CALIFORNIA
DEPARTMENT OF HEALTH SERVICES
OCCUPATIONAL HEALTH BRANCH

TUBERCULOSIS IN HEALTH CARE WORKERS

FINAL PROJECT REPORT
MAY 7, 1999

ROBERT HARRISON, MD, MPH
PRINCIPAL INVESTIGATOR

PROJECT STAFF

PATRICE SUTTON, MPH
LAURA STYLES, MPH
MARGARET MOSSMAN, RN, BSN
ARLENE ERVIN-KING
FLORENCE REINISCH, MPH
MARK NICAS, PHD, CIH, MPH
MARCOS ATHANASOULIS, MPH
CHRISTINE KANE

This Project was supported by a Cooperative Agreement
(#U50/CCU910074) with the
National Institute for Occupational Safety and Health

1515 CLAY STREET, OAKLAND, CA 94612
PHONE (510) 622-4300 FAX (510) 622-4392

ACKNOWLEDGEMENTS

This project was supported by a Cooperative Agreement (#U50/CCU910074) between the National Institute for Occupational Safety and Health (NIOSH) and the California Department of Health Services in collaboration with the Public Health Institute. We wish to thank Teri Palermo, RN and John E. Parker, MD of the Division of Respiratory Disease Studies at NIOSH for their consistent and helpful support of this research.

This study would not have been possible without the generous support and on-going cooperation of the individuals listed below. Their knowledge and commitment to the prevention of hospital-acquired tuberculosis were essential to the successful completion of this study.

San Francisco General Hospital	Alta Bates Medical Center	Highland Hospital
William Charney	Trisha Barrett	Marzi Vatan
Katheleen Turner-Hubbard	Rosalyn Ferman	Kathi Ruel
H.F. Chambers	John Swartzberg	Joni Thomas
Julie Gerberding		Robert Deutch
Rosemary Burke		Steven Lowrey
Lynda Sissons		Robert McCabe
Sarah Jewell		

Over the five years of this study, many other health care workers at the participating hospitals also lent substantial time and talents to this effort. We are very grateful for their assistance and for the invaluable information they shared about their workplace. We hope that the results and recommendations of this study will help them in their efforts to prevent tuberculosis among health care workers and patients.

San Francisco General Hospital

Houmpheng Banouvong (TB Clinic), Pat Berg, Max Bunuan, Jackie Cesar, Mary N. Clancy, Madeline Daley, Doreen Dare, Diane Davies, Ann Dichov, Anita Enriquez, Susan Gearhart, W.K. Hadley, Linda Henson, Mallory Hondorp, Philip Hopewell, Victoria Kellman, Paul Koo, Diane Lui, Katherine Mah, Eric Miller, Bob Montati, Erna Nethercott, Antonio Paz, Jolie Pearl, Hubert Pena, Nayda Romero, Margaret Rykowski, Cornelius Scannell, Gisela Schecter, Rita Smith, Riley Surber, Alvin Sykes, Bob Sypher, Ada Tarkington and Phil Weatherbee.

Alta Bates Medical Center

Debbie Aguilar, Judy Brady, Darby Brandli, Lynda Burrell, Arlene Fleck, Tim Fronek, Cindy Girtz, Alex Hardy, Del Kraft, Roman Kownacki, Mike Leone, Denise Navellier, Joseph Reiger, Kyle Smith, Mark Stanley, Janice Stewart, Katie Tobin, Yvette Webster, and Mark Wood.

Highland Hospital

Erma Albert, Sophia Brown, Barbara Burke, Lenward Cage, Subodh Chowdhry, Jules Garibaldi, Jennie Glover, Lillian Goldston, Ruby Grayson, Levon Hanspard, Leah Henry, Ed Hill, Henrietta Knighten, Tecora McCoy, Nancy McDonnel, Wendy Michelson, James Mittelberger, Edward Portoni, Bob Read, Sheryl Ruben, Charles Sanders, Pat Scott, Rochelle Somers, Norma Stephenson, Kirk Thompson, Carolyn Vallerga, Paulette Walls, Maureen Zekman.

We also want to thank Jim Cone, Joan Sprinson, and Janet Macher of the California Department of Health Services and Ana Maria Osorio (currently with the US EPA), who served as scientific advisors to this effort.

TABLE OF CONTENTS

EXECUTIVE SUMMARY

Background:

In 1993, the California Department of Health Services (CDHS) Occupational Health Branch, in collaboration with the Public Health Institute (formerly the California Public Health Foundation) and the University of California, San Francisco Division of Occupational Medicine, undertook a Cooperative Agreement with the National Institute for Occupational Safety and Health (NIOSH) to develop a model program for the prevention of occupational tuberculosis (TB) in health-care facilities. While there was general agreement among experts that early identification and treatment of patients at risk for infectious TB are the cornerstones of preventing nosocomial TB transmission, there was considerably more debate regarding the relative effectiveness of engineering controls and personal protective equipment in reducing the risk of occupationally acquired TB. An increased understanding of the extent of TB transmission and the efficacy of TB control measures in hospitals was needed to aid in the development of programs capable of preventing TB among health care workers.

The overall goal of the TB in Health Care Workers study was to prevent occupational TB by identifying effective TB control measures for use in a health care setting. Three San Francisco Bay-Area hospitals participated in the five-year study: San Francisco General Hospital, Alta Bates Medical Center, and Highland Hospital. The study had two primary objectives: (1) to assess adherence by health care institutions to TB control measures specified by the Centers for Disease Control and Prevention (CDC) Guidelines;* and (2) to estimate the effectiveness of these control measures through the use of TB skin testing (TST) data and calculation of TB infection rates.

Study accomplishments:

- ### Assessment of CDC Guidelines

  CDHS designed and conducted a comprehensive assessment of adherence to CDC Guidelines at each hospital; designed and implemented prospective quality assurance studies to evaluate adherence to CDC Guidelines for employee TST

---

* Centers for Disease Control and Prevention. Guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health-care facilities. MMWR 1994; 43(No. RR-13).

surveillance and TB patient isolation at each hospital; and developed and implemented a retrospective study to assess adherence to TB patient isolation guidelines at two hospitals.

- **Surveillance of employee tuberculosis infection**

  CDHS selected, implemented, and maintained a computerized employee TB surveillance system at each hospital; compiled and reported employee TST compliance and conversion rates from 1995 to 1997 using uniform data collection and interpretation methods; and designed and implemented a multi-year, epidemiologic study to assess the relationship between risk factors for exposure to *Mycobacterium tuberculosis* (*Mtb*) aerosol and health care worker TST conversion.

- **Dissemination of findings and recommendations to prevent TB among health care workers**

  CDHS disseminated study findings and recommendations through (*i*) 14 comprehensive reports to participating hospitals and their staff; (*ii*) more than 30 presentations to workers, health care providers and public health professionals, (*iii*) four comprehensive state-wide trainings on TB exposure assessment and control for Cal-OSHA compliance officers and for the California Department of Corrections health care worker staff; (*iv*) participation in public hearings and the submission of written comments related to the proposed federal OSHA TB Standard; and (*v*) publication of study findings and recommendations in the peer-reviewed literature.

Key findings and recommendations:

⇒ **Fully implement CDC Guidelines if all health care workers are to be protected**

There was a significant risk of newly acquired TB infection among health care workers at all hospitals. CDHS found that on average, one in every four initially non-infected health care workers (26%) at participating hospitals would become infected with TB over the course of their working lifetime (45 years).† Annual newly-acquired TB infection rates during the three-year surveillance period from

---

† The three-year average TST conversion rate over all three participating hospitals was 0.66% (76/11,519). A standard probability calculation shows that a 0.66% annual TB infection risk acting over a 45-year working lifetime produces a 26% cumulative infection risk, or: $1-(1-0.0066)^{45}=0.26$.

1995 to 1997 were 0% to 1.05%, which corresponds to a zero to 38% cumulative infection risk over a working lifetime. All workers physically located at the hospital were at risk of exposure. None of the hospitals completely adhered to CDC's recommended exposure control measures. A lapse in one control measure led to potential *Mtb* aerosol exposures even when another control measure was present, because different controls were geared towards protecting different groups of health care workers. Avoidable health care worker exposures should be prevented. A comprehensive, multi-pronged approach, such as specified in CDC Guidelines, should be fully implemented if all health care workers are to be protected.

⇒ TB skin test, at least annually, all workers physically located at a building where health care services are provided

The retrospective tracking of the room location of every TB inpatient (N=54) at one hospital over a one-year period found that all workers physically located at the hospital were at risk of exposure. Workers on wards that cared for large numbers of TB patients were subject to uncontrolled sources of *Mtb* aerosol exposure, even if there was good adherence to patient isolation guidelines on the ward. Workers located on wards having no isolation rooms had considerable potential for exposure. In other words, the absence of TB isolation rooms on a ward cannot be equated with the absence of exposure. The findings indicate significant cumulative risk of exposure for individuals who work on a variety of inpatient wards even if the time spent on any one ward is limited.

⇒ Implement quality assurance protocols

There were discrepancies between written TB control policies and actual hospital practices. Health care workers, including those who have no direct patient contact, can incur unrecognized exposures to *Mtb* aerosol during routine hospital operations. Factors contributing to unrecognized exposures were: (1) imperfect containment of *Mtb* aerosol in isolation rooms due to lack of negative pressure. Overall, 11% of 154 patient-room units mechanically capable of providing negative-pressure at one point in time were not under negative-pressure at the time of use for TB patient isolation; (2) failure to ensure the performance of retrofitted or newly designed engineering controls before use; (3) failure to validate the basic assumptions of the TB control plan, such as the risk assessment; and (4) improper use of respirators by health care workers. Prospectively quantifying the implementation of a hospital TB isolation policy while the room is in use may lead to improved estimates of risk and may help identify and thereby prevent avoidable worker exposures to *Mtb* aerosol.

⇒ Improve TST practices and protocols

At two facilities, the validity and reliability of hospital generated TST surveillance data was initially poor. Quality assurance data indicated notable problems with PPD storage and handling procedures, record keeping, TST interpretation and reading, incomplete clinical documentation and results not recorded in mm of induration. At one hospital, data for TST was missing for 25% of the active employees identified through payroll files. A review of a sub-sample of those individuals without TST data found that missing charts, poorly documented or missing TST history in charts, and data entry oversight accounted for the missing data. The risk of TST conversion may have been underestimated due to: (1) the exclusion of potential converters due to missing TST documentation and, (2) increased likelihood of negative TST results due to poor test administration and interpretation practices. A standardized protocol for TST should be developed and implemented to ensure correct and consistent application, interpretation, and documentation of TSTs.

⇒ Increase resources, accountability and authority of staff responsible for TST program implementation

One participating hospital, Alta Bates Medical Center, successfully implemented the CDC guidelines for Employee TST Surveillance. Factors which contributed to the high quality of this TST program were: accountable central administration, accountable program implementation by department managers, responsive Information Systems linkage for payroll datafiles, collaboration between Employee Health and Infection Control staff, and routine surveillance data reporting and review. Obstacles to reliable TST surveillance at the other hospitals included: a lack of resources and staff to implement the program, a lack of administrative authority, a failure to fully utilize the TST surveillance software, and a lack of mechanisms to facilitate exchange of payroll or TST data between the hospital and its affiliated university.

⇒ Utilize a computerized database to maintain employee TST data

Employee Health Programs that did not fully utilize computerized systems for employee census and tracking had lower TST compliance than hospitals that did. High quality programs require adequate computer hardware and software, trained clinical staff, and reliable data entry/administrative staff.

⇒ **Improve TST compliance by linking Employee Health with payroll data systems**

At two hospitals, only about one third to one half of eligible employees received a TB skin test each year (32% to 55%). Compliance with TST was reduced by the difficulty in identifying the work location all TST-eligible persons from available payroll data. Payroll distribution systems could be utilized to notify non-compliant employees whose work location is unknown. Increased linkage and cooperation between Payroll and Information Services and Employee Health may enhance the administration of TST surveillance programs.

