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Using the RE-AIM Framework to Evaluate the Programmatic Management of Latent Tuberculosis Infection in Maine

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August 24, 2021

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Abstract

Background: Treating Latent tuberculosis infection (LTBI) which is asymptomatic and a reservoir for TB disease is essential to end tuberculosis. This project focused on identifying gaps in programmatic management of LTBI in the state of Maine and the creation of minimum data metrics to serve as a framework for potential quality improvement initiatives.

Methods: Participants included Maine Medical Center/TB Clinic, referring primary care sites, their staff, and the Public Health Nursing Central Referral Office. The number of referrals to TB Clinic, number of attendances, number of individuals diagnosed and prescribed with LTBI treatment, number of treatment initiations, number of treatment refusals, number of clients lost to follow-up were retrospectively collected from existing published reports and electronic medical records for 2019. An online survey monkey was used to collect data from partner organizations.

Results: A total of 169 LTBI cases were identified where individual were diagnosed and prescribed treatment by Public Health. The level of adherence to LTBI treatment was 38% which is low, but consistent with average rates in the United States. In the online survey staff had adequate knowledge about LTBI (100%) on integration of preventive therapy and TB disease treatment and 80% agreed that follow up after referral is the primary care provider's responsibility. Identified barriers included lack of a structure, resources, and follow-up systems to ensure optimal outcomes along with lack of recognition of the importance of screening and management of LTBI in the medical community. Most respondents (80%) were supportive of LTBI awareness raising interventions, particularly migrant communities and the screening of new immigrants without delay. Reach scored low for awareness and screening with a lack of data on outreach to at-high risk groups and effectiveness due to lack of a strategic plan and budget.

Conclusion: Adequate planning, implementation and evaluation that apply systems thinking, sector wide approach, data and implementation sciences are needed to narrow identified performance gaps. Additional resources are needed in terms of policies, guidelines and human infrastructure for the state's monitoring and treatment of LTBI.

Keywords: latent tuberculosis infection, treatment, cascade of care, gaps, compliance

Introduction

Many immigrants come from low-income countries such as communities in Sub-Saharan African & Asian countries, seeking asylum and others seeking a better life through the Green Card Lottery (Ramos, Pinargote, Navarrete-Muñoz, Salinas & Sastre, 2017). They tend to have low socioeconomic status and poor education levels resulting in low health literacy (Moriarty et al., 2019). These immigrants also face health challenges associated with the migratory process from their native countries to host countries including non-communicable diseases, infectious diseases, malnutrition and mental health conditions including post-traumatic stress disorder (Abbas et al., 2018).

When resettled in the United States, immigrants are not able to take full advantage of available community resources due to limited English proficiency (LEP), cultural barriers and lifestyle transition in regard to nutrition and the health care system (Vargas, 2017). Immigrants may experience a healthcare system characterized by lack of resources that only allows healthcare professionals to address immediate health problems with no prevention, early detection, ongoing management of chronic and/or asymptomatic health conditions, or emphasis on self-care (Merson, Black & Mills, 2006).

In low-income countries infectious diseases such as malaria, tuberculosis, HIV/AIDS, cholera are more prevalent compared to the United States, whereas non-communicable chronic diseases such as diabetes, high blood pressure and heart disease are the most significant public health problems (Nugent, Husain, Kostova & Chaloupka, 2020). In high-income countries, the health system puts a significant focus on preventing diseases through preventive care including immunization, early detection, and diagnosis as well as the treatment of asymptomatic health

conditions that constitute a potential threat to the public health such as LTBI (Kahwati et al., 2016).

Background

Tuberculosis (TB) is one of the ten leading causes of death and the leading cause from infectious diseases worldwide (World Health Organization [WHO], 2018). Almost two billion people are infected with latent *Mycobacterium tuberculosis* globally (Oxlade et al., 2019). However, less than 5% are screened, diagnosed and treated to prevent active TB infection (Alsdurf, Chill, Matteelli, Getahun & Menzies, 2016). This leaves more than 95% of those with latent tuberculosis as a reservoir for new TB cases globally.

Five to 10% of people infected with latent TB infections (LTBI) are likely to develop active TB disease in their lifetime, usually in the first five years of the initial infection (WHO, 2018). While all countries are affected, LTBI disproportionately affects two-thirds of people living in only seven countries: India, China, Philippines, Pakistan, South Africa, and Nigeria (Floyd et al., 2018). Due to the migratory movement, LTBI is not only a major public health problem for these countries with high TB burden but extends to the high-income and low TB burden countries. People from high TB areas visit and/or resettle to low TB burden countries for protection of human rights, income improvement and better education.

Migrants account for 65% of all active TB cases in Canada, and most of these active TB cases are from "the reactivation of latent tuberculosis infection (LTBI) or inactive TB, post immigration" (Milinkovic et al., 2018, p. 82). Optimal management of LTBI is a key strategy to control the TB epidemic.

This is corroborated by the study of Jagger et al. (2018), which revealed that treatment of LTBI reduces the risk of disease reactivation by 60% to 90%. However, while the public health community is aware of the TB-LTBI interconnectedness, lay individuals and communities are not, especially those from high TB burden countries in which LTBI is not incorporated in a typical TB control program (Mumpe-Mwanja et al., 2015). Consequently, they are reluctant to cooperate with care throughout the cascade of management of LTBI mostly because of lack of knowledge about this asymptomatic health condition and its potential progression to active TB (Sánchez et al., 2016).

In a study conducted by Alsdurf et al. (2016), losses and drop-outs of individuals were noted at sequential stages of LTBI management including: a) screening, b) referral of clients with positive results to TB Clinic settings for chest x-ray/liver function tests, medical evaluation, active TB rule out, LTBI diagnosis and treatment initiation, c) referral to Public Health Nursing (PHN) for education, treatment safety/compliance monitoring, and d) treatment completion (Alsdurf et al., 2016).

In the United States, the actual completion rate of LTBI treatment is low, between 31-59% (McClintock et al., 2017). To address this issue, there is a need to identify possible causes and factors of such a gap by determining and analyzing, in addition to client-related factors, performance gaps at each stage of the cascade of care.

Problem Statement

Latent tuberculosis infection is prevalent among immigrants from low income and high TB burden countries such as Asian and Sub-Saharan African countries (Harries et al., 2019). While 5-10% of infected people are likely to progress to active TB in their lifetime, usually the

first five years of the initial infection (WHO, 2018), they are noted with poor adherence to the preventive therapy (Eastment et al., 2017). This is due to the lack of a consistent strategic plan to control LTBI in the state of Maine.

Organizational "Gap Analysis of Project Site"

Latent Tuberculosis Infection management is noted to have a poor completion rate associated with clients' suboptimal adherence coupled with problems with programmatic management. Having data about losses and drop-outs at each stage can help care providers and policy makers reflect on underlying causes and factors prior to directing corrective measures to improve the management of LTBI. The TB Clinic has no program evaluation and reporting system in place, system that could enable a monitoring process and outcome data. It is very hard currently to obtain data such as number of: referrals, attendances, LTBI cases, LTBI cases started on treatment, discontinued treatments for medical reasons or medication intolerance, those lost to follow-up, and treatment completions.

In the Maine Center for Disease Control and Prevention (MECDC), the management of LTBI is not effective because of lack of data collection and analysis that could help determine performance gaps for eventual corrective measures. The Maine Reportable Infectious Disease Summary 2018 reports 375 LTBI cases with no detail on the number of clients initiated on treatment, the number of those who dropped out or discontinued treatment for medical reasons and those who adhered and completed the treatment (MECDC, 2018).

Although these data are important in the planning and implementation of health interventions targeting LTBI, they are not enough to effectively manage LTBI. Information about compliance rate with and/or treatment completion rate is also needed as consistent and

quality data availability is a key element of the optimal management of LTBI (Essue, Milinkovic & Birch, 2018).

Review of Literature

The purpose of this review of literature of evidence-based interventions was to determine gaps in the cascade of care in programmatic management of LTBI (PMLTBI) and corresponding indicators prior to creating a minimum data metrics for optimal PMLTBI. This review was intended to identify the best evidence-based solutions to address the actual management of LTBI in the state of Maine.

Literature Review Strategy

The search of the literature for evidence included these databases: Cumulative Index of Nursing and Allied Health Literature (CINAHL) and PubMed of the National Library of Medicine. Medical Subject Headings (MeSH) terms used were for CINAHL included: *latent tuberculosis infection, adherence, compliance, cascade of care, randomization, and evidence-based intervention.* For PubMed database, MeSH terms used were: *latent tuberculosis infection, treatment, cascade of care, management, gaps, monitoring evaluation and policies.*

Twenty-seven articles were retrieved with 17 from PubMed and ten from CINAHL. Inclusion criteria were full text articles published in English language. Consistent with the recommendation for updated evidence in the management of health conditions, and TB/LTBI, study articles were selected from the last five years. Exclusion criteria were non evidence-based interventions, non-English language, meta-analysis review articles.

Upon reviewing abstracts and methods, some articles were eliminated due to lack of evidence-based practice process resulting in ten articles which were consistent with certain

criteria such as PICO (Population-Intervention-Comparison-Outcome) questions, randomized controlled trials (RTCs), non-randomized prospective comparative studies of interventions, prospective longitudinal observational studies, retrospective studies, and cross-sectional Knowledge, Attitudes and Practices survey.

Two systematic reviews were reviewed. The first one (Stuurman et al., 2016) reviewed articles on interventions for improving adherence to LTBI treatment while the second reviewed studies particularly focused on initiation and completion rates for LTBI treatment (Sandgren et al., 2016). Study three aimed to understand auxiliary primary healthcare workers' knowledge, attitudes and practices on contact investigation in Brazil.

The third study was a cross-sectional knowledge, attitudes and practices survey was conducted on transmission and prevention among 135 auxiliary healthcare workers (AHWs) in three high TB burden Brazilian cities (Trajman et al., 2019). The article was consistent with the state of health care professionals' knowledge, skills and attitudes in the management of LTBI. The fourth study was an opinion piece on LTBI by two respected public health authorities. The goal was to provide the justification for scaling up TB preventive therapy (TPT) in high TB burden countries. The article focused on high TB burden countries and cascade of care of the PMLTBI (Churchyard & Swindells, 2019).

The fifth study was an evaluation of LTBI surveillance Peel region of Ontario, where half of the population is foreign-born. The study's aim was to formulate recommendations to improve surveillance for Peel region through assessment of data quality and usefulness (Majerovich et al., 2017). The key outcome of the study was the standardization of data entry processes and continuation of direct follow-up with LTBI clients to improve treatment completion rate, which aligns with one of the proposed DNP project's expected outcomes. The sixth selected article

(Hannah & Dick, 2020) was a paper that used an LTBI cascade of care framework to identify gaps in the quality of LTBI management with the goal to address barriers to optimal LTBI management.

The seventh article selected was about a web-based survey in the WHO's African Region involving forty-seven countries conducted between November 2016 and April 2017 regarding policies and practices on the PMLTBI (Sulis et al. 2018). The findings explain the reluctance to adhere to LTBI management on behalf of immigrants from Africa in our public health nursing practice. Similarly, the eight study is about policies and practices on the PMLTBI at the global level (Hamada et al., 2016). Given that the United States is a nation where nearly all nations are represented, the findings are prone to provide information on current control of TB through LTBI management worldwide.

The ninth article is about LTBI management's WHO guidelines for low TB burden countries (Getahun et al., 2015). The article provides key components of the cascade of the PMLTBI in high-income and low TB burden such as the United States. The article is relevant to this project as the reference to the RE-AIM evaluation that examined all components of the PMLTBI through its five dimensions RE-AIM (Reach-Effectiveness-Adoption-Implementation-Maintenance).

