PROTOCOL

1.) TITLE OF PROJECT: Improving Rhode Island's tuberculosis preventive services in primary care: A mixed-methods evaluation of an innovative telementoring model

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2.) Description of Study

A. Specific Aims

This pilot study will use a mixed-methods design called an exploratory sequential translational research design. In this type of study design, the initial qualitative phase informs the design of an intervention (in this case a TB infection ECHO) and an instrument (in this case structured surveys) to study an intervention. The final phase implements the designed intervention and/or instrument to collect data and quantitatively assess the outcomes of interest (in this case feasibility and impact).

Specific Aim 1: Explore the specific knowledge, attitudinal, and skills gaps to TB infection testing and treatment among primary care providers in RI through qualitative key informant interviews.

In Aim 1, at least 40 primary care team members from our Brown Family Medicine and Care New England networks will be purposively sampled to undergo key informant interviews regarding TB infection testing and treatment knowledge, attitudinal, and skill gaps. Questions will be asked to ascertain gaps throughout the entire latent TB infection care cascade. The results from Aim 1 will be used to design the survey instrument and the curriculum for an innovative, telementoring program (TB infection ECHO).

Specific Aim 2: Design and evaluate an evidence-based telementoring intervention (ECHO model) that addresses the identified TB infection gaps in Aim 1, and evaluate this model for feasibility as well as its impact on primary care team member knowledge and TB infection testing and treatment in RI.

In Aim 2, at least 50 primary care team members will be recruited to participate in a virtual six-month TB infection ECHO course. Participants will complete quantitative surveys before and after the course as well as post-session surveys following each session. Survey questions will assess feasibility measures related to process, resources, and management and impact measures related to learning and performance. Paired data from pre- and post-course surveys will be analyzed accordingly depending on the distribution of results. The nature of this pilot project provides budgetary limits for an effective sample size. Therefore, for analyzed question responses that do not demonstrate a significant change between pre- and post- we will carefully note any relevant trends. In addition to the quantitative survey results, we will conduct approximately 15 qualitative interviews with ECHO participants. Given that practice change is difficult to assess quantitatively, questions will be asked regarding the impact of the ECHO course on practice change and about improvements that can be made to future LTBI ECHO courses.

Specific Aim 3: Pilot a retrospective electronic medical record (EMR) data review to examine RI PCPs' testing and treatment before and after ECHO implementation and evaluate the model's reach.

In Aim 3, data will be retrospectively extracted from two participants' clinics to research RI PCPs' testing and treatment patterns before and after the ECHO course. Aim 3 will evaluate the model's reach, or the degree to which the population that is eligible to benefit from an intervention actually benefits. In the case of LTBI, there is one lab test type (interferon gamma release assay) and two medications (rifampin and isoniazid) used. They are used sparingly for other ailments in primary care. Therefore, LTBI lab tests and prescriptions could be an excellent proxy measure of providers' behavior change related to LTBI testing and treatment, and ultimately the reach of the ECHO model.

B. Background

Tuberculosis (TB) remains a significant cause of mortality globally.[1] In the United States (US), 80% of TB disease is a result of untreated, latent TB infection. This persists despite available treatment that can significantly decrease the rate of progression from TB infection to disease.[2] Currently, up to 13 million individuals have latent TB infection in the US, and approximately 10% of these individuals will progress to infectious TB disease.[3] In 2016, the United States Preventive Services Task Force (USPSTF) updated their latent TB infection recommendation to a Grade B based on strong evidence supporting TB infection testing and treatment as a preventive measure, signifying its importance.[4]

Accordingly, the USPSTF recommendation encourages primary care providers (PCPs) to add TB testing to their routine preventive screening and initiate treatment in the primary care setting – tasks that were previously reserved for specialists. Unfortunately, primary care training incorporates only minimal training regarding TB, and therefore, PCPs in the US are not prepared to incorporate testing and treatment for this critically under-addressed infection. Due to this significant gap in training, PCPs continue to refer patients to specialists for treatment. These unnecessary referrals are likely to complicate care for patients, resulting in barriers to initiation and completion of TB infection therapy and, ultimately, increased healthcare costs.

