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SUMMARY

A health hazard evaluation (HHE) was conducted by the National Institute for Occupational Safety and Health (NIOSH) at Jackson Memorial Hospital in Miami, Florida, in response to an employee request to assess nosocomial transmission of tuberculosis (TB) in health care workers. NIOSH investigators evaluated (1) the risk of tuberculin skin test (TST) conversion in employees exposed to patients with infectious TB, (2) adequacy of ventilation in areas of the hospital where patients with infectious TB are treated, (3) potential for exposure to aerosolized pentamidine isethionate (AP) and to *Mycobacterium tuberculosis* in workers who administer AP, and (4) potential for overexposure to ultraviolet (UV) irradiation from germicidal UV lamps.

A cohort analysis showed that employees who worked on wards where patients with infectious TB were cared for ("exposed") had a higher 4-year rate of TST conversion (14.5%) than employees who worked on wards with no such patients ("unexposed") (1.4%) (adjusted relative risk, 13.4; 95% confidence interval, 5.1 to 35.2). Exposed employees had significantly higher rates of TST conversion than unexposed employees for each year during 1989-91, but not for 1992. Among the exposed, ward clerks had a rate of TST conversion (15.6%) only slightly lower than that of nurses (18.2%).

Workers who administered AP treatments to patients had no greater symptom prevalence or rate of TST conversion than other workers. However, exposure to pentamidine at the time of the NIOSH visit was reportedly lower than at the time the HHE request was submitted due to engineering interventions by hospital personnel.

Ventilation was evaluated in hospital rooms and other areas used for treating patients with infectious TB. Some isolation rooms and areas did not meet the Centers for Disease Control and Prevention or American Society of Heating, Refrigerating, and Air-conditioning Engineers general ventilation criteria. Rooms in the Urgent Care Clinic were found to be unsuitable for use as isolation rooms because the air from the rooms was recirculated and not exhausted to the outside.

UV lamps had been purchased for use in the hospital, but had not been activated due to employee concerns about UV exposure. Upon activation during the NIOSH visit, UV radiation levels were found to exceed the NIOSH and the American Conference of Governmental Industrial Hygienist's criteria for 8-hour exposure in nearly every room evaluated.

Employees who worked in areas where patients with active tuberculosis (TB) were cared for, including workers who did not provide direct patient care, had a higher rate of tuberculin skin test conversion than employees who did not work in these areas. A decline in this elevated risk was seen over time. Some hospital areas where patients with infectious TB are cared for had inadequate ventilation. Workers who administered aerosolized pentamidine isethionate treatments to patients had no increase in symptoms or risk of TB infection over workers who did not administer these treatments. The potential for overexposure to ultraviolet irradiation exists for those who work around functioning ultraviolet lamps. Recommendations addressing each of these issues are provided in section X of this report.

KEYWORDS: SIC 8062 (General Medical and Surgical Hospitals), *Mycobacterium tuberculosis*, tuberculosis, TB, pentamidine isethionate, aerosolized pharmaceuticals, respirators, ventilation system, aerosol containment system, health care workers, ultraviolet radiation, germicidal lamps.

INTRODUCTION

In 1990, the Division of Tuberculosis Control, National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC) conducted an investigation at Jackson Memorial Hospital (JMH) in Miami, Florida, to evaluate risk factors for tuberculosis (TB) infection in patients with multiple-drug-resistant tuberculosis (MDR-TB). Technical assistance was provided by personnel from the National Institute for Occupational Safety and Health (NIOSH). The CDC study found that employees working in certain areas of the hospital had higher rates of tuberculin skin test (TST) conversion than employees in other work areas. Recommendations to reduce the potential for nosocomial TB infection were provided by NCID and NIOSH.^{1,2} Health care workers (HCWs) continued to convert from negative to positive TSTs, however, and in April 1991, NIOSH received an employee request to evaluate occupational TB exposures, as well as related exposures to aerosolized pentamidine isethionate (AP) and ultraviolet (UV) germicidal irradiation. NIOSH investigators conducted site visits to JMH in May, June, July, September, and November 1991, and March 1992. Information and recommendations resulting from those visits were provided in letters as the investigation proceeded. This report summarizes all of the information contained in those letters, as well as the most recent findings and recommendations.

BACKGROUND

JMH is a 1500-bed general medical facility located in Miami, Florida. It is the primary public hospital for Dade County and the main teaching hospital for the University of Miami School of Medicine. JMH is one of the busiest hospitals in the United States. During the 1989-90 fiscal year, more than 66,000 patients were admitted, there were over 300,000 outpatient visits, and approximately 108,000 persons were seen at the Emergency Care Center. The hospital employs about 7000 persons, including approximately 450 house-staff.

TUBERCULOSIS

TB is an infectious disease caused by the bacterium *Mycobacterium tuberculosis*. *M. tuberculosis* is carried in airborne particles, known as droplet nuclei, that can be generated when persons with TB of the lungs or throat cough, sneeze, or speak. The droplet nuclei are so small (1-5 microns) that normal air currents keep them airborne and can spread them throughout a room or building. Infection occurs when a person inhales aerosolized* *M. tuberculosis* and the bacteria become established in the alveoli of the lungs and spread throughout the body.³ Within

* "Aerosolized" refers to the dispersion of aerosols. The aerosols of interest in this report are droplet nuclei that may contain *M. tuberculosis*.

2-10 weeks, the immune system is typically able to prevent further multiplication and spread of the bacteria. At this point, a person will usually have a positive TST.

Because infection requires the inhalation of aerosolized *M. tuberculosis*, the probability that a person will become infected depends upon the concentration of infectious droplet nuclei in the air. The actual dose required to initiate infection is not known. Environmental factors that enhance transmission include: the sharing of a relatively small, enclosed space by uninfected persons and an infectious person; inadequate ventilation that results in insufficient dilution or removal of infectious droplet nuclei; and recirculation of air containing infectious droplet nuclei.³

Most persons infected with TB will never have symptoms from this infection. The bacteria will be contained by the immune system and cause no overt illness. In a small proportion of infected persons, the initial infection develops into "active" TB disease. When a patient develops active pulmonary TB, the infection destroys lung tissue as it grows, forming a cavity. When the cavity erodes into an airway, infectious material (which includes live *M. tuberculosis* bacteria) in the airway causes the patient to cough, which can aerosolize *M. tuberculosis*. Cough is the predominant symptom associated with active TB disease. Fever, weight loss and fatigue may also be present. Infected persons are more likely to develop active disease if they experience physical or emotional stress, or if they become immunocompromised as can occur with human immunodeficiency virus (HIV) infection. To decrease the chance of developing active disease once infected, the CDC recommends that all persons with positive TSTs be evaluated for preventive drug therapy.⁴

Since 1984, cases of active TB have been increasing in this country. This increase is thought to be associated with the epidemic of HIV infection, increased immigration from countries where TB is common, and outbreaks of TB in high-risk environments. Populations in the United States known to have a high incidence of TB include:

- medically underserved low-income populations including racial or ethnic minorities (African Americans, Hispanics, Asians/Pacific Islanders, and Native Americans/Alaskan Natives);
- residents of correctional institutions, mental institutions, nursing homes, and other long-term residential facilities;
- persons living under crowded conditions;
- alcoholics and intravenous drug users;
- the homeless;
- the elderly;

- foreign-born persons from areas of the world with a high prevalence of TB;
- immunocompromised individuals such as those infected with the HIV virus;
- and persons living in the same household as members of these high risk groups.^{5,6,7}

Workers who have close contact with individuals with unsuspected TB may have an increased risk of acquiring TB infection.^{3,8}

GUIDELINES FOR CONTROLLING OCCUPATIONAL TRANSMISSION OF TUBERCULOSIS

In October 1994, the CDC published updated guidelines for controlling transmission of TB.³ TB infection-control programs should be based on a hierarchy of control measures. The first level of the hierarchy is administrative control, including (1) developing and implementing a written plan to ensure rapid identification, isolation, and effective treatment of persons who have active TB, (2) implementing effective work practices, (3) training and counseling workers about TB, and (4) screening workers for TB infection and disease. The second level of the hierarchy is the use of engineering controls. These controls may include (1) local exhaust ventilation, (2) directional airflow to prevent dissemination of TB to surrounding areas, (3) dilution and removal of contaminated air, and (4) disinfection of the air by filtration or germicidal UV radiation. The third level of the hierarchy is the use of personal respiratory protective equipment, essential in situations where the first two levels of the hierarchy reduce, but do not eliminate, the possibility of exposure.³

All suggested control measures may reduce a worker's exposure to *M. tuberculosis* to some extent; however, there are no currently-available methods to quantify the degree of reduction that may be achieved by each control measure.

In October 1993, the Occupational Safety and Health Administration (OSHA) issued enforcement guidelines concerning occupational exposure to TB.⁹ Workplaces covered by the OSHA guidelines are those where the CDC has identified workers as having an elevated incidence of TB infection. These include health care settings, correctional institutions, homeless shelters, drug treatment centers and long-term care facilities for the elderly. The OSHA guidelines are based on 1990 CDC guidelines for preventing TB in health-care facilities.^{8,10}

NIOSH representatives provided information about particulate respirators (PRs) to JMH employee and management representatives at an in-service program held September 25, 1991. The focus of the discussion was the use of PRs to reduce the potential for exposure to TB-containing droplet nuclei. Since this in-service, CDC and NIOSH recommendations for respiratory protection for TB have been updated. Detailed information on respiratory protection can be found in "Supplement 4: Respiratory Protection" in **Guidelines for Preventing the Transmission of *Mycobacterium tuberculosis* in Health-Care Facilities, 1994.**³

PRs were originally designed to protect workers from harmful atmospheres in industrial environments. Although data regarding the effectiveness of respiratory protection from many hazardous airborne materials have been collected, the precise level of effectiveness in protecting workers from *M. tuberculosis* transmission in health care settings has not been determined. Standard surgical masks may not effectively prevent inhalation of droplet nuclei, because some do not provide an effective face-seal or are made of materials that may not filter particulates the size of droplet nuclei (1-5 microns).³ Engineering controls (i.e., ventilation measures) and administrative measures (e.g., isolation procedures, early identification and treatment of TB patients) are preferable methods to control exposures to droplet nuclei. Respirators should be used when these control methods are not feasible or when they are not fully effective.

Whenever personal respiratory protection is necessary to protect health-care-facility workers potentially exposed to TB, an effective program must be developed, implemented, administered, and periodically reevaluated. All respiratory protection programs must contain at least the following eight elements: written standard operating procedures; medical surveillance; training; face-seal fit testing; respirator inspection, cleaning, maintenance, and storage; surveillance of the health care facility and worker exposures; respirator selection; and periodic evaluation of the personal respiratory protection program.^{11,12} To be effective, such a program must be supervised by a qualified individual who has sufficient knowledge of respiratory protection.

The OSHA respiratory protection standard requires that all respiratory protective devices used in the workplace be certified by NIOSH. Until recently, NIOSH-approved high-efficiency particulate air (HEPA) respirators (including disposables) were the only available air-purifying respirators that met the CDC recommended performance criteria for TB droplet nuclei. Effective July 10, 1995, NIOSH certification procedures were revised, allowing certification of three new categories of filters.¹³ The new filters are designated the N-, R-, and P-series, with three levels of filter efficiency, 95%, 99%, and 99.97%, in each series. All nine classes of air-purifying, particulate respirators to be certified under the provisions of the new filter tests will exceed the performance recommendations contained in the CDC guidelines.³ Several of these new classes of air-purifying, particulate respirators are expected to be less expensive than respirators with HEPA filters.