⇒ **Absent clear evidence to the contrary, presume that newly-acquired health care worker *Mtb* infections are work-related**

CDHS noted that there was a tendency among hospitals to characterize TST conversions incurred by workers which could not be "explained" by a known TB patient contact, or by a job title or work location recognized as being associated with TB patient exposure, as non-work related. However, CDHS found that health care workers, including those who have no direct patient contact, can incur unrecognized exposures to *Mtb* aerosol during routine hospital operations. Even following accurate identification of TB patients, health care workers at all three hospitals were potentially exposed to *Mtb* aerosol due to breaches in negative pressure isolation, the limitations of dilution ventilation, the failure to maintain engineering controls, and incomplete implementation of respiratory protection controls. Non-occupational risk factors should be assessed for all newly-infected health care workers. However, in the absence of clear evidence that a TST conversion is non-occupational, CDHS study findings lend support to OSHA's policy presumption that, in the absence of clear evidence to the contrary, hospital employee health staff should assume that newly-acquired health care worker TB infections are work-related.

⇒ **Ensure an adequate number of negative-pressure isolation rooms and evaluate the need for isolation rooms at all specialized-medical care locations**

Factors which contributed to uncontrolled sources of *Mtb* aerosol exposure at one hospital were an inadequate number of isolation rooms, a lack of isolation rooms in specialized care areas, and unrecognized TB. Seasonal peaks, not yearly averages of the number of suspect and known TB patients at the hospital, should be considered when anticipating the total number of isolation rooms needed.

⇒ Maintain engineering controls

Numerous, persistent failures in engineering controls were identified in all hospitals. None of the hospitals regularly checked the performance of engineering controls. Regularly scheduled monitoring and maintenance of engineering controls are essential to TB control efforts.

⇒ Routinely verify the reliability of continuous monitoring devices with other qualitative or quantitative measures of negative pressure

Continuous monitoring devices did not accurately reflect the direction of air flow in 12% of 67 patient-room units equipped with these warning systems. The installation of continuous monitoring devices does not obviate the need for initial testing and routine maintenance of ventilation systems. Moreover, although the efficacy of continuous monitoring devices is predicated on the alarm initiating a coordinated and timely response by engineering, infection control, nursing and medical staff, no written procedures or training regarding how to respond to the alarming or malfunctioning of these devices were provided to hospital staff. Policy and procedures for responding to the negative-pressure alarm system should be written, and training should be provided to affected-staff so the policy can be reliably implemented.

⇒ Implement a comprehensive respiratory protection program for TB that emphasizes the importance of a well-fitted respirator

Routine use of NIOSH-approved, N95 disposable respirators for TB was initiated at two hospitals during the course of the study. Only one of these hospitals required that a health care worker's respirator fit properly. The third hospital used disposable dust/mist masks, and the hospital did not provide comprehensive training and fit-testing as required by federal and state regulation. At all three hospitals, although some type of respiratory protection for TB was widely available and used by health care workers, almost two of every three health care workers observed wearing a respirator (40/62) did not don their respirator properly when entering a TB isolation room. Respirators that do not fit or are worn improperly will allow *Mtb* aerosol to leak into the face piece regardless of the filter medium's ability to remove 1 μm particles.

⇒ Routinely use a higher-level of respiratory protection such as a powered-air purifying particulate respirator during autopsy

CDC Guidelines regarding the use of respiratory protection to control exposure to *Mtb* aerosol during autopsy should be more protective. In the case of autopsy and other high-risk procedures, CDC recommends that a higher-level of respiratory protection be implemented only after *Mtb* disease is suspected. However, the routine use of a high level of respiratory protection such as a powered air-purifying particulate respirator (PAPR) is advisable during autopsy because: (i) estimates of the percentage of cases of TB identified at autopsy that have not been diagnosed at the time of death range from 16% to 50%; (ii) a high concentration of *Mtb* aerosol can be generated at autopsy; and (iii) a high risk of infectious disease transmission is associated with autopsy.

⇒ Include health care workers in TB decision-making

Although workers in "hands on" jobs are often in the best position to observe developing or threatening occupational health problems, labor representatives did not participate in hospital committees with responsibility for TB control. Inclusion of labor representatives on these committees may lead to innovative approaches to exposure control, improve compliance with TB policies and procedures, and may diminish unwarranted employee concerns regarding TB transmission in low-risk situations.

⇒ Improve health care worker training on TB

Health care worker training was an underutilized TB prevention measure. In addition, 78% to 80% of the workers with a TST during the first year of the study reported patient contact and 33% to 42% reported being present during procedures with increased risk of exposure to *Mtb* aerosol. These data indicate that most employees need to have knowledge and training about TB. All employees should receive appropriate training on TB disease, transmission, and exposure control methods.

⇒ Provide comprehensive employee counseling regarding risk

Comprehensive employee counseling regarding the risk of active TB disease in immunocompromised health care workers was not routinely provided. As many workers may be reluctant to report or acknowledge their immune status, and immune status might change after hire, comprehensive counseling regarding risks for immunocompromised individuals should be provided to all health care workers.

⇒ Isolate all TB patients in negative-pressure rooms until it has been demonstrated that they are not infectious

In 1996, half of the 54 inpatients who were identified at one hospital as having pulmonary TB were fully isolated and half were not. Most of the 652 TB patient-days were likely contributed by infectious patients. Thirty percent (197/652) of all TB patient-days were unisolated. Isolating all suspect TB patients until they are demonstrated to be non-infectious requires that there be a supply of isolation rooms commensurate with the number of suspect TB patients, and isolation rooms in all specialized care areas.

⇒ Reduce potential exposure to TB through administrative controls such as restricting access to isolation

Of the tested populations during the first year of the study, 78% to 80% reported some level of patient contact and 33% to 42% reported being present during procedures with increased risk of *Mtb* aerosol exposure. The possibility of reducing potential exposure to *Mtb* aerosol through administrative controls (i.e., limiting the number of persons who enter inpatient isolation rooms and who are present during high risk procedures), should be evaluated.

⇒ Emphasize source control

Increased TB incidence in the general community may directly increase the number of infectious TB patients receiving care at a hospital, and thereby increase the risk of hospital-acquired TB. Primary prevention of health care worker exposure to *Mtb* aerosol at hospitals is contingent upon the success of TB prevention measures undertaken by local public health jurisdictions. Full implementation of the CDC Guidelines should be complimented by active support by hospital administrators for the expansion of TB prevention efforts undertaken by local public health agencies, such as directly observed therapy, improved access to medical care, and the provision of housing for homeless TB patients.

NARRATIVE

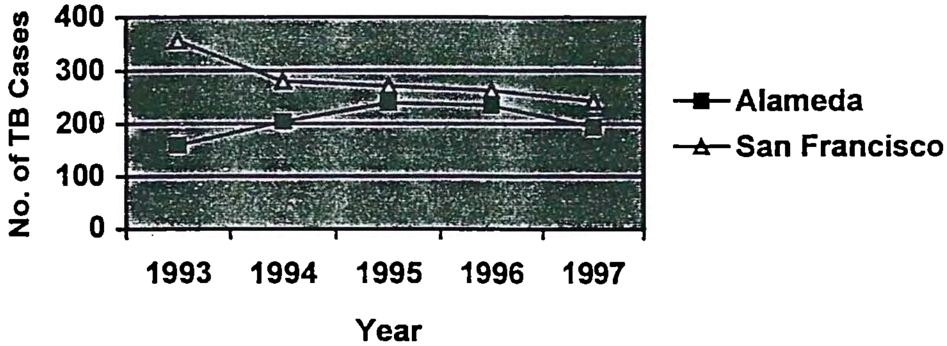
Key objectives which have been accomplished in the Health Care Workers study are summarized below according to the steps outlined in the original proposal.

ORIGINAL PROGRAM OBJECTIVE 1: IDENTIFY, SELECT AND RECRUIT SELECTED HEALTH-CARE FACILITIES

In the first year of the Health Care Worker study, four hospitals were selected for participation from counties in California with large numbers and high case rates of active TB. Study activities were initiated in three of the four hospitals: San Francisco General Hospital (SFGH), Alta Bates Medical Center (ABMC) and Highland Hospital. Upon evaluation of the significant time and effort required to implement the study at each hospital, it was deemed infeasible to include a fourth hospital (Santa Clara Valley Medical Center) in the study as originally planned.

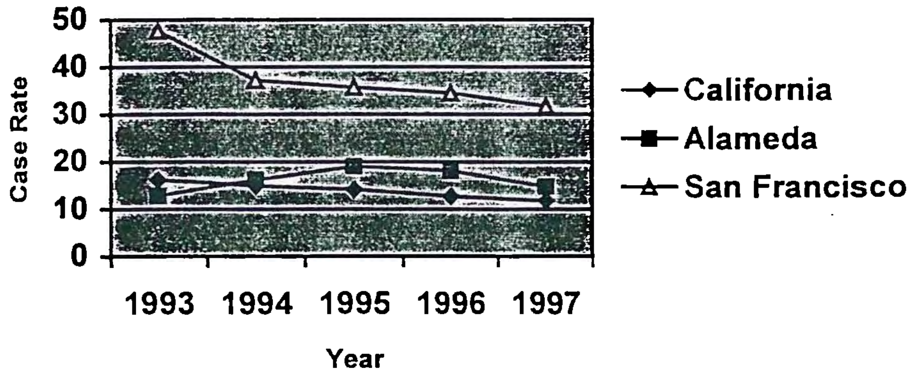
The incidence of TB in counties where participating institutions are located is shown in Figures 1 and 2. San Francisco General Hospital and Highland Hospital are county hospitals located in San Francisco and Alameda Counties, respectively. Alta Bates is a private community hospital also located in Alameda County. Since the inception of the Health Care Worker study in 1993, San Francisco and Alameda Counties have ranked in the top six among California's TB reporting jurisdictions for the number of TB cases, together accounting for approximately 10% of all TB cases reported in California in each of these years. Whereas San Francisco County experienced a decline of 32% in the number of TB cases reported from 1993 to 1997 (from 356 in 1993 to 242 cases in 1997), during this time period the number of TB cases increased by 21% in Alameda County (from 159 to 193 cases) (Figure 1).

Figure 1. TB Case Counts by County



TB case rates between 1993 and 1997 reflect a similar trend, with a decline in San Francisco County (from 47.6/100,000 to 31.7/100,000), and an increase in Alameda County (from 12.8/100,000 to 14.8/100,000). The 1993 Alameda County case rate was 20% lower than California's overall rate of 16.2/100,000; by 1997 the rate of TB in Alameda County had surpassed the statewide rate of 11.8/100,000 by 25% (Figure 2).

Figure 2. TB Case Rates per 100,000 Population



Characteristics of participating hospitals are shown in Table 1.

Table 1
Characteristics of participating hospitals - 1995 to 1997

Hospital/ County	# Employees 1995 1996 1997	# Cases TB[a] 1995 1996 1997	# TB Isolation Rooms 1995b 1996b 1997
Highland/ Alameda	1,917 1,845 1,795	56 48 29	13 14 10[d]
Alta Bates/ Alameda	2,950 3,355 3,029	28 28 13	14 14 n/a[c]
San Francisco General/ San Francisco	4,879 5,030 4,799	57 59 n/a[c]	18 39 n/a[c]

[a] number of active cases of pulmonary tuberculosis
[b] includes rooms in inpatient, outpatient (ER) and procedure and treatment areas
[c] data not available
[d] includes only inpatient wards

ORIGINAL PROGRAM OBJECTIVE 2:
ESTABLISH SURVEILLANCE REPORTING GUIDELINES AND A CASE DEFINITION FOR OCCUPATIONAL TB TRANSMISSION

Case definition for TST conversion

For purposes of the multi-hospital study and consistent with the CDC definition of a conversion, the study definition of a tuberculin skin test (TST) converter was a documented change in TST result from a negative PPD [purified-protein derivative] test to a positive test (1994 CDC Guidelines). The conversion definition included conversions that met the required change in TST status from negative to positive, irrespective of the interval between documented negative to documented positive TST. All designated converters met the study criteria of two documented negative TSTs or a negative pre-employment two-step TST preceding the positive TST. A positive result was defined as a PPD response of 10 mm induration or greater for routine TST surveillance for individuals not known to be immunocompromised, and 5 mm induration or greater for TB exposure follow-up testing or for employees known to be immunocompromised. No TST conversions were excluded based on non-occupational risk factors such as foreign travel.