This proposed project has significant public health implications. To achieve TB elimination in our lifetime, there is a critical need to implement innovative continuing medical education models to expand primary care provider knowledge and capacity regarding TB infection. The Extension for Community Healthcare Outcomes (ECHO) Model™ is an effective, evidence-based telementoring intervention designed to address knowledge gaps in primary care in a manner that fosters convenient and high-level PCP participant to expand patient access to previously specialist-only care.[5-10] The ECHO model incorporates didactics, mentoring, and case review and virtually connects topic experts with primary care teams at the frontline of community care. It has demonstrated improvement in healthcare provider knowledge, attitudes, and skills (KAS) as well as better patient outcomes in several disease areas. There are currently three TB ECHOs in the US, however, the model's impact on PCP knowledge, skills, and attitudes regarding *TB infection* have not yet been studied.

Telementoring Education Intervention for Latent TB Infection: Participation in one-time CME activities is not sufficient to actually develop new understandings, skills, and capabilities.[24] The Extension for Community Healthcare Outcomes (ECHO) Model™ is an effective, evidence-based telementoring intervention that incorporates didactics, mentoring, and case review during a virtual teleECHO session. This model was developed in 2003 in rural New Mexico to help PCPs manage hepatitis C virus.[25] It has been expanded to address other complex chronic diseases such as pain management, osteoporosis, cervical cancer, and substance abuse disorders in underserved areas.[7-9, 26] For other diseases, this model has demonstrated improvement in healthcare provider knowledge, attitudes, and skills as well as improved patient outcomes.[10] There are three TB-related ECHO programs in the country – New Mexico, Washington, and Massachusetts. These three TB ECHOs have been strictly focused on care and have not incorporated formal methodology to explore gaps and rigorously evaluate the model. There is currently no evidence for the model's impact on PCP knowledge related to TB infection testing and treatment practices. There are >150 ECHO hubs in 45 states,[27] yet Rhode Island has to date not developed any ECHO hubs. The RI Department of Health has expressed great interest in the implementation and evaluation of this model as it has potential to improve care beyond LTBI.

This is a unique opportunity to pilot the ECHO model specifically for latent TB infection, and lay the foundation to expand this innovative model to address other high priority diseases in Rhode Island.

C. Experimental Method

This proposal will incorporate an exploratory sequential translational research framework. In Aim 1, we will recruit at least 40 primary care team members throughout the RI community from academic practices, federally qualified health centers, and private practices to participate in qualitative key informant interviews to assess KAS gaps. In Aim 2, we will use the results from Aim 1 to design a TB infection ECHO educational intervention for primary care team members that specifically addresses the KAS gaps. We will also use Aim 1 results to design quantitative surveys to assess *feasibility* and participant *learning* and *performance*. In Aim 3, we will pilot a retrospective EMR data extraction and examine RI PCPs' testing and treatment behavior before and after LTBI ECHO implementation.

To achieve our aims, we propose a cross-disciplinary research collaboration. The PI (Szkwarko), a primary care physician and junior investigator in the Brown department of family medicine has experience in facilitating a TB infection ECHO in Massachusetts. She will work closely with three mentors with complementary expertise: Dr. Jane Carter, a Brown pulmonologist and world renown TB expert with over four years of ECHO experience, will support TB content expertise. Dr. Roberta Goldman, a qualitative researcher in the department of family medicine at Brown, will provide mentorship on qualitative research methods. Dr. Charles Eaton, MD at the Kent Hospital and Steven Kim, a medical student at the Warren Alpert Medical school, will aid the PI in data collection and analysis. We will collaborate with the RI Department of Health to ensure a concerted educational effort and avoid any parallel processes. The results of this study will formally assess, for the first time, primary care team member KAS gaps regarding TB infection. It will also provide quantitative results regarding feasibility and impact and reach of a TB infection ECHO. This will lay the foundation for a larger prospective cohort study to further test the model for effectiveness as well as provide a framework for expansion and evaluation of the ECHO model in RI to other diseases. Additionally, the study will provide the PI with an opportunity to further develop skills in mixed-methods translational research and continue her desire to study TB prevention strategies to achieve TB elimination globally.

D Brief Description of Subjects

For both, the qualitative key informant interviews and the quantitative surveys, the eligibility criteria will be the same. Participants must be:

Primary team members in Rhode Island: This includes MD, DO, nurse practitioners, physician assistants, nurses or other team members who work in a primary care setting. We will exclude urgent care providers as they do not routinely perform preventive screening such as TB infection screening. Individuals must be able to speak English as interviews and ECHO course will be in English.