NIOSH EPIDEMIOLOGIC STUDY

We designed a retrospective cohort study to determine whether the risk of TB infection, as evidenced by a conversion from a negative to a positive TST, is significantly greater for HCWs who work on wards having patients with infectious TB than for HCWs who work on wards without such patients.

A. Background

The numbers of patients hospitalized with TB during each year of our study period (January 1, 1989, through December 31, 1992) were 338 (18 MDR-TB), 339 (44 MDR-TB), 200 (10 MDR-TB), and 197 (9 MDR-TB), respectively. A nosocomial outbreak of MDR-TB occurred in patients on the human immunodeficiency virus (HIV) ward between March 1988 and September 1990.¹⁴ Hospital personnel recognized the outbreak in February 1990 and began implementing new TB infection control measures throughout the hospital. These were incorporated to varying extents during our study period (Figure 1).

Figure 1
Time-line of TB Control Measures Implemented During Study Period
Jackson Memorial Hospital, Miami, Florida, HETA 91-187

1/89	Study Period Begins
3/90	Drug Therapy Modified Isolation Improved Worker Education Improved
4/90	Ventilation System Testing Begins
6/90	Revised Pentamidine Procedures
9/90	*New Particulate Respirator Introduced
1/91	Emerson Booths Installed
9/91	UV Lights Activated
12/92	End of Study Period
*Aseptex 3M 1812 submicron molded surgical masks.	

B. Methods

Hospital personnel provided a copy of the microbiology laboratory's computer file of positive *M. tuberculosis* cultures for January 1988 through December 1989. To limit the study to personnel with exposures to patients with the highest infectious potential, we considered only those cultures that came from a pulmonary or laryngeal site. Thirty-seven wards had submitted at least one such culture during 1988-89. We chose to focus our study on wards that had submitted 15 or more of these cultures during this two-year period in order to maximize the potential for employee exposure. These "exposed" wards included the Medical Intensive Care Unit (18 cultures), five Medicine wards (32, 45, 108, 115, and 121 cultures, respectively), and the Emergency Room (108 cultures).

Wards with no positive cultures during 1988-89 were considered "non-exposed." All of the non-exposed wards whose employees had age and race characteristics similar to employees from the exposed wards were chosen for the study. These wards included Post Partum, Labor and Delivery, Newborn Intensive Care Unit, Newborn Intermediate Care Unit, and Well Newborn.

Persons eligible for inclusion in the study were those full-time employees listed in the computerized hospital payroll data base either as working on one of the exposed or unexposed wards at the time the wards were being chosen (May 31, 1991), or as having left employment at JMH any time between January 1, 1989 (the beginning of our study period), and May 31, 1991, while working on one of those wards.

We followed this cohort of employees through December 1992 to assess the rates of TST conversion during the changing conditions at the hospital, including the termination of the outbreak of MDR-TB and implementation of TB infection control measures. The microbiology laboratory culture data for 1990-92 showed that the exposed wards continued to submit cultures positive for *M. tuberculosis*, and the non-exposed wards submitted no cultures positive for *M. tuberculosis* through 1992.

TSTs were administered, evaluated, and recorded in the employee's health record by the JMH Employee Health Office (EHO) staff. A TST result was recorded as positive if there was a reaction at 48-72 hours of 10 mm or greater to a Mantoux skin test using 5 tuberculin units of purified protein derivative (PPD) tuberculin. Positive results were verified by one of the EHO staff. Any TST reaction of less than 10 mm was recorded as negative; however, *size* of reactions less than 10 mm was not recorded. In addition, employees were instructed as to the signs of a positive test and, because EHO staff resources were limited, told that they needn't return if there was no reaction. Skin tests were therefore also recorded as negative in the health record for those who did not return for TST assessment within 48-72 hours.

Skin testing was performed approximately once every four months on employees on the exposed wards, and once per year on employees on the unexposed wards. During our study period, the hospital changed its policy for workers who had received Bacillus of Calmette-Guérin (BCG)

vaccine. Before fall 1990, TSTs were not given to BCG vaccine recipients; after that, they were given only if at least seven years had elapsed since the last BCG vaccination.

We defined a TST converter as any person whose employee health record documented a positive TST result and a previous negative TST result during the study period. Since conversion could have occurred any time between the positive and prior negative TST, a random date between the negative and positive result dates was assigned using a computerized random-date generator with all dates during the period having an equal probability of selection. This random date was used as the date of conversion for our analyses.

Characteristics of the study population, including age, race, gender, and hourly wage, were obtained from the hospital's computerized personnel records. Work histories from the personnel department were directly reviewed to determine the time period of employment at the hospital, the ward or wards on which employees worked during the study period, and the employee's job title.

C. Results

There were 1371 employees listed in the hospital's payroll data base as having worked on one of the wards chosen for the study. Of these, 590 worked exclusively on exposed wards, and 704 worked exclusively on unexposed wards during the study period; these employees did not move between wards within their exposure category. Seventy-seven employees, who worked on both exposed and unexposed wards, were excluded from the study.

We excluded 132 (22.4%) of the 590 exposed employees because they had a positive TST prior to the beginning of the study period or at the time they were hired, if hired during the study period. We also excluded 69 employees (11.7%) for whom we were unable to obtain a detailed work history, and 140 people (23.7%) who had received BCG vaccination. The remaining 249 exposed workers were included in the data analysis.

We excluded 130 (18.5%) of the 704 unexposed employees because they were TST positive at entry, 82 (11.7%) for whom there was no work history available, and 137 (19.5%) because they had received vaccination with BCG. The remaining 355 unexposed employees were included in the data analysis.

There were significantly fewer females and significantly more whites (than nonwhites) in the exposed group (Table 1, next page). Although hospital personnel recorded the TST as negative if individuals did not return to the Employee Health Office for evaluation, the proportion of employees with an evaluated PPD reaction was similar in the exposed and unexposed employees; the characteristic "PPD Read" in Table 1 refers to this variable.

<p align="center">Table 1 Characteristics of the Exposed and Unexposed Employees Jackson Memorial Hospital, Miami, Florida HETA 91-0187</p>		
Characteristic	Exposed (N=249)	Unexposed (N=355)
Female (%)*	79.5	94.7
Age (Mean ± SD), years	37.3 ± 8.7	40.5 ± 9.7
Race (%)		
White **	43.4	35.5
Black	36.1	47.9
Other	20.5	16.6
Wage (Mean ± SD), \$/hr	14.0 ± 5.0	14.9 ± 5.3
PPD Read (%)	41.2	45.9
<p>*P < .05 **P = .05</p>		

The cumulative incidence of TST conversion was significantly higher in the exposed than in the unexposed group (36/249 [14.5%] vs. 5/355 [1.4%], relative risk, 10.3; 95% confidence interval, 4.1 to 25.8). After adjustment for age, race, gender, and salary, the relative risk was 13.4 (95% confidence interval, 5.1 to 35.2). If we excluded employees who worked on the MDR-TB outbreak ward, the cumulative incidence of TST conversion remained significantly higher in the exposed group (31/232 [13.4%] vs. 5/355 [1.4%], relative risk, 9.6; 95% confidence interval, 3.8 to 24.4).

Table 2 (next page) shows *annual* rates and relative risks for TST conversion. The relative risk was undefined in 1992 because there were no conversions in the unexposed group during that year.

Table 2 Secular Trend in Health Care Worker Rate of Tuberculin Skin Test Conversion Jackson Memorial Hospital, Miami, Florida HETA 91-0187				
Year	Exposed	Unexposed	RR*	95% CI**
1989	6.2 (13/209)	0.6 (2/324)	10.1	2.3 - 44.2
1990	7.5 (16/212)	0.7 (2/309)	11.7	2.7 - 50.2
1991	3.2 (6/189)	0.4 (1/282)	9.0	1.1 - 73.8
1992	0.6 (1/158)	0 (0/251)	Undefined	Undefined
*Relative Risk **Confidence Interval				

Table 3 shows the rate of TST conversion for nurses and ward clerks. The majority (32/36 [89%]) of the converters in our study were employed in one of these job categories. The other four converters were Emergency Room technicians. They are not included in Table 3 because they worked only in the Emergency Room; therefore there were no employees with the same job title on other exposed wards with whom their risk could be compared.

Table 3 Rate or Tuberculin Skin Test Conversion by Job Title Jackson Memorial Hospital, Miami, Florida HETA 91-0187					
Job Title	Exposed	Unexposed	RR*	95% CI	P - value
Nurse	18.2 (27/148)	1.5 (4/269)	12.3	4.4 - 34.4	P<.001
Ward Clerk	15.6 (5/32)	0 (0/39)	Undefined	Undefined	P<.02**
* Relative Risk **Fisher's Exact Test					

Table 4 shows the risks of TST conversion for nurses and ward clerks according to the ward on which they were employed during the study. In the Emergency Room, ward clerks were nearly three times more likely than nurses to have a TST conversion.

<p align="center">Table 4 Rate of Tuberculin Skin Test Conversion for the Exposed Workers by Job Title and Hospital Location Jackson Memorial Hospital, Miami, Florida HETA 91-0187</p>			
Job Title	Medicine Ward	Emergency Room	Medical Intensive Care Unit
Nurse	32.7 (17.52)	8.3 (5/60)	13.9 (5/36)
Ward Clerk	7.7 (1/13)	22.2 (4/18)	0 (0/1)

D. Discussion

Our data show that nurses and ward clerks who worked in areas where patients with culture-positive TB were cared for had a significantly greater risk of becoming infected with *M. tuberculosis* than nurses and ward clerks who worked in areas where there were no such patients. Prior studies have shown that workers who provide direct patient care were at greater risk for infection than workers who did not provide direct patient care.¹⁵ The high risk in ward clerks in our study was unexpected since these workers are not involved in direct patient care.

In the Emergency Room, the risk of TST conversion for the ward clerks was almost three times higher than for the nurses. Ward clerks in the Emergency Room are responsible for clerical processing of patients after triage, handling specimens for the laboratory, and gathering clothing and valuables from admitted patients. During these interactions, there may have been less strict adherence to infection control measures (such as wearing a disposable particulate respirator) than during typical interactions between nurses and patients.

The decrease in TST conversions over time in the exposed group is encouraging. Several factors may have contributed to this decrease. First, since an outbreak of MDR-TB occurred among hospital patients during the first two years of our study period, the decrease in risk of TST conversion could be due in part to the termination of this outbreak. In addition, the *total* number of TB patients decreased over the course of our study period and this also could have contributed to the decline in TST conversions due to a decrease in the opportunity for exposure.

A second factor that may have contributed to the decreased rate of TST conversion in the exposed group is the implementation of TB infection control measures by the hospital over the course of our study period. Our study was not designed to test the specific impact of individual control measures. Discussion continues regarding the effectiveness of various control measures available to hospitals to reduce transmission of TB. To date, studies demonstrating a decrease in risk of infection coincident with institution of control measures have been unable to separate the various effects of control measures from each other or from the effects of other factors, such as changes in the number and infectiousness of TB patients.

