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HEALTH HAZARD EVALUATION REPORT

HETA 90-0330-2479 NEW YORK CITY HEALTH and HOSPITALS CORPORATION NEW YORK, NEW YORK

PREFACE

The Hazard Evaluations and Technical Assistance Branch of NIOSH conducts field investigations of possible health hazards in the work place. These investigations are conducted under the authority of Section 20(a)(6) of the Occupational Safety and Health Act of 1970, 29 U.S.C. 669(a)(6) which authorizes the Secretary of Health and Human Services, following a written request from any employer and authorized representative of employees, to determine whether any substance normally found in the place of employment has potentially toxic effects in such concentrations as used or found.

The Hazard Evaluations and Technical Assistance Branch also provides, upon request, medical, nursing, and industrial hygiene technical and consultative assistance (TA) to federal, state, and local agencies; labor; industry; and other groups or individuals to control occupational health hazards and to prevent related trauma and disease.

Mention of company names or products does not constitute endorsement by the National Institute for Occupational Safety and Health.

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NEW YORK CITY HEALTH and
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NEW YORK, NEW YORK

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I. SUMMARY

On June 28, 1990, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate occupational exposures to aerosolized pentamidine (AP) in the facilities of the New York City Health and Hospitals Corporation (NYCHHC). On December 18-19, 1990, and on September 24-27, 1991, NIOSH representatives conducted health hazard evaluations at four hospitals operated by the NYCHHC. The NIOSH evaluations included interviews with exposed workers, distribution of a symptoms questionnaire to exposed workers and unexposed controls, urine analysis for pentamidine, and personal breathing zone and area air sampling for pentamidine.

In interviews, 12 of 22 exposed workers described symptoms of mucosal irritation. One worker described a single episode of acute bronchospasm which occurred during an exposure that was believed to be exceptionally high; this worker had a previous long history of asthma. In a subsequent investigation, exposed workers and the unexposed control group completed a symptoms questionnaire and contributed urine for analysis of pentamidine. Because an investigation elsewhere associated occupational tuberculosis (TB) infection with proximity to AP treatment, employee health records were reviewed to assess the rate of tuberculosis purified protein derivative (PPD) skin test conversion. The exposed respondents indicated that they gave an average of 11 pentamidine treatments per week (range 0 to 20). There were no statistically significant differences between the percentages of exposed workers reporting symptoms or illnesses, and those of workers not exposed. None of the exposed employees who were PPD skin-test negative before AP was introduced had converted to PPD positive on their most recent test. However, the most recently reported tests for three employees had been administered more than one year previously (ranging from 12 to 18 months). In a subsequent visit, urine was collected from all 14 exposed workers present during the investigation, and control specimens were collected from 5 workers who did not administer pentamidine. Pentamidine was detected in a single urine specimen from an exposed worker at a concentration of 38 nanograms of pentamidine per milligram of creatinine (ng/mg).

Personal breathing zone and area air sampling for pentamidine was conducted in areas where AP was administered. Particle-size selective air sampling was also conducted to determine the mass median aerodynamic diameter (MMAD) of the pentamidine isethionate aerosol. Personal breathing zone concentrations of pentamidine ranged from non-detectable to $46.6~\mu g/m^3$. The highest personal exposures (20 and $46~\mu g/m^3$) were obtained on a nurse and respiratory therapist who were present during drug administration in treatment areas where local exhaust ventilation was not used. The local exhaust ventilation used at two of the facilities surveyed was effective in minimizing

environmental contamination and worker exposures. The particle size selective sampling revealed that over 85% of the pentamidine isethionate mass was collected on the last stage (2 μ m cutpoint) and final filter of the cascade impactor. The MMAD of AP in the workers' breathing zones was estimated to be about 1 micron or less. AP is therefore respirable and is capable of penetrating deep within the lung to the alveoli.

The NIOSH investigators conclude that the administration of aerosolized pentamidine results in potential exposure to respirable pentamidine isethionate. Local exhaust ventilation was effective in minimizing worker exposures and workplace contamination. Although exposed workers in this investigation did not appear to be at increased risk of exposure-related symptoms or disease, the interviews confirm earlier reports that some workers may be at risk of bronchospastic reactions. Recommendations are made to further reduce workers' exposures to aerosolized pentamidine and to *Mycobacterium tuberculosis* while caring for HIV-infected patients, and to improve medical surveillance programs for PPD skin test conversion.

KEYWORDS: SIC 8069 (Hospitals, specialty), pentamidine, pentamidine isethionate, aerosolized pentamidine, AP, tuberculosis, *Mycobacterium tuberculosis*, health care worker, HIV, *Pneumocystis carinii* pneumonia.

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II. INTRODUCTION

On June 28, 1990, the National Institute for Occupational Safety and Health (NIOSH) received a request to evaluate occupational exposures associated with aerosolized pentamidine (AP) administration in the facilities of the New York City Health and Hospitals Corporation (NYCHHC). The request was submitted jointly by the NYCHHC and District Council 37, AFL-CIO.

On December 18-19, 1990, and on September 24-27, 1991, NIOSH representatives conducted health hazard evaluations at four hospitals operated by the NYCHHC. The follow-up visit was conducted after an air sampling method for pentamidine isethionate was developed. On May 28, 1992, the results of the environmental evaluation were provided to union and management representatives, and on April 13, 1993, individual results of urine pentamidine concentrations and PBZ concentrations of pentamidine isethionate were sent to the employees who participated in the NIOSH medical evaluation. This final report includes the combined findings and recommendations from the medical and environmental evaluations at the NYCHHC.

