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The Accuracy of Tuberculin Skin Tests: Self-Assessment by Adult Outpatients

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The research was supported in part by VA Health Services Research and Development funds. Results of the study were presented at the 17th Annual Communicating Nursing Research Conference, sponsored by the Western Society for Research in Nursing, in San Francisco, May 4, 1984.

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Synopsis

Tuberculin skin testing is an accurate, inexpensive screening procedure for detecting tuberculosis infection. The return visit needed to interpret the reaction is inconvenient, costly, and may contribute to under-utilization of the test. Although some clinicians ask patients to read their own purified protein derivative (PPD) test results, patient accuracy and the degree of teaching needed to learn this skill are unclear.

This study evaluated the accuracy with which 145 outpatients read their own Mantoux skin test (PPD) reactions and reported by postcard after brief training by nurse practitioners. A total of 89 instructed patients returned postcards and also returned for clinician readings; 46 submitted postcards without returning; 7 returned but did not complete postcards; and 3 neither returned postcards nor returned for readings. Ten of 135 postcards were uninterpretable.

For 81 subjects with both interpretable tuberculin self-assessment postcards and clinician readings, overall PPD classification agreement was 88 percent; $Kappa_w = +0.905$ ($P < .001$). Compared to clinician readings, 1 of 53 patients falsely reported a positive reaction (≥ 10 mm) and 2 of 25 patients falsely reported negative PPD readings (0–4 mm).

There was 100 percent agreement between postcard readings and clinician classifications in a subgroup of patients ($N = 26$), prospectively identified by nurse practitioners as capable of accurate tuberculin self-assessment. Inter-clinician reading agreement ($N = 37$) was 89 percent; $Kappa_w = +0.943$ ($P < .001$).

The brief standardized teaching protocol described can enable most patients to measure and report their PPD results. Study results suggest that postcard reports, especially negative ones, from a subgroup of patients selected for their skill in measuring their initial PPD wheal and ability to paraphrase instructions, might be substituted for clinician readings.

TUBERCULIN SKIN TESTING, A WIDELY ACCEPTED SCREENING procedure for detecting tuberculosis infection, is recommended on entry into the health care system for selected high-risk patients (*1–4*). Periodic purified protein derivative (PPD) tuberculin testing is also used in surveillance of negative persons likely to be exposed to tuberculosis (*5*). Despite these recommendations, tuberculin skin

Tuberculin Self-Assessment (TSA) Teaching Procedure

1. Review list of patient problems for conditions increasing the risk for accurate TSA (for example, organic brain syndrome, psychiatric diagnoses, peripheral neuropathy, reduced visual acuity)
2. Explain PPD's purpose: "to find out if you have ever been exposed to the tuberculosis (TB) germ"
3. Inject tuberculin solution.
4. Tell patient (and family if present) date and time of day to observe skin test site. Write this date and time on the TSA postcard and printed instructions to take home.
5. Show photograph of negative and positive PPD reactions.
6. Review questions patient is to answer on the TSA postcard.
7. Emphasize difference between redness and firmness. Define firmness as ability to feel any change at the injection site compared to the surrounding skin. Use the intradermal injection wheal as a sample of induration. Ask patient to: (*a*) Locate this firmness (swelling) with closed eyes, and (*b*) Measure the diameter across the wheal using the ruler on the TSA postcard and state the size of his measurement.
8. Finally, ask patient to repeat the steps he will carry out. Ask if he thinks this is a procedure he will be able to do.
9. Give patient (*a*) a written return appointment time and location and (*b*) written directions including a sample diagram. Direct him to review these directions before self-reading. Encourage him to telephone the clinic for any problems or questions, even if he thinks they are minor.

tests are infrequently administered, and only a fraction of PPDs administered are recorded in the medical record (*6–9*).