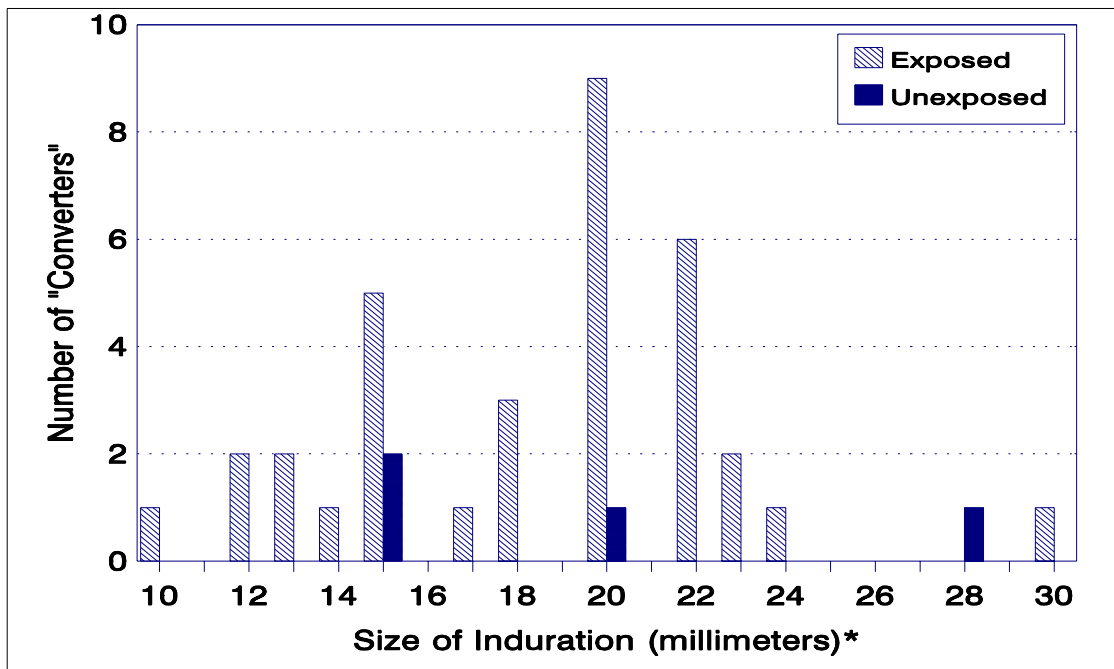
A third factor that may have contributed to the reduced TST conversion rate may be decreased susceptibility to TB infection in some of the individuals in our cohort. Several studies suggest that genetic factors may play a role in resistance to mycobacteria.^{16,17,18,19,20,21} Those employees with a lower resistance may have become infected earlier and then dropped out of the pool of potential TST converters. A less susceptible group of people would have remained, resulting in a decreasing rate of conversion.

Our study has a number of limitations. First, several characteristics of the TST program in place at the hospital during our study period did not meet current CDC recommendations.³ For example, the hospital's definition of a positive TST (any reaction of 10 mm or greater) differed from the current recommendation that only specific *increases* in induration (the magnitude of which depends on a variety of risk factors) be considered evidence of a newly-acquired infection with *M. tuberculosis*, since any lesser increase could be due to "boosting" the immune system's response to a previous infection.^{3,22} Since two-step testing was not performed, and the size of *negative* TSTs was not recorded, the issue of the "booster" phenomenon could not be addressed. However, an analysis of only the TSTs 20 mm or larger (which should eliminate the "boosted" TSTs) revealed that the TST conversion rate was still significantly greater in the exposed than in the unexposed workers (relative risk 13.5; 95% confidence interval, 3.2 to 57.6). Figure 2 (next page) shows the size distribution for the positive TSTs.

A second limitation is that many employees did not have their TST evaluated by a trained individual, and we included these unevaluated TSTs as negative in our analyses. If some of these employees had a positive TST, then our results could have underestimated the TST conversion rates in either or both groups.

A third limitation of our study is that TST data were not available for house staff (physicians in residency training programs) or for recipients of BCG vaccine. Therefore, our results do not provide information regarding the occupational TB risk in these groups. The CDC recommends tuberculin skin testing of *all* health-care facility personnel, including those with a history of BCG vaccination.³ As these recommendations are adopted, data on conversion rates in groups such as those missing from our study should become available.

Figure 2
Size of TST Reactions in “Converters”
Jackson Memorial Hospital, Miami, Florida
HETA 91-0187



*Size results missing for 2 exposed and 1 unexposed.

A fourth limitation involves quantifying exposure. The number of positive *M. tuberculosis* cultures submitted from each ward only reflects *potential* for exposure. It is limited in representing *actual* exposure since risk of infection with *M. tuberculosis* is thought to be related, at least in part, to the concentration of airborne organisms and to the duration of exposure.²³ In addition, the number of positive cultures does not necessarily reflect the number of *patients* with *M. tuberculosis* since more than one culture may have been submitted for each patient.

VENTILATION SURVEY

A ventilation evaluation was conducted at JMH on November 4-8, 1991. The objectives of the evaluation were to 1) identify ventilation factors that may contribute to transmission of TB within the hospital, 2) compare ventilation parameters within the hospital to published recommendations and criteria, and 3) provide background data for the NIOSH epidemiologic study.

The areas evaluated included the Special Immunology Clinic (SPIMC), North Wing 3 (NW3), South Wing 5 (SW5), Medical Intensive Care Unit (MICU) on South Wing 4 (SW4), the tuberculosis trailer (TB trailer), Emergency area, Urgent Care Clinic (UCC), West Wing 6 (WW6), West Wing 15 (WW15), the Newborn Intensive Care Unit (NICU), Maternity (East Tower 3A, 3B), and Labor and Delivery (East Tower 4).

A. Evaluation Methods

The volume rate of air flow (in cubic feet per minute [CFM]) was measured in selected areas on specified wards using Shortridge Instruments Model CFM-88 flow-hoods. For those vents that could not be measured with a flow hood, the average face velocity was determined with a hot-wire anemometer, and the flow rate was calculated by multiplying this average velocity by the vent area using a correction factor to account for the effect of the vent's air diffuser.²⁴ The measured values and estimates of the outdoor air supplied to each area were then compared to guidelines in the American Society of Heating, Refrigerating, and Air-conditioning Engineers (ASHRAE) 1991 Handbook, *Heating, Refrigerating, and Air-Conditioning Applications*, Chapter 7 "Health Facilities" and the 1993 *Guidelines for Construction and Equipment of Hospitals and Medical Facilities* published by the American Institute of Architects (AIA).^{25,26} Where applicable, the results were also compared to the current CDC recommendations.³

In addition to air flow rate measurements, the direction of air flow was observed using smoke tubes to qualitatively determine the pressure relationships of the rooms with respect to adjacent corridors and open areas. Smoke tubes and smoke machines were also used within rooms to determine air flow patterns at selected locations. For many rooms, quantitative determinations of air pressure differential made using an Electron Digital Micromanometer (Neotronics model EDM-I, #2388), capable of reading pressures of ± 0.001 inches of water.

B. Evaluation Criteria

There are two types of ventilation used for control of airborne transmission of TB: local exhaust ventilation and general dilution ventilation. Each of these types of ventilation is explained more fully below.

Local Exhaust Ventilation

Local exhaust is a preferred ventilation technique and should be used whenever the treatment procedures permit. Local exhaust ventilation captures infectious agents in the immediate field of the infectious patient without exposing other persons in the area. This type of ventilation is preferred because the TB organisms are removed before they can disperse throughout the room or work area. The hood portion of a local exhaust system may be of capture design, where the infectious source is near but outside the hood, or an enclosing type, where the infectious source is within the hood (e.g., scavenging booths or vinyl tents). Examples of both capture and enclosure hoods can be found in "Industrial Ventilation, A Manual of Recommended Practice."²⁴ Scavenging booths are used frequently for aerosol-generating activities, such as sputum collection and aerosol therapy. The tent enclosure can be used to enclose the patient during transport from one area to another. These devices may be exhausted directly to the outside (preferred method), or they can exhaust through a HEPA filter back into the room.

General Dilution Ventilation

Dilution ventilation, as the name implies, refers to dilution of contaminated air with uncontaminated air. While dilution ventilation reduces the possibility of exposure to contaminants, it will not in itself eliminate exposure.

General dilution ventilation (GDV) performs two functions. The first is to provide sufficient outside air to maintain comfort. For hospitals, ASHRAE recommends a range of 15-30 CFM of outdoor air per person, depending on the functional area of the space.²⁷ A minimum flow rate of 25 CFM/person outside air is recommended for all patient rooms. The second function of GDV is to provide sufficient exchange of potentially contaminated air with clean air to reduce the risk of exposure.

In addition to supplying the specified airflow, ventilation systems should also provide satisfactory airflow patterns, both from area to area and within each room. Airflow should be from "clean" to "less clean" areas, such as from hallways to treatment rooms. This can be accomplished by creating negative (lower) pressure in the area into which flow is desired relative to adjacent areas. Negative pressure is attained by exhausting more air from the area than is being supplied. For large areas, this requires careful balancing of the ventilation system.

Within a room or small area, a ventilation system should be designed to: (1) distribute air to all areas of the room, (2) prevent short circuiting of the supply to the exhaust (i.e., passage of air directly from the supply to the exhaust point without mixing with room air), and (3) direct the clean air past the worker without recirculating contaminated air through the employee's

breathing zone. Each room or space must be evaluated individually because air flow patterns are affected by air temperature, the precise location of supply vents and exhaust vents, diffuser design, the location of furniture, movement of occupants, and the physical configuration of the space.

Controversy surrounds the optimal level of GDV recommended for hospital isolation rooms. The dose of TB microorganisms needed to cause disease is unknown, and attempts to measure TB concentrations using air sampling have been unsuccessful. Therefore, accurate quantitation of decreases in risk that would result from specific levels of GDV is not possible at the present time.

Recommended ventilation rates in hospitals are frequently expressed in terms of air changes per hour (ACH). An ACH is defined as the theoretical number of times that the air volume of a given space will be replaced in a one-hour period by air supplied to the space or transferred to the space from adjacent spaces. However, the terminology is misleading; air is not actually "changed" the theoretical number of times per hour, even if there is perfect mixing. ACH terminology is generally considered a poor basis for ventilation criteria when control of environmental hazards is required.²⁴ ACH terminology is used in this report to maintain consistency with existing ventilation criteria for hospital isolation rooms.

ASHRAE, AIA, and the CDC have published ventilation guidelines for hospital isolation rooms.^{3,25,26} ASHRAE and AIA recommend a minimum of 6 ACH for TB isolation rooms and treatment rooms. This ventilation rate is based on comfort- and odor-control considerations.³ ASHRAE ventilation criteria in hospital areas other than isolation rooms can be found in Table 5. As with the criteria for isolation rooms, these criteria do not necessarily address TB transmission.

The CDC recommends TB isolation rooms and treatment rooms in existing health-care facilities have an air exchange rate of at least 6 ACH. Whenever possible, this rate should be increased to at least 12 ACH by adjusting or modifying the ventilation system or by using auxiliary means (e.g., recirculation of air through HEPA filtration units). For new construction or renovation of existing health-care facilities, the CDC recommends at least 12 ACH. Air from isolation rooms should be exhausted to the outside of the building, away from air-intake vents and persons.³

Table 5
ASHRAE Ventilation Evaluation Criteria¹
 Jackson Memorial Hospital, Miami, Florida
 HETA 91-0187

Area Designation	Air pressure relationship to adjacent area	Minimum air changes per hour outside air	Minimum total air changes per hour	Recirculated by means of room units ²	All air exhausted directly to outside
Operating room	positive	15	15	No	Yes
Delivery room	positive	15	15	No	Optional
Newborn nursery	positive	5	12	No	Either
Recovery room	No Criteria ³	2	6	No	Optional
Intensive care	positive	2	6	No	Optional
Isolation room	negative ³	2	6	No	Yes
Patient room	No Criteria ⁴	2	4	Optional	Optional
Treatment room	No Criteria ⁴	2	6	Optional	Optional
Examination room	No Criteria ⁴	2	6	Optional	Optional
ER trauma room	positive	5 (3) ⁵	12 (15) ⁵	No	Optional
Autopsy room	negative	2	12	No	Yes

- 1 Selected ventilation guidelines adapted from the 1991 American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) Handbook, *Heating, Ventilating, and Air-Conditioning Applications*, Chapter 7 "Health Facilities."
- 2 Because of cleaning difficulty and potential for buildup of contamination, recirculating room units shall not be used in areas marked "No." Isolation and intensive care unit rooms may be ventilated by reheat induction units in which the primary air supplied from a central system passes through the reheat unit.
- 3 Reverse isolation rooms should be under positive pressure.
- 4 Although directional control is not required, ASHRAE states that "in no case should a lack of directional control allow the spread of infection from one area to another."
- 5 Criteria in parentheses are from the American Institute of Architects (reference #24)

The State of Florida's Department of Health and Rehabilitative Services has ventilation requirements for hospitals.²⁸ The ASHRAE and AIA recommendations are similar to Florida's requirements (with the exception of outside air flow rates) for areas evaluated in this survey.

