

November 1993

VA HEALTH CARE

Tuberculosis Controls Receiving Greater Emphasis at VA Medical Centers



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United States
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Human Resources Division

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November 9, 1993

The Honorable Joseph P. Kennedy II
House of Representatives

Dear Mr. Kennedy:

As you requested, we have examined the circumstances surrounding an outbreak of tuberculosis at the Department of Veterans Affairs (VA) Medical Center in East Orange, New Jersey. Our report discusses the reasons for the outbreak and describes management initiatives VA has taken or plans to take to strengthen tuberculosis controls at its 158 medical centers nationwide. The report also compares the East Orange medical center's experience with this outbreak with non-VA hospitals' experiences.

As arranged with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days after its issue date. At that time, we will send copies of this report to the Secretary of Veterans Affairs, appropriate congressional committees, and other interested parties. If you have any questions about this report, please call me at (202) 512-7101. Other major contributors are listed in appendix V.

Sincerely yours,

A handwritten signature in cursive script that reads "David P. Baine".

David P. Baine
Director, Federal Health Care
Delivery Issues

Executive Summary

Purpose

The resurgence of tuberculosis is one of the most serious public health threats facing the United States today. Still more troublesome is the significant increase in multiple drug resistant tuberculosis, which is more difficult and costly to treat than nonresistant tuberculosis. The increase in tuberculosis has focused attention on infection-control measures to prevent the spread of the disease.

Representative Joseph P. Kennedy II asked GAO to examine the recent outbreak of tuberculosis at the Department of Veterans Affairs (VA) medical center in East Orange, New Jersey. Specifically, he requested that GAO determine the reasons for the outbreak and what management initiatives VA has taken to assist other medical centers to strengthen their tuberculosis-control efforts. GAO also compared the East Orange center's experience with this outbreak with those of non-VA hospitals.

Background

Tuberculosis is mainly caused by airborne bacteria that are transmitted when a person with active pulmonary tuberculosis coughs or sneezes. The immune system of a normally healthy person will prevent the development of active tuberculosis disease when exposure is infrequent. A person who has tuberculosis infection but not active tuberculosis disease will have a positive reaction to a tuberculosis skin test but cannot spread the infection to others. Both preventive therapy and treatment for active tuberculosis consist of the use of one or more common drugs for a period of 6 to 12 months. However, if the patient does not complete the full course of treatment, the tuberculosis bacteria can develop into multiple drug resistant tuberculosis.

The number of tuberculosis cases in the United States had dropped from 84,304 in 1953 to 22,555 in 1984. However, by 1992 the number of cases had risen again to about 26,700. Events that led to the recent increase in active tuberculosis cases include (1) lax infection-control practices in health care settings, (2) a growing number of persons who were exposed to active tuberculosis disease in other countries and did not complete preventive treatment, and (3) an increase in the spread of the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS), which weaken the ability of a person's immune system to help prevent infectious diseases such as active tuberculosis. Because HIV and AIDS weaken the immune system, tuberculosis rates may increase where these diseases are most prevalent.

Fifty-one patients hospitalized at VA's East Orange Medical Center between January 1990 and May 1992 had tuberculosis. Of these, 13 met the definition of multiple drug resistant tuberculosis as specified by the Centers for Disease Control and Prevention (CDC). All 13 of the patients were infected with HIV; 11 of them died—an 85-percent mortality rate. In addition, CDC found that in the infectious disease ward, 5 of 10 employees who previously tested negative for tuberculosis in 1991 tested positive in 1992, indicating exposure to active tuberculosis disease. CDC referred to the situation at East Orange as an outbreak.

GAO obtained data on five independent investigations of the outbreak at the East Orange Medical Center and interviewed key officials of the investigating agencies to discuss factors contributing to the outbreak. GAO also interviewed VA officials to discuss their plans to address the problems and their actions to assist other centers at potential risk. GAO conducted site visits to the East Orange Medical Center to follow up on actions taken as a result of previous audit recommendations and also to CDC to discuss the tuberculosis problem in a national context. GAO analyzed documentation related to other outbreaks and reviewed current and proposed infection-control standards that have implications for health care facilities across the country.

Results in Brief

Lax infection-control practices and inadequate isolation rooms were problems associated with the outbreak of tuberculosis at the East Orange Medical Center. Medical center staff did not consistently use appropriate procedures for isolation of suspected or known tuberculosis patients. Further, until spring 1991, no analysis or evaluation of the tuberculosis cases had been done that would have revealed patterns and trends in the spread of the disease. The center did not have a comprehensive employee-testing program to monitor the staff's exposure to active tuberculosis disease. Isolation rooms did not have proper airflow, and air exhausted from these rooms may have contaminated other areas of the medical center. In addition, certain high-risk areas of the medical center, such as the ambulatory care and intensive care units, lacked proper ventilation to minimize the possibility of spreading tuberculosis.

Since the outbreak, the East Orange Center has made major improvements in its infection-control practices. In addition, VA plans to contract for construction of 19 isolation rooms at the center; these should be completed by October 1994. Since the improvements were made, 13 cases of tuberculosis have been identified at the East Orange Center, and 2 were

multiple drug resistant tuberculosis. VA considers 20 or more cases to be a high number of cases.

VA has taken management initiatives to strengthen tuberculosis controls at its other medical centers. These include recently developed tuberculosis program guidance and procedures and tuberculosis implementation plans for making facility improvements. VA also is providing oversight of centers' tuberculosis-control programs and practices. According to a VA survey, as of December 1992, 10 medical centers each had more than 20 cases of tuberculosis. Six of the 10 also had the highest numbers of AIDS cases.

Tuberculosis outbreaks are not unique to VA. High percentages of patients most vulnerable to tuberculosis coupled with inadequate facilities and procedures have led to outbreaks in other hospitals. Some of these hospitals are implementing corrective measures similar to those employed at the East Orange Center, according to published literature and interviews with hospital officials. Along with corrective measures, GAO believes that continued management oversight of infection-control practices is needed.

Principal Findings

Lax Infection-Control Practices and Inadequate Isolation Rooms

Ambulatory care staff at the East Orange Medical Center did not consistently isolate possible tuberculosis patients. As a result, patients with active tuberculosis disease may have spread the disease to other patients in the center. In addition, some patients suspected of having tuberculosis were admitted to the medical center but were not placed in isolation until 2 or 3 days after admission. Delays in obtaining lab test results contributed to the problem.

CDC found that the East Orange Center placed tuberculosis and AIDS patients on the same ward with a shared bathroom, thus increasing the danger of spreading the disease. Isolation room doors were left open. Known or suspected tuberculosis patients were allowed to leave their rooms without appropriate masks. Staff sometimes wore no protective masks or else wore surgical masks that do not provide protection from tuberculosis because they do not provide a tight seal around the face.

Isolation rooms were also inadequate at the East Orange Medical Center. Isolation rooms did not have the required six air changes per hour, did not exhaust air to the outside, and did not have self-closing doors. Other hospital areas, such as ambulatory care, admissions, and pulmonary care, also did not have adequate ventilation.

After June 1992, the East Orange Center instituted changes in its infection-control practices, including early isolation and treatment with at least four drugs to known and suspected tuberculosis patients. The medical center also implemented interim measures to upgrade isolation facilities, including the installation of exhaust fans with high-efficiency particulate air filters to provide negative pressure and self-closing doors with observation windows.

VA Management Initiatives to Strengthen Tuberculosis Controls Systemwide

VA has developed management initiatives to help control the spread of tuberculosis at its medical centers. Most centers treat tuberculosis patients and many require clinical and construction improvements to reduce the risk of tuberculosis transmission. VA has issued policies and procedures to increase tuberculosis awareness. For example, its April 1993 tuberculosis program planning guidance aids centers in developing and implementing their tuberculosis plans that address both clinical and construction needs. VA's Central Office and the regions have reviewed the centers' construction projects and established priorities. Funding decisions are being made for fiscal year 1994 and later.

Non-VA Hospitals Face Similar Problems

The tuberculosis outbreak at the East Orange Medical Center occurred under conditions that are increasingly common to many urban hospitals. Over the last 3 years, CDC has investigated outbreaks of tuberculosis in at least 10 non-VA hospitals and one correctional facility. An October 1992 Tuberculosis Infection Control Survey of U.S. hospitals conducted by CDC revealed that multiple drug resistant tuberculosis is becoming more widespread in the United States and many hospitals' infection-control programs need improvement to prevent transmission of the disease to patients and employees. In response to these conditions, some hospitals have implemented corrective measures similar to those undertaken at the East Orange Center.

Continued Oversight Needed

While facility improvements and program guidance may be needed, they alone are not enough to provide assurance that similar outbreaks will not

occur at either other VA medical centers or non-VA hospitals. Continued management oversight of infection-control practices is needed along with timely, accurate data on the number and trends in tuberculosis cases and employee test results.

Agency Comments

We obtained oral comments from cognizant VA officials on the draft report. They generally agreed on the need for (1) continued oversight of infection-control practices and (2) timely and accurate data on employee testing for tuberculosis. However, they were uncertain, because of budgetary constraints, when improvements to the Decentralized Hospital Computer System would be completed. (See ch. 5.)

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Abbreviations

AIDS	acquired immunodeficiency syndrome
CDC	Centers for Disease Control and Prevention
DMF	dust-mist-fume (respirator)
HEPA	high-efficiency particulate air (filter)
HIV	human immunodeficiency virus
MDR-TB	multiple drug resistant tuberculosis
NIOSH	National Institute for Occupational Safety and Health
NJSHD	New Jersey State Health Department
OIG	Office of the Inspector General
OSHA	Occupational Safety and Health Administration
TB	tuberculosis
VA	Department of Veterans Affairs
VHA	Veterans Health Administration

Introduction

After years of relatively few reported cases, tuberculosis now poses one of the most serious health risks in the United States. Moreover, new strains have been identified that are resistant to commonly used treatment medications. As a result, tuberculosis can be very costly to treat and often fatal. Because it is mainly caused by airborne bacteria, health care providers are concerned about transmission of tuberculosis not just among patients but staff and visitors as well.

Representative Joseph P. Kennedy II asked us to examine (1) the reasons for the recent outbreak at the Department of Veterans Affairs (VA) medical center in East Orange, New Jersey and (2) VA's efforts to assist the East Orange and other centers to strengthen their tuberculosis-control efforts. We also compared the East Orange center's experience with this outbreak with those of non-VA hospitals.

Background

Tuberculosis is generally transmitted when a person with active tuberculosis coughs or sneezes. The immune system of a normally healthy person will prevent the development of active tuberculosis disease when the exposure is infrequent. The only evidence of infection may be a positive reaction to a tuberculosis skin test. Once a person has a positive skin test, indicating exposure to tuberculosis, all subsequent skin tests are positive. Chest X rays are then needed to help in diagnosing active tuberculosis disease. A person who has tuberculosis infection but not active tuberculosis disease cannot spread the infection to others. Such a person has no symptoms¹ of tuberculosis but does carry the bacteria that can cause tuberculosis disease at a later time.

The drugs most commonly used to treat tuberculosis are isoniazid and rifampin. Usually, preventive therapy consists of the use of these drugs for a period of 6 to 12 months. Similar therapy is also used to treat active tuberculosis disease. If the patient takes the medications for the full period, the disease is generally cured and should not recur. Although the tuberculosis bacteria remain in the patient's body, the patient may remain symptom-free and not contagious to others.

Resurgence of Tuberculosis Cases

A steady three-decade decline in tuberculosis in the United States came to a halt in the mid-1980s. The number of tuberculosis cases declined from 84,304 in 1953 to 22,255 in 1984. The prevalence of tuberculosis disease

¹The general symptoms of active tuberculosis disease include persistent cough, night sweats, fever, and fatigue.

declined from 53 cases per 100,000 population in 1953 to 9.4 cases per 100,000 population in 1984. In 1985, the number of tuberculosis cases began to increase. The following table shows that the increase has continued for the last several years.

Table 1.1: Increase of Tuberculosis Cases in the United States (1990-92)

Year	Tuberculosis cases	Cases per 100,000 population
1990	25,701	10.3
1991	26,283	10.4
1992	26,673	10.5

Much of the recent increase in tuberculosis is linked to patients who may have been exposed to tuberculosis in other countries, substance abuse, and the human immunodeficiency virus (HIV) and acquired immunodeficiency syndrome (AIDS) epidemic. Because HIV and AIDS weaken the immune system, persons who are HIV-positive are at increased risk of developing active tuberculosis disease if they are exposed to the disease. Therefore, transmission of tuberculosis is of particular concern in settings in which persons with either HIV or AIDS receive care.

The nationwide increase in tuberculosis is also related to the emergence in recent years of tuberculosis strains that are resistant to isoniazid, rifampin, or other drugs. If a patient does not take all medication for the time period specified, the tuberculosis bacteria can become resistant to the drugs and develop into multiple drug resistant tuberculosis (MDR-TB). Drug resistant tuberculosis may then be transmitted to other persons. MDR-TB is difficult and expensive to treat because a greater variety—usually at least four—of the more expensive drugs must be employed.² The minimum duration of therapy for MDR-TB is 18 to 24 months and the cure rate is lower than for regular TB. The most important step to prevent the development of MDR-TB is for patients to take all medications.

While tuberculosis, especially MDR-TB, presents a major challenge to health officials, steps can be taken to curb its spread. CDC's 1989 report A Strategic Plan for the Elimination of Tuberculosis in the U.S. provides a three-step plan to (1) develop more effective use of existing prevention and control methods, especially in high-risk populations; (2) develop and evaluate new technologies for treatment, diagnosis, and prevention; and (3) rapidly assess and transfer newly developed technologies into clinical

²Other drugs that may be employed in various combinations to treat MDR-TB include pyrazinamide, ethambutol, streptomycin, paraaminosalicylic acid, ethionamide, cycloserine, capreomycin, and kanamycin.

and public health practice. The plan's objective to eliminate tuberculosis in the United States by the year 2010 has support from major health organizations and identifies activities for short- and long-term implementation.

