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Guide and algorithm creation for hepatitis B vaccination and tuberculosis testing requirements for a nursing program.

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Guide and Algorithm Creation for Hepatitis B Vaccination and Tuberculosis Testing Requirements for a Nursing Program

by

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Abstract

This project developed a guide and algorithm for hepatitis B vaccination and tuberculosis (TB) testing requirements for nursing students at the University of Louisville [UofL] School of Nursing [SON] before clinical placement. Clarifying the requirements for hepatitis B vaccination, testing, and tuberculosis testing was paramount for clinical compliance because the current policy was determined to be ambiguous. The literature review revealed discrepancies with policies for hepatitis B and TB among countries and with individual institutions confirming the need for aligning with evidence-based vaccination guidelines. Based on these findings, an evidence-based guide and algorithm were created. Feedback from the clinical compliance team revealed that the guide is relevant and will streamline the process of clinical compliance.

Guide and Algorithm Creation for Hepatitis B Vaccination and Tuberculosis Testing Requirement for a Nursing Program

Routine immunizations are based on guidelines from regulatory health agencies like the Centers for Disease Control and Prevention [CDC] and World Health Organization [WHO] (Hayes, 2014). The Advisory Committee on Immunization Practices [ACIP] defines healthcare workers as paid or unpaid individuals who risk contacting bodily fluids while working in a healthcare facility, including students (CDC, 2011). This means that students are held to the same standards for immunizations as licensed professionals and healthcare professional students have been identified as possible sources of the spread of communicable disease outbreaks (Dolan et al., 2015).

Regarding clinical compliance, individual institutions determine the required immunizations for their policies based on local, state, or federal guidelines and requirements laid out in contractual agreements with partnering clinical agencies (Barraza et al., 2017). Immunization requirements affect student clinical placements, and the requirements vary amongst different institutions (Libby et al., 2014). Although navigating requirements can be complex, vaccination is essential, especially in high-risk occupations like nursing. Healthcare workers, including nursing, have been identified as belonging to groups with a higher risk of exposure and contracting infectious diseases like hepatitis B (Schillie et al., 2018).

Significance

There are inconsistencies and confusion in recommendations for immunizations among nursing students who often attend clinical in various healthcare facilities. Each facility maintains a different set of immunization requirements. In addition, immunization schedules vary in timing

leading to confusion when immunizations are needed. For instance, the influenza vaccine is only required yearly, while the Tdap vaccine is required every ten years. The hepatitis B vaccine requires three doses at different intervals (Dolan et al., 2015). The guidelines for some immunizations or testing are universally consistent. In contrast, immunizations for hepatitis B and testing for anti-hepatitis B surface antibody (anti-HB) levels and tuberculosis (TB) are more complicated, and requirements can be incongruent among differing agencies (Komatsu et al., 2020). This leads to duplication of immunizations, refusals, or confusion about the best standards of practice.

Nursing students are at risk of contracting communicable diseases due to their clinical experiences and are considered healthcare workers, so they must be current on immunizations (Schillie et al., 2018). De Schryver et al. also noted that healthcare students, including nursing students, are unique because they can be naive to the healthcare setting. Students new to the healthcare setting could be at increased risk if exposure occurs and they are not adequately immunized. Immunization requirements can confuse students new to healthcare, but there are also issues with students already actively participating in the healthcare system. For example, no specific guidelines address TB skin tests among nursing students who work in healthcare facilities and have previously been tested for TB. However, most healthcare facilities ask that new hires have a baseline TB test, either a two-step TB or a blood test (Sosa et al., 2019). This discrepancy leads to inconsistencies when admitting new nursing students. In addition, outdated policies are inconsistent with best practices for requesting immunization records. Inconsistencies with obtaining these records pose a problem for nursing program coordinators when sending students to clinical sites requiring proof of vaccination.

UofL Specific Concerns

A needs assessment of the unit was completed, and concerns regarding inconsistencies in the current clinical compliance policy were identified as an area of concern. For example, there was no information in the current policy for students who already received an annual TB test at their place of employment. Clear guidelines were needed to address policy gaps and inconsistencies. In an interview with the DNP program director, it was found that there were indeed inconsistencies with document retrieval and vaccination status of students citing that these inconsistencies arose due to outdated policies and ambiguous interpretations of benchmarks and guidelines.

Further review of the clinical compliance policy showed that the requirements for Hepatitis B vaccination and testing were also ambiguous. The current policy listed requirements in a manner relevant to a student who had never received the hepatitis B vaccine. However, it did not address those who may already be vaccinated. There were also inconsistencies throughout the policy regarding the minimum acceptable quantitative lab value that indicates complete immunity.