Rooms used for TB isolation should be under negative pressure relative to the corridor or others areas connected to the room. To achieve negative pressure, the room supply and exhaust airflows should be balanced to achieve an exhaust flow of either 10% or 50 CFM more than the supply (whichever is greater). In most situations this specification should achieve a negative pressure of at least 0.001 inch of water.³

C. Results and Discussion

A summary of the ventilation results can be found in Table 6 (page 21). The total ACH and relative air pressures between wings or surrounding areas, are listed for each room evaluated. For easy reference, the respective ASHRAE ventilation criteria are presented within the table. A brief description of each ventilation system is included at the end of each subsection within the table.

The results should be interpreted with caution. There is no health based information which can validate the recommended ACH values, but intuitively, the higher the ventilation rate, the better the dilution effect. Although the ACH results listed in Table 6 are based on actual airflow rates, these results do not consider imperfect mixing of air within the room, which can be affected by supply and exhaust location, diffuser design, objects in the room, etc. Additionally, these results were obtained several years ago; the current status of the ventilation systems may have changed significantly.

For some functional spaces within a hospital (regular patient rooms, examination and treatment rooms), ASHRAE indicates that no directional control of air (i.e., relative pressure relationships) is required. However, ASHRAE qualifies this recommendation, saying that "variations should be minimized and in no case should a lack of directional control allow the spread of infection from one area to another." There are no ASHRAE recommendations regarding the degree of negative pressure required for directional control.

Special Immunology Clinic Six out of the nine examination rooms did not meet the ASHRAE ACH criteria. Although both isolation rooms were under negative pressure, neither room had total ACH rates that met the ASHRAE criteria of 6 ACH. The outside ACH rates were not determined.

North Wing 3 Since August 1991, North Wing 3 has been a respiratory isolation ward where patients infected with HIV are treated. None of the rooms met the total ACH criteria recommended by ASHRAE or CDC. All of the rooms were under negative pressure, which should reduce the potential for transmission of TB from patients inside the room to staff outside of the room. However, the amount of air exhausted from the patient rooms did not meet the criteria for isolation rooms.

In cases where the patient is immunosuppressed, it is generally recommended that a positive pressure be maintained between the patient room and adjacent areas. When a patient is both immunosuppressed and contagious, ASHRAE recommends that isolation rooms within the unit be designed to provide an equal or negative pressure relationship with respect to adjacent areas.

South Wing 5 South Wing 5 is a general medical ward, housing a large number of respiratory isolation patients. Most of the patients treated on the ward have tested positive for HIV. All the evaluated rooms except one met the ASHRAE total ACH recommendations for regular patient

rooms, and some rooms also met the ASHRAE requirements for isolation rooms. Room No. 510 did not meet the ACH criteria for a regular patient room. Outside air ACH were not determined.

Medical Intensive Care Unit, and TB Trailer The Medical Intensive Care Unit met all the ASHRAE ventilation criteria for total ACH. Outside air ACH were not determined. The relative pressure differential of the medication room was not assessed. The TB trailer, which exhausts all air directly to the outside, met all the ASHRAE ventilation criteria.

Newborn Intensive Care Unit, Maternity, and Labor/Delivery (control wards for the epidemiologic study) The Newborn Intensive Care Unit and Maternity 3A sections met the applicable ASHRAE ventilation criteria. Eight of the 20 rooms in Maternity 3B section did not meet the ACH criteria for regular patient rooms. All but one labor room in the Labor/Delivery area met the ASHRAE total ACH criteria.

Urgent Care Clinic All the rooms evaluated in the UCC met the total ACH ASHRAE recommendations for examination rooms. Outside air ACH rates were not determined. At the time of the investigation, there was concern about the possibility of respiratory isolation patients being kept in these rooms. Since the ventilation system in this area recirculates air through the building, these rooms are not suitable for isolation. Furthermore, most of these rooms were under positive pressure.

West Wing 6 and 15 Thirty-seven of 50 rooms on WW6 and WW15 did not meet the ASHRAE total ACH recommendations for regular patient rooms, and 8 rooms did not meet the outside air ACH recommendations. On WW15, inspections were made of five fan-coil units. At least two of these units served transplant rooms and one other unit served a transplant intensive care unit room. All units had a lint material around the frame of the filter indicating air bypassing the filter. Accumulations of water and a layer of slimy debris were found in the condensate pans of all units. The presence of water and debris in these units often results in fungal and/or microbiological growth.

Emergency Area Several rooms in the Medical Emergency Area did not meet the ASHRAE total ACH recommendations. However, the Trauma Emergency area, Surgical Emergency area, and Obstetrics/Gynecology Emergency Area (except two rooms) met all the ASHRAE criteria. In the Trauma Emergency area, the Resuscitation rooms and the suture suite did not meet the criteria for trauma rooms, but the areas met the criteria for examination or treatment rooms.

Table 6 Ventilation Results Jackson Memorial Hospital, Miami, Florida HETA 91-0187 November 4-8, 1991		
Room Number	Air Changes per Hour (ACH are total air)	Air Pressure in Room Relative to Adjacent Areas
Special Immunology Clinic (SPIMC)		
ASHRAE Criteria for Examination Rooms	6	Directional Control Not Required (see text)
112, Exam #1	5.5	-
113, Exam #2	5.9	+
114, Exam #3	6.2	+
115, Exam #4	3.8	+
116, Exam #5	6.2	+
117, Exam #6	5.4	-
118, Exam #7	5.1	-
119, Exam #8	5.8	+
120, Exam #9	6.2	-
ASHRAE Criteria for Isolation Rooms	6	-
127 Isolation	5.7	-
128 Isolation	4.1	-
<p><i>The SPIMC ventilation system supplies a mixture of recirculated air and approximately 20 percent outside air to all rooms and corridors on the first floor of the clinic wing. Recirculated air is returned to the air handling unit and filtered through HEPA filters before being supplied back into the area. The exhaust air from the isolation rooms is ducted directly to the outside of the building. The actual amount of outside air supplied to each room was not determined.</i></p>		

North Wing 3 (outside ACH)		
ASHRAE Criteria for Regular Patient Rooms	Outside Air: 2 Total Air: 4	Directional Control Not Required (see text)
316 Patient Room - Low	2.9	-
316 Patient Room - Med	2.9	-
316 Patient Room - High	2.9	-
338 Patient Room - Low	1.8	-
338 Patient Room - Med	1.8	-
338 Patient Room - High	1.8	-
342 Patient Room - Low	3.2	-
342 Patient Room - Med	3.2	-
342 Patient Room - High	3.2	-
348 Patient Room - Low	2.9	-
348 Patient Room - Med	2.9	-
348 Patient Room - High	2.9	-
ASHRAE Criteria for Isolation Rooms	Outside Air: 2 Total Air: 6	-
330 Isolation Room	2.8	-
<p><i>The patient room ventilation system on North Wing 3 utilizes a ceiling-mounted fan-coil unit containing heating and cooling coils and a 3-speed blower. The fan-coil unit intake and outlet grills are both ceiling mounted. The outside air exchange is accomplished by a dampered supply from the main supply duct to the fan coil inlet. This air is mixed with the room air entering the fan coil inlet and discharged into the room from the fan coil outlet. The exhausts are in the bathrooms. All exhausted air is ducted directly to the outside. The air from the isolation room, which has an anteroom, is exhausted directly to the outside. Since outside air also was supplied to the corridors outside the rooms, outside ACH rates were based on bathroom exhaust measurements. The outside ACH values are equivalent to total ACH values, since the air recirculated in the fan coil units was not counted as transfer air.</i></p>		
South Wing 5		
(ACH are total air)		

ASHRAE Criteria for Regular Patient Rooms	4	Directional Control Not Required
500 Patient Room	14.4	-
508 Patient Room	9.8	-
510 Patient Room	2.6	-
514 Patient Room	7.9	-
529 Patient Room	10.3	+
534 Patient Room	8.8	-
Visiting Room	7.9	-
<p><i>Most of the air to South Wing 5 is supplied from a dual-deck (separate ducts for heated and cooled air) constant volume ventilation system. All of the air is exhausted to the outside (no recirculation). The supply air is a mixture of transfer air (from other areas of the hospital) and outside air. Some of the rooms have auxiliary cooling units which recirculate room air. The actual amount of outside air supplied to each room was not determined.</i></p>		
Medical Intensive Care Unit, South Wing 4		
ASHRAE Criteria for Intensive Care Areas	6	+
Intensive Care	6.4	+
ASHRAE Criteria for Isolation Rooms	6	-
Isolation Room	12.7	-
ASHRAE Criteria for Medication Rooms	4	+
Medication Room	6.8	not determined
<p><i>The central ventilation system serving this area is a recirculating system, except for the isolation room. The exhaust from the isolation room was exhausted directly to the outside. Outside ACH rates were not determined.</i></p>		

Tuberculosis Trailer		
ASHRAE Criteria for Examination Rooms	Outside Air: 2 ACH Total Air: 6 ACH	Directional Control Not Required
103 Exam Room	16.4	+
104 Exam Room	19.4	-
105 Exam Room	19.0	-
106 Exam Room	13.8	+
107 Exam Room	19.1	+
108 Booth Room	15.9	Not Determined
ASHRAE Criteria for Medication Rooms	Outside Air: 2 ACH Total Air: 4 ACH	+
109 Medication Room	41.7	+
<i>The Tuberculosis Trailer is equipped with a 100-percent outside air ventilation system which exhausts all air out of the trailer, returning none to the supply fan. Therefore, outside air ACH values would be equal to the total ACH values.</i>		
Labor and Delivery		
ASHRAE Criteria for Labor rooms	Outside Air: 2 ACH Total Air: 4 ACH	neutral
6 Labor Room	4.2	+
7 Labor Room	4.8	+
8 Labor Room	3.5	+
ASHRAE Criteria for Delivery Rooms	Outside Air: 15 ACH Total Air: 15 ACH	+
3 Delivery Room	26.5	+
<i>The ventilation system for the Labor/Delivery/Recovery areas provides 100% outside air with no recirculation back into the building. The outside ACH values are equal to the total ACH values.</i>		
Newborn Intensive Care Unit		
ASHRAE Criteria for Nursery Suites	Outside Air: 5 ACH Total Air: 12 ACH	+
Nursery Suite	15.7	not determined
<i>The ventilation system for the New Born Intensive Care Unit provides 100% outside air with no recirculation back into the building. The outside ACH value is equal to the total ACH value.</i>		

Maternity, East Tower 3, Section 3A (ACH are outside air)		
ASHRAE Criteria for Regular Patient Rooms	Outside Air: 2 ACH Total Air: 4 ACH	Directional Control Not Required
3077	6.9	-
3079	11.7	+
3081	6.6	-
3083	4.7	-
3085	6.1	+
3087	6.5	+
3089	6.3	+
3091	5.7	+
3099	6.2	+
3101	12.0	+
3103	6.4	neutral
3105	4.9	+
3107	5.7	+
3109	6.8	+
3111	10.2	+
3113	5.9	+
3115	5.2	+
3117	10.0	+
3119	7.4	+
3121	4.3	-

The ventilation system serving the maternity areas provides 100% outside air with no recirculation back into the building. The outside air ACH values are equal to the total ACH values.

