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Pharmacy-Based Tuberculosis Skin Testing (TST): Approaches to Legal Authority

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Abstract

The Mantoux Tuberculin Skin Test (TST) is the standard method for detecting latent tuberculosis and has been provided by pharmacists since at least 2006. In the largest published study of pharmacy-based TST involving 578 patients, the most common reason for obtaining the test were employment or school requirements. Pharmacists have demonstrated high rates of follow-up for the reading of the test, reported to be 92.8% to 94.4%. The biggest barrier to pharmacy-based TST is that a prescription is required for the two tuberculosis (TB) purified protein derivative products available on the market in the United States. States have adopted three strategies to enable pharmacy-based TST prescribing: 1) collaborative practice agreements; 2) statewide protocols; and 3) independent prescribing. These three approaches are reviewed, with a focus on the New Mexico statewide protocol and the recent statutory authority in Idaho that grants pharmacists independent prescriptive authority for TST. States may consider pursuing more autonomous models of TST prescribing given the safety and track record of this service at pharmacies.

Key Words: Scope of Practice; Tuberculosis Skin Testing; Mantoux Test; Permissionless Innovation

Background

The Mantoux Tuberculin Skin Test (TST) has been the standard method for detecting latent tuberculosis since the 1930s.¹ The TST involves three steps: 1) intradermal administration into the forearm; 2) reading of the test result 48 to 72 hours after administration; and 3) interpretation of the result by measuring the induration in millimeters and comparing that measurement to thresholds listed by the Centers for Disease Control and Prevention (CDC).² In interpreting the result, the healthcare provider must first conduct a risk assessment that takes into account recent travel, country of childhood, and comorbid conditions that may increase the risk for tuberculosis. If a patient tests “positive” in the TST, they should be referred for a medical evaluation including follow-up diagnostics and consideration for treatment.³

The TST has been provided by pharmacists since at least 2006.⁴ In the first published study on the topic, 18 TSTs were administered by two pharmacists in a grocery store setting. Hecox noted that TSTs were “easily incorporated into workflow” and estimated that each test took roughly 10 minutes.⁴ The types of patients who seek the TST at pharmacies tend to be low-risk for tuberculosis infection. In the largest published study of pharmacy-based TST involving 578 patients, the most common reason for obtaining the test were employment or school requirements.⁵ Other studies have reported pharmacists screening pharmacy students prior to their experiential rotations; patients prior to starting

immunosuppressive biologic therapy; and patients beginning drug treatment programs.^{4,6-7} Pharmacists have demonstrated high rates of follow-up for the reading of the test, reported to be 92.8% to 94.4%.⁴⁻⁵ This is likely attributable to the convenience and accessibility of pharmacies, which are often open nights and weekends when many other health professional offices are closed. In addition, common venues for care, such as county health departments, may be difficult to access for many patients and have limited hours of operation that pose challenges for a test that requires two trips within 72 hours.

Some schools of pharmacy have started teaching TST as part of the Doctor of Pharmacy curriculum. The University of Washington taught second year professional pharmacy students, and found significant gains in comfort and willingness to perform TST following completion of the course.⁷ The CDC offers a free online video training on the Mantoux TST that may be leveraged by pharmacists and other healthcare professionals.⁸ Further, the Washington State Pharmacy Association offers a TST certificate training program for pharmacists, comprised of a 1.5 hour online module, and a practicum with a demonstration of technique and reading of the result on practice arms.⁹

Despite the potential benefits of pharmacy-based TST, the biggest barrier to widespread adoption is that a prescription is required for the two tuberculosis (TB) purified protein derivative products available on the market in the United States (**Table 1**). As such, either pharmacists must receive a prescription for each TST, or there must be a mechanism in place for pharmacists to prescribe the products. Current state approaches to prescriptive authority have occurred across a continuum. This manuscript will describe different approaches

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states have taken to pharmacy-based TST prescribing as a guide to other states considering this service.

Pharmacist Prescriptive Authority for TST

As described by Adams and Weaver, pharmacist prescriptive authority occurs along a continuum with the two primary categories being 1) collaborative prescribing; and 2) autonomous prescribing.¹⁰ We identified two states that allow autonomous models of pharmacists prescribing TST: Idaho (independent prescribing) and New Mexico (statewide protocol). Most remaining states allow TST under collaborative practice models of prescriptive authority in some form or fashion, though the feasibility varies by state.

1) Collaborative Practice Authority

Collaborative Practice Agreements (CPAs) form the basis of collaborative prescribing. CPAs are agreements between a prescriber and a pharmacist that allow the pharmacist to provide certain services that are outside his or her traditional legal scope of practice, but for which the pharmacist is educationally prepared and capable of performing.¹¹ CPAs are voluntarily negotiated between the prescriber and the pharmacist. As such, CPAs serve as a framework to allow pharmacists to provide new services like TST.

Not all collaborative practice laws are created equally, however. Adams and Weaver distinguished between “patient-specific” and “population-specific” CPAs.¹⁰ In a patient-specific CPA, the patients who may receive service from the pharmacist are limited to those patients listed in the agreement, or limited to the patient panel of the collaborating prescriber. Thus a patient-specific CPA is not conducive to TST in an outpatient setting, as it is difficult to predict in advance which patients may benefit from a service. A patient-specific CPA may prove useful in some limited situations, such as in a clinic, or in a situation in which the known population of potential patients is well established (such as for a class of pharmacy students prior to experiential rotations). In addition, some patient-specific CPA laws restrict the *initiation* of new medications, and allow only *modifying* existing regimens. Such laws may prevent the initiation of a new TST.

