U.S. Department of Health and Human Services
Centers for Disease Control and Prevention

Print Date: 2/20/20

Title:	Formative Work to Understand Influences, Barriers, and Facilitators for LTBI Testing and Treatment among High Risk Non-U.S. Born Individuals and the Healthcare Providers that Serve Them
Project Id:	0900f3eb81a93d31
Accession #:	NCHHSTP-CT-12/23/19-93d31
Project Contact:	Parmer_John E. (bkz8)
Organization:	NCHHSTP/DTBE/CEBSB/CT
Status:	**Project In Progress**
Intended Use:	**Project Determination**
Estimated Start Date:	09/30/2019
Estimated Completion Date:	09/29/2020
CDC/ATSDR HRPO/IRB Protocol #:	
OMB Control #:	

Determinations

Determination	Justification	Completed	Entered By & Role
HSC: **Does NOT Require HRPO Review**	Not Research	1/24/20	Dodson_Janella R. (jhd7) CIO HSC
PRA: **PRA Applies**		1/24/20	Bonds_Constance (akj8) CTR OMB/PRA Coordinator

ICRO: **Returned with No Decision**		1/28/20	Zirger_Jeffrey (wtj5) ICRO Reviewer

Description & Funding

Description

Priority:	Standard
Date Needed:	01/29/2020
Determination Start Date:	01/16/20
Description:	The United States reported 9,025 Tuberculosis (TB) cases during 2018. Although TB cases continue to decline, the annual percentage decrease in case count and incidence rate from 2017 to 2018 is the smallest year-to-year decrease observed since 1993. Over two-thirds of total cases of TB disease in the U.S. occurred among non-U.S.-born persons. The most common countries of birth among non-U.S.-born TB patients include Mexico, the Philippines, India, Vietnam, and China. More than 80% of U.S. TB cases are now believed to be associated with longstanding untreated latent TB infection (LTBI). Expanding targeted testing and treatment of LTBI is key to eliminating TB disease in the U.S. CDC has funded Weber Shandwick to develop and implement a communication campaign under the CDC#s Office of the Associate Director (OADC) Blanket Purchase Agreement (BPA). In order to develop an effective communications campaign that educates individuals at high risk for TB and the healthcare providers who serve them, CDC DTBE seeks to conduct public health program activities for testing draft messages with consumers (in-language mainly, but in English for Indian and Filipino audiences) and healthcare providers, and learn their preferences for seeking information, and gain a better understanding of the various knowledge, attitudes, beliefs, and misconceptions around LTBI across the different audience segments and geographic locations.
Goals/Purpose	CDC#s DTBE seeks to conduct public health program activities for testing messages with individuals who were born in the top six countries of origin that contribute to the U.S.#s current TB rates#a critical target audience group that is considered at high risk for TB disease - and the healthcare professionals (primary care physicians and nurses/nurse practitioners) that serve them. The primary goal for this research effort is to explore and understand influences, barriers, and facilitators for testing and treating latent tuberculosis infection (LTBI) in order to develop a communication campaign to reach these audiences.
Objective:	Project objectives for the public health program activities are as follows: # Understand levels of awareness, knowledge, attitudes, beliefs, practices, and cultural influences related to TB and latent TB infection among at-risk consumer audiences and their healthcare providers # Understand key barriers to latent TB infection testing and treatment # Understand key motivators to latent TB infection testing and treatment, as well as trusted sources and messengers of health information # Assess the most effective communications channels for information about latent TB infection for foreign-born community members and their healthcare providers # Test key messages, materials, and creative to communicate about latent TB infection among key target audiences
Activities or Tasks:	New Collection of Information, Data, or Biospecimens
Target Populations to be Included/Represented:	Asian, Healthcare Personnel, Hispanic or Latino
Tags/Keywords:	Latent Tuberculosis, Tuberculosis, Focus Groups, Interview
CDC's Role:	Activity originated and designed by CDC staff, or conducted at the specific request of CDC, or CDC staff will approve study design and data collection as a condition of any funding provided

