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Evidence-Based Tuburculosis Screening and Testing Clinical Protocol for Public Health and Primary Care Providers

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EVIDENCE-BASED TUBERCULOSIS SCREENING AND TESTING CLINICAL PROTOCOL FOR PUBLIC HEALTH AND PRIMARY CARE PROVIDERS

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ABSTRACT

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Tuberculosis is a treatable and preventable disease; however, tuberculosis continues to be a leading cause of morbidity and mortality around the globe. Per the World Health Organization (2016), tuberculosis (TB) disease was responsible for 10.4 million illnesses and 1.8 million deaths in 2015. Strategic plans by public health entities are continually under development at the global, national, and state levels to utilize innovative methods for identifying, treating, and preventing transmission of TB. Newer testing technologies and recommendations, are available for screening patients at risk for developing TB disease, creating an opportunity for development of a new tuberculosis screening and testing clinical protocol

The purpose of this project was to develop a point-of-care clinical protocol that would assist public health workers and primary care providers with screening and testing for tuberculosis. An online survey was developed to assess the effectiveness, efficiency, and evidence-based content of the protocol. The protocol and survey were sent to 229 subject-matter experts for review and survey feedback. There were 25 responses to the online survey. Overall, 79.6% of the participants thought the protocol was effective, 76.5% agreed it was efficient, and 85.2% stated it was evidence-based. Although the response rate was low, respondents represented a variety of health disciplines, were

experienced in TB screening, and provided specific feedback. The point-of-care evidence-based screening and testing protocol has potential to provide effective and efficient guidance in TB screening in public health, community health, and primary care clinics.

Keywords: interferon gamma release assay, latent tuberculosis infection, tuberculosis, tuberculosis testing, tuberculosis screening

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CHAPTER I

INTRODUCTION

New tuberculosis testing technologies have been introduced in the United States within the past 15 years. Guidelines for interferon gamma release assay (IGRA) testing for detection of mycobacterium tuberculosis were published by the Centers for Disease Control (CDC) in the 2010 *Morbidity and Mortality Weekly Report* (MMWR; Mazurek et al., 2010). In 2016, The U.S. Preventative Services Task Force (USPSTF) published its final recommendation for tuberculosis screening of at-risk populations. In January 2017, new clinical practice guidelines for diagnosing tuberculosis were published by the American Thoracic Society and the CDC (Lewinsohn et al., 2017).

The other widely accepted test available to detect mycobacterium tuberculosis is the tuberculin skin test (TST) developed by Von Pirquet and Mantoux in 1907-1908 (CDC, 1982). Given the original skin test is well over 100 years old, new developments and technology to detect mycobacterium tuberculosis are long overdue. Treatment of tuberculosis (TB) is becoming increasingly challenging as drug resistance is also on the rise. It is imperative for providers to accurately diagnose and treat both latent and active TB to avoid further increasing drug resistance, save limited healthcare resources, and provide high quality care for patients. To accurately diagnose TB, it is important to understand which test is best for the patient and how to interpret the results.

In September 2016, the USPSTF finalized a recommendation statement for latent tuberculosis screening. A grade B was assigned for screening populations at increased risk of latent tuberculosis infection. Grade B means there is great certainty of a moderate to substantial net benefit and screening at-risk populations is recommended (USPSTF, 2016). An evidence report supporting the USPSTF recommendations was published in 2016 by Kahwati et al.

In January 2017, the most recent guidelines available for diagnosing tuberculosis were published by the American Thoracic Society, Infectious Diseases Society of America, Centers for Disease Control and Prevention, and Clinical Practice Guidelines (Lewinsohn et al., 2017). These recommended guidelines also supported screening populations at risk for tuberculosis. Additionally, preferences for the IGRA test over TST were established in most clinical situations. The exception to this was if the IGRA test was too expensive, too burdensome, or not available. While these new guidelines did not aim to impose a strict standard, they were meant to guide the clinician's decision-making based upon available evidence. Often many unique patient factors are associated with clinical decision-making for TB screening and testing (Lewinsohn et al., 2017).

The purpose of this project was to design and implement a user-friendly clinical protocol to assist providers in deciding which tuberculosis test would be most appropriate based upon the patient's clinical situation, risk factors, available financial resources, and reason for screening. In addition, a decision-making tool was developed to assist providers in determining clinical decision-making following positive, negative, or indeterminate test results based upon the most current evidence-based guidelines for both

the TST and the IGRA test. The most recent guidelines for TB diagnosis supported the clinical protocol and decision-making tool (Lewinsohn et al., 2017).

Background and Significance

The United Nations Millennium Development Goals were committed to stopping the TB epidemic by the end of 2015 through an initiative named the Stop TB Partnership. This initiative was first developed in 2000. The efforts resulted in saving 43 million lives between 2000-2014. Not all the objectives were met and progress toward TB elimination showed a slow decline between 2000-2014 (Stop TB Partnership, 2015). Barriers were identified that contributed to slow progression toward TB elimination: poor health systems, poverty, malnutrition, migration, aging populations, smoking, and chronic health conditions. There was also a lack of resources available to perform the optimal work needed to fulfill the goal (Stop TB Partnership, 2015). In 2014, The World Health Organization (2015a) created a renewed initiative called the End TB Strategy. This updated initiative aimed to address barriers to progress previously identified.

Ending the TB epidemic requires identification of key populations most at risk for developing TB disease. Medically underserved populations, individuals with increased risk to TB exposure, and certain individuals who are immunocompromised due to certain health issues and behaviors are at the highest risk. Target populations differ between countries so it is the responsibility of each country to identify their own at-risk populations. The updated initiative aims to treat 90% of the population with TB disease, increase care for 90% of all vulnerable populations, and reach a 90% cure rate for all people diagnosed with TB (Stop TB Partnership, 2015).

Elimination of tuberculosis in the United States is dependent upon implementing strategic plans to screen, test, and treat individuals at increased risk for developing active TB disease. Screening and treatment of Latent TB Infection (LTBI) is the primary method used for eliminating TB in the United States (Linas, Wong, Freedberg, & Horsburgh, 2011). In both public health and primary care settings, it is important to effectively screen for, test, and treat LTBI and active TB in a cost-effective manner. In the most recent statement written by the USPSTF (2016), a moderate benefit of screening for LTBI was noted in persons at increased risk for TB.

In addition to the TST, IGRA tests have been developed and are being used to test for LTBI and TB disease. A wide variety of studies and literature have been published assessing reliability, usefulness, and cost-effectiveness of both tests in many populations at various risks for developing active TB (Linas et al, 2011). Few resources have been found that compiled this information into a user-friendly, evidence-based, point-of-care, clinical decision-making protocol applicable to all persons with various TB risk factors.

Populations at risk for tuberculosis include immigrants; refugees; foreign born individuals from countries with a high prevalence of TB; immunocompromised individuals including those with HIV, diabetes, and chronic health issues; people who are homeless or in jail; individuals who inject drugs; and children and adults with recent exposure to active TB disease (Horsburgh & Rubin, 2011). In addition to clearly identifying who should be tested for TB, providers must choose which test to use--the IGRA test or the TST. It is important for the provider and/or clinic staff to know how to properly administer the test, interpret the results, and order additional diagnostic studies to rule out active TB disease.

Problem Statement

Resources and clinical guidelines are available to assist providers with clinical decision-making regarding tuberculosis screening and testing. New guidelines for the preferred use of the IGRA test in certain populations and situations were published by the American Thoracic Society, Infectious Diseases Society of America, and Centers for Disease Control (Lewinsohn et al., 2017). Several barriers were identified that contributed to provider resistance to utilizing new testing techniques. One barrier identified leading to potential challenges with clinical decision-making regarding TB testing was a significant diversity in recommendations for IGRA testing in the literature. Denkinger, Dheda, and Pai (2011) identified four different testing approaches in 33 different guidelines from 25 countries, the CDC, and American Academy of Pediatrics: (a) a two-step approach using the TST first followed by the IGRA test; (b) IGRA test only to replace the TST; (c) both the TST and the IGRA test together; and (d) either the TST or the IGRA test but not both. With so many available choices for testing, providers might be challenged with which diagnostic test to use given the patient's clinical situation.

An additional challenge to clinical decision-making found in the literature was many studies focused on testing specific populations at risk for TB. There were too many unique patient situations and risk factors to rely specifically on any one guideline for choosing the best TB diagnostic tool. Valuable clinic time could potentially be lost while providers research best testing options for their patients. The Infectious Diseases Society of America addressed this in its latest guidelines (Lewinsohn et al., 2017). Both the TST and the IGRA are indirect tests with no ability to determine whether a patient has LTBI or active TB disease. The test result itself provides limited information regarding next steps

for the patient and this can be challenging to providers. The TST and IGRA sometimes result in false positives. Newest recommendations by the Infectious Diseases Society of America suggested considering confirmatory testing in situations when the patient being tested is at low risk for TB and the initial test is positive (Lewinsohn et al., 2017). The TST and the IGRA test do not distinguish active TB from latent TB. Further assessment is needed in the form of symptom evaluation and chest radiograph in patients with positive test results (Lewinsohn et al., 2017).

Gap Analysis and Opportunities

To move closer to TB elimination, it is important for providers to actively participate in testing high risk individuals for TB. Currently, two types of approved tests are available for determining exposure to TB: the TST and the IGRA. New evidence-based guidelines are available to assist providers in choosing who should be tested and how testing should be done. Clinical decision-making needs to be streamlined into an easy to access clinical tool to improve quality of care, effectiveness, and efficiency.

An opportunity exists to create a point-of-care clinical protocol for TB testing in support of the most current evidence-based guidelines for providers to use. The goal of this project was to improve the quality of patient care and clinical efficiency through an easily accessible and user-friendly guide. The main objective in relationship to the goal was to promote use of the best technology available for TB testing given a patient's unique clinical situation. The type of tool used for the clinical protocol was a decision-making clinical algorithm available in printed format.

Population, Intervention, Comparison, Outcome, and Time Question

For patients at high risk of TB disease presenting to the public health or primary care clinic (P), will implementing a clinical protocol to assist providers with TB testing decision-making (I) allow providers to choose the TB testing method that is most effective, efficient, and evidence-based leading to accurate clinical decision-making and proper identification of TB infection (O) at the time of the visit (T)?

Theoretical Framework

The Stetler (2001) model of research utilization was used to implement the new clinical protocol and tool for TB testing. The Stetler model is a practitioner-based model used as a guide to implement evidence-based research knowledge into practice. The type of research utilization appropriate for this project was to use research to create a process for routine problem-solving or clinical decision-making. The Stetler model contains a series of steps that include critical-thinking and decision-making to facilitate use of research findings. Criteria applicable to the studies include substantiating evidence, current practice related to desire to change, fitness of the findings to the clinical setting, and feasibility regarding risk compared to benefit. The assumptions of the Stetler model include:

1. The formal organization might or might not be involved in the individual's utilization of research.
2. Utilization might be instrumental, conceptual, and/or symbolic.
3. Other types of evidence and/or non-research related information are likely to be combined with research findings to facilitate decision-making or problem solving.
4. Internal and external factors can influence an individual's or group's view and use of evidence.
5. Research and evaluation provide us with probabilistic information--not absolutes.

6. Lack of knowledge and skills pertaining to research utilization and EBP can inhibit appropriate and effective use. (Stetler, 2001, p. 7)

The Stetler (2001) model contains five phases. Phase I is preparation. Preparation includes searching, collecting, and sorting research evidence and defining the purpose and outcomes of the issue. Phase II is validation, which involves performing a utilization-focused critique or synopsis of the issue. If the synopsis is accepted, Phase III is the comparative evaluation/decision-making step. Phase III incorporates Phase II findings into the setting, feasibility, substantiation of evidence, and current practice to consider application. Phase IV is the translation/application step of the process and Phase V is the evaluation phase (Stetler, 2001).