The tenth study selected was conducted in the remote arctic region of Canada of most Inuit population with the highest incidence of TB in Canada (Pease et al., 2019). The study's aim was to identify factors associated with non-initiation and poor completion of LTBI treatment. Its findings can provide information on how to proceed to identify barriers to adherence to LTBI management prior to recommending tailored solutions. For evaluation and critique of the

evidence, the Johns Hopkins Evidence Level and Quality Guide was used (See Appendix A for Literature Review Matrix).

Global Significance of LTBI

Latent tuberculosis infection is a global public health problem. It is estimated that nearly one-quarter of the world's population is infected with dormant *Mycobacterium tuberculosis* (Hannah & Dick, 2020). While this is an asymptomatic and non-contagious health condition, it is a potential public health threat since the lifetime risk of reactivation TB for a person with documented LTBI is between five and 10%, with the majority developing TB disease within the five years after initial infection (Getahun et al., 2015).

Once LTBI progresses to active TB, those infected people become sick and spread *Mycobacterium tuberculosis* to other people. Therefore, diagnosing and treating people infected with latent TB is a preventive measure and a key component of the "End TB Strategy" (Trajman et al., 2019) as evidenced by 60-90% efficacy of existing LTBI preventive treatment regimens (Getahun et al., 2015).

Global Disparity in the Management of LTBI and Consequences

Although LTBI is a global public health, it is unequally distributed across the world with low and high burden countries. The greatest burden of TB is found in Southeast Asia, Western Pacific and Sub-Saharan countries (Churchyard & Swindells, 2019). Consequently, the greatest burden of LTBI is in those regions given the interconnectedness of the two conditions. For example, in the sole WHO African Region (AFRO) made with 47 countries there are over 25% of global TB, which implies the existence of significant LTBI cases (Sulis et al., 2018). However, the WHO's recommendations to diagnose and treat LTBI are extended to only high-

risk groups in low TB burden countries, limited to only immunosuppressed individuals and children < 5 years old exposed to household TB case index in high TB burden countries (Getahun et al., 2015). Such paradoxical guidelines are susceptible to jeopardize the "End TB Strategy" in the setting of globalization, international trade, travels and the unstoppable migration movement of people from low-income and high TB/LTBI burden countries to high-income and low TB/LTBI burden countries.

Barriers to Optimal Treatment Initiation, Adherence and Completion

In most low-income and high TB burden countries, LTBI is not included in the national TB programs (Mumpe-Mwanja et al., 2015). This is not only a barrier to screen, diagnose and treat LTBI, but also to develop a human capital for the programmatic management of latent tuberculosis infection (PMLTBI). Trajman et al. (2019) conducted a study to assess knowledge, attitudes and practices regarding contact investigation among 135 AHWs in three high TB burden Brazilian cities. The researchers found 64% were not able to provide the difference between LTBI and active TB, 63% had no knowledge about LTBI diagnosis and 52% didn't know how to prevent reactivation to TB disease. It was also found that LTBI clients with higher risk of progression to active TB, such as people with HIV co-infection, were noted with higher initiation and completion rates perhaps because they perceived benefits of preventing TB-HIV/AIDS co-infection (Sandgren et al., 2016).

Inadequate education of LTBI clients on potential risk factors for progression to active TB, such immunosuppressive diseases, health conditions, medications, is a further barrier to initiation, adherence and completion of treatment is obviously a problem. Similarly, longer medication regimens, patient-related behavior, low socioeconomic status, inadequate case

management and overestimation of possible side effects such as hepatotoxicity stand as important barriers (Stuurman et al., 2016).

A lack of policies and practices on the PMLTBI constitutes a significant barrier to optimal management of LTBI (Sulis et al., 2018). While there were no financial reasons, most of the 47 countries of the WHO African Region were found with no LTBI guidelines. Thus, LTBI diagnosis is not based on routine testing methods such as the tuberculin skin test (TST) or interferon gamma release assay (IGRA), but clinical evaluation (Sulis et al., 2018). In low TB burden countries, which are expected to expand screening, diagnosing and treating LTBI to all risk groups consistent with the WHO guidelines, 8.1% did not provide LTBI preventive treatment to child contacts to household TB cases and people living with HIV (PLHIV). Similarly, among countries that had both policies and practices of management of LTBI for at risk populations, a data recording and reporting system was only available in 62% and 53% respectively for child contacts and PLHIV (Hamada et al., 2016).

Cascade of Care in the Programmatic Management of LTBI in Maine

The programmatic management of LTBI includes sequential steps of the cascade of care. However, there exist various cascade of care frameworks. Getahun et al. (2015) limits the cascade of care to five logical steps: 1) identification and prioritization of high-risk groups; 2) testing individuals with high risk for LTBI reactivation; 3) treatment initiation; 4) treatment completion; and 5) monitoring the development of active TB during and after completion of LTBI treatment.

For Alsdurf et al. (2016), the cascade of care includes seven logical steps, namely: 1) identification of high-risk groups; 2) testing; 3) provision of test results; 4) referral for medical

evaluation if tested positive; 5) medical evaluation; 6) education and recommendation for LTBI treatment; 7) treatment initiation; and 8) treatment completion.

From these two LTBI cascade of care frameworks, similarities and differences emerge and neither is complete (Churchyard & Swindells, 2019). Some population groups such as immigrants from high TB burden countries or homeless groups are known to be of high-risk for TB and LTBI. Thus, there is a need to conduct awareness educational sessions prior to embarking on screening and testing because people need to know why they are suspected as high-risk groups, what needs to be done and consequences of doing nothing for individuals, families, communities and populations.

Therefore, the complete cascade of care for the PMLTBI includes additional components to aforementioned frameworks as follows: 1) identification of high-risk groups; 2) awareness education sessions; 3) testing; 4) provision of test results; 5) referral for medical evaluation if positive result; 6) medical evaluation; 7) education of diagnosed individuals with LTBI and recommendation for treatment; 8) treatment initiation; 9) education reinforcement and medication safety and compliance monitoring; and 10) treatment completion (Sandgren et al., 2016). At each step there may be corresponding process and outcome indicators. Monthly review and evaluation public health nursing meetings are required to assess eventual gaps for timely corrective measures.

In summary, this review provided information about solutions that can be used to address the programmatic management of LTBI. Barriers to optimal management of LTBI, determinants of successful management of LTBI and various frameworks susceptible to influence the management of LTBI were reviewed. However, the identification of gaps in the PMLTBI requires a proven evaluation framework. Thus, the RE-AIM framework will be used. Used to

report findings from health research in the beginning, the RE-AIM framework evolved and is currently used at all stages of the project cycle – that is, planning, implementation, and evaluation (Gaglio, Shoup & Glasgow, 2013).

The RE-AIM Framework

The evaluation of the PMLTBI in Maine will use the RE-AIM framework which uses five dimensions: Reach-Effectiveness-Adoption-Implementation-Maintenance (Bhuiyan et al., 2019). The use of RE-AIM framework evaluates the intervention fidelity to determine whether the program implementation plan was delivered as planned. However, the intervention fidelity cannot be evaluated if all or almost all RE-AIM framework's dimensions are not used to evaluate how the intervention was delivered (Kessler et al., 2012). The RE-AIM evaluation plan includes the following:

- Reach is used to measure the absolute number, proportion and representativeness of people willing to participate in a program
- **Effectiveness** measures the impact of a program on outcomes such as potential negative effects, quality of life and economic outcomes
- **Adoption** measures the absolute number, proportion and representativeness of settings and staff willing to start a program
- **Implementation** measures the consistency of delivery as planned and the time and cost of the intervention
- Maintenance measures the institutionalization level of a program in the routine organizational practices and policies. At the individual level, maintenance is measured as

the long-term effects of an intervention on outcomes at least at 6 months after the most recent exposure to the intervention (Gaglio, Shoup & Glasgow, 2013).

The RE-AIM Evaluation Plan

For the evaluation of the PMLTBI in Maine, the RE-AIM framework will be used to identify performance gaps in the management of LTBI and associated factors. A mix of quantitative and qualitative data will be collected to identify performance gaps and answer the question of how to pave the way for possible change in future (Green & Thorogood, 2018). The application of the RE-AIM framework, inspired by the UPSTREAM program's guide (2016), is displayed in the appendix B.

Methods

This Quality Improvement Project was implemented at Maine Medical Center/Tuberculosis Clinic (MMC/TB Clinic), one of few PMLTBI settings in Maine. It is staffed by two infectious disease and internal medicine physicians, one pulmonary medicine specialist and one experienced nurse who, in addition to infectious diseases, has a wealth experience in public health nursing (PHN).

The project population consisted of individuals referred by Employee Health and Maine Medical Partners, that is, primary care settings around MMC in Portland, ME and its surrounding communities. Referrals included individuals who tested positive with TST or IGRA for medical evaluation consisting of CXR and physical exam to rule out active TB and diagnose LTBI prior to initiating preventive treatment. These were mostly foreign-born individuals from high TB burden countries and several US-born citizens infected consistent with travels to high TB burden countries or TB cases contacts. For reference and understanding, once LTBI treatment is

recommended by MMC/TB Clinic, a referral is sent to TB Control and PHN Division. As the MMC/TB Clinic is a component of the Maine PMLTBI system, it is worth describing performance gaps across Maine.

Performance Gaps in the Programmatic Management of LTBI in Maine

The MECDC has a TB Control Program that oversees all activities aimed at controlling TB through prevention and treatment of TB. In addition to the identification of TB cases, directly observed therapy (DOT), isolation of infectious respiratory TB patients, contact tracing, screening, diagnosis and prophylactic treatment, TB Control runs a programmatic management of LTBI that expands screening, diagnosis and treatment to all risk groups for TB/LTBI according to WHO guidelines (WHO, 2018). Nonetheless, the management of LTBI is not supported by data that could help determine the performance level at each stage of the cascade of care for possible corrective actions.

For instance, the Maine Reportable Infectious Summary 2017 presents 647 LTBI cases with no break down into the number of clients initiated on treatment, the number of lost to follow-up, discontinued treatment for medical reasons and those who adhered and completed the treatment (MECDC, 2018). Similarly, in Maine Surveillance Report 2018, there were 375 patients diagnosed with LTBI. This number was broken down into clinical characteristics such as treatment type, immunity status, substance abuse, risk factor and racial and ethnic groups (MECDC, 2018) with no mention of the number of individuals screened and tested, percentage of individuals who received a test result, percentage of referred individuals for positive result, percentage of referred individuals who completed medical evaluation, percentage of people with recommended LTBI preventive treatment, percentage of people started on treatment, percentage

of drop-outs, lost to follow-up or discontinued treatment for medical reasons or percentage of treatment completion (Hannah & Dick, 2020).

These gaps at all sequential steps of the continuum of PMLTBI are structural barriers at the foundation of the public health pyramid, that is, infrastructure services (Issel & Handler, 2018). For instance, there is no standardized evaluation and reporting system established by Maine TB Control Program (MECDC, 2020). Therefore, a standardized and agreed upon minimum data metrics for the PMLTBI is needed to improve TB control in Maine (See Appendix C).

Measurement

To measure the outcomes of the DNP Project, the following data were collected:

- Baseline data such as number of referrals to TB Clinic, number of attendances, number of referrals diagnosed and prescribed with LTBI treatment, number of treatment initiation, number medication adherence, number of treatment discontinuation for medical reasons or intolerance, number of lost to follow-up, number of treatment completion and number of U.S.-born versus number of foreign-born with LTBI were collected through the review of existing PMLTBI documents and electronic medical records, online survey to collect quantitative and qualitative data from TB Clinic and referring primary care sites, and observation at the programmatic setting during my practicum (Jacobsen, 2017).
- Qualitative data collection included open-ended questions, changed to a multiple-choice questionnaire and free spaces between questions to obtain more opinions from participants, to key informants to determine challenges, barriers to optimal outcomes and strategies identified to overcome them (Kwan et al., 2019).

 A review of LTBI management-related medical records from existing electronic medical records and hard published reports for the prior one year.

