A PROSPECTIVE STUDY OF THE TUBERCULIN SKIN TEST CONVERSION RATES IN DENTAL HEALTH CARE WORKERS

Case Report 1 submitted in partial fulfillment of the
Residency in Dental Public Health

by
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Table of Contents

A. NAME OF PROJECT

A Prospective Study of the Tuberculin Skin Test Conversion Rates in Dental Health Care Workers.

B. APPLICANT'S ROLE IN PROJECT

The applicant was the principal researcher in planning, implementing, analyzing, interpreting and reporting this study.

C. STATEMENT OF PURPOSE

The purpose of the study was to assess the exposure of a group of dental health care workers to Mycobacterium tuberculosis over a twelve month period in Cameron, Hidalgo and Starr counties in South Texas. These counties are located in the Lower Rio Grande Valley.

Figures for 1993 show that Texas is the third leading state in number of tuberculosis cases and the fourth leading state with a case rate of 13.3 per 100,000 population, preceded only by New York, California, and Hawaii. In 1994, in Texas, there was an increase of 6 percent in the number of reported cases of tuberculosis (TB) over 1993. Seventy two percent of the total cases were reported in the coastal and U.S. Mexico border regions of the state (1).

D. BACKGROUND AND REVIEW OF THE LITERATURE

1. <u>Description of the Problem</u> According to the World Health Organization (WHO), tuberculosis (TB) is the largest cause of death from a single infectious agent in the world. After decades of declne, it has emerged in the nineties as the world's worst infectious disease (2). In the U.S., there was a decline from 784,000 cases in 1953 to 22,000 in 1984. By 1992, the number of cases had risen to 27,000 with a steady decline to 24,000 cases in 1994.

One of the national objectives for Healthy People 2000 and for the Advisory Council for the Elimination of Tuberculosis (ACET) is to reduce the number of TB cases to 3.5 cases per

100,000 population for the year 2000. ACET also established a national goal of 1 case of tuberculosis per million population by the year 2010 (3).

2. **Epidemiology and Transmission of Mycobacterium tuberculosis** TB is an airborne transmitted disease. When a person with active pulmonary or laryngeal TB coughs, sneezes, speaks or sings, a portion of the cloud of respiratory droplets evaporate into droplet nuclei. These droplet nuclei are estimated to be 1-5 u microns in size and contain one or several tubercle bacilli. They can be carried in normal air currents throughout a room or a building. When a susceptible host inhales the droplet nuclei, they travel through the airway to reach the alveoli. They are then taken up by the alveolar macrophages and spread throughout the body. After 2-10 weeks, the body's normal immune system prevents the further spread of the bacilli. Some of the bacilli remain dormant for many years, a condition known as latent TB infection. People with latent TB infection are not infectious and usually have a positive tuberculin skin test (TST).

The risk for developing active TB is greatest during the first two years after infection, with an estimated 10 percent risk during their lifetime. The probability that a person who is exposed to to Mycobacterium tuberculosis will develop active TB depends on a number of factors such as the concentration of infectious droplet nuclei in the air and the duration of the exposure. Environmental factors such as exposure in confined spaces, inadequate ventilation and recirculation of air containing infectious droplet nuclei also increase the likliehood of transmission (4). A study by Nardell et al concluded that as the infectiousness of an active TB carrier increases, the protection provided to persons through increased ventilation may be limited (5).

The Centers for Disease Control (CDC) investigated six instances when passengers or flight crew on commercial airlines were infected with M. tuberculosis. They concluded that transmission had occured from one crew member to another in one instance and from passenger to passenger in the other instance. Both were associated with proximity to the infected person and long duration of exposure (6).

3. **Human immunodeficiency virus (HIV) infected persons** Much of the increase in cases of TB in recent years is believed to be due to TB among immunocompromised patients who have a greater risk for the progression of latent TB infection to active TB disease. Human imunodeficiency virus (HIV) infection is the most important risk factor for this progression. Persons with latent TB infection who become infected with HIV have an 7-10 percent risk per year for developing active TB (7). Conversely HIV-infected persons who become newly infected with tubercle bacillus have an increased risk of progressing from infection to active disease within weeks or months. Other immuncompromising conditions, such as treatment with certain medications, renal failure and diabetes mellitus increase the risk of progression to a lesser extent than HIV infection (8)

4. **Multidrug-Resistant Tuberculosis** An increasing proportion of TB cases in the U.S. is occurring among patients born outside the U.S., homeless people, those with substance abuse problems, mental illness and other socioeconomic problems that make drug compliance therapy difficult (9). Resistant strains of the bacteria have been formed, giving rise to multi drug resistant TB (MDR-TB). There is no evidence that MDR-TB is more virulent than the strains from which they originate. Most of the propagation of this type of TB appears to be entirely due to host immunosuppression and unfavorable environmental settings (10,11). Clusters of cases have been reported in crack house contacts in California (12). Shelters for the homeless and crowded correctional facilities provide areas of potential transmission (13, 14). Some studies have shown that certain organisms are resistant to as many as seven drugs. Treatment of patients with MDR-TB and those at risk of becoming infected is a complex process involving a panel of drugs and directly observed therapy (DOT). In response to the emergence of MDR-TB, a federal task force was convened in 1991 for the development of a national action plan to help control the problem (2, 15, 16).