Using clinical results recorded in the databases and TST conversion logs maintained by Employee Health, potential converters (all positive test results and all TST results >5mm) were identified. The project epidemiologist and occupational physician met with the hospital employee health nurse and/or hospital epidemiologist and/or head of infection control at the close of each surveillance year to review the medical records of each potential TST converter case and ensure that all designated converters met the same standard for documented conversion.

Conduct of TB skin testing

Participating hospitals accomplished TB skin testing through centralized administration and application or through decentralized TST application. Two of three hospitals relied on nursing staff on medical units for the placement, reading, and documentation of most TSTs. Departments without medical staff were tested by the employee health departments. At the third hospital (Highland Hospital), the employee health nurse responsible for the program administration also handled most of the placement, reading, and documentation.

Hospital employee health clinics or contract health agencies provided pre-employment medical screening to establish TST status at time of hire. Pre-employment, two-step testing began in 1995 or before at participating hospitals.

TB skin testing was performed for all eligible employees in a department during scheduled testing intervals. The CDC recommendation to "stagger" TB skin testing so that health care workers in a given area or occupational group receive a TST on different scheduled dates is advantageous in that it may send an "early warning signal" if a problem exists. However, computation of incident TST conversion rates by work area is less meaningful if all employees in an area contribute a different number of "months at risk" to the denominator. For example, prior to the Health Care Worker study, one hospital screened employees on the anniversary of their hire date, rather than at set intervals based on their department. Given the staggered screening at this hospital, meaningful location-based, or department-based incident conversion rates could not be calculated. TST screening scheduled by department was already in existence at two hospitals and the third facility made this transition in Year 2 of the study.

During the study, the policy at two hospitals was to administer TSTs to all skin test negative employees at 6 or 12-month intervals based on the employee's assigned department. At the third facility (Alta Bates), only employees located in the hospital building were eligible for continued testing on a semi-annual or yearly basis; employees located in a separate administrative building were excluded from routine testing. The exclusion criteria at Alta Bates Medical Center eliminated approximately 200 employees from routine surveillance. Departments were designated as "high-risk" for potential exposure to *Mtb* aerosol by the employee health and infection control departments and were thus scheduled for semi-annual TST testing. None of the hospitals provided quarterly testing or tested at three-month intervals following identification of conversion clusters (2 or more converters in a work location).

Eligibility for inclusion in study

Initial TST status for existing employees was determined from computerized datafiles at two hospitals (San Francisco General Hospital and Alta Bates Medical Center) and from paper records at Highland Hospital (Table 3). All employees identified from payroll data, who were not documented to be TST positive (or part of a department excluded from TST surveillance), were considered eligible for inclusion in TST screening. Employees lacking TST data were considered eligible for screening. The baseline assessment of TST status found that TST data was missing for 6% to 26% of all employees.

The workforce at each participating hospital included individuals who were excluded from study TST data because they were contractors, temporary workers, volunteers, or employees of other city/county agencies that could not or would not provide computerized payroll files. For example, no facility systematically included data for all physicians who worked at the hospital in their assessment of TB transmission among the "at risk" population, primarily because medical staff were frequently residents and contractors, rather than employees of the hospital. The contracting agencies had responsibility for medical surveillance. TST data for physicians were not routinely included in the surveillance database at SFGH. At Highland Hospital, the subset of county employed physicians was included in the database while contract physicians were excluded. At Alta Bates Hospital, most physicians were contract employees and were therefore excluded.

In addition to medical staff, hospital employees reported the extensive use of non-employee staff in nursing, respiratory therapy, security, food services and maintenance departments. At one hospital, the number of security badges issued annually was used as a surrogate for counting individuals on-site. Through this means, Alta Bates staff estimated that approximately 325 of 2414 (14%) of the long-term (>6 months) workforce was comprised of non-employees who are excluded from their TST surveillance data. Attempts to enumerate the overall proportion of non-employee workers at each site were unsuccessful because staff from the hospitals could not provide accurate data. The only accurate and sustainable way for institutions to identify all persons who work at complex facilities such as teaching hospitals is to establish administrative protocols for human resources/payroll departments, volunteer staffing administrators, and contract staffing administrators to regularly transfer datafiles. The task of obtaining and merging datafiles from multiple sources went beyond the administrative scope and authority of the employee health services participating in this study.

ORIGINAL PROGRAM OBJECTIVE 3: DEVELOP STANDARDIZED REPORTING MECHANISMS

Computerization of TST surveillance data

At the inception of the Health Care Worker study, all participating hospitals lacked the capability to collect and analyze data to assess employee risk of TST infection. Computerization was absent or incomplete, and not "user-friendly". Consequently, none of the hospitals could accurately calculate TST compliance or conversion rates by facility, department, or job title. Two of the three hospitals could not reasonably determine the population appropriate for TST surveillance.

The ability to identify employees for TB skin testing at participating hospitals was improved by the purchase and installation of a customized commercial software package. When compared to other available commercial products, the selected software (STIX, by Integritas, Inc.) most closely matched the project's surveillance goal: storage and management of all data necessary to comply with the CDC Guidelines for employee TST surveillance. The primary selection criteria for software were: relatively low initial and on-going cost; compatibility with existing software/hardware; ease of use; product track record; quality of documentation; ability to customize software to include data elements needed to undertake risk assessment; and the ability to import and export employee payroll data and clinical data.

The surveillance data analysis and administrative features in most available employee health and TB surveillance software were inadequate. Despite the limitations of commercial software products, in-house software development was ruled out in the beginning of the study based on the long start-up time and continued resources needed to support users. During Year 1, significant staff resources were devoted to working with the software manufacturer to enhance the software's surveillance and analysis capabilities and data export features. Staff from all participating hospitals attended an eight hour training in Year 2 and technical support and training were provided to hospitals by the Health Care Worker study staff and the software manufacturer for the duration of the study. The selected software proved to be a successful and stable system for the participating hospitals and study researchers.

The software in place at participating hospitals provided the ability to calculate compliance and conversion rates, as well as record key clinical data. Many practical administrative features were included in the software, such as automatic TB skin testing date calculation functions, customized letter templates for employee skin test notification and compliance, and various report generation capabilities.

Over the course of the study, the following limitations of the software were identified: inability of the user to modify most aspects of the product; a problematic screen design which allowed users to inadvertently overwrite historical health records during data entry of new test results; poorly designed user interface which required users to scroll through multiple screens in order to enter one patient record; poor product documentation and technical support; slow response time by product manufacturer to remedy software bugs that led to corrupted data; inability to interrupt long import and report generation procedures; no capacity to generate a summary report that would combine TST compliance with PPD positive symptom review survey compliance; inability to create useable data entry templates for supplemental questionnaire data; and inaccessibility of encrypted data in the relatively obscure Clarion programming language.

At each hospital, selected employee demographic information was routinely transferred electronically from payroll files into the surveillance database. The employee census was updated quarterly or semi-annually to provide accurate identification of all paid employees working at the facility. At two of the three hospitals, the employee health departments had difficulty obtaining payroll datafiles in the appropriate format on a regular quarterly basis. System-wide computer migrations, the difficulty in combining payroll files from two different sources, and low priority processing status for employee health accounted for the delays in obtaining quarterly files at all facilities throughout the study.

For each employee, data files included date of hire and termination, typical hours worked per week, job title, cost center/department, gender, and social security number. Individuals not contained in the payroll data files (i.e., volunteers and contract employees) were excluded from the analysis. Each facility addressed surveillance of non-paid and contract staff at the facility differently, though these groups of workers were often overlooked for TST surveillance.

Overall the software proved successful for storing and managing the key data and thus remained in place for the duration of the study. One hospital continues to utilize the software implemented by the study, one facility is in the process of changing to another employee health clinical software package as part of a hospital wide software migration, and one hospital no longer utilizes the software.

Questionnaire Data: Risk factors for TST conversion

Routine administration of a questionnaire containing information on potential exposure to *Mtb* aerosol enhanced the interpretation of TST data. A self- administered employee TST screening questionnaire was developed in collaboration with NIOSH staff, and infection control and employee health personnel at participating hospitals during the first year of the study. Hospital Human Subjects Research Review Committees at Alta Bates Medical Center and San Francisco General Hospital approved the administration of the employee questionnaire and retrospective review of TB patient location data. Highland Hospital waived the Human Subjects review and approved the study questionnaire. Information collected on the questionnaire included health care worker risk factors for *Mtb* aerosol exposure, such as: job title, presence during high-risk procedures, number of hours worked per week, work location/department, entry into isolation rooms, work in areas of the hospital that treat or provide services for TB patients, race/ethnicity, country of origin, contact with household members, family or friends with TB, work at other medical or social service facilities, and foreign travel (attachment 1).

The questionnaire was pre-tested at two hospitals, and finalized on the basis of pre-test results. Use of the questionnaire began in the second year of the study. To increase the ease of use, the questionnaire format was modified in December 1995. Questionnaire completion took approximately three minutes and was required at all facilities. For initial employee screening, questionnaires were administered at the time of new employee orientations or pre-employment medical evaluations. For existing employees, questionnaires were completed at the time of periodic TB skin testing. Hospitals did not administer questionnaires during case-contact investigation follow-up screenings.

Employee Health Services staff at each hospital were responsible for distribution and review of the self-administered questionnaire for completeness during 1995 and 1996. In 1997, field staff positions were added at each hospital to assist with TST surveillance efforts and improve the quality and timeliness of data collection and input into the surveillance database. Since January 1997, Health Care Worker project staff handled all aspects of questionnaire distribution and review.

Questionnaires were regularly edited, coded, and entered into a Foxpro database by field staff at each hospital site, ensuring accurate and timely data entry. Data entry quality was maintained at an estimated 97% accuracy rate through the application of rigorous data entry protocols and verified through data confirmation of a random sample of 10% of questionnaires. Efforts were made to improve data entry procedures by developing and utilizing a computer-scannable version of the questionnaire in Year 4 of the study. The benefits of converting the questionnaire into a scannable format were evaluated and it was determined that the most time intensive aspects of data entry on literal fields could not be eliminated by moving to a scannable version. Efficient data entry screens were created in FoxPro and were used for the duration of the study. Questionnaire data was linked with exported TST data for analysis purposes. .

ORIGINAL PROGRAM OBJECTIVE 4:
DEVELOP CRITERIA FOR EVALUATION OF CDC GUIDELINES

Protocol for Evaluating Adherence to CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities

Standardized criteria were developed and specified in the *Protocol for Evaluating Adherence to CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities* (attachment 2). To assess adherence to 1994 CDC Guidelines, TB control practices at participating hospitals were systematically compared to the criteria in this survey tool in years one and two.

The protocol was organized by administrative, engineering and respiratory protection control measures; criteria were developed by which to measure adherence to CDC's Guidelines in each of these areas. Criteria were specified in a tabular format with hospital practice at the time of the survey. Data were collected and verified by Health Care Worker study industrial hygienists through (1) interviews with employee health, infection control, facility management and other persons with responsibility for TB control; (2) observation of TB control work practices; (3) measurement of room ventilation performance; (4) observation of employee TB training videos; and (5) review of written policies and procedures. Evaluation of adherence to CDC Guidelines included:

- ***Administrative controls:*** assessment of assignment of responsibility for TB control; development and implementation of TB control plan; performance of TB case surveillance, infection control practices, employee TB surveillance program, and detection and reporting of TB cases; AFB isolation practices; and health care worker training.

- ***Engineering controls***: assessment of the extent and nature of ventilation systems and practices throughout the facility including general use areas, procedure rooms, treatment areas, and AFB isolation rooms; documentation of ventilation system design including location of supply air diffusers and exhaust/return air grilles, location of windows and doors, presence and layout of anterooms, and means of controlling room pressurization; documentation of the presence and use of air-cleaning equipment, germicidal lamps, tents, booths, hoods and other enclosures used to isolate patients or contain aerosols generated by patients with infectious TB; measurement of negative pressure, air mixing, and air supply, exhaust and change rates; and determination of the effectiveness of maintenance practices.