Maternity, Section 3B		
ASHRAE Criteria for Regular Patient Rooms	Outside Air: 2 ACH Total Air: 4 ACH	Directional Control Not Required
3139	4.8	neutral
3141	7.9	+
3143	7.3	+
3145	3.5	-
3147	5.2	+
3149	8.0	+
3151	6.5	-
3153	3.5	neutral
3155	1.9	+
3157	1.7	+
3159	3.5	+
3161	2.1	+
3169	4.1	+
3171	7.9	+
3173	6.9	+
3175	1.5	-
3177	4.9	+
3179	1.8	-
3181	7.6	+
3183	5.7	+
<p><i>The ventilation system serving the maternity areas provides 100% outside air with no recirculation back into the building. The outside air ACH values are equal to the total ACH values.</i></p>		
<p>Urgent Care Clinic (ACH are total air)</p>		

ASHRAE Criteria for Examination Rooms	Total Air: 6 ACH	Directional Control Not Required
Exam Room 102	17.4	+
Exam Room 118	9.4	+
Exam Room 120	10.8	+
Exam Room 122	10.1	+
Exam Room 123	8.3	-
Exam Room 124	16.8	+
Exam Room 125	6.4	-
<p><i>The ventilation system in the Urgent Care Clinic provides a mixture of recirculated and outside air. The actual amount of outside air supplied to the individual rooms was not determined.</i></p>		

West Wing 6 (outside ACH)		
ASHRAE Criteria for regular patient rooms	Outside Air: 2 Total Air: 4	Directional Control Not Required
601	2.0	-
603	2.1	-
605	3.4	-
607	2.0	-
609	2.0	neutral
611	2.8	+
613	2.2	neutral
615	1.9	+
617	5.0	+
619	2.7	+
621	4.6	+
623	5.5	+
625	2.6	neutral
629	1.7	-
631	2.4	neutral
633	2.7	+
635	2.7	+
637	1.7	+
639	2.0	neutral
641	2.2	+
643	2.4	neutral
645	1.6	+
647	1.9	neutral
649	1.7	+
651	1.8	-

On West Wing 6, each patient room has a constant supply volume induction unit. A constant volume of outside air is supplied to each unit. The outside air is used to induct room air into the unit and across a cooling coil in the unit. The return air intake is located in the ceiling and the supply air outlet is a register located in the wall area above the vestibule in the main part of the patient room. The outside ACH values are equal to total ACH, since the air recirculated in the induction unit was not counted as transfer air.

West Wing 15		
ASHRAE Criteria for Regular Patient Rooms	Outside Air: 2 ACH Total Air: 4 ACH	Directional Control Not Required
1501	6.0	-
1503	5.3	-
1505	2.2	-
1507	3.7	-
1509	4.1	-
1511	3.0	-
1513	4.0	-
1515	2.5	-
1517	2.9	neutral
1519	2.7	-
1521	3.3	+
1523	4.7	+
1525	3.7	+
1529	5.0	+
1531	3.2	+
1533	3.4	+
1535	3.2	neutral
1537	4.4	+
1539	3.1	+
1541	4.0	-
1543	2.5	-
1545	4.7	-
1547	3.1	-
1549	1.9	-
1551	2.8	-

On West Wing 15, each patient room has a constant supply volume induction unit. A constant volume of outside air is supplied to each unit. The outside air is used to induct room air into the unit and across a cooling coil in the unit. The return air intake is located in the ceiling and the supply air outlet is a register located in the wall area above the vestibule in the main part of the patient room. The outside ACH values are equal to the total ACH values, since the air recirculated in the induction unit was not counted as transfer air.

Medical Emergency Area (ACH are outside air)		
ASHRAE Criteria for Exam or Treatment Rooms	Outside Air: 2 ACH Total Air: 6 ACH	Directional Control Not Required
M-1	8.3	+
M-2	3.4	+
M-3	6.2	neutral
M-4	8.3	-
M-5	9.1	+
M-6	4.2	+
M-7	2.0	-
M-8	8.3	+
M-9	3.3	-
M-10	11.2	+
M-11	6.5	+
M-12	10.1	+
Trauma Emergency Area (ACH are outside air)		
ASHRAE Criteria for Trauma Rooms	Outside Air: 5 ACH Total Air: 12 ACH	+
Resus 1	8.4	+
Resus 2	6.3	+
Trauma 1	14.8	+
Trauma 2	16.8	+
Suture Suite	10.0	-
<p><i>The Medical Emergency Area and Trauma Emergency Area are served by constant volume ventilation systems that provide 100% outside air to all areas. No air from these areas is recirculated into the buildings. The outside ACH values are equal to the total ACH values.</i></p>		

Surgical Emergency Area (ACH are outside air)		
ASHRAE Criteria for Exam or Treatment Rooms	Outside Air: 2 ACH Total Air: 6 ACH	Directional Control Not Required
S-1	8.9	+
S-2	5.5	-
S-3	7.6	+
S-4	7.7	+
S-5	3.1	+
S-6	6.4	-
S-7	8.1	+
S-8	7.1	neutral
<p><i>The Surgical Emergency Area is served by a constant volume ventilation system that provides 100% outside air to all areas. No air from this area is recirculated into the building. The outside ACH values are equal to the total ACH values.</i></p>		
Obstetrics/Gynecology Emergency Area (ACH are outside air)		
ASHRAE Criteria for Exam or Treatment Rooms	Outside Air: 2 ACH Total Air: 6 ACH	Directional Control Not Required
G-1	8.9	-
G-2	5.5	-
G-3	7.6	-
3	7.7	+
4	3.1	-
<p><i>The Obstetrics/Gynecology Emergency Area is served by a constant volume ventilation system that provides 100% outside air to all areas. No air from this area is recirculated into the building. The outside ACH values are equal to the total ACH values.</i></p>		

ASSESSMENT OF PENTAMIDINE ISETHIONATE EXPOSURE

Pentamidine isethionate, an aromatic diamine compound (CAS #140-64-7), was synthesized in the 1930's and was subsequently used as a pharmaceutical treatment for protozoal diseases, including infections with *Trypanosoma rhodesiense* and *Leishmania donovani*. It is also effective in the treatment of *Pneumocystis carinii* pneumonia, a common opportunistic infection in patients with compromised immune function.²⁹

Pentamidine can be administered by the intravenous or intramuscular route. In 1989, the Food and Drug Administration approved aerosol administration.³⁰ The small particle size of the pentamidine aerosol (0.8 micron mass median aerodynamic diameter) permits deep penetration of the drug into the lung.³¹

A. Occupational Concerns Related to Pentamidine Administration

The administration of aerosolized pentamidine isethionate (AP) raises two concerns related to occupational health: passive exposure to the pentamidine aerosol and nosocomial transmission of *M. tuberculosis*.

Eye and respiratory irritation, including conjunctivitis and bronchospasm, as well as a metallic or bitter taste in the mouth, have been associated with occupational exposure to AP.^{32,33,34} These effects have also occurred in patients receiving AP.^{35,36,37} Other side effects in patients have included rash, neutropenia (low white blood cell count), pancreatitis, renal insufficiency, dysglycemia (abnormalities of blood sugar level), and local effects on the respiratory tract. A single case of reduction in pulmonary diffusing capacity in a health care worker has been described.³⁸ However, this finding is contrasted by the absence of effects on pulmonary diffusing capacity in a recent year-long study of immunocompromised patients receiving monthly treatments with AP.³⁹

In studies of pregnant Sprague-Dawley rats that received pentamidine by injection, the rate of malformation was not increased, but more pregnancy resorptions were noted than in the control group, suggesting embryocidal rather than teratogenic effects.⁴⁰ No positive responses for mutagenicity were noted in six *Salmonella typhimurium* cultures, and a Chinese hamster ovary test for chromosomal aberration was negative.⁴¹ Because the actual degree of risk from worker exposure to AP has not been determined, there are presently no established exposure limits recommended for AP.

Active TB occurs with a greater frequency among persons with HIV infection than among the general population. When persons coinfecting with HIV and TB receive AP, the cough associated with the treatment increases the risk of TB exposure in the HCW administering the treatment. In one investigation, there was an association between TST conversion and being in a room where AP was administered.⁴² The risk is thought to be significant enough that recent CDC guidelines for preventing TB transmission in health care facilities have included recommendations to be followed when administering pentamidine therapy.³

B. Administration of Pentamidine Isethionate

At the time of the NIOSH investigation, AP administration was conducted in two areas at JMHI; the in-patient AIDS clinic identified as North Wing 3 (NW3), and the out-patient AIDS clinic in the Special Immunology Clinic (SPIMC). Pentamidine administration in the SPIMC has since been moved to the TB trailer.

Pentamidine administration was conducted in the SPIMC within Emerson® Aerosol Treatment and Sputum Induction Chambers (Cambridge, Massachusetts) which were located inside isolation rooms. These chambers are self-contained and isolate the patient during treatments by passing a flow of air by the patient (who is seated in the chamber) and out through the rear of the booth through a HEPA filter. The chamber supplies a variable air flow rate, reportedly from 250 to 460 ACH, or 150 to 270 CFM. Alarms sound when the blower malfunctions, when leaks in the chamber occur, and when the filters need changing.⁴³

There were three such treatment chambers used in the SPIMC. Two chambers were used for AP administration and one was used for sputum induction. The chambers were intended to trap aerosols generated by the patient or the pentamidine nebulizer. The employees wore Aseptex® 3M sub-micron molded surgical masks (not NIOSH/MSHA approved) when working inside the isolation rooms or treatment chambers.

A treatment session begins with monitoring the patient's vital signs and then giving the patient a nebulizer containing pentamidine. The patient then enters the chamber and connects the nebulizer to the air flow, which starts the flow of pentamidine aerosol. The HCW normally does not have to enter the chamber.

The only nebulizer approved for AP administration by the Food and Drug Administration is the Respirgard II® jet nebulizer, which incorporates an expiratory filter that is intended to reduce the release of pentamidine into the environment. A solution containing pentamidine isethionate in sterile water is placed into the reservoir, and an air source is connected to the nebulizer at a flow rate of 6 liters per minute. A series of one-way valves is used to direct airflow and reduce the number of large particles delivered to the patient.

The duration of treatment for a 300-milligram (mg) dose of pentamidine is approximately 20-30 minutes. If the patient experiences fatigue or coughing, the air flow rate may be decreased or the patient may take rest periods by disconnecting the nebulizer from the air flow. When a treatment is completed, the patient is instructed to remain in the chamber for at least 5 minutes to allow the remaining pentamidine aerosol to be scavenged and any pentamidine-induced coughing to subside.

During treatment, the nebulizer operates continuously, allowing escape of the medication into the environment if the patient removes the nebulizer to talk, cough, or rest. Additionally, there may be some escape of AP through the exhalation filter, or as a result of improper use of the

nebulizer, or from the patient during nose breathing. Because pentamidine isethionate has negligible vapor pressure, only the aerosol poses an exposure risk.