Of the confirmed reported cases in Texas in 1994, 6.8 percent were resistant to one or more drug. This represents a 36 percent decrease in resistant cases from 1993, and occurred

despite an overall rise of 6 percent in the number of reported TB cases in 1993 in the state. The reduction is thought to be due to increased surveillance, applying DOT and consultation with medical experts in all difficult cases (1).

5. **Other High Risk Groups** A priority for the Advisory Council for the Elimination of Tuberculosis (ACET) is to provide TB screening and preventive interventions to high risk populations. Based on data from a survey carried out by the Centers for Disease Control (CDC), the risk of TB in migrant farm workers is estimated to be six times greater than the general population (17). Racial and ethnic minorities accounted for 77 percent of all reported cases in Texas in 1994. Hispanics accounted for 40 percent, African Americans 29 percent. Eight percent were reported in Asians and Pacific Islanders. Twenty six percent of cases were in foreign born persons. The country of origin for 58 percent of those was Mexico (1).

6. **Tuberculosis in Health Care Facilities** The occupational risk for health care workers (HCW's) has long been recognized. In 1925, it was determined that 2.5 percent of all nurses in Chicago had TB. A study carrried out in the 1930's showed that 100 percent of student nurses had become infected with TB by the end of their three years of training at Philadelphia General Hospital (18). A parallel decline in TB in HCW's occured with the overall decline in TB cases. over three decades. However, in 1993, HCW's accounted for 3.2 percent of TB cases in the U.S. (19). Because patients coinfected with HIV and TB are being cared for in hospital facilities, nosocomial outbreaks of TB affecting both the patients and HCW's have been reported in New York and other areas in the U.S. (20, 21). A major problem for HCW's is the delay in diagnosing the presence of M.tuberculosis because of the masking effect of overgrowths of cultures by other mycobacteria (22).

Not all HCW's are at the same risk. CDC documented outbreaks of TB in nearly 300 patients and at least 17 health care workers in eight hospitals in New York, New Jersey and Florida. Most of the bacterial isolates from infected patients were resistant to at least two drugs and some were resistant to as many as seven. About 80 percent of the patients and eight of the

health care workers who had active, MDR-TB were known to be HIV positive. According to CDC, seven of the nine fatal cases of occupationally acquired MDR-TB in HCW's were HIV positive (23, 24).

A study to compare pulmonary fellows and infectious disease fellows showed that pulmonary fellows showed higher TST conversion rates. This was thought to be due to more invasive procedures and more time in intensive care spent by the pulmonary fellows (25). According to the CDC, the magnitude of the risk in health care facilities varies according to the type of facility, the prevalence of TB in the community, the patient population served, the HCW's occupational group, the area of the health care facility where the HCW works, and the effectiveness of TB infection control interventions.

7. **Protection of the Health Care Worker** Eight major controlled trials on the efficacy of the bacille-Calmette-Guerin (BCG) vaccination in the U.S. have not led to a concensus on its use. Despite the concern about masking recent TB infection, BCG has been suggested as a preventive measure in HCW's (26). The CDC issued guidelines to help prevent the spread of TB in health care facilities in 1994. A baseline risk assessment is recommended for all facilities and an appropriate protocol is then recommended, depending on the number of risk factors for facilities and occupational groups. Skin testing of HCW's may or may not be included in the risk assessment. In situations where it is recommended, and TST conversions are found they are then followed with chemoprophylaxis (27). A study by Barrett-Connor showed that annual TST was completed by less than 50 percent of housestaff in seven California medical schools. More than half of the recent converters did not take chemoprophylaxis and 25 percent of those who began isoniazid prophylaxis failed to complete the course (28). In a self-report survey of dentists in the Indian Health Service (IHS) and Fedreal Bureau of Persons (FBoP), 46 percent reported having a known exposure to a person with active TB, but less than 60 percent had been tested annually (29). The CDC published an interpretation of the TB prevention guidelines specifically for dental settings in 1995. Baseline TST's are recommended for all dental workers in all risk

groups except for those at minimal risk and annual TST's are recommended for all dental workers in low to high risk groups (30).

8. **Significance of the Problem** Like most other health care facilities, the dental environment also has risk factors associated with the transmission of TB, for example the undiagnosed active TB patient, HIV/AIDS positive patients, and other immunocompromised persons with oral symptoms, foreign-born persons, aerosolized and potentially cough-inducing procedures. The magnitude of the risk has not been established as data are limited. It has been shown by Belting at al. that tubercle bacilli are aerosolized during dental treatment, but the study did not clarify if the organisms were carried in droplets or droplet nuclei (30). Standard surgical masks are designed to protect the operative field and not the operator. While they act as barriers to droplet inhalation, they have an inability to filter out droplet nuclei 1-5um (14, 31). A study, carried out to confirm that droplet nuclei containing M. tuberculosis could be generated during scaling with an ultrasonic scaler failed to do so. This study, however, did not control for factors such as dilution of air and contamination of the Petri dishes with other bacteria growths (32).

The self-report survey of dentists in the Indian Health Service (IHS) and the Federal Bureau of Prisons (FBoP) also identified TST practices and results. It concluded that the prevalence of reactive TST's among this group was consistent with the prevalence of TB infection in the U.S. despite the seemingly high risk environment. Being a self-report, a number of biases were present, including a recall bias and the inability to verify any results (29).

