were diagnosed with TB disease by the panel physician and who successfully completed treatment and had negative follow-up smears and cultures receive a B0 classification from the panel physicians. After receiving a B1 classification, immigrants have a travel clearance to the US that is valid for three months from the date that the final cultures are reported as negative. Applicants diagnosed with extra pulmonary TB with a normal chest x-ray and negative sputum smears and cultures receive also receive a class B1 classification. Their travel clearance is also valid for three months from the date final cultures are reported as negative. Finally, applicants who have a positive Interferon gamma release assay (IGRA) or TB skin test (TST) but otherwise have a negative evaluation for TB disease receive a B2 classification (latent TB infection, LTBI). This designation is limited to applicants ages 2-14. Travel clearance is valid for 6 months from the time the evaluation is complete.

From a public health perspective, it is optimal to maximize the proportion of new arrivals who are evaluated for TB and who receive appropriate care once in the US at their local health department. Overall, in 2018, there were 24,305 B1 and B2 classifications assigned to immigration applicants processed by US Consular Offices around the world. Upon arrival to the United States, 10,485 (43.1%) individuals with B1/B2 classifications had data uploaded into EDN by state and local health departments (via the "EDN Tuberculosis Follow-up Worksheet for Newly Arrived Persons with Overseas Tuberculosis Classifications"). Among those with data, 1,615 (15.1%) new arrivals were never evaluated. It is unknown what proportion of those with missing records were never evaluated, but it is assumed to be high.

Of Mexican immigrants who arrived to the US in 2017 with a B1 classification, up to 39.7% may not have completed their follow-up evaluation (25.7% had no follow-up information in EDN and 14% were reported to have not completed an evaluation). Among Mexican immigrants who arrived to the US in 2017 with a B2 classification, up to 51% may not have completed their follow-up evaluation (31% had no follow-up information in EDN and 20% were reported to have not completed an evaluation) (Zanju Wang, 10/19/2018). Among those with no follow-up information in EDN, it is unknown what proportion were never evaluated, but it is assumed to be high.

To better understand the inhibitors for seeking follow-up services, CDC/DGMQ conducted a small formative project in 2018. Sixty-three applicants and recent immigrants with B1 or B2 classifications from Mexico were interviewed (unpublished). Thirty-eight percent cited not knowing how to locate the health department (via phone number, address, physically find and arrive at). A larger percent, 52%**,** described not receiving an explanation of the B1/B2 process, while 19% reported not understanding the B1/B2 process.

The information collection for which approval is sought is in accordance with DGMQ's mission to reduce morbidity and mortality among immigrants, refugees, travelers, expatriates, and other globally

mobile populations, and to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States. This mission is supported by delegated legal authorities.

A.2. Purpose and Use of the Information Collection

Based on these observed gaps and challenges, we are undertaking a new project to assess a newly developed targeted educational intervention for Mexican immigrants arriving to the US.

The newly developed intervention consists of several components. Briefly, the first element is a targeted education session conducted at the panel physician sites for immigrants with class B1 and B2 conditions. The session includes a 3-minute educational video that gives a brief explanation of tuberculosis, the difference between active and latent tuberculosis, explains the importance and process to seek follow up TB care in the United States. After the video, the applicant will also receive low literacy level written health education information in the form of a story book (photo novella). Finally, the applicant will be directed to a local health department at their final arrival destination. The panel physician staff will use a newly developed online TB control program directory to look up and print the contact and location information for the appropriate health department in the US. The directory will also be available to the applicants themselves before and after arrival to the US. It is envisioned that officials at a US port of entry may also be able to use the directory to provide information to immigrants at the time of arrival, which might be especially useful if the immigrants intended residence address has changed since the consular interview.

The project is a mixed-method design and will be conducted in two phases. The first phase includes a data collection at two panel physician sites among Mexican immigrant applicants with a B1/B2 classification. The purpose of this phase is to assess whether intervention successfully enhances attitudes, knowledge and intentions for following up at US health departments among participants who receive the intervention. This data collection is the focus of this OMB submission.

The second phase of this project includes retrieval of TB follow-up worksheet data via the Electronic Disease Notification (EDN) system to compare follow-up rates for time periods when only the standard health education was administered to time periods when only the enhanced education was administered. We will use a cohort approach to determine whether immigrants exposed to the health education at the panel physician sites are more likely to follow up with the health department within 30 days of arrival to the US than those who were not exposed. These administrative clinical data will be used to make judgments about the success of the intervention. However, the phase 1 data collection will be instrumental in interpreting the phase 2 results, as phase 1 findings will provide critical insight about whether and how the intervention worked as intended, namely by changing respondent's knowledge, attitudes and intentions.