Stakeholders

The stakeholders for this project included clinical coordinators, program directors, faculty, the Assistant Dean of the nursing school, clinical agencies, and students. The Dean and health department officials were considered sleeping giants among the stakeholders because although the topic is relevant for the admission and clinical placement process, it is one of many other vital issues related to the overall running of the program. The program directors and clinical coordinators were the champions of this project because they were responsible for ensuring students were compliant with immunizations for the school and before clinical rotations began.

Finally, the students and clinical placement coordinator were the key stakeholders because they would benefit significantly from a streamlined process of immunization requirements.

Literature Review

Problem

The identified problem related to hepatitis B testing/vaccination and tuberculosis testing among nursing students at the University of Louisville School of Nursing. This problem affected the placement of students for clinical rotations. In addition, the policy review revealed ambiguity with the hepatitis B testing/vaccination and tuberculosis testing requirement. It informed the need for an evidence-based guide and algorithm creation for the abovementioned vaccination and testing protocol.

Discrepancies in hepatitis B testing were discovered among healthcare facilities in different countries (Komatsu et al., 2020). For instance, while the United States of America [USA] considers an anti-HB level ≥ 10mlU/mL adequate coverage, Germany and the United Kingdom (UK) consider sufficient coverage to be ≥ 100mlU/mL; and while the USA and UK do not recommend a challenge dose if coverage is determined to be adequate, Germany offers a challenge dose after ten years of initial vaccination. Japan does not have any policies for hepatitis B vaccination among healthcare workers (Komatsu et al., 2020).

Furthermore, healthcare facilities with different departments might have varying employee policies, creating discrepancies (Luthy et al., 2016). For instance, an outpatient department at a facility may not include their employees in the facility's mandates as they consider themselves to not be in direct patient care (Luthy et al., 2016). Vaccine policies also differ between schools, as some do not require vaccinations, while others only require specific or

inadequate immunizations (Dolan et al., 2015). Also, some schools did not follow the ACIP vaccination guidelines (Dolan et al., 2015).

A different perspective on the implications of vaccine guidelines was that healthcare workers continue working even with prior exposure to infectious diseases, which puts them at a higher risk of spreading diseases (Lee et al., 2018). Differences in the rate of vaccination depended on policies in place at institutions. Facilities with vaccine mandates had an increased vaccination rate among their employees (Lee et al., 2018). Sending students to clinical sites with varying vaccination requirements stresses program coordinators and students (Williamson et al., 2018).

Intervention

Standardization

The collected evidence informed the best practices for immunizing against hepatitis B and testing for tuberculosis among nursing students at the University of Louisville School of Nursing. Of all the articles reviewed for relevance and quality, 13 remained and ranged in level of evidence from systematic reviews to guidelines. These articles were deemed relevant because of their purpose, study type, samples/settings, significant variables studied, data analysis/findings, and appraisal.

Hepatitis B

The two systematic review articles discussing hepatitis B vaccination identified that healthcare workers needed to be immunized against hepatitis B (Awoke et al., 2020; de Geus et al., 2021). Healthcare workers new to healthcare practice and those who received initial childhood vaccinations should also be vaccinated against hepatitis B (Bookstaver et al., 2016).

The immune status of healthcare workers must be verified before they are exposed to healthcare facilities where the risk of contracting hepatitis B is high (Bini et al., 2018). The hepatitis B vaccine must be provided to new hires and antibody levels may be rechecked every five years for healthcare workers with repeated exposure to blood-borne pathogens.

Full vaccination coverage was defined as three doses of the hepatitis B vaccine (Awoke et al., 2020), two doses of the HepliSav-B vaccine, which can be administered at zero and one month (Schillie et al., 2018), or four doses depending on the vaccine type or pre-existing medical condition (Murthy et al., 2022). The vaccination schedule consists of three doses of Engerix-B for adults > 20 years old at zero, one, and six months, or four doses at zero, one, two, and six months for immunocompromised adults or those on hemodialysis. For adults >18 years old, three doses of TwinRix (Hep A-Hep B combination) can be administered at zero, one, and six months (standard dosing), or four doses at day zero, day seven, days 21-30 and 12 months (accelerated dosing). Three doses of the PreHebvrio vaccine can be administered to adults >18 years old at zero, one, and six months. If HepliSav-B was combined with other hepatitis B vaccinations, then three doses must be administered to immunize fully. If the schedule is interrupted, the series can be resumed as soon as the interruption is deciphered. No need to restart the dosing, but the interval should be separated by more than eight weeks (Weng et al., 2022). A seropositivity test may be conducted 1-2 months after the last doses to confirm immunity (De Geus et al., 2021). Obtaining the antibody levels post-administration will help to identify healthcare workers who have achieved complete coverage/immunity and those who may need challenge doses to provide definitive coverage/immunity (Trevisan et al. (2021).