VA's Health Care System

VA administers the nation's largest health care network, which consists of 171 hospitals, 362 outpatient clinics, 129 nursing homes, and 35 domiciliaries. Most of these facilities are part of VA's 158 medical centers. For fiscal year 1992, VA spent about \$14 billion on veterans' medical care, including about 1 million inpatient hospital stays and about 24 million outpatient visits.

VA provides medical care to veterans with a wide range of conditions, including both tuberculosis and HIV or AIDS. As of December 1992, VA had treated 14,649 AIDS cases since 1979, when VA began tracking them. VA also treated more than 976 active tuberculosis cases during 1992.

Federal and State Roles in Addressing Tuberculosis

Several federal agencies have major responsibilities for providing leadership and oversight of tuberculosis-related issues. These agencies include the Department of Health and Human Services' Centers for Disease Control and Prevention (CDC) and a component of CDC, the National Institute for Occupational Safety and Health (NIOSH), and the Labor Department's Occupational Safety and Health Administration (OSHA). CDC serves as the national focal point for developing and applying disease-prevention and control guidelines.³ NIOSH coordinates a national program to recommend occupational safety and health standards to assure safe and healthful working conditions for employees. OSHA enforces standards to assure employee protection against workplace safety and health hazards.

State health departments have responsibility for monitoring tuberculosis cases and reporting them to CDC. Hospitals report tuberculosis cases to state health departments, report the disposition of cases, and report when tuberculosis patients leave the hospital. State health departments will stay in touch with tuberculosis patients who are discharged and may also contact family and friends of tuberculosis patients to ascertain whether they, too, should be tested for tuberculosis. As a federal agency, VA is not required to report to state health departments; however, as a matter of

³Current CDC guidelines were published in 1990. See Guidelines for Preventing the Transmission of Tuberculosis in Health-Care Settings, with Special Focus on HIV Related Issues, Morbidity and Mortality Weekly Report, Vol. 39, No. RR-17 (Atlanta: CDC, Dec. 1990).

policy, VA medical centers do report information about their tuberculosis patients to state health departments.

The East Orange Outbreak

In June 1992, CDC, assisted by NIOSH and the New Jersey State Health Department (NJSHD), visited VA's East Orange Medical Center to investigate the increase in tuberculosis cases experienced by the medical center over the prior 2 years. CDC found that 51 patients hospitalized at the East Orange Center between January 1990 and May 1992 had contracted active tuberculosis. Of the 51, 13 had MDR-TB. All 13 of the patients were HIV-positive; 11 of them died—an 85-percent mortality rate. CDC believed that some patients acquired tuberculosis while hospitalized at the East Orange Center.

VA and CDC policies require skin-testing of all employees at the time of their employment. However, East Orange either did not have records of the test results on all medical center employees at the time of their employment or did not have follow-up test results to determine whether employees had contracted the disease since their employment. The East Orange Center reported to CDC that 5 of 10 infectious-disease-ward employees who had previously tested negative for tuberculosis in 1991 tested positive in 1992. This indicated exposure to active tuberculosis disease. However, no cases of active tuberculosis disease among the medical center staff had been reported.

Between June and October 1992, CDC, NJSHD, and several VA components took steps to help the medical center address the tuberculosis outbreak. During its June visit, CDC, assisted by NIOSH and NJSHD staff, examined the center's infection-control policies and procedures. These agencies reviewed the East Orange Center's compliance with infection-control guidelines and inspected the medical center's ventilation system for deficiencies. Several VA components also studied the outbreak. In October 1992, VA's Program Director for Infectious Diseases and VA's Office of Inspector General conducted separate reviews of the East Orange Center's infection-control program with particular emphasis on tuberculosis.

Scope and Methodology

To assess reasons for the outbreak, we obtained data on five independent investigations of the operating policies and procedures at the East Orange Medical Center. The investigations were conducted by CDC, NIOSH, VA's Office of Inspector General (OIG), VA's Program Director for Infectious

Diseases, and the center's Tuberculosis Task Force.⁴ During our review, we interviewed key officials of these agencies to discuss factors contributing to the outbreak. We met with VA's Central Office and Region I staff to discuss VA's plans to address the problems and their actions to assist other centers at potential risk. We visited CDC to discuss the outbreak and whether it is unique to VA's health care system. We also visited the East Orange Center to follow up on actions taken as a result of the five independent investigations.

Through discussions with CDC officials and a review of tuberculosis literature, we identified 10 non-VA hospitals that CDC had investigated that had experienced tuberculosis outbreaks. We analyzed the reported causes and corrective actions for these outbreaks and compared them to VA's experience at the East Orange Medical Center. We reviewed current and proposed infection-control standards that have implications for health care facilities across the country. We visited VA's Regional Office at Fort Howard, Maryland, to discuss its oversight of the East Orange Center and other medical centers' tuberculosis infection-control practices.

We performed our work between August 1992 and October 1993 in accordance with generally accepted government auditing standards.

⁴See the bibliography for reports on the tuberculosis outbreak at the East Orange VA Medical Center.

East Orange Medical Center's Experience With Tuberculosis

Failure to consistently isolate tuberculosis patients, poor enforcement of isolation requirements, and inadequate isolation rooms contributed to an outbreak of MDR-TB at East Orange between 1990 and 1992. East Orange's management was ineffective in overseeing tuberculosis-control practices. To address these weaknesses, the medical center developed a comprehensive corrective action plan which has enabled East Orange to increase awareness of the tuberculosis problem and make major improvements in identifying, isolating, and treating tuberculosis cases within its facility.

Isolation of Patients Not Consistent

Before June 1992, the East Orange Center's procedures for isolation of suspected or known tuberculosis patients were not applied consistently. Our review of nine charts on patients who were hospitalized between fiscal years 1990 to 1992 revealed that sometimes patients with suspected tuberculosis were isolated immediately and at other times they were not initially isolated for 2 or 3 days. Employees of the East Orange Center's Infectious Diseases Service, who treated most of the patients involved in the outbreak of MDR-TB, did not want to isolate and treat patients they believed might have the disease before the lab test confirmed a positive result. Further, because all outpatients waited in crowded waiting rooms before being screened for tuberculosis, they were potentially being exposed to tuberculosis from other patients. Such contacts would allow tuberculosis to spread within the medical center. VA's Office of the Inspector General (OIG) reported the following concerns during its review in October 1992:

"Ambulatory Care Triage Increased Patient And Employee Risk Of Infection. A common means by which highly infectious diseases are communicated among susceptible patients is through interaction in poorly ventilated or crowded conditions. Our inspection of the Ambulatory Care area found it to be extremely crowded with patients standing in lines awaiting eligibility interviews. Patients were standing or walking around the area because the area did not have adequate seating to accommodate all of the patients and visitors. All Ambulatory Care patients, including walk-in and clinic patients, had to report to the eligibility clerk, and then to another Medical Administration Service employee before being seen by the nurse. If the nurse suspected that the patient had an infectious disease she informed the physician who would expedite the patient's admission to the hospital. However, until a nurse examined patients, they were able to interact with everyone in the Ambulatory Care area."

Since the outbreak, the medical center has changed its admission process to separate suspected tuberculosis patients from others. A nurse screens

coughing or sneezing patients as soon as possible after they register, then sends them to a physician for evaluation. Medical center officials noted that staff now isolate both suspected tuberculosis patients as well as known infectious patients more quickly. In fact, nurses on the pulmonary ward may isolate patients even without a physician's order.

Untimely Lab Results

Untimely lab test results contributed to the inconsistent isolation of patients when staff did not want to isolate a patient before the lab test results were received. Sputum smears from suspected tuberculosis patients were sent to the lab two or three times per week and the results for these smears took 3 to 7 days to be returned. In addition, the East Orange Center sent these smears by regular mail to the West Haven, Connecticut, VA Medical Center to (1) confirm whether the patient had tuberculosis, (2) determine whether the patient had MDR-TB, and (3) determine whether drugs¹ given to treat the disease were effective. This process took between 6 to 8 weeks. The slow return of lab results may also have delayed appropriate treatment for tuberculosis and MDR-TB patients.

Since the outbreak, the center has reduced the turnaround time for smear results by transferring staff into the lab and enhancing its laboratory facilities to provide for tuberculosis smear analysis. For instance, officials reported that they collect lab smears daily and provide results within 24 hours. Positive smears are sent to the West Haven Center by Express Mail the same day. The West Haven Center reports the lab results to the East Orange Center using a computerized electronic mail system. With this system, officials told us that lab results are more widely disseminated to all employees involved with the patient and the results are entered into the patient's chart immediately. Identifying positive smears each day has reduced the time needed to diagnose patients with tuberculosis. However, since the tuberculosis smear is a slow-growing culture, identifying MDR-TB still takes 6 to 8 weeks according to center officials.

Failure to Follow Isolation Precautions Endangered Patients and Staff

The East Orange Medical Center did not strictly enforce isolation precautions for control of tuberculosis. The 1990 CDC guidelines stipulate that suspected or known infectious tuberculosis patients should remain in isolation rooms with the doors closed and only leave the rooms when medically necessary. Also, persons entering isolation rooms should wear

¹After June 1992, the East Orange Center used at least four drugs to treat known and suspected tuberculosis patients.

appropriate respiratory protection and patients should wear respiratory protective devices when they leave the rooms. By failing to enforce these precautions, the medical center increased the chances of spreading the disease among patients, employees, and visitors.

Poor Adherence to Isolation Precautions

Investigations by CDC and VA's OIG found poor adherence to tuberculosis isolation precautions before the outbreak at the medical center. For example, some patients in isolation left their rooms without masks and doors of isolation rooms were kept open most of the time.

To encourage isolated patients to stay in their rooms and keep doors closed, the medical center has made isolation rooms more attractive and easier to use. For instance, the medical center has provided television sets and telephones in isolation rooms. The medical center installed self-closing doors with observation windows. These changes mean that doors will need to be opened less frequently and are less likely to be left open. The center also installed signs at isolation room doors. The Chiefs of Services have been assigned the responsibility for monitoring compliance with respiratory protection practices among their staff.

The medical center has taken steps to deal with patients who do not comply with the isolation restrictions. These steps include counseling patients about the importance of isolation and close monitoring, on a 24-hour basis, if necessary. In addition, employees now escort all isolation patients when they leave their rooms. Staff doctors have been given more authority to make patients follow the rules. As of March 1993, there have been no involuntary discharges for noncompliance, but some patients have left the hospital because they did not want to follow the rules. According to medical center officials and the OIG report, the East Orange Center has achieved improved compliance with isolation precautions.

East Orange also did not follow proper procedures in separating HIV-positive patients with tuberculosis from HIV-positive patients without tuberculosis. In fact, some of these patients shared the same bathrooms. The 1990 CDC guidelines note that controlling tuberculosis transmission where immunosuppressed patients receive care is particularly important. According to CDC, MDR-TB patients in isolation still posed a risk to other HIV patients on their ward because of nonadherence to appropriate isolation precautions by ambulatory patients, employees, or both. Since the outbreak, one infectious disease physician told us that the East Orange

Center no longer houses tuberculosis patients on the same wards with HIV patients who do not have tuberculosis.

Ineffective Respiratory Protection

CDC and VA issued guidance in 1990 and 1992, respectively, on appropriate respiratory protection. The guidance suggests the use of respirators that are effective in protecting employees against tuberculosis. Before the outbreak, medical center staff used surgical masks or no respiratory protection at all. Surgical masks² do not provide the same level of filtration and tight face seal as dust-mist respirators and are considered ineffective in stopping the spread of tuberculosis.

After the outbreak, medical center officials reported that they had purchased dust-mist-fume (DMF) respirators. DMF respirators provide higher levels of filtration than dust-mist respirators. The medical center specified that an industrial hygienist or a representative of the manufacturer would conduct training in the use of DMF masks for more than 1,000 at-risk employees. Medical center staff complained that it is harder to communicate wearing a DMF mask. In spite of this, more center employees are complying with respiratory protection guidance, according to OIG and medical center staff.

Inadequate Isolation Rooms for Tuberculosis Patients

An important element in the treatment and control of tuberculosis is to have isolation rooms with negative pressure, at least six air exchanges per hour, and exhaust air vented to the outside. In the late 1980s, the East Orange Center renovated its heating, ventilating, and air conditioning systems; however, the isolation rooms were never designed properly nor did they satisfy the center's projected needs, even after Center staff brought problems to the attention of VA Central Office. VA Central Office officials cited cost as a primary concern. Our review of the history of ventilation deficiencies showed that the center tried over the years to address the deficiency in the system with minor adjustments, but could not obtain adequate ventilation.

In June 1992, NIOSH reported³ that the isolation rooms at the East Orange Center were inadequate. NIOSH's ventilation system evaluation found that

²Standard surgical masks are not certified by NIOSH. They may not be effective in preventing inhalation of tuberculosis bacteria because they are not designed to provide a tight face fit and to filter out the airborne bacteria. Users cannot be assured that they are receiving adequate protection because there are no proven fit tests for these masks and they cannot be fit-checked.

³Health Hazard Evaluation Report, VA Medical Center, East Orange, New Jersey, U.S. Department of Health and Human Services, Public Health Service, CDC/NIOSH, HETA 92-296-2243 (August 1992).

the isolation rooms did not meet ventilation requirements.⁴ Deficiencies included items such as (1) patient rooms that were positively pressurized, which is not recommended for the isolation of infectious respiratory patients, (2) variances in airflow below designed levels, and (3) air not exhausted to the outside.