- ***Respiratory Protection Controls:*** identification and confirmation of criteria for use of personal protective equipment and respirator selection criteria; and review of a comprehensive respiratory protection program, including components such as assignment of responsibility, standard operating procedures, medical screening, training, face seal testing and fit checking, respirator cleaning, maintenance and storage, program evaluation and costs.

The results of these evaluations are summarized under Objective 5 and presented fully in attachments 4 and 5.

Implementing a Quality Assurance Program for TB Patient Isolation

The assessments of adherence to CDC Guidelines conducted in the first two years of the Health Care Worker project found a lack of full adherence to CDC Guidelines at all three hospitals. Reports about work practices varied among hospital staff, and documentation to verify that hospital policy had been implemented was often absent. These findings indicated that the stated hospital TB control policy differed from actual day-to-day practice.

The protocol for years three and four was therefore revised to incorporate a quality assurance approach. TB control measures assessed were: the isolation of patients suspected or known to have TB until they are non-infectious in negative pressure isolation rooms, and the use of respiratory protection for TB by health care workers entering a TB isolation room. Assessment criteria were developed to quantify adherence to each of these measures. Data were gathered in two ways: (1) laboratory and clinical records were reviewed to gather retrospective data on the room placement of all individuals with culture-proven pulmonary TB during a one year period; (2) project industrial hygiene staff directly observed patient rooms while in use for TB isolation to gather prospective, quantifiable data on adherence to CDC Guidelines for TB patient isolation.

The finalized protocols and forms used to record data from abstracting medical records, observations of TB patient rooms, the use of respirators by health care workers, and hospital location of suspect and known TB patients are in attachment 3. Prior to full implementation, the quality assurance protocol was pilot-tested at one hospital. The tool developed was not effective in assessing adherence to TB control measures in the emergency room because the chance of identifying a coughing patient or a TB patient in the emergency room during a weekly audit was very low. During weekly assessments over the course of 14 weeks, none of 119 patients observed in the emergency room were coughing and no TB patients were identified in the emergency room.

The results of these quality assurance evaluations are summarized under Objective 5 and presented fully in attachments 4, 6 and 7.

Implementing a Quality Assurance Program for TB-Skin Test Surveillance

Unexpected Year 1 surveillance results at Highland Hospital (no TST conversions) combined with random observations of TST practices prompted the staff epidemiologist and research associate to design and implement a systematic and objective assessment of the mechanics of the TB skin testing program at each hospital. Numerous explanations, including chance, provide reasons why a high-risk facility with 48 TB cases would have no TST conversions among paid employees. Many factors can effect the variability and outcome of TSTs including, storage and handling of PPD media, placement and reading errors, and clinical documentation. A TST quality assurance evaluation tool that could be implemented by the study field staff was designed in 1996 and was based on CDC Guidelines, CDC TST training materials, the pharmaceutical insert for PPD material, and extensive review of published research (attachment 3).

With the exception of some important aspects of a TST program that could not be fully observed (ie. TST readings done by designated department readers at varying times), field staff researchers attended every scheduled hospital TST screening for 14 weeks beginning February 1, 1997. Subsequently, Health Care Worker project staff attended and evaluated at least 10% of all TST department screenings for the duration of the study. Even with the limitations of the largely observational quality assurance component, key aspects of the program were observed multiple times. It was presumed that each documented deviation from recommended TST procedures represented a fraction of all sub-standard practices. In addition to the observation of employee TST screening practices, study researchers compiled data from all skin test result forms from 1997 to assess self-reading of TST results, reading TST results outside of the 48-72 hour recommended interval, and TST results recorded without noting the millimeters of induration.

The most important findings from the evaluation of TST practices were that two of the three participating hospitals had poor TST documentation practices and sub-optimal TST administration and interpretation practices. In 1997, test placement and reading dates were frequently missing (35% at Highland), the person responsible for reading test results was always missing (100% at Highland), and the majority of test results were not recorded in millimeters of induration (64% at SFGH). Practices which could have reduced the consistency and validity of TST results included self-reading of TST results (2% at SFGH), reading TST results without feeling for induration (14% at Highland), reading "negative" TST results outside of the recommended 48-72 hour interval (6% at SFGH), failure to apply PPD within five minutes of loading syringes (94% at Highland), and failure to regularly determine both recent illness and immunization status (Highland, SFGH, and ABMC).

Study researchers reported to each hospital following the first 14 weeks of TST practices evaluation and all three hospitals subsequently improved many of their practices. However, undesirable TST practices were not fully eliminated.

Through the assessment of TST protocols and practices study researchers documented that only one of three participating hospitals, Alta Bates Medical Center, consistently applied the most important administrative and clinical practices for TST surveillance. The other two hospitals had notable deficiencies with TST implementation and also had the largest percentage of employees with missing TST data (20% at SFGH and 26% at Highland). These program deficiencies could have led to under-ascertainment of new TST infection. This was because the study definition of TST conversion required proper documentation of two negative TSTs or a two-step TST prior to the documented positive result. Employees lacking this documentation were considered "reactors" and were not accounted for in the conversion rate statistics. Poor test administration and interpretation practices may have also led to reduced validity and increased likelihood of negative TST results. Therefore, the actual risk of TST infection at these hospitals may be greater than what was documented in this study.

ORIGINAL PROGRAM OBJECTIVE 5: CONDUCT BASELINE AND PERIODIC EVALUATIONS OF CDC GUIDELINE IMPLEMENTATION AND USE OF TB TRANSMISSION CONTROL METHODS

An initial evaluation of TB control measures was made at each hospital by conducting meetings and facility walk-throughs with employee health, infection control and facilities management personnel. A comprehensive assessment of adherence to CDC Guidelines was then conducted at each hospital. CDC Guideline criteria to which each health care facility TB control practices were compared were specified in the protocol described previously. Results of the assessments were summarized and reported to each hospital (attachment 4). The study findings were published in *Infection Control and Hospital Epidemiology* (1998) (attachment 5).

Comprehensive assessment of adherence to CDC Guidelines

Overall, the assessment of adherence to CDC Guidelines found that 28% of isolation rooms tested (7/25) were under positive pressure; 83% of rooms tested (20/24) had six or more nominal air changes per hour (ACH), but supply air did not rapidly mix with room air. Therefore, the nominal ACH likely overestimated the effective ACH and the subsequent protection provided. In virtually all rooms tested (26/27), air potentially containing *Mtb* aerosol moved towards, rather than away from likely worker locations. None of the hospitals regularly checked the performance of engineering controls. Only one hospital adhered to the CDC minimum requirements for respiratory protection. Training of health care workers was generally underutilized as a TB prevention measure. Hospitals did not provide comprehensive counseling regarding the need for health care workers to know their immune status and the risks associated with *Mtb* infection in an immunocompromised individual. Employee representatives did not have a voice in TB-related decision making.

The study concluded that subsequent to the identification of TB patients, health care workers at all three hospitals were potentially exposed to *Mtb* aerosol due to breaches in negative pressure isolation, the limitations of dilution ventilation, and the failure to maintain engineering controls and to fully implement respiratory protection controls. These findings lend support to OSHA's policy presumption that, absent clear evidence to the contrary, newly acquired health care worker *Mtb* infections are work-related.

In addition to a lack of full adherence to CDC Guidelines at all three hospitals, CDHS found that the stated hospital TB control policy, which was based in large part on CDC Guidelines, differed from actual work practice. The inadequacy of and/or lack of adherence to the hospital's TB control plan can lead to inaccurate conclusions regarding the routine (i.e., non-outbreak) risk of health care worker exposure to *Mtb* aerosol. For example, health care workers may incur exposures that are not recognized because of unexamined assumptions that effective control measures are in place. We therefore undertook a study to quantify implementation of measures for TB patient isolation as specified by CDC Guidelines and the hospital's TB control policy.

Prospective quality assurance study of TB patient isolation

A complete description of the study protocol was published in Handbook of Modern Hospital Safety (Wm. Charney Ed, 1999) (attachment 6). Briefly, at each hospital, CDHS conducted once weekly audits for 14 weeks at all inpatient hospital locations. At each location, nursing supervisory staff were asked to identify the room of any known or suspect TB patients present. Therefore, the unit of observation was the "TB patient-room". If the same individual was found or the same room was used on more than one occasion, it was considered a separate observation. For the purpose of this study, a "suspect" and "known" TB patient were defined as any patient whose clinical status was understood by the nursing supervisor to be that of a suspect or known TB case, respectively.

For each TB patient-room unit observed, the following were assessed:

(1) Was the room on the list of designated TB isolation rooms?

(2) Was a respiratory precautions sign on the door?

(3) Was the door to the hallway closed?

(4) If the room was designated for TB isolation, was the room under negative pressure?

(5) At the room entry, was there available a supply of NIOSH-approved respirators for TB?

(6) Did health care workers who were observed entering the room use respiratory protection appropriately?

The study findings have been accepted for publication in *Infection Control and Hospital Epidemiology* (1999) (attachment 7) For 70% of 170 TB patient-room units observed, the patient was in a designated TB isolation room, the room was under negative pressure, the door was closed, and a respiratory precautions sign was on the door (Table 2). The study found that 19% of TB patient-room placements involved rooms that were not under negative pressure or not designated as negative pressure rooms; 11% of patient-room units mechanically capable of negative pressure at a prior point in time were not under negative pressure at the time of use. Respiratory protection was available at the entry of 93% of the rooms and most of the 66 health care workers observed (94%) used respiratory protection for TB. However, almost two of every three health care workers observed using a respirator for TB did not don the respirator properly (40/62).

TABLE 2
ADHERENCE TO TB ISOLATION CRITERIA AMONG TB PATIENT ROOMS AT THREE HOSPITALS OVER 14 WEEKS

CDC Guideline for TB patient isolation	Hospital 1 N = 91	Hospital 2 N = 24	Hospital 3 N = 55	Overall N = 170
TB patient placed in rooms designated as having negative pressure	82%	100%	100%	91%
room door closed	90%	83%	98%	92%
warning sign posted on room door	98%	96%	87%	94%
patient placed in room designated as having negative pressure with the finding that the door was closed, a sign was posted, and negative pressure was measured	67%	71%	82%	70%
room has NIOSH approved N95 respirators available	90%	0%	96%	79%
room has any healthcare worker respiratory protection available	90%	100%	96%	93%

The study concluded that implementing CDC Guidelines for TB patient isolation was feasible but imperfect in the three hospitals. Day-to-day work practices varied from hospital policy. As a result, health care workers, including those who have no direct patient contact, may incur unrecognized exposures to *Mtb* aerosol during routine hospital operations (i.e., not an outbreak setting involving a massive failure of TB control measures). There may be significant cumulative infection risk among health care workers stemming from exposure to *Mtb* aerosol involving incomplete implementation of TB patient isolation measures. Prospectively quantifying the implementation of a hospital TB isolation policy while the room is in use may lead to improved estimates of risk and may help identify and thereby prevent avoidable health care worker exposures to *Mtb* aerosol.

Retrospective study of TB patient isolation practices

A retrospective evaluation of TB patient isolation practices was developed and implemented at two hospitals (San Francisco General and Alta Bates). This methodology also served as a surrogate measure of employee exposure to *Mtb* aerosol (see Objectives 6 and 7). The study had two parts: (1) an evaluation of the isolation of all inpatients suspected of having pulmonary TB over a seven-week period (SFGH only); and (2) an evaluation of the isolation of all inpatients with confirmed pulmonary TB over a one-year period (SFGH and Alta Bates). All hospital room locations of each inpatient with confirmed pulmonary TB was identified for the one-year period (January 1 through December 31, 1996). All room locations were compared to a list of designated negative-pressure isolation rooms for the same period. Patients placed in a designated isolation room were considered isolated.