E. DESCRIPTION OF THE PROJECT

1. **Purpose of the Project** The purpose of the study was to assess the TST conversion rates in dentists, dental assistants and dental hygienists in selected counties along the U.S./Mexico border over a twelve month period. This area, in the Lower Rio Grande Valley, with a high percentage of people in lower socioeconomic groups, and a dynamic border population, certainly satisfies at least one of the major risk factors for transmission of TB.

The counties chosen were Cameron, Hidalgo and Starr. In 1994, the prevalence rate of active Tuberculosis (TB) for Cameron was 31.6 per 100,000 population, 25.1 for Hidalgo and 16.4 for Starr Counties. Compared to Texas where the rate was 14.3 per 100,000 and the U.S. rate of 13.9, these figures are alarmingly high (1).

The planning phase of the study was initiated in January 1994. A survey instrument was designed, along with a letter to dentists requesting participation, a statement of informed consent and the study protocol. All were submitted for approval by the Institutional Review Board (IRB) at the University of Texas Health Science Center at San Antonio (UTHSCSA) during the same month. When approval was received from the IRB, the questionnaire was distributed for pilot testing. A research assistant (R.A.) was hired in March 1994. Arrangements were made for supplies to be received from the Texas Department of Health (TDH) at Harlingen, the headquarters of Public Health Region 11. The R.A. was calibrated for TST according to CDC guidelines in April 1994 by the first phase of the study, which began with the first mailing for recruitment of participants in April 1994.

A letter informing dentists about the study and requesting participation were placed in an outgoing envelope (Appendix 1). The subjects were told to expect a follow-up phone call from the research assistant (R.A.) to arrange appointments for TST at the subjects' convenience. Educational booklets, from TDH, on tuberculosis were placed with the letters in the envelope. A follow-up telephone call was made by the R.A, to arrange appointments ten days after receipt of the letters. Data collection ran from May 1994 to July 1994 for the first phase and from May 1995 to July 1995 for the second phase. The study was closed out in July 1995. The final paper was submitted to the Residency Committee of the Department of Community Dentistry at UTHSCSA in October 1995, in partial fulfillment of the requirements for the completion of the Residency in Dental Public Health.

F. PROCEDURES AND METHODS

1. Population to be Studied All subjects tested were recruited from a complete list of private dental offices and public clinics in Cameron, Hidalgo and Starr counties. All dental personnel including dentists, dental hygienists and dental assistants with direct patient contact were included.

2. Training and Calibration of the Research Assistant A Procedures Manual (Appendix 2) was compiled and given to the R.A. Calibration for TST according to CDC guidelines was carried out at the regional office of the TDH at Harlingen. It consisted of three stages. One week prior to the beginning of the study, the R.A. spent one morning at the TB clinic participating in TST. This was supported with audio and visual aids during the afternoon of the same day. Three weeks after commencement of the study, a nurse from the TB clinic observed the R.A. during field administration and reading of TST. Four weeks later, the R.A. again returned to the TB clinic at TDH in Harlingen for re-calibration. The same process was duplicated during the second phase of the study.

3. Materials and Methods A letter of informed consent, with assurance of confidentiality (Appendix 3) was given to each subject on arrival at the dental clinics/offices. The subjects read and signed the consent forms and returned them to the R.A. Each subject was also requested to complete a pretested, self-administered questionnaire (Appendix 4). The questionnaire was designed to collect data on demographic variables and relevant information on risk factors associated with the transmission of TB, such as treatment of HIV positive patients. Each subject was assigned an identification number (I.D.). Data was stored under their I.D. number. No individual was identified as such.

A tuberculin Mantoux skin test was administered to all participating dental health care providers with direct patient contact. One tenth of a milliliter of tuberculin containing five tuberculin units (TU) of purified protein derivative (PPU) was injected intradermally on the volar surface of the left arm. A single dose plastic syringe was used with a 26-27 gauge needle.

Injection was done with the needle bevel pointed upward. A wheal 6-10 millimeter in diameter should have occurred immediately following injection. After a period of forty eight to seventy two hours, the result was read. The presence of a palpable induration greater than or equal to 10 mm. in diameter was considered a positive reaction. A negative result was an induration less than 10 mm. in diameter. Induration size was measured with a ruler. Recordings were made of the induration size, the antigen strength, lot number, date of testing and date of reading.

All reactors were referred to a physician or the TB service at the Texas Department of Health. These were tested further for tuberculosis infection. All non-reactors were identified from the baseline data. Prior to commencement of phase 2 of the study one year later, a letter requesting participation was mailed to all the non-reactors from the first phase (Appendix 5). The letter was followed up by a telephone call from the R.A. Appointments were arranged accordingly and these persons were tested again.

4. **Data Entry and Analysis** Data were entered into a microcomputer, using the spreadsheet program Excel. All data were then verified for coding accuracy. Statistical analyses were carried out by microcomputer using Statview and Excel. Analyses were carried out after both phases of the study and included descriptive and analytical components. The data collected in the second year provided information on the TST conversion rates of tuberculin among dental health care workers These incidence rates were then investigated for each subgroup of provider (dentist, hygienist or dental assistant), as well as by county of practice. The descriptive and analytical tests, carried out in the first phase of data collection, were repeated again in the second phase. The descriptive tests included percentages and/or proportions of each type of dental health care provider (dentist, dental assistant and dental hygienist), who were positive/negative to the tuberculin test. The same parameters were applied to each county. Measures of central tendency (mean, median or mode) were used for continuous variables, such as age of the participants. Frequency and percent distribution denoted the type of practice and gender of each

dental care provider and/or for the total study population. Specific prevalence rates of tuberculin conversion were calculated for type of provider, gender and county.