On the basis of its evaluation, NIOSH recommended that VA construct a dedicated hospital wing or floor for infectious patients and take interim corrective measures for systems already in place. VA's OIG report⁵ and our site visit, both completed in March 1993, similarly concluded that the East Orange Center had made progress in responding to CDC and other recommendations. VA plans to contract for construction of 19 isolation rooms, which should be completed by October 1994 at a cost of \$2.3 million. Following the outbreak, the center initiated several interim measures to provide additional protection against tuberculosis transmission, such as installing (1) ultraviolet lamps⁶ in patient rooms, (2) self-closing doors and observation windows, (3) isolation precaution signs outside patient rooms, and (4) exhaust fans with high-efficiency particulate air filters to provide negative pressure. Since these measures were implemented and infection-control practices followed, the East Orange Center has reported 13 cases of tuberculosis to the NJSHD, 2 of which were MDR-TB. By analyzing the wards these patients occupied and the drug-resistance patterns of their infections, the infection-control staff determined that none of these cases was transmitted within the hospital.

Other hospital areas that pose a risk for tuberculosis transmission due to deficiencies in the ventilation system at the East Orange Center include ambulatory care, admissions, pulmonary, and surgical and medical intensive care units. The center also initiated interim measures in some of these areas, such as installing ultraviolet lights, posting isolation precaution signs, and improving administrative processes in the Ambulatory Care area. The Center plans improvements in these areas, including modification or replacement of the heating, ventilating, and air conditioning system in ambulatory care, and conversion of rooms to provide negative pressure for isolation and treatment. East Orange Center officials reported that construction should be started by September 1993

⁴NIOSH compared East Orange's airflow measurements to the design specifications on its mechanical plans and guidelines of the American Society of Heating, Refrigerating, and Air-Conditioning Engineers and the American Institute of Architects.

⁵Review of Infection Control Program, VA Medical Center East Orange, New Jersey, VA's Office of Inspector General, Office of Healthcare Inspections, Rpt. No. 3HI-A28-068 (March 1993).

⁶Ultraviolet lamps can be used in ceiling or wall fixtures or within air ducts of recirculating ventilation systems. These lamps can kill many bacteria, including mycobacterium tuberculosis.

and completed by July 1994 at a cost of \$3.1 million. Thus, the total construction costs for a hospital wing and other areas are estimated at \$5.4 million.

Management Oversight of Tuberculosis-Control Practices Ineffective

When the outbreak occurred, the East Orange Medical Center management was ineffective in overseeing tuberculosis-control practices. Various practitioners were aware that tuberculosis cases were increasing but did not have sufficient information on trends and patterns of these cases until spring 1991 when staff began reviewing charts and tracking patients.

Lack of Tuberculosis Case Analysis

Until spring 1991, no analysis or evaluation of tuberculosis cases had been done that would reveal patterns and trends in the spread of the disease. One infection-control practitioner stated that before the CDC visit in June 1992, the medical center's tuberculosis surveillance program consisted of recording individual cases in a log and reporting them to NJSHD. The medical center has now begun analytical work that facilitates tracking and trending of cases.

The medical center has made improvements in its management of tuberculosis data. It hired a data manager to assist the infection-control practitioners with data collection, data input to a new automated database, and reporting. According to medical center staff, the information on tuberculosis is more readily available and has improved the center's ability to track and analyze data for reporting purposes and to determine whether hospital transmission has occurred.

Limited Data on Employee Testing

Before the outbreak, the East Orange Center had little baseline data on employee tuberculosis tests. According to VA and CDC policy, the Center should have had an active-employee skin-testing program so that the number of ward-specific conversions from a negative to a positive result could be calculated. Further, all employees should have skin tests at least annually or the frequency of repeat testing should be based on the risk of developing a new infection. For example, the high-risk employees on the infectious diseases ward should have skin tests at least every 6 months. New employees received skin tests or chest X rays upon initial employment. According to a union representative, the medical center would send a reminder note about annual follow-up testing but did not promote it aggressively. At the time of the outbreak, the medical center

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had current information on previous employee testing only for a small group on the infectious-disease ward. Among this group, 10 employees who tested negative in 1991 were retested in 1992 and 5 had converted to positive skin tests, a 50-percent conversion rate.

The medical center began hospitalwide employee testing in mid-1992 using the CDC-recommended method of injecting tuberculosis derivatives under the skin by needle. In November 1992, one medical center official said that the center had completed 6-month follow-up testing for 500 staff working in high-risk areas. Fewer than 1 percent of these employees converted to positive skin tests. (The medical center offers preventive therapy to those who convert.) The medical center plans (1) annual skin-testing for personnel at high risk for tuberculosis transmission (persons in direct patient contact or in contact with secretions, body fluids, and/or tissues), (2) semiannual testing for personnel at very high risk (persons in daily contact with tuberculosis patients), and (3) annual testing on a voluntary basis for personnel at low risk (persons with no patient contact).

Further, the center has taken other steps to improve its knowledge base about employee exposure. Reports on employee testing, one medical center official said, are now compiled by the employee health nurse and transmitted to the Assistant Chief of Staff for Ambulatory Care. In addition, the official told us that the medical center has begun using a new CDC-designed computer program to track employee testing and follow-up.

Both medical center and VA Central Office officials told us that follow-up employee skin-testing is voluntary. At the East Orange Center, the Director and Chief of Staff now promote it strongly. Through education activities, town meetings, and organizational changes, the East Orange Medical Center has increased awareness of the tuberculosis problem and enhanced staff participation in testing.

VA Management Initiatives to Strengthen Tuberculosis Controls Systemwide

Most of VA's 158 medical centers treat patients who have tuberculosis and AIDS; some centers have workloads that are comparable to or exceed that of the East Orange Center. VA has developed management initiatives to help centers avoid the types of problems that the East Orange Center experienced. These initiatives include newly developed tuberculosis-control policies and procedures, locally developed implementation plans, and regional efforts to provide oversight of centers' tuberculosis-control practices.

Most VA Medical Centers Treat Tuberculosis and AIDS Patients

VA's 1993 Infectious Diseases Control Survey shows that medical centers treated more than 976 tuberculosis-infected patients as of December 1992. (This figure does not include two facilities¹ because their survey data had not been received by VA's Central Office). Sixteen centers have tuberculosis workloads that are similar to or greater than those at the East Orange Center. The number of tuberculosis patients treated varied by region, ranging from 152 in Region IV to 453 in Region III. In contrast, 31 medical centers reported that they did not treat any tuberculosis patients in 1992, according to the survey. VA's Program Director for Infectious Diseases is currently verifying each center's reported cases.

VA's Program Director told us that the results of the 1993 Infectious Diseases Control Survey provide a more accurate risk assessment of tuberculosis cases in VA. He said that VA is working toward developing a program to computerize infection-control data that will capture specific information on tuberculosis cases involving patients and employees and provide statistics on other infectious diseases for inclusion in the Decentralized Hospital Computer System. This program initiative, the Program Director said, would improve VA's reporting capability and facilitate the transmission of data within the agency.

As of December 1992, VA had treated 14,649 AIDS cases since 1979, when VA began tracking them. CDC has estimated that the incidence of tuberculosis in HIV-infected individuals is 500 times greater than in the general

¹Oklahoma City and Honolulu.

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population.^{2,3} Some centers face potential risk with high numbers of AIDS patients,⁴ tuberculosis patients, or both (see fig. 3.1).

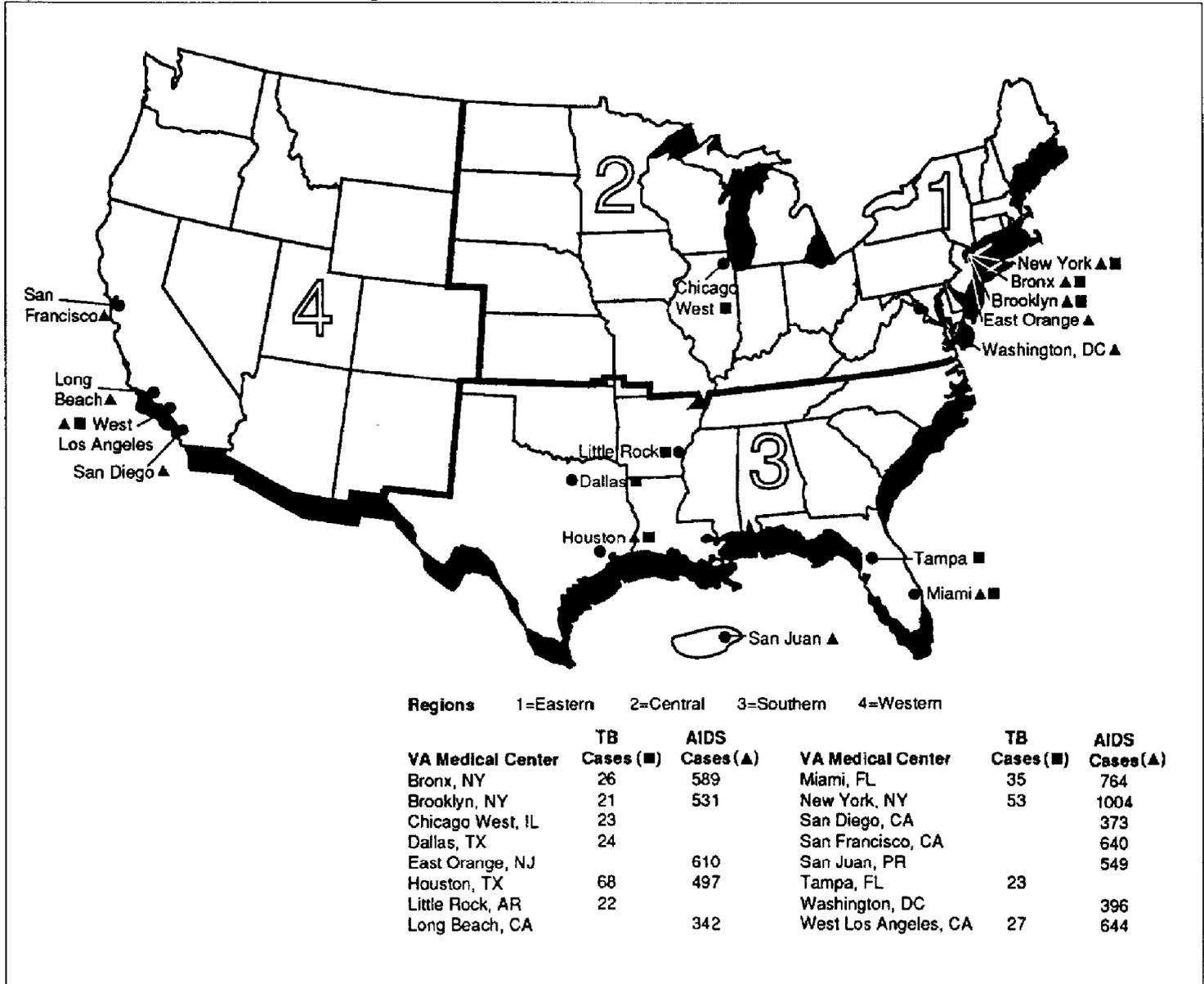
²For an otherwise healthy person infected with tuberculosis, the chance of developing active tuberculosis is 10 percent over a lifetime. HIV-positive persons infected with the tuberculosis bacterium have over a 10-percent chance each year of developing symptoms.

³Significant increases in tuberculosis morbidity are occurring in certain areas with a high prevalence of patients with HIV-infection. The increase in annual tuberculosis morbidity seen in the United States occurs mainly in geographic areas and demographic groups with large numbers of AIDS cases. This suggests that the HIV epidemic has begun to influence tuberculosis morbidity.

⁴Twelve VA medical centers account for almost half of the AIDS cases in VA—the East Orange Center was ranked fifth.

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Figure 3.1: VA Medical Centers With High Numbers of Tuberculosis and/or AIDS Cases



Source: Tuberculosis Data—VA's 1993 Infectious Diseases Control Survey as of December 1992. The number of tuberculosis cases are shown for medical centers with 20 or more, which VA considers high. Those centers where numbers are not shown such as East Orange, New Jersey, have tuberculosis cases, but they are less than 20.

AIDS Data—VA's AIDS Patient Registry as of December 1992. These data represent VA's top 12 medical centers with the highest cumulative number of AIDS cases, excluding Chicago since four centers were combined. This exclusion was made for consistency purposes, because other centers were reported individually.

Two surveys show that some hospitals have lax infection-control practices and inadequate environmental conditions similar to those at the East Orange Center.^{5,6} These surveys identified concerns regarding VA's compliance and oversight activities.

VA requires all centers, especially those where HIV-infected patients receive care, to implement the most current published guidelines for prevention of tuberculosis transmission.⁷

Policy and Procedural Changes Strengthen Tuberculosis Awareness

VA Central Office has issued new and updated policies and made procedural changes to raise the level of consciousness about tuberculosis. For example, in December 1992, VA Central Office established a Tuberculosis Planning Group to develop tuberculosis program planning guidance for medical centers' use in assessing the potential risk for tuberculosis transmission in their facilities. (See app. III.) The guidance addresses both clinical and construction improvement needs. VA instructed centers to address clinical procedures for managing suspected or known tuberculosis patients in areas such as identification, isolation, employee testing, and respiratory protection. The construction improvements relate to ventilation systems, isolation room facilities, and high-risk infection areas.

To effectively plan and implement a systemwide tuberculosis program, VA officials said that the guidance will provide a consistent framework for program planning and a base of information to accomplish the tasks involved. In addition, VA Central Office updated its tuberculosis employee-testing program and provided instructions to centers on the respirators to be used for tuberculosis protection. In these areas, VA is encouraging centers to also use CDC guidelines for tuberculosis screening and the wearing of protective respiratory devices.