Positive results >10mlU/mL demonstrate complete immunity (de Geus et al., 2021). Lamberti et al. (2015) stated that healthcare workers with antibody levels <10mlU/mL should be

considered not immune and would require challenge doses to ensure complete immunity. This finding coincided with the recommendations of the Advisory Committee on Immunization Practices (ACIP), which stated that fully vaccinated individuals with antibody levels <10mlU/mL should receive challenge doses and further antibody testing 1-2 months after the challenge dose to validate immune status (Schillie et al., 2018). The committee further stated that those with levels <10mlU/mL after challenge doses should be considered non-responders and, thus, do not require further vaccination or testing. The total doses must not exceed four for HepliSav-B or six for other types of Hep B vaccine (Schillie et al., 2018).

Based on the results of a prospective cohort study, healthcare workers fully vaccinated in childhood with antibody levels <10mlU/mL would only require one challenge dose to provide complete immunity (Lu et al., 2016). Hess et al. summarized the requirements for hepatitis B vaccination and coverage by stating that healthcare personnel should get tested and challenge doses are to be administered where necessary. According to the guidelines developed by the ACIP in 2003, healthcare workers without adequate documentation of hepatitis B coverage must be considered unvaccinated. They must be given a total of three doses of the hepatitis B vaccine (Schillies et al., 2013), while the updated guideline in 2018 included recommendations that healthcare institutions or schools may obtain proof of complete vaccination or obtain antibody tests to determine coverage levels (Schillies et al., 2018). Cocchio et al. (2021) recommended that healthcare workers fully vaccinated against hepatitis B and can provide proof that antibody levels are >10mlU/ml, do not require post-exposure prophylaxis, serological testing, or additional vaccination.

Healthcare workers who are fully vaccinated but cannot provide proof of anti-HB levels >10mlU/mL and have been exposed to the hepatitis B virus must be tested to determine

immunity. The source of exposure must also be tested for hepatitis B surface antigen (HBsAg) (Schillie et al., 2018). For example, suppose the result of the anti-HB levels is less than 10mlU/mL, and the source is HBsAg positive or unknown. In that case, the individual must receive hepatitis B immunoglobulin (HBIG) and be vaccinated with the second series' first dose. The series should be completed per the vaccination guidelines for hepatitis B, and anti-HB testing should be done 1-2 months after the final vaccination (Schillie et al., 2018).

Suppose a previously vaccinated healthcare worker exposed to hepatitis B has less than 10mlU/mL of anti-HB levels, and the source was HBsAg negative. In that case, a single hepatitis B vaccine dose should be administered, and the healthcare worker must be retested 1-2 months after the vaccination. If the results of the anti-HB test are less than 10mlU/mL, the vaccination series must be completed, and the individual retested 1-2 months after to determine the immune status (Schillie et al., 2018). If the results of a post-exposure test are greater than 10mlU/mL, there is no need for post-exposure vaccination regardless of the source's HBsAg status (Schillie et al., 2018).

Healthcare workers that were not vaccinated and were exposed to hepatitis B do not need anti-HB testing. However, the source of exposure must be tested for HBsAg. If the source is positive or the result is inconclusive, the healthcare worker must immediately receive HBIG and the first series of the hepatitis B vaccine, complete the series per vaccination schedule, and retest six months after the last dose. The healthcare worker is immune if the result is >10mlU/mL (Schillie et al., 2018). If the result is <10mlU/mL, the second series should be completed per the schedule, and the individual should be retested to determine the immune status (Schillie et al., 2018).

Tuberculosis

Two guidelines were determined to be the most relevant data for this project based on the problem definition to identify the appropriate test approach for tuberculosis among healthcare students who have had previous tests in a different facility. The Tuberculosis Controllers Association and the CDC guidelines advise that all healthcare personnel should have a baseline tuberculosis test and risk assessment. Two-step tuberculin skin test (TST) testing should be done to decrease the chances of a boosted reaction from an old infection being misinterpreted as a recent infection. The tuberculin skin test (TST) identifies cell-mediated immunity to mycobacterium tuberculosis via a delayed-type hypersensitivity reaction (Lewinsohn et al., 2017). Also, the two-step testing should be used as the initial skin testing of individuals who will be re-tested periodically (Sosa et al., 2019). However, the interferon gamma-release assay (IGRA) test can also be performed if inexpensive and without burden (Lewinsohn et al., 2017). The outcome of the risk assessment would determine how to interpret the result. If the reaction to the first step TST is negative or positive, a second step TST should be administered 1 to 3 weeks after the first test is read. If the second result is negative, the individual is not infected with tuberculosis bacteria. In contrast, if the first result is positive and the individual has no symptoms, there is a low risk. However, the individual must undergo a second test, the interferon-gamma release assay (IGRA) or TST (Sosa et al., 2019). If both results are positive, the individual is considered infected with mycobacterium tuberculosis (Lewinsohn et al., 2017). If the second test result of a two-step TST is not read within 48-72 hours, a TST should be administered as soon as possible (even if several months have elapsed), and that test must be read within 48-72 hours. The TST should be repeated if the individual does not return within 72 hours and has a negative test result. TSTs can be repeated at any time and generally poses no