Analytical tests were utilized to detect any association between a dependent variable (TB positive) and relevant independent variables (type of provider, gender, county of practice, country of birth, infection control practices and other risk factors). The analytical test were bivariate. Chi-square and Fisher's Exact tests were applied to test any association between a dependent (positive TST) and an independent (e.g. gender) variable.

G. FINDINGS

Out of a total of 80 dental offices and clinics in Cameron, Hidalgo and Starr counties, 58 participated yielding a 73 percent practice participation rate. In those practices, one hundred percent of all workers with direct patient contact were tested giving a sample size of 284 for the first phase of the study. The thirteen subjects who had positive reactions in the first year were excluded during the second phase, one dentist chose not to continue to participate and thirty assistants had left their place of employment and could not be traced. Consequently, over the twelve month period, the sample size was reduced to 240 for the second phase of the study.

Table I shows the general demographic characteristics of the study population. The sample was comprised mainly of dental assistants, 69 percent, with 21 percent dentists and 10 percent dental hygienists. Ninety two percent of the assistants, and 97 percent of the dental hygienists were female. The dentists on the other hand were 95 percent male.

The age for the total population ranged from 18 to 70 years. The mean age for dentists was 43, with a range of 28 to 70. Dental assistants ranged from 18 to 57 with a mean of 30. The age range for dental hygienists was 22 to 69, the mean being 35 years.

The mean number of years in practice for dentists was 15, with a range from 1to 43, dental assistants had a mean number of years in practice of 7 with a range from 0 to 35 and the mean for dental hygienists was 11 with a range from 1 to 26.

Most of the dentists were white (58 percent). Ninety percent of the dental assistants were Hispanic, with only 10 percent white. Seventy six percent of the dental hygienists were Hispanic. Ninety eight percent of the participants worked in private dental offices, with two percent working in public clinics. Of those who worked in private offices, seventy seven percent were in general dentistry practices. Workers in orthodontic offices made up 7.4 percent of the sample, those in offices limited to pediatric dentistry accounted for 5.3 percent, oral surgery 4.9 percent, periodontics 2.8 percent, and .4 percent of the sample were dental workers in offices limited to prosthodonics (Table II). One hundred and eighty five (65 percent) of the practices were located in Hidalgo county, thirty one percent in Cameron and only 4 percent in Starr county (Table III).

Phase I Thirteen of the participants (4.6 percent) in the first phase of the study had positive TST's. Of those thirteen cases, ten (77 percent) were dental assistants, two (15 percent) were dentists and one (8 percent) was a dental hygienist. Ten (77 percent) worked in Hidalgo county, and three (23 percent) were located in Cameron county. In two instances, positive TST's were noted in two persons in the same practice. Both practices were located in Hidalgo county. Table IV shows that those who had negative TST's were more likely to have been born in the U.S. than outside the U.S ($p<.001$).

Of the thirteen positive reactors in phase 1, ten proceeded to have radiographs taken. Three of those were prescribed prophylactic medication. A year later, three had not obtained medical consultation as advised.

Phase 2 In the second phase, four participants had positive TST's, giving a tuberculin conversion rate of 1.7 percent over a twelve month period. Two (50 percent) subjects were male and two were female. One (25 percent) was a dentist and three were dental assistants. Two were in Cameron and two were in Hidalgo county. Three of the reactors were Hispanic, one was white. All four reactors were born in the U.S. Three worked in a private general dental office, and one worked in a private orthodontic office.

Only one of the reactors had ever worked in a residential facility, such as a hospital or jail. Three out of the four reactors used or assisted in the use of an ultrasonic scaler (cavitron) which generates aerosols. Only one of the reactors had a TB skin test in the past two years. The result had been negative. Three out of four said they never had BCG vaccine, one said they didn't know. All four said that nobody in their household had a cough lasting longer than six weeks. None of the four said they treated HIV positive patients, two saying no and the other two saying they didn't know. Two reactors said they use surgical masks 100 percent of the time. One said they never use them and the other said that they use masks 0-50 percent of the time. Half of the reactors didn't use rubber dam routinely, the other half said they use them 0-50 percent of the time. No specific infection control procedures for TB were used by any of the reactors.

Table V shows the frequency of exposure of all those with positive TST's, both first year reactors and those with twelve month conversions, to selected established variables associated with the transmission of M. tuberculosis. No significant association between reactors and variables, or between the two groups was found. It was interesting to note that in comparison with first year reactors, none of those who converted over twelve months were born outside the U.S.

Experience of both first year TST reactors and twelve month TST converters with factors known to affect the TST response are shown in Table VI. A greater percentage of those with first time reactions than those who converted over a year said they had a previous TST in the past two years (38 Vs. 25 percent). Overall, only 28 percent of the study population had previous TST's. No significant association was found individually or between groups. The overall percentage of those who had BCG vaccine in the previous two years was 17 percent. None of the 17 subjects with positive TST's had BCG vaccine.