VA informed medical centers of procedures to minimize the risk of tuberculosis before and after the outbreak at the East Orange Center. These procedures, discussed in agencies' investigative reports and the

⁵ VA's Office of Facilities Survey (Nov. 1992.)

⁶ How Prepared Are U.S. Hospitals to Control Nosocomial Transmission of Tuberculosis? Centers for Disease Control and Prevention, Atlanta, GA and the American Hospital Association, Chicago, IL. CDC included municipal, university, and VA hospitals and a random sample of all private hospitals with more than 100 beds.

⁷ VA Employee Tuberculosis Testing Program. Department of Veterans Affairs, Veterans Health Administration (Directive 10-93-064) (June 1993).

medical center's corrective action plan, reiterate the control measures that lacked emphasis before officials were aware of the tuberculosis outbreak. (See app. II.) These measures are categorized into six major areas: identification, isolation, diagnosis, treatment, reporting, and education. Our work shows that VA issued guidance related to these areas as well as instructed centers to comply with other guidelines, such as those published by CDC. For example, VA issued tuberculosis program planning guidance that the medical centers recently used as criteria to develop their tuberculosis construction plans and aid them in assessing and implementing tuberculosis strategies. This guidance made frequent references to CDC guidelines.

In October 1992, CDC convened a meeting of health care experts to review and assess the need to revise the 1990 CDC guidelines covering tuberculosis transmission in health care facilities. These health experts observed "a need to share, in some formal way, successful prevention models and experiences so that others replicate effective strategies." An official at the East Orange Center told us that CDC has signed an agreement that provides for the center to share information about its tuberculosis experience.

Medical Centers Are to Develop Tuberculosis Implementation Plans

In June 1993, VA medical centers were to develop a tuberculosis implementation plan, using the tuberculosis program guidance. The plans were to address current and projected tuberculosis workloads, patient and employee care needs, and construction improvement projects necessary to meet minimum acceptable CDC guidelines.⁸ VA required centers to submit in writing, through their regional offices, only those construction projects necessary to correct deficiencies in accordance with the tuberculosis program guidance.

VA's four regional offices conducted reviews of their medical centers' tuberculosis construction projects and developed regional priorities for submission to VA's Central Office. A VA Central Office official told us that the regions used similar procedures for determining project priorities. Specifically, Region I's priorities were determined from the number of tuberculosis cases and the risk of transmitting tuberculosis through procedures or areas within a center. According to VA's guidance, all projects were required to include only tuberculosis-related work.

⁸Where current VA criteria exceed the CDC requirements, VA recommends the use of its criteria. However, if system configuration or costs do not allow compliance to more stringent criteria, then the CDC requirements are the minimum acceptable.

VA Central Office Reviews Tuberculosis Projects and Makes Funding Decisions

In August 1993, VA's Tuberculosis Project Review Committee, chaired by the Program Director for Infectious Diseases, reviewed regional priorities and identified projects that should be funded in fiscal year 1994 and later. VA officials told us that most of the medical centers need to undertake extensive and expensive renovations to their heating, ventilation and air-conditioning systems, isolation room facilities, and high-risk infection areas to ensure that VA patients, staff, and visitors are adequately protected from tuberculosis.

Given VA's allocation of \$20 million for tuberculosis projects out of fiscal year 1994 nonrecurring maintenance funds,⁹ the review committee identified specific tuberculosis projects for funding in 1994 from the projects submitted by the regions. The tuberculosis projects identified were those determined by the committee to be the most critically needed, given the limited amount of tuberculosis funds available. According to VA officials, the percentage share of the allocation for each region was determined from tuberculosis priorities systemwide, the number of tuberculosis cases, and region priorities. They said that the \$20 million funded for these projects, using fiscal year 1994 nonrecurring maintenance funds, would need to be replaced whenever additional resources are approved because these monies were designated for other clinical improvements.

According to VA officials, the overall cost of the tuberculosis projects is about \$86 million. The estimate for satellite and free-standing outpatient clinics in leased space will cost another \$10 to \$15 million. (VA officials said they are in the process of obtaining data from clinics in leased space and will be able to report the costs involved.) VA officials said that about \$100 million (total cost of specific tuberculosis project requirements) in funding would be necessary to ensure that VA patients, staff, and visitors are adequately protected from tuberculosis at VA facilities. On August 23, 1993, VA told us that this amount would be absorbed within its fiscal year 1995 budget request and later budget submissions rather than sought through a supplemental appropriation. Tuberculosis projects designated for funding will be selected on their level of priority.

⁹VA officials said that fiscal year 1994 nonrecurring maintenance funds total \$270 million.

Regional Offices Are to Oversee Medical Centers' Tuberculosis-Control Practices

VA's Central Office and regions share responsibility for oversight of infection control. According to VA's policy, the Director, Medical Service, is designated as the central focus for overseeing VA's infection-control program and works in concert with the Infectious Disease Field Advisory Group in formulating policies and procedures for the program. The Program Director for Infectious Diseases has day-to-day program responsibility for developing guidance to the medical centers on infectious disease issues.

VA regional offices are responsible for assuring that each medical center's infection-control program is adequately reviewed and practices and procedures are being carried out in accordance with agency and other guidelines. The region also works with infection-control program officials in VA's Central Office to develop appropriate review criteria. For example, regional representatives were among VA's Tuberculosis Planning Group that developed the guidance used by medical centers to prepare their tuberculosis plans.

VA regions are involved in monitoring medical centers' compliance with infection-control requirements and distributing information on related issues. VA regions reported that they conduct annual program evaluations that now include the tuberculosis criteria. One regional office reported implementing an electronic mail survey of its medical centers during February 1993 to learn the number of newly diagnosed tuberculosis cases, the increase or decrease compared to the prior year, the number of known drug-resistant patients, the number of employees converted to positive, and the existence of employee-testing programs.

During our site visit, Region I officials said that although the region functions mainly in a support role to medical centers it also conducts annual reviews to determine how effectively infection-control and safety programs are working. The regional industrial hygienist and safety staff look closely at center materials such as infection-control and safety committee minutes for trends and significant occurrences as well as whether clinicians handled activities appropriately. If deficiencies are found, regional officials said that steps are taken to correct problems. The region also provides technical consultation on specific issues as needed. Further, regional officials said that many organizations, such as the Joint Commission on Accreditation of Healthcare Organizations, OSHA, and external peer review groups, were overseeing medical center activities as well.

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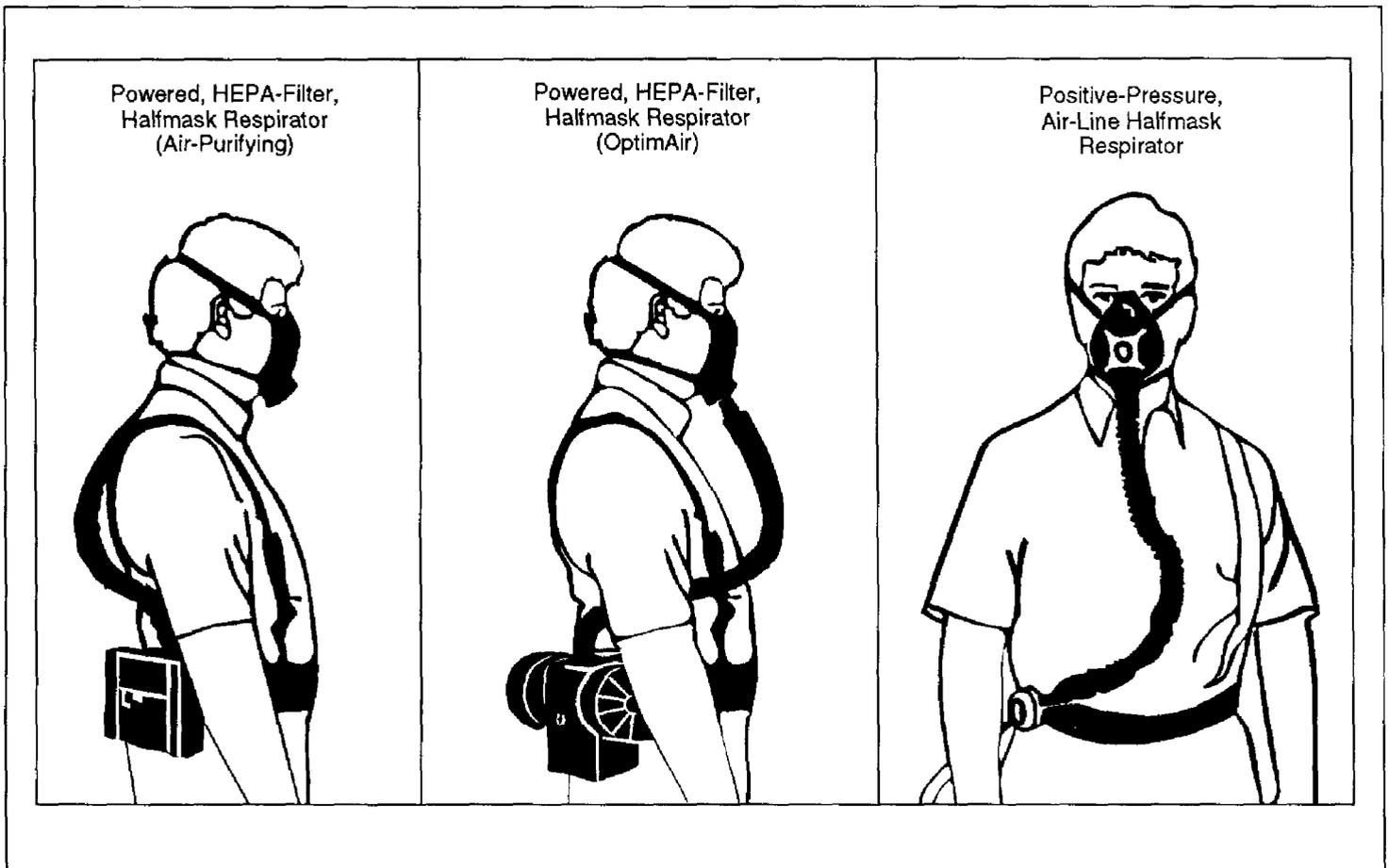
VA's regional offices have disseminated technical information and updates on many topics to assist medical centers. For instance, the regions have shared materials on tuberculosis, bloodborne pathogens, and respiratory protection, including related federal guidelines, such as those from CDC and OSHA. Region I officials told us that they circulated guidance to Eastern Region medical center directors on personal respiratory protection for employees.

According to CDC and OSHA guidelines, the use of respirators should be accompanied by a comprehensive respiratory protection program that includes specific elements such as face-seal fit-testing and fit-checking, training, and follow-up. The question of appropriate respiratory protection is complicated by current uncertainty about what the future standards will be. NIOSH has recommended use of powered air-purifying respirators with high-efficiency particulate air (HEPA) filters¹⁰ but OSHA and CDC have not concurred with this recommendation because the need for more stringent respiratory equipment for tuberculosis control has not yet been scientifically proven (see fig. 3.2).

NIOSH assessment of and recommendations for these respirators did not address issues such as feasibility, user acceptability, and cost implications. The respirators cost about \$344 each. The NIOSH-recommended respirators will assure protection against tuberculosis consistent with the criteria specified in the Occupational Safety and Health Act of 1970, section 20(a)3.

¹⁰NIOSH Recommended Guidelines for Personal Respiratory Protection of Workers in Health-Care Facilities Potentially Exposed to Tuberculosis. Department of Health and Human Services, Public Health Service, Centers for Disease Control. Atlanta, GA; (September 1992).

Figure 3.2: Illustrations of NIOSH-Recommended Respiratory Protection Equipment for Employees Potentially Exposed to Tuberculosis



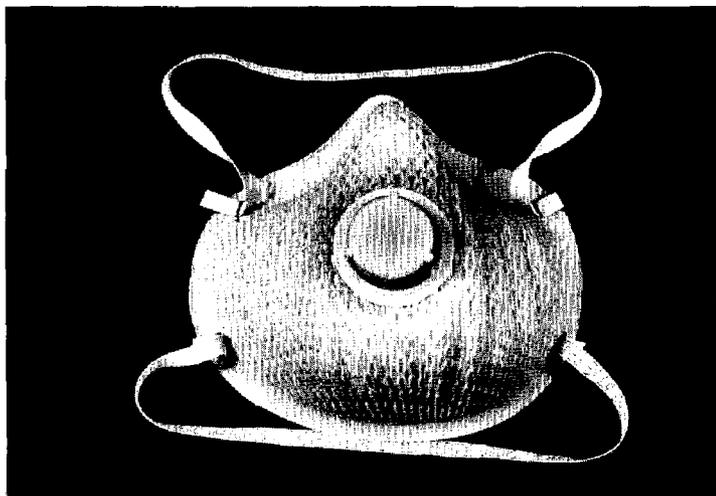
Uncertainty over the extent to which OSHA will incorporate NIOSH recommendations has led VA, like other hospitals, to move slowly in changing requirements for respiratory protection.

In efforts to assist medical centers in avoiding tuberculosis outbreaks, VA's Program Director for Infectious Diseases has instructed centers to use the minimum CDC standard (see fig. 3.3) for respiratory protection. However, in some instances more rigorous respirator standards may be reasonable. VA medical centers will generally follow the most current guidance of oversight agencies such as OSHA and CDC.