To facilitate the collection of phase 2 data in a timely manner, DGMQ will develop data collection instruments, facilitate interviews at panel sites in Mexico, analyze and interpret data, and summarize findings. CDC will oversee and approve all interview materials related to this project.

A.3. Use of Improved Information Technology and Burden Reduction

The information that is requested for this project is in compliance with the Government Paperwork Elimination Act (GPEA), Public Law 105-277, title XVII.

Data will be collected using a password secured tablet (provided to the clinics by DGMQ) and use the secure CDC-approved REDCap interface with respondents at CMI and SMF panel sites in Ciudad Juarez, Mexico. Using REDCap to collect and maintain the data will allow the on-site team to upload each interview record upon completion via the facility's wireless internet connection. After careful consideration of the totality of the project, this method presents the greatest opportunity to collect data and impose minimal burden.

The questions have been carefully curated to minimize the burden on the respondents while also collecting the necessary data. Interviewers will physically enter responses into the tablet interface while they are conducting the interview, which will last between 7-15 minutes.

A.4. Efforts to Identify Duplication and Use of Similar Information

A review of the scientific literature indicates that no other agency is collecting similar data. There are no similar published data available on the impacts of panel physicians' educational interventions on TB care follow up rates in the United States. This pilot program would be the first time that an educational session for immigrants with class B1 and B2 conditions has been incorporated into overseas medical examinations. Because DGMQ oversees medical examinations for immigrants at panel sites, the Division is in a unique position to implement and evaluate an educational intervention.

A.5. Impact on Small Businesses or Other Small Entities

The necessary participants include two panel sites in Ciudad Juarez, Mexico that are contracted by the department of state. Evaluation research efforts will minimize the burden on these healthcare provider practices, which are voluntarily serving as data collection sites.

A.6. Consequences of Collecting the Information Less Frequently

This information collection will happen only one time. If this information is not collected, DGMQ's ability to effectively communicate messages to mobile populations who may be at increased public health risk will be compromised. These particularly high risk groups not only have a greater chance of converting to active disease but also face various linguistic and cultural barriers. This potential lost benefit could lead to increased TB rates in the United States, which would have a true public health impact.

According to the CDC's Introduction to Program Evaluation for Public Health Programs: A Self-Study Guide (Koplan 1999) evaluation is critical for engaging in scientifically sound communication, training, and educational efforts. If a concept and/or a message is not tested, then resources could be expended without evidence that the activity is likely to succeed.

There are no legal obstacles to reducing the burden.

A.7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request will full comply with the guidelines of 5 CFR 1320.5.

A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

There have been efforts to consult outside of the agency. DGMQ routinely works with a variety of government and non-governmental agencies and partners to inform our work with globally mobile populations. This specific project has been discussed with: National Tuberculosis Controllers Association (NTCA), California TB Controllers Association (CTCA), Department of State (US Consulate), and both panel sites in Ciudad Juarez (SMF and CMI).

The following individuals were consulted to obtain their views on availability of data, frequency of collection, clarity of instructions and record keeping, disclosure, or reporting format, and on the data elements to be recorded, disclosed, or reported:

Individual	**Contact Information**
Donna Wegener (NTCA)	dhwegener@tbcontrollers.org
Judith Thigpen (CTCA)	jthigpen@ctca.org
Brooke Wehrenberg (US Consulate)	wehrenbergbe@state.gov
Joaquin Cervantes (CMI)	jcervantes@cmi-medical.com
Isaías Orozco Andrade (SMF)	iorozcoa@yahoo.com.mx

A.9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be provided to the respondents for this project.

A.10. Protection of Privacy and Confidentiality Information Provided to Respondents (Ethical Considerations)

This information collection request has been reviewed by the National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), and it has been determined that the Privacy Act does not apply.

No personally identifiable information will be filed or retrievable by CDC. No additional individually identifiable information is being collected. All data will be reported in a de-identified way. The interviews will not be audio recorded. Participants will not be able to be identified either directly or indirectly from the information that appears in the final data set and report. The respondent will be assigned a unique identification number by REDCap to ensure that the pre and post assessment are associated with the same respondent.

The proposed interviews will pose little risk to the patient's privacy.

This project will only purposely recruit those who meet the target audience criteria. The project involves vulnerable populations including potential immigrants to the US as well as pregnant women, who will not be screened out of interviews. Potential participants will be identified on the morning of their appointment clinic through a review of clients and their potential TB classifications.