H. DISCUSSION

The Mantoux tuberculin skin test is the only method currently available that demonstrates infection with the tubercle bacillus, even in the absence of active TB. However, there are

limitations to the test (33, 34). The positive-predictive value of the PPD reaction is dependent on the prevalence of the infection in the population being tested and the specificity of the test. The prevalence of TB in this community is known to be high, but no previous studies have been carried out to assess the prevalence in dental HCW'S. The Mantoux skin test is not 100 percent specific. Technical errors, such as improper handling, storage and poor technique of administration of the material can result in insignificant results. Errors in reading the result can also lead to misinterpretation. False-negative reactions may also occur. Persons who have immunosuppression because of disease e.g. HIV infection or drugs, may have a limited response to tuberculin even if they are infected with the tubercle bacillus (35, 36). A booster phenomenon may occur in persons who have been previously sensitized to mycobacterial antigens through BCG vaccine, other environmental mycobacteria or previous infection with Mycobacterium tuberculosis (37, 38). In health care workers in the U.S. the booster phenomenon is most prevalent in non-whites, and those older than 45 years.

Since this study was planned, the two-step tuberculin skin test has been recommended for baseline data by the CDC for HCW's who have not had a documented negative tuberculin skin test in the previous year (27). A high number of the total study population, 72 percent in all, had not had a skin test in the preceding two years. This finding, consistent with that of dentists in the Indian Health Service and Federal Bureau of Prisons that less than 60 percent had been tested annually (29) may be indicative of a general trend for all dental workers. It was not feasible to employ a two-step procedure for testing because of a time constraint, and a limited source of funding. Consideration was also given to the fact that as high a participation rate may not have been received if the number of visits to the dental offices were doubled.

Although technical problems associated with the Mantoux TST were reduced by the study methodology, other factors must be kept in mind when interpreting the results. All subjects in this study were considered healthy. Non-reactors may have been immunosuppressed and it can be conclusively stated that only one of the reactors was a true converter. However,

the TST conversion rate (1.7 percent) in this group of dental HCW's is comparable to rates shown in other HCW's. One study showed annual conversion rates ranging from 0 to 1.8 percent in a five year period, with a 3.9 percent rate one year coinciding with a hospitalized undiagnosed active TB patient . These studies that are available for comparison have been carried out in hospital facilities where the risk of transmission would seem to be greater. Other cited studies, with 2.4 percent TST conversion rate in infectious disease specialists and 3.6 conversion rate in IHS and FBoP dentists, have relied on self-reporting (24, 29).

Strengths of the study include a high participation rate. The R.A. arranged appointments and traveled to the subjects' workplace to carry out skin testing at their convenience. This was seen as a service to the dentists and their staff.

During the course of the study close contact was maintained with the regional office of TDH at Harlingen. For those who were identified as positive reactors in either phase of the study appropriate action has been taken by the TDH. All reactors were immediately referred for chest radiographs and the appropriate follow-up procedures were taken. Contact investigations were done on family members.

I. CONCLUSION

Because of the lack of power due to the small numbers in this study, the results must be interpreted with caution and not extrapolated to the general population of dental HCW's. However, this pilot study has provided valuable information.

1. The risk for transmission of TB in this study population is not zero, but does not appear to be high and the TST conversion rate of 1.7 percent is found to be similar to rates found in other HCW's. If two-step testing had been carried out, the number of reactors would either have been the same or lower. Thus, in an area with such a high rate of active TB in the community, the risk for transmission of Mycobacterium tuberculosis would seem to be no greater than for the general population

2. The prevalence of positive TST's of 4.6 percent found in the first phase is within the range of the estimated 5-10 percent of TB infection in the U.S. However, this population infection rate may also include false-positives derived from TST, and as a normative value is based on unpublished CDC data.

3. Based on the CDC guidelines for TB prevention, a risk assessment should be carried out, either in an individual dental setting or in a specific geographical area. One of the elements may be to assess TST conversion rates in dental HCW's. The findings of this study can then be used for comparison to decide on appropriate protocol procedures.

4. For similar studies on dental HCW's in a specific geographical area, the results can be used to do a power analysis, using the conversion rates in this study as the expected TST value over twelve months.

For all participants, the study has not only been an opportunity for them to establish their current TB status but has also been a useful educational tool to increase awareness among dentists and their staff and has motivated them to be tested for infection in the future.

J. SUGGESTED CHANGES IF PROJECT WERE REPEATED

Overall the study progressed in an acceptable manner. Three further questions could have been added to the questionnaire:

(a)Were patients asked about their current TB status as part of their medical history.

(b)Were subjects knowingly HIV positive or had any other illness that caused suppression of the immune system.

(b) Were they taking any medication that caused immunosuppression.

The last question on specific infection control measures for TB cause a lot of confusion, especially among dental assistants. It was noted after the first phase of the study that most of them had given positive answers to the questions and dentists had given negative responses. During the second phase of the study, the problem was identified as an unfamiliarity with recommended TB infection control measures. This question should have been made clearer.