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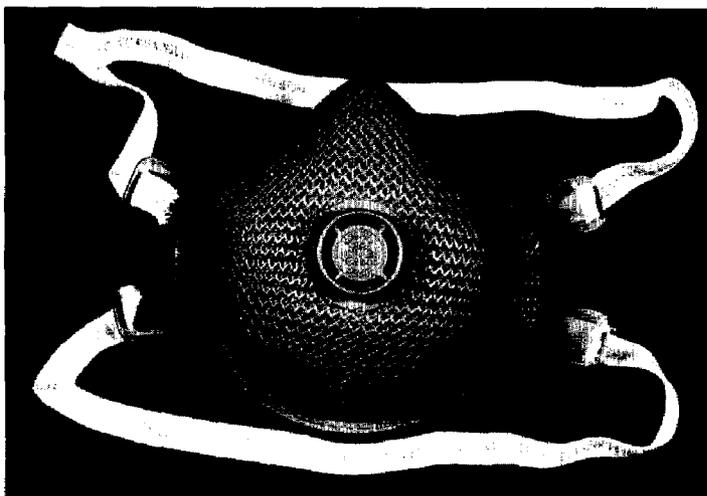
Figure 3.3: Two of the Respiratory Protection Devices VA Suggests for Employees Potentially Exposed to Tuberculosis

Dust and Mist
Respirator (DM)

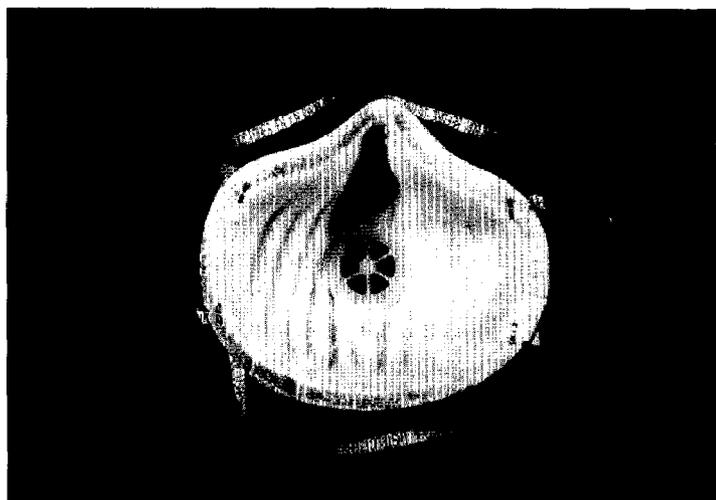


Outside View

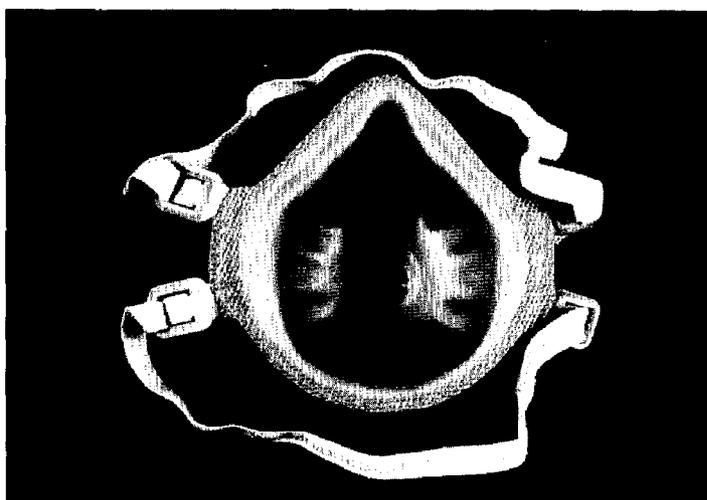
Dust-Mist and Fume
Respirator (DMF)



Outside View



Inside View



Inside View

Non-VA Hospitals' Experience With Tuberculosis

The resurgence of tuberculosis is not unique to VA hospitals. Many non-VA hospitals also have experienced tuberculosis outbreaks in recent years due to conditions like those at the East Orange Center, including lax infection-control practices and inadequate isolation facilities. CDC found these conditions to be increasingly common to many urban hospitals. In response, these hospitals have implemented corrective measures similar to those used by the center. Some state and local health agencies in New York conducted surveys to identify effective measures in controlling tuberculosis.¹

Lax Infection-Control Practices and Other Conditions Led to Tuberculosis Outbreaks at Non-VA Hospitals

Over the last 3 years, CDC has investigated outbreaks of tuberculosis in at least 10 non-VA hospitals and one correctional facility (see bibliography). CDC concluded, in many of the investigations, that incomplete adherence to isolation precautions by patients and employees contributed to the exposure of HIV and AIDS patients to tuberculosis and that MDR-TB was readily transmitted among these patients. Problems contributing to these outbreaks included a rising number of hospitalized HIV and AIDS patients who are at risk of contracting tuberculosis combined with lax adherence to CDC's infection-control guidelines.

The following examples—two hospitals investigated between June 1990 and May 1991—show that the problems contributing to outbreaks at non-VA hospitals were similar to those at the East Orange Medical Center.

- A private nonprofit hospital in New York² experienced one of the first outbreaks of MDR-TB among hospitalized HIV and AIDS patients. The outbreak involved 32 patients with MDR-TB and all had HIV-related infection. Hospital officials stated that factors contributing to this outbreak were: (1) known tuberculosis and HIV and AIDS patients treated in the same clinical area, (2) poor ventilation in isolation rooms, (3) delayed lab results that slowed recognition of tuberculosis infections, and (4) patient noncompliance with infection-control requirements.
- A large nonprivate hospital in Florida experienced an outbreak of tuberculosis involving 29 patients. All these patients had HIV-related infection when they were infected with MDR-TB. CDC found problems similar to those in the New York hospital.

¹Among the states, New York ranked first in terms of increases in tuberculosis cases between 1985 and 1990 and also had the highest number of AIDS cases.

²The New England Journal of Medicine. *An Outbreak of Multidrug-Resistant Tuberculosis Among Hospitalized Patients with AIDS*. New York Hospital. Vol. 326:23 (June 1992).

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Non-VA Hospitals' Experience With
Tuberculosis**

We also examined CDC reports of outbreaks at hospitals in Georgia and Puerto Rico and found that they also shared common problems that contributed to tuberculosis outbreaks during December 1989 and March 1992. Table 4.1 compares the problems at the East Orange Center and the 10 non-VA hospitals reviewed by CDC.

Table 4.1: Problems Contributing to Tuberculosis Outbreaks in Non-VA Hospitals Similar to the East Orange Center's Profile

Problems	East Orange center's profile		Non-VA hospitals' profiles			
	New Jersey	New York ^a	Florida	Georgia	Penn.	Puerto Rico
Lax infection-control practices						
Late diagnosis and TB precautions	X	X	X	X	X	X
Inadequate isolation of tuberculosis/ other patients (for example, HIV)	X	X	X	X	X	X
Improper treatment procedures	X	X	X	X	X	X
Limited employee-testing program	X	X ^b		X	X	X
Inactive surveillance program	X	X ^b	X	X		X
Delayed lab results	X	X	X	X		X
Inadequate ventilation system	X	X	X	X	X	X
Structural limitations						
No self-closing doors	X	X	X	X	X	X
No private baths	X	X ^b				
Insufficient respiratory protection	X	X	X	X	X	X
Noncompliant patients, employees, visitors	X	X	X	X	X	X

^aSix hospitals investigated in New York.

^bReports of these hospitals revealed that one hospital had both a comprehensive employee-testing and surveillance program and five hospitals had private baths.

Source: CDC reports, medical journals, and interviews with hospital officials.

CDC's investigations of these hospitals concluded that unrecognized transmission of tuberculosis within hospitals is probably occurring in other institutions. Such transmissions will likely remain a serious problem until increased hospital staff awareness and strict adherence to CDC guidelines are achieved. In October 1992 CDC surveyed tuberculosis infection-control measures used in hospitals. This survey found that

MDR-TB is widespread in the United States and many hospitals' infection-control programs need improvement to prevent transmission of the disease to patients and employees.

Most Non-VA Hospitals Used Similar Corrective Measures

In response to the outbreaks, most hospitals implemented similar corrective measures to control tuberculosis. For example, shortly after the outbreak, the New York hospital instituted various corrective measures, such as (1) establishing guidance for prompt identification and isolation of suspected and known tuberculosis patients, including procedures for special treatment performed on these patients; (2) allocating \$25,000 for installation of ultraviolet lamps in several hospital areas; (3) placing tuberculosis and HIV and AIDS patients on separate wards; (4) improving ventilation in isolation rooms by installing exhaust fans in the windows to create negative pressure; (5) purchasing new respirators; and (6) hiring a nurse to conduct employee skin-testing. Further, the hospital issued a separate tuberculosis policy that was previously covered only briefly in the infection-control manual and opened a new building with nine isolation rooms that met CDC requirements. Hospital officials could not provide data on the total cost of these measures. They reported that the number of MDR-TB cases declined from 30 in 1990 to 8 in 1992.

The Florida hospital took similar measures. One hospital official believed that the most effective measures involved changes in diagnostic and treatment procedures for tuberculosis and HIV and AIDS patients and strong enforcement of isolation practices. The number of MDR-TB cases declined from 44 in 1990 to 9 in 1992.

State and Local Health Agencies Continue to Examine Tuberculosis-Control Measures

State and local health agencies conducted surveys to evaluate tuberculosis-control measures in New York City. For example, in July 1992, the New York State Health Department conducted on-site visits of 20 New York City hospitals and used a questionnaire to determine how well the hospitals were following state infection-control guidelines. The Department's report confirmed the existence of haphazard policies and practices for protective masks. Although nearly every regulatory agency in the country has advised that standard surgical masks are not sufficient to prevent the spread of tuberculosis, about 67 percent of the isolation rooms in hospitals relied solely on surgical masks to protect employees and other visitors. Further, the report found that more than 30 percent of isolation rooms had no protective methods to keep tuberculosis-causing bacteria from entering the ventilation system.

In August 1992, the Tuberculosis Task Force of the Greater New York Hospital Association³ conducted a survey that was mailed to engineers of its nonprofit member hospitals. The intent of the survey was to review existing and other potential measures designed to reduce the transmission of tuberculosis. For example, these measures include the use of ultraviolet lights and HEPA filters, proper ventilation, and maintenance of negative pressure rooms. In September 1992, the task force met with engineers from the member hospitals that treated patients with tuberculosis and have old buildings where current infection-control guidelines and engineering controls were not easily accomplished. The participants evaluated the survey results and compiled a list of effective engineering controls for tuberculosis risk areas that are categorized under (1) modifying existing systems, (2) installing major new systems, and (3) adding on portable devices.

VA, in its efforts to reduce the risk of tuberculosis transmission, has identified measures similar to those of non-VA hospitals. As previously discussed, VA's medical centers are taking steps to improve their ventilation systems, isolation room facilities, and high-risk infection areas.

Cost of Tuberculosis-Control Measures Vary

In 1992, New York City accounted for 15 percent of the nation's tuberculosis cases and had the largest absolute number of tuberculosis patients in any urban center. In 1990, Central Harlem reported more than 233 cases per 100,000 population, a rate more than 20 times the national average. To address the problem, the aforementioned New York health agencies conducted surveys to review infection-control measures and their costs.

The New York State Health Department's survey revealed that many of the hospital problems were structural, and costs would range from \$10,000 to \$60,000 to properly equip isolation rooms for the effective treatment of tuberculosis. These costs seem to deter hospitals from making the recommended changes. Physicians at many urban hospitals stated that the cost of upgrading large numbers of old hospital rooms, where the current ventilation system may consist of only opening a window, is high. The Tuberculosis Task Force distributed a list of control measures to its members as a tool to determine what could be implemented at the individual hospitals. Appendix IV outlines these controls, associated cost,

³Greater New York Hospital Association, founded in 1904, is a hospital association comprising 152 nonprofit hospitals and nursing homes in the New York metropolitan area. This association acts as principal advocate for its members in improving access to quality health care and reducing costs in New York City and surrounding communities.

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Non-VA Hospitals' Experience With
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and the range of costs and presents corresponding information related to the cost of implementing these measures.

VA engineering officials stated that the engineering control measures identified by non-VA hospitals are similar to those VA has undertaken to improve its facilities. They also noted that these measures were consistent with CDC guidelines.

Conclusions and Agency Comments

Conclusions

The East Orange Medical Center has made major improvements in identifying, isolating, and treating tuberculosis cases within its facility. Through policy and procedural changes (see app. D) and interim control measures, the East Orange Center has demonstrated that it can be a successful model in sharing the importance of strict observance of infection-control procedures and requirements to minimize the risk of tuberculosis for both patients and employees.

VA's Central Office has taken steps over the past year to increase tuberculosis awareness and promote the need for systemwide planning to address both clinical as well as construction deficiencies at its facilities. We believe that VA is moving in the right direction by identifying high-risk areas and developing tuberculosis program guidance to aid medical centers in implementing their specific plans for reducing the risk of tuberculosis transmission. VA's greater emphasis on tuberculosis control is also demonstrated through its most recent efforts to establish priorities and redirect funding to provide for construction improvements.

While planning for construction improvements that will take many months to complete is reasonable, ensuring that medical centers are practicing sound infection-control practices in accordance with CDC and other guidelines is essential. But facility improvements and program guidance alone are not enough to provide assurance that similar outbreaks will not occur at other VA medical centers or non-VA hospitals—for tuberculosis outbreaks are not unique to VA. In our view, continued management oversight of infection-control practices is needed, together with timely and accurate data on the number and trends in tuberculosis cases and employee test results.

Agency Comments

We provided copies of a draft of this report to the Secretary of Veterans Affairs for review. On October 20 and 21, 1993, we discussed our findings with and obtained oral comments from VA officials, including the Acting Associate Deputy Chief Medical Director for Clinical Programs, the Program Director for Infectious Diseases, the Health Systems Specialist for the Eastern Region Office, and the Director of the East Orange VA Medical Center. In general, these officials agreed that there is a need for continued management oversight of infection-control practices and reaffirmed VA's commitment to proceed with monitoring activities in ways that will not be too burdensome. The officials believe that more autonomy must be provided to medical center directors in view of decreasing clinical

resources and the constant need to refocus on competing agency priorities.