health risks regardless of the frequency. A two-step TST is unnecessary if the individual has a documented TST result during the previous 12 months. A single TST can be administered if an individual has had a documented negative TST within 12 months. This additional TST represents the second stage of two-step testing (Lewinsohn et al., 2017). If the reaction is greater than 5 mm, the result is determined to be positive if the individual is in close contact with tuberculosis cases; if the individual is immunocompromised, as in with HIV infection; if the individual has clinical or radiographic proof of current or prior TB; or if the individual is receiving tumor-necrotizing factor blocking agents (Lewinsohn et al., 2017). Reactions greater than 10 mm are considered positive for individuals at increased risk of latent tuberculosis infection (LTBI) (e.g., individuals born in countries with a high prevalence of TB and those at risk of occupational exposure to TB), individuals with medical risk factors that increase the chances of conversion from LTBI to TB, and healthcare personnel (Lewinsohn et al., 2017; Thanassi et al., 2020).

If there has been a known exposure to TB without appropriate personal protective equipment use, and the individual had no prior documented evidence of TB or latent TB, a timely symptom evaluation and testing with TST or IGRA should be done within 8-10 weeks after the exposure (Sosa et al., 2019). Serial screening should be individualized and based on factors that might cause exposure; however, no routine annual tests are recommended if there are no exposure or threats (Sosa et al., 2019). Sosa et al. (2019) also recommend consulting with local or state health departments to aid decision-making. Since healthcare personnel may be at risk of TB exposure due to numerous work-related factors, such individuals must be educated annually (Sosa et al., 2019). The decision to perform TB testing after initial baseline testing depends on the exposure risk of the individual and has been left to the facilities' discretion. This was based on a systematic review that showed that healthcare workers have a low percentage of

positive TB tests at baseline and annually (Sosa et al., 2019). Treatment for those identified with latent tuberculosis might be more beneficial in reducing tuberculosis infection and transmission among healthcare workers (Lewinsohn et al., 2017).

The Official American Thoracic Society, Infectious Diseases Society, and the CDC guidelines recommend not testing healthcare workers at low risk for tuberculosis (Lewinsohn et al., 2017). This recommendation coincided with the Tuberculosis Controllers Association and the CDC recommendations (Sosa et al., 2019). Further, it identified healthcare workers at high risk for contracting tuberculosis as respiratory therapists and pulmonologists. However, it understood that institutions and facilities may opt to perform TB testing due to governing or licensing agency requirements (Lewinsohn et al., 2017). Healthcare workers with new positive results need a chest x-ray to determine the presence of tuberculosis. In contrast, those with negative chest X-rays do not need repeated radiographs unless they present with new TB symptoms. At that time, they would require treatment for latent tuberculosis (Sosa et al., 2019). A positive result is two positive TST or a positive blood test. A negative result is a chest X-ray that shows no granuloma or evidence of TB disease on the radiograph (Thanassi et al., 2020). Although not recommended, the decision to obtain repeat chest radiographs in previously normal X-rays is left to the facility's discretion. However, it should be performed and documented consistently (Thanassi et al., 2020).

In summary, the initial recommendation is a two-step test to establish a baseline, initiation of treatment modalities for healthcare workers diagnosed with latent tuberculosis, and symptom evaluation for newly positive tests (including a chest radiograph) for low-risk individuals. No repeat chest radiograph is required for normal radiograph unless symptomatic or on treatment for latent TB, yearly screening for symptoms among healthcare workers with

untreated latent tuberculosis infection should be performed, notification of the health department should be completed for all suspicion of TB, and annual TB education should be provided to all HCP (Lewinsohn et al., 2017; Sosa et al., 2019).

Conceptual Framework

The IOWA Model of Evidence-Based Practice [EBP] to promote quality care is an amalgamation of different theories and models, namely "Roger's theory, Diffusion of Innovations, and the Quality Assurance Model Using Research [QAMUR]" (Buckwalter et al., 2017). A group of nurses developed the model to provide safe and quality care. The model was initially titled "*The Iowa Model of Research-Based Practice to Promote Quality Care*" (Titler et al., 2001) but was eventually changed to its current name because it was discovered that research utilization was one of the concepts of EBP. The model is considered a heuristic model designed for problem-solving experimentally or by trial and error. The model adopts current standards of practice based on the evidence at the time of change and updates as evidence changes or evolves (Buckwalter et al., 2017). It was formalized by Dr. Titler and her colleagues in 1994, and the 'research-based focus' was changed to an 'evidence-based focus' (Titler, 2014). It was developed as a guide to initiate evidence-based practices and quality improvement projects (Titler, 2014).