Data Collection Procedure

The data collection included a survey covering all dimensions of the RE-AIM framework. A programmatic management of LTBI survey was used to collect data about the continuum of management of LTBI, and secondary data from medical records (Issel & Wells, 2018). The survey monkey was conducted online with qualitative data coming from open-ended questions and multiple-choice questions (Appendix D). The goal was to obtain the meaning of actual inconsistent PMLTBI at each dimension of the RE-AIM framework.

Data Analysis

Quantitative data were analyzed using descriptive statistics including percentages computed for care sequences. The analysis of RE-AIM dimensions – that is, Reach; Effectiveness; Adoption; Implementation; and Maintenance (Glasgow et al., 2019) used qualitative scores due to lack of quantitative data such as total number of individuals reached out for screening and number of screenings in various at-high risk groups. For data collected through open-ended questions a thematic content analysis approach was applied (Green & Thorogood, 2018).

Ethical Consideration/Protection of Human Subjects

The University of Massachusetts, Amherst (UMass) Internal Review Board (IRB) along with the Maine Medical Center/Maine Health Office of Research Compliance reviewed the proposal and IRB waivers were obtained prior to initiating the DNP Project. During the cycle of this project, that is, planning, implementation and evaluation, ethical consideration and

protections of human subjects were observed. Confidentiality and privacy were complied with according to Health Insurance Portability and Accountability Act (The Unites States Department of Health & Human Services, n.d.). Only health care providers participated in this project by answering the survey's questions.

Results

This results section will first cover the results of the online surveys and collection of state data and then apply the Reach Framework to the data collected. Due to Covid-19 context delayed review and approval of the DNP Project Proposal by the Maine Medical Center/Maine Health IRB, the project commenced in March 2021. The survey monkey (Appendix D) was sent to four primary care sites and one Tuberculosis Clinic located in the Greater Portland area, which includes the Cities of Portland, South Portland and Westbrook. The primary care sites identified for the project refer individuals suspected of having latent tuberculosis infection (LTBI) to MaineHealth's TB Clinic for diagnosis and treatment. They were few responses to the online survey even after being reminded to contribute their experience, knowledge, data, and opinions to this quality improvement project by answering the online survey monkey.

Primary care sites openly stated that requested data were not available, whereas the TB Clinic suggested that the project leader requests the authorization to get data from the MMC electronic medical record system. One primary care site sent an email to explain the inability to respond to the quantitative portion of the survey in these words: "We took a look at our LTBI data and it is going to require a lot of quality improvement work on our end to produce accurate answers to the questions you pose. These questions are ones we would love to be able to answer and hope to use to guide our own revamping of the LTBI program". In the last paragraph, the project leader was advised to contact TB control to get certain data. "We do report all of our

LTBI enrollments and completions to the TB Control Program if you are able to contact them for those numbers" (Appendix E).

Given that most questions were asked to ensure data were stored for all sequences of the cascade of care, the project leader next obtained data from the Public Health Nursing Central Referral Office, which dispatches individuals diagnosed and prescribed with LTBI treatment to field public health nurses (PHNs) in different counties across the state of Maine. Data obtained from the PHN Central Referral Office were for individuals diagnosed and prescribed with LTBI treatment in both Cumberland and York counties. These data were important because PHNs perform the following activities in the cascade of care of LTBI management (State of Maine Public Health Nursing, 2019):

- Treatment initiation
- Monitoring for safety and compliance with treatment
- Identification and reporting clients that are lost to follow-up
- Identification and reporting on clients that refuse treatment
- Determination and reporting clients who completed the treatment
- Discharge clients from the PHN Services
- Delivery of the treatment completion card.

Quantitative Data Presentation

While no quantitative data were obtained from TB Clinic or referring primary care sites, data aligning with PHNs' roles in the cascade of care were provided as shown in the table below related to clients discharged upon completion of the treatment. Data presented in the following table were obtained from the PHN Central Referral Office.

Table 1

Latent Tuberculosis Infection Treatment in Cumberland & York Counties

Care Sequences	Number	Percentage (%)
Referrals to Public Health Nursing Central Referral Office	169	100
Clients not admitted to field Public Health Nursing	54	32
Clients admitted to field Public Health Nursing	95	56
Clients discharged for non-compliance and services refusal	43	25
Clients discharged upon completion of treatment	64	67
Level of adherence to LTBI treatment	64	38

From a total of 169 clients prescribed with LTBI treatment, only 95 or 56% were referred to PHN and only 64 or 67% completed the treatment. This leaves 54 individuals or 32% were not admitted to field PHN either because they were not reachable or declined initial encounter with assigned PHNs.

Among the 95 clients who were initiated on treatment, 43 or 25% were discharged before treatment completion for non-compliance or treatment refusal. The level of adherence to LTBI treatment throughout all care sequences was 38%. The treatment completion rate represents the proportion of individuals initiated on treatment who completed it whereas the level of adherence represents the proportion of all enrollments who completed the treatment.

Clients who are referred to PHN are individuals that are diagnosed and prescribed with LTBI preventive therapy. They are different from referrals to TB Clinic from primary care sites. As for most sequences of the cascade of care, we were not able to obtain the referrals to TB Clinic. In other words, it was not possible to determine the proportion of individuals suspected with LTBI who were prescribed with LTBI treatment upon completion of medical evaluation. It

can be stated that TB Clinic's inability to provide data, which were partly provided by PHN, is a clear proof that the Programmatic Management of LTBI is marked by lack of sound structure and process to ensure data sharing between different partners for effectiveness and optimal outcome.

Regarding the level of adherence, although 38% of adherence to LTBI treatment is consistent with average rates in the United States, it is also an expression of a significant performance gap compared to the national target of 83% of LTBI treatment (Center for Disease Control & Prevention, 2015). Primary care sites, TB Clinic and PHN have shared roles in the management of LTBI and should have a collaborative framework that emphasizes the structure and process of data sharing (Zamudio-Haas et al., 2019).

For example, if an individual prescribed with LTBI preventive treatment is lost to follow-up or refuses to initiate treatment, the assigned PHN needs to notify TB Clinic, which would notify the referring primary care provider (PCP) to help get the individual back to the PHN for treatment initiation and monitoring. The relationship between the client and PCP is an existing and trusting relationship, which is susceptible to boost the PCP's persuasive power needed to fruitfully reinforce the client's education by both the TB Consultant and the PHN. The suggested collaborative framework of data sharing is displayed in the following figure.

Figure 1

LTBI Data Sharing Collaborative Framework between LTBI Management Partners

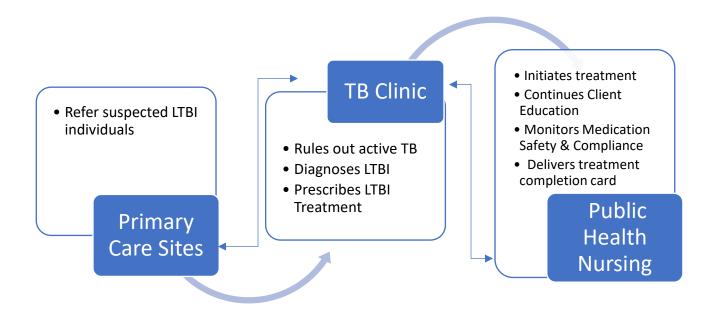


Figure 1 displays a feedback loop between key partners in the management of LTBI. For instance, if a PCP had referred an individual with suspected LTBI to the TB Clinic who did not show up to the scheduled medical evaluation, the TB Clinic needs to notify the PCP of client's non-attendance. Based on the existing care provider-consumer relationship, client may be convinced to attend the catch-up medical evaluation appointment scheduled by the TB Clinic. Otherwise, the individual will remain a suspected LTBI case.

It is important to highlight that an LTBI case who does not start on or complete an LTBI treatment plan remains an LTBI case. This makes it hard to determine the prevalence of LTBI, which equals the existing cases plus new cases (Cohen, Mathiasen, Schön & Wejse, 2019). In addition to cascade of care-related questions that were not answered, questions about the number of U.S.-born versus foreign-born and questions about the cost of the programmatic management

of LTBI were not answered either. It is worth noting that lack of birthplace data reveals suboptimal effectiveness of the management of LTBI, as it undermines outreach- and awareness-raising interventions targeting specific populations at high risk for LTBI, such as recent immigrants from high TB burden countries/areas of the world (Essue, Milinkovic & Birch, 2018).

These public health interventions are required for effective and efficient LTBI management. Regarding lack of annual budget data for a program that utilizes 3 TB consultants and 1 nurse, it can be stated that the hidden cost of all activities performed by the entity is prone to jeopardize the effectiveness and sustainability of the management of LTBI. Similarly, it can be argued that the programmatic management of LTBI runs less as a public health intervention but a routine medical activity. Regarding priority needs to maintain and improve the LTBI management, one administrative staff suggested a standardized evaluation and reporting system across the state.

Qualitative Data Presentation

The qualitative portion of the survey mostly consisted of open-ended questions phrased in statements broken down into different possible responses, which was then organized into multiple choices for participants to choose or rank their opinions. To enable participants to provide more information and opinions, some statement-based multiple choices were followed by open-ended questions. The questionnaire aimed at exploring understanding of the management of LTBI issues, eliciting opinions regarding the barriers to optimal outcomes and recommendations for quality improvement.

Regarding the level of participation, 4 responses (66%) were returned by PCS3, 1 response (16%) by PCS1 and 1 response (16%) by PCS2. For the results presentation and analysis, data were grouped into five themes that emerged from the survey. The following themes formed the basis of the thematic content analysis:

- Knowledge
- Data and responsibilities sharing
- Barriers
- Strategies
- Recommendations.

Thematic content analysis is a qualitative analysis method, which identifies recurrent concepts about opinions, experiences and beliefs expressed by participants on a particular issue (Green & Thorogood, 2018).

Knowledge

Respondents were noted to have sufficient knowledge about the reciprocal risk factor between active TB and latent TB infection. All 6 (100%) responses determined that integration of LTBI preventive therapy and TB disease treatment is the optimal approach to prevent and control TB. For the issue of significant LTBI prevalence and paradoxical suboptimal management in terms of screening, diagnosis and treatment to prevent active TB, lack of awareness in at-risk population groups (83%) was ranked first as the main reason followed by lack of consistent and standardized policies across the world (66%).

There was a divide about low appreciation of its significance in the causation of active TB (50%). Lack of sufficient resources worldwide was determined as the last reason (33.33%).

Citing lack of awareness in at-risk population groups as the main reason for suboptimal management of such a prevalent health condition ascertains a sufficient knowledge of the issue. Regarding the reason why inadequate resources are allocated to the management of LTBI, 50% of respondents contended that hesitancy about the return on investment (ROI) was the main reason. This seems to be true since assurance of the ROI could otherwise result in optimal management of LTBI.

Data and Responsibilities Sharing

While 80% of responses highlighted the PCP's responsibility to follow-up whether the referred suspected LTBI case was diagnosed and prescribed with treatment, 20% of responses agreed upon keeping a log of referrals' data, and 40% stated that referring the client to a TB specialist was the last step of the PCP's care for the client. Similarly, 40% of respondents assigned the treatment outcome such as the treatment completion to the TB consultant. It can be argued that these results align with the practice of LTBI management at the capstone project site and referring primary sites, which were noted with reluctance to answer the quantitative survey questionnaire. This also corroborated lack of the communication feedback loop to share data and responsibilities to improve effectiveness and optimal outcome.

Barriers

The following barriers were underscored by 50% of respondents:

- Transportation limitations and health literacy challenges
- Long course of treatment and potential medication side effects
- Client's poor adherence to LTBI management
- Lack of immediate clinical consequences from the client's perspective

- Need for the monitoring of blood work such as liver function tests (LFTs)
- Lack of recognition of the importance of screening and management of LTBI in the medical community
- Lack of LTBI awareness in the general population and in at-risk population groups
- Shortage of health care professionals
- Lack of a structured approach and follow-up system to ensure adequate treatment
- Competing demands of other health conditions with more resources, attention and reimbursement attached to their management.