One obstacle to screening is the need for a return visit 2 or 3 days following tuberculin administration to measure the reaction size (*10*). A compliance problem exists. Asymptomatic outpatients may feel this effort is not worth their time and trouble. Clinicians may be less likely to screen with a test that cannot be completed during a single visit. One strategy to reduce return visits is to instruct patients receiving tuberculin skin tests to return only if test sites are red or swollen (*9,10*). Another procedure is to teach the patient to read and report his own PPD (*11*).

When parents rather than clinicians read and reported their children's test reactions, charts contained higher rates of reported multipuncture tuberculin skin test results (*9,12*). In one study, parents performed accurate measurement of their childrens' qualitative multipuncture tuberculin tests (*12*).

Unlike multipuncture tests, Mantoux tuberculin skin test reaction assessments require a quantitative measurement. Although other complex self-measurement skills have been learned successfully by people with hypertension and diabetes (*13,14*), the accuracy with which adults read and report their own PPD skin test results is unknown. In one study in which adults received brief verbal directions without practice opportunity, only 37 percent of adults with positive skin tests interpreted their results correctly (*15*). We have seen several educational aids, such as pictures of positive and negative reactions and self-report postcards, which were prepared and distributed by pharmaceutical firms, but none had been field tested with adults.

We conducted this study to determine if adult outpatients could learn to perform their own tuberculin skin test measurements with enough accuracy that their tests need not be read by health professionals. This study compares the accuracy of patient tuberculin self-assessment (TSA) to test measurements made by staff clinicians. During the initial study, some patients were unable to learn to perform TSA satisfactorily. Therefore, we designed and tested a simple clinic procedure to identify prospectively such persons in the second half of this study.

Methods and Materials

Subjects. Subjects in this study had previously volunteered to attend an annual screening program. As part of a preventive care study, 71 percent of 300 randomly selected Seattle VA Medical Center outpatients attended the Health Promotion Clinic (HPC), a nurse practitioner-staffed clinic designed to screen for remedial diseases and disease risk factors. HPC attendees have a median age of 60 years, an average of three active medical problems, and about 12 years of formal education. About 90 percent are white males. They are a representative sample of medical, surgical, and psychiatric outpatients at our institution.

Tuberculin testing. An HPC tuberculosis screening algorithm was developed to provide guidelines for tuberculin administration. Patients who were known to be positive for tuberculin, had a previous history of tuberculosis, or who had a negative PPD test within 5 years were excluded from skin testing. From August 1981 to March 1982, 154 of 213 consecutive HPC attendees required PPDs on their first

annual HPC visit. Either of two nurse practitioners who recently had completed a PPD training program conducted by the Seattle-King County Department of Public Health administered Mantoux skin tests. The test material, 0.1 ml (5 TU) Parke-Davis Tween-stabilized tuberculin PPD, was placed intradermally on the volar surface of the left forearm using a standardized technique (*1,5,16*). After 48 to 72 hours, an HPC clinician measured the largest transverse diameter of any palpable induration. The reaction was classified as negative (0–4 mm), doubtful (5–9 mm), or positive (10 or more mm) (*17*).

Tuberculin self-assessment training. HPC patients who agreed to participate in training to learn how to measure and record their skin test results on a postcard were given a standardized set of instructions which required about 5 minutes to complete. Components of the training included the following.

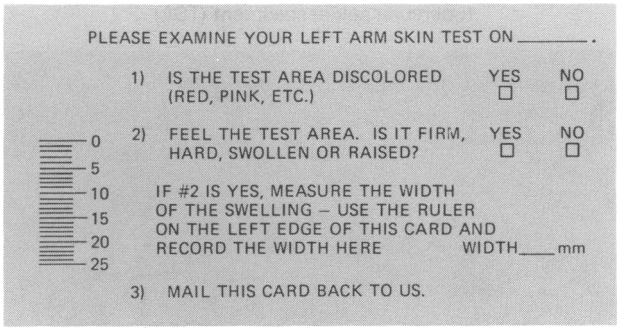
Test reaction measurements. Participants were instructed with the guidelines listed in the accompanying box and given written directions to take home.