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Table I

Characteristics of Study Population

	Dentist	Dental Assistant	Dental Hygienist	Total
	n=60 (21%)	*n*=195 (69%)	*n*=29 (10%)	*n*=284
Age Distribution Mean (S.D.)	43 (±9)	30 (±9)	35 (±10)	33 (±10)
No. Yrs in Practice Mean (S.D.)	15 (±9)	7 (±7)	11 (±8)	9 (±8)
Gender [*n* (%)] Male Female	 57 (95%) 3 (5%)	 15 (8%) 180 (92%)	 1 (3%) 28 (97%)	 73 (26%) 211 (74%)
Race/Ethnicity [*n* (%)] White Hispanic	 35 (58%) 25 (42%)	 20 (10%) 175 (90%)	 14 (48%) 15 (52%)	 69 (24%) 215 (76%)

Table II

Percent Distribution of Type of Practice

Public Clinic	2.1%
General Dentistry	77.1%
Orthodontics	7.4%
Pediatric Dentistry	5.3%
Oral Surgery	4.9%
Periodontics	2.8%
Prosthodontics	.4%

Table III

Percent Distribution of Practice Location

Cameron County	31%
Hidalgo County	65%
Starr County	4%

Table IV

Association Between Positive Tuberculin Skin Test (TST) and Birth in the U.S. - Phase I

	U.S. Born	
	Yes	**No**
Positive TST	7 (54%)	6 (46%)
Negative TST	250 (93%)	21 (7%)

$p<.001$

Table V

Percentage of TST Reactors with Exposure to Risk Factors Associated with Transmission of TB

	% with positive TST in first year (n=13)			% with TST conversion 1-12 mos. (n=4)			
	Yes	No	Don't Know	Yes	No	Don't Know	p value
Worked in residential facility	8	92		25	75		N/S
Ultrasonic scaler use - Aerosolized procedure	69	31		25	50	25	N/S
Treatment of HIV patients	23	31	46		50	50	N/S
U.S. born	54	46		100			N/S
Person in household had cough > 6 wks.		92	8		100		N/S

N/S indicates not significant

Table VI

Percentage of TST Reactors with Previous TST and BCG Vaccine

	% with positive TST in first year (n=13)			% with TST conversion 1-12 mos. (n=4)		
	Yes	No	Don't Know	Yes	No	Don't Know
TST in previous 2 years	38	54	8	25	75	
BCG Vaccine		100			75	25

APPENDICES

Appendix I

Dear Doctor,

You and your staff have been invited to take part in a prospective study of tuberculosis (TB) in dental health care workers. We want to learn what the prevalence and incidence of TB is in dental health care workers over a one year period. You have been invited because we are asking all the practicing **dentists, dental assistants and dental hygienists** in the Counties of Cameron, Hidalgo and Starr.

If you wish to participate, you will receive a phone call from Ms.Connie Lyles to schedule an appointment for you and your staff at your convenience. A TB skin test will be administered on the inside of the left arm. You will also be asked to complete a simple questionnaire to give us information on demographics and infection control. Within forty eight to seventy two hours, the reaction at the test site will be read by measuring with a ruler and the result will be recorded. Any redness or swelling less than 10 mm. in diameter will be considered a negative reaction. Should you test positive, you will be referred to the TB services at the Texas Department of Health, or a physician of your choice, for further TB tests. A positive reaction does not necessarily mean that you have active TB. You will be responsible for all physician charges. The time needed for the study will be 15 minutes to administer the test and complete the questionnaire and 5 minutes to read the result. If your reaction to the skin test is negative, you will be retested one year later.

No discomfort is expected from the test. If you are injured as a result of the research procedures, medical care will be provided. You will be responsible for all charges. We are not able to give you money if you are injured.

Everything we learn about you in the study will be kept confidential. Any information we publish or distribute about this study will be as a group and you or your staff will not be identified in any way.

You can benefit from participating by knowing your current TB status and also by allowing us to provide data that will be of benefit to other dental health care providers.

The study is being conducted by Dr. Nuala Porteous, who will be happy to answer any questions you may have about this study. Dr. Porteous can be reached at (210)567-3210 or (512)328-2408 after hours. The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as research subject.

Thank you in anticipation for your cooperation.

Sincerely,

Nuala B. Porteous, BDS, MPH
Resident in Community Dentistry

Appendix 2

PROCEDURES MANUAL

for

A PROSPECTIVE STUDY OF THE TUBERCULIN SKIN TEST CONVERSION RATES IN DENTAL HEALTH CARE WORKERS

Principal Investigator: Dr. Nuala Porteous

Co-Investigators: Dr. Sena Narendran
Dr. John Brown

Research Assistant: Mrs. Connie Lyles R.N.

Introduction

You have been hired as a research assistant (RA) for **A Prospective Study of the Tuberculin Conversion Rates in Dental Health Care Workers.** The project staff welcomes you to the research team of this important study and hopes that you find your responsibilities challenging, interesting and enjoyable. The project team is relying on your most sincere effort in collecting data.

Background and Purpose of the Study

The purpose of the study is to assess the tuberculin skin test conversion rates in dentists, dental assistants and dental hygienists over a twelve month period. There appears to be a lack of documentation about the transmission of tuberculosis (TB) among dental health care providers. We will be recruiting dentists, dental assistants and dental hygienists in the counties of Cameron, Hidalgo and Starr.

Recruitment and Consent Procedures

A letter, providing information and requesting participation in the study, will be mailed from the University of Texas Health Science Center at San Antonio (UTHSCSA) to each dentist registered and practicing in Cameron, Hidalgo and Starr counties. Each dentist will be told to expect a follow-up phone call from the RA.