There will be no age limits for recruited participants. However, given our training inclusion criteria, all participants will be over the age of 18 since a higher level of training after high school is required for all eligible primary care providers. Therefore, children will not be eligible to participate in this study.

We will use purposive sampling for the recruitment of both qualitative interview participants and ECHO course participants. In our alumni and community provider network at Brown Family Medicine and Care New England, there are many female and male primary care team members. Given our small sample of at least 40 key informant interviews and at least 50 participants for the TB infection ECHO, we do not anticipate any challenges in recruiting an equal number of men and women.

Regarding minorities, our primary care network has < 10% minority primary care providers. Using purposive sampling, we will make every effort to ensure that our sample includes 10% or more minorities to represent the general PCP population in RI.

E **Study Design**

Exploratory Sequential Translational Research Design Overview: Primary care team member KAS gaps are suspected barriers that impact all steps of the LTBI care cascade yet they have not been formally studied in the literature. This study will utilize a four-phase exploratory sequential mixed methods design[23], in which we will: 1) Explore these TB infection KAS gaps qualitatively (Aim 1), 2) Translate the qualitative findings to inform curriculum design within an innovative, evidence-based telementoring model, and inform quantitative surveys that measure key implementation outcomes (Aim 2), and 3) Implement a LTBI ECHO intervention for RI primary care teams and utilize the survey instrument as well as qualitative interview feedback to assess *feasibility* and *impact* of the LTBI ECHO intervention (Aim 2), and 4) Pilot a retrospective EMR review to assess the reach of the LTBI Echo on patients' care.

Qualitative Methods

In the first phase of this four-phase exploratory sequential translational research study, we will use qualitative key informant interviews to explore, for the first time, the potential gaps listed above that impact latent TB infection testing and treatment.

Key Informant Interviews (KIIs): In collaboration with the RI Department of Health, we will identify a purposive sample of key informants from our Brown Department of Family Medicine and Care New England networks of primary care provider teams practicing outpatient primary care and serving immigrant populations. In total, there will be at least 40 KIIs. Interviews will be conducted to the point of data saturation such that no new information is obtained, adding more KIIs if needed.

Instrument Development and Interview Structure: With mentorship from Roberta Goldman, PhD, a semi-structured question guide for the KIIs will be developed based on the knowledge, attitudinal, and skill gaps in Table 1. The semi-structured guide will include open-ended core questions that will be supplemented with spontaneous probes and follow-up questions to explore the possible barriers impacting all latent TB infection steps.

The ECHO Model

The ECHO Model uses a virtual hub-and-spoke educational approach to successfully link interdisciplinary expertise to generalists to increase their ability to manage complex medical cases and ultimately address growing public health problems.[10] Unlike "telemedicine" where specialists assume care of the patient, the ECHO model allow generalist clinicians to retain responsibility for managing patients. Participants from similar settings with similar barriers learn from each other through shared case management discussion and decision-making. The ECHO model typically consists of a fifteen-minute didactic presentation by a content expert followed by

case-based discussions of one or two de-identified latent TB infection cases presented by participants. Cases are prepared and submitted prior to each ECHO session using an ECHO case presentation form. Cases are reviewed by ECHO leads (in our case, these will be reviewed by the PI and Dr. Jane Carter) to ensure adequate data are included for discussion. As part of the ECHO model, descriptive data for each session (date, topic, length, case presentations, participant demographic information) are collected through 'iECHO' and accessible to hub members at any time through a web-based, password protected platform.

A *TB infection ECHO educational intervention* will be designed that specifically addresses the KAS gaps identified in Aim 1 so that the course content is specific to Rhode Island primary care team members .

Participant Recruitment: A random and representative sample of at least 40 primary care team members will be purposively recruited. Gender, race, and practice setting during recruitment will be considered to enhance the diversity of our sample. However, given the two-year time frame, it may not be possible to achieve equal demographics for our participant sample. Participants who attend at least four out of six latent TB infection ECHO sessions will receive CME credits.