Method Categories:	Focus Group, Individual Interviews (Qualitative)
Methods:	DTBE has funded Weber Shandwick to conduct 12 in-person consumer focus groups with non-U.S.-born individuals considered at high risk for TB. The majority of focus groups will be conducted in-language, with four conducted in English. We will also conduct 4 focus groups among nurses, nurse practitioners, and physician assistants, and 12 in-person interviews with primary care physicians.
Collection of Info, Data or Biospecimen:	CDC is sponsoring, but not conducting data collection. Weber Shandwick will conduct all focus groups and interviews in three cities representing different geographic regions in the U.S. Consumers participating in the focus groups will have immigrated from: Mexico, the Philippines, India, Vietnam, China, and Guatemala. In each metropolitan area, sessions will be conducted with between three and five consumer focus groups, between one and two focus groups with nurses, and four physician interviews. Cities were selected based on 2018 TB case rate data, the latest population data, locations which would provide a geographically diverse sample, as well as markets that have ethnic or in-language media outlets for each of our target consumer populations. The metropolitan areas are: Los Angeles, California; Houston, Texas; and New York City, New York. Each metropolitan area#s TB case rate exceeds the national average of 2.8 cases per 100,000 population and represents metropolitan areas with some of the highest rates of TB within the U.S. Additionally, individuals born in the top countries of origin for TB are well-represented among the populations of these cities. Focus groups sessions will last approximately 120 minutes. The in-person interviews will last approximately 60 minutes. DTBE plans to seek OMB approval via the Health Message Testing System (HMTS) ICR # 0920-0572. A level-setting activity will be conducted in each focus group prior to aided discussion around TB and LTBI. The activity will consist of sharing brief information with the respondents, including definitions of terms and basic TB information (for consumer audiences), and CDC guidelines (for healthcare providers). The team will also test a total of 4 message pillars, with two to four messages per theme, across the 12 consumer focus groups, four nurses focus groups and 12 in-person interviews with physicians. Themes and messages will be rotated across focus groups and interviews (to test all messages while not overburdening any one focus group or interview).
Expected Use of Findings/Results:	The findings from these activities will inform a communication campaign strategy, messaging, creative, and tactics for a national education campaign on latent TB infection to reach at-risk audiences and their healthcare providers.
Could Individuals potentially be identified based on Information Collected?	Yes

Funding

Funding Type	Funding Title	Funding #	Original Budget Yr	# Years Award
CDC Contract	Latent Tuberculosis Infection Educational Campaigns and Communication Support	75D301-19F-05695	2020	3

Regulation and Policy

Do you anticipate this project will be submitted to

the IRB office

Estimated number of study participants

Population - Children

Population - Minors

Population - Prisoners

Population - Pregnant Women

Population - Emancipated Minors

Suggested level of risk to subjects Do you anticipate this project will be exempt research or non-exempt research

Requested consent process waviers

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection
Alteration of authorization under HIPPA Privacy Rule	No Selection

Requested documents of informed consent

Informed consent for adults	No Selection
Children capable of providing assent	No Selection
Parental permission	No Selection

Consent process shown in an understandable language

Reading level has been estimated	No Selection
Comprehension tool is provided	No Selection
Short form is provided	No Selection
Translation planned or performed	No Selection
Certified translation / translator	No Selection
Translation and back-translation to/from target language(s)	No Selection
Other method	No Selection

Clinical Trial

Involves human participants	No Selection
Assigned to an intervention	No Selection
Evaluate the effect of the intervention	No Selection
Evaluation of a health related biomedical or behavioral outcome	No Selection
Registerable clinical trial	No Selection

Other Considerations

Exception is requested to PHS informing those bested about HIV serostatus	No Selection
Human genetic testing is planned now or in the future	No Selection
Involves long-term storage of identfiable biological specimens	No Selection
Involves a drug, biologic, or device	No Selection
Conducted under an Investigational New Drug exemption or Investigational Device Exemption	No Selection

Institutions & Staff

Institutions

Institutions yet to be added .....

Staff

Staff Member	SIQT Exp. Date	CITI Biomedical Exp. Date	CITI Social & Behavioral Exp. Date	CITI Good Clinical Practice Exp. Date	Staff Role	Email	Phone	Organization
John Parmer	12/21/2021		12/17/2022		Program Lead	bkz8@cdc.gov	404-639-4598	Communications Team

Data

DMP

Proposed Data Collection Start Date: 3/2/20

Proposed Data Collection End Date: 6/26/20

Proposed Public Access Level: Non-Public

Non-Public Details:

Reason For Not Releasing Data: Other - focus group and individual interview data

Public Access Justification: The raw data collected by Weber Shandwick will be reflected in transcripts of up to 44 hours of focus group session and individual interview activity. CDC does not have plans to make available these raw data, however these data will be used to develop public messages in campaign materials that will be made publicly available.

How Access Will Be Provided for Data: Not applicable given the description above.

Plans for Archival and Long Term Preservation: Raw data from this data collection effort will never become part of a system of records containing permanent identifiers that can be used for retrieval. CDC has no direct contact with participants and no identifiers will be available.

Spatiality

Country	State/Province	County/Region
United States	Texas	Houston
United States	New York	New York
United States	California	Los Angeles

Dataset

Dataset Title	Data Publisher /Owner	Public Access Level	Public Access Justification	External Access URL	Download URL	Type of Data Released	Collection Start Date	Collection End Date
Dataset yet to be added...								

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