III. BACKGROUND

New York City Health and Hospitals Corporation is a municipal entity which operates the city hospitals in Manhattan and the other boroughs of New York City. These include both inpatient and outpatient treatment facilities. Beginning in 1988, aerosolized pentamidine therapy was introduced into NYCHHC facilities to prevent the development of *Pneumocystis carinii* pneumonia in patients infected with the human immunodeficiency virus type 1 (HIV-1). At the time of the request, 14 NYCHHC facilities were either administering AP therapy or planning to begin shortly. Of those already administering AP, the number of treatments given each month ranged from 4 to 130.

The facilities included in the NIOSH evaluation were Elmhurst Hospital Center, North Central Bronx Hospital, Bellevue Hospital Center, and Woodhull Medical and Mental Health Center. These sites were chosen after visiting five hospitals and reviewing data on AP use at all 14 facilities. The facilities chosen had varying levels of AP use and administration techniques. Facilities with and without engineering controls were included, as well as one facility which provided both inpatient and outpatient AP treatments.

IV. PENTAMIDINE ISETHIONATE

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Pentamidine isethionate is an aromatic diamidine compound. It was synthesized in the 1930's and used initially in the treatment of protozoal diseases such as *Trypanosoma rhodesiense* and *Leishmania donovani*. More recently, it has been used in the treatment and prevention of *P. carinii* pneumonia (PCP), a common opportunistic infection in patients with compromised immune function, including those with HIV-1 infection. Although pentamidine was originally administered by the intravenous or intramuscular route, in 1989 the Food and Drug Administration approved the administration of aerosolized pentamidine for prophylaxis against PCP. A hand-held Respirgard® nebulizer is approved for delivery of the drug. Since that time, concern has been expressed over the risk which exposure to AP may pose to health care workers. The medication may escape 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, through improper use of the nebulizer, or from the patient during nose breathing. Because pentamidine isethionate has negligible vapor pressure at room temperature, exposure occurs only as a result of aerosolization.

Reports have been published citing the occurrence of eye irritation and acute bronchospasm among health care workers administering AP.^{3,4,5} These effects have also been reported in patients receiving AP.^{6,7} A single case of reduction in pulmonary diffusing capacity in a health care worker has been described.⁸ This, however, is contrasted by the absence of effects on pulmonary diffusing capacity in a year-long study of immunocompromised patients receiving monthly treatments with AP.⁹ In a separate study of 16 health care workers administering AP at nine California hospitals, a significant mean decrease in cross-shift forced expiratory volume at one second (FEV₁) was seen. 10 However, the clinical significance of these findings is unclear. Pancreatitis, hypoglycemia, and hyperglycemia have been associated with intravenous administration of pentamidine, and several cases have also been reported in patients receiving AP, indicating the potential for systemic absorption of the drug. 11,12 Although a significant association between pneumothorax and aerosolized pentamidine therapy has been shown, the incidence of *P. carinii* pneumonia in the affected patients was high enough to suggest the possibility that the occurrence of pneumothorax might result from a synergistic effect between aerosolized pentamidine and P. carinii pneumonia.¹³

Concerns have been expressed about the potential teratogenicity of pentamidine.¹⁴ In studies of pregnant rats administered pentamidine by injection, pentamidine transfer across the placenta and accumulation in fetal tissues was demonstrated; litter size was decreased, but the rate of malformation was not increased compared to the offspring of unexposed rats, suggesting embryocidal but not teratogenic effects.^{15,16} An Ames test did not yield any responses suggesting mutagenicity, and a Chinese hamster ovary test for chromosomal aberration was negative.¹⁷

One investigator detected pentamidine in the urine of 11 of 36 health care workers

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studied. The levels of pentamidine in the urine of exposed workers ranged from 0.15 to 8.19 nanograms of pentamidine per milligram of creatinine per milliliter of urine (ng/mg/ml). This overlaps the range of pentamidine levels (from 1.3 to 247 ng/mg/ml) found in the urine of patients who were receiving monthly pentamidine therapy.¹⁸ Another study of 16 health care workers failed to detect the presence of pentamidine in urine samples; however, the limit of detection was much higher, at 229 ng/ml.¹⁰ There is no information available regarding potential health effects associated with chronic exposure to low levels of pentamidine isethionate, nor are there applicable occupational exposure limits.

Because HIV-infected persons are at increased risk for tuberculosis (TB), and persons infected with both HIV and *Mycobacterium tuberculosis* often do not react to the standard TB skin test, concerns have been expressed regarding the risk of health care workers' exposure to *M. tuberculosis* while caring for patients with unrecognized infectious TB. The opportunity for aerosols containing *M. tuberculosis* to be spread into the air is increased by the propensity of pentamidine to irritate the airways, causing the patient to cough. In one investigation, there was an association between purified protein derivative (PPD) skin-test conversion and being in a room where AP was delivered. In 1990, the Centers for Disease Control and Prevention (CDC) issued guidelines for preventing TB transmission in health care settings, including recommendations to be followed when administering AP. In October 1994, CDC released a revision to these guidelines.