We will obtain individual verbal consent and will review key consent points with the individual before beginning both the pre and the post assessment interviews. Participants will be told that the information obtained from the data collection activity will be combined into a report so that details of individual responses cannot be linked to a specific participant. In addition to the required elements of content, the script will emphasize that participation in the interviews is unrelated to an individual's immigration process.

The interviews will be conducted in both Spanish and English depending on the preference of the respondent. We will use a consent script in Spanish (Attachment 1-2).

The risks to participating in the collection of data for this project are minimal. Participants do not have to respond to any questions they do not want to answer, and they may stop participating at any time. There are no direct benefits of participating.

Participants may become distressed or experience discomfort talking about and answering questions related to Tuberculosis, particularly if this is an unfamiliar disease to them, or if they are unaware of their health status as it relates to TB. In order to reduce their anxiety, in particular after the pre-assessment, the interviewer will have the training and discretion to discontinue the interview.

A.11. Institutional Review Board (IRB) and Justification for Sensitive Questions

The National Center for Emerging and Zoonotic Infectious Diseases has determined this project is a non-research program evaluation. The purpose of this activity is to assess the impact of a newly developed educational session and materials targeted for immigrants with TB conditions to improve follow up and completing consults and treatment for TB. The evaluation of the educational program will include pretest and posttest of current educational sessions and the newly developed to show that the new program has a positive impact on programmatic goals. Results will be used to inform adopting the new educational session and may be published in a peer reviewed journal. As the purpose of this activity is to evaluate the impact of a newly developed standard educational session, it is consistent with non-research program evaluation. This activity is not designed to contribute to generalizable knowledge (Attachment 3).

The questions that will be asked are not sensitive in nature since they are primarily based on key concepts from the Health Belief Model (HBM) (Rosenstock, 1974), Theory of Reasoned Action (TRA) and Theory of Planned Behavior (TPB). In summation, these frameworks focus on perceptions of susceptibility, severity, belief in the benefits of action, barriers to action, and cues to action.

A.12. Estimates of Annualized Burden Hours and Costs (Sample Size)

Based on previous experience from the project sites, of about 647 potential participants, we expect to recruit 388 participants for a response rate of 60%. The participants will be screened (Attachments 9 and 11) to determine which potential participants meet the eligibility criteria, which includes the following: being 18 years of age or over, speaks Spanish, and not having any other member of their household interviewed for this project. An average of 5 minutes per respondent will be spent for the screening for a total of burden hours (388 participants x 5 min = 1940 mins; 1940 ÷ 60 mins. = 32.33 (32) hrs.).

388 patients total will respond to the interview (Attachments 4-7).

For the intervention group, 194 patients will respond to interview questions for approximately 15 minutes for the first session, and approximately 18 minutes for the second session as it includes the educational intervention of a video, resulting in a total of 33 min of their time (194 x 33 mins. = 6402 mins.; 6402mins ÷ 60 mins = 106.7 (107) hrs.).

For the non-intervention group, 194 patients will respond to interview questions for approximately 15 minutes for the first session, and approximately 15 minutes for the second session as it does not include the 3 min educational video, resulting in a total of 30 min of their time (194 x 30 min= 5820 min; 5820 min ÷ 60 min= 97 hours)

The total burden of the information collection for the intervention group is 122.86 (123) hours. The total burden of time for the non-intervention group is 113.16 (113) hours. The total burden for both the intervention and non-intervention groups is 236 hours.

Estimates for the average hourly wage for respondents are based on the average wage in Mexico (Salario Minimo) in the free zone of the northern border (http://salariominimo.com.mx/salario-minimo-2019/). Thus considering, an average hourly wage of $22.09 Mexican pesos, or $2.35 USD, is used to estimate for all 388 respondents. The hourly wage is converted from Mexican pesos to USD using the World Bank's PPP conversion factor for 2018, based on local currency unit per international dollar. (https://data.worldbank.org/indicator/PA.NUS.PPP?end=2018&locations=MX&start=1990) The total burden cost on respondents is thus $555.