Literature Review

Several online databases were searched for research literature including Google Scholar, Cochrane, CDC.gov, and the general University of Northern Colorado library search engine. Search terms used for literature included *interferon gamma release assay, tuberculin skin test, latent tuberculosis infection, tuberculosis, tuberculosis testing* and *tuberculosis screening*. The terms *recommendations* and *diagnosis of* were also added to these search terms to narrow the focus of the search for articles containing testing recommendations and comparison of tests. More than 1,000 articles were scanned for relevance to this project. An iterative search was also done from paper and electronic references. A total of 19 articles were chosen for the literature review based upon five different foci of information: evidence-based recommendations, test comparisons, clinical decision support tools, discordant results, and effectiveness. A literature review table is provided in Appendix A.

Clinical Decision Support Tools

Only one article specifically addressed use of a clinical decision support tool for TB screening; however, this clinical support tool did not address which test would be most appropriate to choose given the patient's risk. The tool was a computer-based clinical decision support to alert the provider that testing was recommended (Steele et al., 2005). The CDC (2016) provided many articles and provider resources that were helpful for clinical decision-making for diagnosing TB including a mobile application for tablets and smart phones.

Evidence-Based Recommendations

Three evidence-based recommendations published within the past 12 months were utilized to create the clinical protocol. The Infectious Diseases Society of America (IDSA) guideline for diagnosing TB in adults and children was the most recent (Lewinsohn et al., 2017). The guideline recommended testing with the IGRA test over the TST in most situations except for children under the age of five. The TST was also an acceptable test if the IGRA was unavailable, too expensive, or too troublesome (Lewinsohn et al., 2017). The USPSTF evidence report reviewed 72 studies and determined both the TST and IGRA were sensitive and specific for TB in countries with low TB burden like the United States (Kahwati et al., 2016). Pai and Menzies (2017) offered TB recommendations for HIV-uninfected adults. This article and other associated links in this article contained comparable recommendations to the IDSA and USPSTF.

Test Effectiveness

Seven test comparison studies are included in the literature review. The studies compared the two commercially available IGRA tests--QFT and T-SPOT--with each other

and/or the tuberculin skin test. Kobashi et al. (2008) evaluated differences between the two commercially available blood tests for TB. Their study determined blood tests were more useful than the TST in identifying patients with active TB disease. One study compared TST with the QFT and Quantiferon-TB Gold test (QFT-G) and IGRA, resulting in the QFT-G being slightly more specific than the TST in Navy recruits (Mazurek, Zajdowicz et al., 2007). A study done by Manusco et al. (2012) determined an insignificant statistical difference between the two commercially available IGRA tests and the TST in U.S. military recruits. The two studies performed on military recruit subjects in the United States provided valuable information for test choice since most new military recruits are low risk for TB infection.

One study compared the TST with two commercially available IGRA tests in individuals with suspected TB (Mazurek, Weis et al., 2007). In this study, all three tests had similar sensitivity. Painter et al. (2013) compared the TST with QFT-G in immigrant populations vaccinated with bacillus Calmette–Guérin (BCG) vaccine. The QFT-G sensitivity was 86.4% compared with a TST sensitivity of 52.3% in this population. This study confirms the preference for the IGRA test over the TST in persons with the BCG vaccination. Another study compared two IGRA tests (Higuchi et al., 2008). This study resulted in the T-SPOT test being more sensitive (100%) than the QFT-G (87.2%) but the T-SPOT was less specific than the QFT at 83.3% and 98.8%, respectively (Higuchi et al., 2008). A systematic review of IGRA tests in comparison to the TST for diagnosis of active TB revealed the IGRA tests were more sensitive than the TST but not sensitive enough to use IGRA tests to rule out a diagnosis of active TB (Sester et al., 2010).

Diagnosing TB infection is challenging. Both IGRA tests and TST results might be falsely positive, falsely negative, or indeterminate. Many factors influence discordant results. Jeon et al. (2013) published a study that determined patients with high inflammation markers such as C-reactive protein, immune compromised patients, or older patients had a higher probability of indeterminate and false negative results with the QFT-In Tube Gold IGRA test. Another study reviewing literature from 33 different guidelines in 25 countries showed much diversity in TST and IGRA testing recommendations (Denkinger et al., 2011). This study recommended more transparent, evidence-based guidelines for IGRA testing and noted a possible lack of disclosure of conflicts of interest with the commercial IGRA tests. Lastly, a study was done regarding screening of Italian healthcare workers for TB infection (Olivieri et al., 2016). Evidence in this study supported use of the IGRA test to confirm positive TST tests in this population. The newest IDSA (Lewinsohn et al., 2017) guidelines also provided recommendations for considering additional confirmative testing with the IGRA after a positive TST in some clinical situations.

Cost

Cost might be a contributing factor in test choice for some providers and clinics. Review of literature using the search terms resulted in two appropriate research articles containing information about testing specific high-risk populations with the IGRA test and/or TST to determine cost-effectiveness. Pareek et al. (2012) conducted an observational study and economic analysis of tuberculosis screening in 231 immigrants using the TST and IGRA testing in the United Kingdom. Using the IGRA test in immigrant populations might eliminate the need for a chest X-ray, which would improve

cost effectiveness of using the IGRA test over the TST. Linas et al. (2011) indicated screening in some groups was more cost effective using the IGRA test over the TST in the United States. These groups included foreign-born persons, individuals at high risk of TB reactivation, vulnerable populations (homeless, drug users, and prisoners), and patients with medical co-morbidities such as diabetes. Data for this study were collected through CDC surveillance data and National Health and Nutrition Examination Survey estimates of positive TST prevalence (Linas et al., 2011). U.S. census population estimates were used to determine equation variables. Life expectancy gains were calculated comparing no screening at all with TST screening. Screening with the TST resulted in a gain of 0.00-0.24 life months. In comparison to TST screening, IGRA screening resulted in life expectancy gains of 0.00-0.01 life months (Linas et al., 2011). Articles like these are useful in determining the most cost-effective test choice in relationship to patient risk for disease.

CHAPTER II

PROJECT DESCRIPTION

Project Objective

The objective for this project was to design and evaluate an easy to use clinical protocol for future implementation in primary care, public health, and community health clinics to assist clinicians with decision-making regarding the most effective, efficient, and evidence-based testing methods for latent and active tuberculosis based upon the patient's identified risk factors for TB. To support decision-making, guidance on test result interpretation and what to do if the results were indeterminate was provided. The project assessed effectiveness and potential usefulness of the clinical protocol and, if possible, assessed for improvements in properly screening and testing individuals at risk for TB per evidence-based guidelines. This protocol included a clinical decision-making algorithm, providing point of care assistance to health care providers.

Project Plan

The project was planned in five phases while incorporating the Stetler (2001) model as a framework. Phase I was the preparation phase. Preparation for the project included reviewing, collecting, and summarizing clinical evidence. A project site was selected to provide expert advice in development of the clinical protocol. The optimal site was one that focused on general TB prevention activities, especially in high-risk populations. Populations at risk for tuberculosis per the CDC (Lewinsohn et al., 2017)

definition included adults and children who were foreign-born, immunocompromised, homeless, incarcerated, underserved, or had recent exposure to TB disease including travelers potentially exposed to TB in countries where TB was prevalent. The clinic site was also familiar with TB testing technologies including both tuberculin skin tests and IGRA tests. It was important to receive acceptance from the chosen site in development of the protocol and assessment of usefulness while avoiding disruption of staff daily work flow.

Phase II involved developing the clinical protocol utilizing the review of literature findings and expert opinions. Expert opinions were provided by the clinical site staff experts along with experienced TB clinic providers and nurses. The protocol was designed to enhance and complement current TB elimination objectives and assessment tools already designed by the state health department.

Phase III was the process of distributing the TB testing protocol to volunteer participants for review. Participants included TB experts and staff at local health departments, community health clinics, and primary care providers. The tool was e-mailed to potential volunteer participants. The state TB program assisted with distributing the protocol to volunteer participants.

Phase IV was the application phase of the project. A Qualtrics survey was distributed to volunteer participants via e-mail. The survey consisted of three focus areas that addressed components of the PICOT question. The first section assessed potential clinical efficiency of the protocol while seeking feedback regarding the protocol design and content. Another section sought information regarding current evidence-based choices of tuberculin skin tests and IGRA blood tests. Information was sought regarding

how use of the protocol would assist with evidence-based TB care. The survey also assessed the provider's perception of clinical efficiency and effectiveness including why one test might be preferred over the other.

Phase V was the process of evaluating survey results. If results of the survey revealed implementation of the protocol would improve clinical efficiency, effectiveness, and success with evidence-based TB clinical decision-making, future implementation of the protocol in clinical practice would be reasonable.

Congruence of Organization's Strategic Plan to Project

The Colorado Department of Public Health and Environment (CDPHE; 2017) provided guidance and recommended participants for protocol review. This project supported the state health department's strategic plan to eliminate TB. The project committee consisted of one individual from the state health department along with two university faculty members with interest in infectious disease control, public health, and/or community health of patients in high risk populations.

Timeline of Project Phases

The project timeline was just over one year in length beginning with development of the phenomenon of interest and ending with the final project defense. The project began in January 2017 and ended in February 2018. The research committee was chosen and the project proposal was written, proposed, and accepted by the end of spring semester of 2017. During summer semester of 2017, the clinic site was assessed and chosen for the pilot project. Development of the clinical protocol began during the summer semester of 2017 with the objective of having the completely developed protocol available by mid-June 2017. The project was implemented in October 2017. Final

evaluation, completion, and defense of the project were completed in February, 2018, which was three months later than originally planned in the timeline. A copy of the original timeline graph is provided in Appendix B.

Resources

The budget for development of the clinical protocol was minimal. The clinical protocol was developed utilizing technology currently available to the student at no cost. Evaluation of the project was conducted using Qualtrics software available through the university for no additional cost. No expenses were anticipated for additional personnel to assist with project development. The protocol and survey regarding the protocol were sent to participants in an electronic format via an e-mail attachment for printing on-site at the expense of the agency. A budget of $800.00 was planned for travel and printing expenses, which were incurred by the Doctor of Nursing Practice (DNP) student.

Ethical Considerations

Prior to project implementation, approval was obtained from the University of Northern Colorado's Institutional Review Board (IRB) on September 21, 2017. An IRB approved consent form was developed and sent out with the recruitment letter, protocol, and link to the online survey. Participation in the survey constituted consent; therefore, no signature was required (see Appendix C for the recruitment email, IRB approval letter, and consent form). A statement of mutual agreement with the CDPHE was also developed and signed by the project committee prior to project implementation (see Appendix D).

CHAPTER III

EVALUATION OF OBJECTIVES

The main objective was to design and evaluate a clinical-based protocol for determining the most appropriate TB testing method to use for specific patients based upon risk factors for having or acquiring TB and test feasibility. The protocol included evidence-based guidance about how to interpret TB test results, what the next clinical steps should be if the test was positive or negative, and what to do if a test was indeterminate or borderline. It was important to evaluate the effectiveness of test choice and clinical efficiency of the protocol. A Qualtrics survey (see Appendix E) was administered to participants along with protocol distribution to include questions related to usefulness of the protocol and evidence-based guidance related to TB test result interpretation. Data collection through the survey revealed preference for choice of test, if the guidance for test result management was helpful, and if use of the protocol encouraged practices to follow evidence-based guidelines. The survey also assessed if the protocol would be helpful and practical for use in clinical sites.