TSA postcard recording. Subjects were given a self-addressed and stamped postcard (fig. 1) to report their skin test results at 48 hours. Because pilot tests showed that some patients had difficulty differentiating skin reaction redness from skin firmness or induration, information about both color change and presence of swelling or firmness were to be noted on the response card. If induration was present, the patients were asked to use the ruler on the card margin to measure the transverse reaction diameter.

PPD measurements. Those patients who agreed to return for PPD readings were asked to complete and mail the postcard immediately before the professional reading, but not to inform the clinician of their results. All clinicians' measurements were made without knowledge of either the patient's or the other clinician's readings. The two HPC practitioners made measurements of about 85 percent of the tests, and other nurse practitioners or one of the clinic internists read the remaining 15 percent. Since significant variability between experienced readers of Mantoux skin test results has been shown to exist (*18–20*), two provider readings were done whenever two providers were available.

The patient information on the TSA card was classified independently by two nurse practitioners as negative (0–4 mm induration), doubtful (5–9 mm induration), positive (at least 10 mm induration), or unsatisfactory (TSA card information was either contradictory or too incomplete to classify). If the two nurse practitioners disagreed about interpretations, patient TSA card results were classified as unsatisfactory. The differences in mm between patient and clinician skin test readings were calculated for all paired readings, except for those classified as unsatisfactory. These differences were then averaged for various groups.

Figure 1. Tuberculin self-assessment postcard

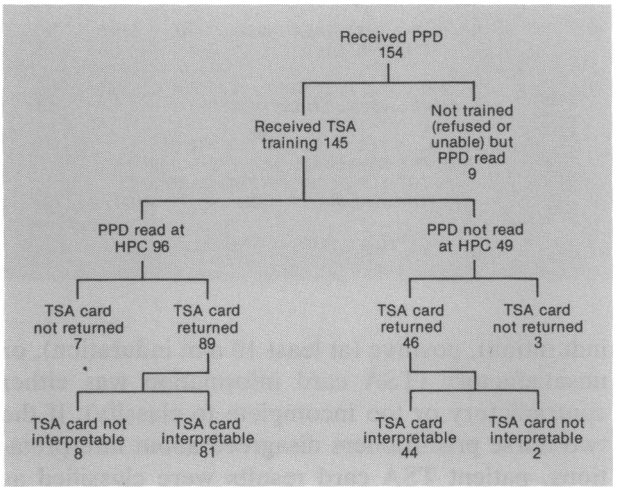


For each PPD reaction for which two independent clinician readings were available (N = 37), mean difference between readings were calculated and paired classifications were analyzed as described subsequently.

TSA performance related to predicted success. Initially, in this study we asked all subjects to attempt TSA. With experience, we recognized that some subjects could not perform TSA. Several had obvious cognitive, sensory, or psychiatric incapacitation, while others had more subtle disability. During the second half of this study (N = 72), each nurse practitioner recorded a prediction whether or not she thought the patient could perform TSA accurately. The prediction was based on observations of patient ability to paraphrase the TSA measuring and recording instructions and to measure accurately the skin wheal produced by intradermal tuberculin administration. These predictions were available for 37 study subjects who also had matched clinician readings.

Data analysis. With the eight unsatisfactory patient readings excluded, the proportion of overall agreement, sensitivity, and specificity between patient and clinician were calculated for all 81 paired PPD readings (*21*). For sensitivity and specificity calculations only, TSA responses were categorized based on need for further clinician intervention as (*a*) negative (0–4 mm) or (*b*) doubtful or positive (≥5 mm).

Figure 2. Outcome of Health Promotion Clinic patients who received tuberculin skin tests and were asked to perform tuberculin self-assessment (TSA)



When two independent provider readings were available for one PPD reaction, a coin flip determined which clinician reading to use as the standard of accuracy.

A weighted kappa statistic (K_w) was used to provide a statistical measure of agreement. This statistic corrects for chance agreement and assigns a greater degree of seriousness to disagreements which are two classifications apart than to disagreements only one classification apart. Kappa measurements range from −1 (complete disagreement) through 0 (agreement indistinguishable from chance alone) to +1 (perfect nonchance agreement). Kappa results are conventionally interpreted with a value of +0.75 or greater, reflecting excellent agreement, while +0.40 or less reflects poor agreement (*22*).