One respondent expressed the barrier to optimal management of LTBI in these words:

"I think there is a lack of recognition of the importance of screening and management of this in our medical community as it is not something we often diagnose or see. The lack of a structured approach, protected resources, and follow up system to ensure adequate treatment and monitoring also contribute. The way our healthcare system is reimbursed also affects what conditions are optimized in terms of our focus and attention as a medical community too."

To overcome these barriers to optimal management of LTBI, strong strategies need to be developed. The qualitative survey questionnaire elicited opinions about strategies

Strategies

Two main strategies emerged from the qualitative survey responses. 50% of respondents supported that more resources be allocated to high TB burden countries whereas 100% contended that expansion of LTBI preventive therapy to all at-high-risk groups in low-income and high TB burden countries would be also beneficial to high-income and low TB burden.

Similarly, 80% of respondents were supportive of LTBI awareness raising intervention in migrant communities and screening new immigrants for LTBI without delay to protect both immigrant and host communities against TB disease.

Recommendations

The last theme is about recommendations by respondents to improve the quality of LTBI management. The following recommendations were formulated:

- Schedule PCP- client follow-up appointment to discuss any issue regarding LTBI treatment
- Share ownership between TB consultant, PHN and PCP for clients prescribed with and initiated on treatment
- Standardize tracking systems
- Improve data management of the LTBI continuum of care
- Design the management of LTBI as a data-guided program
- Develop global standardized policies for optimal management of LTBI.

Although descriptive statistics and thematic content analysis methods have been used to analyze quantitative and qualitative data, the RE-AIM framework was mainly used to evaluate the programmatic management of LTBI in Maine. The goal was to identify performance gaps that impeded the attainment of the optimal outcome at each sequence of the cascade of care. Thus, the PMLTBI was evaluated through the RE-AIM five dimensions: Reach, Effectiveness, Adoption, Implementation and Maintenance (Bhuiyan, Singh, Harden & Mama, 2019).

Application of The RE-AIM Evaluation Framework

Reach-Reach is used to measure the absolute number, proportion and representativeness of people willing to participate in a program (Sweet, Ginis, Estabrooks & Latimer-Cheung, 2014). Thus, the first and foremost question to answer was whether the PMLTBI in Maine had initiated outreach to population groups at high-risk for LTBI such as: new immigrants from high TB burden, homeless persons, pulmonary TB close contacts, prisoners and illicit drug users (Ai, Ruan, Liu & Zhang, 2016). In 2019, there were 17,995 foreign-born persons in the Cumberland County, and among them new immigrants from high TB burden countries from Sub-Saharan Africa (United States Census Bureau, 2019), and 2368 prisoners in Maine (Maine Department of Corrections [MDOC], 2020). Among those prisoners, 1397 were illicit substance users who received care and services such as medication assisted treatment, and training and education during their imprisonment with no mention of TB screening (MDOC, 2020). Similarly, 396 individuals were homeless in Cumberland and York Counties (Maine State Housing Authority, 2019). These reports do not mention any outreach intervention for TB screening except for 137 close contacts of active TB cases (Maine Tuberculosis Control Program, 2021). Lack of data on outreach for TB screening leads to believe that screening was performed on the routine medical evaluation encounters. Lack of the number of people from the LTBI high risk groups who could have participated in the screening intervention made it impossible to calculate the reach percentage (Sweet, Ginis, Estabrooks & Latimer-Cheung, 2014). Therefore, reach can only be qualitatively estimated as very low. Awareness needs assessment in various at-risk groups and potential awareness raising interventions are initial activities in public health programs that require community adherence such as LTBI management (McKenzie, Neiger & Thackery, 2017).

Effectiveness- Effectiveness refers to the impact of a program on outcomes such as potential negative effects, quality of life and economic outcomes. It was noted that the PMLTBI as implemented in the Capstone project site was not based on any strategic plan including operational plan with goals, objectives, activities, process, timeline, evaluations, process and outcome indicators or budget. The target outcome such as the rate of LTBI treatment completion was not determined. However, given the poor adherence to LTBI treatment, that is, 38% compared to the national target of 83%, it can be concluded that the PMLTBI in the Capstone project site and served counties is very low. Such a poor adherence to LTBI treatment leaves a significant number of LTBI cases untreated, 5-10% of whom could potentially progress to TB disease, thus becoming a source of more LTBI and active TB cases, deaths, poor quality of life, unemployment and increased budget burden to families, communities and society at large.

Adoption-Referred to as the proportion of possible settings and stakeholder organizations as well as staff that have adopted the program (King, Glasgow & Leeman-Castillo, 2010), adoption of the PMLTBI was deemed poor. In the Greater Portland area, there are numerous stakeholder organizations in the management of LTBI consistent with their broad interests or some influence vis-à-vis high-risk groups (Strome, 2013). For instance, the following organizations could join with healthcare settings to improve community engagement in the PMLTBI (MEDHHS, 2019):

- African for Improved Access
- Catholic Charities Maine
- Refugee Health
- Maine Access Immigrant Network
- Faith-based organizations

- Community-based associations
- City of Portland Public Health Department
- City of Portland Minority Health Program
- City of South Portland
- Community Advocate & Community Health Educator
- Cross Cultural Consulting Group
- Frannie Peabody Center
- Homeless Health Partners
- House of Languages
- School Districts in Cumberland and York counties
- Cumberland Public Health District
- Cumberland County Jail
- Maine CDC, District Public Health Liaison
- Maine Department of Corrections
- Maine Immigrant's Rights Coalition
- Maine Migrant Health
- Maine Alliance to Prevent Substance Abuse
- York Public Health District
- York County Jail
- Schools of Nursing in the Greater Portland
- The City of Portland Shelter
- Adult Education Centers
- Prebble Street Learning Collaborative

- University of New England
- University of Southern Maine
- Coastal Healthy Communities Coalition
- Sanford Community Adult Education
- Partners for Healthier Communities
- York Public Health District.

All the organizations/agencies play an important role in the well-being of members in high-risk groups. In the past and today, faith-based organization leaders believed in the integrated body and mind health model as evidenced by the Latin expression "mens sana in corpore sano" meaning "a healthy mind in a healthy body". Based on this belief, faith-based organization leaders are ready to contribute their efforts to keep individuals and communities healthy. Similarly, engagement of affected communities and their resources, in terms of cultural and linguistic brokers such as community health workers, is a necessity (LoBue & Mermin, 2017) that, unfortunately, was overlooked by the PMLTBI leadership.

Based on the absence of potential stakeholder organizations and agencies that otherwise could have joined primary care sites, TB Clinic, and the Public Health Nursing division to build a coalition, it can be concluded that the PMLTBI adoption was very low. To reverse the actual situation, a sector-wide approach is needed to streamline the PMLTBI in Maine. This approach had led to optimal outcomes in different public health interventions (Durham, Schubert, Vaughan & Wills, 2018).

Implementation-In the cycle of public health intervention this stage is preceded by planning, which determines strategies, barriers and facilitators of the implementation delivery (Smith, Li & Rafferty, 2020). Similarly, the implementation process is aligned with process of evaluation such as fidelity. (McKenzie, Neiger & Thackery, 2017). The system needs explicit goals and objectives to evaluate outcomes. Given that the PMLTBI in the project site was noted to have a poor outcome according to Federal guidelines, and that the implementation was not based on an explicit strategic plan with both process and outcome indicators, it can be concluded that the implementation was inconsistent.

Maintenance-Maintenance refers to the maintenance of the achieved outcome after 6 months at the individual level, and the sustainability of the implemented intervention at the organizational level (Sweet, Ginis, Estabrooks & Latimer-Cheung, 2014). All respondents to the online qualitative survey expressed the need to improve the quality of care and formulated recommendations toward quality improvement of the PMLTBI. However, as the five dimensions of the RE-AIM are interrelated, lack of application of the system-wide approach to set up an effective collaborative framework with key stakeholders, structure and process, was prone to jeopardize the sustainability. Therefore, there was inconsistent maintenance of the PMLTBI. Furthermore, the hidden cost of the program is likely to impede the allocation of adequate resources to potential LTBI management quality improvement interventions (King et al., 2018), thus making uncertain the program maintenance.

Upon completion of the evaluation of the PMLTBI using the RE-AIM framework in all its five dimensions, it was impossible to numerically determine levels of achievement due to lack of data such as the total number of individuals at risk for LTBI and those who participated in the screening for reach, the number of expected settings, stakeholders and staff to measure the level

of adoption of the program, lack of data in terms of process and outcome indicators, as well as lack of data on resources allocated to the program to help measure the level of consistency of the implementation delivery, to name a few.

Creation of the Minimum Data Metrics

Along with the identification of performance gaps, the creation of a standardized minimum set of data metrics was the second deliverable of this quality improvement project. The objective was to provide the LTBI management partners with a tool to continuously monitor clients' compliance levels for timely application of corrective measures and outcomes evaluation. The creation of the minimum set of data metrics enabled the collection of current data with tools developed by the project leader (Appendix G).

The process of its creation was also an educational opportunity and a demonstration that collecting data does not demand a special computer program but a routine activity with an excel spreadsheet. An excel data collection tool was distributed to both the Clinic nurse and PHN Central Referral Office. Data were collected weekly and returned to the project leader monthly from March through July 2021. Data collected from TB Clinic were about numbers of appointments for LTBI diagnosis and treatment, attendees, attendees diagnosed with LTBI, attendees prescribed with LTBI treatment.

Data collected from PHN Central Referral Office were about numbers of referrals for LTBI treatment from TB Clinic, lost-to follow up, treatment refusal, treatment initiation, discharges for non-compliance and treatment completion. For each data, numbers of US-born versus foreign-born were also requested. However, more metrics are needed from primary care sites to complete

EVALUATION OF PROGRAMMATIC MANAGEMENT OF LTBI IN MAINE

the minimum data metrics required for optimal management of LTBI: numbers of TB screenings, positive screenings, and referrals to TB Clinic.

List of Minimum Data Metrics by PMLTBI Partners

Primary Care Sites

- Number of TB screenings
- Number of positive screenings
- Number of referrals to TB Clinic

Tuberculosis Clinic

- Number of appointments for diagnosis and treatment
- Number of attendees
- Number of individuals diagnosed with LTBI
- Number of individuals prescribed with LTBI treatment

Public Health Nursing

- Number of referrals for LTBI treatment monitoring and education
- Number of lost to follow-up
- Number of treatment refusal
- Number of treatment initiation
- Number of discharges for non-compliance
- Number of discharges for intolerance
- Number of treatment completion.

To ensure optimal use of minimum data metrics, the following data and responsibilities sharing model was suggested (Appendix I).

Data Collected from March through July 2021

Consistent with the creation of minimum data metrics, current data about LTBI treatment were collected at TB Clinic and Public Health Nursing from March 2021.

Table 2

US Born versus Foreign Born

USB table # of appointments # of attendees # of diagnosed with LTBI # of prescribed with LTBI treatment # of referrals to PHN # of lost to follow-up # of treatment refusal	March 6 6 6 4 4 4 0 0 0	April 0 0 0 0 0 0 0 2 0 2 0 2	May 5 5 5 4 2 0 1	June 10 10 9 7	July 4 1 1 1 1
# of treatment initiation	3	0	1		
FB Table # of appointments # of attendees # of diagnosed with LTBI # of prescribed with LTBI treatment	March 3 3 2	April 7 7 7 6	May 10 10 10 8	June 7 6 6 5	July 4 0 0 0

Table 2 is about individuals referred to TB Clinic for LTBI diagnosis and treatment. The collection of data commenced in March 2021. The table is divided into two categories, that is, U.S.-born versus Foreign-born. The subdivision is necessary to guide public health interventions

Table 3 that follows is about the adherence and compliance with LTBI treatment. It is intended to measure LTBI treatment outcomes under various regimens such as rifampin (RIF) for 4-6 months, 3HP (isoniazid and rifapentine for 3 months once weekly, isoniazid (INH) for 6-9 months, and daily isoniazid plus rifampin (3HR) for 3 months (CDC, 2020).