Evaluation of the DNP project included assessment of the protocol regarding its helpfulness in decision-making. The literature review revealed recommendations for preferred use of the IGRA test in some high-risk populations but it also revealed potential barriers to use of IGRA testing. The survey assessed expert participants' preferences of test choice and why one test might be chosen over the other. Evaluation of the project is

represented by Phase Five of the Stetler (2001) model of evidence-based practice (see Figure 1).

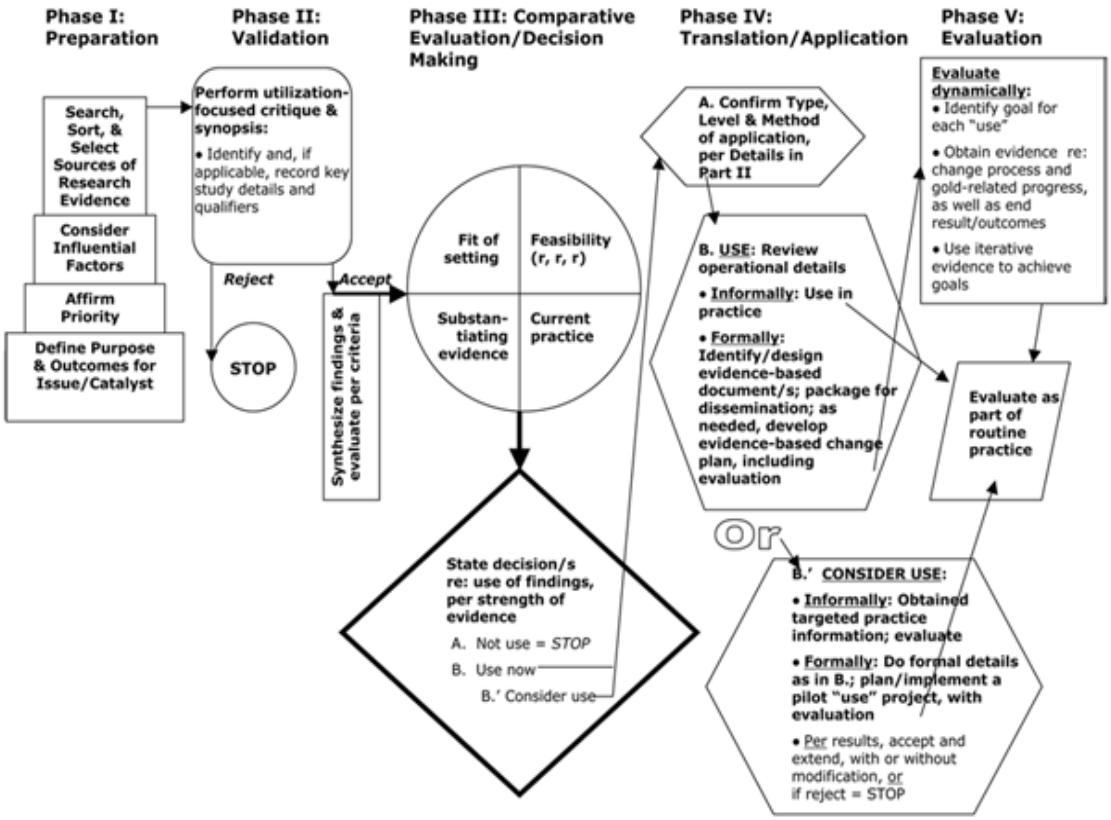

Figure 1. Model of evidence-based practice (Stetler, 2001, p. 276).

Application of Evidence-Based Measures

The PICOT question served as a basis for project evaluation: For patients at high risk of TB disease presenting to the public health or primary care clinic, (P) will implementing a clinical protocol to assist providers with TB testing decision-making (I) allow providers to choose the TB testing method that is most effective, efficient, and evidence-based leading to accurate clinical decision-making and proper identification of

TB infection (O) at the time of the visit (T)? Evaluation of the project focused on answering all components of the clinical question. Evidence-based measures as recommended in the most recent guidelines were the basis of all clinical guidance provided in the protocol.

Method of Analysis

Analysis of the evaluation data was descriptive in nature. Data were organized with a focus on answering specific parts of the PICOT question: effectiveness, efficiency, and evidence-based. Both qualitative and quantitative data from the participant surveys were analyzed. Analysis of the participant surveys regarding usefulness and practicality of the clinical tool was done by providing a descriptive report of the results obtained from the Qualtrics survey.

Conclusion

The battle to eliminate TB continues to be a priority around the globe. The initiative to stop TB involves several objectives including use of evidence-based testing techniques for diagnosing TB infection. Newer technologies in the form of two commercially available IGRA tests are available for TB testing. Opportunities exist to assist clinicians to make best evidence-based choices with well-designed point-of-care clinical protocols. Information obtained from TB providers and staff about the clinical protocol helped determine the usefulness, efficiency, effectiveness, and utilization of best clinical evidence in TB testing techniques. There may be future opportunities to implement the clinic protocol if the tool proves to be useful.

CHAPTER IV

RESULTS

This chapter presents the results of the project including survey responses from subject matter experts. The purpose of this project was to develop a TB clinical protocol for future use in public and community health clinics. The protocol was designed to be clinically efficient, effective, and evidence-based. Additionally, expert feedback was received evaluating the efficiency, effectiveness, and evidence-based content. Case examples were presented in the survey for participants to test the protocol as it would be used in the clinical setting.

Although there were 25 total responses to the survey, not every participant answered each question. Overall responses to the survey supported implementation of the TB protocol in practice. A few participants felt too many barriers existed for the protocol to be useful in practice. Many suggestions were provided to assist with modifying the protocol for improved efficiency, effectiveness, and evidence-based practice.

Responses to Survey Questions

The following paragraphs discuss the responses to each survey question including support or lack of concurrence based upon recent evidence-based guidelines. Overall, most subject matter experts agreed the protocol was effective, efficient, and evidence-based. Feedback received for suggested additions, omissions, and changes to the

protocol pointed out several areas for improvement. The responses also suggested changes that did not align with current evidence-based recommendations, leading to the necessity for further research prior to implementing suggested edits.

Question One: Effectiveness of Screening Tool

The first question sought to address the effectiveness of the TB screening tool, testing protocol, and result guidelines. Of 22 responses, 68.2% of the survey participants strongly agreed or agreed that the TB screening tool would be effective for implementation in practice in their clinic. Approximately18.2% of the participants either somewhat agreed or neither agreed or disagreed as to the effectiveness of the screening tool. A small percentage of participants (4.6%) strongly disagreed with the effectiveness of the screening tool.

There were 21 responses to Question #1 regarding the effectiveness of the TB testing protocol. Most participants (80.9%) either strongly agreed, agreed, or somewhat agreed that the TB testing protocol would increase effectiveness of TB testing in their clinic. The remaining 19.1% of the participants neither agreed or disagreed, disagreed, or strongly disagreed that the testing protocol would increase effectiveness of TB testing in their clinic.

Of the 21 responses regarding the effectiveness of the TB test results guidelines, 76.2% strongly agreed, agreed, or somewhat agreed to the effectiveness of the guidelines in their clinic setting and 23.8% of the participants neither agreed, disagreed, or strongly disagreed that the test results guidelines would be effective for use in their clinic.

Question Two: Protocol Evidence-Based?

Survey question #2 asked participants to determine if the TB screening tool, testing protocol, and result guidelines were evidence-based. Of 22 responses, 85.5% strongly agreed, agreed, or somewhat agreed the TB screening tool was evidence-based. Only two participants (9.6%) somewhat disagreed or disagreed that the screening tool was evidence-based. Similarly, 85% of the participants strongly agreed, agreed, or somewhat agreed that both the TB testing protocol and results guidelines were evidence based. No respondents strongly disagreed that the testing protocol and results guidelines were evidence-based.

Question Three: Protocol Efficient?

Survey question #3 addressed the efficiency of the clinical protocol. Overall, 82.1% of the participants agreed the TB screening tool was efficient, 9.1% neither agreed or disagreed, and 14.2% somewhat disagreed, disagreed, or strongly disagreed that the TB screening tool would be efficient for clinical use. The TB testing protocol and TB test result guidelines were tied at 76% strongly agreeing, agreeing, or somewhat agreeing that these components of the protocol would be efficient for use in the clinic setting.

Question Four: Suggestions Regarding Additional Information

Survey question #4 sought suggestions for additional information to be added to the screening tool. This question collected qualitative data from participants through an open text box for comments. A total of nine comments were received.

The first comment referred to the second screening question located on the tuberculosis screening questionnaire: *Russia seems more specific than necessary. The*

FSR such a Tajikistan, etc., would have similar risk. Wouldn't "countries in Asia and Eastern Europe work?" The participant suggested limiting the question to include countries in Asia and Eastern Europe. The screening question followed recommended screening guidelines from the CDC (2016), which specifically refers to individuals from Russia be recommended for TB testing. It would be worth considering changing the question if the CDC recommends it in the future.

No additional changes were indicated in the second comment: *Can't think of anything.*

The third comment reflected the efficiency of the entire TB protocol: *I think the simplicity is part of its utility--we can always dig deeper as needed.* The participant understood the protocol provided a quick, point-of-care reference that could be further expanded upon as necessary.

In response to the fourth comment (*Suggest removing all of Latin America when only BRAZIL is on any list of HBC. Makes everything else suspect*), the CDC (2016) recommended individuals from most countries in Latin America be tested for TB. Twenty-two countries were listed on the World Health Organization's (2015b) TB high burden list: Afghanistan, Bangladesh, Brazil, Cambodia, China, DR Congo, Ethiopia, India, Indonesia, Kenya, Mozambique, Myanmar, Nigeria, Pakistan, the Philippines, Russian Federation, South Africa, Thailand, Uganda, UR Tanzania, Viet Nam, and Zimbabwe. It was estimated in the year 2000 that 80% of new TB cases in the world originated in these countries (World Health Organization, 2015b). It is true that Brazil is the only Latin American country on the high burden list; however, the CDC still recommends screening individuals from most Latin American countries. This protocol

follows current CDC recommendations. A link is provided to view countries with high TB burden for use as an additional reference.

The fifth comment suggested clarification to terminology used in the screening guidelines:

> Nothing to add. Needs more clarification however. Be sure to define terminology consistently. For example, define "lived in country where TB disease is common" consistently. Do you mean for one month or longer for all questions? Define health care worker? IV drug use should be referred to as "persons who inject drugs." Some persons should have serial testing if risk factors are still present, not just if new risk factors.

Terminology in the screening guidelines was based upon CDC (2016) guidelines. It would be helpful to provide a clearer definition of which countries experience TB more commonly and who to test based upon how long an individual resides in the country. Adding a precise definition for “health care worker” would be possible but would also add to the complexity of the tool. It is possible to easily change the wording regarding IV drug use to persons who inject drugs.

The sixth comment suggested assessing pregnancy or future planned pregnancy: *Is the person pregnant or planning to be pregnant?* Asking if a person is pregnant or planning to become pregnant is not currently a question recommended as part of the screening tool according to CDC (2016) guidelines. Pregnancy might alter treatment decisions but might not affect the outcome of test results. The tuberculin skin test and IGRA are safe to administer to pregnant persons. Testing recommendations are available for pregnant persons through the CDC website.

The seventh comment suggested testing contacts of active TB cases: *Information about testing contacts to actives, and the recommendation for testing as soon as possible after exposure and the 8-10 week follow up testing.* The process of testing contacts to

active TB cases requires additional detailed information beyond what is currently included in the protocol. Testing contacts to active cases of TB disease is important for avoiding spread of disease in the population. Additional information regarding contact testing for individuals exposed active TB disease would be a good addition to the screening tool for providers participating in contact investigation testing.