Generally, the officials also agreed on the need for timely and accurate data on employee testing for tuberculosis. In this regard, VA does not yet have aggregate data on employee test results; however, it is working on plans to upgrade the Decentralized Hospital Computer System to ensure that critical data on tuberculosis can be obtained, especially at the medical center level, in a more efficient manner. Due to budgetary constraints and the workload demands on VA's computer system, VA officials were uncertain about when upgrading of the system would be complete.

The East Orange Medical Center's Experience Enhanced Tuberculosis Awareness

To increase tuberculosis awareness, including the importance of isolation precautions, and improve employee and patient education, the East Orange Center issued new policies and procedures for tuberculosis control. The guidance placed greater emphasis on (1) the enforcement of tuberculosis precautions and enhancement of patient compliance; (2) respiratory protective devices; (3) responsibilities for implementation of tuberculosis education to patients, family members and employees; (4) engineering environmental controls; and (5) procedures for detection and management of tuberculosis. In addition, the East Orange Center implemented initiatives in many other areas, as part of its action plan (see table I.1).

Table I.1: Tuberculosis Initiatives Taken by the East Orange Center to Enhance Tuberculosis Awareness

Specific area	Initiatives that improved tuberculosis awareness
Respiratory protection	Respirators and other supplies were ordered for the protection of staff.
Employee testing	Employee testing for tuberculosis was enhanced in April 1992 and continues through the present under the direction of the Assistant Chief of Staff/Ambulatory Care, employee health physicians, and nursing staff.
Environmental controls	A comprehensive package was developed to outline ventilation and isolation needs of the center to meet CDC and OSHA guidelines for a safe patient care and working environment.
Organizational changes	Organizational changes were made that included new assignments of responsibility within the infectious diseases and pulmonary sections of the hospital.
Public awareness	Medical Center Director met individually with various members of the State congressional delegation in an attempt to keep interested parties apprised of the situation.
Staff awareness	Town meetings were conducted to share CDC and NIOSH preliminary findings with employees and to stress the importance of practicing universal precautions.
	Discussions were held on use of masks. Individual staff meetings were held on nursing units to discuss staff concerns; employee health staff were available for questions during testing.
	Suggestion and question boxes were installed to solicit questions about tuberculosis and other medical center issues.
	A publication entitled "Tuberculosis News Update" was instituted; articles on tuberculosis testing and CDC visits were published in a newsletter that was sent to veterans groups and employees.

Source: East Orange Medical Center Tuberculosis Management Initiatives (Aug. 1992).

Tuberculosis-Control Measures Requiring Greater Emphasis After the East Orange Outbreak and Related VA Guidance

Tuberculosis-control measures	Guidance issued	Before Outbreak	After Outbreak
Identification			
An active surveillance program should be established for tuberculosis among patients and employees and for skin test conversions among employees.	CDC Guidelines for Preventing the Transmission of Tuberculosis in Health Care Settings, with Special Focus on HIV-Related Issues (12/90).	X	
Maintain baseline data on tuberculosis cases for such purposes as identifying high risk groups, trends in morbidity and related mortality, candidates for preventive therapy, and the quality of infection-control practices.	VHA Directive 10-92-033 on Infection Control Program (3/92).	X	
	VHA Directive 10-92-019 on Employee Tuberculosis Testing Program (2/92).	X	X ^a
Patients who are hospitalized on the same ward as any "case-patient" during an outbreak period should be immediately identified, located, and offered tuberculin skin-testing.	CDC Guidelines, Vol. 40: No. 5 (4/91).	X	
	CDC Guidelines, Vol. 43: No. 11 (6/92).		X
Tuberculosis should be suspected in all HIV-infected patients who have respiratory disease.	CDC Guidelines (12/90).	X	X ^b
	VHA Circular 10-91-084 on Administration of Aerosolized Pentamidine to HIV Positive Patients (8/91).	X	
Patients seen in detox and admitted for substance abuse should be screened for tuberculosis.	VA's Tuberculosis Program Planning Guidance (4/93).		X
An active-employee skin-testing program should be established so that ward-specific conversion rates can be calculated. (All employees should have tests at least annually. Employees considered at risk should be tested at least every 6 months.)	CDC Guidelines (12/90).	X	
	VHA Guidance on Geriatrics and Extended Care (12/90).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X
	VHA Directive 10-92-019 on Employee Tuberculosis Testing Program (2/92).	X	X ^a
	VHA Circular 10-91-084 on Administration of Aerosolized Pentamidine to HIV Positive Patients (8/91).	X	X ^b
	Health Services MP-5, Part 1, Chapter 792, Change 7 (6/80).	X	
Isolation			
Patients with suspected or known infectious tuberculosis should be placed in acid fast bacilli (AFB) isolation in a private room.	CDC Guidelines: Isolation Precautions in Hospitals (1983).	X	
	CDC Guidelines (12/90).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X

(continued)

**Appendix II
Tuberculosis-Control Measures Requiring
Greater Emphasis After the East Orange
Outbreak and Related VA Guidance**

Tuberculosis-control measures	Guidance Issued	Before Outbreak	After Outbreak	
Patients with suspected tuberculosis should remain in their rooms until diagnosis of tuberculosis is excluded.	CDC Guidelines: Isolation Precautions in Hospitals (1983).	X		
	CDC Guidelines (12/90).	X		
AFB isolation should be continued until sputum specimens are repeatedly AFB smear negative and clinical improvement is evident.	CDC Guidelines: Isolation Precautions in Hospitals (1983).	X		
	CDC Guidelines (12/90).	X		
Tuberculosis patients should not be placed in a room with other patients, until the sputum smear is free of bacilli on 3 consecutive days.	CDC Guidelines: Isolation Precautions in Hospitals (1983).	X		
	CDC Guidelines (12/90).	X		
AFB isolation rooms (including treatment rooms, waiting rooms, clinics) should conform with published recommendations for ventilation such as (1) negative pressure, (2) at least 6 air changes per hour, (3) air from the room exhausted directly to the outside, and (4) use of supplemental approaches, namely HEPA filters and ultraviolet lights.	American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) (1987).	X		
	ASHRAE (1989).	X		
	VHA Guidance on Heating, Ventilation and Air-Conditioning (HVAC) Design Criteria and Instructions (2/90).	X		
	CDC Guidelines (12/90).	X		
	Engineering Conference Call Regarding Information on Isolation Room Criteria for Use in Tuberculosis Patients. (HVAC and CDC guidelines were sent to centers) (8/92).			X
	Infection Control Communique (VA Newsletter) (9/92).			X
	VA's Tuberculosis Program Planning Guidance (4/93).			X
	VHA Circular 10-91-084 on Administration of Aerosolized Pentamidine to HIV Positive Patients (8/91).		X	X ^o
Patients should remain in their isolation rooms with the door closed. If a patient must leave the room (for example, medical procedure) while potentially infectious, an appropriate respiratory protective device must be worn.	CDC Guidelines (12/90).	X		
Persons who enter a room in which AFB isolation precautions are in place should wear an appropriate respiratory protective device.	CDC Guidelines (12/90).	X		

(continued)

**Appendix II
Tuberculosis-Control Measures Requiring
Greater Emphasis After the East Orange
Outbreak and Related VA Guidance**

Tuberculosis-control measures	Guidance Issued	Before Outbreak	After Outbreak
	OSHA Guidelines on Respiratory Protection sent to VA centers (7/91).	X	
	Conference Calls on Respiratory Protection for Tuberculosis (7/92 and 10/92).		X
	Infection Control Communique (VA Newsletter) (9/92).		X
	VA's Tuberculosis Program Planning Guidance (4/93).		X
	VHA Circular 10-91-084 on Administration of Aerosolized Pentamidine to HIV Positive Patients (8/91).	X	X ^b
Isolation room doors must be kept closed.	CDC Guidelines: Isolation Precautions in Hospitals (1983).	X	
	CDC Guidelines (12/90).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X
Diagnosis			
AFB smear results should be available within 24 hours of receipt in the laboratory.	VA's Tuberculosis Program Planning Guidance (4/93).		X
Susceptibility testing for first and second line anti-tuberculosis drugs should be considered for all tuberculosis isolates.	VA's Tuberculosis Program Planning Guidance (4/93).		X
Results of susceptibility testing should be made known to clinicians managing tuberculosis patients, so that patients' treatment can be modified.	VA's Tuberculosis Program Planning Guidance (4/93).		X
Treatment			
Preventive therapy should be offered to those with positive tests results.	CDC Guidelines (12/90).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X
	VHA Directive 10-92-019 on Employee Tuberculosis Testing Program (2/92).	X	X ^a
	VHA Circular 10-91-084 on Administration of Aerosolized Pentamidine to HIV Positive Patients (8/91).	X	X ^b
Known tuberculosis patients should not be discharged until they are either smear negative or discharged into a setting where appropriate AFB isolation facilities are available and adequate therapy can be ensured.	VHA Directive 10-92-063 on Tuberculosis Control Responsibilities of VA (6/92).		X ^c

(continued)

**Appendix II
Tuberculosis-Control Measures Requiring
Greater Emphasis After the East Orange
Outbreak and Related VA Guidance**

Tuberculosis-control measures	Guidance Issued	Before Outbreak	After Outbreak
Patients should be treated with two additional drugs than rifampin and isoniazid until susceptibilities are known.	CDC Guidelines, Vol. 40: No. 5 (4/91).	X	
	CDC Guidelines, Vol. 43: No. 11 (6/92).		X
Reporting			
State health departments should be notified when tuberculosis is suspected or diagnosed so that appropriate contact investigation can be performed.	VHA Directive 10-92-033 on Infection Control Program ^d (3/92).	X	
	Infection Control Communique (VA Newsletter) (9/92).		X
	VHA Directive 10-92-063 on Tuberculosis Control Responsibilities (6/92).		X ^c
	VA's Tuberculosis Program Planning Guidance (4/93).		X
Follow-up care of tuberculosis patients after discharge from the hospital should be coordinated with the state health department.	VHA Directive 10-93-063 on Tuberculosis Control Responsibilities of VA (6/92).		X ^c
	VA's Tuberculosis Program Planning Guidance (4/93).		X
Education			
Employees and patients should be made aware of the medical consequences of tuberculosis, the need to enforce isolation precautions such as respiratory protection devices, and other infection-control procedures.	OSHA Guideline on Respiratory Protection sent to VA centers (7/91).	X	
	VHA Directive 10-92-033 on Infection Control Programs ^d (3/92).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X
Current work practices and procedures should be reviewed to assure that they are consistent with current CDC and other guidelines regarding isolation procedures, infection control, and medical surveillance of staff and patients.	CDC Guidelines (12/90).	X	
	VHA Directive 10-92-033 on Infection Control Program ^d (3/92).	X	
	VA's Tuberculosis Program Planning Guidance (4/93).		X
	VHA Directive 10-92-063 on Tuberculosis Control Responsibilities of VA (6/92).		X ^c
	VHA Directive 10-92-019 on Employee Tuberculosis Testing Program (2/92).	X	X ^a
The tuberculosis program infrastructure should be reviewed to assure the appropriate chain of command, coordination between committees, clear and continuous communication among key personnel charged with oversight responsibility to prevent redundancy and avoidance of fragmentation.	None issued. See VA's evaluation of the East Orange Tuberculosis Outbreak by site reviewers (10/92).		X

(Table notes on next page)

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Tuberculosis-Control Measures Requiring
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Note: The reissue information is important to show that VA policies provided to the field continue to be updated and current.

^aUpdated and reissued as 10-93-064 (6/93).

^bReissued twice as Supplements No.1 (7/92) and No.2 (7/93).

^cUpdated and reissued as 10-93-094 (8/93).

^dThis directive expired 1 year from the date shown but is being incorporated into VA Manual M-2, Part 1, Chapter 6.

Source: Reports and corrective action plans related to the investigation of the tuberculosis outbreak at the East Orange Medical Center and VA, CDC, and other published guidelines.

VA's Tuberculosis Program Planning Guidance

DEPARTMENT OF VETERANS AFFAIRS
VETERANS HEALTH ADMINISTRATION

PROGRAM AND FACILITY PLANNING GUIDANCE
FOR TUBERCULOSIS PROGRAMS

April 6, 1993

OVERVIEW

Over the last two to three years, the issue of tuberculosis has gained prominence in both the medical literature and the national press. During this period, the number of cases of active tuberculosis has increased nationwide, particularly along the coastal areas of the United States. However, no section of the country has been spared, and sporadic cases of tuberculosis have been identified in all VA regions.

To effectively plan and implement a Tuberculosis program, VHA Health Care Networks, medical centers, satellite and independent outpatient clinics must develop information on current and projected TB workload, define and decide on facility/network missions and programs, and develop integrated plans for patient care, employee health, and needed facilities. This program guidance will provide both a consistent framework for VA TB program planning and a base of information to accomplish this task.

This planning guidance is organized into four sections: general facility ventilation guidelines; program specific guidelines; a glossary; and, a reference bibliography.