Table 3
The Outcomes of LTBI treatment

The outcomes of LTBI treatment can be categorized as follows:

Results	Non- compliant	Suboptimal Adherence	Optimal Adherence	Total Completion (sub + opt)
Rifampin			2	
3НР			2	
Isoniazid				
3HR	1			
Grand Total				

- Non-compliant category is about clients unable to complete the treatment with six months for rifampin for instance
- Suboptimal adherence category is about clients who missed significant doses during treatment thus completing the treatment with rifampin, for example, after four months and before the end of the sixth month.
- Optimal adherence category is about clients who didn't miss a dose during treatment.
 Using the example of rifampin, the client would take 120 doses within four months.

Table 3 only shows data for optimal adherence to all LTBI treatment regimens except isoniazid, which is taken between 6 and 9 months to complete the treatment (CDC, 2020). This is consistent with the date of current data collection, March 2021. Therefore, the table will be filled out clients under LTBI treatment who complete or do not complete treatment in timely manner.

Discussion

The goal of this project was to improve the effectiveness of the programmatic management of LTBI in Maine through gaps identification and creation of a standardized minimum data metrics. The specific objectives with expected outcomes were formulated in the following table.

Table 4Objectives and Expected Outcomes

Objective	Expected Outcomes
Identify data required to monitor and	The list of monitoring and evaluation data
evaluate the implementation of the	was established.
programmatic management of LTBI	
(PMLTBI) by the end of September	
2020.	
2. Define key indicators to inform	Key indicators were defined to serve as the
effective implementation of the	guidepost for necessary adaptation and
PMLTBI by the end of September	change in the delivery of the PMLTBI.
2020.	
3. Determine gaps in data collection and	Gaps were determined to serve as areas for
analysis throughout the continuum of	quality improvement interventions.

	the PMLTBI by the end of October	
	2020.	
4.	Identify key stakeholders in the local	Key stakeholders were identified to facilitate
	healthcare system and other	adoption of potential public health
	organizations by the end of November	intervention to improve the delivery of the
	2020.	PMLTBI.
5.	Create a minimum data metrics to be	A minimum data metrics was created to serve
	used as gold standard method to	as a standard to monitor and evaluate the
	monitor and evaluate the delivery of	PMLTBI.
	the PMLTBI in Maine by mi-	
	December 2020.	
6.	Organize a meeting with the PMLTBI	The resulting agreed upon minimum data
	stakeholders to present and agree upon	metrics will facilitate efficiency and
	the minimum data metrics by the end	effectiveness of the PMLTBI (expected
	of January 2021.	outcome was not achieved during the project
		implementation).
7.	Apply the agreed upon minimum data	The application of the minimum data metrics
	metrics in the PMLTBI project site	will improve the PMLTBI delivery thus
	from the beginning of February	serving as the model for its application in the
	through the end of March 2021.	rest of PMLTBI across Maine (expected
		outcome was not achieved during the project
		implementation).

8.	. Evaluate the impact of the use of the	The impact evaluation findings will facilitate
	minimum data metrics on the	the understanding of the relevance of a
	effectiveness of the PMLTBI by mi-	standardized monitoring and evaluation data
	April 2021.	metrics for optimal PMLTBI delivery
		(expected outcome was not achieved during
		the project implementation).
9.	. Organize a dissemination session to	The dissemination session may result in
	adopt and expand the new PMLTBI	adoption and expansion of a standardized
	data monitoring and evaluation tool to	minimum data metrics to the entire PMLTBI
	all stakeholders in Maine	system in Maine (expected outcome was not
		achieved during the project implementation).
1		

While certain objectives were achieved some few others were not. For instance, data required for monitoring and evaluation of the management of LTBI were identified, areas of quality improvement were determined, the minimum data metrics was created, and key stakeholder organizations were identified. However, specific objectives relating to the organization of a meeting with the PMLTBI stakeholders to present and agree upon the minimum data metrics, the dissemination of the project results, etc. are planned to be achieved in near future.

While all participating primary care sites declined to respond to the quantitative datarelated questionnaire, TB Clinic minimally responded with no data on the cascade of care.

However, primary sites expressed through emails and phone communications inability to answer questions due to lack of data management structures. TB Clinic answered a few questions about

numbers of TB Consultants (3), TB Nurse (1) and administrative staff (0) as well as existence of the monitoring and evaluation system. Lack of the monitoring and evaluation system in the remaining sites was the answer.

Lack of quantitative data on sequential and interrelated steps of the PMLTBI cascade of care was consistent with inexistence of the strategic plan, delivery plan and evaluation process aligned with process and outcome indicators. This finding aligns with the 2019 TB Control annual report on LTBI (Maine Tuberculosis Control Program, 2021). The report did not include data on treatment initiation, lost to follow-up and treatment completion rate.

As discussed in the literature review section, having data about each stage of the delivery process helps care providers and policymakers reflect on underlying causes and factors prior to directing corrective measures to enhance the implementation fidelity. Strome (2013), highlighted the relevance of aligning data with indicators at all sequences of the program. In the setting of lack of data from both TB Clinic and participating primary care sites, subsequent data about referrals, diagnosis and treatment of LTBI, that is, treatment initiation, lost to follow-up, non-compliance with treatment and treatment completion were elicited from the PHN Central Referral Office. These retrospective data indicated a progressive loss with poor outcome of 38% of level of adherence to LTBI treatment. Due to inexistence of data management with process evaluation of the delivery plan, no corrective actions to improve the care delivery were taken.

For the qualitative portion of the survey, six participants answered the online survey monkey and five themes emerged from their responses: knowledge, data and responsibilities sharing, barriers, strategies, and recommendations. The thematic content analysis was applied, and primary care providers were noted with adequate knowledge about LTBI and TB. For instance, all six respondents (100%) were able to determine that the integration of LTBI

preventive therapy and TB disease treatment is the optimal approach to prevent and control TB. Similarly, 83% of participants associated lack of awareness in at-risk population groups with the main reason of poor adherence to the management of LTBI. This aligns with what was underscored in the literature review with regard to barriers to optimal treatment initiation, adherence, and completion. It was found out that, in most low-income and high TB burden countries, LTBI was not included in the national TB programs (Mumpe-Mwanja et al., 2015), thus resulting in lack of awareness of LTBI and potential consequences for immigrants even when they are resettled in high-income countries where LTBI management is incorporated in the TB control programs (Centers for Disease Control and Prevention, 2020).

Regarding data and responsibilities sharing, although 80% of responses highlighted the primary care provider's responsibility to follow-up their clients diagnosed and prescribed with LTBI treatment, 40% of respondents stated that referring clients suspected with LTBI was the last step and that they had no responsibility about the outcome. The primary care provider's perception is consistent with the literature review finding. It was noted that lack of policies, procedures, and practices in the management of LTBI stands as a significant barrier (Sulis et al., 2018).

The theme of barriers produced a long list including poor health literacy, lack of recognition of the importance of screening and management of LTBI in the medical community, lack of structured approach and follow-up system to ensure adequate treatment to name a few. These barriers were noted at the project site. There was only one weekly TB Clinic medical evaluation from 8 am to 12 pm. Two or three TB Consultants conducted medical evaluation, diagnosed, and prescribed LTBI treatment. This result is consistent with the literature review findings about the cascade of care, which is limited to less than required sequences (Getahun et

al., 2015). The allocation of few hours to the TB Clinic aligns with increased responsibilities of care providers who most of times work in various healthcare settings.

For the theme of strategies, two main strategies were determined by respondents. 50% of respondents were supportive of the increase of resources allocated to low-income and high TB burden countries whereas 100% of respondents supported the expansion of LTBI preventive therapy to all at-risk groups in those countries. 80% of respondents suggested LTBI awareness-raising interventions as a solid strategy. Suggested strategies could reverse the global disparity in the management of LTBI partly caused by the WHO's paradoxical guidelines that limit LTBI diagnosis and treatment to only immunosuppressed individuals and children < 5 years old exposed to household TB case index in high TB burden (Getahun et al., 2015).

To improve the quality of the PMLTBI respondents formulated the following recommendations:

- Share ownership between TB Consultants, PCPs & PHNs for clients prescribed with
 LTBI treatment and admitted to PHN services
- Design the PMLTBI as a data-guided program
- Develop global standardized policies for optimal control of LTBI
- Engage communities through partnerships with community groups
- Develop an information technology infrastructure to support data management and sharing across LTBI treatment partners.

These recommendations from participating primary care sites align with the global significance of LTBI. It is a global public health problem affecting one-quarter of the world's population, thus requiring an adequate global response (Hannah & Dick, 2020).

Upon completion of data analysis, the RE-AIM framework was applied, in all its five dimensions, to evaluate the PMLTBI.

Reach was used to measure to what extent people participated in the screening intervention for LTBI diagnosis. It was found that no intentional awareness raising intervention to promote informed decision making to participate in the management of LTBI was conducted. This confirms what was determined in the literature review about the cascade of care in the management of LTBI. Most of times, the actual cascade of care excludes the awareness raising campaign in the at-high risk population groups such as recent immigrants from high TB burden countries, homeless persons, prisoners and illicit drug users (Ai, Ruan, Lin & Zhang, 2016). In our search for data regarding the reach, we found out that only 137 pulmonary TB close contacts were reached across the state of Maine in 2019. In the setting of lack of data on other high risk groups to serve as the denominator, and lack of total number of people who participated in the screening event to serve as the numerator, it was impossible to calculate the score. Nonetheless, PCPs occasionally screened people from high-risk groups during routine medical evaluation. Therefore, the reach was scored as very low.

Effectiveness is defined as the impact of a program on outcomes such as potential negative effects, quality of life and economic outcomes. It was found out that potential consequences were likely. The PMLTBI outcome in the project site area was poor as evidenced by 38% of adherence to treatment versus the national target of 83%. Lestari et al. (2019) contended that adequate treatment of 35 LTBI cases prevented 1 case of TB disease. In other words, ineffective PMLTBI will likely result in several TB cases and corollaries such as premature deaths, poor quality of life, unemployment, social isolation to name a few.

Adoption was used to evaluate to what extent the PMLTBI engaged possible healthcare settings and stakeholder organizations. It was noted that the program leadership failed to strategically utilize the sector-wide approach and systems thinking to set up a multisectoral and multidisciplinary coalition susceptible to synergize their efforts and resources to control LTBI. Effective management of LTBI needs to build a more inclusive coalition of local community associations, faith-based organizations, Maine Access Immigrant Network, Maine Catholic Charities, Portland Public Health Division, Portland Minority Health, etc. In the setting of lack of possible healthcare settings and stakeholder organizations that could serve as the denominator to help calculate the adoption percent, a non-numeric but qualitative score of very low was given to the adoption dimension.

For the *implementation* dimension, no data was elicited from the online survey monkey or secondary data regarding the strategic plan, the delivery plan, the evaluation process, or the cost of the PMLTBI. This corroborated earlier observation mentioned in the problem statement that PMLTBI was not based on a consistent strategic plan to control LTBI in the state of Maine.

The examination of *maintenance* of the achieved outcome at both individual level and organizational level showed that the program sustainability is uncertain. Primary care providers expressed the pressing need to improve the quality of care and formulated recommendations towards quality improvement of the PMLTBI. However, it is less certain that these recommendations will be capitalized without an agreed upon structure, process, and outcomes system to enhance the management of the program. Failure to increase the adoption level of the program had a significant negative impact on the maintenance, and there is a need to create an effective multisectoral and interprofessional collaborative framework that will lead to a more encouraging outcome, which individuals and organizations would maintain and sustain.