The ventilation system in the SPIMC recirculates a portion of the air; however, HEPA filters have been added in the HVAC units to reduce the potential for distribution of *M. tuberculosis* organisms to the rest of the building. The isolation rooms reportedly exhaust air directly to the outside. The ventilation system is a constant volume system.

In NW3, pentamidine administration was conducted at the patient's bedside, without the use of any scavenging equipment. An Emerson chamber is reportedly now used on NW3. If patients from other wards require pentamidine treatment, administration is usually provided in a room at the end of the hallway (Room 330). Employees also wear Aseptex® masks on NW3.

A Peace Medical Demistifier® isolation tent (Peace Medical, Orange, NJ) was used on a trial basis during one pentamidine administration in NW3 (during the September 23, 1991, NIOSH visit). The Demistifier® isolates the patient in a vinyl canopy enclosure. When free standing, the canopy falls to within 2 inches from the floor. Air is drawn upward from the open area near the floor and is exhausted by a 220 CFM fan through a HEPA filter, which scavenges aerosols from the interior of the tent.⁴⁴ The tent fits over the patient's bed enabling administration of the pentamidine in the patient's room.

The ventilation system in NW3 supplies outside air to the ward. However, the fan-coil units located in the patient rooms recirculate a portion of the air in each individual room. The system has three fan speeds and can be turned off. Each patient room has one exhaust in the bathroom which operates continuously. There are no other supply diffusers (other than the one associated with the fan-coil unit) in the patient rooms. The ventilation system is a constant volume system.

C. Air Monitoring Methodology

Personal breathing zone and area air monitoring for AP was conducted during administration in the Emerson® chambers (SPIMC - June 13, 1991, and September 26, 1991), the Peace Medical Demistifier® scavenging tent (NW3 - September 23, 1991), and at the bedside with no engineering controls (NW3 - June 11, 1991).

A sampling and analytical method for pentamidine isethionate in air was recently developed at NIOSH (NIOSH Method 5032).⁴⁵ This method involves air sampling with 37-millimeter, 5-micrometer pore polyvinyl chloride (PVC) filters in opaque closed-face cassettes at a flow rate of 2 liters per minute using battery operated personal sampling pumps. The pentamidine isethionate was recovered from the filters with 3-milliliters of 50:50 ethanol:water with 0.085% phosphoric acid and 0.04% tetramethylammonium chloride in an ultrasonic bath. Analysis was performed using high pressure liquid chromatography with fluorescence detection. The limit of

detection (LOD) and limit of quantitation (LOQ) were 8 and 50 nanograms (ng) per sample, respectively. Up to 35% of the pentamidine isethionate was recovered from the inside surface of the cassettes. This was believed to be due to electrostatic effects from the PVC cassettes.

Room air flow rates were measured with an Alnor Balometer® to characterize the ventilation conditions under which AP monitoring was conducted. Additionally, the direction of air flow between the administration areas and adjacent areas was determined with smoke tubes.

D. Air Monitoring Results

Emerson Chamber - SPIMC The results of AP air monitoring are presented in Table 7 (next page). The average concentration of AP inside the Emerson chamber was 93.6 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) (range 63.5 to 122.0 $\mu\text{g}/\text{m}^3$) as a time-weighted average (TWA) over the actual sampling period. In contrast, nearly all concentrations outside the booths (isolation rooms, general work area, nurses station, and waiting area) were below the analytical LOQ of 50 ng/sample (0.07 $\mu\text{g}/\text{m}^3$, based on 700 liter sampling volume). Concentrations outside the chambers were 150 to 1300 times lower than inside the chambers. All four personal samples were below the LOQ. Smoke tube tests did not indicate any gross leakage from the booths.

On June 13 and September 16, 1991, both isolation rooms were noted to be under negative pressure (direction of air movement was *into* the isolation rooms) with respect to the adjacent area. On June

Table 8 Pentamidine Isethionate Peace Medical Demistifier® September 23-26, 1991 Jackson Memorial Hospital, Miami, Florida HETA 91-0187		
Sampling Location	Sampling Duration (minutes)	Concentration ($\mu\text{g}/\text{m}^3$) ¹
Inside Tent	29	1.4
Outside Tent	29	ND ²
Near HEPA ³ Outlet of Tent	29	ND
Outside Door of Room	30	ND
Nurse (PBZ) ⁴	35	ND
1. Time-weighted average concentration of pentamidine isethionate in micrograms per cubic meter air. 2. ND = Non-detected (limit of detection \approx 0.83 $\mu\text{g}/\text{m}^3$) 3. High efficiency particulate air filter. 4. Personal breathing-zone concentration.		

13, the exhaust ventilation in isolation rooms A and B was 62 and 59 CFM, respectively, and the supply flow rate was 52 and 59 CFM, respectively. These results equated to 5 ACH, based on the exhaust flow rate. On September 26, the exhaust ventilation in isolation rooms A and B was 77 and 75 CFM, respectively, and the supply was 70 and 60 CFM, respectively. These results equated to slightly more than 6 ACH. Air flow measurements were made in the general work area on September 26. There were three supply diffusers, having a total flow of 640 CFM, and one exhaust, having a flow of 275 CFM.

Peace Medical Demistifier - NW3 AP administration was conducted with the patient in bed. During the treatment, the patient and bed were enclosed by the Peace Medical Demistifier® tent. None of the area air samples collected outside the tent had detectable pentamidine (Table 8, next page). The personal air sample also had no detectable pentamidine,

<p align="center">Table 7 Pentamidine Isethionate Exposures Emerson® 7-AT Treatment Chamber July 8-11, 1991 and September 23-26, 1991 Jackson Memorial Hospital, Miami, Florida HETA 91-0187</p>		
Sampling Location	Sampling Duration (minutes)	TWA Concentration (µg/m³)¹
Inside Chambers	370 [8] ²	63.5
	352 [9]	104.1
	137 [3]	84.9
	362 [8]	122.0
Inside Isolation Rooms	371 [8]	(0.07) ³
	352 [9]	(0.07)
	201 [4]	(0.14)
	365 [8]	(0.07)
Outside Isolation Rooms	361	(0.07)
	351	0.62
	352	(0.07)
Nurses' Station	363	(0.07)
	351	(0.07)
	354	(0.23)
Nurses Administering Pentamidine (PBZ) ⁴	300 [14]	(0.08)
	289 [14]	(0.09)
	361 [5]	(0.07)
	231 [9]	(0.11)
1.	Time-weighted average concentration of pentamidine isethionate in micrograms per cubic meter air.	
2.	Values in brackets indicate number of treatments administered.	
3.	Concentrations are between the limit of quantification and detection	
4.	Personal breathing-zone samples	

but it was noted that the nurse spent only 5 minutes in the treatment room, out of a 30-minute treatment duration. The concentration inside the Demistifier® tent was relatively low, compared to the Emerson chamber, indicating that the Demistifier rapidly scavenged the pentamidine aerosol. Smoke tube tests did not indicate any gross leakage from the tent.

During the sampling period, the fan coil unit was running at a low speed (supply=60 CFM, return=50 CFM). The bathroom return was measured at 80 CFM. The patient's room was under negative pressure with respect to the adjacent hallway.

No Engineering Controls - NW3 The highest area samples and personal breathing zone samples were found during aerosol administration without engineering controls. Area concentrations ranged from 113.9 to 127.1 $\mu\text{g}/\text{m}^3$ (Table 9, next page). The personal breathing zone sample concentration was 9.75 $\mu\text{g}/\text{m}^3$ as a TWA over the 66-minute sampling period. The personal exposure, as a time-weighted average, was much less than the room area concentrations since the nurse only spent about 2½ minutes in the treatment room.

The concentration of AP in the hallway was less than 1% of the concentration measured in the patient's room during treatment. The general ventilation system appeared to substantially limit the potential for pentamidine to spread outside the patient's room.

During the sampling period, the fan coil unit was not running and the bathroom return was exhausting at 50 CFM. The patient's room was under negative pressure with respect to the adjacent hallway.

E. Biological Monitoring Methodology and Results

To determine whether workers who are exposed to pentamidine absorb the drug, urine was collected from 7 exposed workers. Control specimens were collected from 3 workers who did not administer pentamidine and were not present in areas where pentamidine was administered. In order to verify laboratory consistency, two specimens (one from an exposed worker and one

from an unexposed worker) were split and submitted to the laboratory as duplicate specimens. All samples were submitted under random number labels; the laboratory was not aware of the exposure categories or the duplicate samples. The pentamidine level was analyzed according to published methods.⁴⁶ The limit of detection was 0.5 ng of pentamidine per milliliter of urine. The creatinine content of each specimen was also analyzed, and pentamidine results were corrected for dilution by dividing by the creatinine concentration, and are expressed as nanograms of pentamidine per milligram of creatinine (ng/mg). Pentamidine was not detected in any of the submitted specimens.

F. Questionnaire Results

Thirteen employees completed the symptoms questionnaire. The mean age of the respondents was 40 years (standard deviation=8.3 years). Twelve respondents (92%) were female; three (23%) were black and 10 (77%) were white. Of 11 employees who answered the question asking whether they were of Hispanic origin, three (27%) said they were. All 13 employees said they were nurses. Four respondents (31%) had smoked at some time in their lives; one of those four still smoked at the time of the survey.

Six of the respondents (46%) reported that they administered pentamidine at the time of the survey. Only three of them reported the number of treatments they administered in a week; the reported numbers were 7, 20, and 21 treatments per week. One respondent reported staying in the room during the treatment.

Respondents were asked about the personal protective equipment they wore while administering treatments. Three of six respondents said they wore gloves. Five of the six respondents described the type of respirator they wore: two said they wore disposable paper dust masks, and

Table 9 Pentamidine Isethionate No Engineering Controls September 23-26, 1992 Jackson Memorial Hospital, Miami, Florida HETA 91-0187		
Sampling Location	Sampling Duration (minutes)	Concentration (µg/m ³) ¹
Patient's Table ²	66	113.9
Patient's Telephone	66	119.4
Adjacent Bed	66	127.1
Hallway	66	0.78
Nurse (PBZ) ³	66	9.75
1. Concentration of pentamidine isethionate in micrograms per cubic meter air. 2. Sample was collected three to four feet from the nebulizer. 3. Personal breathing-zone sample.		

three said they wore filter-type respirators. One of five reported wearing a gown, and one of six wore eye protection.

Respondents were asked whether they experienced symptoms of allergies or respiratory illness, including shortness of breath on exertion, production of sputum (phlegm), runny nose, or irritated eyes. Workers were also asked if they had a history of respiratory illness such as asthma, hay fever, emphysema, bronchitis, or tuberculosis. The responses of those who administered pentamidine treatments (“exposed”) were compared with the responses of those who did not (“unexposed”). These are summarized in Tables 10 (symptoms) and 11 (illnesses). Although exposed workers were more likely than unexposed workers to report eye irritation and shortness of breath, there were no statistically significant differences between the reported symptoms or illness among exposed and unexposed workers. However, the lack of statistical significance may be due to the small number of participants in the survey.