The study findings have been summarized in a report to SFGH (attachment 8). The report to Alta Bates will be completed and forwarded to NIOSH in June 1999. At SFGH, there were 54 inpatients with confirmed pulmonary TB in 1996. Half of the TB patients (27/54) were fully isolated in a negative-pressure isolation room and half were not. The 54 TB patients were in the hospital a total of 652 days. Most TB patient-days were likely contributed by infectious patients. Thirty percent (197/652) of all TB patient-days were unisolated. Factors which contributed to uncontrolled sources of *Mtb* aerosol exposure at the hospital were an inadequate number of isolation rooms, a lack of isolation rooms in specialized care areas, and unrecognized TB. All workers physically located at SFGH were at risk of exposure to *Mtb* aerosol.

On the basis of these findings, CDHS recommended to SFGH that: (*i*) the hospital should adopt and enforce a policy that requires all suspect TB patients to be isolated in negative-pressure rooms until it has been demonstrated that they are not infectious; (*ii*) the hospital should add negative-pressure TB isolation rooms to all hospital locations that provide specialized-medical care, and should increase the number of isolation rooms on wards that routinely care for TB patients; (*iii*) all workers physically located at SFGH should be TB skin-tested at least annually.

ORIGINAL PROGRAM OBJECTIVE 6: ANALYZE TB SKIN TEST CONVERSION AND NEW TB CASE DATA

Surveillance Data Summary

The prevalence of PPD positive employees at the start of the study ranged from 24% to 30% (Table 3). There was a significant risk of newly acquired TB infection among health care workers at all hospitals. CDHS found that on average, one in every four non-infected health care workers (26%) at participating hospitals would become infected with TB over the course of their working lifetime (45 years). A total of 76 TST conversions were reported during this period. The three year average conversion rate among employees at all three hospitals was 0.66% (76/11,519). Annual hospital conversion rates ranged from 0% to 1.05% over the three years of TST surveillance (Figure 3). A summary of annual TST conversion rates at each hospitals is presented in Tables 4-6. Details of TST surveillance at each hospital are presented in attachment 9.

Three-year average conversion rates were 0.53% at Highland Hospital, 0.74% at San Francisco General Hospital, and 0.64% at Alta Bates Medical Center. Job categories with the highest conversion rates included: Registered Nurse/Nurse Assistant/LVN (0.9% average conversion rate for all hospitals), housekeeper (2.5% average conversion rate for all hospitals), and Respiratory Therapist (1.8 % at ABMC).

Conversion rates were recalculated using the "hours worked per week" variable derived from hospital payroll files. In this alternate calculation, part-time workers contributed proportionately less to the denominator and/or numerator (# converters/# tested). The adjusted conversion rate for Alta Bates Medical Center in 1995 was 0.23% versus 0.36% (unadjusted rate). The adjusted conversion rate for SFGH in 1995 was 0.88% versus 0.83%. Adjusted conversion rates were not calculated for Highland Hospital due to missing hours worked per week data from payroll datafiles. Because the conversion rates were only slightly affected by proportionally adjusting hours worked for each employee, only simple conversion rates were used for the remainder of the analysis.

Two of the three facilities had sub-optimal compliance with TST. Only one hospital, Alta Bates Medical Center maintained high TST compliance throughout the study. Annual compliance rates ranged from 32% to 52% at San Francisco General Hospital, 48% to 55% at Highland Hospital, and 63% to 75% at Alta Bates Medical Center (Tables 4-6).

For employees who received a TST, annual questionnaire completion rates were 78% to 80% at SFGH, 77% to 82% at Highland Hospital, and 83% to 92% at Alta Bates Medical Center. Computerized databases, assistance with data entry of clinical results, and administrative assistance for hospital TB screenings did not improve TST compliance, because other obstacles to program implementation were beyond the scope of CDHS researchers. However, this assistance did assure timely and accurate data entry.

Questionnaire and payroll data indicated that the majority (62% to 78%), of the workforce was female at all three hospitals and 10% to 16% of the participants were foreign-born. Of the tested populations during the first year of the study, 78% to 80% reported some level of patient contact and 33% to 42% reported being present during procedures with increased risk of *Mtb* aerosol exposure. These data show that most employees need to have knowledge and training about TB. Additionally, the possibility of reducing potential exposure to *Mtb* aerosol through administrative controls (i.e., limiting the number of persons who enter inpatient isolation rooms and who are present during high risk procedures), should be evaluated.

Figure 3. Hospital Employee TB Conversion Rates

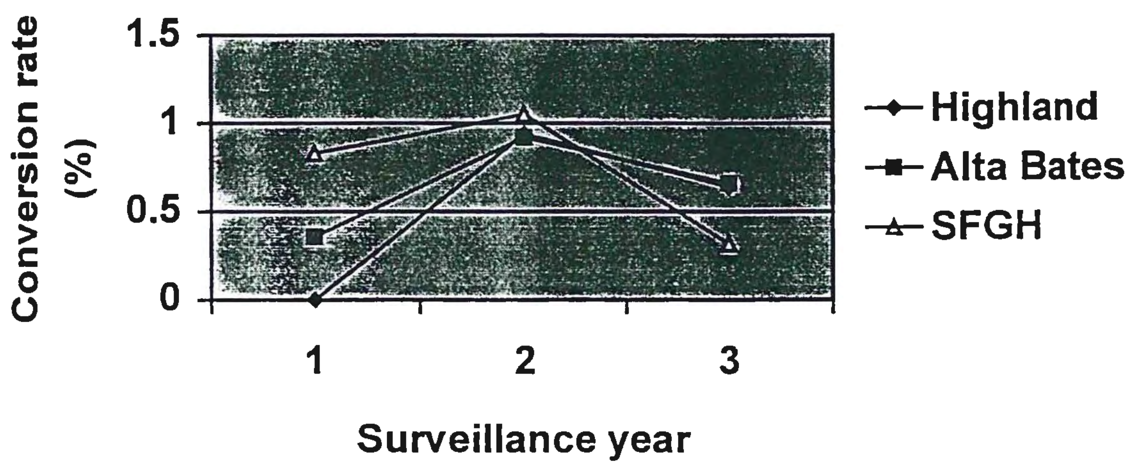


Table 3
Employee Tuberculosis skin test status at start of the surveillance period – Year 1

Hospital	Positive N (%)	Negative N (%)	Missing N (%)	Total
Highland	504 (26.3%)	924 (48.2)	489 (25.5)	**1917**
Alta Bates	693 (23.5%)	2088 (70.8)	169 (5.7)	**2950**
San Francisco General	1479 (30.3%)	2417 (49.5)	983 (20.1)	**4879**

Table 4
Tuberculosis Skin Test Results
Highland Hospital

Year	Total eligible	Tested N (%)	Converters N (%)
1	1413	711 (50)	0 (0.0)
2	1351	744 (55.1)	7 (0.94)
3	1309	622 (47.5)	4 (0.64)
Total	4073	2077 (51.0)	11 (0.53)

Table 5
Tuberculosis Skin Test Results
Alta Bates Medical Center

Year	Total eligible	Tested N (%)	Converters N (%)
1	2257	1690 (74.9)	6 (0.36)
2	2572	1630 (63.3)	15 (0.92)
3	2383	1660 (69.7)	11(0.66)
Total	7212	4980 (69.1)	32(0.64)

Table 6
Tuberculosis Skin Test Results
San Francisco General Hospital

Year	Total eligible	Tested N (%)	Converters N (%)
1	3400	1085 (31.9)	9 (0.83)
2	3478	1803 (51.8)	19 (1.05)
3	3206	1574 (38.7)	5 (0.32)
Total	10,084	4462 (44.2)	33 (0.74)

TST surveillance: Highland Hospital

TB skin testing for new employees was performed at time of hire by an outside contractor and data were received by the Employee Health Department. Two-step pre-employment TST began in 1995. All subsequent testing was performed by the Employee Health Nurse and her medical staff. Baseline TB skin test data were abstracted from employee medical records and entered into the software program by Health Care Worker project staff. Data for TST was missing for 25% of the active employees identified from county payroll datafiles. A ten percent sample review of those individuals without TST data found that missing charts, poorly documented or missing TST history in charts, and data entry oversight accounted for the missing data.

Beginning in April 1995, Highland staff entered TST data into the clinical database. In early 1996, Health Care Worker project staff identified numerous deficiencies in the timeliness and accuracy of data entry completed by hospital staff. Because hospital resources were scarce during this uncertain period for the county hospital, Health Care Worker project staff were utilized to rehabilitate the surveillance database. From January 1997 through March 1998, the Health Care Workers project provided Highland Hospital with a part-time research assistant on site to assist with data entry, questionnaire administration, and TST quality assurance data collection.

Annual conversion rates varied dramatically over the three-year surveillance period, ranging from 0% to 0.94% (Table 4). The cost centers with the highest conversion rates and more than one converter were Medical/Surgical ICU (2.8% in 1996 and 2.8% in 1997) and Housekeeping (5.4% in 1997). Job categories with the highest conversion rates were Administrative/Clerical worker (1.5%), Nursing Assistant (1.5%), Housekeeper (2.4%), and Physician, non-surgical (7.7%).

The lack of any TST conversions in 1995, among employees at this facility which treats large numbers of TB patients (56 inpatient TB cases in 1995) led study researchers to design a TST practices evaluation tool. Although not represented in the reported statistics, two workers at Highland Hospital (one volunteer and one contract physician) had documented TST conversion in 1995.

TST compliance, ranging from 48% to 55%, was poor throughout the study. Obstacles to TST compliance were insufficient employee health staff, a lack of administrative authority, and a failure to fully utilize the computerized system designed to identify persons eligible for TST. TST practices and protocols did not universally comply with CDC Guidelines (attachment 9). Quality assurance data indicated notable problems with PPD storage and handling procedures, record keeping, and TST interpretation and reading.

TST surveillance: Alta Bates

TB skin testing for new and existing employees was performed by Employee Health staff. Baseline TST data were transferred electronically from the previous software program into the current software by Health Care Worker project staff in 1994. In 1995, 71% of the 2950 employees at Alta Bates were TST negative and 24% were TST positive. Data were absent for approximately 6% of all employees. Health Care Worker project staff periodically provided data entry assistance for TST results and routinely managed all of the employee questionnaire data. Beginning in 1997, the Health Care Worker project provided a half-time study research assistant to manage all TST and questionnaire data entry and to implement the quality assurance protocol at Alta Bates.

Alta Bates Medical Center nad the highest TST compliance rates among the three hospitals, ranging from 63% to 75% (Table 5). These rates reflect a consistent and successful surveillance program. TST quality assurance data also indicated excellent program implementation. The TST program was administered with central responsibility and oversight from the Employee Health Nurse at Alta Bates Medical Center. Implementation of the testing program occured in a decentralized manner, with most clinical departments responsible for administration and reporting of TSTs. Department managers were held accountable for timely employee testing and employee health offered small incentives for timely completion of department TST.

During the study period (1995 to1997) annual conversion rates were 0.36%, 0.92%, and 0.66%, respectively. The average conversion rate for the three year study period was 0.64%. All verified TST conversions met the ≥ 10mm induration definition, except for two verified TST conversions which were >5mm induration and were identified during TB exposure incident follow-up testing. Job categories with more than one converter over the three year study period and with the highest conversion rates were Respiratory Therapist (1.8%), Non-lab technician (1.6%), Housekeeper (1.6%), Licensed Vocational Nurse (1.4%), and Registered Nurse (0.9%).

TST conversions are presented by cost center in attachment 9. TST conversions were reported in more than one study year in Admitting, Respiratory Therapy/Pulmonary Function, and Environmental Services cost centers. The highest TST conversion rates for cost centers with more than one conversion in a single year were 4 West – Medical Surgical (10.0% in 1996), Emergency (2.9% in 1997), and Respiratory Therapy/Pulmonary Function (5.9% in 1996).