During the implementation and evaluation of this project, there were barriers that were thought of being insurmountable. Most of barriers were covid-19 context-based. For example, the review of the proposal by the Maine Medical Center/MaineHealth Office of Research Compliance – IRB took more than 2 months. Similarly, inability to organize in-person meetings to provide more information about the relevance of the project and related survey questionnaires was another barrier. Nonetheless, there were facilitators that helped us keep working on the project. Faculty members, particularly the advisor, were supportive and had a wealth experience about the project and possible barriers.

Similarly, the principal mentor Dr. DeMatteo, C. and mentor Dr. Agmas, W. were very supportive. They tirelessly followed up the evolution of the proposal approval. They also made follow-up phone calls to participating primary care sites in the case of unsuccessful phone calls by the project leader. The other facilitator was the active presence of the project leader as a resource person in the Greater Portland health care community. He worked as a medical interpreter for more than 15 years, a nurse for almost 14 years and a PHN for 9 years as well as and an initiator of public health interventions such as African Health Classes, focused on non-communicable chronic health conditions, in 2010 and LTBI Awareness Raising Workshops for immigrants in 2018. For example, the project leader was able to obtain retrospective data from the PHN Central Referral Office. This was done to bypass the inability to get retrospective data from the project site.

Setting Facilitators and Barriers

The TB Clinic is a component of the MMC International Medicine Clinic and is a major facilitator of the DNP project. The project was performed under the mentorship of Christina DeMatteo, MD, the internal medicine and infectious disease specialist. Furthermore, the process

of cooperation and a related collaborative framework formulation between TB Clinic and the Portland PHN Office is underway.

The evaluation of the PMLTBI faced barriers such as some delay consistent with administrative and operating procedures of the setting about the approval of the proposal (Bamberger, Rugh & Mabry, 2012). Similarly, the project could have faced barriers in terms of fear of plausible additional workload and incurred costs to the setting. However, the nurse leader communicated the benefits of the project to all parties involved and obtained buy in and support (Issel & Wells, 2018).

Cost-Benefit Analysis

The PMLTBI prevents TB disease in latently infected individuals and the public by averting its reactivation to TB disease. In 2017, 1.7 billion people were infected with latent TB from whom 10% are likely to progress to TB disease in their lifetime, thus becoming a risk factor for further TB diseases and LTBI. Similarly, in 2017, 1.6 million of the global population died from TB (Churchyard & Swindells, 2019). Therefore, the PMLTBI is a key strategy to avoid TB and related costs, morbidity, deaths, disabilities, poor quality of life and low productivity (Campbell, Sasitharan & Marra, 2015).

However, these benefits depend on the effectiveness of PMLTBI and the resulting optimal preventive treatment completion rate (Johnson, Churchyard, Sohn & Dowdy, 2018). In one study, the comparison of cost of the management of LTBI with the cost of treating TB disease revealed that treating one LTBI case was nearly eight times less expensive than treating one active TB case (€1938 vs €15,489) (Haukass, Arnesen & Winje, 2017). From these findings, it can be stated that the DNP proposal is cost-benefit consistent with its goals to identify the

PMLTBI gaps and create a minimum data metrics for effective management and optimal outcome achievement. As earlier indicated, in 2018, 375 people were diagnosed with LTBI in Maine. However, the report misses data about treatment initiation, lost to follow-up and treatment completion rate. Therefore, contributing to the improvement of the PMLTBI in Maine will make it more cost-effective and cost-benefit.

Project Cost-Benefits

(Appendix H).

In a study conducted by Goodell et al. (2019) about the cost of TB testing and treatment compared to targeted testing and treatment (TTT) for those with LTBI, it was found out that from 2017 to 2065 the cost will be \$12 billion. Increasing the uptake of TTT resulted in higher testing and LTBI treatment costs and a reduction in TB disease costs: treatment of active TB will cost \$1.4 billion, while treatment of LTBI will cost \$0.6 billion. Thus, the benefit in terms of dollar equals the sum of TTT resulting TB disease cost and LTBI management cost (\$1.4+\$0.6=2.0 billion) subtracted from 12.0 billion, which is \$10 billion. If we use the cost of \$1.4 billion for active TB treatment and \$0.6 billion for LTBI treatment, the ratio is 1.4:0.6=2.33333 rounded to 2.4. Therefore, for \$1 of LTBI there are \$1.4 saved in addition to additional innumerable benefits such as better quality of life, prevented deaths, avoided unemployment, social isolation, stigma, reduction of TB incidence and LTBI incidence, economic gains for the individual, the family, the community and the society at large.

Applying this scenario to the DNP proposal that will ultimately cost \$2,040 and given that \$1 of LTBI management cost result in \$1.4 saved, the project will save \$2,040 x 1.4 = \$2,856

Conclusion

Immigrants from low-income and high TB burden countries continuously resettle in high-income and low TB burden countries such as European nations, Canada, and the United States. Consistent with lack of awareness about LTBI, and cultural and linguistic barriers, immigrants don't take full advantage of available resources to control LTBI. During the implementation and evaluation of this quality improvement project, the focus was on the programmatic management of LTBI. It was noted that there was no consistent strategic plan to control LTBI in the project site area and probably across the state of Maine. This key finding was determined using the RE-AIM framework, which revealed low scores throughout its dimensions: Reach, Effectiveness, Adoption, Implementation, and Maintenance. Similarly, lack of retrospective data throughout all logical sequences of the cascade of care at the project site is a manifestation of poor LTBI management and a missed opportunity to align the program with the "End TB Global Goal".

In the setting of poor data management for such a data-guided program, the minimum data metrics were created. Despite identification of performance gaps and creation of minimum data metrics, the project's primary goals, there are further actions aimed at narrowing and/or eliminating noted gaps:

- Organize the stakeholders' workshop to agree upon minimum data metrics
- Organize reviews, determination of evidence-based care practices
- Implement evidence-based care as well as evidence-based public health practices in the PMLTBI across the Maine healthcare system.

The project leader will conduct the results dissemination among TB Clinic consultants and nurses, primary care sites and PHNs in the Greater Portland by September 2021, Maine TB

Consultants during next quarter meeting (Sep 2021), Maine PHNs during the two-day annual conference scheduled in October 2021, and Maine Sigma/Kappa Zetta at-Large Chapter Nurse Leader meeting scheduled on January 12th, 2022. For further follow up the project leader intends to work with a PHN team to conduct clinical research that will ultimately result in an evidence-based practice. The tentative clinical research title is "Latent TB Infection treatment client-centered intensive education and formative evaluation for improved outcome". Its aim consists of improving safe treatment completion. The second initiative will be to work with TB Control leadership to build the Maine sector-wide coalition for TB elimination.

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Appendix A

Presentation Outline

- Goal of the presentation
- Introduction
- Background
- Problem statement
- Literature review findings
- Clinical question
- Theoretical framework
- Project plan
- Methodology
- Project sample
- Tools for evaluation
- Expected implementation process
- Expected project outcomes
- Time for questions and comments from the audience (Burson, 2017)

A power point presentation will be developed and delivered to TB Clinic and referring primary care settings' managers and care providers involved in the management of LTBI through a zoom meeting one week before the beginning of the DNP capstone project. For absent participants, the presentation will be sent online. Thereafter, the project manager will interact with participants to receive comments and answer questions via emails and phone calls.

Appendix B

RE-AIM Application to the Programmatic Management of LTBI in Maine

RE-AIM	Level	Objectives	Measures	Instrument
Dimension				
Reach	Individual	What target	Number of TB	Staff records in
	Healthcare	population	consultants	last two years
	provider	groups were	(physician,	Strategic and
		identified for	physician	implementation
		this	assistant, nurse	plans
		intervention?	practitioner)	Quarterly TB
		What were	Number of	Consultants
		strategies used	registered	meetings
		to identify and	nurses (RN)	attendance
		engage the	who	sheets and
		target	participated in	reports
		population	the	Annual reports
		groups?	intervention	Referrals to TB
		What were	Demographic	clinic records
		their specific	data about	Referrals of
		characteristics?	participants	LTBI cases to
		What	(gender, age,	public health
		percentage of		

	target	race/ethnicity,		nursing
	population	education)		Division
	groups			
	participated in			
	the			
	intervention?			
Organization	How many	Number of	•	Maine's map of
Maine TB	programmatic	healthcare		primary care
Control	management	settings		and acute care
Program	settings of	participating in		settings
	LTBI exist	PMLTBI	•	ME TB
	within the	Number of		Control
	program?	healthcare		Program
	What	settings		electronic
	percentage of	referring		records
	the settings	suspected	•	ME TB
	participate in	LTBI/TB to		Control
	the PMLTBI?	PMLTBI		Program
		settings.		reports
Community	What	Number of	•	Community
Portland, ME	percentage of	primary care		health needs
	primary care	settings in the		assessment
	settings in the	community		documentation

		community	Number of	• In-depth
		participate in	primary care	interviews with
		PMLTBI?	settings	key community
			participating in	stakeholders
			PMLTBI.	such as
				Refugee Health
				Program,
				Maine Access
				Immigrant
				Network
				(MAIN)
				ME Catholic
				Charities
				Documentation
				of number of
				organizations
				participating in
				the PMLTBI
RE-AIM	Level	Objectives	Measures	Instrument
Dimension				
Effectiveness	Individual	What is the	Number of	• Treatment
	Healthcare	proportion of	LTBI clients	completion
	provider	LTBI clients	adhered to the	

	completed the	management of		electronic
	treatment?	LTBI until		records
	What impact	treatment	•	LTFU and
	(positive and	completion		drop-outs
	negative) did	Quantitative		electronic
	LTBI	(Retrospective)		records
	management	assessment of		
	have on	dropouts and		
	clients?	lost to follow-		
		up (LTFU) in		
		last 2 years		
		Qualitative	•	Semi-
		assessment of		structured
		stakeholders to		interviews
		explore the		
		perception of		
		barriers and		
		facilitators.		
Organization	Were there	Quantitative	•	Treatment
Maine TB	significant	assessment		completion
Control	variations in	(retrospective)		electronic
Program	outcomes	of LTBI		records
	between	management		

		participating	outcomes in	•	LTFU and
		settings?	last 2 years		drop-outs
			Qualitative		electronic
			assessment of		records
			staff's	•	ME TB
			perception of		Control
			LTBI		comparative
			management		reports
			facilitators and	•	In-depth
			barriers		interviews
	Community	Not applicable	NA	NA	
	Portland, ME	(NA)			
RE-AIM	Level	Objectives	Measures	Instru	ıment
Dimension					
Adoption	Individual	What	Qualitative	•	Semi-
	Healthcare	percentage of	assessment of		structured
	provider	involved health	stakeholders'		interview with
		care providers	experiences		stakeholders
		would	with LTBI		
		recommend the	treatment.		
		recommend the adoption and	treatment.		

	minimum data			
	metrics?			
Organization	What	Number of	•	ME TB
Maine TB	percentage of	primary care		Control
Control	primary care	settings that		Program
Program	settings	adopted the		reports
	adopted the	PMLTBI	•	Community
	PMLTBI?	Quantitative		health needs
	What were key	assessment of		assessment
	decision-	factors that		documentation
	making factors	affected the	•	Maine Healthy
	to adopt the	adoption		People 2020
	program?			document
Community	What type of	Number of	•	Documentation
Portland, ME	community-	community-		of community-
	based	based		based
	organizations	organizations		organizations
	adopted the	in the		
	PMLTBI?	community		
	To what extent			
	were	Quantitative	•	Reports of
	community	assessment of		PMLTBI
	stakeholders	key decisions		settings

		involved in the	made along	
		decision to	with	
		adopt and	community	Strategic plans
		implement the	stakeholders	of participating
		program?		community
		How does the	Identification	stakeholders
		PMLTBI align	of components	
		with mission of	of community	
		involved	stakeholders'	
		organizations?	mission	
			statements	
			aligning with	
			the program	
RE-AIM	Level	Objectives	Measures	Instrument
Dimension				
Implementation	Individual	What	Number of	Electronic
	Healthcare	percentage of	LTBI clients	records in last
	provider	partners	remaining on	2 years
		adhered to all	the program	
		steps of the	through steps	
		PMLTBI and	Qualitative	
		related data?	assessment of	
			clients to	