V. METHODS

A. Initial Assessment

In late Summer, 1990, questionnaires were sent to the 14 NYCHHC facilities which administered aerosolized pentamidine. This questionnaire asked for the number of treatments given each month, the types of environmental controls that were present, the use of personal protective equipment during AP administration, and a description of the symptoms reported by exposed employees. Twelve of the 14 reported administering 4 to 130 treatments each month, while 2 hospitals anticipated beginning AP therapy in the near future. Workers at the 12 hospitals reportedly complained of mucosal irritation in the upper respiratory tract and the eyes, although respondents were not asked to estimate how many workers had these complaints. Concern about potential long-term or reproductive effects of AP exposure were also noted on the questionnaires.

On December 18-19, 1990, NIOSH representatives visited 5 NYCHHC hospitals: Bellevue, Woodhull, Bronx Municipal, Lincoln, and Elmhurst. These hospitals were selected as examples of facilities with a high level of AP use (70-100 or more per treatments week), an intermediate level (40-60 treatments per week), and

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a low level (fewer than 40), based on responses to the mailed questionnaire. NIOSH personnel were accompanied by representatives of the NYCHHC and District Council 37, AFL-CIO. At each hospital, a walk-through inspection was conducted in the areas where AP was used, and interviews were conducted with health care workers who administered the drug.

During these visits, 22 nurses and respiratory therapists who administered AP were interviewed. Ten workers did not report any symptoms. One worker with a long history of severe asthma described an episode of bronchospasm after direct exposure to the output of the AP nebulizer; she believed this exposure to be exceptionally high. The bronchospasm was reversed with medical treatment, and the worker had no subsequent episodes. Eleven other workers described mild symptoms of upper respiratory or mucosal irritation, such as burning of the eyes, nose, or throat; 4 of the workers reporting these symptoms said they primarily occurred in the past, before their institutions installed protective measures such as booths or designated delivery suites with increased ventilation. The other 7 workers reported that these symptoms were occurring under conditions present at the time of the site visit, usually in intermittent episodes. None of these workers described symptoms suggestive of acute or delayed-onset bronchospasm.

These results did not provide evidence of a widespread problem of severe respiratory complaints among health care workers. However, the frequency of complaints of upper respiratory symptoms suggested that some health care workers might incur enough of an exposure to cause these effects. For this reason a more detailed medical investigation was conducted.

B. Follow-up Assessment

1. Medical evaluation

a. Questionnaire survey

A questionnaire was developed to ascertain whether workers exposed to AP experienced an increased prevalence of respiratory symptoms compared to workers not exposed to AP. The questionnaire asked for information about exposure frequency and demographics. The questions about respiratory symptoms had previously been developed and tested by the NIOSH Division of Respiratory Disease Studies in Morgantown, West Virginia.

b. PPD conversion investigation

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To determine whether AP exposed workers were at increased risk of infection with *M. tuberculosis*, we reviewed the records of employee skin tests for TB. A conversion from a previously negative PPD skin test to a positive test is evidence that the person has been infected with *M. tuberculosis*. The exposed population consisted of employees who administered AP as part of their routine duties. Controls were selected from employees working in areas where a low prevalence of tuberculous infection was expected because the patients were present for other than respiratory illness: orthopedic surgery, obstetrics and gynecology, or psychiatric wards.²³ Only workers with an initial negative baseline PPD test were to be included in the investigation.

c. Biological monitoring for AP

At the four hospitals evaluated in this study, the participating exposed workers and unexposed controls were asked to contribute a sample of urine on the day that they completed the questionnaire. Samples were collected when convenient during the day. (The half-life of aerosolized pentamidine in the lung was greater than 2 weeks in a study of rats.²⁴ This figure was confirmed in studies of urinary pentamidine excretion by patients receiving aerosolized pentamidine therapy.¹⁸ These studies indicated that time of collection of a biological sample did not need to be closely tied to the time of exposure that day).

All urine samples were collected in standard disposable plastic urine collection cups without preservative. A 10 ml aliquot was decanted from each sample and placed in a clean tube without preservative. The tube was then capped and frozen. Urine samples were packed in dry ice for shipping, and were shipped by overnight express to a contract laboratory for analysis of pentamidine. The pentamidine level was analyzed according to a published method.²⁵ The limit of detection was 0.5 ng of pentamidine per ml 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 were expressed as nanograms of pentamidine per milligram of creatinine (ng/mg). No other substances were measured in any samples collected.

2. Environmental evaluation

a. Exposure assessment

Air monitoring for pentamidine isethionate was conducted at each of the

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four hospitals included in the follow-up evaluation in accordance with NIOSH Method 5032. 26,27 Air samples were collected using 37-millimeter, five-micron (μm) polyvinyl chloride (PVC) filters in opaque, closed-face cassettes. The samples were collected at a flow rate of 2 liters per minute using calibrated, battery-operated air sampling pumps. Personal breathing zone (PBZ) and area air samples were obtained at each site. Analysis of filter extracts was performed using high performance liquid chromatography with fluorescence detection. Preliminary analyses indicated that a fraction of the pentamidine isethionate had deposited on the inside surface of the cassette, presumably due to electrostatic attraction. Thus, extracts of the inside surfaces of the front piece of the cassette filter holders were also analyzed and the quantity added to the filter sample results. The limits of detection for the PVC filters and inside surfaces of the cassettes were 8 ng and 1 ng, respectively.

Particle-size selective air sampling was also conducted to determine the size characteristics of the pentamidine isethionate aerosol. Four-stage, Marple personal cascade impactors (Series 290) operating at 2 liters per minute were used for particle size determinations. The stage cut-points were 21 μ m, 15 μ m, 10 μ m, and 2 μ m. Five-micron PVC substrates were used on the impaction stages and for the back-up filter. Each of the PVC substrates was separately analyzed using the procedure listed above. Personal breathing zone and area air samples were collected at each site.