The same data analyses (proportion of overall agreement between pairs, sensitivity, specificity, and K_w) were done for the paired clinician readings and separately for the subgroup of 37 subjects for whom we had nurse practitioner predictions of TSA performance competency.

Results

Participation in the TSA study. Figure 2 shows that skin test reports were obtained from 96.5 percent (140 of 145) of patients receiving TSA instruction, either by return of satisfactory TSA postcards, by return for clinician test readings, or by both methods. Overall, 93 percent (135 of 145) of instructed patients returned the TSA postcards. Of the patients returning TSA postcards, 92.5 percent (125 of 135) could be satisfactorily interpreted.

About one-fifth of all HPC patients receiving PPDs did not produce a satisfactory TSA postcard. Six percent (9 of 154) of veterans were not trained because of blindness, organic brain disease, severe peripheral neuropathy, or refusal to participate. Another 6.5 percent (10 of 154) were trained but failed to submit a TSA card, while 6.5 percent (10 of 154) submitted TSA postcards that could not be interpreted.

For the 46 subjects who submitted postcards but did not make a return visit, TSA accuracy could not be assessed. More than half of these subjects telephoned one of the nurse practitioners to describe their reactions and state that they were not returning to the clinic to have their skin test checked because it seemed unnecessary. The two with unsatisfactory cards and the seven with positive TSA cards were asked to return for a reading or retesting. These retest results are not included in the analysis of TSA accuracy.

This study population had a high enough rate of positive tuberculin skin test to permit evaluation of ability to interpret positive reactions. For the 89 subjects who had paired patient and clinician readings, 31 percent had positive reactions. Of the 44 subjects who mailed satisfactory TSA postcards but did not return to the clinic, 15 percent also reported positive reactions.

Accuracy of patient TSA. Table 1 shows that patients' TSA measurements generally agreed with those made by HPC staff. There were two false negatives for 25 subjects who had completed satisfactory TSA cards and had clinician-identified positive PPD reactions. Both of these were potentially avoidable if competency selection criteria had been applied. One occurred in a subject predicted as unable to do accurate TSA. The other false negative occurred early in the study when all patients receiving PPDs were asked to attempt self reading, regardless of the clinicians' opinion of their ability to perform TSA successfully. Retrospective review of the chart of this patient revealed that he had attributes that would have allowed prediction of inability to do TSA accurately.

For patients whose test reactions had any induration reported by clinicians, errors and unsatisfactory postcards occurred at more than twice the rate they did when the reactions read by clinicians were 0 mm induration (21.6 percent versus 7.7 percent). The patients' age was not significantly related to the accuracy or completeness of TSA cards.

Inter-clinician comparison. Table 2 displays the measurement agreement between clinician pairs.

Table 1. Comparison of patients' and clinicians' tuberculin readings by classification of tuberculin reactions

Clinician reading (mm of induration)	Patient tuberculin self-assessment (TSA) readings (mm of induration)					
	Negative		Doubtful	Positive	Unsatis-	
	0 mm	1–4 mm	(5–9 mm)	(≥10 mm)	factory[1]	Total
Negative						
0 mm, all paired clinician-patient readings	46	2	0	1	3	52
0 mm, subgroup[2]	14	0	0	0	1	15
1–4 mm, all paired clinician-patient readings	4	0	0	0	2	6
1–4 mm, subgroup[2]	0	0	0	0	0	0
Doubtful (5–9 mm)						
All paired clinician-patient readings	0	0	2	1	0	3
Subgroup[2]	0	0	1	0	0	1
Positive (≥10 mm)						
All paired clinician-patient readings	2	0	0	23	3	28
Subgroup[2]	0	0	0	11	0	11
Totals:						
All paired clinician-patient readings	52	2	2	25	8	89
Subgroup[2]	14	0	1	11	1	27

[1] TSA card was incomplete or contradictory.