Nurses relied on demonstration projects before developing EBP models and frameworks to initiate quality improvements (Titler et al., 2001). It has undergone revisions since the model's inception, with the most recent in 2015. The initial revised model in 1998 had two focus areas: problem and knowledge-focused triggers. The 2015 revised model dived into identified triggering issues and opportunities. The revisions were necessary due to the evolution of

healthcare and user feedback. The revised model responds to the healthcare market's needs and includes other evidence levels (e.g., case studies). This gives researchers ideas to carry out investigations to support the practice change.

Purpose and Specific Aims

Purpose

The purpose of this scholarly project was to create a guideline and algorithm for hepatitis B vaccination and tuberculosis (TB) testing requirements for nursing student clinical compliance at the University of Louisville [UofL] School of Nursing [SON]. The aim of this project was to clarify and streamline the process of clinical placement.

The first aim of this project was achieved by developing an algorithm and guide for the TB testing and hepatitis B vaccination policy to reflect current evidence-based guidelines. The second aim was achieved by clarifying TB testing and Hepatitis B vaccination requirements before students' clinical placement. The third aim was to ensure that program administrators have confidence in the accuracy of the new guideline. This aim was achieved after the guide and algorithm were completed by providing opportunities for review, questions, and feedback.

Guideline Review and Recommendations

	Old Policy	New/Revised Policy
Hepatitis B	• Three (3) doses of vaccine followed by HepBSAb titer, reported with a QUANTITATIVE value.	• Two (2) of HepliSav B, or three (3) doses depending on the brand, will be required of all new hires or other individuals who cannot demonstrate proof of vaccination. • Initial proof of vaccination would be immunization records showing two, three, or four completed doses depending on the vaccine or

		condition, and a positive anti-HB serum test with levels >10mlU/mL (Komatsu et al., 2019; Murthy et al., 2022; Schillie et al., 2018). • Individuals who report two or three doses administered must obtain an anti-HB serum test at least 1-2 months after the second or third dose- a positive result >10mlU/ml proves complete immunity. • If the test result is negative (<10mlU/mL), a challenge dose will be administered. The individual will be retested at 1-2 months to validate immune status. • The individual can only receive two challenge doses of the HepliSav-B or three (3) challenge doses if retest levels are less than 10mlU/mL, after which the individual will be considered a non-responder; no further doses or testing will be required. At this point, they will submit a signed non-responder form. This will meet clinical compliance. • Individuals fully vaccinated in childhood with antibody levels <10mlU/mL will require one challenge dose and subsequent test to determine coverage. • Individuals fully vaccinated against hepatitis B and can provide proof of antibody levels >10mlU/mL do not require post-exposure prophylaxis, serological testing, or additional vaccination (Schillie et al., 2018).
Tuberculosis	No previous TST or your testing has elapsed >14 months: • Complete two TSTs, at least one week apart. No prior history of positive TST:	A two-step tuberculin skin test or a negative serum interferon-gamma release assay (IGRA) (QuantiFERON TB Gold or T-Spot) within the previous 12 months starting from the first day of the semester, is required for clinical compliance.

	• Proof of two annually consecutive TSTs: one within 90 days of your start date, OR • Interferon Gamma Release Assay (IGRA) (Quantiferon TB Gold or T-spot) within 90 days of your start date. Prior history of (+) TST or IGRA, or active TB: • Provide documentation of positive test results, medication treatment, and latest Chest x-ray report. • If you received the Bacillus Calmette–Guérin (BCG) vaccine and your first or second TST was "positive," you must obtain an IGRA blood test. • Complete the TB Questionnaire (TBQ) upon starting and on an annual basis.	If there is no documentation of previous tuberculin skin test (TST) in the last 12 months: • Two-step TST, QuantiFERON Gold, T-Spot, or IGRA blood test must be administered on acceptance to the program. • If a two-step TST is administered, the result of the first test must be read 48-72 hours after administration. • The second step must be administered one to three weeks after reading the first test. Both tests must be negative to rule out TB. • A positive first or second-step test will warrant a chest x-ray. If there is documentation of a previous tuberculin skin test (TST) in the last 12 months: • A single TST can be administered. This additional TST will represent the second stage of two-step testing. • The second test should be administered at least one week and no more than 12 months after reading the first test. • If the second test result of a two-step TST is not read within 48-72 hours, a TST should be administered as soon as possible (even if several months have elapsed), and that test must be read within 48-72 hours. The TST should be repeated if the individual does not return within 72 hours.

