94.277

University of Kentucky Hospital
Infection Control

Chandler Medical Center

NIOSH Docket Office
Robert A. Taft Laboratories
Mail Stop C34
4676 Columbia Parkway
Cincinnati, OH 45226

July 20, 1994

Dear Sir/Madam:

The University of Kentucky Hospital Department of Infection Control would like to go on record as being a proponent for the Department of Health and Human Services 42 CFR Part 84 Respiratory Protective Devices; Proposed Rule (HHS/NIOSH Respiratory Protective Devices). This proposed rule is welcomed as a step toward recognizing the unique situation faced by health care organizations in providing a safe work place and reasonable expectations of employees based on current scientific knowledge.

The new testing and certification procedure as outlined for "Class C" respirators (which provide 95% filter protection at the 0.3 micron size) will provide for a greater range of respirators to be tested. Currently, OSHA requires use of a HEPA filter respirator for worker protection; the benchmark for testing respirators should include CDC's criteria performance for respiratory protection against TB.

The need to implement this proposed rule as soon as feasible can not be over stressed. According to a recent article in the Annals of Internal Medicine (1) the use of high-efficiency particulate respirators to treat patients with known or suspected tuberculosis may cost $7 million per case of tuberculosis prevented and $100 million per life saved. Cost estimates by another author (2) suggest that preventing a single case of occupational tuberculosis over the next 41 years for that facility implementing proposed requirements for HEPA filtered respirator, could cost between $1,333,090 and $18,058,947. HEPA filter respirators are a very costly measure to healthcare organizations already facing tightening budgets with looming health care reform. Additionally, respirators should be the last line of defense with an effective



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Tuberculosis Control program - as currently viewed it appears that appropriate early patient assessment, isolation and treatment of the patient are "de-emphasized".

An additional fact of note is that CDC implemented the 1990 Guidelines for Prevention of Tuberculosis prior to utilization of HEPA filtered respirators. When those recommendations were followed, TB outbreaks ceased. Specifics cited in outbreak situations included inadequate administrative and engineering measures (2). Two specific examples: 1) exhaust air from a sputum induction room was recirculated into the HIV clinic, 2) (TB) patients were permitted to go to common areas for group activities without keeping their masks on.

Please give this information your careful review.

HEPA filter respirators are a very expensive solution in the treatment of TB patients when a Class C respirator could meet this same need.

Enclosed are copies of the articles referenced, which are included as a matter of public record.

Sincerely,

Martin Evans

Martin Evans, M.D.
Hospital Epidemiologist

Kathy Hall RN

Kathy Hall, RN
Nurse Epidemiologist


1) Nettleman MD, Fredrickson M, Good NL and Hunter SA. Tuberculosis control strategies: the cost of particulate respirators: the cost of particulate respirators. Ann Intern Med. 1994; 121: 37 -40.

2) Adal KA, Anglim AM, Palumbo CL. The use of high-efficiency particulate air-filter respirators to protect hospital workers from tuberculosis. New Eng J Med. 1994; 331: 169 - 173.

# Tuberculosis Control Strategies: The Cost of Particulate Respirators

Mary D. Nettleman, MD, MS; Mary Fredrickson, RN; Natalie L. Good, MHA; and S. Ann Hunter, MA, BSN

■ *Objective:* To assess the cost of the mandatory use of high-efficiency particulate respirators to treat patients with known or suspected tuberculosis.

■ *Design:* A questionnaire was used to determine the number of high-efficiency particulate respirators required and the number of cases of tuberculosis in employees that could potentially be prevented. Indirect costs included the training and fitness testing of employees. The clinical efficacy of respirators is not known. To provide a best-case scenario, it was assumed that the respirators could prevent as many as 25% of tuberculosis cases in health care workers.

■ *Setting:* 159 acute care facilities administered by the Department of Veterans Affairs.

■ *Participants:* Quality improvement, infection control, and employee health specialists.

■ *Measurements:* Cost of the respirators compared with their maximum predicted efficacy.

■ *Results:* The use of the respirators would cost $7 million per case of tuberculosis prevented and $100 million per life saved.

■ *Conclusions:* High-efficiency particulate respirators are a costly means of trying to prevent tuberculosis. Costs could be reduced by reusing masks or by restricting the number of health care workers allowed to have contact with potentially infectious patients. As the health care budget undergoes further restrictions, specific means of accommodating the cost of new regulations must be found.

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From the Iowa City Veterans Affairs Medical Center and the University of Iowa College of Medicine, Iowa City, Iowa. For current author addresses, see end of text.