Quantitative Methods

Aim 2: Survey Design: Quantitative pre- and post- ECHO course surveys and post-session surveys will be designed based on qualitative results from Aim 1 (Sample surveys have been uploaded in IRBnet and an amendment will be submitted with modified surveys after Aim 1 results are available). The PI will seek support from Advance-CTR faculty to build and manage surveys in REDcap or comparable survey program. These surveys will be used to assess the model's *feasibility* and *impact* on primary care team member knowledge and TB infection testing and treatment practices in RI. If it appears from Aim 1 results that there are several thematic segments in knowledge, attitudes, and skills, we will develop several questions related to each thematic segment. The surveys will include single-item binary and likert-type questions depending on the measure of interest. For example, questions related to learning as described below will be likert-type to improve reliability of our survey. The PI will ask mentors and Advance-CTR faculty to preliminarily review the surveys to ensure the questions are clear, concise, and not complex. The surveys will be pretested with five primary care volunteers.

To assess *feasibility*, we will explore process, resources, and management.[36] Feasibility data will be attained from iECHO, post-session evaluations, and post-ECHO course surveys. Process will include participant attendance, participant retention, case submission, and timing of the ECHO sessions. Resources will relate to connectivity issues and videoconferencing equipment availability at all sites. Management questions will relate to content expert facilitation and ease of communication with ECHO coordinator and content experts.

To assess *impact on providers*, we will use Moore's Expanded Outcomes Framework for Assessing Learners and Evaluating Instructional Activities[24] to study participants' self-reported learning and performance. Learning questions will focus on procedural knowledge (the degree to which participants state *how* to do what the activity intended them to know how to do). Procedural knowledge questions will focus on participants' self-reported confidence in latent TB infection testing and treatment. Performance questions will focus on the degree to which

participants *do* what the ECHO activity intended them to be able to do in their practices. Performance questions will ask participants to provide approximate estimates for the number of patients they have tested and/or treated for latent TB infection. To supplement the quantitative survey and assess impact on providers' practice changes, we will conduct in-depth qualitative interviews with approximately 15 ECHO participants. A semi-structured interview guide will be created following a similar process as described in Aim 1.

Aim 3: Reach of the ECHO: To assess reach on patients, we will perform a retrospective EMR data extraction that will examine RI PCPs' testing and treatment behavior before and after LTBI ECHO implementation. Specifically, regarding the interferon gamma assay and rifampin and isoniazid prescriptions. Data will be obtained from two clinics that anticipate having participants in Rhode Island's LTBI ECHO course. Blackstone Valley Community Health Center (BVCHC) will be one of the sites. Respective IRB approval will be sought once clinics are identified and prior to clinics' data personnel accessing EMR for study purposes.

F **Specific Procedures or Treatments**

Specific Aim 1: In this aim, at least 40 key informant interviews with primary care team members in Rhode Island will be performed. The department of Family Medicine has a list of all primary care providers who are alumni or are community preceptors. There is also a list of primary care providers including other specialties like internal medicine and pediatrics throughout Care New England. Using these contact lists, participants will be recruited via email initially. Several chief medical officers at federally qualified health centers have given us permission to also circulate recruitment emails via health center listserves to recruit their primary care team members. For those who do not respond positively or negatively, a phone call to their primary care office during business hours will be made. If the participant agrees to be interviewed, a convenient time will be arranged to meet with the participant. Interviews will be performed in a quiet, private location either at the participant's office or in the department of Family Medicine at 111 Brewster St. Pawtucket RI. We will attempt to reschedule interviews up to three times for participants in order to retain them in the interview process. Written consent will be obtained at the start of the interview.

Specific Aim 2: In this aim, participants will be recruited to participate in the TB infection ECHO course. The same recruitment procedure will be used as in Aim 1 to recruit at least 50 participants. Participants will be invited to complete the survey via email and will complete online consent prior to initiating the survey. Participants who did not complete the quantitative surveys, but volunteer to participate in qualitative interviews will undergo consent virtually prior to the start of the interview.. This study aims to assess the TB infection ECHO course in a real-world setting. Therefore, we will not make any additional efforts to retain participants in the course outside of routine course email reminders.