		Prior History: If there is a prior history of positive TST or have received BCG: • QuantiFERON blood test is preferred and should be done within one to three weeks of admission acceptance or 90 days before clinical placement. • Negative chest X-ray results will be accepted instead of a blood test. If there is a prior history of treatment for latent TB: • Proof of completion of TB treatment and negative chest radiograph should be provided. New Positive: • New positive results need a chest x-ray to determine the presence of tuberculosis. • Symptomatic individuals with positive results require treatment for latent tuberculosis. Annual testing • One-step TST, QuantiFERON Gold, T-Spot, or IGRA blood test must be administered annually. • Those with negative chest X-rays do not need repeated radiographs unless they present with new TB symptoms. All students must complete an annual risk assessment and TB education.

Procedures

The project lead facilitated a meeting with stakeholders to present and receive feedback on recommendations. The meeting occurred as a part of the monthly director's meetings. The meeting included the distribution of the immunization policy confidence scale, administered to determine program administrators' thoughts on the current clinical placement policy, specifically regarding Hepatitis B and TB testing. The pretest was conducted using Survey Monkey, a survey tool; it included questions about their confidence in the current policy on hepatitis B and TB.

After the pretest, a brief literature review was presented in PowerPoint format along with the new guideline on hepatitis B and TB clinical compliance. The presentation reviewed basic knowledge of hepatitis B vaccination/testing and tuberculosis testing. The current evidence on hepatitis B vaccination/testing and TB testing was revealed to the participants.

Although the initial plan was to change the policy, this was not possible due to the policy being held within the Office of Student Health and not the School of Nursing. It was determined that the focus should be on creating a guide and algorithm that will apply to nursing students and assist the clinical placement coordinators. The guide was made available to the attendees. Attendees were asked to provide feedback on the initial guide.

The clinical compliance coordinator was liaised with, and feedback was provided by the clinical compliance coordinator who recommended changes specific to the school to be included in the guide. A compliance team was formed that included individuals within the school that were responsible for clinical compliance. A final version of the guide, along with a corresponding algorithm, was presented to the compliance team six weeks later. A qualitative

post-guide analysis was provided to the clinical compliance participants with opportunities for feedback. The qualitative analysis was analyzed for themes.

Measures

The pre-implementation measure was a survey which was divided into two parts: a demographics section, and an immunization policy confidence questionnaire measured with a Likert scale. The post-implementation measure was a three-question qualitative post-guideline analysis.

Demographics:

- Length of time employed.
- Position within the school.

Immunization policy confidence scale:

- How clear is the current policy on hepatitis B and TB?
- How confident are you at explaining the hepatitis B and TB policy to the students?
- How confident are you that the current policy covers the school's needs for a clinical compliance guideline?

Qualitative post-guideline analysis:

- Do you find the guide and algorithm useful?
- How will the guide and algorithm help the process of clinical compliance?
- Do you have any recommendations or suggestions?

Data Analysis

The overview of demographic and years of service data were analyzed using descriptive statistics, including frequency and percentage. Likert-scale questions regarding the usability and clarity of the current policy were analyzed individually using frequency data. After the guideline

was developed and distributed, qualitative questions regarding usability and clarity of the guideline were analyzed for themes.

Results

Quantitative

At the director's meeting (pre-intervention), seven members of the administrative team were surveyed on their understanding of the current Hepatitis B and TB policy. These members were program directors, associate deans, and the clinical compliance coordinator. Most had more than 14 years of experience in academia. Six of the seven members indicated that the current policy was somewhat unclear or very unclear. Five members were less than confident in explaining hepatitis B and TB clinical compliance recommendations to students, and four members were not confident that the current policy covered the school's needs for hepatitis B vaccination/testing and TB testing.

Qualitative

Post-intervention, the clinical compliance coordinators were asked to provide a qualitative post-analysis. Initial constructive feedback indicated the need to clarify the recommendations for U.S. born students who cannot provide proof of vaccination. This was done by explaining that based on the recommendations, any individual who cannot provide proof of vaccination must be tested for antibody level >10mlU/mL to determine immunity. Themes from the qualitative post-analysis revealed that the guide and algorithm clearly explained hepatitis B testing/vaccination and TB testing. It was revealed that the guide was user-friendly with clearly stated outlines that would be functional and beneficial.

A participant stated, " I find the algorithm extremely helpful, especially for continuity in my compliance specialist role. The Decision Tree Word document contains more description and detail that supports your algorithm." Another participant stated that they found the algorithm useful because it "provides guidance for multiple scenarios for clinical compliance; it is helpful to have a decision tree for the variability of student situation. That will help us as a faculty group to maintain consistency." A recommendation from the feedback was to apply the guide to include all nursing students, not just graduate nursing students. Overall, all participants agreed that the guide would maintain consistency in the clinical placement process.