The air samples were generally collected over the entire AP administration period, which lasted from a few hours to most of the workshift. In many situations the health care workers (HCWs) would initiate the treatment and then leave the room until the AP administration was completed or the patient required assistance.

Efforts were made by NIOSH investigators to evaluate the UV radiation levels in the two facilities where it was in use; however, the data were not valid due problems experienced with the equipment.

b. Ventilation assessment

To evaluate air distribution within the treatment rooms, the volume rate of airflow (in cubic feet per minute [CFM]) was measured at the supply air diffusers and exhaust grilles using a Shortridge Airdata Multimeter/Flowhood Model 860/8405. Using the airflow data, the number of room air changes per hour (ACH) was calculated. In addition, ventilation smoke tubes were used to visually assess the pressure

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differential at the entrance to the pentamidine treatment rooms.

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VI. RESULTS and DISCUSSION

A. Medical evaluation

1. Questionnaire survey

We identified 15 workers who administered AP as part of their jobs. These workers, representing all pentamidine-exposed workers who were working on the days we visited the hospitals, all completed the questionnaire. One of these workers indicated on the questionnaire that he/she did not "currently" administer AP and so was included in the analysis as an unexposed worker. With the assistance of management representatives in each hospital we identified areas where pentamidine was not used, and with the assistance of the union representative recruited 15 volunteers to serve as unexposed controls. An unexposed control was found for each exposed worker at each hospital. In all, 30 employees completed the questionnaire. They were employed by the following hospitals: Bellevue (4 employees), Elmhurst (10 employees), North Central Bronx (4 employees), and Woodhull (12 employees). The mean age of the respondents was 43 years (standard deviation=9.7 years). Eight respondents (27%) were male; 6 (20%) were white, 15 (50%) were black, 6 (20%) were of Asian or Pacific origin, one respondent indicated "other," and two did not answer the question. Of 17 employees who answered the question asking if they were of Hispanic origin, 16 (94%) said they were not. Most of the respondents (24, or 80%) said they were nurses, 5 (17%) said they were respiratory therapists, and one was described as "other."

Thirteen respondents (43%) had smoked at some time in their lives; 8 of the 30 respondents (27%) still smoked at the time of the survey. Fourteen of the respondents (47%) reported that they administered AP at the time of the survey. The exposed respondents indicated that they gave an average of 11 treatments per week, ranging from 0 to 20 treatments per week. Seven of 14 respondents (50%) said they stayed in the room during the treatment. Respondents were asked about the personal protective equipment they wore while administering treatments: 3 of 11 respondents (27%) said they wore gloves; 8 of 14 respondents said they wore surgical masks; 2 of 10 respondents said they wore particulate respirators; 1 of 10 (10%) reported wearing a gown, and 2 of 10 (20%) 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 itchy or irritated eyes. Workers were also

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asked if they had a history of respiratory illness including asthma, hay fever, emphysema, bronchitis, or tuberculosis. The responses of those administering pentamidine treatments were compared with the responses of those not administering pentamidine, and are summarized in Tables 1 (symptoms) and 2 (illnesses). There were no statistically significant differences between the two groups with respect to the prevalence of symptoms or illnesses. Two of the four symptoms of primary interest (phlegm production, runny nose) were more frequently reported by exposed workers, and the other two (shortness of breath, irritated eyes) were more frequently reported by unexposed workers. Similarly, two illnesses (hay fever, pneumonia) were more frequently reported by exposed workers, while asthma was more frequently reported by unexposed workers. None of the workers reported having emphysema or bronchitis.

Thirteen of 30 respondents (43%) said they had a positive tuberculin skin test at some time. Of those, only one respondent reported receiving preventive treatment for tuberculous infection. Nine of 30 respondents said they had received the Bacillus of Calmette and Guerin (BCG) vaccination against tuberculosis. All 30 respondents gave a date for their most recent tuberculin skin test. The mean time in months since the reportedly most recent test was 7 months; the time ranged from zero (tested in the same month as our visit) to 40 months. Five employees reported that their most recent test was more than a year prior to our visit.

2. PPD Conversion investigation

The medical records of the 14 pentamidine-exposed workers were examined to compare their most recent skin test with a test conducted before pentamidine therapy was instituted at the hospital. Three of these employees had been positive on PPD skin tests since 1989 or earlier; 2 of these were ascribed to prior BCG vaccination. The third had been PPD-positive since 1970, long before the institution of AP therapy. None of the 11 exposed employees who had a previous negative TB skin test had converted on any test through their most recent test, although the most recently reported tests for three of these had been more than one year previously (ranging from 12 to 18 months). Because there were no documented conversions among workers who administered aerosolized pentamidine during the time pentamidine was used, no further comparison to unexposed workers was conducted.

3. Biological monitoring for pentamidine

To determine whether workers who administer AP absorb detectable quantities of the drug, urine was collected from all 14 potentially exposed workers.

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Specimens were also collected from 5 workers who did not administer pentamidine; these workers were randomly selected from the unexposed workers who completed the questionnaire. To verify laboratory consistency, 4 specimens (3 from exposed workers and 1 from an unexposed worker) were split and submitted to the laboratory as independent specimens. All samples were identified only by sequential number; the laboratory was not aware of the exposure categories or the duplicate samples. Pentamidine was detected in a single specimen, at a level of 38 ng per mg of creatinine. The specimen, which was obtained from an exposed worker, had not been split before submission to the laboratory. Pentamidine was not detected in any other specimens submitted. No additional analysis was conducted.