Recent studies showing that tuberculosis can be acquired in the health care setting (1–7) have prompted consideration of environmental control measures to minimize exposure to airborne bacilli. Such measures include private rooms with negative airflow pressure and personal respiratory protection. In October 1993, the Centers for Disease Control and Prevention (CDC) issued draft recommendations for the use of high-efficiency particulate (HEPA) respirators to protect workers from patients who are known or suspected to have tuberculosis (8). In the same month, the Occupational Safety and Health Administration (OSHA) issued a statement concurring with the use of these respirators.

Standard surgical masks are not designed to exclude very small particles and do not provide a tight face-to-mask seal (9, 10). Particulate respirators fit better and have better filtering capacity than do standard surgical masks. Because particulate respirators are thicker than standard masks, air resistance can make breathing difficult. Therefore, OSHA requires that users be trained and fit-tested to assure an optimal seal between the face and the respirator (11). This must occur before the respirator is used and must be repeated annually.

High-efficiency particulate respirators are expensive, and the training is time-consuming. Unresolved issues include how to deal with workers whose facial hair precludes a tight facial seal. In addition, the efficacy of these respirators is not known. For these reasons, many health care professionals have questioned the choice of the high-efficiency particulate respirators. To characterize the impact and to assess the cost of the mandatory use of the respirators for patients with known or suspected tuberculosis, a questionnaire was given to acute care facilities administered by the Department of Veterans Affairs.

## Methods

In June 1993, a questionnaire was sent to the 159 acute care, inpatient Veterans Affairs facilities in the United States. The questionnaire was addressed to the persons in charge of quality improvement, infection control, and employee health. A second questionnaire was sent to nonresponders, and telephone contact was made as necessary to ensure completion.

Acute care facilities were asked about the types of masks or respirators used at their facilities, the number of patients requiring respiratory isolation because of suspected or confirmed tuberculosis each month, and the number of cases of confirmed pulmonary tuberculosis in the past year. Acute care facilities were also asked how many employees converted to a positive protein derivative (PPD) skin test result in the past year and how many developed active tuberculosis in the past 5 years. Facilities estimated the percentage of employees who received annual PPD skin tests by choosing one of five ranges (0% to 20%, 21% to 40%, 41% to 60%, 61% to 80%, or 81% to 100%).

The efficacy of the high-efficiency particulate respirators in preventing tuberculosis is unknown. Tuberculosis may result from community-based exposure or may occur in the health care setting when tuberculosis is not identified promptly and contagious patients are not isolated at admission (12, 13). Transmission may also occur when contaminated air is exhausted into patient care areas (7, 8). In each of these cases, particulate respirators would not be used and therefore could not prevent disease. For analysis, it was assumed that half of the cases of tuberculosis in health care workers were acquired in health care settings (14) and that half of exposures in health care settings occurred before patients were effectively isolated (12, 13). Thus, as many as 25% of exposures would occur after isolation when particulate respirators would be used. Therefore, to simulate a best-case scenario, we assumed that the high-efficiency particulate respirators would prevent 25% of all employee exposures to tuberculosis.

The mortality rate for tuberculosis in health care workers is unknown but was estimated to be 7% based on the annual

**Table 1. Results of Questionnaire**

| Variable | Number | | Percentage of Responding Facilities |
|---|---|---|---|
| | Range | Median | |
| Patients isolated for known or suspected tuberculosis per month, *n* | 0–60 | 3 | 95 |
| Cases of confirmed pulmonary tuberculosis in patients in the last year, *n* | 0–68 | 3 | 98 |
| Cases of active pulmonary tuberculosis in employees in the last 5 years, *n* | 0–4 | 0 | 97 |

incidence of disease and the annual death rate from tuberculosis (15, 16).

A 1-month study of patients in the Iowa City Veteran Affairs Medical Center and at the University of Iowa Hospitals and Clinics showed that an average of 20 masks per 8-hour shift were used for patients in respiratory isolation. The average duration of isolation per patient was assumed to be 14 days for patients with confirmed tuberculosis and 5 days for uninfected patients who were isolated while test results were pending. Standard surgical cup masks cost $0.10 each, whereas the dust-mist, dust-mist-fume, and high-efficiency particulate respirators cost $0.62, $2.75, and $4.10, respectively.

## Results

### Questionnaire

All 159 facilities returned the questionnaire (100% response). Seventy-nine facilities (50%) already used particulate respirators, 40 used dust-mist respirators, 38 used dust-mist-fume respirators, and 1 used high-efficiency particulate respirators.