	What were	explore	•	Semi-
	barriers to	perceptions of		structured
	consistent	the		interview
	adherence to	management of		
	the	LTBI		
	management of	Number of		
	LTBI?	losses through		
	What was the	steps of the	•	Electronic
	attrition rate at	continuum of		records
	each step of the	the	•	Report
	cascade care of	management of		documents
	PMLTBI?	LTBI		
Organization	What	Quantitative	•	Documentation
Organization Maine TB	What percentage of	Quantitative assessment of	•	Documentation of process and
			•	
Maine TB	percentage of	assessment of	•	of process and
Maine TB Control	percentage of PMLTBI	assessment of the program	•	of process and outcome
Maine TB Control	percentage of PMLTBI settings	assessment of the program implementation	•	of process and outcome indicators
Maine TB Control	percentage of PMLTBI settings implemented	assessment of the program implementation Qualitative	•	of process and outcome indicators Electronic
Maine TB Control	percentage of PMLTBI settings implemented the	assessment of the program implementation Qualitative assessment	•	of process and outcome indicators Electronic records
Maine TB Control	percentage of PMLTBI settings implemented the intervention as	assessment of the program implementation Qualitative assessment exploring	•	of process and outcome indicators Electronic records Monitoring and
Maine TB Control	percentage of PMLTBI settings implemented the intervention as planned?	assessment of the program implementation Qualitative assessment exploring involved	•	of process and outcome indicators Electronic records Monitoring and evaluation

	the	barriers and	•	Qualitative
	implementation	facilitators to		evaluation
	of intervention	the program		reports
	as planned?	implementation	•	Implementation
	What			plan document
	proportion of			
	PMLTBI			
	settings applied			
	corrective			
	measures to the			
	intervention?			
Community	To what extent	Quantitative	•	Implementation
Portland, ME	was the	assessment of		plan document
	program	the program	•	Monitoring and
	implemented in	Qualitative		evaluation
	the community	assessment		reports
	as intended?	targeting	•	In-depth
	What were the	identification		interviews
	barriers to	of barriers and		reports
	effective	facilitators to		
	implementation	the program		
	of the	implementation		
	program?			

RE-AIM	Level	Objectives	Measures	Instrument
Dimension				
Maintenance	Individual	What were the	Quantitative	Electronic
(While the	Healthcare	long-term (≥ 6	assessment of	records
evaluation the	provider	months) effects	outcome	• Evaluation
maintenance		after the	indicators	reports
dimension is		phasing-out?	Qualitative	• Clients'
beyond the DNP			assessment of	satisfaction
Project, the			appreciation of	survey results
readiness for			the program	documentation
maintenance			and intent to	
could be			share program-	
assessed through			related benefits	
strategic plan,			with	
intent to recruit			community	
the PMLTBI			members	
qualified staff,				
etc.).				
	Organization	What	Number of	Participating
	Maine TB	proportion of	involved	Organizations
	Control	implementing	organizations	reports
	Program	organizations	who intend to	
		had a		

	continuation	continue the	•	Strategic and
	plan to	program		operational
	implement?	Number of		plans
	What are	organizations	•	Proportion of
	specific	with		budget
	characteristics	organizational		allocated to the
	noted in	charts		program
	organizations	including LTBI		
	continuing the	management		
	implementation	Number of		
	versus those	organizations		
	that	with a budget		
	discontinued?	item on LTBI		
		management		
Community	How did	Level of	•	Implementation
Portland, ME	participating	integration of		budget report
	community-	the program	•	Training
	based	into		reports
	organizations	organizational	•	Evaluation
	integrate the	structures.		reports
	program into	Number of		
	their	staff trained to		

EVALUATION OF PROGRAMMATIC MANAGEMENT OF LTBI IN MAINE

organizational	run the	
structures?	program	
What is the	Position level	
capacity and	in the chain of	
position levels	command	
of staff in		
charge of the		
program?		
	structures? What is the capacity and position levels of staff in charge of the	structures? program What is the Position level capacity and in the chain of position levels command of staff in charge of the

Appendix C

Minimum Data Metrics (MDM)

Minimum Data Metrics (MDM)

Minimum Data Metrics for the Programmatic Management of Latent Tuberculosis Infection (LTBI)

I. Demographics data

- 1 Date of birth:
- 2 Sex at Birth:

Female

Male

3 Ethnicity

Hispanic or Latino

Not Hispanic or Latino

Unknown

4 Race

American Indian or Alaska Native

Asian (specify:

Black or African American

Native Hawaiian or another Pacific Islander (Specify:

White

Other Race (Specify:

Unknown

4 Nativity

Country of Birth

If different from United States, Date of first U.S. Arrival:

II. Minimum Data Metrics

- 1 Number of referrals to tuberculosis clinic (TB Clinic)
- 2 Number of attendances
- 3 Number of referrals diagnosed and prescribed with LTBI treatment
- 4 Number of treatment initiation
- 5 Medication adherence rate
- 6 Number of treatment discontinuation for medical reasons or intolerance
- 7 Number of lost to follow-up
- 8 Treatment completion rate
- 9 Number of U.S.-born among LTBI cases
- 10 Number of foreign-born among LTBI cases

Minimum Data Metrics MMC TB Clinic-Related Questionnaire

You are one of the Maine Programmatic Management of tuberculosis (TB) and latent tuberculosis infection (LTBI) clinics.

1.	Where do you get referrals for suspected LTBI from?
2.	How many referrals did you receive in 2019?
3.	Where were these cases born?
	In the United States (US-born), provide the number
	Outside of the United States (foreign-born), provide the number
4.	How many attended the scheduled medical appointment for diagnosis and treatment?
5.	How many were diagnosed and prescribed treatment for LTBI?
6.	Of those who were diagnosed and prescribed with LTBI treatment, how many initiated
	the treatment?
7.	How many of those who initiated treatment were discontinued for medical reasons or
	intolerance?
8.	How many LTBI clients were lost to follow-up?
9.	How many LTBI clients completed their prescribed treatment?
10.	. From those who completed the treatment, give the number of U.Sborn vs. foreign born
	• U.Sborn
	• Foreign-born

11. Were you able to find this data easily?
YesNo
12. If you were able to find this data easily, please give an estimate of the amount of time it
took you to retrieve the data (in minutes, hour, and/or days)
Minutes
Hours
Days
• No
If it was not easy to retrieve this data, please explain what could have made it difficult
• Other (please specify)
13. Do you have an LTBI program monitoring and evaluation system?
• Yes
• No
If yes to the question #13, please describe the system (please answer n/a if not applicable)
If no to the question #13, please explain why (please answer n/a if not applicable).

Minimum Data Metrics MMPs (Maine Medical Partners) & Employee Health Settings-Related Questionnaire

Have you referred clients suspected with latent tuberculosis infection (LTBI) to Maine
Medical Center (MMC) TB Clinic in 2019?
Yes
No
If yes, please provide the total number of referrals made to the MMC TB Clinic in
2019
How many were born in United States?
How many were foreign-born?
How many of those referrals were sent at the MMC TB Clinic attended the medical
appointment?
How many were diagnosed and prescribed with LTBI treatment?
How many initiated LTBI treatment?
How many LTBI treatments were discontinued for medical reasons or intolerance?
How many LTBI clients were lost to follow-up?
How many LTBI clients completed the treatment as prescribed?
Of those who completed the LTBI treatment, please provide the number of U.Sborn vs
foreign born
• U.Sborn
• Foreign-born
. Were you able to retrieve these data easily?
Yes

• No
If yes, approximately how long did the data retrieval process take? (Please estimate
the amount of time in days, hours and/or minutes)
Minutes
Hours
Days
11. Do you have an LTBI program monitoring and evaluation system?
If yes, please describe it
If no, please explain why.

Minimum Data Metrics Greater Portland Health LTBI Clinic-Related Questionnaire

Please answer the following questions if you are part of the Maine Programmatic

Management of latent tuberculosis infection (LTBI) clinics for Greater Portland Health.

1.	Where do you get referrals for suspected LTBI from?
2.	How many referrals did you receive in 2019?
3.	How many were born in the United States?
4.	How many were born outside of the United States?
5.	How many of those referred to Greater Portland Health attended the scheduled medical
	appointment for diagnosis and treatment in 2019?
6.	How many were diagnosed and prescribed with LTBI treatment?
7.	How many initiated the treatment?
8.	How many LTBI treatments were discontinued for medical reasons or intolerance?
9.	How many LTBI clients were lost to follow-up?
10.	How many LTBI clients completed the treatment as prescribed?
11.	From those who completed the LTBI treatment, please provide the number of U.Sborn
vs.	foreign born
U.S	Sborn
Fo	reign-born
12.	Were you able to retrieve these data easily?
•	Yes
•	No .

EVALUATION OF PROGRAMMATIC MANAGEMENT OF LTBI IN MAINE

If yes, approximately how long did the data retrieval process take? (Please estimate
the amount of time in days, hours and/or minutes)
Minutes
Hours
Days
Do you have an LTBI program monitoring and evaluation system?
If yes, please describe it
If no, please explain why.

Appendix D

The Programmatic Management of Latent Tuberculosis Infection Survey

Latent tuberculosis infection (LTBI) is a component of the State of Maine Tuberculosis

Control Program. To ensure effective management of TB/LTBI, TB Control Program oversees
various programmatic management of TB/LTBI statewide. To contribute to efforts to improve
the effectiveness of programmatic management of LTBI, please assist this Doctor of Nursing

Practice (DNP) capstone project by answering the following open-ended questions.

- 1. Tuberculosis and latent tuberculosis infection are intertwined in that active TB is a risk factor for LTBI, which is a reservoir for potential active TB.
- How do you perceive LTBI management as a key strategy to control and prevent TB disease in the state of Maine?
- 2. Almost two billion people are infected with latent TB. However, less than 5% are screened, diagnosed and treated to prevent active TB infection.
- What are the major barriers that prevent more consistent management of LTBI?
- How would you improve your current policies to promote consistent and effective management of LTBI and to prevent active TB in Maine?
- 3. Five to 10% of people infected with latent TB are likely to develop active TB disease in their lifetime. On the other hand, treatment of LTBI reduces the risk of disease reactivation by 60% to 90%.
- In your experience or estimation, how adequate is the allocation of resources to meet the goal of reducing the risk of LTBI progressing to active TB in your practice?
- What are your recommendations to ensure adequate resources to the programmatic management of LTBI?

- 4. You are a primary care provider (PCP) and regularly refer some of your clients to MMC/TB Clinic to rule out active TB, diagnose, and treat LTBI.
- What are your next steps to ensure consistent and effective management of LTBI in your clients?
- If you keep a log of your referrals, what key data points or variables are documented?
- 5. In the United States, the actual completion rate of LTBI treatment is low, between 31-59%.
- In your experience or estimation, what are the significant barriers to an optimal outcome?
- What would you reasonably recommend to overcome existing barriers?
- 6. In 2018, there were 375 LTBI cases as reported by the Maine Center for Disease Control and Prevention. However, the report did not show important data such as treatment adherence and completion rates.
- How would this information change your current practices around LTBI?
- 7. Whereas most of LTBI cases are found in countries with high TB burden and low income, the World Health Organization (WHO)'s recommendations to diagnose and treat LTBI are restricted to immunosuppressed individuals and children less than 5 years old who exposed to household TB case index. These recommendations are extended to all high-risk groups in high-income and low TB burden countries such as Canada, the U.S. and European Union.
- What are your perceptions about the WHO recommendations? Do you believe it is sufficient?
- How would you improve or change the WHO recommendations?

- 8. In Canada, one study found out that migrants account for 65% of all active TB cases, and most of these cases are from the reactivation of LTBI post-immigration.
- Given that the migration movement from low-income and high TB burden countries to high-income and low TB burden keeps growing, what are your suggestions to mitigate the associated TB burden?