B. Environmental monitoring

The pentamidine air sampling results are shown in Table 3. A brief description of the number of treatments administered and the ventilation conditions at each facility is given in the table.

1. Woodhull Medical and Mental Health Center

Both inpatient and outpatient AP treatments were administered at this facility. As shown in Table 1, seventeen outpatient treatments were given on the day of the survey. There were four AP administration stations (beds) in the treatment room, allowing up to four outpatient treatments at one time. No local exhaust ventilation, such as isolation booths, hoods, or tents, was used for AP administration. The airflow measurements indicated that the room provided 25 air changes per hour, and smoke tube traces confirmed that the room was under negative pressure with respect to the hallway. However, on the day of the NIOSH survey, the room door was left open during AP administration. Room air was exhausted directly to the outside. A portable fan-powered germidical UV radiation unit was used as an air cleaning device, intended to minimize the potential for tuberculosis transmission.

One nurse and one respiratory therapist were responsible for administering AP on the day of the survey. These workers went in and out of the room during the course of the day. Surgical masks and gowns were worn by these workers while in the room; however, other health care workers entering the room for brief periods of time did not wear surgical masks.

Personal breathing zone samples obtained on the nurse and respiratory therapist measured 20.2 and $46.6 \,\mu g/m^3$ pentamidine isethionate, respectively. The respiratory therapist was responsible for administering two inpatient treatments,

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as discussed below, in addition to the outpatient treatments. An area air sample collected in the outpatient treatment room had a concentration of 43.2 $\mu g/m^3$ pentamidine isethionate. The area air sample obtained in the adjacent blood bank lab contained 0.2 $\mu g/m^3$ pentamidine isethionate, indicating that there was some contamination of surrounding areas.

Two inpatient treatments were administered by the respiratory therapist on the day of the survey. Despite the use of the modified nebulizer mask (Continuous Positive Air Pressure [CPAP]), environmental contamination occurred. Area air samples collected within three feet of the nebulizer measured pentamidine isethionate concentrations at 43.1 and 85.5 $\mu g/m^3$. The sampling periods for these single patient treatments covered the entire administration period which was approximately 40 minutes. Hopital personnel believed that this mask would minimize worker exposures and contamination of the surrounding environment due to its tighter fitting facepiece and use of a filter from a Respirgard nebulizer on the exhalation valve. Workers indicated that a croup tent was used to administer AP to inpatients who could not tolerate the CPAP mask.

2. North Central Bronx

Six outpatient treatments were administered at this facility on the day of the survey. No local exhaust ventilation was used for pentamidine administration. The administration room was supplied with 100% outside air, and all air was exhausted directly to the outside. Airflow measurements indicated that the room was providing approximately 14 room air changes per hour. Smoke tube traces confirmed that the room was under negative pressure with respect to the hallway. In an effort to minimize health care workers' exposures, the nurses did not remain in the room during AP administration. Patients received AP at one of two stations in the room. There was a glass window and glass door panel which allowed the health care workers to view the patients from outside the room. Patients were asked to turn off the nebulizer before leaving the room or when requesting assistance, and to dispose of the nebulizer in the biohazard waste receptacle when the treatment was completed. The nurses would enter the room only if patients were coughing or needed assistance. Surgical masks were worn by nurses when in the room during the AP administration.

The concentrations of pentamidine isethionate in the two PBZ samples obtained on the nurses were "trace" concentrations (between the minimum detectable concentration $[0.1\mu g/m^3]$ and minimum quantifiable concentration $[0.6 \, \mu g/m^3]$), and $3.1 \, \mu g/m^3$. The pentamidine isethionate concentration in the area air sample obtained on the table approximately two feet from the administration area was

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23.4 μ g/m³. Pentamidine was not detected in the area air sample obtained at the workstation outside the treatment room; the minimum detectable concentration for this sample was approximately 0.1 μ g/m³.

3. Elmhurst Hospital Center

Twelve outpatient AP treatments were administered on the day of the survey. This facility had recently installed six Emerson 7-AT Aerosol Treatment and Sputum Induction Chambers. These are self-contained units (booths) which isolate the patient during treatments. An exhaust fan draws air into the chamber through a top-mounted inlet; the air flows past the patient, through a high efficiency particulate air (HEPA) filter, and out through an exhaust vent at the rear of the booth. The chamber is capable of supplying a variable airflow rate, from 150 to 270 cubic feet per minute (CFM). This is equivalent to a rate of 250 to 460 air changes per hour. Internal alarms indicate when the blower malfunctions, when leaks in the chamber occur, or when filters need changing. The aerosol booths are located in a treatment room which had no mechanical ventilation. A window air-conditioning unit and personal fans were used to provide ventilation and air mixing. Two wall-mounted UV radiation lamps were used.

On the day of the survey, one of the windows was partially open, as was the treatment room door. Glass panels located in the wall facing the hallway allowed the health care workers to monitor the patients from outside the treatment room. Health care workers wore gowns, but no surgical mask or respirator, while in the room.