The eighth comment was in response to updating testing information: *QFT -Plus information, possibly adding to TST interpretation that one of the problems with reading of the test can be a very subjective*. The QuantiFERON Gold-Plus is the newest generation of IGRA test available by Qiagen corporation released in October 2017. Updating the protocol to include the most up to date test is appropriate and would be done prior to implementing the protocol in practice. The participant stated the TST interpretation could be subjective so it would be important for clinical staff administering and interpreting TST results to be properly trained to avoid inaccurate results. This is stated in the protocol.

In response to the ninth comment (*I would add the link for TST in 3D*), an online TST and IGRA test result interpreter is available for use free of charge. The tool was developed by researchers from McGill University Health Center (n.d.) in Montreal, Canada. The interpretation tool is supported by The Public Health Agency of Canada and the Stop TB Partnership (McGill University Health Center, n.d.). The tool appears to be easy to access and use. More research is needed to confirm whether this tool is evidence-based and recommended for use. Information about the TST/IGRA test result interpreter is available directly from McGill University Health Center's website:

> The following tool estimates the risk of active tuberculosis for an individual with a tuberculin skin test reaction of ≥5mm, based on his/her clinical profile. It is

> intended for adults tested with standard tuberculin (5 TU PPDS, or 2 TU RT-23) and/or a commercial Interferon Gamma release assay (IGRA). (p.1)

Question Five: Recommendations for Additions to Testing Protocol

Survey question #5 assessed recommendations for additions to the TB testing protocol. Seven comments/suggestions were provided by respondents. The first response suggested adding the IGRA test for individuals with a history of BCG vaccine and a positive TST: *A second test - IGRA is indicated for TST-positive individuals from countries where BCG is used. Many false-positive TSTs can be identified by IGRA testing.* The IGRA test is preferred for individuals with a history of BCG vaccine as indicated in the test selection protocol.

One comment suggested a more specific definition of risk for disease progression:

> Needs more clarification however. For IGRA, define what is meant by "low or intermediate risk of disease progression." Also, it is confusing to have "LTBI testing is recommended" only under the IGRA column. Under table for performing both TST and IGRA, make it clearer that left column (Initial test negative) is likely referring to TST. Also, IGRA is used in children under five years of age. Look up a few published studies about that.

Further definition of what is meant by low or intermediate risk of disease progression would be a helpful addition to the protocol. Upon further investigation, it was difficult to find an exact definition of "low or intermediate risk of disease progression." The CDC (2017) recommendations focused upon testing individuals at high risk for progression to active TB disease:

> Most U.S. TB cases are associated with reactivation of longstanding, untreated latent TB infection. Testing for and treating latent TB infection in high-risk populations is the most effective way to prevent TB disease. Although anyone can get TB, some people have a higher risk of getting infected with TB germs, and should get tested for TB infection. These groups include:
>
> - People born in or who frequently travel to countries where TB disease is common.

- People who currently, or used to, live in large group settings, such as homeless shelters or prisons and jails where TB is more common.
- Health care workers and others who work in places at high risk for TB transmission, such as hospitals, homeless shelters, correctional facilities, nursing homes, and residential homes for people living with HIV.
- Someone who has spent time with a person who has infectious TB disease.
- Others with weaker immune systems, such as those with certain health conditions or taking certain medications, have a higher risk of developing TB disease once infected. (p. 1)

It could be assumed that any group or individual not meeting the testing criteria might be at a lower risk of disease progression.

The participant also thought there was some confusion with part of the table under the IGRA testing section. The statement "LTBI testing is recommended" is listed in the IGRA preferred test choice section of the test selection protocol. It is possible to clarify this further by changing the phrase to "for any person recommended to receive LTBI testing." This same participant also suggested adding information to the algorithm better explaining why testing with both TST and IGRA would be recommended. The participant assumed the initial test was a TST. The chart does not assume the initial test is a TST because there is a possibility that the initial negative test could be an IGRA.

There was support by at least one subject matter expert in favor of testing children under age five with IGRA. The most current guidelines have not yet confirmed nor adopted the IGRA test as recommended for children under age five at this time even though it is accepted by some in practice based upon recent research studies. According to Adams and Starke (2017),

> There is insufficient evidence to support routine use of IGRAs in children <5 years for evaluation of TB infection in the absence of symptoms. Some experts favor use of IGRAs to evaluate children ages 2 to 4, especially in the setting of

> BCG vaccination. Most experts do not favor IGRA use in children <2 years due to insufficient data; TST is preferred in this age group. (Whom to test section)

Information about the QFT-Plus test was again recommended to be added to the protocol in survey question # 5. As previously recommended, all components of the protocol need to be updated to the most currently recommended approved IGRA test. It is uncertain precisely what the following response to question #5 referring to "At our agency, we also enter testing data for our patients into the TST" would be as documentation of testing data would be specific to clinic policy. It would not be necessary to add a recommendation for data entry in the protocol.

Question Six: Suggestions for Additions To Result Guidelines

Six total comments were made suggesting additions to the TB result guidelines section of the protocol. One participant recommended adding more information to the protocol regarding false positive tests in U.S. healthcare workers: *A bit more on false positives. US health care workers are now low-risk for TB and most positives without prior exposure are false positives.* Adding more information regarding healthcare worker risk for TB and potential false positive tests would require further investigation by the provider. The TB result guidelines are designed to be a simple point-of-care tool. Links to access additional information are provided. Other than updating the testing information to reflect the new QFT-Plus test, the remainder of the subject matter experts had no additional recommendations for additions to the TB result guidelines.

Questions Seven, Eight, and Nine:
Omitting Information from
Protocol

Survey questions #7, #8, and #9 asked participants to suggest omissions from the TB screening tool, testing protocol, and TB test result guidelines. Two suggestions were offered for omissions from the screening tool. One participant suggested not recommending screening all individuals with diabetes: *I don't think screening all diabetics is indicated without TB exposure risk*. Diabetes mellitus increases the risk for progression from LTBI to active TB disease. According to the CDC (2000), it is appropriate to test populations with diabetes for LTBI. Additionally, changes were recommended for the TB test result guidelines to test all populations who recently arrived from medium and high burden countries; one participant suggested not including recommendations for testing populations from most Latin American countries since Brazil is the only country listed as a high burden country: *As noted ALL of Latin America is not HBC only one country is on lists--BRAZIL*. The entire protocol was developed with the most currently available screening and testing guidelines from the CDC (2016). Most participants had no suggestions for omitting information from the three sections of the protocol.

Questions # 10, #11, and #12:
Case Examples

Questions #10, #11, and #12 provided three different case examples for participants to review. Each case example represented a different clinical scenario for a fictitious individual with risk factors for TB. The participants were asked to utilize the TB protocol to determine whether the patient should be tested. It also asked which test the participant would choose based upon what was offered in their clinic setting and why

that specific test was chosen. Appendix E provides specific details regarding the case examples.

For question #10, of 15 responses received, 14 chose IGRA as the test of choice. This demonstrated accuracy and consistency with use of the protocol. Most participants agreed the IGRA was a better test choice to avoid a potential false positive response with the TST since the patient had a history of receiving the BCG vaccine. Interestingly, one participant did not feel it was appropriate to utilize the protocol for answering the case example question since the participants were already subject matter experts.

Of the 14 responses to the case example in question #11, six participants chose the IGRA test, seven chose the TST, and one chose both. The protocol recommended tuberculin skin testing for children under five years of age. Some clinicians chose to use the IGRA based upon more recent recommendations to do so. As previously stated, there are no current formal recommendations in favor of performing IGRA testing for children under age five (Adams & Starke, 2017). If IGRA testing is recommended for children under age five in the future, the protocol would need to be updated to reflect that recommendation.

Thirteen total responses were given to the case example in question #12. The test selection protocol stated the IGRA is the preferred test of choice assuming the individual should be tested. A TST is also an acceptable test for individuals. Significant variations existed in the participants' test choice for this case example. It is possible more specific information should have been added to the case study including country of travel and whether baseline testing was done prior to travel. While there was no right or wrong answer to this case example question, responses were sought to test use of the protocol.

Clinical expertise and professional judgement were used as an adjunct to the tool in answering this question by some participants rather than just answering the question based upon the protocol's recommendations. Two participants indicated either test might be used but IGRA would be preferred over TST. Five total participants stated the IGRA was the better test choice, while three participants would use the TST. One participant choosing the TST also added he/she would send the patient for a chest x-ray in addition to the TST. One participant would use both tests even though it was not indicated initially for testing based upon the protocol. Two participants stated they would not test, while one stated they would wait 8-10 weeks after travel before testing.

Questions #13 and 14: Usefulness of Protocol in Public Health and Community Health Settings

Questions #13 and #14 asked participants if they thought the protocol would be useful in the public health and community health settings and to comment why or why not. Sixteen total responses were received. Twelve agreed it would be useful and four disagreed. Those agreeing the protocol would be useful stated the protocol would be user-friendly in the clinic setting; the protocol is a clear guideline; it increases awareness of TB prevalence and risk for progression; it is simple and easy to use; it works well for rural clinics where TB testing is not done as frequently; and it reminds providers to think about TB. Two participants mentioned cost and insurance coverage for IGRA testing might affect the test choice, which would be a potential barrier to increasing appropriate testing. Those who felt the protocol would not increase appropriate TB testing stated the protocol was unorganized, inaccurate, and missing information; public health already has

similar tools available; and it might not increase testing but might improve quality of testing.

Questions #15 and #16: Usefulness of Protocol in Primary Care Setting

Questions #15 and #16 asked about potential for increased appropriateness of TB testing in the primary care setting. Of 16 total responses, 13 stated the protocol would increase appropriate testing in the primary care clinic. Negative comments indicated the tool was not well organized; it had inaccurate and missing information; it lacked incentives; there was lack of knowledge and lack of properly trained staff; and providers were hesitant to treat LTBI in primary care. One comment stated primary care settings saw more patients with health insurance, which might affect how testing was done. Comments in favor of increased appropriateness of testing in primary care included clear guidance, concrete guidelines, increased awareness of TB and TB testing, ease of use, standards for testing, clinical clarification, improved approach to testing, and served as a reminder to assess for TB risk factors.

Questions #17, #18, and #19: Profession of Experts, Work Settings, and Experience with Tuberculosis Screening and Testing

The purpose of questions #17, #18, and #19 were to collect demographic information of the subject-matter experts. Professions (question #17) included registered nurses, physicians, one medical assistant, a community health promoter, and epidemiologists. As noted in the results section, all participants except one reported working in public health departments and one participant reported working in a community health clinic. Most participants had more than five years of TB clinical

experience, confirming the participants had knowledge and training in TB clinical activities.

Fifteen participants reported working in public health departments and one worked in a community health clinic (question #18). The survey was sent out to public health and community health agencies to seek expert opinion in reviewing the protocol.

Fourteen of 15 participants who answered question #19 had experience with TB screening and testing. Six participants had five years or less of experience, nine had more than five years of experience, and five had 10 years or more experience, thus confirming the respondents were subject-matter experts.

Evaluation

The objective of this DNP project was to design and evaluate a clinical protocol for TB screening and testing to be utilized at the point-of-care. Intended clinics for utilization of the TB clinical protocol in the future included public health, community health, and primary care clinics. The protocol was designed to aid in clinical decision-making that was efficient, effective, and evidence-based. It was important to include the ability to identify risk factors for TB indicating need for testing, recommended test type, and how to interpret test results. The objective was achieved as all desired elements were included the clinical protocol, which was based upon the most recent testing guidelines available.