[2] Number from subgroup that clinicians predicted would be able to perform TSA satisfactorily.

On three occasions, one clinician rated doubtful a reaction that a second clinician read as positive. In all cases, disagreements in clinician classifications were never more than one category apart, while patient-clinician disagreements as described in table 1 at times spanned more than one category.

Predicted versus actual TSA performance. Nurse practitioner predictions about the ability of a patient to perform TSA were available for 72 subjects. Of these, 28 percent were judged unlikely to carry out TSA accurately. Thirty-seven of these 72 patients both returned TSA cards and returned for clinician readings.

Ten subjects with paired clinician readings (27 percent) were predicted to be unable to read their skin test results correctly. Of these 10, 2 misinterpreted tests (1 false positive and 1 false negative), 3 submitted unsatisfactory TSA cards, and 5 correctly interpreted negative reactions. For the 27 subjects judged able to perform the TSA, 1 returned an unsatisfactory card, and 26 returned TSA cards that correctly matched clinician readings. These differences in ability to report accurate results by TSA are statistically significant ($P = .003$) using the Fisher Exact Test (*23*).

Overall agreement, sensitivity, and specificity. Table 3 describes the proportion of overall agreement between all clinician-patient pairs, for the subgroup of clinician-patient pairs in which patients were predicted able to perform accurate TSA, and between clinician-clinician pairs. The data do not include unsatisfactory card results, assuming these persons would be called back for repeat skin testing. In all three groups, K_w values suggest significant agreement between pairs beyond that expected by chance. The variability of clinician PPD readings in this study compares favorably to results reported elsewhere (*18,19*).

Table 2. Comparison of clinician readings by classification of tuberculin reactions

Clinician 2 readings (mm induration)	Clinician 1 readings (mm induration)			
	Negative (0–4 mm)	Doubtful (5–9 mm)	Positive (≥10 mm)	Total
Negative 0–4 mm	18	1	0	19
Doubtful 5–9 mm	0	0	3	3
Positive ≥10 mm	0	0	15	15
Total	18	1	18	37

Difference between paired readings. For tuberculin reactions for which at least one reader reported induration, mean differences were 3.0 mm (SD = 3.1) between clinician pairs (N = 22), 3.5 mm (SD = 4.7) between pairs of clinicians and patients predicted able to do TSA (N = 12), and 5.9 mm (SD = 6.5) between clinicians and all patient pairs, including patients predicted unable to do TSA (N = 37). Although a test of significance between these groups is not appropriate because measurements are not independent, results suggest that patients

Table 3. Comparison of paired tuberculin skin test readings by overall agreement, $Kappa_w$, sensitivity, and specificity values

Measure	Type of comparison		
	All patient-clinician pairs[1] (N = 81)	"Capable" patient-clinician pairs[2] (N = 26)	Clinician-clinician (N = 37)
Proportion of overall agreement (percent)	88	100	89
$Kappa_w$	.905	1.00	.943
Probability value	<.001	<.001	<.001
Sensitivity (percent)[3]	92	100	...
Specificity (percent)[3]	98	100	...

[1] Subjects without satisfactory tuberculin self-assessment (TSA) cards are excluded.
[2] Capable denotes patients predicted able to perform TSA.
[3] Calculated after dichotomizing results into negative (0–4 mm) versus doubtful or positive (≥5 mm), using providers as the standard for accuracy.

predicted competent to do TSA do not differ in accuracy compared to HPC clinicians.

Discussion

In this study, an 86 percent (125 of 145) return rate of satisfactory TSA cards by all instructed subjects markedly exceeds PPD administration and reporting rates described in the literature. Despite current recommendations for PPD testing in our institution, less than 5 percent of a random sample of 1,000 outpatient charts contained any documented clinic or hospital PPD results. Recorded PPDs usually had been administered to evaluate current respiratory symptoms rather than for screening purposes. The lack of documented tuberculosis infection status is especially relevant in the VA outpatients studied. They are middle-aged or older, predominantly male, and usually from urban areas, all attributes associated with an increased risk for developing tuberculosis (*1*).