Personal breathing zone air samples were collected on three nurses who did not remain in the room during drug administration. The pentamidine isethionate concentrations ranged from trace to $2.6~\mu g/m^3$. An area air sample obtained inside one of the Emerson aerosol booths indicated a concentration of $37.3~\mu g/m^3$; air samples obtained outside the chambers measured concentrations of $0.5~and~1.2~\mu g/m^3$. These results indicate that the chambers were effective in reducing contamination of the surrounding work areas. The area air sample obtained on the table outside the treatment room had only a trace concentration of pentamidine.

4. Bellevue Hospital Center

Six outpatient treatments were administered on the day of the survey using two Emerson 7-AT Aerosol Treatment and Sputum Induction Chambers. The respiratory therapist was present in the room during AP administration. With the door to the treatment room open, as was the case on the day of the

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survey, the room was under positive pressure with respect to the waiting area. The airflow measurements revealed an average supply airflow of 140 CFM and an exhaust airflow of 139 CFM. Thus, the room had approximately 5 air changes per hour. Pentamidine isethionate was present inside the right Emerson aerosol booth (used for 3 AP treatments) at a concentration of 60.8 $\mu g/m^3$. Pentamidine was not detected above a limit of detection of approximately 0.1 $\mu g/m^3$ in air samples obtained on the respiratory therapist, on the desk in the treatment room, or outside the treatment room in the waiting area. Again, the Emerson booth was effective in minimizing environmental contamination.

5. Particle Size Selective Air Sampling

The results of eight personal and area air samples collected using Marple Personal Cascade Impactors revealed that greater than 85% of the total pentamidine isethionate mass was found on the last stage (cut point of 2 μ m) and the final filter. The mass median aerodynamic diameter (MMAD) of AP was thus estimated to be around 1 μ m or less. AP is therefore respirable and is capable of penetrating deep within the lung to the alveoli. These findings are in agreement with previous reports that the Respirgard II nebulizer delivers a pentamidine aerosol with a MMAD of 0.72-0.78 μ m²⁸ and 0.93 μ m.²⁹

VII. CONCLUSION

These surveys have shown that health care workers have potential exposure to pentamidine isethionate while administering drug treatments to patients, and that exposure levels are influenced by work practices and ventilation. All of the facilities had developed written procedures for performing AP administration to minimize worker exposures to pentamidine and *M. tuberculosis*. However, the specific administration conditions, work practices, and use of local and general ventilation varied among the facilities we surveyed.

The highest personal exposures (20 and $46 \,\mu\text{g/m}^3$) were measured on a nurse and respiratory therapist who were present during drug administration in treatment areas where engineering controls were not used. Although limited, the air sampling data collected during these surveys indicate that the treatment booths used at Elmhurst and Bellevue were effective in minimizing workplace contamination and worker exposures. At Bellevue Hospital, no pentamidine was detected on a respiratory therapist who remained in the treatment room during 6 AP administrations using Emerson booths. In addition, at Elmhurst hospital where 12 AP treatments were administered using Emerson booths, only very low or trace concentrations of pentamidine were detected in the room (0.1 to $1.2 \,\mu\text{g/m}^3$). The nurses responsible for AP administration also were exposed to low concentrations of pentamidine, ranging from about 0.1 to $2.6 \,\mu\text{g/m}^3$; however, their exposures were also influenced by the fact that they did not remain in the treatment room during drug administration. While this practice will aid in minimizing pentamidine

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exposures, there is still some potential for exposure if the HCW must enter the room suddenly to assist a patient who is having difficulty. Workers may also be exposed to residual pentamidine when entering the room after treatments are completed. For this reason, local exhaust ventilation is the preferred control measure. The practice of having HCWs remain outside the treatment room during AP administration may further reduce the potential for pentamidine exposure, but should not be relied upon as the primary control measure. It should be noted that the air sampling data indicated that the modified CPAP mask used for inpatient AP administration at Woodhull was not effective in containing the pentamidine aerosol.

The use of local exhaust and dilution ventilation in the AP administration areas will also serve to reduce exposures to *M. tuberculosis* if it is present in the environment. Droplet nuclei containing *M. tuberculosis* can be aerosolized when a person with infectious tuberculosis coughs, sneezes, or vocalizes. Because HIV-infected persons are at increased risk for developing active TB, and the diagnosis of TB is complicated in such persons (for example, a skin test may be erroneously negative), there is concern about the potential for these patients to have unrecognized disease.

In this hazard evaluation we did not find evidence of any of the health effects of concern that prompted the investigation. It is possible that pentamidine exposure is seldom associated with these respiratory symptoms or illnesses. However, the exposures of some of the participating health care workers had already been reduced by the installation of the control technologies mentioned above. In addition, the number of AP treatments given at these facilities decreased from the time of initial NIOSH involvement to the time that this evaluation was performed due to the increased use of oral medications for PCP prophylaxis. It should be noted that the only health care worker with detectable pentamidine in the urine reported staying in the room while treatments were given without the use of containment booths, hoods, or tents. The only respiratory protection this worker described using was a surgical mask, which cannot be closely fit to the wearer's face to ensure adequate protection. However, another worker at the same hospital who described the same exposures and used the same mask did not have any detectable urine pentamidine. These two workers reportedly administered similar numbers of treatments per week (18 per week for the worker without detectable urine pentamidine vs. 20 per week for the worker with detectable urine pentamidine). It is possible that other factors, including individual work practices and metabolism, may be responsible for the difference.