Table 10 Proportion of pentamidine-exposed and unexposed workers who reported respiratory <i>symptoms</i> . Jackson Memorial Hospital, Miami, Florida HETA 91-0187			
Symptom	Exposed	Unexposed	p*
Shortness of breath	3/3 (100%)	1/7 (14%)	0.27
Phlegm production	1/6 (17%)	0/7 (0%)	0.41
Runny Nose	1/6 (17%)	2/7 (29%)	1.00
Irritated Eyes	3/5 (60%)	2/6 (33%)	0.57
* Two-tailed Fisher's exact test			

Table 11 Proportion of pentamidine-exposed and unexposed workers who reported respiratory <i>illness</i> . Jackson Memorial Hospital, Miami, Florida HETA 91-0187			
Illness	Exposed	Unexposed	p*
Asthma	1/6 (17%)	0/7 (0%)	0.46
Hay Fever	0/6 (0%)	1/7 (14%)	1.00
Emphysema	0/6 (0%)	0/7 (0%)	1.00
Bronchitis	2/6 (33%)	2/7 (29%)	0.68
Pneumonia	1/6 (17%)	1/7 (14%)	1.00

* Two-tailed Fisher's exact test

G. Tuberculin Skin Test Conversions

Two of 13 respondents (15%) said they had a history of a positive TST. Of those two, one reported receiving prophylactic treatment for TB. Three of 13 respondents (23%) said they had received BCG vaccination.

All 13 respondents gave a date for their most recent TST. The time ranged from zero (tested in the same month as our visit) to 256 months prior to our visit. It is possible that the employee who reported 256 months (indicating last being tested in 1970) made an error in completing the survey. When this entry is not included in the analysis, the mean time since the last reported test is 3 months; the only employee who had not been tested in the past year reported that their most recent test had been 22 months prior to our visit.

Part of the intended study design was to compare the rate of TST conversion among a randomly selected subset of HCWs who administered AP with the conversion rate among a group of workers who did not administer pentamidine. The medical records of 5 exposed workers were examined to compare their most recent TST results with a test conducted before pentamidine therapy was instituted at the hospital. One of these employees had a positive TST in 1979. Of the four remaining exposed employees, all of their most recent TST results (performed between March and November, 1991) were negative. Because there were no documented conversions among workers who administered AP, no further comparison was conducted.

In this evaluation we were not able to demonstrate any health effects related to pentamidine exposure. However, our sample of potentially exposed workers was relatively small, and at the time of our visit, measured worker exposures to pentamidine were quite low, probably as a result of the installation of control technologies such as treatment booths, tents, and room exhaust ventilation. These measures would be expected to reduce exposures to both AP and *M. tuberculosis*.

ULTRAVIOLET LAMP EVALUATION

A. Background

"Germicidal" UV lamps are low-pressure mercury vapor lamps that emit UV radiation predominantly at a wavelength of 254 nanometers (nm). The lamps irradiate the upper ceiling area of rooms with UV radiation. To irradiate microorganisms released from a patient, the ventilation system must generate air currents that will bring the TB microorganisms into the irradiated area of the room.

Research has demonstrated that germicidal UV radiation is effective in killing *M. tuberculosis* under experimental conditions. In one study, guinea pigs that were exposed to air exhausted from rooms containing patients with infectious TB, and subsequently treated with germicidal UV radiation, were completely protected from infection with *M. tuberculosis*.^{47,48} Other studies cite the effectiveness of germicidal UV radiation in hospitals,⁴⁹ military housing,⁵⁰ and classrooms.^{51,52,53} One recent study noted that use of germicidal UV lamps reduced culturable airborne bacteria by 14-19% (*M. tuberculosis* was not used for the study); however, the lamps did not reduce the concentration of gram-positive, rod-shaped bacteria.⁵⁴

The effectiveness of germicidal UV radiation in killing airborne tubercle bacilli depends on the intensity of the UV radiation, the duration of contact the organism has with the UV radiation, and the relative humidity. Studies show that an adverse effect on germicidal UV radiation effectiveness occurs at relative humidity levels above 70% for *Serratia marcescens*.⁵⁵

Although germicidal lamps have been used for many years, there are currently no standardized recommendations regarding intensity, exposure time, and wavelength of germicidal UV radiation needed to inactivate TB microorganisms in the air; therefore an evaluation of these factors was beyond the scope of this investigation.

B. Health and Safety Issues

The critical organs of exposure for the 254 nm radiation are the eyes and skin. At this wavelength, the radiation is absorbed by the outer surface of the eye, and overexposure can result in inflammation of the cornea (keratitis) and/or conjunctiva (conjunctivitis).⁵⁶

Keratoconjunctivitis caused by UV radiation is a reversible injury, lasting 24-48 hours, but it is a debilitating condition while it runs its course. There is a latent period of a few hours, depending upon the dose, so it is sometimes not recognized as an occupational injury. Skin exposure to UV radiation can result in erythema (reddening). This is also a reversible injury and the time course depends on the severity of the burn.

UV radiation in the UV-C range (100-290 nm) has been reported to cause sarcomas and squamous cell carcinomas in mice.^{57,58} No epidemiological studies have been conducted to ascertain whether radiation in the UV-C range, such as that produced by germicidal lamps, causes cancer in humans. However, UV-C is known to induce DNA dimers in human cell cultures.⁵⁹ The carcinogenic effect of UV radiation in mammals is generally thought to be caused by the formation of pyrimidine dimers in cellular DNA that leads to errors in DNA replication and targeted gene mutations.⁶⁰ Recently, UV-C was classified by the International Agency for Research on Cancer as "probably carcinogenic to humans (Group 2A)."⁶¹ This classification is based on studies suggesting that UV-C radiation can induce skin cancers in animals; and DNA damage, chromosomal aberrations, and sister chromatid exchange and transformation in human cells *in vivo*. In the animal studies, a contribution of UV-B to the tumor effects could not be excluded, but the effects were greater than expected for UV-B alone.

Recent studies also suggest that, in lab samples, 254-nm UV radiation or sunlight can induce the HIV promoter gene (i.e., the gene that prompts replication of the virus is stimulated to produce more HIV).^{62,63,64,65,66,67} The potential for UV-C to cause cancer and promote HIV in humans is unknown, but skin penetration may be an important factor. It has been reported that approximately 20% of incident 250-nm UV penetrates the stratum corneum, compared to approximately 30-60% of 300-nm UV.⁶⁸

In 1972, NIOSH formulated criteria for a recommended standard for occupational exposure to UV radiation. Because the biological effects from exposure to UV radiation are dependent on the intensity and energy

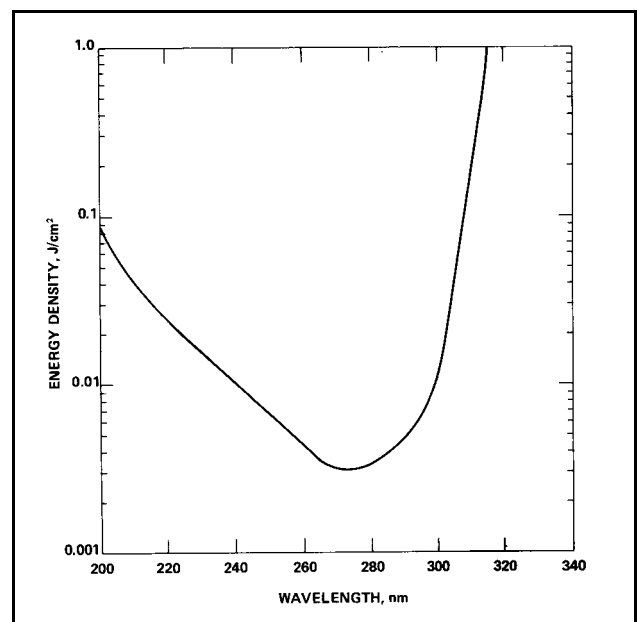


Figure 3: Recommended UV Radiation Exposure Standard

distribution of the source, as shown in Figure 3, the NIOSH recommended exposure limit (REL) is wavelength-dependent in the spectral region of interest (200-315 nm). The REL is based on an action spectrum derived from thresholds for acute effects of erythema and keratoconjunctivitis from both human and animal studies. The REL does not consider possible carcinogenic effects. The REL for 8-hour exposures has a minimum permissible dose level of 0.003 joules per square centimeter (J/cm^2) at 270 nm. At 254 nm (the predominant UV wavelength of germicidal lamps) the REL is $0.006 J/cm^2$, since the spectral effectiveness of 254 nm UV is 0.5.⁶⁹

If the UV energy is from a broad-band source, the *effective* irradiance relative to a 270 nm monochromatic source must be calculated using a formula described in the NIOSH criteria document. If the UV energy is from a narrow-band or monochromatic source, permissible dose levels for a daily 8-hour period can be read directly from Figure 3. For unprotected workers, permissible exposure times in seconds can be calculated by dividing the NIOSH REL (i.e., $0.006 J/cm^2$ at 254 nm) by the effective UV irradiance in W/cm^2 . The American Conference of Governmental Industrial Hygienist (ACGIH) has established Threshold Limit Values (TLVs) for 254-nm UV radiation exposures which are similar to the NIOSH RELs.

The NIOSH and ACGIH occupational exposure limits are listed in Table 12 (next page). Since UV radiation at a wavelength of 254 nm has a spectral effectiveness of 0.5, the permissible exposure levels at 254 nm wavelength are twice the values listed as "effective irradiance." Some UV meters will provide values in terms of "effective irradiance," while other meters will read direct irradiance without correcting for the spectral effectiveness.

<p align="center">Table 12 Maximum Permissible Exposure Times for 254-nm Ultraviolet Radiation Jackson Memorial Hospital, Miami, Florida HETA 91-0187</p>		
Duration of Exposures per day	Effective Irradiance ($\mu W/cm^3$)	Irradiance at 254 nm ($\mu W/cm^3$)
8 hours	0.1	0.2
4 hours	0.2	0.4
2 hours	0.4	0.8
1 hour	0.8	1.6
30 minutes	1.7	3.4
15 minutes	3.3	6.6

C. Methods

During the second half of 1991, over 100 ultraviolet (UV) lamp *fixtures* were installed in three areas of JMH: the Urgent Care Clinic (UCC), Emergency Ward, and Special Immunology Clinic (SPIMC) located in Acute Care Center East (ACC East). UV *lamps* were to be installed into these fixtures to help control nosocomial transmission of TB. However, before lamp installation, hospital personnel requested that NIOSH evaluate the potential for HCW overexposure to UV radiation.

During the July 8-11, 1991, NIOSH visit, measurements of UV radiation were made in all rooms having UV lamp fixtures in the Emergency area (registration and waiting areas), SPIMC (waiting room and reception areas), and UCC (exam rooms 5, 6, 7, 8, 9, and rooms 123 and 102). In addition, measurements were also made in selected rooms of the Emergency Ward. At the beginning of the evaluation, there were no UV lamps in any of the lamp fixtures. In each evaluated room, NIOSH representatives temporarily installed UV lamps (provided by JMH) in the fixtures, made measurements of UV radiation, and then removed the UV lamps from the fixtures. There were no HCWs or patients in the immediate area where the lamps were evaluated.

The SPIMC and UCC had wall-mounted fixtures with louvers (American Ultraviolet, Murray Hill, New Jersey). These fixtures could accommodate one 30-watt UV bulb (General Electric, Cleveland, Ohio) each. The ceiling height in the UCC is 9 feet, and the fixtures were placed 7 feet off the floor. In the SPIMC, the ceiling height was 8½ feet, and the fixtures were also placed 7 feet off the floor. The fixtures in the Emergency area were hung from the ceiling, and could contain two 30-watt bulbs each. The ceiling height was 9½ feet, and the fixtures were placed 7 feet off the floor. All of the fixtures had parabolic reflectors behind the bulbs to increase the intensities of UV radiation emitted from the fixtures.