Discussion

This scholarly project was first designed to be a policy revision; however, due to barriers with the student health department of the university holding the policy, a guide and algorithm were deemed appropriate. To develop the guide and algorithm, a literature review was conducted to discuss the importance of the problem. The literature review showed that hepatitis B vaccination and TB testing for clinical compliance are complicated. For instance, the requirements for hepatitis B vaccinations differ by country, and for both hepatitis B and TB, policies vary per institution. One of the main reasons for the complication of hepatitis B vaccination is that multiple pharmaceutical manufacturers are being approved for immunization in the United States. Each product differs on vaccination timing or dosing, which creates barriers to efficiently ensuring that individuals are vaccinated appropriately. The evidence for TB testing showed the complexities of determining appropriate initial and subsequent testing and the need to address multiple scenarios for a streamlined approach.

The primary purpose of the immunization confidence scale administered at the director's meeting was to confirm the need for the development of a guide, and it showed that the current policy was indeed vague on the process of hepatitis B and TB testing for clinical compliance as it was insufficient to address the varied scenarios affecting clinical compliance.

A review of evidence-based guidelines was the basis for a school-based clinical compliance guide for nursing students. The initial phase of the guide development included liaising with the clinical compliance coordinator. It was revealed that the process for clinical compliance needed to be streamlined to ensure efficiency with the process. To achieve this aim, the guide and algorithm addressed several scenarios for hepatitis B vaccination and TB testing.

Specific scenarios which were addressed for Hepatitis B addressed the following: students who do not have proof of childhood immunizations, students who have negative titer and/ or have received different brands of vaccine alone or in combination, and the timing of titers after dosing. The guideline also addressed the following scenarios for tuberculosis: individuals with no previous baseline testing, last IGRA or TST placed greater than 12 months ago, previous positive TST, previous BCG vaccination, previous positive IGRA, individuals with newly positive TST or IGRA, and recommendations for annual testing and renewal requirements (12 months from previous testing).

These specific scenarios were addressed in the guide, with directions given on how to implement them. For instance, any individual not vaccinated for hepatitis B would require an initial vaccination with the hepatitis B series. The guide also detailed the variation in timing for all vaccinations currently used for hepatitis B in the U.S. Also, information on determining immunity was provided by stating that once the initial vaccination series was completed, the

individual needed to obtain quantitative anti-Hb levels, and the resulting anti-Hb levels must be >10mlU/mL to confirm. The guide also clearly defined non-responders as individuals with < 10mlU/mL of anti-HB levels after completing both vaccination and booster series, regardless of the type of vaccine used. Recommendations for post-exposure hepatitis B testing for unvaccinated and fully vaccinated individuals were also provided. The guide for tuberculosis explained that every student must report a negative TB test before clinical placement, and it clarified varied scenarios involving testing, including new positive tests, prior history of TB, prior history of treatment for latent TB, and annual testing. The guide was created in a stepwise pattern that answered questions that may arise as each step is addressed, providing direction.

After the initial review of the guide and algorithm by the clinical coordinator, the qualitative post-guide analysis created another opportunity for the clinical compliance team, including the clinical compliance coordinator, several directors/coordinators of academic programs, the project chair, and the co-chair, to determine the feasibility of the guide and provide feedback. The qualitative feedback indicated the guide would streamline the process of clinical compliance. The clinical placement coordinator recommended that the verbiage be changed to be inclusive of all nursing students within the school; this was done. Other statements within the analysis denoted the guide would maintain consistency with clinical compliance since the guide addressed several scenarios with a simplified algorithm. Since it has been determined that hepatitis B vaccination and TB testing are complicated, a recommendation will be to ensure that necessary updates are made as new evidence is discovered.

The limitations of this project were that there was limited quantitative data to analyze due to the limited number of key administrative stakeholders. Another limitation was the inability to modify/change the overall clinical policy to be specific to the School of Nursing since the policy

is being held within the Office of Student Health. It would have also been beneficial to have more directors and clinical compliance coordinators to give input on the guide.

Ethical Considerations

HIPAA standards were maintained throughout the project. No protected health information was recorded for the completion of this project. All surveys were anonymous.

Budget

Because the Director's meeting was an event already scheduled to occur, there was no expense to the university, and the services to review the policy were free of cost. To build the algorithm, the algorithm design software- SmartDraw was purchased.