None of the workers in this investigation became infected with tuberculosis (as evidenced by TB skin tests) during the time they administered aerosolized pentamidine. According to employee health records and worker reports, however, some workers had not received TB skin tests within the past year. This fails to meet current CDC recommendations. ²²

In 1991, the National Institutes of Health concluded a study comparing the efficacy of aerosolized pentamidine therapy with that of oral trimethoprim-sulfamethoxazole in

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preventing *P. carinii* pneumonia. That study indicated that oral trimethoprim-sulfamethoxazole was more effective and resulted in the recommendation that trimethoprim-sulfamethoxazole, rather than aerosolized pentamidine, be used as the primary therapy for prophylaxis against *P. carinii* pneumonia. Because there are some patients who cannot tolerate trimethoprim-sulfamethoxazole, it is likely that aerosolized pentamidine therapy will still be used to care for these patients. Although there is presently no recommended occupational exposure limit for pentamidine isethionate, health care workers' exposures to AP should be minimized in order to protect against irritant effects or bronchospastic reactions in sensitive workers. In addition, efforts should be made to prevent transmission of aerosolized *M. tuberculosis* from patients who may have unrecognized TB disease.

VIII. RECOMMENDATIONS

The following recommendations are offered to reduce or prevent exposure to AP and to *M. tuberculosis* during AP administration.

- Local exhaust ventilation systems such as isolation booths, hoods, tents, or other enclosures should be used for AP administration at all facilities. The exhaust air from these units should pass through a HEPA filter before being released into the room or exhausted to the outside. These local exhaust ventilation systems capture the air contaminants at or near the source and remove them without exposing persons in the area. Local exhaust ventilation is preferable and more efficient than general ventilation, which involves the dilution and removal of contaminants in a much larger volume of air, such as a whole room. If local exhaust ventilation cannot be used, or during the interim period when controls are being implemented, efforts should be made to ensure that the pentamidine administration room is under negative pressure relative to adjacent areas and that a minimum of six air changes per hour are provided in accordance with guidelines for respiratory isolation rooms. Air should be exhausted directly to the outside, not recirculated to other areas within the facility. If this is not possible, room air must be passed through a HEPA filter before being recirculated back into the room or to other areas of the facility. Ideally, the pentamidine administration rooms should be set up to meet these guidelines even if local exhaust ventilation is used, to further reduce the potential for exposure to pentamidine and M. tuberculosis.
- 2. The doors and windows to the administration rooms should be kept closed during treatments to minimize the potential for contamination of the air in surrounding areas and to maintain negative pressure in the rooms. The use of window air conditioning units and personal cooling fans in place of mechanical ventilation systems is not appropriate. Additionally, the air pressure differential should be checked on a periodic basis (i.e., weekly) to ensure that air flows into the room from surrounding areas (i.e., from "clean" to potentially contaminated areas).

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- 3. Patients should be instructed to remain in the isolation room and/or chamber for a period of time after the treatment is completed and until coughing subsides. (The manufacturer of the Emerson booth recommends that patients remain in the booth for 2-3 minutes following treatment to minimize the spread of contaminants into the room when the door is opened.) The time should be sufficient to allow at least 99% of particles to be removed before the next patient enters.²²
- 4. The HEPA filter in the Emerson chamber requires proper installation, testing, and meticulous maintenance to prevent aerosol contaminants (pentamidine and infectious particles) from escaping into the work environment. Once a chamber or booth is installed on site, it should be tested and its performance evaluated. The National Sanitation Foundation (NSF) Standard No. 49 lists criteria for evaluating Class II biohazard cabinetry. The HEPA filter leak test could be adapted for the Emerson chambers. These tests should be performed at least annually, whenever HEPA filters are changed, when maintenance is performed, if the chamber is damaged, or when the chamber is relocated. It may also be necessary to enclose the HEPA filter insertion sites in the chamber to reduce the potential for tampering and leakage. The used HEPA filters should be carefully handled so as not to jar or drop the filter element during or after removal. Appropriate respiratory and hand protection should be worn while performing maintenance and testing procedures.
- 5. Gloves and eye protection should be worn by HCWs when handling the nebulizer containing pentamidine isethionate or preparing the drug mixture.
- 6. Many employees wore surgical masks while in the treatment room. Surgical masks do not provide adequate respiratory protection against small aerosols such as pentamidine isethionate or *M. tuberculosis* due to inadequate filter efficiency and face seal leakage. NIOSH-approved respirators should be worn in situations requiring respiratory protection. The CDC recommends that respirators be worn by HCWs during cough inducing or aerosol-generating procedures on patients with known or suspected infectious tuberculosis. The Occupational Safety and Health Administration (OSHA) requires the use of respirators by HCWs when performing such procedures on patients with suspected or confirmed TB. High-efficiency particulate air respirators are the minimum acceptable level of respiratory protection required by OSHA³¹, and which currently meet the performance criteria established by CDC.²²
- 7. All employees who work in pentamidine treatment areas should be educated about the potential risks of tuberculosis transmission and AP exposure. This training should include ways of minimizing exposure, proper work practices, and use of personal protective equipment.
- 8. Employees who administer AP should be screened with PPD skin tests at least every

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six months.²²

9. Ultraviolet radiation levels should be measured, and appropriate measures taken, if necessary, to reduce exposures below the NIOSH Recommended Exposure Limit.³² The CDC TB guidelines can be consulted for further information concerning the safe use of germicidal UV radiation.²²

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Nursing Department, Rm 3501, North Central Bronx Hospital
Respiratory Care, Woodhull Hospital
Respiratory Care, Bellevue Hospital
OSHA Region II

For the purpose of informing affected employees, copies of this report shall be posted by the employer in a prominent place accessible to the employees for a period of 30 calendar days.