TST surveillance: San Francisco General

In Year 1 of the study, baseline TST data at SFGH were electronically transferred from an existing D-Base system into the STIX database. Of the 4879 employees at SFGH, 50% were TST negative and 30% were TST positive. Baseline TST data were absent for 20% of employees. From February 1995 through December 1996, TST data for newly hired employees and routine surveillance data were entered into the software program by SFGH Employee Health staff. Due to deficiencies with data entry timeliness and completeness, a full-time Health Care Worker project staff research assistant began entering TST and questionnaire data on site, administering TB questionnaires at TST departmental screenings, and collecting direct observation quality assurance data.

TST compliance was lowest the first year of the study, 32%, and only marginally improved over the next two years, 52% and 39%, respectively (Table 6). In a supplemental assessment of the "at-risk" population that works at SFGH, available TST data for UCSF interns and residents that work at SFGH was data entered and summarized for 1995 and 1996. TST compliance among this group was 42% in 1995 and 44% in 1996. In addition to inadequate SFGH staffing to administer the TST program, the lack of institutional pathways between SFGH and University of California, San Francisco to regularly exchange TST data for more than 900 University of California interns and residents that work at SFGH, contributed to the inadequate TB surveillance program.

Two different administrative obstacles contributed to sub-optimal TST compliance rates during the study. During 1995 and 1996 the staff position responsible for the employee TST program was vacant for more than six months and testing did not occur on a regular basis (except for departments that administered their own TSTs or were tested as part of another ongoing study). The other obstacle to comprehensive TST was the difficulty of identifying the work location of all persons eligible for TST from the payroll files. Payroll files contained cost centers, the closest proxy to work department, which did not always indicate or correlate with a person's work location. One possible solution to the problem of untested individuals whose work location is unknown to Employee Health or who are missed during routine department based screenings is to utilize the payroll departments to notify non-compliant employees at the end of each calendar year using existing paycheck distribution systems. These untested, non-located employees could be required to obtain an annual TST by visiting the employee health clinic.

Annual TST conversion rates were 0.83%, 1.05%, and 0.32% over the years 1995 to 1997 (Table 6). The three -year average conversion rate was 0.74% and a total of 33 TST conversions were documented. All verified TST conversions met the 10mm induration or greater definition. The highest conversion rates based on questionnaire job category responses in Year 1 were among housekeepers (9.5%) and Licensed Vocational Nurses (8.3%). In Year 2, Registered Nurse (3.7%) and Nurse Assistant (3.4%) had the highest rates and in Year 3 housekeeper (3.8%) and Licensed Vocational Nurse (2.0%) had the highest TST conversion rates among job categories reported from questionnaires (attachment 9). The cost centers with repeated TST conversions over the study years included General Medicine 5C (12.5% in 1995 and 14.3% in 1996), Medical/AIDS 5A (20% 1996 and 5.6% 1997), and Environmental Services (9.5%, 2.6%, and 3.2% 1995 to1997) (attachment 9). The cost centers with the highest conversion rates and more than one converter were Med/Aids 5A (20% in 1996), General Medicine 5D (13.3% in 1996), Environmental Services (9.5% in 1995), and Emergency Department (5.1% in 1996).

Although Health Care Worker project staff confirmed a total of 33 TST converters at SFGH during the three surveillance years, poor documentation of medical records and missing medical charts hindered efforts to confirm all suspected TST conversions. More than ten potential converters were eliminated from the conversion rate statistics because there were insufficient data to meet the case definition. Therefore, the reported conversion rate is likely to underestimate the risk of TB infection, since large amounts of missing data led to an under -ascertainment of TST conversion.

The quality assurance evaluation in 1997 found that the program had excellent PPD storage and handling practices and appropriate test placement and reading technique. Program deficiencies included self-reading of PPD results (2%), inclusion of TST results that were read outside of the 48-72 hour post-placement interval (6%), and incomplete clinical documentation as 64% of the results were not recorded in millimeters of induration. These practices all reduce the validity and interpretation of the PPD test and are likely to result in an underassessment of new TB infection.

Model to analyze risk factors for conversion

A logistic regression model was designed to predict the Odds Ratios for risk factors thought to influence the likelihood of TST conversion. The risk model synthesizes TST surveillance data, self-administered questionnaire data completed at the time of TST screening, employee payroll data, and data on the hospital location of inpatient, active TB cases. The full analysis will be submitted to a peer-reviewed publication later this year.

The logistic analysis will be performed using data from San Francisco General Hospital and Alta Bates Medical Center. Highland Hospital was not selected for the logistic analysis because the TB patient location data (i.e., exposure data) could not be collected at this site and the limited number of TST conversions reduced the value of the logistic analysis. As part of the analysis, various logistic models will be tested for strength of association and ability to explain variance. The unit of analysis is an employee who is susceptible and tested. The components of the logistic regression model are:

(1) Health care worker exposure to Mtb aerosol

The model evaluates if there is an association between health care worker exposure to *Mtb* aerosol and TST conversion. Health care worker exposure to *Mtb* aerosol was indirectly assessed by comparing the employee's work location to the hospital location of culture positive TB patients. *Mtb* aerosol exposure was assumed to occur in those hospital locations where infectious TB patients were present. The quantity of *Mtb* aerosol present in a location during a given time period was estimated in two ways: (1) the sum of the number of infectious TB patients present in the location (# TB patients/time) and (2) the cumulative sum of time spent by all infectious TB patients in the location (# TB patient-days/time). TB patient location data were collected for 1996 for SFGH and ABMC and the exposure estimates for 1996 will be applied to 1995-1997 data. A data collection instrument for identifying the room location of TB inpatients was developed and pilot-tested at SFGH and Alta Bates. Data were compiled from existing hospital databases, as well from patients' charts and other clinical records, such as directly observed therapy clinic records. All data were entered into an Excel spreadsheet.

Because unrecognized exposure to *Mtb* aerosol prior to case identification may play an important role in occupationally acquired TB, characterizing employee exposure by means of sampling air directly for *Mtb* would have had the advantage of not relying on health care worker or institutional knowledge of exposure. Air sampling would also provide a quantitative measure of *Mtb* aerosol under a range of exposure scenarios. However, exposure to *Mtb* aerosol could not be measured directly in air because no validated air sampling technique was available.

Several other indirect methods to assess exposure were considered. Prospective self reporting of exposure to infectious TB patients in diaries or on a log sheet posted outside of the TB isolation room would minimize the recall bias of a retrospective questionnaire, but both of these methods would not include those exposures unknown to the health care worker. In addition, the time and effort needed to reliably collect exposure data in this manner was deemed to be unrealistically high. Direct observation of health care workers by research staff was also ruled out as infeasible.

A potential source of misclassification in utilizing TB patient location data as an estimate of employee exposure to *Mtb* aerosol may be unmasked TB patients may leave their isolation room (e.g., a patient going to the cafeteria or phone booth). Such breaches in isolation have been identified during the assessments of TB control measures described earlier. Alternatively, health care workers who report working in locations where infectious TB cases have been may not have actually incurred exposure to *Mtb* aerosol, and therefore will be misclassified as "exposed".

Another limitation of the use of TB patient location as a surrogate for exposure is that TB patients placed in isolation rooms may not be a "controlled" source of *Mtb* aerosol exposure. As previously described, CDHS' assessments of adherence to CDC Guidelines at participating hospitals found 28% of isolation rooms tested to be under positive pressure; the quality assurance survey found that 11% of rooms mechanically capable of negative pressure at a prior point in time were not under negative pressure at the time of use. A related issue, particularly on the AIDS ward at SFGH, where most rooms are negative-pressure isolation rooms, is that being located in an isolation room does not necessarily equate with being under the restrictions of respiratory isolation (i.e., keeping the room door closed).

Another limitation of TB patient location as a surrogate for health care worker exposure is that all TB patients are not equally effective in disseminating an infectious aerosol. In other words, all TB patients and TB patient-days do not pose the same risk of infection for health care workers. In this regard, we did not identify which patients were coughing, and did not determine the bacilliary load of each patient at the time they were unisolated. Overall, most TB patient-days (402/652) were contributed by AFB smear-positive patients, most (426/652) occurred during days one to 14 of the hospital admission, and more than one-third (249/652) were contributed by AFB smear-positive patients during days one to 14 of the hospital admission. While the greatest risk of infection may be exposure to AFB smear-positive patients, AFB smear-negative patients can also transmit TB, and in the proper environment patients remain capable of transmitting TB even after two weeks of effective therapy. In summary, although the infectivity of each patient was unknown, most TB patient-days were likely contributed by infectious patients.

(2) Employee work location

Because payroll datafiles only provide surrogate information about the work location for each employee, self-administered questionnaire data was used for identifying each employee's primary work location. The questionnaire form collected data on the location where employees worked in two ways: (1) generic work locations were provided in a checklist format and (2) respondents provided a literal description of their work location.

Study researchers spent a considerable amount of time during Year 5 attempting to categorize all responses to the specific work location question (literal field) provided by employees. However, more than one thousand unique responses were collected from SFGH. Responses varied considerably in specificity and not every response could be categorized. Therefore, study researchers narrowed the work location categories to all inpatient hospital locations and to the emergency room. A combination of questionnaire data and payroll data was used to assign an inpatient, emergency room, or a "no-inpatient location" code for each questionnaire. When employees worked in more than one location, the higher risk location was assigned.

(3) Other risk factors for exposure to Mtb aerosol

In addition to the hours of employee exposure to *Mtb* culture positive patients (isolated and unisolated) by hospital location, the following potential risk factors for exposure to *Mtb* aerosol will be included as variables in the logistic regression model: presence during high-risk procedures (autopsy, sputum induction, intubation, open abscess irrigation, thoracotomy, administration of aerosolized medications, or bronchoscopy); entry into isolation rooms; job title; reported patient contact; work at other medical or social service facility; non-occupational risk factors for TST conversion including reported contact with active TB outside of work, foreign travel to countries with high rates of TB disease, and BCG status; demographic variables (age, race, gender, country of origin); and home residence zip code linked with population TB case rates to assign non-occupational TB risk variable.

ORIGINAL PROGRAM OBJECTIVE 7: DEVELOP AND APPLY CRITERIA FOR EVALUATING THE EFFECTIVENESS OF TB TRANSMISSION CONTROL METHODS IN PREVENTING OCCUPATIONAL TB INFECTION

Administrative, engineering and respiratory protection control methods for TB were described over the course of the study and the risk of transmission was documented by TST surveillance data at each health-care facility. Risk of TB transmission is a function of exposure to *Mtb* aerosol and the presence of exposure control measures. Assessing the exposure of each health care worker to *Mtb* aerosol was described under Objective 6.

An "environmental protection factor" (EPF) categorical variable(s) was initially considered to estimate the nature and extent of adherence to CDC guidelines (i.e.; presence of control measures) as determined in the course of facility assessments. After studying the inconsistent implementation of CDC Guidelines at participating hospitals, the number of unisolated TB patients and TB patient days was deemed to be the only reliable quantitative exposure measure. For example, health care workers at one hospital used a HEPA respirator while performing bronchoscopy, sputum induction and other high risk procedures, and out-patient sputum induction was well controlled in an Emerson booth. However, the bronchoscopy suite was under positive pressure, so health care workers *outside* of the bronchoscopy suite may have been exposed to *Mtb* aerosol generated *inside* of this room. At all hospitals, the performance of negative pressure rooms was inconsistently maintained over the period of observation. The efficacy of a *single* exposure control method could not be estimated under such circumstances.

In addition, a tracer particle study was proposed to evaluate the effectiveness of dilution ventilation in reducing health care worker exposure intensity to *Mtb* aerosol in AFB isolation rooms. The relevance of CDC's dilution ventilation ("air changes per hour") criterion in reducing exposure to *Mtb* aerosol was to be explored through a study of the rate of contaminant removal in three locations in an isolation room: (1) at the health care worker breathing zone level about three feet from the aerosol release point; (2) at the health care worker breathing zone level near the entry door to the room; and (3) at one of the room exhaust air grilles. Although the room *average* concentration of TB aerosol (i.e.; the average of the concentrations at different room locations) should be reduced as the number of nominal ACH are increased, the local concentration of *Mtb* aerosol near the patient (i.e.; in the near field of the source) will be higher than the room average. In imperfectly mixed rooms, the calculated dilution ventilation rate based on measurements taken at supply diffusers and exhaust grilles tends to overestimate the dilution ventilation rate actually achieved in the zone of occupancy, and thereby underestimates the concentration of infectious particles in the health care worker breathing zone.