After the July NIOSH visit, UV shields (supplied by the fixture manufacturer) were incorporated into the fixtures in the UCC to reduce lower room (occupational) UV radiation intensities. During the return NIOSH visit (September 23-26, 1991), UV lamps were activated by JMH management personnel in 10 patient rooms in the UCC.

The measurement system used to evaluate potential occupational exposures consisted of a calibrated model 1400A International Light (IL) radiometer connected to a SEL 240 detector that permitted the system to read UV levels directly in units of microwatts per square centimeter ($\mu\text{W}/\text{cm}^2$). The measurement range is 0 to 1 milliwatt per square centimeter (mW/cm^2) for emissions in the 200 to 320 nm range. The radiometer used in this evaluation was calibrated with a 254 nm UV source within 6 months of use by the manufacturer.

Measurements were made at different distances from the floor: 4 feet (average eye height of sitting person), 5 feet (average eye height of standing female), and 8 feet (approximate height of intended irradiation area). Measurements were then taken at different locations in the vicinity of the lamp, with the detector facing the lamp.

D. Results

Since no UV lamps were initially installed in the fixtures, there were no occupational UV exposures from the lamps in evaluated areas. However, based on the measurements made when NIOSH representatives installed lamps in the fixtures, substantial occupational exposures would have occurred had the lamps been installed and activated. Levels of UV radiation measured at worker positions exceeded the NIOSH and ACGIH criteria for an 8-hour exposure in every room evaluated. In many cases, a reflection of the bulb in the parabolic mirror could be seen from standing locations in the room.

In the UCC exam rooms, measurements were made at 15 locations in each exam room (4, 5, and 8 feet from floor in five different areas). At heights of 4 feet from the floor, the levels of UV radiation averaged $0.40 \mu\text{W}/\text{cm}^2$ (range: $0.1\text{-}0.87 \mu\text{W}/\text{cm}^2$, depending on the exact location in the room). At heights of 5 feet from the floor, the irradiance averaged $0.67 \mu\text{W}/\text{cm}^2$ (range: $0.1\text{-}1.5 \mu\text{W}/\text{cm}^2$). Assuming an average exposure of $0.67 \mu\text{W}/\text{cm}^2$, the permissible exposure time would be only 2.5 hours. At heights of 8 feet from the floor, the irradiance varied widely depending on the location in the room. In the center of the rooms (about 45 inches from the bulb), the values ranged from $37\text{-}140 \mu\text{W}/\text{cm}^2$.

In the UCC registration area, measurements were made at 28 points in the room at two heights (4 and 8 feet from floor). At 4 feet, the irradiance averaged $1.5 \mu\text{W}/\text{cm}^2$ (range: $0.15\text{-}2.9 \mu\text{W}/\text{cm}^2$, while at 8 feet, the irradiance averaged $50 \mu\text{W}/\text{cm}^2$ (range: $6.5\text{-}140 \mu\text{W}/\text{cm}^2$). Based on an average exposure of $1.5 \mu\text{W}/\text{cm}^2$, the permissible exposure time would be 1.1 hours.

The irradiance in the SPIMC reception area was similar to levels measured in the UCC, since the same type of fixture was utilized. The reception area, which had three wall mounted fixtures, had irradiance levels of $1.2\text{-}4.0 \mu\text{W}/\text{cm}^2$ at a height of 4 feet from the floor (permissible exposure time 0.4-1.4 hours). In exam room #9, irradiance averaged $1.5 \mu\text{W}/\text{cm}^2$ (6 measurements) at 4 feet, $1.8 \mu\text{W}/\text{cm}^2$ at 5 feet, and $71 \mu\text{W}/\text{cm}^2$ at 8 feet.

In the registration area of the Emergency Ward, with lamps installed in only one fixture, irradiance levels were $3.2 \mu\text{W}/\text{cm}^2$ at a distance of 10 feet from the fixture and 5 feet off the floor. This level of UV irradiance would result in a permissible exposure time of only

30 minutes. The emergency area has a metallic ceiling, which may cause additional reflections and increase irradiance in the lower part of the room.

In the emergency room reception area, an elevated podium was installed for the reception clerk. From a standing position, the UV bulbs could be seen in several fixtures around the room. In a sitting position, with bulbs installed in one fixture, the receptionist could potentially receive $1.4 \mu\text{W}/\text{cm}^2$, resulting in a permissible exposure time of about 1.2 hours per day.

The lamp fixture geometry and louver design were probably the major causes of the unacceptably high UV radiation measured in the work areas during the tests. They may have been creating unique scattering angles that would enhance worker's potential exposure to UV radiation.

As a result of these findings, JMH representatives installed manufacturer-supplied shields to reduce occupational exposures from the lamps. During the September 23-26, 1991, NIOSH visit, UV irradiance levels were measured in three of ten patient rooms in the UCC where UV lamps had been activated. The other seven rooms, similar in design, were not evaluated because they were occupied by patients with infectious TB.

At a height of five feet above the floor (eye height of the average woman), the UV radiation irradiance throughout the room averaged $0.15 \mu\text{W}/\text{cm}^2$ (range = $0-0.3 \mu\text{W}/\text{cm}^2$). A direct continuous exposure of $0.15 \mu\text{W}/\text{cm}^2$ would be permitted for approximately five hours per day. At a height of approximately six feet from the floor, intensities ranged from $0.4-0.7 \mu\text{W}/\text{cm}^2$ in the rooms. A tall person would thus be limited to approximately 2.4-4 hours of continuous exposure per day.

Some of the UV fixture louvers in the UCC appeared to have been bent. This could increase or decrease both upper and lower room UV intensities to some degree.

RECOMMENDATIONS

1. A TB screening policy and program that follows the 1994 CDC Guidelines should be established for *all* employees potentially exposed to TB. Employee representatives should be involved in the development of the policy and program. The program should be offered at no cost to employees.
2. *All* TSTs should be read by a qualified person 48-72 hours after injection. The size of the reaction in millimeters of induration should be recorded for *all* tests, even "negative" tests. This is because the definition of a positive TST reaction varies according to several factors, including age and the immune status of the tested individual.
2. Since our study demonstrated a high risk for *M. tuberculosis* infection among workers with and without close patient contact, JMH should provide effective TB transmission control not only in areas of the hospital where direct patient care is taking place, but in all areas where employees may be exposed to infectious individuals.
4. In all hospital areas where there is potential for exposure to TB, ongoing evaluation of the effectiveness of various environmental and administrative control measures, as well as the use of personal protective equipment, should be undertaken as recommended in the CDC Guidelines.³
5. The medical evaluation following a skin test conversion should include inquiries about potential sources of TB infection. This history should include all travel outside the United States.
6. Individual TST results and clinical evaluations should be maintained in confidential employee health records, and should be recorded in a retrievable aggregate data base of all employee test results. Identifying information should be handled confidentially.

Summary data (e.g., the percentage of positive reactions among all tested) can be reported to management and employees. Individual test results should remain confidential.

7. The rate of skin test conversions should be calculated periodically to estimate the risk of acquiring new infection and evaluate the effectiveness of control measures. On the basis of this analysis, the frequency of periodic testing may be altered accordingly.
8. Area usage and the respective ventilation systems for all areas of the hospital should be evaluated considering current recommendations for patient isolation. Until new isolation areas are completed, areas showing most promise for meeting current recommendations should be renovated to meet the criteria and should be used for respiratory isolation. For instance, many of the examination rooms in the emergency area had adequate air flow to meet the criteria for isolation rooms. Many of these rooms could be balanced to maintain negative pressure and used as isolation rooms, if required. Treatment and examination rooms used for patients with undiagnosed pulmonary disease and who are at risk for active TB should meet the ventilation requirements for isolation rooms.
9. All ventilation systems should be inspected, checked for proper operation, cleaned where necessary (especially fan-coil units on West Wing 15), and balanced to achieve current specifications. HEPA filters should be inspected and leak tested on a regular basis.
10. The examination rooms in the Urgent Care Clinic should not be used for respiratory isolation as long as the air from these rooms is recirculated.
11. Pressure relationships of all isolation rooms should be checked with smoke tubes on a regular basis in accordance with current guidelines.³ These relationships should be determined at a cracked doorway. A 50 CFM difference between the supply and exhaust flow (exhaust flow higher than supply) is recommended to maintain negative pressure in a typical isolation room. Additionally, air flow rates in the isolation rooms should be monitored to ensure that a minimum of 6 ACH is supplied to each room. Whenever possible, ventilation rates in isolation rooms should be increased to 12 ACH. Portable HEPA filtration units may also be considered for rooms not meeting the 12 ACH recommendation.
12. Jackson Memorial Hospital personnel should implement policies that are consistent with CDC/NIOSH recommended respiratory protection guidelines and the Occupational Safety and Health Administration (OSHA) respiratory protection standard (29 CFR 1910.134).^{70,71}

13. Employees should receive training about the potential risks associated with AP administration.
14. AP treatments should be administered to patients in a room or chamber [booth] with negative pressure relative to adjacent rooms and hallways, ideally with room or booth air exhausted directly to the outside and away from all windows and air intake ducts.
15. When AP administration in a chamber is not possible, administration rooms should be under negative pressure with respect to adjacent areas and provide a minimum of 6 ACH (substantially higher ventilation values are desirable e.g., 12 ACH). Air should be exhausted directly to the outside (not recirculated to other areas).
16. Air pressure in the AP administration room should be evaluated each day before AP administration is started. This can be accomplished by observing the direction of airflow at the doorway by holding a piece of tissue paper at the cracked doorway. An isolation room is under negative pressure when air flows *into* the room.
17. Patients should remain in the isolation room and/or chamber until coughing subsides. The hospital policy requiring patients to remain in the chamber for at least 5 minutes following AP administration should be continued.
18. Once a chamber or booth is installed, it should be tested and its performance evaluated on-site. The National Sanitation Foundation (NSF) Standard #49 lists criteria for evaluating Class II biohazard cabinetry.⁷² Although this standard was not originally intended for chambers, certain performance tests, such as the HEPA filter leak test, could be adapted for chambers. These tests should be performed at least annually, when HEPA filters are changed, when maintenance is performed, or when the chamber is relocated.
19. The filter insertion sites in the Emerson® booths should be enclosed to reduce the potential for tampering and leakage around the HEPA filters.
20. Designate a person responsible for maintaining UV lamps and ensuring their safe operation.
21. When UV lamps are installed, an experienced person should measure the level of UV radiation at all locations where people are exposed. These measurements need to be made in every area where a lamp is activated, even if areas appear to be identical. If UV levels in excess of the occupational exposure limits are measured in the work area, the UV lamps should be deactivated until the problem is resolved.
22. Place labels on UV lamp fixtures to warn people to avoid direct eye and skin contact.

23. All UV lamps should be on separate circuits with inaccessible or key operated switches to prevent tampering.
24. A preventive maintenance program should be developed to insure that UV lamps are dusted as needed and replaced at the end of their service life. A timing device that turns on a red light at the end of the rated life of the lamp is available to alert personnel that the lamp needs to be replaced. Maintenance personnel should be cautioned that fixtures should be turned off before they are inspected or serviced.
25. UV lamps should be considered a supplement to, not a replacement for, other TB control measures such as prompt detection, isolation and treatment of patients with active TB.
26. As part of employee training on TB, include information on the purpose of installing UV lamps and potential hazards of overexposure to UV radiation.
27. Medical surveillance of workers potentially exposed to UV radiation should include a review of the worker's past medical history to determine if there are any existing conditions that could be exacerbated by exposure to UV radiation, and if any medications associated with UV phototoxicity are used. Any suspicious skin lesion should be examined by a physician.

XI. REFERENCES

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