Protocol information was categorized into three sections: tuberculosis screening questionnaire and guidelines, a test selection protocol, and interpretation of test results; although designed to be used together, they might also be used separately. The algorithm created for test choice was a simple, easy-to use-chart. The algorithm could easily be

updated to accommodate new recommendations and provider or clinic preferences, thus accommodating individual needs for protocol organization.

Clinical experts in TB screening and testing evaluated the protocol and provided feedback through an online Qualtrics survey (see Appendix E). An average of 79.6% of the participants strongly agreed, agreed, or somewhat agreed the entire protocol including all three sections was effective. The guidelines for interpreting results scored lowest in effectiveness with 76.2% respondents agreeing. The strongest area of agreement was that 85% stated the entire protocol was evidence-based by strongly agreeing, agreeing, or somewhat agreeing. Clinical efficiency scored the lowest overall with an average of 76.5% strongly agreeing, agreeing, or somewhat agreeing that the protocol was efficient for clinical use.

The survey assessed recommended additions and omissions from the protocol by the subject matter experts. Rationale for this evaluation supported potential protocol modifications to improve efficiency, effectiveness, and evidence-based content. Each recommendation was reviewed and responded to following the comments in the results and outcomes section of this chapter. Comments were received seeking additional clarification regarding geographic locations of birth country to assess risk for testing. Additionally, suggestions were received to clarify and update terms and/or phrases written in the protocol. Terminology used in the protocol was adopted from the most current guidelines used in the United States from the CDC (2016) but could be easily modified to meet the needs of individual clinics. One necessary update to the protocol included the most recently approved IGRA test--the QFT-Plus. It was also recommended that a link to the TST in 3D web site be added as a clinical tool for TB testing. This

could be added to the protocol by clinics utilizing the tool. More research needs to be done to evaluate the tool for evidence-based practicality.

The survey assessed validity of protocol effectiveness through three case example questions. The case examples included different patient scenarios for participants to review. Participants were asked whether testing was indicated and which test they would choose based upon what their specific clinic would offer. The patient in the first case study question was an adult with a history of BCG vaccination. All participants chose the IGRA test as recommended in the protocol. This case study question validated the protocol's effectiveness.

The second case study was a child under age five. Many participants chose the IGRA test rather than TST for this patient based upon recent literature available supporting use of IGRA in this population. The protocol recommended use of TST in children under age five, which was based upon most current evidence-based recommendations. Perhaps recommendations in favor of testing children under age five with IGRA will change in the future based upon more recent studies. While some participants chose the TST as the protocol suggested, others felt the IGRA was preferred and chose not to follow the protocol as written.

The third case example evaluated a college student with a recent history of travel. It is important to note that more information needs to be added to this example including exact geographic location of travel. It was assumed the student needed to be tested since the student was exposed to a population with increased risk factors for acquiring TB infection and disease. All but one participant stated the student should be tested and both tests were chosen equally by the participants based upon what they would use in their

clinics. This case study was accurate with the suggestions in the testing protocol, also proving protocol effectiveness.

The survey also asked participants' professional opinions about usefulness of the survey in both public/community health and primary care practice settings. The purpose of this question was to assess efficiency of use in the clinic setting and to seek confirmation that the protocol was necessary. Most participants (75% and 81%, respectively) stated the survey would be useful in both settings. Comments in favor of usefulness included clear guidance and ease of use. Comments against the usefulness included inorganized/inaccurate information and that tools like this were already being used in the public health setting so it might be more useful in primary care.

Demographic information collected in the protocol evaluated the amount of TB clinical experience and profession of the survey participants. It was important to gain this information to confirm participants had some TB clinical knowledge and experience. Eleven of the 16 participants had two or more years of TB clinical experience and five participants had two years or less experience. Ten participants were registered nurses; other participants included epidemiologists, physicians, medical assistants, and a community health promoter. All participants worked in health departments or community health clinics.

Key Facilitators

Successful outcomes for the development of an efficient, effective, and evidence-based TB clinical protocol depended upon this researcher's ability to identify the problem. For this project, a need to develop a user-friendly tool was identified and supported through the literature review. The literature review revealed much information

existed for clinical decision-making regarding TB screening and testing; however, a simple point-of-care tool was not found. Thus, the literature review served as a key facilitator for this DNP project.

Development of partnerships is one of five criteria necessary to meet the outcomes of a successful doctoral nursing project (Waldrop, Caruso, Fuchs, & Hypes, 2014). Intraprofessional collaboration requires use of resources provided by nursing faculty and clinical nurse staff (Moran, Burson, & Conrad, 2017). Nursing faculty members served as a guide for this researcher while clinical nursing staff served as subject matter experts in review and evaluation of the project. Interprofessional collaboration outside the discipline included public health experts in epidemiology, administration, physicians, and other clinical staff with experience in TB testing. Moran et al. (2017) shared several models supportive of interprofessional collaboration and its importance in improving healthcare outcomes. Interprofessional and intraprofessional collaboration among the researcher, scholarly faculty at the University of Northern Colorado, TB elimination work group, and the CDPHE (2017) was the main key facilitator that made this objective achievable. The researcher collaborated with both faculty and professionals having knowledge, expertise, and common goals related to TB prevention activities.

In December 2016, the Volunteer TB Elimination Planning Task Force presented a 10-year plan to eliminate tuberculosis in Colorado. This elimination plan served as a facilitator for development of the TB clinical protocol. Six goals were developed along with strategies and objectives to support elimination of TB statewide. Goal two specifically addressed the need to test individuals at risk for TB. Activities related to

development of a screening tool and standardizing use of IGRA testing. The task force also sought to provide communication strategies with medical providers in the fifth goal. The first objective for this goal was to "develop and implement a strategy promoting clear and simple guidelines for screening, testing and treatment of TB infection" (Volunteer TB Elimination Planning Task Force, 2016, p. 17). An activity for this strategy was to facilitate implementation of the screening/risk assessment tool and provide a toolkit to providers (Volunteer TB Elimination Planning Task Force, 2016). The group had previously developed a screening and risk assessment tool; however, this project expanded upon that tool by adding evidence-based information for use of IGRA testing, appropriate test choice in the test selection protocol, and a set of guidelines for test interpretation. This project could be used with all three sections together or individual sections as needed for inclusion in a provider toolkit.

Recommendations for diagnosing TB in adults and children were introduced in January 2017 by the American Thoracic Society, Infectious Diseases Society of America, and The Centers for Disease Control and Prevention (Lewinsohn et al., 2017). This served as a facilitator for developing the protocol testing recommendations. The guidelines served as the most current information available for TB diagnosis and were utilized in the clinical protocol. The new guidelines supported use of IGRA testing as a standard of practice.

Use of the nursing process was another key facilitator to formulating and developing the objective. The assessment phase of the nursing process expanded upon information obtained in development of the identified need for developing the clinical protocol. The TB elimination task force strategies were used to assist with defining the

project objective. Diagnosis was the phase of the nursing process where data obtained through the literature review assisted with developing the need for the protocol. The planning phase included a significant amount of time developing ideas for creation of the project. Evaluation of the project collected information from the survey results and dissemination of the outcomes for future projects (Moran et al., 2017).

The Stetler (2001) model of research utilization served as the facilitator for the objective by assisting with closing the gap between evidence-based research and practice through transformation of research into practice. Similar but also different than the nursing process, the Stetler model has five phases: preparation, validation, comparative evaluation/decision making, translation/application, and evaluation. Chapter III described how the Stetler model was used in more detail. The model was versatile for protocol development.

Additional facilitators for meeting the objective included a minimal budget beyond time invested by the student, slight to no risk for volunteer participants, and easily obtainable technology for protocol and survey development. Without these facilitators, project delays and complications would have been inevitable.

Key Barriers

The DNP proposal required revisions to create a practical project. The project timeline was affected by the researcher's need to revise the proposal frequently as the project was designed. Initially, implementation of the project in the clinic setting was planned. A decision was then made to change the project to an expert review of the protocol with the possibly of future implementation in the clinic setting. This process allowed the researcher to seek feedback from subject matter experts to determine the

potential efficiency, effectiveness, and evidence-based content of the protocol. It also allowed for recommended modifications to be made prior to future implementation in the clinic setting. Additional revisions were made to the project, thus affecting timeliness related to the newly published guidelines by the Infectious Diseases Society of America in 2017 (Lewinsohn et al., 2017). Time delays were a key barrier during this process.

The literature review revealed an abundance of information available to providers for TB screening and testing. Developing a comprehensive tool that was simple to use at the point-of-care served as a challenge in meeting the objective. A few comments received regarding additions to the protocol would have led to a longer, more cumbersome protocol and a less efficient point-of-care guide. To proactively address this concern, links were added to the protocol for the provider to look up additional information if needed. One survey comment addressed this well: the provider may "dig deeper" for additional resources as necessary.

The key barrier to protocol development was professional decisions might overrule protocol as was proven in the case examples. Choices were made in the survey case studies by some participants that differed from recommendations in the protocol. Professional opinion beyond commonly available testing recommendations was used by some clinicians. For example, one subject matter expert recommended reviewing more recent studies for use of IGRA testing in children under age five. While evidence-based studies might be available, the most recent CDC (2017) guidelines do not yet recommend use of the IGRA in children under five.

Comments received from subject matter experts identified potential barriers for use of the protocol beyond professional clinical decision-making. It was anticipated that

cost would be a contributing factor in test choice during protocol development. While cost was not directly discussed in the responses, patient insurance coverage might force clinicians to choose one test over another even if it was not the most preferred test. Staff must be properly trained to perform both the IGRA and TST, which could be a problem for some clinics. Providers might not be aware of who to screen, were unfamiliar with treatment for LTBI, or felt no incentive for screening and testing. These factors were not key barriers for development of this protocol but could be potential barriers for success with future clinical effectiveness and efficiency.

Finally, a key barrier in the collection of data was a low response rate to the survey. The goal for survey responses was less than expected with 25 responses of 229 e-mail invitations to participate--a 10.9% participation rate. The survey was delivered on October 18, 2017. The link to the survey remained open for more than three weeks until November 10, 2017. A reminder e-mail for participation was sent on October 30, 2017. For unknown reasons, only 15-16 subject matter experts answered most questions by the end of the survey. More information would have been collected if everyone had completed the survey.

Unintended Consequences

A positive unintended consequence of the project was the ability to participate in an opportunity to partially meet objectives for the TB elimination plan in Colorado. Once the problem statement was decided upon, the researcher contacted the state TB epidemiologist to request advisement and support for the project (CDPHE, 2017). Introduction to the Volunteer TB Elimination Planning Task Force (2016) and the TB elimination plan were offered. Development of a project to align with the goals and

objectives written in the TB elimination plan was an opportunity to bridge the scholarly project with a tangible plan for public health prevention activities.

A negative unexpected consequence was the need to update the protocol prior to implementation in practice. In October 2017 a newer version of the IGRA test was introduced by Qiagen--the QFT-Plus. The protocol would need to be modified with the latest approved tests prior to moving forward with future phases. Modifications to the protocol are easily made but the protocol must continually be reviewed and updated as changes are recommended. It would be important to identify practical ways to provide updates as needed to providers utilizing the protocol.