The RA will be responsible for calling dentists to:

(1) confirm receipt of letter from the principal investigator (PI)

(2) answer any questions or concerns about TB skin testing

(3) establish how many dentists, dental assistants and dental hygienists work at each practice and whether each one works full or part-time

(4) assess the number of dentists, dental assistants or dental hygienists who work part-time in any other dental practice or public health clinic in Cameron, Hidalgo and Starr counties

(5) schedule appointments to administer and read TB skin tests

The RA will document the information after each phone call in the Participants Log provided. When the RA arrives at the dental office, she will first ask each participant to read and sign a consent form and and complete a self-administered questionnaire. An I.D. number, assigned to each subject will be written on the questionnaire. This code number will be used for data entry into the computer by the PI.

TB skin testing will be carried out according to the Centers for Disease Control (CDC) guidelines. Forty eight to seventy two hours after administration of the test, the reaction will be read. A TB surveillance card supplied by the Texas Department of Health, an associate work sheet for patient referral and the Data Collector's Log will be filled in.

Assignment of I.D. numbers

Each practice will be assigned a numerical I.D. in the order that they are contacted by the RA (1 through 142).

Each dental health care worker from each practice will be assigned a numerical I.D., in the order that TB skin testing is done (1,2,3,4,etc.).

The I.D. for each worker is distinct or seperate from the I.D. assigned to the practice. For example, if there are four dental health care workers in practice no.1, they would have four distinct I.D.'s (11,12,13,14).

Similarly, if there were three workers in practice no. 142, their I.D.'s would be (1421,1422,1423)

Example: 11, 12, 13 14 1=Practice I.D. 1, 2, 3, 4 = Personnel I.D.

1421,1422,1423, 142=Practice I.D. 1,2,3, = Personnel I.D..

Completed Case

At the end of every working week, the RA will be required to mail the following documents to the PI:

(1) a completed Practice Log for each working day (Use construction sheets as necessary.)

(2) a completed TB surveillance card with no name and I.D.# only for each participant

(3) a completed Data Collector's Log for each working day (Use construcion sheets as necessary.)

(4) one signed consent form for every participant

(5) one completed questionnaire for each subject

For a case to be considered complete, all five forms must be received by the PI. The RA will be required to keep photocopies of all mailed documents for her records.

Anonymity and Confidentiality

Maintaining the confidentiality of the data and the anonymity of the respondents are an important part of the research process. The identity of survey respondents remains anonymous and the information respondents provide is confidential. All information regarding respondents must not be divulged to anyone other than authorized study representatives. Completed or unused survey instruments are not to be given to anyone other than authorized project staff and duplication of materials is strictly prohibited. This study follows standard procedures designed to comply with all applicable regulations and ethical considerations. Two major policies that are regularly implemented for data collection efforts are described:

Project staff members are

1. Routinely appraised of legislation and guidelines concerning protection of human subjects and their right to privacy.

2. The University of Texas Health Science Center at San Antonio Institutional Review Board ensures that all of surveys of human populations comply with applicable regulations concerning informed consent, confidentiality, and protection of privacy.

To be certain that you understand and agree to the anonymity and confidentiality requirements of the study, you will be asked to review and sign a Data Collection Agreement during the training session .

Quality Control Procedures

As part of our quality control procedures, the RA will be calibrated for TB skin testing, according to CDC guidelines at the Texas Department of Health at Harlingen. Calibration will consist of three phases:

The first phase will take place before any TB skin testing is administered on study participants.

The second phase will take place three weeks after the study has begun.

The third phase will take place seven weeks after the study has begun

The RA is responsible for scheduling appointments for calibration at her convenience.

Materials and Supplies Checklist

Operating manual for RA

Monthly calendar for May, June and July for scheduling appointments

Data Collection Agreement to be signed by the RA and returned to the PI before study begins.

Consent form to be signed by each study participant

Questionnaire to be signed by each study participant

Practice Log to be completed by RA after initial phone call to dental offices. One log must be started each working day.

Data Collector's Log to be completed by RA each working day.

Mileage Log to be completed by RA each working day.

Needles and syringes
Purified Protein Derivative(PPU)
Cotton swabs
TB surveillance cards
Associate work sheets for patient referral, in the case of a positive reactor, and any other necessary supplies may be got from the Texas Department of Health at Harlingen.

Appendix 3

SUBJECT CONSENT TO TAKE PART IN A PROSPECTIVE STUDY OF THE OF TUBERCULIN SKIN TEST CONVERSION RATES IN DENTAL HEALTH CARE WORKERS

The University of Texas Health Science Center at San Antonio
Department of Community Dentistry

We are asking you to take part in a research study of tuberculosis (TB) in dental health care providers. We want to learn what the incidence of TB in dental providers is over a one year period. We are asking you to take part in this study because we are including all dental providers, in both public and private sectors, in the counties of Cameron , Hidalgo and Starr.

The study will consist of two phases. If you decide to take part, a TB test will be conducted. A TB skin test will be administered on the inside of the left arm. You will also be asked to complete a simple questionnaire to give us some general information, and some infection control information. Within forty eight to seventy two hours, a reading will be taken of the reaction at the test site. Any redness or swelling less than 10mm. in diameter will be considered a negative reaction. A positive reaction (>10mm), will be measured with a ruler and should you react positively to the test, you will be referred to a physician for further tests. You will be responsible for physician charges. The time needed for the study will be 15 minutes to administer the test and complete the questionnaire and 5 minutes to read the result. If your reaction is negative, you will be retested one year later,

No discomfort is expected from the test. You can benefit from participating by knowing your current TB status and also by allowing us to provide data that will be of benefit to other dental health care providers and health care workers.