A pilot study was conducted by Dr. Shelly Miller, Department of Mechanical Engineering, University of Colorado, Bolder, CO. Dr. Miller used a test chamber and carbon dioxide as a tracer gas. The inconsistency of the results indicated that the study protocol would require significant resources to develop a field method capable of addressing this issue. Therefore, no further work on the tracer gas study was performed.

ORIGINAL PROGRAM OBJECTIVE 8: MAKE RECOMMENDATIONS TO MAXIMIZE COMPLIANCE WITH CURRENT CDC GUIDELINES

Participating hospitals received recommendations to maximize compliance with 1994 CDC Guidelines. Recommendations were developed and disseminated through on-going collaboration with staff from infection control, environmental health, employee health, and labor representatives at participating hospitals. Hospital specific written progress reports, including recommendations to strengthen adherence to CDC Guidelines, were provided to each hospital (attachments 4, 8 and 9). Results of the completed assessments were also disseminated to hospital staff through presentations at regularly scheduled staff meetings. Health Care Worker project staff also provided extensive technical assistance regarding recommendations for maximizing compliance with CDC Guidelines to other institutions upon request (for example, see attachment 11).

Project results and recommendations were disseminated in more than 30 presentations, including at the American Public Health Association (1995,1996, 1997, and submitted for 1999), and the American Industrial Hygiene Association meeting (May 1997). Study results to date were published in the peer-reviewed literature as a chapter entitled, *"Implementing a Quality Assurance Project for Tuberculosis Control"*, in, "Handbook of Modern Hospital Safety", edited by William Charney (1999) (attachment 6), and in three articles in *Infection Control and Hospital Epidemiology* (1998, 1999, 1999) (attachments 5 and 7).

The experience of and recommendations from the Health Care Workers project formed the basis of protocols, case studies, and recommendations in a statewide training of all Cal-OSHA compliance officers (attachment 10). Project staff collaborated with the California Division of Industrial Relations in the development and implementation of a three day course on compliance with CDC recommendations and Cal-OSHA enforcement guidelines in high-risk institutions. The goal of the course was to train all Cal-OSHA compliance officers about occupational TB to improve their ability to knowledgeably conduct inspections in hospitals, correctional facilities and other high-risk institutions.

TB in Health Care Workers project staff also collaborated with staff from the Francis J. Curry National Tuberculosis Center in the planning and conducting a TB training for physicians, and in two statewide training for the California Department of Corrections' health care staff. CDHS study findings and recommendations were also disseminated at public hearings and in the submission of extensive written comments related to the proposed federal OSHA TB Standard (attachment 13).

The final results of this study will be reported to hospital administration, employee health and infection control staff, employees and employee representatives, and other interested parties.

Study findings and recommendations:

⇒ Fully implement CDC Guidelines if all health care workers are to be protected

There was a significant risk of newly acquired TB infection among health care workers at all hospitals. CDHS found that on average, one in every four initially non-infected health care workers (26%) at participating hospitals would become infected with TB over the course of their working lifetime (45 years).* Annual newly-acquired TB infection rates during the three-year surveillance period from 1995 to 1997 were 0% to 1.05%, which corresponds to a zero to 38% cumulative infection risk over a working lifetime. All workers physically located at the hospital were at risk of exposure. None of the hospitals completely adhered to CDC's recommended exposure control measures. A lapse in one control measure led to potential *Mtb* aerosol exposures even when another control measure was present, because different controls were geared towards protecting different groups of health care workers. Avoidable health care worker exposures should be prevented. A comprehensive, multi-pronged approach, such as specified in CDC Guidelines, should be fully implemented if all health care workers are to be protected.

⇒ TB skin test, at least annually, all workers physically located at a building where health care services are provided

The retrospective tracking of the room location of every TB inpatient (N=54) at one hospital over a one-year period found that all workers physically located at the hospital were at risk of exposure. Workers on wards that cared for large numbers of TB patients were subject to uncontrolled sources of *Mtb* aerosol exposure, even if there was good adherence to patient isolation guidelines on the ward. Workers located on wards having no isolation rooms had considerable potential for exposure. In other words, the absence of TB isolation rooms on a ward cannot be equated with the absence of exposure. The findings indicate significant cumulative risk of exposure for individuals who work on a variety of inpatient wards even if the time spent on any one ward is limited.

---

* The three-year average TST conversion rate over all three participating hospitals was 0.66% (76/11,519). A standard probability calculation shows that a 0.66% annual TB infection risk acting over a 45-year working lifetime produces a 26% cumulative infection risk, or: $1-(1-0.0066)^{45})=0.26$.

⇒ Implement quality assurance protocols

There were discrepancies between written TB control policies and actual hospital practices. Health care workers, including those who have no direct patient contact, can incur unrecognized exposures to *Mtb* aerosol during routine hospital operations. Factors contributing to unrecognized exposures were: (1) imperfect containment of *Mtb* aerosol in isolation rooms due to lack of negative pressure. Overall, 11% of 154 patient-room units mechanically capable of providing negative-pressure at one point in time were not under negative-pressure at the time of use for TB patient isolation; (2) failure to ensure the performance of retrofitted or newly designed engineering controls before use; (3) failure to validate the basic assumptions of the TB control plan, such as the risk assessment; and (4) improper use of respirators by health care workers. Prospectively quantifying the implementation of a hospital TB isolation policy while the room is in use may lead to improved estimates of risk and may help identify and thereby prevent avoidable worker exposures to *Mtb* aerosol.

⇒ Improve TST practices and protocols

At two facilities, the validity and reliability of hospital generated TST surveillance data was initially poor. Quality assurance data indicated notable problems with PPD storage and handling procedures, record keeping, TST interpretation and reading, incomplete clinical documentation and results not recorded in mm of induration. At one hospital, data for TST was missing for 25% of the active employees identified through payroll files. A review of a sub-sample of those individuals without TST data found that missing charts, poorly documented or missing TST history in charts, and data entry oversight accounted for the missing data. The risk of TST conversion may have been underestimated due to: (1) the exclusion of potential converters due to missing TST documentation and, (2) increased likelihood of negative TST results due to poor test administration and interpretation practices. A standardized protocol for TST should be developed and implemented to ensure correct and consistent application, interpretation, and documentation of TSTs.

⇒ Increase resources, accountability and authority of staff responsible for TST program implementation

One participating hospital, Alta Bates Medical Center, successfully implemented the CDC guidelines for Employee TST Surveillance. Factors which contributed to the high quality of this TST program were: accountable central administration, accountable program implementation by department managers, responsive Information Systems linkage for payroll datafiles, collaboration between Employee Health and Infection Control staff, and routine surveillance data reporting and review. Obstacles to reliable TST surveillance at the other hospitals included: a lack of resources and staff to implement the program, a lack of administrative authority, a failure to fully utilize the TST surveillance software, and a lack of mechanisms to facilitate exchange of payroll or TST data between the hospital and its affiliated university.

⇒ Utilize a computerized database to maintain employee TST data

Employee Health Programs that did not fully utilize computerized systems for employee census and tracking had lower TST compliance than hospitals that did. High quality programs require adequate computer hardware and software, trained clinical staff, and reliable data entry/administrative staff.

⇒ Improve TST compliance by linking Employee Health with payroll data systems

At two hospitals, only about one third to one half of eligible employees received a TB skin test each year (32% to 55%). Compliance with TST was reduced by the difficulty in identifying the work location all TST-eligible persons from available payroll data. Payroll distribution systems could be utilized to notify non-compliant employees whose work location is unknown. Increased linkage and cooperation between Payroll and Information Services and Employee Health may enhance the administration of TST surveillance programs.

⇒ Absent clear evidence to the contrary, presume that newly-acquired health care worker *Mtb* infections are work-related

CDHS noted that there was a tendency among hospitals to characterize TST conversions incurred by workers which could not be "explained" by a known TB patient contact, or by a job title or work location recognized as being associated with TB patient exposure, as non-work related. However, CDHS found that health care workers, including those who have no direct patient contact, can incur unrecognized exposures to *Mtb* aerosol during routine hospital operations. Even following accurate identification of TB patients, health care workers at all three hospitals were potentially exposed to *Mtb* aerosol due to breaches in negative pressure isolation, the limitations of dilution ventilation, the failure to maintain engineering controls, and incomplete implementation of respiratory protection controls. Non-occupational risk factors should be assessed for all newly-infected health care workers. However, in the absence of clear evidence that a TST conversion is non-occupational, CDHS' study findings lend support to OSHA's policy presumption that, in the absence of clear evidence to the contrary, hospital employee health staff should assume that newly-acquired health care worker TB infections are work-related.

⇒ **Ensure an adequate number of negative-pressure isolation rooms and evaluate the need for isolation rooms at all specialized-medical care locations**

Factors which contributed to uncontrolled sources of *Mtb* aerosol exposure at one hospital were an inadequate number of isolation rooms, a lack of isolation rooms in specialized care areas, and unrecognized TB. Seasonal peaks, not yearly averages of the number of suspect and known TB patients at the hospital, should be considered when anticipating the total number of isolation rooms needed.

⇒ **Maintain engineering controls**

Numerous, persistent failures in engineering controls were identified in all hospitals. None of the hospitals regularly checked the performance of engineering controls. Regularly scheduled monitoring and maintenance of engineering controls are essential to TB control efforts.

⇒ **Routinely verify the reliability of continuous monitoring devices with other qualitative or quantitative measures of negative pressure**

Continuous monitoring devices did not accurately reflect the direction of air flow in 12% of 67 patient-room units equipped with these warning systems. The installation of continuous monitoring devices does not obviate the need for initial testing and routine maintenance of ventilation systems. Moreover, although the efficacy of continuous monitoring devices is predicated on the alarm initiating a coordinated and timely response by engineering, infection control, nursing and medical staff, no written procedures or training regarding how to respond to the alarming or malfunctioning of these devices were provided to hospital staff. Policy and procedures for responding to the negative-pressure alarm system should be written, and training should be provided to affected-staff so the policy can be reliably implemented.

⇒ Implement a comprehensive respiratory protection program for TB that emphasizes the importance of a well-fitted respirator

Routine use of NIOSH-approved, N95 disposable respirators for TB was initiated at two hospitals during the course of the study. Only one of these hospitals required that a health care worker's respirator fit properly. The third hospital used disposable, dust/mist masks, and the hospital did not provide comprehensive training and fit-testing as required by federal and state regulation. At all three hospitals, although some type of respiratory protection for TB was widely available and used by health care workers, almost two of every three health care workers observed wearing a respirator (40/62) did not don their respirator properly when entering a TB isolation room. Respirators that do not fit or are worn improperly will allow *Mtb* aerosol to leak into the face piece regardless of the filter medium's ability to remove 1 μm particles.

⇒ Routinely use a higher-level of respiratory protection such as a powered-air purifying particulate respirator during autopsy

CDC Guidelines regarding the use of respiratory protection to control exposure to *Mtb* aerosol during autopsy should be more protective. In the case of autopsy and other high-risk procedures, CDC recommends that a higher-level of respiratory protection be implemented only <u>after</u> *Mtb* disease is suspected. However, the routine use of a high level of respiratory protection such as a powered air-purifying particulate respirator (PAPR) is advisable during autopsy because: (i) estimates of the percentage of cases of TB identified at autopsy that have not been diagnosed at the time of death range from 16% to 50%; (ii) a high concentration of *Mtb* aerosol can be generated at autopsy; and (iii) a high risk of infectious disease transmission is associated with autopsy.

⇒ Include health care workers in TB decision-making

Although workers in "hands on" jobs are often in the best position to observe developing or threatening occupational health problems, labor representatives did not participate in hospital committees with responsibility for TB control. Inclusion of labor representatives on these committees may lead to innovative approaches to exposure control, improve compliance with TB policies and procedures, and may diminish unwarranted employee concerns regarding TB transmission in low-risk situations.