DNP Project: Qualitative Evaluation of the ProgrammaticManagement of LTBI inMaine

Exploring LTBI Clinics' Primary Care Providers' Opinions

Latent tuberculosis infection (LTBI) is a component of the State of Maine Tuberculosis Control Program. To ensure effective management of TB/LTBI, TB Control Program oversees various programmatic management of TB/LTBI statewide. To contribute to efforts to improve the effectiveness of the programmatic management of LTBI, please assist this Doctor of Nursing Practice(DNP) capstone project by answering the following questions.

pro	oject by answering the following questions.
1.	What facility do you work at?
wh	Tuberculosis and LTBI are intertwined in that primary TB is a risk factor for LTBI, nich is a reservoir for potential active TB. In your opinion, what do you think should be ne to control TB disease? Check all that apply
	□ LTBI does not pose any individual or public threat as it is asymptomatic and not contagious
	$\hfill\Box$ Focus on LTBI management is prone to divert public health and medical attention from the treatment of active TB
	$\hfill\Box$ integration of LTBI preventive therapy and TB disease treatment is the optimal approach to prevent and control TB
	□ Adequate treatment of active TB does not pose any risk for LTBI or TB disease.
3	Almost two billion people are infected with latent TR. However, less than 5%

	are screened, diagnosed, and treated to prevent active TB disease. From your experience, what do you think is/are the main reason/s? Check all that apply □ Poor management of LTBI is due to lack of sufficient resources worldwide
	$\hfill\Box$ Inadequate management of LTBI is due to low appreciation of its significance in the causation of active TB
	☐ Poor management of LTBI is associated with lack of awareness in at risk populationgroups
	□ Poor management of LTBI is associated with lack of consistent and standardized policies across the world
4.	Five to 10% of people infected with latent TB are likely to develop active TB disease in their lifetime. On the other hand, treatment of LTBI reduces the risk of reactivation to TB disease by 60% to 90%. In your opinion and from your experience, why do you think is/are the reason/s for inadequate resource allocation? Check all that apply
	□ In accordance with the likelihood of LTBI reactivation to TB disease, allocation of resources to LTBI management does not guarantee the return on investment
	□ LTBI treatment reduces the risk for active TB
	□ LTBI treatment reduces the risk for LTBI
	☐ The return on investment of optimal LTBI management is important.
5.	Please provide any other reason that could explain the discrepancy between the prevalence of LTBI and its poor management.
6.	You are a primary care provider (PCP) and regularly refer some of your clients to MMC TB Clinic to rule out active TB, diagnose, and treat LTBI. From your experience and your institution's referral system, what happens to the relationship between those referred patients and you (PCP)/your clinic? Check all that apply \[\text{Your client is in the hands of a specialist, and this is the last step in your care for the client.} \]

	□ Your next step is to follow-up whether client was diagnosed with and
	treated for LTBI
	□ You need to keep a log of your referral's data
	□ LTBI management outcome such as treatment completion rate is the responsibility of the TB Consultant.
7.	Please provide your recommendation for optimal management of your referrals to TB Clinic
8.	In the United States, the actual completion rate of LTBI treatment is low, between 31-59%. From your experiences, what are the common barriers you have observed? Check all that apply □ Shortage of health care professionals is the barrier to optimal outcome
	□ Client's poor adherence to LTBI management is the barrier to optimal outcome
	☐ Lack of LTBI awareness in the general population and in the at-risk population
	groups is a barrier to optimal outcome
	□ Allocation of inadequate resources to LTBI is the challenge.
	Please state what you think could explain such a poor LTBI atment outcome.
Di im	In 2018, there were 375 LTBI cases as reported by the Maine Center for sease Control and Prevention. However, the report did not show portant data such as treatment adherence and completion rates. What is ur opinionabout this report? Check all that apply
	☐ This data instructs less about epidemiological information such as prevalence
	□ The programmatic management of LTBI needs to be data-guided
	□ It is not easy to estimate how many of these people will progress to active TB in
	future
	□ Data management. is a key in the programmatic management of LTBI in Maine.

11. Whereas most of LTBI cases are found in countries with high TB burden and low-income, the World Health Organization (WHO)'s recommendations to diagnose and treat LTBI are restricted to immunosuppressed individuals and children less than 5 years old who are exposed to household TB case index. These recommendations are extended to all high-risk groups in high-income and low TB burden countries such as Canada, the U.S. and European Union. What is your opinion about WHO's recommendations? Check all that apply
☐ The World Health Organization's recommendations are fair and rational
☐ The World Health Organization's recommendations exacerbate the global health
disparity between high-income countries and low-income countries
☐ More resources need to be allocated to high TB burden countries
☐ More expanded LTBI preventive therapy to all high-risk groups in low-income and
high TB burden countries is also beneficial to high-income and low TB burden countries
12. In Canada, one study found out that migrants account for 65% of all active TB cases, and most of these cases are from the reactivation of LTBI post immigration. What methods would you suggest to mitigate the burden of TB? Check all that apply ☐ Immigrants should be settled in separate communities because they pose a threat of TB disease to the host community and immigrant community
□ LTBI awareness in immigrant communities is an important public health intervention
☐ The migratory movement needs to be halted to protect the public health in low TBburden and high-income countries
☐ Screening new immigrants for LTBI without delay is a preventive measure for bothimmigrant and host communities
13 Please comment on the above stated study's finding

Appendix E

Refusal Email to Answer online Survey Monkey Quantitative Questionnaire

Jovin,

I apologize for the delay in response! We took a look at our LTBI data and it is going to require a lot of quality improvement work on our end to produce accurate answers to the questions you pose. These questions are ones we would love to be able to answer and hope to use to guide our own revamping of the LTBI program at XYZ!

Our team is in the midst of staffing changes so it is not feasible that XYZ will be able to produce accurate data in a timely fashion. Hopefully, my responses to the qualitative portion can give you an idea of how the LTBI program functions at XYZ.

We do report all of our LTBI enrollments and completions to the TB control if you are able to contact them for those numbers.

Thank you for your understanding.

Appendix F

Timeline

Presentation of DNP proposal to MMC TB Clinic for approval Baseline data X collection Identification of required X	Task	Sep. 2020	Oct. 2020	Nov. 2020	Dec. 2020	Jan. 2021	Feb. 2021	Mar. 2021	Apr. 2021	May 2021
of DNP proposal to MMC TB Clinic for approval Baseline data X collection Identification of required X			2020	2020	2020	2021	2021	2021	2021	2021
proposal to MMC TB Clinic for approval Baseline data X collection Identification of required X		X								
MMC TB Clinic for approval Baseline data X collection Identification of required X										
Clinic for approval Baseline data X collection Identification of required X										
approval Baseline data X collection Identification of required X										
Baseline data X collection Identification of required X										
collection Identification of required X										
Identification of required X		X								
of required X										
data for the		X								
uata for the	data for the									
PMLTBI	PMLTBI									
Definition of	Definition of									
key process X	key process	X								
and outcome	and outcome									
indicators	indicators									
Determination	Determination									
of the X	of the		X							
PMLTBI's	PMLTBI's									
gaps	gaps									
Identification X	Identification			X						
of key	of key									
stakeholders										
Creation of a	Creation of a									
minimum data X	minimum data				X					
metrics	metrics									
Presentation										
of created X	of created					X				
minimum data										
metrics to	_									
stakeholders										
for critique										
and	_									
improvement										
Application of X							X			
the minimum										
data metrics										

to the project					
to the project					
site (TB					
Clinic)					
Evaluation of			X		
the impact of					
the minimum					
data metrics					
on the					
PMLTBI					
Organization				X	
of a findings'					
dissemination					
session					
Presentation				X	
of results to					
UMass					
faculty					
Corrections as					X
requested and					
submission of					
final Capstone					
Project Project					
110]501					

Appendix G

Budget

Input	Cost (\$) per unit	Total
Collection of baseline data x	30	180 (in kind)
6 hours total		
Data collection through	30	600 (in kind)
mixed quantitative and		
qualitative methods under		
RE-AIM framework x 20		
hours total		
Data analysis x 20 hours	30	600 (in kind)
Creation of a minimum data	30	240 (in kind)
metrics x 8 hours		
Results presentation to	300	300
stakeholders x session		
Presentation of the project's	120	120 (in kind)
results to faculty at UMass		
Submission of final version	0	0
of the DNP capstone Project		
Total		\$2,040

Appendix H

TB Clinic and PHN Central Referral Office Data Collection Tools

THE PROGRAMMATIC MANAGEMENT OF LATENT TUBERCULOSIS INFECTION (LTBI)

The Programmatic Management of LTBI is a data-driven program. Data management is a key to ensure effective implementation by monitoring the level of

delivery fidelity to the program planning, to determine performance gaps and evaluate outcomes

Data to be collected by TB Clinic Mar-21

Week 1

# of appointments for LTBI diagnosis & treatment = # of attendees = # of attendees diagnosed with LTBI = # of attendees prescribed with LTBI treatment =	U.S-born	Foreign- born	Total
Week 2			
# of appointments for LTBI diagnosis & treatment = # of attendees =	U.S-born	Foreign- born	Total
# of attendees diagnosed with LTBI = # of attendees prescribed with LTBI treatment = Week 3		Foreign	
	U.S-born	Foreign- born	Total
# of appointments for LTBI diagnosis & treatment = # of attendees = # of attendees diagnosed with LTBI = # of attendees prescribed with LTBI treatment = Week 4		Foreign-	Total
	U.S-born	born	Total

of appointments for LTBI diagnosis &
treatment =
of attendees =
of attendees diagnosed with LTBI =
of attendees prescribed with LTBI
treatment =
Week 5

Foreign-U.S-born born Total

of appointments for LTBI diagnosis &

treatment =

of attendees =

of attendees diagnosed with LTBI =

of attendees prescribed with LTBI

treatment =

Monthly Report

Foreign-

U.S-born

born Total

of appointments for LTBI diagnosis &

treatment =

of attendees =

of attendees diagnosed with LTBI =

of attendees prescribed with LTBI

treatment =

of LTBI treatment clients referred to TB Control for treatment initiation and monitoring

Comment

THE PROGRAMMATIC MANAGEMENT OF LATENT TUBERCULOSIS INFECTION (LTBI)

The Programmatic Management of LTBI is a data-driven program.

Data management is a key to ensure effective implementation by monitoring the level of

delivery fidelity to the program planning, to determine performance gaps

Data to be collected by Public Health Nursing Mar-21

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<pre># of referrals for LTBI treatment education, safety & compliance monitoring = # of treatment initiation WK 3 & 4 of Feb. plus WK 1 March 2021 = # of unreachable clients = Week 2</pre>	U.S- born	Foreign- born	Total
# of referrals for LTBI treatment education, safety & compliance monitoring = # of treatment initiation from WK 1 & 2 referrals = # of unreachable clients =	U.S-born	Foreign- born	Total
<pre># of referrals for LTBI treatment education, safety & compliance monitoring = # of treatment initiation from WK 1, 2 & 3 referrals = # of unreachable clients =</pre>	U.S- born	Foreign- born	Total
<pre># of referrals for LTBI treatment education, safety & compliance monitoring = # of treatment initiation from WK 1, 2, 3 & 4 referrals = # of unreachable clients =</pre>	U.S- born	Foreign- born	Total
<pre># of referrals for LTBI treatment education, safety & compliance monitoring = # of treatment initiation from WK 1, 2, 3 & 4 referrals = # of unreachable clients =</pre>	U.S- born	Foreign- born	Total
Monthly Report	U.S- born	Foreign- born	Total

EVALUATION OF PROGRAMMATIC MANAGEMENT OF LTBI IN MAINE

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# of referrals for LTBI treatment education, safety & compliance monitoring =
# of treatment initiation from WK 1, 2, 3, 4 & 5 referrals =
# of unreachable clients =
Comment
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Appendix I

Latent Tuberculosis Infection Management Communication and Data Sharing Model