The great majority of patients (98 percent) readily participated in PPD measurement either by sending in TSA cards or by returning for clinician measurement. The 91 percent compliance rate for submission of TSA cards when requested compares favorably to reports of a 67 to 90 percent rate of parents mailing results of their children's Tine tests (*9,12*). A few patients (5 percent) preferred to have a clinician read their test rather than perform TSA. For the one-third of subjects who did not return to have clinicians check their test results, half had stated at the time of PPD administration that other responsibilities or transportation costs would preclude their return. For such persons, use of a TSA postcard system permits enrollment of patients in a tuberculin screening program who otherwise might refuse a test requiring a return visit.

VA outpatients who received TSA instruction achieved a high level of accuracy. Their overall false positive rate (false positives divided by false positives plus true negatives) was 2 percent (1 of 53). For the 25 subjects with positive reactions (≥10 mm) and satisfactory TSA readings matched to clinicians' results, 92 percent (23 of 25) correctly classified their test as positive. Among patients prospectively predicted able to perform TSA correctly, there were no false negative or false positive classifications. The accuracy of these TSA results by capable patients compares favorably with clinician-clinician PPD classification agreement in our study.

The accuracy of our adult TSA is similar to that achieved by parents using a comparison photograph card to read positive and negative Tine test reactions (*12*). Our 92 percent TSA accuracy also compares favorably to the only other study of adult tuberculin self-assessment which used only verbal directions; only 37 percent of 212 adults correctly identified their PPD reactions as positive (*15*).

Efficient use of limited outpatient care resources is a major concern of all health care providers. An effective TSA method would reduce staff time and costs for unnecessary return visits. Recent guidelines suggest adults who are tested periodically require two-stage testing due to a booster effect, with a second test given in a week if the first test reaction was less than 10 mm induration (*18*). From our experience, tuberculin screening using a TSA instruction procedure for capable patients would halve the number of return visits and recalls when compared to a conventional approach of asking all patients to return for clinician reading. This estimate assumes (*a*) a 68.2 percent return visit rate, (*b*) that all who fail to return in person or return postcards would be recalled for repeat testing, and (*c*) that all patients doing TSA would be asked to return for clinician confirmation of positive TSA reports. The need for return visits would be even lower if

populations with positive test rates below this group's 31 percent were involved.

The high levels of TSA participation and accuracy in our study may not occur in other settings. Because they had volunteered to attend a screening program, these subjects may be more willing to assume responsibility for TSA than other patients. The patients who returned also knew their results would be checked. On the other hand, one might expect better compliance with reporting results and a higher percentage of accurate TSA readings if the patient population were younger, more highly educated, and had less co-existing disease which hindered accurate TSA performance.

More research is needed to determine the easiest and most accurate method of teaching self-measurement of tuberculin reactions. During the pilot phase of this study, we tested 40 subjects' ability to use two punch holes (5 and 10 mm diameter) compared to a straight edge ruler printed on the postcard. We chose the ruler method which tended to yield more accurate results, seemed to be a more familiar task for most subjects, and allowed measurement of transverse induration diameter, the preferred method of skin test measurement (*5*).

Two important factors for successful implementation of this TSA program were the standardized 5-minute structured teaching method and the identification of patients who were unable to complete the TSA procedure accurately. These components could be applied feasibly in most outpatient settings. When symptomatic persons are tuberculin tested for diagnostic or medico-legal purposes, we recommend that PPD measurements be made by personnel trained and experienced in PPD reading.

This study suggests that TSA reports from selected patients receiving this teaching approach, especially negative reaction reports, might be substituted for readings by clinicians. Patients with unsatisfactory or positive TSA reports need to be recalled for professional readings and further diagnostic testing. The further testing and implementation of these convenient teaching and reporting techniques should be considered by others concerned about extending the use of tuberculin screening.

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