⇒ Improve health care worker training on TB

Health care worker training was an underutilized TB prevention measure. In addition, 78% to 80% of the workers with a TST during the first year of the study reported patient contact and 33% to 42% reported being present during procedures with increased risk of exposure to *Mtb* aerosol. These data indicate that most employees need to have knowledge and training about TB. All employees should receive appropriate training on TB disease, transmission, and exposure control methods.

⇒ Provide comprehensive employee counseling regarding risk

Comprehensive employee counseling regarding the risk of active TB disease in immunocompromised health care workers was not routinely provided. As many workers may be reluctant to report or acknowledge their immune status, and immune status might change after hire, comprehensive counseling regarding risks for immunocompromised individuals should be provided to all health care workers.

⇒ Isolate all TB patients in negative-pressure rooms until it has been demonstrated that they are not infectious

In 1996, half of the 54 inpatients who were identified at one hospital as having pulmonary TB were fully isolated and half were not. Most of the 652 TB patient-days were likely contributed by infectious patients. Thirty percent (197/652) of all TB patient-days were unisolated. Isolating all suspect TB patients until they are demonstrated to be non-infectious requires that there be a supply of isolation rooms commensurate with the number of suspect TB patients, and isolation rooms in all specialized care areas.

⇒ Reduce potential exposure to TB through administrative controls such as restricting access to isolation

Of the tested populations during the first year of the study, 78% to 80% reported some level of patient contact and 33% to 42% reported being present during procedures with increased risk of *Mtb* aerosol exposure. The possibility of reducing potential exposure to *Mtb* aerosol through administrative controls (i.e., limiting the number of persons who enter inpatient isolation rooms and who are present during high risk procedures), should be evaluated.

⇒ **Emphasize source control**

Increased TB incidence in the general community may directly increase the number of infectious TB patients receiving care at a hospital, and thereby increase the risk of hospital-acquired TB. Primary prevention of health care worker exposure to *Mtb* aerosol at hospitals is contingent upon the success of TB prevention measures undertaken by local public health jurisdictions. Full implementation of the CDC Guidelines should be complimented by active support by hospital administrators for the expansion of TB prevention efforts undertaken by local public health agencies, such as directly observed therapy, improved access to medical care, and the provision of housing for homeless TB patients.

LIST OF TABLES AND FIGURES

LIST OF ATTACHMENTS

1. Employee TB Surveillance Questionnaires

2. Protocol for Evaluating Adherence to CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Facilities

3. TB Program Quality Assurance Protocols and Forms

4. Results of Assessments of Adherence to CDC Guidelines at Alta Bates Medical Center, San Francisco General Hospital, and Highland Hospital

5. Sutton PM, Nicas M, Reinisch F, Harrison R. Evaluating the control of Tuberculosis among healthcare workers: Adherence to CDC Guidelines of three urban hospitals in California. *Infection Control and Hospital Epidemiology*. 1998;19:487-493.

   Sutton PM, Nicas M, Reinisch F, Harrison R. Is a Tuberculosis exposure a Tuberculosis exposure if no one is infected? *Infection Control and Hospital Epidemiology*. 1999;20:92-94.

6. Sutton PM, Nicas M, Harrison R. Implementing a Quality Assurance Project for Tuberculosis Control. In Handbook of Modern Hospital Safety, William Charney, ed. 1999.

7. Sutton PM, Nicas M, Harrison R. Preventing healthcare worker exposure to *mycobacterium tuberculosis* aerosol: a quality assurance study to assess implementation of hospital tuberculosis control measures. Accepted for publication *Infection Control and Hospital Epidemiology* 1999.

8. Isolation of Tuberculosis Patients At San Francisco General Hospital in 1996. Report to SFGH March 1999

9. Employee Tuberculin Skin Test Surveillance Data 1995 –1997 and Employee Tuberculin Skin Test Quality Asssurence Reports: Alta Bates Medical Center, San Francisco General Hospital, Highland Hospital

10. Examples of training materials developed by TB in Health Care Workers Project

11. Example of CDHS technical assistance: a CDHS report of an evaluation of TB control measures at a County TB clinic

12. List of Health Care Worker Project staff trainings, presentations, and publications

13. CDHS written comments on OSHA's proposed TB Standard

```
GMISP125          THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM            03/23/00
GMISM035                       GRANT AWARD RECORD                          13:43
AH07AH00                       ( SCREEN NO.1 )

AWARD NO........:  910074   PROGRAM CODE......: U50   AWARD DATE.: 09/24/1993
CRS EIN..: 1-941646278-A1   AWARD TYPE..........: C   FED CAT NO.....: 93.283
CIO CODE..........: NIOSH   OBJ CLASS.......: 41.51   PHS LIST NO: CR-322-V98
PROJ PER FROM: 09/30/1993   PROJ PER TO: 03/31/1999   ANNOUNCEMENT NO.: 93058
PREV AWARD NO:              PROGRAM CATEGORY...: 20   FC CODE............:
PROJECT NAME:          AUTHORIZATION: OSHA SEC 20 PHSA SEC 301(A) AND 317
 OCCUPATIONALLY RELATED TB AND TB INFECTION IN HEALTH-CARE WORKERS
         GRANTEE NAME...: CALIFORNIA PUBLIC HEALTH FOUNDATION
         BUSINESS OFFICE: CONTRACT & GRANTS ADMINISTRATOR
         STREET.........: 2001 ADDISON STREET, #210
         CITY...........: BERKELEY
         STATE: CA   ZIP CODE: 94704-1103     PHONE:( 510 ) 644-8200 -

         PROJ DIRECTOR..: ROBERT HARRISON, CHIEF
         DEPARTMENT.....: OCCUPATIONAL HEALTH & SURVEILLANCE SECT.
         STREET.........: 2151 BERKELEY WAY ANNEX #11
         CITY...........: BERKELEY
         STATE: CA   ZIP CODE: 94704-1103     PHONE:( 510 ) 540-2189 -
      DISPLAY        PF10-RETURN GRANT AWARD MENU       PF16-MAIN MENU
```

GMISP125 THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM 03/23/00
GMISM036 GRANT AWARD RECORD 13:43
AH07AH00 (SCREEN NO.2)

AWARD NO.: 910074 SPECIALIST CODE:......... SH CONG DISTRICT:...... 8
PMS PAY CODE:... P INSTITUTION CODE:.... 1618201 ORG DESCRIPTORS: 3--260
ETHNIC CODE:.... 9 PMS CLOSEOUT DATE:
CLOSEOUT FIRST LETTER DATE: CONTAINS RESEARCH ACTIVITY(S):

GRANTS MANAGEMENT OFFICER:.. LISA T. GARBARINO
PROJECT OFFICER:............ JOHN PARKER, M.D.
PROJECT OFFICER TITLE:......

REMARKS:
6-MONTH NO-COST EXTENSION W/USE OF U/O FOR $11,561 FROM THE 03 YEAR

FOOTNOTES:
ATTACHED:
HUMAN EXEMPTION: IRB DATE: IRB DUE DATE:

DISPLAY PF10-RETURN GRANT AWARD MENU PF16-MAIN MENU

```
GMISP125       THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM         03/23/00
GMISM037                    GRANT AWARD RECORD                       13:43
AH07AH00                    ( SCREEN NO.3 )

 AWARD NO: 910074            YEAR.....: 5               FISCAL YEAR......: 1997
 ACTION TYPE...: 4           AMEND NO.: 1               ACTION DATE: 09/23/1998

 APPROVED BUDGET (1):        GRANT FUNDS ONLY (Y/N): Y
          SALARIES WAGES.............:    120,764
          FRINGE BENEFITS............:     32,607
          TOTAL PERSONNEL COSTS...:       153,371
          CONSULTANT COSTS...........:     12,000
          EQUIPMENT..................:
          SUPPLIES...................:      2,114
          TRAVEL.....................:      4,250
          OTHER......................:     27,074
          CONTRACTUAL COSTS..........:     24,778
          TRAINEE EXPENSES...........:
          TRAINEE STIPENDS...........:
          TRAINEE TUITION & FEES.....:
          TRAINEE TRAVEL.............:
          TOTAL DIRECT COSTS (FA):        223,587
     DISPLAY       PF10-RETURN GRANT AWARD MENU        PF16-MAIN MENU
```

GMISP125 THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM 03/23/00
GMISM125 GRANT AWARD RECORD 13:43
AH07AH00 (SCREEN NO.4)

AWARD NO: 910074 YEAR.....: 5 FISCAL YEAR......: 1997
ACTION TYPE...: 4 AMEND NO.: 1 ACTION DATE: 09/23/1998

APPROVED BUDGET (2):

INDIRECT COST RATE...............:	18.9000
INDIRECT COST RATE CODE..........:	G
INDIRECT COSTS (FA)..............:	35,389
SBIR FEE.........................:	
TOTAL APPROVED BUDGET.........:	258,976
NON FEDERAL SHARE.............:	

AWARD COMPUTATION FOR GRANT:

FED SHARE/PHS ASSISTANCE.....:	258,976
UNOB FINANCIAL ASSISTANCE....:	83,976
CUM PRIOR AWARD THIS BUD (FA):	175,000
AMOUNT THIS ACTION (FA).....:	

DISPLAY PF10-RETURN GRANT AWARD MENU PF16-MAIN MENU

```
GMISP125        THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM          03/23/00
GMISM101                     GRANT AWARD RECORD                       13:43
AH07AH00                     ( SCREEN NO.5 )

   AWARD NO: 910074             YEAR: 5                 FISCAL YEAR: 1997

   APPROVED DIRECT ASSISTANCE BUDGET:

          PERSONAL SERVICE.............:
          TRAVEL.......................:
          VACCINE......................:
          OTHER........................:
          OTHER DESCRIPTON:
          TOTAL DIRECT COSTS (DA)..:
          UNOB DIRECT ASSISTANCE...:
          CUM PRIOR AWARD THIS BUD (DA):
          AMOUT THIS ACTION (DA)......:

          COMPETITIVE ACTION (Y/N): N

    DISPLAY         PF10-RETURN GRANT AWARD MENU          PF16-MAIN MENU
```

AWARD NO: 910074 YEAR: 5
UNOBLIGATED AMOUNT: 83,976

UNOB YEAR FROM	UNOB AMOUNT
2	43,260.00
3	29,155.00
2	0.53
3	11,560.47

PF10-RETURN GRANT AWARD MENU PF16-MAIN MENU

GMISP125 THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM 03/23/00
GMISM110 GRANT AWARD RECORD 13:43
AH07AH00 (SCREEN NO.6)

AWARD NO.:....... 910074 YEAR:.............. 5 FISCAL YEAR:...: 1997

CAN AWARD DATE	ALLOW CODE	FY-CAN	AMT FIN ASSIST	AMT DIR ASSIST
07/09/1997	A492V	7-9278159	175,000	
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		
		-		

DISPLAY PF10-RETURN GRANT AWARD MENU PF16-MAIN MENU

```
GMISP125          THE CDC GRANTS MANAGEMENT INFORMATION SYSTEM                03/23/00
GMISM038                               GRANT AWARD RECORD                          13:43
AH07AH00                               ( SCREEN NO.7 )

AWARD NO.:....... 910074     YEAR:............... 5      FISCAL YEAR:...: 1997
BUD PER FROM:. 09/30/1997    BUD PER TO:. 03/31/1999    PROGRAM INCOME:.... B
PROJ PER FROM: 09/30/1993    PROJ PER TO: 03/31/1999
RECOMMENDED FUTURE SUPPORT:
 YEAR  TOTAL DIRECT COST   YEAR  TOTAL DIRECT COST    YEAR  TOTAL DIRECT COST


 FREQ     REPORT       DUE DATE       REC DATE       LTR 1 DATE      LTR 2 DATE
          FSR          06/30/1999
  S       PRO REP1     04/30/1998     07/07/1998
          PRO REP2     04/30/1999
          PRO REP3
          PRO REP4
          PRO REP5
          PRO REP6
          PRO REP7
          PRO REP8
      DISPLAY            PF10-RETURN GRANT AWARD MENU        PF16-MAIN MENU
```