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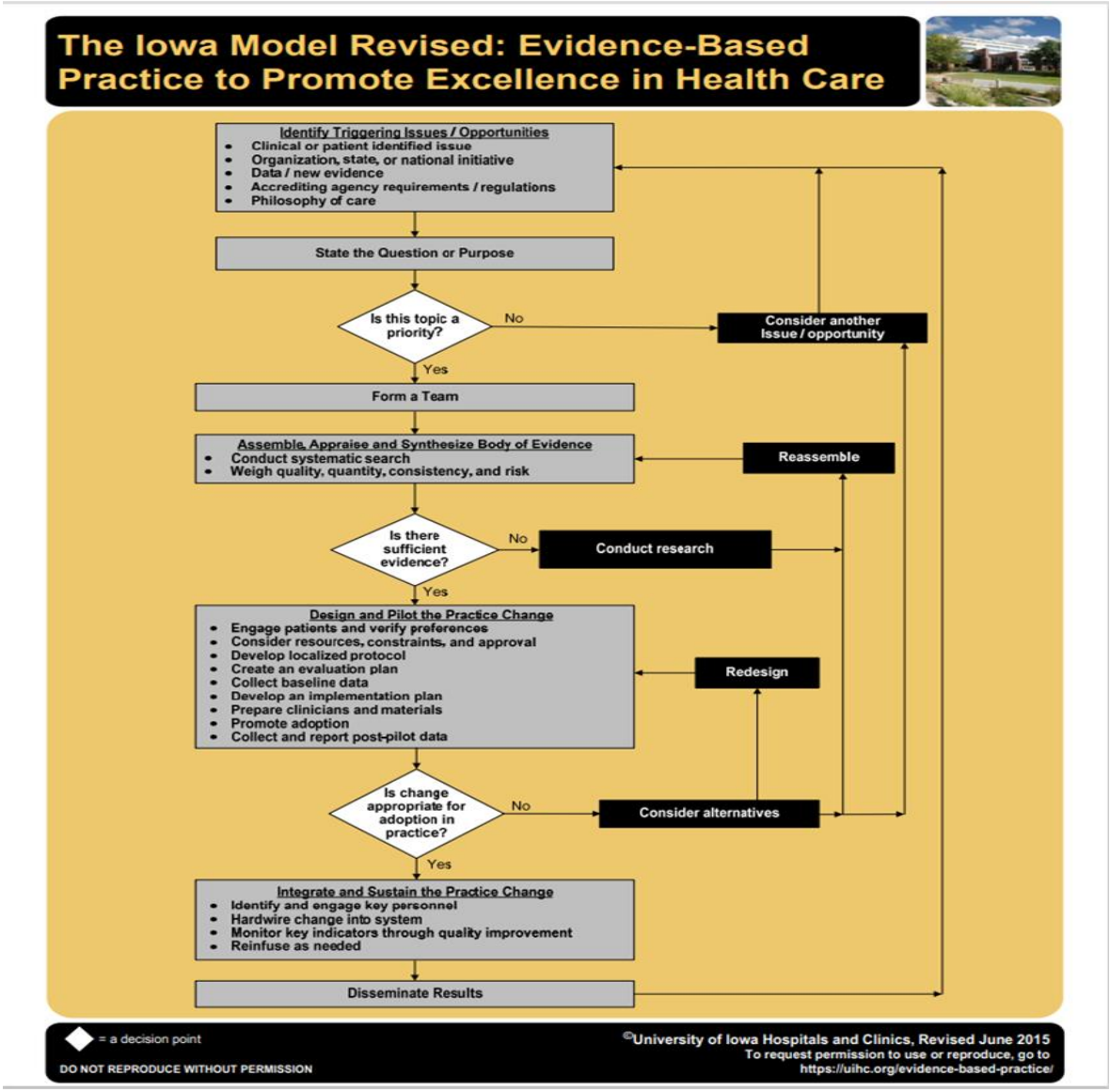
Appendix A

The Iowa Model-Revised: Evidence-Based Practice to Promote Excellence in Healthcare



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Appendix B

Tb Testing Recommendations

Group	Testing Strategy	Considerations
Likely to be Infected **High** Risk of Progression (TST ≥ 5mM)	**Adults** **Acceptable**: IGRA OR TST Consider dual testing where a positive result from either result would be considered **positive** **Children ≤ 5 years of age** **Preferred**: TST **Acceptable**: IGRA OR TST Consider dual testing where a positive result from either would be considered **positive**[1]	Prevalence of BCG vaccination Expertise of staff and/or laboratory Test availability Patient perceptions Staff perceptions Programmatic concerns
Likely to be Infected **Low** to **Intermediate** Risk of Progression (TST ≥ 10mM)	**Preferred**: IGRA where available **Acceptable**: IGRA or TST	
Unlikely to be Infected (TST > 15mM)	**Testing for LTBI is not recommended** **If necessary:** **Preferred:** IGRA where available. **Acceptable**: Either IGRA OR TST **For serial testing**: **Acceptable**: Either IGRA OR TST Consider repeat or dual testing where a negative result from either would be considered **negative**[2]	

1. Performing a second diagnostic test when the initial test is negative is a strategy to increase sensitivity. This may reduce specificity, but the panel decided that this is an acceptable tradeoff in situations in which the consequences of missing LTBI (i.e., not treating individuals who may benefit from therapy) exceed the consequences of inappropriate therapy (i.e., hepatotoxicity).
2. Performing a confirmatory test following an initial positive result is based upon both the evidence that false-positive results are common among individuals who are unlikely to be infected with Mtb and the committee's presumption that performing a second test on those whose initial test was positive will help identify initial false-positive results.