Estimated Annualized Burden Hours and Cost: Intervention and Non-Intervention Groups							
Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours	Hourly Wage ($USD)	Total Respondent Costs ($USD)
Mexican Applicant at either the CMI or SMF Panel Physician site (Intervention Group)	Applicant Screener [Attachment 9 and Attachment 11]	194	1	5/60	16.16	$2.35	$37.98
	Pre-assessment [Attachment 4 and Attachment 6]	194	1	15/60	48.5	$2.35	$113.98
	Post-assessment + Educational Intervention (3 min video) [Attachment 5, Attachment 7, Attachment 14]	194	1	18/60	58.2	$2.35	$136.77
Mexican Applicant at either the CMI or SMF Panel Physician site (Non-Intervention Group)	Applicant Screener [Attachment 9 and Attachment 11]	194	1	5/60	16.16	$2.35	$37.98
	Pre-assessment [Attachment 4 and Attachment 6]	194	1	15/60	48.5	$2.35	$113.98
	Post-assessment [Attachment 5 and Attachment 7]	194	1	15/60	48.5	$2.35	$113.98
Total					236.02 **(236)**		$554.65 **($555)**

A.13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

None

A.14. Annualized Cost to the Government

Estimated Annualized Cost to the Federal Government		
Annualized Cost to the Government	**No. of Hours per Year**	**Annualized Cost**
Co-Principal Investigator – Medical Officer	104	$6,864.70
Co-Principal Investigator – Behavioral Scientist	182	$8,162.17
Investigators and Collaborators – ORISE Fellow	260	$5,882.50
Investigators and Collaborators– ORISE Fellow	260	$5,882.50
Investigators and Collaborators- ORISE Fellow	260	$6,219.90
Investigators and Collaborators- Health Communications Specialist	182	$8,162.17
Investigators and Collaborators- Epidemiologist	50	$2,269.63
Investigators and Collaborators- Epidemiologist	50	$2,649.78
Investigators and Collaborators- Public Health Analyst	50	$2,649.78
Investigators and Collaborators- Health Communications Specialist	182	$6,588.40
TOTAL		**$55,331.50**

A.15. Explanation for Program Changes or Adjustments

This is a new information collection being conducted under generic approval 0920-0932.

A.16. Plans for Tabulation and Publication and Project Time Schedule

In some cases, the results of information collection will not be published; instead, the information will be used to inform communication, training and/or education activities across DGMQ. In other cases, results will be presented at professional conferences and in peer-reviewed journals. Project timelines will vary, depending on the program requirements and the activity itself. The project timeline will be dependent on the nature of the data collection.

For Phase 1, a pilot data collection will be conducted approximately January 2020 at the two panel physician sites in Ciudad Juarez, Mexico (SMF and CMI). To conduct the pilot, the project team will visit the panel physician clinics to conduct orientation and training for the project. At this time, the team will also test and revise the data collection manual, as well as pilot the data collection instruments and make any final adjustments to the English and Spanish versions. The first round of data collection at

SMF and CMI will begin January 2020. We estimate that in March 2020, the project team will again visit the clinics to train them on the delivery of the educational intervention. Immediately following, SMF and CMI will begin delivering the enhanced education intervention to clients. From March 2020- July 2020, we will conduct the last set of interviews.

Phase 2 involves retrieval of TB follow-up worksheet data via the Electronic Disease Notification (EDN) system. We will compare follow-up rates for time periods when only the standard health education was administered to time periods when only the enhanced education was administered. We estimate retrieving data from CDC's EDN system in September 2020. The reporting periods include January 2020- March 2020 for baseline observations (comparison condition) and March 2020- July 2020 for the intervention condition observations. No additional data from individuals will be collected for Phase 2.

Write-up of findings that will inform communication, be presented at professional conferences and in peer-reviewed journals, will take place in June 2020 following the collection and analysis of data collected.

A.17. Reason(s) Display of OMB Expiration Date is Inappropriate

No exemption is being requested. The display of the OMB expiration date is not inappropriate.

A.18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

1. B1 Applicant Consent Script
2. B2 Applicant Consent Script
3. Non-Research Determination Protocol
4. Data Collection Instrument B1 Pre-test
5. Data Collection Instrument B1 Post-test for Comparison and Program Groups
6. Data Collection Instrument B2 Pre-test
7. Data Collection Instrument B2 Post-test for Comparison and Program Groups
8. B1 Applicant Recruitment Script
9. B1 Applicant Screener
10. B2 Applicant Recruitment Script
11. B2 Applicant Screener
12. B1 Photo Novella
13. B2 Photo Novella
14. B1B2 Educational Video Script
15. Directory

REFERENCES (APA)

Koplan, J., Milstein, R., & Wetterhall, S. (1999). Framework for Program Evaluation in Public Health. Retrieved from https://www.cdc.gov/mmwr/preview/mmwrhtml/rr4811a1.htm

Rosenstock, I.M. (1974). Historical origins of the Health Belief Model. *Health Education Monographs,* 2, 328-335.