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**PROGRAM AND FACILITY PLANNING GUIDANCE FOR TB PROGRAMS
April 6, 1993**

GENERAL FACILITY VENTILATION GUIDELINES

- A. The CDC guidelines (minimum requirements) are noted below for rooms designated for use in treating patients with suspected or known infectious TB (S/KI TB). "AFB isolation rooms" are patient bedrooms.
1. Six (6) total air changes per hour, including at least two (2) outside air changes per hour
 2. Exhausted 100% to outside (CDC does not require HEPA filtration on this exhaust). The air should be exhausted in a manner and location so it is not pulled into intake louvers or windows without significant dilution. As a minimum the exhaust shall be 25 feet from any air intake. However, other factors such as wind direction, wind velocity, stack effect, system sizes and height of building must be evaluated and location of intakes and exhaust outlets adjusted as required. Refer to Chapter "Air Flow Around Buildings" of ASHRAE fundamentals Handbook for analyzing these factors.
 3. Exhaust air quantity must be 20% greater than the supply air. It is further recommended that the exhaust system should serve only the TB room(s), (AFB isolation rooms and/or AFB rooms) and not be part of the general exhaust system. If this is not practical then use of the general exhaust system is acceptable provided appropriate precautions are taken to assure that these systems are adequately designed, installed, balanced and maintained. These requirements result in providing additional outside air through the air handling system which then impacts heating and cooling capacities for both air side and primary equipment. In all applications, thermal load calculations or occupancy of the space may require a higher air change rate. The CDC requirements are the minimum acceptable level and should be increased where required to satisfy other criteria or engineering requirements.
 4. Rooms should be under negative pressure when occupied by a patient with S/KI TB.
 5. The direction of air flow for TB rooms should be monitored periodically and documented. There are currently no specific CDC guidelines for documentation.

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However, the goal is to assure that the rooms remain under negative pressure when appropriate.

- B. Any room other than the "AFB Isolation Room" (S/KI TB patient's bedroom) used for S/KI TB patients for diagnostic procedures, treatments, examinations, etc., is defined as an "AFB Room." The major difference between an AFB Isolation Room and an AFB Room is in the exhaust system. The exhaust in an "AFB Room" may be exhausted directly to the outside or recirculated through properly installed and maintained HEPA filters.
- C. In rooms where patient turnover is expected, CDC guidelines for air changes vary in accordance with expected room use occupancy rate (MMWR 1990;39 (No. RR-17)).
- D. Proper air flow and pressure differentials between areas are difficult to control because of open doors, movement of patients, and staff, temperature and the effect of vertical openings. Air pressure differentials can only be maintained in completely closed rooms. An open door reduces or eliminates the desired effect of negative pressure rooms. Doors on negative pressure rooms should remain closed, except for entering or exiting the room.
- E. Where current VA criteria exceed the CDC requirements we recommend the use of the VA criteria. However if system configuration or costs do not allow compliance to more stringent VA criteria, then the CDC requirements are the minimum acceptable.
- F. Medical centers and OPCs that experience frequent and/or lengthy power disruptions should consider providing emergency power to exhaust systems serving inpatient AFB isolation rooms and to some of the ambulatory care rooms designated for management of S/KI TB patients. The potential risks to patients and staff, available emergency power system capacity, and relative priorities of other functions covered by emergency power should be carefully evaluated when considering costly emergency power system expansion.

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PROGRAM AND FACILITY PLANNING GUIDANCE FOR TB PROGRAMS

April 6, 1993

PROGRAM SPECIFIC GUIDANCE

I. ACUTE CARE

A. MS&N Nursing Units (Medical, Surgical, and Neurological)

1. DETERMINING THE NUMBER OF TB BEDS:

Use the following formula to determine number of patient bedrooms for suspected or known infectious TB (S/KI TB)

CURRENT NEED: (identify the maximum number of patients in respiratory isolation for S/KI TB at any one time within the past 12 months,) X (change in incidence of TB in community over the past year) (cognizance of actual cases of diagnosed infectious TB and each suspect and peak known may impact).

PROJECTED NEED: Using the estimated change in the population in the facility Distributed Population Planning Base (DPPB) for any future year, calculate future needs based on current estimate as determined above multiplied by this population change ratio.

2. NURSING UNIT ORGANIZATION:

a. HIGH INCIDENCE AREA OR NETWORK REFERRAL CENTER:
Medical centers with sufficient workload or those assigned the mission of network referral center may choose to concentrate all TB bedrooms on an existing MS&N nursing unit which will be designated for TB inpatient care. Or, they may designate bedrooms to be used for TB care throughout their facility. In establishing a TB unit on an MS&N nursing unit, a medical center should renovate a contiguous sub-set of the bedrooms on the unit to meet HVAC and bathroom requirements; not necessarily the entire ward. The number of bedrooms included in the sub-set would be based on anticipated workload determined for that facility. The following facility requirements must be met

- All one-bed rooms designated for TB must meet CDC guidelines for infectious TB.
- Each one-bed room must have a private bathroom.

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- An anteroom is not required for the negative pressure rooms designated for infectious TB.
- On a designated TB unit, the examination/treatment room and any other special treatment room in which sputum induction, aerosol treatments and/or cough or aerosol-generating procedures are performed should meet CDC requirements for infectious TB with the additional requirement that 12 air changes per hour must be exhausted. If a medical center does not have a designated TB unit, the above procedures should be performed in rooms meeting CDC Guidelines for preventing transmission from S/KI TB patients.

b. LOW INCIDENCE AREAS:

For those facilities anticipating a low TB workload, little or no change to existing nursing units may be required. Existing VA space planning criteria for MS&N nursing units (see Planning Criteria for VA Facilities, H-08-9 Chapter 100.04) requires two isolation suites. These rooms will be capable of providing negative or positive pressure and have an anteroom and attached private bathroom. Minimum air changes are 8 air changes with 100% exhaust through a HEPA filter. If these rooms are not currently provided or if additional rooms are required for infectious TB patients then these additional rooms must meet CDC requirement for infectious TB and have a private bathroom. An existing 2-bed room which has appropriate ventilation, airflow and bathroom facilities meeting, at a minimum, current CDC guidance for infectious TB, may be scheduled for use by a single TB patient as a low cost alternative to constructing or renovating an additional 1-bed room.

Sputum induction, aerosol treatments and/or cough or aerosol-generating procedures should be performed either in TB bedrooms or other rooms that meet CDC requirements for infectious TB.

B. MH&BS Nursing Units (Mental Health and Behavioral Sciences)

In general, no rooms are required for S/KI TB. Patients with S/KI TB should be transferred to an appropriate MS&N nursing unit for treatment until they are no longer infectious.

C. Intensive Care Units (ICUs)

1. Existing ICUs should meet current VA space planning criteria (see Planning Criteria for VA Facilities, H-08-9

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Chapter 102.05) for the number of isolation suites and at a minimum meet CDC criteria for ventilation for infectious TB.

2. All ICU's which utilize return air systems shall have the return air HEPA filtered. Installation of UV lamps may be considered in ICUs in which there is a high risk of TB transmission. Systems shall provide a minimum of eight (8) air changes per hour with two (2) air changes of outside air. All ICU rooms housing S/KI TB patients must meet the CDC requirements for infectious TB.

D. Post Anesthesia Recovery Units (PARUs)

Medical centers should have at least one recovery room within the PARU meeting at a minimum CDC ventilation criteria for S/KI TB. As an option, especially in low-incidence areas, medical centers may recover surgical patients with S/KI TB in an SICU isolation suite that meets CDC requirements for infectious TB.

E. Surgical Suite

1. Existing VA facility criteria (see HVAC Design Manual) and standards for surgery are appropriate for surgical care of S/KI TB patients. Current VA criteria exceed the CDC requirements. No changes will typically be required unless return air is used in the OR. VA criteria have not allowed the use of return air in ORs for many years.
2. Traffic patterns should be designed to reduce unnecessary movement throughout the surgical suite.

F. Prevention/Patients

PPD testing for high risk patients (methodology and an on-going plan to meet current CDC guidelines)

G. Respiratory Protective Devices for Patients

Patients with S/KI TB should (when appropriate) wear at a minimum a mask consistent with most current CDC guidelines

II. LONG TERM CARE

A. Facility/Air

No rooms are required for S/KI TB. Patients with S/KI TB should be transferred to an appropriate MS&N nursing unit for

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treatment until they are no longer infectious.

B. Prevention/Patients

1. Screening to be designed to prevent the admission of an S/KI TB patient to long term care
2. PPD testing for patients and employees to meet methodology in current CDC guidelines
3. To have a written plan for ongoing TB screening of long term care inpatients and employees

III. AMBULATORY CARE

A. DETERMINING THE NUMBER OF TB ROOMS:

The following is a suggested method for determining the number of exam/treatment or special treatment rooms designated for S/KI TB patients in unscheduled ambulatory care areas (hospital-based, satellite, and independent OPCs). This assumes that isolation rooms in unscheduled areas and specialized high-risk treatment rooms (AIDS clinic, AP rooms, etc.,) in scheduled areas already meet or are planned to meet VA and CDC criteria for S/KI TB patients.

1. Obtain the estimated eligible veteran population for the facility Distributed Population Planning Base (DPPB) for any specified future year and the current eligible veteran population for the facility.
2. Each facility should generate the estimated number of potential unscheduled S/KI TB patient visits per year.
3. Calculate the projected number of potential unscheduled S/KI TB Patient visits per year using the following formula:

A = Estimated eligible veteran population for the facility DPPB for any specified future year

B = Current eligible veteran population for the facility DPPB

C = Estimated number of potential unscheduled S/KI TB patient visits per year in unscheduled areas

X = Projected potential unscheduled S/KI TB patient visits per year

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4. Provide the number of designated TB exam/treatment or special procedure rooms as determined below using the potential S/KI TB patient visit estimate generated in No. 3 above.

<u>CALCULATED POTENTIAL UNSCHEDULED S/KI TB PATIENT VISITS (PER YEAR)</u>	<u>DESIGNATED TB EXAM/ TREATMENT ROOMS</u>
500 OR LESS	Use ER isolation rooms.
501-1000	One TB room.
each add/1. 1000	One additional TB room.

Designated TB rooms determined above may be located in the Walk-in clinic module and/or in other modules to meet local operating procedures and needs.

B. FACILITY/AIR:

1. Meet at a minimum current CDC guidelines for unscheduled areas and high risk clinics
2. Meet at a minimum current CDC guidelines for ventilation and airflow for S/KI TB:
 - a. E.R. Isolation room(s) (ante room not required)
 - b. ENT room(s)
 - c. Aerosolized pentamidine room(s)
 - d. Designated exam/treatment/procedure room(s)
3. Unscheduled areas - All unscheduled ambulatory care areas and associated waiting areas should have ventilation designed and maintained to reduce the risk of tuberculosis transmission and have at least 10 air changes per hour. Germicidal UV lamps and/or HEPA filters may provide additional benefit when used to supplement ventilation, particularly in facilities located in areas of high incidence of TB.
4. Scheduled Areas (clinics) serving patients who are at high risk for tuberculosis transmission should be designed to reduce the risk of TB transmission. Air from clinics serving patients at high risk for tuberculosis should not be re-circulated unless it is first passed through an effective high-efficiency filtration system. (HEPA filters are currently the effective high-efficiency filtration system available.)

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5. Designated exam/treatment rooms for S/KI TB - VA ambulatory care programs in medical centers and in satellite/independent outpatient clinics must have some facilities that are adequate to treat S/KI TB patients. These TB rooms can be exam/treatment rooms and/or special procedures rooms that are designated for S/KI TB patients. These rooms will meet CDC requirements for infectious TB with the additional requirement that a minimum of 12 air changes per hour must be exhausted. These rooms would normally be located in or near the walk-in clinic module.

C. PREVENTION/PATIENTS - PREVENTION/EMPLOYEES:

1. Improve traffic patterns - facility processing of patients should be designed to decrease unnecessary movement of patients.
 - a. MAS triage functions
 - b. Clinical triage functions
 - c. Clinic assignments
2. Rapid triage (to include mental health)
3. For high risk patient and employee groups do the following (in accordance with most recent CDC guidelines):
 - a. Timely initial screening for TB
 - b. Ongoing screening program for TB

IV. LABORATORY

A. Facility/Air

1. There are no changes required in the facility criteria and standards for Laboratories at this time. Current VA criteria for Laboratories exceeds CDC requirements for infectious TB.
2. VACO Pathology Service will review all of their facility criteria and standards as part of a project to develop a VA Laboratory Design Guide. If any changes are needed, they will be implemented at that time along with an amendment to this guidance.

B. Prevention/Patients - Prevention/Employees

1. AFB Smears

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- a. Available 5 days/week
 - b. Consider 7 days/week for areas with high incidence of TB
 - c. Results completed within 24 hours
 - d. One sputum per patient per day
2. Cultures (Mycobacterium tuberculosis)
- a. Available 5 days/week
 - b. If smear is positive, direct sensitivities
 - c. Rapid identification methodology
3. Reporting smears and cultures
- Immediate reporting to designated person(s)
4. Susceptibility testing (Mycobacterium tuberculosis)
- a. First isolate
 - b. Additional isolates if:
 - (1) Failure to convert cultures within three months beginning therapy
 - (2) Clinical evidence of failure to respond to therapy
 - (3) Other specific circumstances may dictate additional susceptibility testing
- C. PPE (Personal Protective Equipment - respiratory protective devices)
- Routine use of respiratory protective devices should not be necessary.
- V. HIGH RISK AREAS
- A. POTENTIAL AEROSOL PRODUCING PROCEDURE AREAS:
1. The pulmonary function laboratory (including spirometry and exercise rooms), bronchoscopy area(s), pulmonary function treatment rooms, and sputum induction areas and any other special procedure room in which S/KI TB patients are treated must meet CDC guidelines for infectious TB with the additional requirement that a minimum of 12 air changes per hour must be exhausted.
 2. Any room (e.g. examination/treatment room, procedure room) in the health care facility in which aerosolized pentamidine (AP) procedures are performed must meet CDC guidelines for infectious TB with the additional

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requirement that a minimum of 12 air changes per hour must be exhausted.

3. If a booth is used for any potential aerosol producing procedure, booth air flow and exhaust should meet CDC guidelines.

B. RADIOLOGY:

At least one radiology room (chest x-ray) must meet CDC requirements for infectious TB. Both ambulatory care and in-patient programs can share this negative pressure radiology room if feasible.