One hundred fifty-one facilities (95%) provided data on the numbers of patients in isolation. In these facilities, 1063 patients were reported to be isolated each month for known or suspected tuberculosis. If facilities that did not respond to the question are assumed to have results similar to those of responders, approximately 1119 patients would be estimated to be in isolation for known or suspected tuberculosis every month in the Veterans Affairs system. When the data were analyzed by facility, the median number of patients isolated was 3 per month per facility (range, 0 to 60) (Table 1).

The median number of patients with confirmed pulmonary tuberculosis in the last year was 3 per facility (range, 0 to 68) (Table 1). The number of employees who developed active tuberculosis in the past 5 years ranged from 0 to 4 per facility. Fifty-four cases of tuberculosis in employees were identified; 117 (75%) of the 155 responders reported no known cases of tuberculosis in employees. If facilities that did not respond to the question are assumed to have results similar to those of the responders, approximately 11 cases would be expected each year.

One hundred forty-one facilities provided data on PPD test conversions by employees within the past year. The results ranged from 0 to 75, with a median of 2, but this number may not be a reliable estimate for several reasons. Written comments indicated that some facilities were unable to separate employees who had not received a PPD test in several years. Employees with known exposures outside the health care setting were included. Some hospitals included positive PPD test results found during physical examinations done before employment. In addition, most hospitals did not actually provide annual skin tests to all employees. Thirty-three (23%) of the 141 facilities reported no skin-test conversions in employees.

One hundred forty-nine facilities provided estimates of the proportion of employees who received annual PPD tests (Figure 1). Written comments indicated that many hospitals in the lower range were aware of the problem and were instituting new programs to improve compliance.

### Cost of Particulate Respirators Used during Patient Care

Compared with the use of the standard cup surgical mask, use of the high-efficiency particulate respirator in the Veterans Affairs system would result in excess costs of $19 million annually. Compared with the use of dust-mist or dust-mist-fume respirators, use of the high-efficiency particulate respirators would result in annual excess costs of $16 million and $6 million, respectively.

Assuming that 25% of cases of pulmonary tuberculosis in employees could be prevented by the high-efficiency particulate respirators, their use would result in an excess cost of $6.6 million per case of pulmonary tuberculosis prevented compared with the standard surgical cup mask. Tuberculosis in employees may be under-reported because employees may seek care outside of the Veterans Affairs system. If the rate of tuberculosis in physicians, housestaff, and nurses was twice that of the general population (17, 18), 14.5 cases of pulmonary tuberculosis would be expected each year, and the excess cost per case prevented by the high-efficiency particulate respirators would be $5.1 million. Using these figures, these respirators would result in excess costs of $72 to $95 million per life saved.

### Other Costs

Use of these respirators also requires fit-testing and training of all health care workers involved in treating

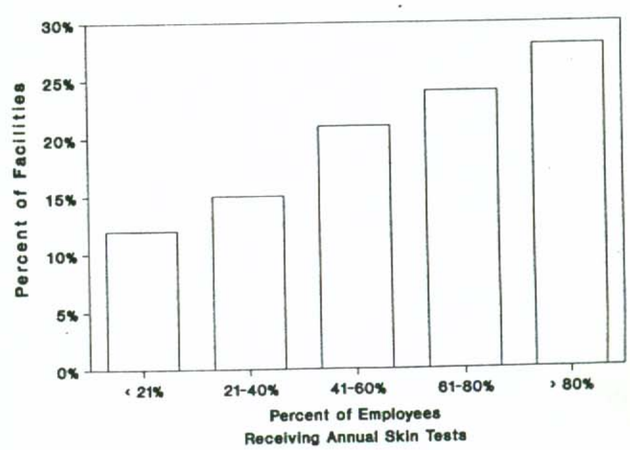


**Figure 1. Percentage of employees receiving annual purified protein derivative skin tests at each facility (149 facilities providing data).**

**Table 2. Excess Costs Resulting from Using High-Efficiency Particulate Respirators Compared with Surgical Cup Masks**

| Variable | Excess Cost Per Case of Pulmonary Tuberculosis Prevented | Excess Cost Per Life Saved |
|---|---|---|
| | $ | |
| Respirators used during patient care | 6.6 million | 94.7 million |
| Respirators used to train employees | 0.1 million | 1.5 million |
| Time lost from work | 0.2 million | 3.5 million |
| Total | 6.9 million | 99.7 million |

patients suspected of having tuberculosis. The Veterans Affairs system currently employs 13 967 physicians, 14 589 residents, and 40 699 nurses (17). If no other staff were trained and if one high-efficiency particulate respirator was used for each person who had fit-testing, $283 946 would be spent annually for respirators used for training ($102 000 per case of tuberculosis prevented and $1.5 million per life saved) (Table 2). The time lost from work was calculated using the average salary for physicians, nurses, and residents, assuming that training and fit-testing would require 30 minutes per person. Training and fit-testing would annually cost $678 000 in time lost from work.