Specific Aim 3: In this aim, two health centers or clinics with participants who enrolled in the Rhode Island LTBI ECHO will be selected. One of these sites will be Blackstone Valley Community Health Center where the staff is conducting a clinical chart review for latent TB infection. Dr. Verma, a family medicine physician and public health student, has been added as a co-investigator to assist in the analysis of the de-identified patient database. Further information

about the second site will be provided to the IRB. We will pilot the extraction of electronic medical record data from these two sites. The PI has significant experience with data queries in EPIC at the Family Care Center and has confirmed that prescription data can be queried from this system. The Brown Department of Family Medicine has a strong relationship with health centers and primary care sites throughout Rhode Island. Further, the Center for Primary Care and Prevention has active projects involving data query from EMRS at other clinic sites. Potential variables related to testing and treatment will be discussed with the health centers or clinic sites, and data extraction will be requested through the site's data team. Data variables to be queried will include provider ECHO enrollment, HIPAA compliant patient demographic information, ICD-10 diagnosis code to separate TB disease from TB infection, TB infection laboratory testing data, and LTBI prescriptions. At Blackstone Valley Community Health Center, the following additional information will be included in the database: age, gender, primary language, country of origin, refugee status if available, ICD-10 diagnoses to separate TB disease from TB infection, date of IGRA test, type of IGRA test, IGRA test result, LTBI evaluation including chest x-ray and documentation of symptom screen, LTBI treatment plan including referral and/or LTBI treatment initiation(medications such as rifampin or isoniazid), and treatment completion or documentation from specialist of LTBI treatment completion. Data will be retrospectively collected to capture the three months prior to LTBI ECHO implementation, six months during the LTBI ECHO, and three months after LTBI ECHO implementation. We will work with health center sites to determine the best way to link ECHO participants to health center data. This could include health centers including provider names in the database if acceptable or providing health centers with names of their ECHO provider participants and having them code the database in a way that enables the study team to differentiate ECHO participants from other providers and protect anonymity. Dr. Verma in her role as co-investigator will oversee the ECHO participant linkage with health center data.

G **Data Analysis**

Qualitative Data Analysis*:* With direct oversight from Roberta Goldman, PhD, an expert in qualitative methods, as well as continued support from the Advance-CTR Clinical Research Design, Epidemiology, and Biostatistics Core, the PI will work closely with the research assistant to analyze the data using immersion/crystallization and analysis methods.[30] KII transcripts will be analyzed in an iterative fashion as they become available. This ensures that ideas from early transcript analyses can be explored during KIIs, and the guide can be revised to effectively capture relevant information. The transcripts will first be read for familiarity with content. During this reading, broad themes will be isolated while notes are taken in the process. Next, a codebook will be created based on the KAS constructs at each cascade step, and on themes that emerged during the KIIs.[31] The codebook will be tested, refined, and used for line-by-line coding of transcripts with the data analysis software, NVivo.[32, 33] We will maintain flexible coding schemes to accommodate expansion as new codes are established.[34] Using the resulting code reports, the data will be categorized into meaningful topical and/or thematic segments to reach final data interpretation. Findings will be discussed with mentors to reach consensus and prevent under or over-interpretation.[35]

Quantitative Data Analysis: Anonymous data from surveys will be automatically populated into an electronic database via REDCap or a comparable survey program. Data will be imported into STATA for analysis. Statistical analysis will be conducted with support from Advance-CTR

faculty. For feasibility analysis, descriptive statistics will be performed to determine proportion of registered participants attending each session and to determine proportion of participants retained at the end of the course. For the remaining feasibility measures, the proportion of participants reporting adequate connectivity, adequate equipment, adequate content expertise, and adequate communication with ECHO hub will be computed. Guidance will be sought from the University of New Mexico Project ECHO team at the time of the latent TB infection ECHO intervention to select appropriate feasibility cutoff measures so that the cutoff is consistent with national data from other ECHO hubs.
For the impact analysis, the majority of these questions will be likert-scale type. The distributional properties of the pre- and post- responses will be examined. The paired data will be analyzed using Wilcoxon-signed rank test or a paired t-test depending on whether or not the responses seem to be following a normal distribution. Significance will be considered if *p-value* is < 0.05.