Both positive and negative unintended consequences were received from subject matter experts about accepting the protocol for clinical use. Most supported use of this simple protocol in the clinic setting. Responses in favor of or against utilization of the protocol were unknown prior to sending it out for review so a mostly favorable response was truly a positive consequence for the project. One comment received created an idea that simply having a TB screening and testing protocol available would raise TB awareness by serving as a reminder to screen patients for TB risk factors and test patients at risk for TB. Negative unintended consequences revealed potential barriers to future implementation of the project. There was concern that staff might not be appropriately trained in testing techniques and insurance might not cover preferred tests.

CHAPTER V

RECOMMENDATIONS AND IMPLICATIONS FOR PRACTICE

This chapter contains final recommendations and implications for practice. Several key facilitators and key barriers contributed to successes and challenges of the project development and outcomes. Recommendations are included in support of key facilitators while potential solutions for key barriers are addressed along with recommendations for identified unintended consequences of the project. Suggestions are provided for ongoing evaluation of the clinical protocol beyond the conclusion of this project. Additional settings for project application are discussed. Personal leadership goals for the DNP graduate including how this doctoral nursing project met the essentials of DNP education are provided in this chapter as well.

Recommendations

The problem statement identified issues contributing to provider challenges with TB screening and testing including diversities amongst recommendations, the focus only on specific populations, and unique patient situations in the literature. The opportunity existed to create an evidence-based protocol for improved and efficient clinical decision-making at the point of care. Recommendations for the problem statement remained to improve the quality of patient care and clinical efficiency with use of the TB protocol.

The CDPHE (2017) TB program served as the lead supporting organization for this project. The TB program manager was very supportive and was a connection to subject matter experts statewide. Recommendations for the site include continued pursuit toward TB elimination in Colorado by working toward meeting the objectives as written in the strategic plan. Continued work with graduate students interested in TB prevention might maintain momentum with the volunteer task force.

Key stakeholders were public health, community health, and primary care clinics with access to patient populations at risk for latent TB infection and active disease. Recommendations for key stakeholders are to implement this protocol in the clinic setting to increase testing for populations at risk and increase awareness of the importance of TB prevention.

The university setting offers a great opportunity for graduate nursing students to bridge the gap between scholarly work and clinical practice. Many opportunities are available for the DNP student interested in population health to create clinical protocols for population health prevention activities including communicable diseases like TB. Connections with organizations such as state health departments persuade the health and safety of populations. It is recommended that schools of nursing encourage doctoral students to reach out to these organizations in support of scholarly projects.

Recommendations for the DNP student would be to narrow the focus of the project and consider how projects should be developed in phases over time. The original plans included testing the protocol in the clinic setting but it would be best to receive subject matter expert feedback prior to live testing in the clinic. Waiting to implement the protocol for a future project is a good choice while offering the option to update and

improve upon the protocol, which would lead to a greater chance of success in the clinical setting.

Recommendations and implications for practice exist for key facilitators. The scholarly literature review provided a baseline for identifying the opportunity to develop the protocol. It is recommended that an ongoing literature review be conducted throughout the process to ensure the project is up to date with the most current information.

Collaboration with key stakeholders was an important facilitator for success when developing and meeting the objective. Collaboration also facilitated success with current and future phases of the project. Ongoing collaboration with the volunteer task force is recommended to move forward with the next phase of the project. Members of the task force are experts in the profession and have great influence in promoting TB awareness, increasing screening and testing, and supporting recommendations.

The Stetler (2001) model of research utilization along with the nursing process facilitated forward movement of the project while allowing for continuous evaluation and flexibility for transformation. The Stetler model provided flexibility and supported utilization of research into evidence-based practice. Preparation, validation, decision-making, translation/application, and evaluation might be either formal or informal in nature. It is recommended that use of this model be continued as a guide for future work on the project.

A minimal budget was planned for this project, which primarily involved the cost of time spent by the DNP student. A larger budget that included costs of professional assistance with survey development and providing an incentive might have resulted in a

greater response to the survey. A greater number of responses might have led to additional recommendations for the protocol. Moving forward, offering an incentive for clinics and providers to test the protocol in practice is recommended. The incentive might include a small gift of appreciation such as gift card or perhaps a meal could be furnished to providers along with an educational session about use of the tool in practice.

Modern technology was a great facilitator for protocol development, online surveys, and communication with stakeholders. In the future, it would be essential to collaborate with computer professionals to add protocol access in electronic health records. The paper format is useful during development but providers rely on electronic devices for access to records and clinical resources. Integrating the protocol into electronic health systems once it is implemented in the practice setting would increase access at the point of care.

Recommendations for identified barriers to meeting the objective include reducing time spent on revisions, reviewing literature regarding IGRA testing in children under age five, adding more links for additional testing information, considering test cost and insurance coverage, and identifying ways to improve survey participation. Time spent revising the project was stretched out over several months, which led to research advisors and the DNP student to refamiliarize themselves with the details over time. Improvements with time management would lead to smoother flow with both proposal writing and protocol development.

Interferon gamma release assay testing for children under the age of five is not currently recommended; however, subject matter experts were relying on more recent studies for clinical decision-making for TB testing. It would be recommended to conduct

an additional literature review of the topic in anticipation of changes to future testing recommendations for children under age five.

The protocol recommended use of tuberculin skin testing as an acceptable alternative when IGRA is too costly. While insurance coverage and cost are factors in test choice, the protocol addressed an acceptable alternative. No additional recommendations are currently proposed so decisions will continue to be based upon agreements made between the provider and patient given the patient's unique situation.

Several factors were identified affecting survey response rates. A systematic review by Fan and Yan (2010) examined challenges with web surveys contributing to low response rates. Factors in survey development include survey content and presentation. Factors in delivery include sampling error in that not all participants have access to the survey, modes of delivery, design of the invitations, use of pre-notifications and reminders, and incentives. Factors affecting completion response rates include theories about decision to participate. Factors affecting response rates when returning the survey include software product used and data safety (Fan & Yan, 2010). In taking a closer look at the present survey, many participants started the survey but did not complete all the questions. Based upon recommendations by Fan and Yan, future surveys should involve expert design to maximize responses. Additionally, the survey was sent to a large contact list with a lengthy invitation. Improvements to the invitation design might improve response rates along with a pre-notification of the upcoming protocol and survey. It is also important to consider potential issues such as technical challenges limiting access to and receipt of the survey.

Continued progress and success with the TB clinical protocol will be dependent upon continued support by the Volunteer TB Elimination Planning Task Force (2016). It would be important to align future phases of the project with the objectives and activities identified by the organization's strategic plan. As written in the plan's executive summary, TB control is challenging but new technologies are improving the way TB is diagnosed and treated. Work must continue to support efforts toward TB elimination (Volunteer TB Elimination Planning Task Force, 2016). Success with future protocol use will be dependent upon general upkeep and maintenance with most recent testing technology and evidence-based recommendations. A plan needs to be made to address updates and method of delivery to providers.

The researcher recommends this project be continued. Next steps include clinical updating of the protocol based upon expert recommendations and implementation at point of care. Continued collaboration with the state health department and task force would assist with locating volunteer settings for testing the protocol in the clinical setting. Additionally, it will be important for providers to have electronic access to the protocol so additional stakeholders must be added to the project for technological assistance. Decisions will need to be made regarding who will be responsible for updating the protocol in the future.

Ongoing Evaluations

Evaluating success of the clinical protocol in the practice setting will be important beyond the scope of this DNP project. Clinicians and administrators will be responsible for monitoring the effectiveness, efficiency, and evidence-based content of the protocol in the practice setting. This might be done through data mining of electronic records at

the clinical site to evaluate appropriate screening and testing of patients at risk for TB. Clinics will need to develop goals, objectives, and activities to support such ongoing evaluation. The TB elimination strategic plan has a goal to support tracking and evaluation of programs to measure progress of integrating new technologies (Volunteer TB Elimination Planning Task Force, 2016). Public health and community health providers will be responsible for providing support, education, communication, and disease monitoring at the population level in response to future phases of the project.

Recommendations for Project Application in Other Settings

Any setting with populations at high-risk for TB would be able to utilize the protocol. Correctional facilities, university health clinics, homeless shelters, and mobile health vans providing care to underserved populations would be ideal settings for project application beyond public health departments, community health centers, and primary care clinics. These settings should be screening for and testing individuals for TB risk factors. Public health authorities would be responsible for identifying settings with high-risk populations and providing education and toolkits for successful screening and testing programs. The clinical protocol should be part of that toolkit.

Personal Leadership Goals

As a DNP graduate student, personal leadership goals included gaining the knowledge and skills to bridge the gap between theory and clinical practice. The DNP graduate program is designed for the student to successfully comprehend all the elements of the scholarly project and assemble them into a final scholarly work designed for practical use. The ultimate result of combining scholarly work with practice should contribute to improvements in health care and increase knowledge in a specialty area

(Moran et al., 2017). This project prepared the student to identify quality articles, research best evidence for practice, identify an opportunity, and develop a project that will improve population health care outcomes that align with current strategic plans.

It was important for this DNP graduate to provide leadership within interprofessional teams. Experience gained with collaboration with university faculty, public health, nursing, and primary care provided the skill set needed for leadership in an advanced health care profession. The National Center for Healthcare Leadership (2017) strives to improve health care through leadership and organizational excellence. Creating collaboration was a main objective along with creating a base of evidence for optimizing leadership in healthcare. Quality health care relies on the ability for professionals to work together across many disciplines, which met this professional leadership goal.

Essentials of Doctor of Nursing Practice Education

Doctor of Nursing Practice education consists of eight essentials for doctoral education developed by the American Association of Colleges of Nursing (AACN; 2006). The following section explains the eight essentials along with how this project met each item.

Essential I: Scientific Underpinnings for Practice

This essential expectation is best described by the DNP educated advanced practice nurse when demonstrating understanding of complexities of practice. It is important for the DNP student to effectively translate knowledge to practice. Preparations for meeting this essential include integrating nursing science with a variety of other sciences, use theory and concepts to improve health care delivery, and develop new approaches to healthcare delivery through application of theory (AACN, 2006).

Development of a new clinical protocol for TB screening and testing met the requirements for this first essential. Knowledge regarding TB screening and testing was obtained through combined nursing clinical experience and a review of literature. The Stetler (2001) model was utilized to facilitate development of the evidence-based protocol derived from the research findings in the literature review. Healthcare delivery will be improved through use of this effective, efficient, and evidence-based project.

Essential II: Organizational and Systems Leadership for Quality Improvement and Systems Thinking

To best summarize this essential, DNP prepared graduates must understand organizations and systems leadership to improve health outcomes in populations. This essential extends beyond direct patient care into having the skills to work on strategies for quality improvement in the health care setting (AACN, 2006). This scholarly project met Essential II by the development of a protocol that not only assisted with clinical care activities but also aligned with the strategic plan to eliminate TB in the population. The population at risk for TB requires much sensitivity, working within a limited budget (many volunteer hours from professionals), and excellent communication skills for success.

Essential III: Clinical Scholarship and Analytical Methods for Evidence-Based Practice

This essential is best summarized as successful application of scholarship into practice. According to the AACN (2006), this also includes the ability to evaluate practice, improve outcomes, and participate in research. The objective for this project was to develop a useful protocol based upon research that was applicable to practice,

which met Essential III. Additionally, a thorough evaluation of the protocol was achieved through an online survey and collaboration with subject matter experts. The protocol was designed to improve quality of care that was effective, efficient, and evidence-based. Findings of the survey were intended to lead to developing a quality product for use in practice.

Essential IV: Information Systems/ Technology and Patient Care Technology for the Improvement and Transformation of Health Care

This essential requires graduates to be proficient in the use of information systems and technology. Five requirements are needed to meet the expectations: use of programs, analyzation of health care information systems, ability and technical skills for data extraction, leadership, and evaluation (AACN, 2006). Use of technology during development of this project was abundant. Technology was used to obtain and evaluate information. An online survey was used to collect and evaluate data. Communication networks including e-mail and phone conferencing were used to attend regular meetings to share and execute plans.