C. ANATOMIC PATHOLOGY:

The morgue must meet at a minimum CDC requirements for infectious TB. We strongly recommend that a minimum of 12 air changes be provided, exhausted 100% to outside with all exhaust air HEPA filtered as stated in current VA criteria.

D. DENTAL:

At network referral centers and at facilities in which emergency dental care is provided, at least one dental operator must meet CDC requirements for infectious TB. Other health care facilities may refer S/KI TB patients for dental care to referral centers based on workload and travel distance.

VI. HIV-RELATED ISSUES

A. Facility/Air

1. None specific to HIV infection

B. Prevention/Patients - Prevention/Employees

1. Timely initial screening for TB
2. An ongoing screening program for TB.
3. TB screening to follow most current CDC methodology

VII. DIALYSIS PROGRAM

A. Facility/Air

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A room must be available for dialysis of S/KI TB patients which meets at a minimum current CDC ventilation and airflow guidelines for infectious TB.

B. Prevention/Patients - Prevention/Employees

1. Timely initial screening for TB (use most current CDC methodology)
2. Ongoing screening program for TB

VIII. SPECIAL PROGRAMS

A. HBHC (Other such programs), adult day care, etc.

Prevention/patients - Prevention/Employees

1. Screening should be designed to identify patients who may be infected with Mycobacterium tuberculosis. Appropriate intervention should be undertaken as indicated.
2. PPD testing for patients and employees to meet methodology in current CDC guidelines
3. To have a written plan for ongoing TB screening of patients and employees

B. VEHICULAR TRANSPORT OF PATIENTS WITH S/KI TB

Follow CDC guidelines.

C. CHILD DAY CARE

Follow state and local guidelines regarding TB screening and/or TB programs

IX. PERSONNEL HEALTH

A. TB Screening using most current CDC methodology

1. Initial employment (all employees)
2. Interval screening as determined by the station
3. Recommended at the time of separation for all employees
4. Follow VACO Directives and Manuals

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- B. Record keeping
 - 1. Critical need
 - 2. Comply with VHA directives, manuals, and regulatory agencies' requirements
- C. Return to work clearance
 - 1. At a minimum, to follow current CDC guidelines
 - 2. Monitor for lack of infectiousness
- D. Respirator Program
 - Proper clearance for all appropriate employees
- X. COMPONENTS FOR EVERY HEALTH CARE FACILITY TB PLAN
- A. Implementation of screening programs designed to identify patients who may be infected with Mycobacterium tuberculosis. Appropriate intervention should be undertaken as indicated.
- B. PPE (Personal Protective Equipment - respiratory protective devices)
 - 1. Task-specific for type of respiratory protective device
 - 2. At a minimum be in compliance with most recent CDC guidelines pertaining to protective respiratory devices
 - 3. Respirator program to encompass all appropriate employees
 - 4. To be worn by all employees who have occupational exposure to S/KI TB
 - 5. Identify work site for the wearing of respiratory protective devices
- C. Designation of responsibility for:
 - 1. Preventive therapy for patients
 - 2. Treatment for patients
 - 3. Preventive therapy for employees
 - 4. Treatment for employees

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5. Post-exposure follow-up of patients
6. Post-exposure follow-up of employees
7. Reporting/release of TB information
- D. Education of employees and patients Ongoing program as appropriate
- E. Facility Requirements for at least the following should be developed and incorporated into medical center Facility Development Plans (FDPs) and Five-Year Facility Plans:
 1. Acute Care Units
 - a. MS&N Units or Respiratory TB Unit
 - b. ICUs
 - c. PARUs
 2. Ambulatory Care
 3. High Risk Areas
 - a. Pulmonary Medicine
 - b. Radiology
 - c. Anatomic Pathology/Morgue
 - d. Dental
 4. Dialysis

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FOR FURTHER INFORMATION:

For further information, contact the offices listed below.

CLINICAL ISSUES: Gary A. Roselle, M.D.
Program Director for Infectious Diseases
VAMC Cincinnati, Ohio
FTS 700-773-5047

SPACE PLANNING CRITERIA: Lawrence V. Bifareti
Director, Criteria, POE, and Planning
Support Service
VA Central Office
(202) 233-7019

HVAC SYSTEMS ISSUES: Kurt D. Knight
Director, Mechanical Engineering Service
VA Central Office
(202) 233-2191

ENGINEERING OPERATIONS: Richard A. McCrone
Staff Engineer, Facility Engineering and
Field Support Office
VA Central Office
(202) 233-3105

INDUSTRIAL HYGIENE: Rita D. Pittillo
Industrial Hygienist, Facility
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GLOSSARY

AFB = Acid-fast bacilli are organisms that retain certain stains, even after being washed with acid alcohol. Most are mycobacteria. When seen on a stained smear of sputum or other clinical specimen, a diagnosis of tuberculosis should be considered.

AFB Isolation Room = The room used for the bedroom of a patient suspected or known to have infectious tuberculosis.

AFB ROOM = Any room (other than the patient's bedroom) used for diagnostic procedures, treatments, examinations, etc., for the patient suspected or known to have infectious tuberculosis.

AP = Aerosolized pentamidine, a drug treatment given to patients with HIV infection to treat or to prevent Pneumocystis carinii pneumonia. The drug is put into solution, the solution is aerosolized, and the patient inhales the aerosol.

ASHRAE = American Society of Heating, Refrigerating, and Air Conditioning Engineers, Inc.

CDC = Centers for Disease Control and Prevention in Atlanta, Georgia where the MMWR (Morbidity and Mortality Weekly Report) is prepared.

DPPB = Distributed Population Planning Base, based on actual veteran utilization of the facility.

HEPA = High-efficiency particulate air filter with test efficiencies of $\geq 99.97\%$ of particles > 0.3 microns in diameter.

High Incidence Area = A VA facility in which 20 or more cases of infectious tuberculosis were managed during the past 12 month period.

HIV = Human immunodeficiency virus, the virus that causes AIDS.

Infectious Tuberculosis = The presence of active tuberculosis organism in droplet nuclei.

Isolation Suite = For MS&N Nursing Units the isolation suite consists of a patient bedroom with ante room and private bathroom while the isolation suite for the ICUs consists of (at a minimum) patient bedroom and ante room that meets established VA criteria (Planning Criteria for VA Facilities H-08-9). These isolation

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suites (in the negative air pressure mode) may be used for patients with S/KI TB.

Low Incidence Area = A VA facility in which less than 20 cases of infectious tuberculosis were managed during the past 12 month period.

Referral Center = The tertiary care VA facility usually within the network to which complex or special needs patients are referred.

Scheduled Ambulatory Care Area = Outpatient areas designated for patients generally seen in follow up or by consultation following an initial assessment. This generally includes the clinic rooms (treatment/exam) and waiting areas. Generally, this should not include patients for whom a VA Form 10-10m was generated for that visit.

S/KI TB = Suspected or known infectious tuberculosis refers to the status of a patient. A person suspected or known to have infectious tuberculosis.

TB = Tuberculosis, a condition in which tuberculosis organisms (Mycobacterium tuberculosis, Mycobacterium bovis, or Mycobacterium africanum) are present in the body.

Tuberculosis Infection = A condition in which tuberculosis organisms (Mycobacterium tuberculosis, Mycobacterium bovis, or Mycobacterium africanum) are present in the body, but no active disease is present.

Tuberculosis Transmission = Spread of tuberculosis organisms from one person to another, usually through the air.

Unscheduled Ambulatory Care Area = Outpatient areas designated for the patients for whom a VA Form 10-10m was initiated for that visit. This includes waiting areas, triage areas, and exam/treatment rooms.

UV = Ultraviolet.

**Appendix III
VA's Tuberculosis Program Planning
Guidance**

PROGRAM AND FACILITY PLANNING GUIDANCE FOR TB PROGRAMS

April 6, 1993

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Engineering Control Measures and Related Cost

Items (per unit/room)	Approx. cost/unit ^a	Code recom. ^b	Risk area ^c	Annual main. cost ^d	Annual oper. cost ^e
Modifying existing systems^f					
HEPA filter in main fan	\$12,000 (H)	1,2,5	M	M	L
Duct type UV light	1,000 (L)	5	L	M	L
Installing major new systems					
New room exhaust system	4,000 (M)	1,2,3,4	L/M	L	H
New toilet exhaust	5,000 (M)	1,3,4	L/M	L	H
Compliant isolation room	75,000 (H)	1,2,3,4	H	M	H
Separate floor renovation	200/sq. ft (H)	1,2,3,4	H	M	H
Add-on portable devices					
UV light with fan (self-contained)	1,000 (L)	5	L	M	L
Window exhaust with shutter	500 (L)	1,2,3,4	L	L	H
Fan/HEPA filter construction	7,000 (H)	1,2,5	M	L	L
Portable HEPA filter ^g	2,000 (M)	2,5	M	L	L
Portable HEPA filter with UV ^g	3,000 (M)	2,5	M	H	M
HEPA filter wall mounted (beams)	3,000 (M)	2,5	M	L	L

Note: L=low; M=medium; and H=high. Factors such as areas and square footage will make a difference.

^aL=\$0-\$2,000; M=\$2,000-\$10,000; and H=\$10,000-up.

^b(1) Negative pressure; (2) 6 total air exchanges per hour; (3) air exhausted by separate exhaust; (4) room air exhausted at least 25 feet from fresh air intake; and (5) ultraviolet light and/or HEPA filter.

^cH=Bronchoscopy Suite; M=Patient Room and Emergency Room for emergency and outpatient department care; and L=Outpatient and Emergency Departments waiting areas.

^dL=\$0-\$500; M=\$500-\$1,500; and H=\$1,500-up.

^eL=\$0-\$1,000; M=\$1,000-\$5,000; and H=\$5,000-up. Heating and cooling costs included in this category.

^fOther alternatives include rebalancing the system or increasing the air supply and/or exhaust.

^gDescribes self-contained units.

Source: Greater New York Hospital Association, Tuberculosis Task Force (Aug. 1992).

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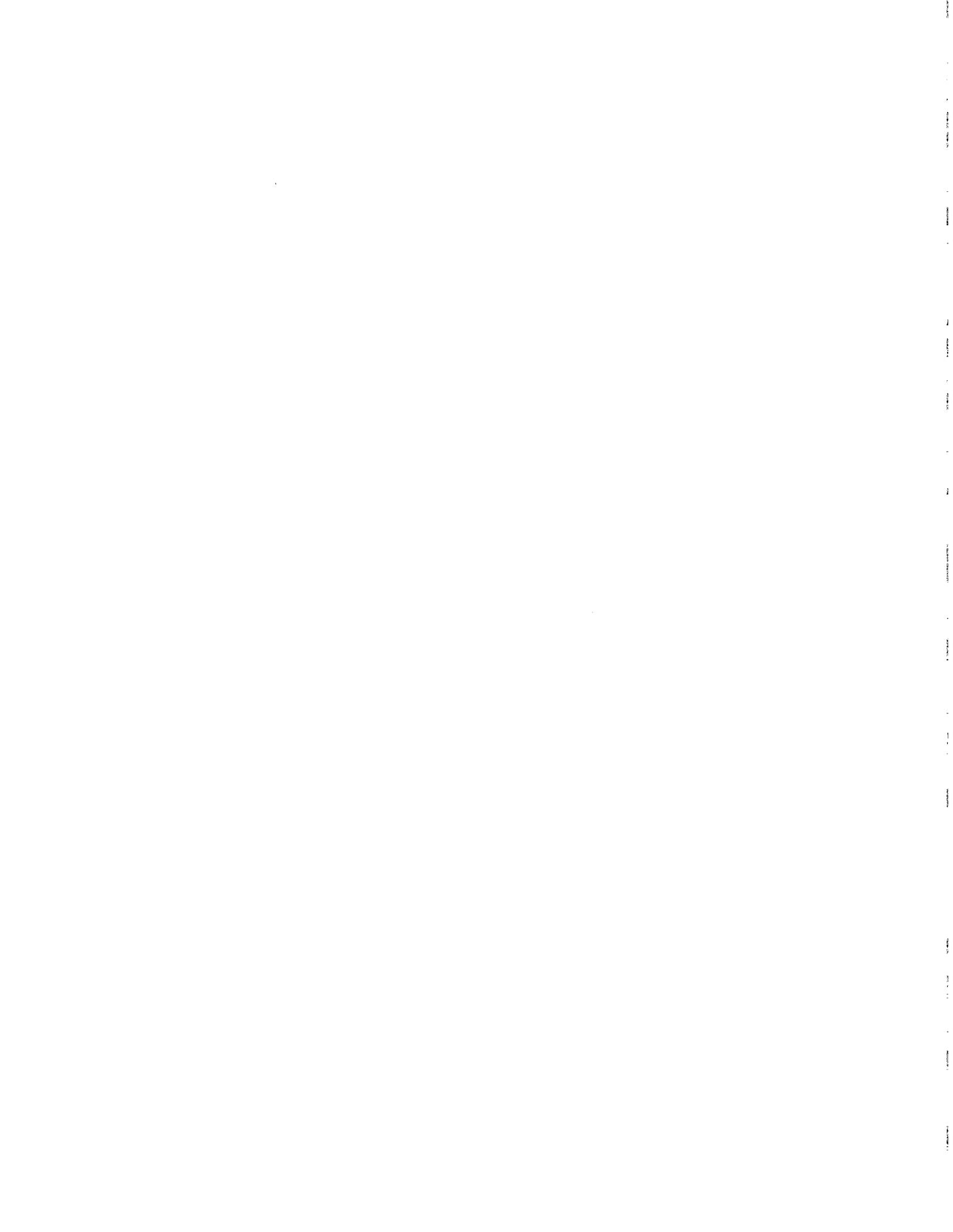
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