Regarding Aim 3, Blackstone Valley Community Health Center has been selected as one of our sites. Currently, BVCHC staff are reviewing patient charts for clinical purposes in order to design a latent TB infection clinic. Therefore, a de-identified database with LTBI tests ordered and LTBI prescriptions written by PCPs exists. For the purpose of this study and after written approval from BVCHC, this de-identified patient database will be provided to the study team as per the data sharing agreement. Once we identify another site, data variables from the two EMRs will be sorted, matched, and coded synchronously so that all data can be analyzed together. We will work with health center sites to determine the best way to link ECHO participants to health center data. Descriptive statistics will be performed to determine the number of LTBI tests ordered and LTBI treatment prescribed by PCPs in each time period (before, during, after). We will study potential denominators including total number of patient visits, number of wellness visits, number of patients diagnosed with LTBI, and number of visits with immigrant/refugee patients to explore the best potential measures of effectiveness in future studies. Comparison between the ECHO participants and non- ECHO participants will also be considered to assess initial trends.

H. Material Inducements

Knowledge gained.

I. Training of Research Personnel

Steven Kim, a medical student, will serve as our research assistant for this study. He will receive qualitative training from Dr. Roberta Goldman and Dr. Daria Szkwarko via online lectures and recordings as he will attend the ECHO immersion training and will also assist Dr. Szkwarko with the qualitative interviews. Our study team will provide him with any necessary research training to ensure that he can conduct his duties as the research assistant. Dr. Shelly Verma is a family medicine physician and global health fellow at the Department of Family Medicine at Brown University. She is currently receiving a Masters in Global Public Health at Brown University School of Public Health. We will ensure that her CITI training is up to date and that she receives training and mentorship in quantitative data analysis.

3) Human Subjects

A. Subject Population

For both the qualitative key informant interviews and the quantitative surveys, the eligibility criteria will be the same. Participants must be:

Primary care team members in Rhode Island: This includes MD, DO, nurse practitioners, physician assistants, nurses or other team members who work in a primary care setting. We will exclude individuals who work in urgent care as they do not routinely perform preventive screening such as TB infection screening. Individuals must be able to speak English as interviews and ECHO course will be in English.

There will be no age limits for recruited participants. However, given our training inclusion criteria, all participants will be over the age of 18 since a higher level of training after high school is required for all eligible participants. Therefore, children will not be eligible to participate in this study.

We will use purposive sampling for the recruitment of both qualitative interview participants and ECHO course participants. In our alumni and community provider network at Brown Family Medicine and Care New England, there are many female and male primary care team members. Given our small sample of at least 40 informant interviews and 40-50 participants for the TB infection ECHO, we do not anticipate any challenges in recruiting an equal number of men and women.

Regarding minorities, our primary care network has < 10% minority primary care providers. Using purposive sampling, we will make every effort to ensure that our sample includes 10% or more minorities to represent the general PCP population in RI.

The retrospective chart review will involve data from ECHO participants as well as data from other providers who have ordered a TB test or prescribed LTBI medication at the two health care centers or clinics that are selected.

B. Recruitment and Consent Procedures

Specific Aim 1: In this aim, at least 40 key informant interviews with primary care team members in Rhode Island will be performed. The department of Family Medicine has a list of all primary care providers who are alumni or are community preceptors. There is also a list of primary care providers including other specialties like internal medicine and pediatrics throughout Care New England. Using these contact lists, participants will be recruited via email initially. Several chief medical officers at federally qualified health centers have given us permission to also circulate recruitment emails via health center listserves to recruit their primary care team members. For those who do not respond positively or negatively, a phone call to their primary care office during business hours will be made. If the participant agrees to be interviewed, a convenient time will be arranged to meet with the participant. Interviews will be performed in a quiet, private location either at the participant's office or in the department of Family Medicine at 111 Brewster St. Pawtucket RI. Given primary care team members' busy schedules, interviews may also be conducted via phone. In this case, informed consent documents will be sent via the participant's preferred method, email or mail. The consent will be read aloud over the phone, and the verbal consent will be documented by the study team by signing the informed consent and writing a note that informed consent was obtained over the phone for the participant. We will attempt to reschedule interviews up to three times for participants in order to retain them in the interview process.