Essential V: Health Care Policy for Advocacy in Health Care

Governmental involvement is important in creating, enforcing, and supporting healthcare policy to deliver healthcare services. This essential required the DNP graduate student to assume a leadership role on behalf of the public and the profession. Many issues are involved with delivery of health care (AACN, 2006). Patients at risk for TB are culturally diverse and many have additional healthcare disparities contributing to increased risk. Healthcare policy greatly influences the way TB is prevented and

controlled. As a volunteer on the task force for TB elimination in Colorado and as a student willing to share the project with local government health agencies, the researcher met the requirements for Essential V.

Essential VI: Interprofessional Collaboration for Improving Patient and Population Health Outcomes

The DNP graduate must be able to work effectively with multiple disciplines and exhibit appropriate leadership in teams (AACN, 2006). Communication and collaboration with multiple teams was necessary for development of this protocol. Epidemiologists, program managers, providers, nurses, university faculty, and outreach workers were involved in providing feedback throughout the process. The researcher provided leadership and guidance throughout the process by coordinating meetings and providing updates to advisors.

Essential VII: Clinical Prevention and Population Health for Improving the Nation's Health

Implementation of clinical prevention and population health activities summarizes this essential (AACN, 2006). This DNP project was based upon goals to prevent and eliminate TB from the population at the state level. The strategies for local population health are a part of a greater strategy developed by the WHO (2015) to eliminate TB. The DNP student extensively analyzed TB data as it related to population health and also developed a protocol to assist with screening and testing high-risk populations for TB. This project met the requirements of Essential VII.

Essential VIII: Advanced Nursing Practice

This essential requires the DNP graduate prepare for advanced practice in a specialized area of nursing. It is important to note that the essential provides a foundation for practice as a DNP. Essential VIII is a culmination of skills required by essentials I through VII with application to practice. The DNP must be able to assess health and illness in complex situations, provide therapeutic interventions, have therapeutic relationships, demonstrate advanced levels of clinical judgement and thinking, support and mentor other nurses, educate and guide others, and demonstrate strong analytical and conceptual skills (AACN, 2006). This project aimed to design an evidence-based protocol with the goal of improving outcomes for patients and the TB population. Various clinical experiences in family practice were obtained throughout the program. Additionally, specialty TB clinical knowledge, nursing knowledge, and advanced analytical skills in population health issues were required to develop the TB protocol, thus meeting the requirement for Essential VIII.

Summary

Clinical use of evidence-based tuberculosis testing technologies based upon newer recommendations released by the USPSTF in 2016 and the Infectious Diseases Society of America, Centers for Disease Control and Prevention and American Thoracic Society (Lewinsohn et al., 2017) provided an opportunity to create a new efficient, effective, and evidence-based TB screening and testing protocol. Goals to eliminate TB both globally and locally supported increased screening and testing for individuals at high risk of TB. Providers need assistance with clinical decision-making at the point-of-care to encourage appropriate TB screening and testing. The Stetler (2001) model of research

utilization served as a model to guide the project. Development of the protocol aligned with the strategic plan to eliminate TB in Colorado (CDPHE, 2017). Once the protocol was developed, expert feedback was received through a Qualtrics survey. Most respondents agreed the protocol was efficient, effective and evidence-based. Respondent comments were reviewed regarding recommended edits, omissions, and additions to the protocol. Once the protocol is updated with the newest test and modified based upon expert suggestions, it will be ready for testing in practice. This DNP project met the eight essentials required of the DNP graduate.

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APPENDIX A

LITERATURE REVIEW TABLE

Year	Author, Title, Journal	Purpose	Design (descriptive, systematic review, observational, etc.)	Sample	Method	Results/other
1995	Bloch, A. B.	Recommendations for screening for TB by the advisory council for the elimination of tuberculosis	Expert Opinion	N/A	N/A	Provides CDC recommendations for identification of and screening high risk populations for TB
2005	Steele et al.	Determine impact of computerized clinical decision-making support and guided web-based documentation on screening rates for LTBI	Nonrandomized prospective intervention study	8463 patients in two primary care, outpatient, public community health care clinics	Utilization of computerized clinical tools	Screening of high risk patients for LTBI increased from 8.9% to 25.2% with the computerized clinical decision support tools which included alerts and guided web-based documentation.
2007	Mazurek, Weis et al.	Comparison of TST, QFT, and QFT-G in subjects suspect for TB	Prospective, cross-sectional comparison study	148 subjects with suspected TB	All subjects were tested with three tests simultaneously	All 3 tests have similar sensitivity in subjects with culture confirmed TB, but negative tests should not be used to exclude diagnosis of TB in patients with symptoms of TB.

2007	Mazurek, Zajdowicz et al.	Comparison of TST, QFT, and TB-SPOT test in Navy recruits	Cross-sectional comparison study	856 Navy Recruits	Subjects were tested with TST, QFT, and QFT-G for comparison of results	Specificity of QFT-G (99.8%)and TST (99.1%) were higher than QFT (92.3%)
2008	Kobashi et al.	Study assessing transitional change of TB blood test results during TB treatment	Comparison study	48 patients with confirmed active TB disease and 50 healthy subjects	TST, QFT-TB, and T-SPOT test were done, serial testing was done during treatment of the active TB subjects	Both commercial blood tests were more useful than TST for patients with active TB, no significant differences between the two tests, several false negatives and indeterminate tests were found in 13% of immune compromised subjects
2009	Higuchi et al.	Comparison of two TB blood tests for diagnosing TB	Comparison study	47 patients with active TB and 84 healthy subjects	QFT-G and T-spot were administered to each participant	T-SPOT sensitivity was 100% and QFT-G sensitivity was 87.2% in this study
2010	Sester et al.	Review of IGRA tests for diagnosing active TB	Systematic review and meta-analysis	27 articles met inclusion criteria	PRISMA And QUADAS Guidelines	Diagnostic sensitivities for IGRA are higher than TST, but IGRA should not be used solely to rule out active TB

2010	Mazerek et al.	Provide recommendations for use of IGRA	Expert opinion	N/A	Literature review	Provides recommendation for use of IGRA-newer guidelines have since been published
2011	Linas et al.	Identify cost effective TB screening tests and estimate costs of testing for both TST's and IGRA's	Comparison Study	Subjects were defined by CDC risk groups for TB, Data was retrieved from a large US database, cost of test varies by age and risk factors	Cost analysis utilizing Markov model	This article is a comparison study between the TST and IGRA tests utilizing a Markov model to determine cost effectiveness of both TB tests in high risk populations.
2011	Denkinger et al.	Identify diversity in TB testing recommendations	Systematic Review and Descriptive Study	33 guidelines And 50 expert consultations	Review of evidence-based guidelines and expert opinions	4 main approaches to TB testing recommendations exist (2-step, IGRA only, both TST and IGRA, either TST or IGRA-not both); overall increased use of IGRA's but current guidelines are not objective or transparent (disclosing conflicts of interest)

2011	Horsburgh & Rubin	Identify candidates for TB screening, select a test, and choose a treatment	N/A	Guidelines review and recommendation	Review of evidence-based guidelines	This article is a review of current TB testing/treatment guidelines and recommendations based upon those guidelines
2012	Mancuso et al.	Comparison of diagnostic tests for TB	Cross-sectional comparison study of 3 commercially available tests	2,017 military recruits	Risk factor questionnaire and QFT-GIT, T-spot, TST were given to each participant	In populations with a low prevalence of TB, there is not much difference in specificities in any of the three tests. TST (99.3%), QFT-GIT (98.8%) and T-SPOT(98.7%). 88 subjects had positive tests, only 10 of these were positive to all three tests
2013	Pareek et al.	Comparative performance and cost effectiveness of IGRA tests and TST test with and without chest x-ray in UK	Comparison Study	231 foreign-born immigrants	Comparison and Cost analysis of IGRA and TST test	CXR could be eliminated if IGRA testing is used which would be cost effective in the newly arriving immigrant population.

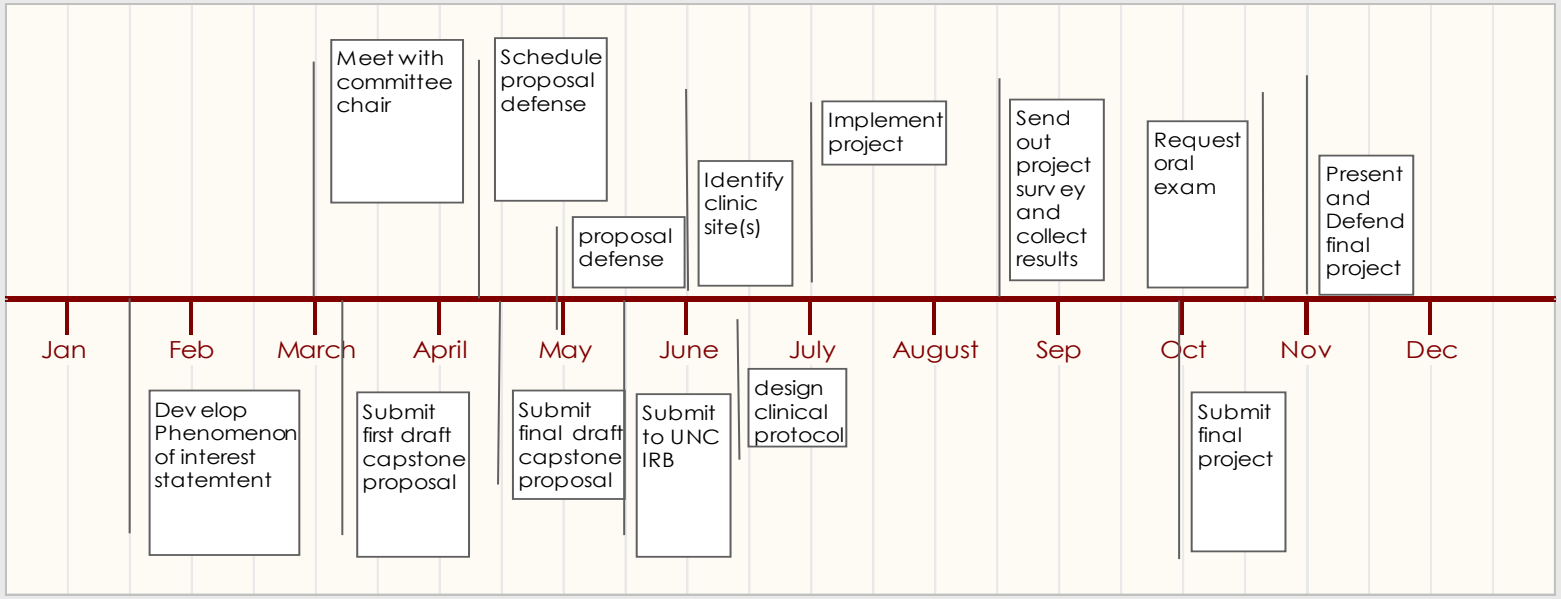
2013	Jeon et al.	Study analyzing factors that contribute to discordant TB test results	Retrospective study	Analysis of laboratory and clinical data of 1301patients diagnosed with TB in Seoul, Korea	Analysis of discordant test results	In patients with high inflammatory markers like CRP, or older age QFT-GIT results may have higher indeterminate or negative results
2013	Painter et al.	Compare sensitivity of QFT and TST in immigrant population with universal vaccination with BCG vaccine at birth	Comparison study	996 Viet Nam immigrants with abnormal chest x-ray and 479 immigrants with normal chest x-ray	QFT and TST results were obtained	QFT is just as sensitive as TST in detecting TB in this population, fewer chest x-rays were necessary with QFT making QFT preferred test for this population
2016	Olivieri et al.	Study of results of IGRA test in addition to TST in Italian health care workers	Retrospective study of LTBI screening program	2136 Italian healthcare workers	All subjects with initial positive TST test were tested with QFT-GIT along with a group of TST negative subjects	Use of QFT-GIT test as a second step is useful for detecting LTBI, especially in BCG vaccinated healthcare workers
2016	USPSTF	Screening recommendations for adults at increased risk for tuberculosis	Recommendations based on review of evidence	N/A	Grading of testing recommendations for TB	Recommendation: Screen adults at increased risk for tuberculosis, Population description provided

2017	Lewinsohn et al.	Evidence-based guidelines for diagnosing TB	Review of evidence by task force	23 evidence-based recommendations were reviewed	GRADE approach	Updated diagnostic testing recommendations for LTBI were developed
2017	Pai and Menzies	Evidence-based guidelines for diagnosing TB	Recommendations based on review of evidence	N/A	Review of literature	Screening recommendations for adults without HIV infection. Includes information about TST and IGRA tests.