Adding these costs to the cost of respirators used in patient care settings, the excess cost per case of tuberculosis prevented would be approximately $7 million, and the excess cost per life saved would be $100 million (Table 2).

National Estimates

Using the above estimates and assuming that 26 000 cases of pulmonary tuberculosis occur per year (18), an excess of $462 million would be spent annually on high-efficiency particulate respirators used for patient care alone. The cost of training and fit-testing would increase this cost because of the need for sample masks and time lost from work.

## Discussion

At the time of the survey, the high-efficiency particulate respirators were not routinely used in Veterans Affairs hospitals. It was estimated that a maximum of 25% of all employee exposures to tuberculosis occurred after the patient was effectively isolated (12–14). Even if the risk for disease transmission from these exposures was as high as the risk after are exposure to patients who are not isolated, and even if the respirators prevented all of these exposures, the respirators would cost $7 million per case of tuberculosis prevented and $100 million per life saved. This is far more than is spent to prevent most diseases in the general population.

In fact, the efficacy of these respirators is unknown. No evidence suggests that their use has ever prevented a single case of tuberculosis. Thus, our results represent a minimal estimate of the cost per life saved and the cost per prevented case of tuberculosis.

How much should we pay to prevent tuberculosis in health care workers? Ideally, cost would not be an issue at all. The United States has prided itself on providing reasonably safe workplaces for all employees. Environmental controls have been imposed on many industries in an attempt to maximize the safety of the workplace. However, most industries have the ability to pass the cost of environmental controls on to consumers (19). In other instances, the government has provided money in the form of grants or subsidies to help ease the burden of regulations (20, 21). With the advent of fixed payments and the promise of managed care, the health care industry will not be able to pass costs freely to consumers.

Even if cost were not an issue, the unknown efficacy of the high-efficiency particulate respirators would remain a central problem. Unfortunately, the high-efficiency particulate respirators have not been compared with less expensive respirators or masks in a clinical setting (8). The high-efficiency particulate respirators are uncomfortable to wear and require time-consuming fitness testing and training. It is possible that cumbersome environmental controls might discourage clinicians from testing some patients for tuberculosis or might give a false and destructive sense of security. This would be especially unfortunate because unrecognized tuberculosis in unisolated patients is already a major threat to workers and patients (1–6, 12, 13).

Some measures could be adopted to help decrease the cost of the respirators. If fewer particulate respirators were used per patient per day, costs would be reduced proportionately. Respirators could be reused, and the number of persons with access to isolation rooms could be restricted. If only a few health care workers were allowed to care for patients with known or suspected tuberculosis, the total costs of fit-testing and training would be reduced. However, 13 patients were placed in isolation for every 1 patient that had tuberculosis. Thus, the many patients requiring isolation could easily overwhelm the ability of a few employees to provide care. Use of the respirators could be restricted to institutions that have a high incidence of tuberculosis, but this approach would not provide a uniform standard of protection for all employees who are exposed to the disease. Unfortunately, no hospital can consider itself immune from tuberculosis: The rising incidence of tuberculosis ensures that the number of cases will continue to increase, even in previously low-incidence areas. Finally, the cost per respirator could be reduced through competitive market forces, government subsidies, or mandated price controls.

In summary, high-efficiency particulate respirators are a costly means of trying to prevent tuberculosis. As Congress considers new legislation to restrict the health care budget, it must also address specific means of accommodating the cost of new regulations. Optimally, funds should be set aside to investigate the efficacy of proposed regulations so consumers can know the expected value of their investment.

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## SPECIAL ARTICLE

# THE USE OF HIGH-EFFICIENCY PARTICULATE AIR-FILTER RESPIRATORS TO PROTECT HOSPITAL WORKERS FROM TUBERCULOSIS

## A Cost-Effectiveness Analysis

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**Abstract** *Background.* After outbreaks of multidrug-resistant tuberculosis, the Centers for Disease Control and Prevention proposed the use of respirators with high-efficiency particulate air filters (HEPA respirators) as part of isolation precautions against tuberculosis, along with a respiratory-protection program for health care workers that includes medical evaluation, training, and tests of the fit of the respirators. Each HEPA respirator costs between $7.51 and $9.08, about 10 times the cost of respirators currently used.