Table 1

Proportion of Respondents Who Reported Respiratory Symptoms New York City Health and Hospitals Corporation New York, New York HETA 90-0330

Symptom	Exposed	Unexposed	P-value ¹
Shortness of breath	2/14 (14%)	5/15 (33%)	p=0.39
Phlegm production	3/14 (21%)	1/16 (6%)	p=0.31
Runny nose	5/14 (36%)	3/16 (19%)	p=0.41
Irritated eyes	2/12 (16%)	6/13 (46%)	p=0.20

¹Two-tailed Fisher's exact test

Table 2

Proportion of Respondents Who Reported Respiratory Illnesses New York City Health and Hospitals Corporation New York, New York HETA 90-0330

Illness	Exposed	Unexposed	P-value ¹
Asthma	0/14 (0%)	2/16 (13%)	p=0.49
Hay fever	5/14 (36%)	4/14 (29%)	p=1.00
Emphysema	0/12 (0%)	0/14 (0%)	p=1.00
Bronchitis	0/12 (0%)	0/14 (0%)	p=1.00
Pneumonia	4/13 (31%)	4/15 (27%)	p=1.00

¹Two-tailed Fisher's exact test

Table 3

Pentamidine Isethionate Air Sampling Data New York City Health and Hospitals Corporation New York, New York HETA 90-0330 September 24-27, 1991

Job/Location	Sampling Time (min)	Sample Volume (L)	Pentamidine Isethionate (μg/m³) ¹
Woodhull Outpatient Treatment: 17 AP treatments administered. Treatment room was under negative pressure, had 25 ACH, and all air was exhausted directly to the outside. No local ventilation was used. Respiratory Therapist and Nurse were in and out of the room during AP administration.(9-25-91)			
Respiratory Therapist - inpatient & outpatient treatments	305	580	46.6
Nurse - outpatient treatments only	204	432	20.2
Work table in middle of treatment room	204	408	43.2
Outside treatment room - on desk in blood bank lab	216	432	0.2
Above patient's head	208	416	1.0
Woodhull Inpatient Treatment: 2 AP treatments administered by the Respiratory Therapist (above) in individual patient rooms that were under positive pressure. No local ventilation was used.(9-25-91)			
3 feet from nebulizer - Patient A	38	86	85.5
3 feet from nebulizer - Patient B	42	76	43.1
North Central Bronx: 6 AP treatments given in room with 100% outside air and 14 ACH. Treatment room was under negative pressure. No local ventilation was used. Nurses did not remain in room during admin. (9-27-91)			
Nurse 1 - 3 AP treatments	107	214	3.1
Nurse 2 - 3 AP treatments	42	84	trace ²
On table, 2 feet from administration area	263	526	23.4
On table in corner of administration room	265	530	3.5
Workstation outside treatment room - 10' from door.	258	542	ND^3

¹ Concentration is expressed in micrograms of pentamidine isethionate per cubic meter of air $(\mu g/m^3)$ as a time-weighted average over the sampling period.

² Trace concentrations are between the minimum detectable concentration (0.1µg/m³) and the minimum quantifiable concentration $(0.6\mu g/m^3)$. These concentrations assume a sample volume of 84 liters. 3ND = none detected; the limit of detection was 8 nanograms of pentamidine isethionate per filter.

Table 3 (Continued)

Pentamidine Isethionate Air Sampling Data New York City Health and Hospitals Corporation New York, New York HETA 90-0330 September 24-27, 1991

Job/Location	Sampling Time (min)	SampleV olume (L)	Pentamidine Isethionate (µg/m³)¹
Elmhurst: 12 outpatient AP treatments administered in booths (Emerson Aerosol Treatment Chambers). The treatment room was not supplied with mechanical ventilation; however, a window air-conditioning unit and exhaust fan were used. The nurses did not remain in the room during AP administration. (9-26-91)			
Nurse 1	129	258	trace ²
Nurse 2 (supervisor)	127	254	0.2
Nurse 3 (head nurse)	92	193	2.6
Inside chamber A, on rear shelf	134	268	37.3
In treatment room, between chambers A and B, 3 feet from exhaust	126	252	0.5
On table in middle of treatment room	130	260	1.2
Outside treatment room, on table	123	234	trace
Bellevue : 6 outpatient AP treatments administered in booths (Emerson Aerosol Treatment Chambers). The treatment room was under positive pressure, and the room door was open. The respiratory therapist remained in the room during AP administration. (9-24-91).			
Respiratory Therapist	167	334	ND^3
Respiratory Therapy Tech (sputum ind room)	392	784	0.1
In treatment room, by gas cylinder	169	338	ND
Inside right chamber, on rear shelf (3 treatments administered)	153	306	60.8
On desk in treatment room		766	ND
In waiting room, outside treatment area		774	ND

¹ Concentration is expressed in micrograms of pentamidine isethionate per cubic meter of air (μg/m³) as a time-weighted average over the sampling period.

² Trace concentrations are between the minimum detectable concentration $(0.1 \mu g/m^3)$ and the minimum quantifiable concentration $(0.6\mu g/m^3)$. These concentrations assume a sample volume of 84 liters. 3ND = none detected; the limit of detection was 8 nanograms of pentamidine isethionate per filter.