APPENDIX B

PROJECT TIMELINE

2017 Tuberculosis Project Timeline



APPENDIX C

RECRUITMENT EMAIL, INSTITUTIONAL REVIEW BOARD APPROVAL, AND CONSENT FORM

Date: October 17, 2017

Re: Evidence-based Tuberculosis Screening and Testing Clinical Protocol for Public Health and Primary Care Providers: A Doctorate of Nursing Practice capstone project by Kimberly Senn

Greetings,

I am writing to inform you about an opportunity to participate in a Doctorate of Nursing Practice capstone project reviewing a tuberculosis testing clinical protocol. You are being asked to complete a short online survey to provide feedback on the proposed protocol. The survey should take no more than 10 minutes of your time. The purpose of this project is to develop a clinical protocol for future use in both public health and primary care settings.

This letter is being sent by the Colorado Department of Public Health and Environment (CDPHE) TB program on behalf of the graduate student, Kimberly Senn. Your participation in this research project is completely voluntary. You may decline altogether, or choose not to answer specific question(s). There are no known risks to participation in this project beyond those encountered in daily life. Your responses will remain confidential and anonymous. Data from this research will be reported only as a collective combined total.

The protocol and survey may be accessed through attachments and a link provided in the e-mail (below). If you have any questions about this project, feel free to contact me via phone or e-mail. Your assistance with this project is greatly appreciated.

Once you have reviewed the attached protocol, you may access the survey by clicking on the link below:

TB Screening and Testing Protocol Survey

Sincerely,

Kimberly Senn, Principal Researcher

UNIVERSITY OF
NORTHERN COLORADO

Institutional Review Board

DATE:	September 21, 2017
TO:	Kimberly Senn, BSN, RN
FROM:	University of Northern Colorado (UNCO) IRB
PROJECT TITLE:	[1090805-2] Evidence-based Tuberculosis Screening and Testing Clinical Protocol for Public Health and Primary Care Providers
SUBMISSION TYPE:	Amendment/Modification
ACTION:	APPROVAL/VERIFICATION OF EXEMPT STATUS
DECISION DATE:	September 20, 2017
EXPIRATION DATE:	September 20, 2021

Thank you for your submission of Amendment/Modification materials for this project. The University of Northern Colorado (UNCO) IRB approves this project and verifies its status as EXEMPT according to federal IRB regulations.

Kimberly -

Thank you for the memo and the clear and thorough consent form. Be sure to use this form in your participant recruitment and data collection protocols. Your application is verified/approved exempt and you may begin your research.

Best wishes with this study.

Sincerely,

Dr. Megan Stellino, UNC IRB Co-Chair

We will retain a copy of this correspondence within our records for a duration of 4 years.

If you have any questions, please contact Sherry May at 970-351-1910 or Sherry.May@unco.edu. Please include your project title and reference number in all correspondence with this committee.

This letter has been electronically signed in accordance with all applicable regulations, and a copy is retained within University of Northern Colorado (UNCO) IRB's records.

Institutional Review Board

CONSENT FORM FOR HUMAN PARTICIPANTS IN RESEARCH
UNIVERSITY OF NORTHERN COLORADO

Project Title: Evidence-based Tuberculosis Screening and Testing Clinical Protocol for Public Health and Primary Care Providers

Researcher: Kimberly Senn, DNP Student Phone Number: (970) 371-2887
E-mail: mill4151@bears.unco.edu
Project Advisor: Jeanette McNeill Phone Number: (970) 351-1704
E-mail: Jeanette.McNeill@unco.edu

The purpose of this doctoral capstone project is to develop a point-of-care evidence-based clinical protocol. The protocol will assist public health, community health, and primary care providers with screening and testing for tuberculosis (TB) in adults and children. The protocol and link to the online survey will be e-mailed to participants with the assistance of the Colorado Department of Public Health and Environment TB program staff.

Participants are being asked to complete an online survey providing feedback on the proposed protocol. Survey questions will assess the proposed protocol for effectiveness, efficiency, and evidence-based content. Participants are asked to provide minimal demographic information including profession (MD, RN, Administrator, etc.), work setting, and years of work experience with TB. Participants will not be asked to provide any personal identifying information. Data from this research will be reported only as a collective combined total.

There are no known risks to participate in this project beyond those encountered in daily life. Responses will remain confidential and anonymous. Benefits to the participant include the opportunity to provide feedback on the development of a clinical protocol. This feedback may lead to improved evidence-based clinical practice for TB screening and testing in the future.

Participation is voluntary. You may decide not to participate in this study and if you begin participation you may still decide to stop and withdraw at any time. Your decision will be respected and will not result in loss of benefits to which you are otherwise entitled. Having read the above and having had an opportunity to ask any questions, please complete the survey if you would like to participate in this research. By completing the survey, you will give us permission for your participation. You may keep this form for future reference. If you have any concerns about your selection or treatment as a research participant, please contact Sherry May, IRB Administrator, Office of Sponsored Programs, Kepner Hall, University of Northern Colorado Greeley, CO 80639; 970-351-1910.

APPENDIX D

STATEMENT OF MUTUAL AGREEMENT

Statement of Mutual Agreement

University of Northern Colorado Doctorate of Nursing Practice Capstone Project

Kimberly Senn

April 14, 2017

The purpose of the "Statement of Mutual Agreement" is to describe the shared view between Colorado Department of Public Health and Environment (CDPHE) and Kimberly Senn, DNP Candidate from University of Northern Colorado, concerning her proposed capstone project.

Proposed Project Title: Evidence-based Tuberculosis Screening and Testing Clinical Protocol for Public Health and Primary Care Providers

Brief Description of Proposed Project: Create an evidence-based clinical protocol for tuberculosis screening and testing. CDPHE staff may participate in the project by providing expert advice throughout development of the clinical protocol. CDPHE staff will assist with strategic and operational plans to disseminate the clinical protocol to the TB elimination task force, local public health departments, primary care clinics, and community health clinics willing to participate in reviewing and providing feedback about the clinical protocol. No individual patient records or databases will be accessed beyond information available to the public. The researcher will have no direct contact with patients.

Goal of Capstone Project: Create a clinical protocol for possible future implementation in primary care clinics, community health clinics, and public health agencies. The clinical protocol is significant to the overall goal of TB elimination in Colorado. There is a need for appropriate use of evidence-based TB tests according to patient risk and clinical situation. It is important to correctly diagnose patients with or at risk for TB disease. A user-friendly clinical protocol will assist with reminding providers to 1) screen for TB risk factors among patients 2) test patients found through screening to be at risk for TB 3) work with their patients to choose the most appropriate and cost-effective test for their clinical situation and 4) assist the provider with proper evaluation of test results and provide appropriate follow-up care.

Proposed On-site Activities: Utilize expertise of TB staff in development of the clinical protocol and provide additional assistance as needed to address TB elimination plan objectives.

Confidentiality of Patient Records: No patient records will be accessed for this project.

The designated Capstone Community/Agency member will agree to participate in the review and approval of the proposal and presentation of the final version of the project. He/she will attend (on campus or remotely) the meetings for both. The DNP Capstone project will include a final report, an abstract, potential publication or oral presentation of the report. No personal identifiers will be included and all data will be reported in aggregate form. The author welcomes any comments or suggestions from the Agency, but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the Author agrees to follow the Agency preferences in how it is to be named (or not) in the work.

Signature of DNP Student Date

Peter Dupree Digitally signed by Peter Dupree DN: dc=local, dc=dphe, ou=Divisions, ou=DCEED, ou=Users, cn=Peter Dupree, email=peter.dupree@state.co.us Date: 2017.08.01 12:05:11 -06'00' 8-1-17

Signature of Agency Member Date

Signature of DNP Capstone Chair Date

APPENDIX E

SURVEY

Tuberculosis Screening and Testing Protocol Survey

Question	5 Strongly Agree	4 Agree	3 Neither Agree or Disagree	2 Disagree	1 Strongly Disagree
Effectiveness The **TB screening tool** would increase effectiveness of TB testing in your clinic.					
The **TB testing protocol** will increase effectiveness of TB testing in your clinic.					
The **TB test results guidelines** will increase effectiveness of diagnosing Latent TB Infection in your clinic.					
Evidence-based The TB screening tool follows the most recent evidence-based guidelines.					
The **TB testing protocol** follows the most recent evidence-based guidelines.					
The **TB test result guidelines** follow the most recent evidence-based guidelines.					
Efficiency The **TB screening tool** would be efficient to use in the clinic setting.					
The **TB testing protocol** would be efficient to use in the clinic setting.					
The **TB test result guidelines** would be efficient to use in the clinic setting.					

What would you suggest adding to
the TB screening tool?
the TB testing protocol?
the TB test result guidelines?

What would you suggest omitting from
the TB screening tool?
the TB testing protocol?
the TB test result guidelines?

Case examples: Please answer the following questions based utilizing the TB screening tool, protocol and test result guidelines. ***Choose the test that would most likely be offered in your clinic setting.***

1. A 49-year-old adult male born in Mexico visits your clinic for a diabetes follow-up visit. The patient has never been tested for TB. He remembers spending time with a family member with active TB as a child. The patient has a history of receiving BCG vaccine as a child.

   Would you recommend testing, and if so which test would you choose the TST or IGRA?

   Why would you choose this test?

2. A 4-year-old female refugee from Somalia visits your clinic. The patient's mother is currently being treated for active TB disease.

   Which test would you choose for this patient?

   Why would you choose this test?

3. A 20-year-old male college student visits the campus clinic one month after travelling on a 3-month long medical mission trip working in a remote HIV clinic.

   Would you recommend testing for TB, and if so which test would you use? TST or IGRA?

   Why would you use this test?

Additional questions:

1. In your opinion, will these screening and testing protocols increase appropriate TB testing in the public/community health clinic setting? Yes No

   Why or why not?
2. Will these screening and testing protocols increase appropriate TB testing in the primary care clinic setting? Yes No

   Why or why not?

Demographic Information:

1. What is your profession?

- Registered Nurse
- Physician
- Medical Assistant
- Other: _____

2. What type setting do you work in (check all that apply)?

- Public Health Clinic
- Primary Care Clinic
- Community Health Clinic
- University Health Clinic
- Specialty clinic _____
- Other_____

3. How much experience do you have with TB screening and testing?

- None
- 0-2 years
- 2-5 years
- 5-10 years
- More than 10 years