Specific Aim 2: In this aim, participants will be recruited to participate in the TB infection ECHO course. The same recruitment procedure will be used in Aim 1 to recruit participants for the ECHO course. Since all registration for the ECHO course is being conducted electronically, an informed consent form will be included at the beginning of the online survey. Participants will confirm their understanding of the consent form and will be provided an email address to send any comments or concerns prior to participation. If an individual does not agree to participate, they will not be able to proceed to the survey. Study participants names will be linked to surveys to allow for possible clinical outcome tracking in Aim 3. Study participants will provide unique IDs so that names will only be included on a codesheet (see below). Only de-identified data with unique IDs will be included in the final database. This study aims to assess the TB infection ECHO course in a real-world setting. Therefore, we will not make any additional efforts to retain participants in the course outside of routine course email reminders. We will email ECHO participants at the end of the course to ask for volunteers to participate in qualitative interviews. Those who agree will undergo the same consent process as described in Aim 1.

Specific Aim 3: The retrospective chart review will be requested through the data teams of the two selected sites and will be de-identified to not include HIPAA protected information.

C. Potential Risks

a. This research is classified as non-exempt human subjects research. All procedures of this research will be conducted in accordance with 45 CFR Part 46 and will be approved by the Care New England affiliated Institutional Review Board. This study involves quantitative surveys that will be conducted electronically with at least 50 recruited and consented primary care team members participating in the TB infection ECHO course intervention. The pre- and post- ECHO course surveys and post-session surveys aim to assess feasibility of the intervention and impact – PCPs' learning and performance before and after the course. The final survey database will be coded with a unique identifier and a codesheet linking unique identifiers to participants will be locked in a filing cabinet in the PI's locked office. The unique identifier will be used to pair pre-, post-, and session surveys. Additionally, qualitative data collection via key informant interviews (KIIs) with at least 40 primary care team members will inform the course and the survey design.

b. Aim 1: Study procedures and materials - For KIIs in Aims 1 and 2, we will have participants share demographic information at the end of their interview which we will record on a tracking form. This form will collect the following demographic information: age, gender, provider type, specialty, and years out of training. Potential risks – There is a small risk of disclosure of sensitive information during KIIs during or after recorded sessions. *Minimization:* To reduce risk, participants' responses will be treated confidentially by the study team. All paper documents and/or digital recordings will be stored in locked filing cabinets in the Center for Primary Care and Prevention or on a computer requiring at least two levels of security. Due to the trusting and intimate nature of interviews, participants may wish to retract personal stories that were shared during these sessions. This will be included in the consent process. If requested by the participant during or following data collection, we will remove the sensitive material from the transcribed record and delete from the digital recordings.

Aim 2: Study procedures and materials – The TB infection ECHO course is an evidence-based, educational intervention. The ECHO course will take place over a virtual platform

(Zoom) every month for six months. Participants will receive continuing medical education credit if they attend 4/6 sessions. Clinical cases presented during ECHO sessions will be de-identified and no identifiable information will be shared with participants. All quantitative surveys will be designed and administered via qualtrics. Each participant will be asked to complete eight surveys: one pre-course, six post-session, and one post-course. Demographic information (same as in Aim 1) will be collected on the pre-course survey. Potential Risks – There is a small risk of disclosure of sensitive information during the TB infection ECHO course by participants . *Minimization:* To reduce this risk, standard ECHO procedures will be followed and clinical cases will be reviewed by the ECHO coordinator, content expert, and/or principal investigator prior to the session to ensure no identifiable information is included.

Aim 3: Study procedures and materials – For the retrospective EMR data query, two clinic sites will be chosen. In order to explore this EMR data query, we are acquiring a de-identified database from BVCHC, obtained via the terms of the data agreement plan, in order to assess preliminary LTBI testing and treatment. We had several BVCHC staff participate in Aim 1 so we are hopeful that this site will include participants from the ECHO course who attended at least 4/6 sessions. the database will include provider names (not considered patient identifiers by BVCHC) which will allow linkage to ECHO provider participants. The data query will involve the variables listed in part 2 section F: Specific Procedures or Treatments. Additional de-identified variables may be added in consultation with the two clinic sites if they are important variables to consider that may impact LTBI testing and treatment. Potential Risks – There is a small risk of disclosure of PHI during the data query process. We will work closely with the clinic sites' data teams to ensure that no PHI is provided to our team during this process and will follow the procedures as stated in the data sharing agreement. The database will be kept in a password protected file on password protected computers, and only the study team will have access to it.