For a CPA to be practical for TST in outpatient settings, a population-specific CPA law is necessary. In a population-specific CPA, inclusion and exclusion criteria are written by the collaborating professionals, but the service is not limited to individual patients of that prescriber. As of 2016, 17 states allowed population-specific CPAs, and thus may provide a framework to enable TST.¹⁰

2) Statewide Protocol

The New Mexico state legislature passed legislation in 2011 authorizing the Board of Pharmacy to issue a statewide protocol outlining conditions under which pharmacists may prescribe and administer TST.^{5,12-13} Pharmacists must follow

the Board’s protocol in order to lawfully prescribe TST in the state. The New Mexico protocol requires pharmacists to follow the CDC guidelines for skin testing. Further pharmacists must “take patient histories and consult with patients’ medical providers as appropriate.” With respect to the history, the following are required for the health screening: patient history, family history, current living environment, concurrent illness, allergies and hypersensitivities, and medication history. The New Mexico protocol details specific procedures for pharmacists to follow (e.g., inject 0.1 ml into the inner surface of the forearm) and reiterates clinical guidelines (e.g., read test between 48 and 72 hours). The protocol specifies recordkeeping requirements including the consent form, records of prescriber notification, billing, and prescription orders. All positive reports must be sent to the Department of Health and to the patient’s primary care provider. In addition, notification must be made to the patient’s primary care provider within 15 days of writing the TST prescription.

3) Independent Prescribing

The Idaho state legislature recently passed House Bill 3, which will allow unrestricted pharmacist prescribing of tuberculin purified protein derivative products when it takes effect on July 1, 2017.¹⁴ Thus, no CPA will be needed, and there is no statewide protocol that the Board of Pharmacy is expected to issue.

In order to exercise this independent authority, pharmacists must first complete a course on “proper test administration and interpretation of results” from the CDC, and pharmacists must follow the recommendations for Mantoux TST. Idaho law requires pharmacists to maintain documentation of tests provided and provide a copy of the test results to the patient upon request. If a patient is found to have a positive TST reading, the pharmacist “shall coordinate a timely referral” to follow-up care. Further, the positive test results should be reported “in accordance with the rules governing Idaho reportable diseases.”

Discussion

Pharmacy-based TST holds potential for improving patient access, convenience, and affordability in a manner similar to pharmacy-based immunizations. Even after two decades of experience with immunizations, pharmacists still struggle with a patchwork of state laws allowing their prescribing and administration. While pharmacy-based immunizations are permissible in all 50 states, strategies include independent prescribing, statewide protocols, and CPAs and variation remains in the types of immunizations pharmacists may provide, and to the patient populations they may provide.

The current legal environment for TST is much more limited than immunizations. We believe TST can be feasibly done in outpatient settings in at least 17 states under population-

specific CPAs. In addition, two states have created autonomous pathways for TST. **Table 2** reviews the core elements of the existing state laws that allow autonomous TST. Both New Mexico and Idaho provide similar structure, though Idaho defers more to clinical guidelines rather than reiterating these guidelines in law. For example, New Mexico delineates health screening requirements as part of the legal protocol whereas Idaho does not specifically list similar requirements in law. This does not absolve Idaho pharmacists from having to undertake a patient health screening; indeed, the clinical requirements require pharmacists to do so in order to properly evaluate the size of the induration when the patient returns in 48 to 72 hours. Similarly, Idaho's law is much less specific than the New Mexico protocol in terms of required pharmacist procedures. Idaho's reference to the CDC guidelines covers the pharmacist procedures, and Idaho is spared from having to update their law every time clinical guidelines change.

While CPAs will be the most common path forward for pharmacists looking to provide TST today, pharmacy stakeholders may consider pursuing more autonomous authority because it removes the burden of having to find a collaborating prescriber for a service that has already been established as safe and effective in pharmacies.¹⁵ Removing this "permission" step can lead to broader and more efficient uptake by pharmacists in all state, to the benefit of patients.¹⁶ States looking to move TST to a more autonomous legal authority may consider approaches similar to Idaho and New Mexico when pursuing this authority.

Conflicts of Interest: None

Disclaimers: The views expressed in this manuscript are those of the authors alone, and do not necessarily reflect those of their respective employers.

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Table 1: Tuberculin Purified Protein Derivative Products Available in the U.S. for Mantoux TST.

Product	Manufacturer	NDCs
Tubersol®	Sanofi Pasteur Inc.	49281-752-78 (1mL) 49281-752-98 (5mL)
Aplisol®	Par Pharmaceutical, Inc.	42023-104-01 (1mL) 42023-104-05 (5mL)

Table 2. Core Elements of Autonomous TST Prescribing Models

Core Element	New Mexico Protocol Requirements ¹²⁻¹³	Idaho Statutory Requirements ¹⁴
Pharmacist Education Requirement	The pharmacist must successfully complete training as specified by the New Mexico department of health tuberculosis department and continuing education as specified by the CDC	CDC online training
Clinical Guidelines	CDC guidelines	CDC guidelines
Health Screening Requirements	Patient history, family history, current living environment, concurrent illness, allergies and hypersensitivities, medication history.	Follow clinical guidelines
Patient Education Requirements	Skin test reaction drug information, lifestyle modifications, other information as appropriate	Follow clinical guidelines
Pharmacist Procedures	Specific requirements are noted regarding the injection and the reading of the test.	Follow clinical guidelines
Notification to Primary Care Physician	Within 15 days of writing any prescription	Only for positive tests when coordinating a timely referral
Notification to Department of Health	Only for positive tests	Only for active cases
Recordkeeping Requirements	Consent form, records of notification, billing, prescription order	Documentation to be made available to patient upon request