If you are injured as a result of the research procedures, medical care will be provided. You will be responsible for all charges. We are not able to give you money if you are injured.

Everything we learn about you in the study will be confidential. If we publish the results if the study in a scientific journal or book, we will not identify you in any way.

Your decision to take part in the study is voluntary. You are free to choose not to take part in the study or to stop taking part at any time. If you choose not to take part or to stop at any time, it will not affect your future medical or dental care at the University of Texas Health Science Center at San Antonio.

If you have any questions now, feel free to ask us. If you have additional questions later or you wish to report a medical problem which may be related to this study, Dr. Porteous can be reached at (210) 567-3210 or (512) 328-2408 after office hours. The University of Texas Health Science Center committee that reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject (210) 567-2351.

We will give you a signed copy of this form to keep.

YOUR SIGNATURE INDICATES THAT YOU HAVE DECIDED TO TAKE PART IN THIS RESEARCH STUDY AND THAT YOU HAVE READ AND UNDERSTAND THE INFORMATION GIVEN ABOVE AND EXPLAINED TO YOU.

_____ _____

Signature of Subject Signature of Investigator

_____ _____

Signature of Witness Date

Appendix 4

The University of Texas Health Science Center at San Antonio

A PROSPECTIVE STUDY OF THE TUBERCULIN SKIN TEST CONVERSION RATES IN DENTAL HEALTH CARE WORKERS

I.D.#_____

1. Occupation : Dentist ___ Dental Assistant _____ Dental Hygienist _____

2. Age : _____years

3. How many years have you been in practice? _____years

4. Gender : Male ____ Female _____

5. Race/Ethnicity : White _____ Black _____ Hispanic _____

Native American _____ Other _____

6. Were you born in the United States Yes_____ No_____

7. Type of Dental Practice : Private Office ____ Public Clinic _____

8. If Private Office : General _____

or is your practice limited to : Endodontics _____ Orthodontics _____

Pediatric Dentistry _____

Prosthodontics_____

Periodontics _____ Oral Surgery _____

Other _____

9. County of practice : Cameron ____ Hidalgo _____ Starr _____

10. Have you ever worked in a residential facility such as :

Hospital_____ Jail_____

Other long term facility (Please Specify) _____

11. How many hours/\week do you work in direct patient contact?_____

12. Do you use or assist in the use of a cavitron (ultrasonic scaler) ?

Yes _____ No ___

13. If Yes, how many times a week do you use it, on average? _____times/week

14. What is the average length of each use? _____

15. Have you had a tuberculosis (TB) skin test in the past two years?

Yes _____ No ____ Don't know____ Don't remember____

16. If Yes, was the test

Positive _____ Negative _____ Don't know_____ Don't remember_____

17. Have you ever had a B.C.G. vaccine?

Yes _____ No _____ Don't know _____

18. Has anyone in your household had a cough lasting longer than six weeks?

Yes_____ No_____ Don't know____

19. Do you treat persons who are infected with Human Immunodeficiency Virus (HIV) at your office?

Yes ____ No _____ Don't know ____

20. If Yes, how often do you treat these patients?

_____/week _____/month

21. What percentage of the time do you use the following infection control measures in your office?

Surgical Masks	0%____	1-50%_____	51-99%_____	100%____
Gloves	0%_____	1-50%_____	51-99%_____	100%____
Particulate Respirator	0% ___	1-50% ___	51-99% ___	100% ____
Dust-Mist (DM) Respiator	0%____	1-50%____	51-99% _____	100%_____
Dust-Fume-Mist (DFM) Respirator	0%____	1-50%____	51-99%____	100%____
HEPA Respirator	0%____	1-50%_____	51-99%_____	100%____
Rubber dam	0% ___	1-50% ___	51-99% ___	100% ____
Ultraviolet lights	0%___	1-50% ___	51-99% ___	100% ____

APPENDIX 5

April 20,1995

Dear Doctor,

In May 1994, you and your staff participated in the first phase of a prospective study of tuberculosis (TB) in dental health care providers. The results showed that thirteen of the participants (4.6%) had positive reactions to the TB skin test. This did not mean that they had active TB. It did indicate that they had an unknown previous exposure to the tubercle bacillus. These were all referred for further testing.

The second phase of the study will begin in May 1995. All participants who had a negative reaction in phase one will again have a TB skin test administered and read forty eight to seventy two hours later.. Any positive reactors in this phase will help identify an occupational exposure among dental health care providers.

The study is being conducted by Dr. Nuala Porteous, who will be happy to answer any questions you may have about this study. Dr. Porteous can be reached at (210) 567-3200 or at (512) 328-2408 after hours. The University of Texas Health Science Center committee thay reviews research on human subjects (Institutional Review Board) will answer any questions about your rights as a research subject.

You will receive a phone call from Ms. Connie Lyles, R.N. to schedule an appointment for you and your staff at your convenience.

We appreciate your continued cooperation in this study.

Sincerely,

Nuala B. Porteous, DDS, MPH
Resident in Community Dentistry

ACKNOWLEDGMENTS

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