D. Protection of the Subject

1. Adequacy of Protection Against Risks

a. Informed Consent: Informed consent for study participation will be obtained prior to subject participation commencement adhering to Kent IRB guidelines. Written informed consent will be the preferred method of consenting process. Should the participant not be able to provide written consent, verbal consent will be obtained and documented. Informed consent will be read aloud to key informants and ECHO participants and participants will be given time to ask questions before consenting to participate. The participants will be offered a copy of the informed consent documents to keep. For Aim 2, consent forms will be embedded within the electronic survey and participants will have the opportunity to ask questions about the study via email.

b. Protections Against Risk: To minimize risks from potential disclosure of sensitive information, key informants and participants will have study procedures fully explained or described in writing before giving consent, with explanations about potential risks involved in participation. All participants will have ample time to ask questions prior to giving consent. No identifiable information will be collected during the interviews or surveys except names which will be kept in a linked codesheet and removed from the final database. All study materials will be stored either in a locked filing cabinet or electronically with two layers of security.

c. The data safety monitoring plan will be designed by the principal investigator and mentors and will be submitted and reviewed in detail by the Care New England affiliated Institutional Review Board prior to any study procedures. Only the core study team will have access to survey data and transcribed interview data. The core study team includes the principal investigator (Daria Szkwarko), mentors (Jane Carter, Roberta Goldman and Charles Eaton), and the medical student research assistant (Steven Kim). No identifiable information will be collected during interviews or survey administration. We will code interviews and surveys with a unique identifier. Enrollment log linking unique IDs to participants (in the event that we need to contact them regarding interview or survey content) will be locked in a filing cabinet. Signed informed consent forms and any other study material will be stored in a separate locked filing cabinet.

d. Qualitative data will be recorded using a digital voice recorder. Prior to interviews, demographic forms will be completed by each participant. These forms will be coded with a unique study ID. After each recording, the study team member will transfer all new recordings from the device to a password-protected computer in a locked office. The files will be labeled with the participants' unique study ID. The research assistant or the principal investigator will listen to the recording in the digital file and we will use NVivo to edit out any names or identifying information that may appear in the recordings, while incorporating unique IDs into the recordings so that participants can later be compared by characteristics. The original recordings with identifiable information will be deleted from the computer and the recording device after transcript cleaning takes place. Transcript files will be encrypted and stored securely in a password-protected file, on a password-protected computer and backed up on two password- protected external hard drives. Once analysis and research is completed, all recordings will be deleted from the computer and external hard drives.

e. Quantitative data will be collected via REDCap or comparable survey program. Survey links will be shared with participants via email. At the time of informed consent, participants will provide their unique ID to the study team which will be stored on a separate page as listed above. The data from the surveys will be auto-populated into an electronic database. Only de-identified data will be entered into survey database. The database will be exported and saved on a password protected computer with at least two layers of protection. The database will be backed up on two password protected external hard drives after each of the eight survey periods. Hard drives will be stored in the locked filing cabinet with other study material.

f. EMR data will be queried by the clinic sites' data team. We will provide them with the ECHO participant names and ask the team to code these names so that no provider names are identifiable to the study team at the time of database acquisition. BVCHC will be one of the clinic sites. The research team will acquire a de-identified database from the clinic, via the terms of the shared data agreement plan, with preliminary LTBI testing and treatment data. . The database will include provider names (not considered patient identifiers by BVCHC) which will allow linkage to ECHO provider participants. The database will be saved as a password protected file on password protected computers. The database will be backed up as explained above for the survey data.

Potential Benefits

Potential Benefits to Research Participants and Others: There will be no direct benefit to key informants. Participants who participate in the ECHO course will gain knowledge regarding TB infection testing and treatment that they may also pass on to colleagues and co-workers in their practices. If the ECHO course has a positive impact on learning and performance, this may ultimately increase the number of patients who are tested for TB infection and started on treatment. A successful ECHO course will also be an important component of an ECHO translational research framework at Brown and could be a model for future ECHO programs for other diseases in Rhode Island.

C. Risk-Benefit Ratio

Importance of the Knowledge to be Gained: This study will provide us with important information regarding the impact of the ECHO model on primary care team members' knowledge and performance regarding TB infection testing and treatment. The study will also provide, for the first time, important information about the knowledge, attitudinal, and skill gaps related to TB infection testing and treatment in primary care.

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