*Methods.* We conducted a cost-effectiveness analysis using data from the University of Virginia Hospital on exposure to patients with tuberculosis and rates at which the purified-protein-derivative (PPD) skin test became positive in hospital workers. The costs of a respiratory-protection program were based on those of an existing program for workers dealing with hazardous substances.

*Results.* During 1992, 11 patients with documented tuberculosis were admitted to our hospital. Eight of 3852 workers (0.2 percent) had PPD tests that became positive. Five of these conversions were believed to be due to the booster phenomenon; one followed unprotected exposure to a patient not yet in isolation; the other two occurred in workers who had never entered a tuberculosis isolation room. These data suggest that it will take more than one year for the use of HEPA respirators to prevent a single conversion of the PPD test. Assuming that one conversion is prevented per year, however, it would take 41 years at our hospital to prevent one case of occupationally acquired tuberculosis, at a cost of $1.3 million to $18.5 million.

*Conclusions.* Given the effectiveness of currently recommended measures to prevent nosocomial transmission of tuberculosis, the addition of HEPA respirators would offer negligible protective efficacy at great cost. (N Engl J Med 1994;331:169-73.)

SINCE 1985 the incidence of tuberculosis in the United States has increased,[1,2] and nosocomial transmission has occurred.[3-5] Multidrug-resistant *Mycobacterium tuberculosis* has become a problem causing high mortality among persons infected with human immunodeficiency virus (HIV).[6-9] Nosocomial outbreaks of multidrug-resistant tuberculosis, mainly among HIV-seropositive patients, have had mortality rates ranging from 72 percent to 89 percent.[10-14] There has been transmission to health care workers, with five deaths (four among HIV-infected workers).[10,11,14-17] In each outbreak there was noncompliance with the administrative and engineering measures for control recommended by the Centers for Disease Control and Prevention (CDC).[18,19] The outbreaks ceased when these measures were implemented.

The CDC recently published a draft guideline proposing new measures to prevent nosocomial tuberculosis, including the use of respirators with high-efficiency particulate air filters (HEPA respirators) in isolation rooms for patients with possible tuberculosis.[20] The Occupational Safety and Health Administration (OSHA) announced in October 1993 that it would require the use of HEPA respirators and a respiratory-protection program. We used data from the University of Virginia Health Sciences Center to estimate the feasibility and cost effectiveness of these additional requirements in hospitals such as ours, which are complying with the control measures recommended by the CDC.

From the University of Virginia Health Sciences Center, Box 473, Charlottesville, VA 22908, where reprint requests should be addressed to Dr. Farr.

Supported in part by a training grant (T32AI07046) from the National Institutes of Health.

### METHODS

The University of Virginia Hospital is a tertiary care center that moved in 1989 to a new facility with 700 beds and 47 negative-pressure–ventilation rooms with anterooms. The airflow at the doors of these isolation rooms is checked semiannually and whenever patients known to have multidrug-resistant tuberculosis are admitted. Hospital policy requires the immediate isolation of any patient with possible tuberculosis, including HIV-infected patients with cough and a new respiratory illness.

The frequency with which patients with tuberculosis were admitted was obtained from lists reported to the health department. The number of patients in isolation rooms was obtained from computer records of isolation orders from June 1992 through May 1993. Weekly logs of patients in isolation were used to validate these records. To provide a record of the number of health care workers entering isolation rooms and the number of visits per day, such personnel were asked to sign a sheet each time they entered the room.

Data on the annual screening of health care workers with purified protein derivative (PPD), required by hospital policy, were obtained from previously published studies[21,22] and from the employee health department at the hospital. A conversion was defined as a newly positive PPD test with induration of 10 mm or more at 48 to 72 hours.[23]

The costs of masks were obtained from the manufacturers and from the purchasing department of the hospital. Annual costs were derived by multiplying the estimated number of masks used in one year by the price of the mask. These estimates ranged from a minimal amount, which assumed adherence to recommended patterns of mask use, a minimal number of health care workers caring for each patient kept in isolation, or both, to a maximal amount, which assumed premature disposal of the mask, a maximal number of health care workers caring for each patient, or both. Estimates of lost time and costs associated with the respiratory-protection program were obtained from data on an existing program for maintenance workers with occupational exposure to hazardous materials. The average salary for full-time hospital employees, excluding physicians on the faculty, was obtained from the hospital administration. Costs were expressed in 1993 dollars.

## Results

Tuberculosis was diagnosed in 11 of 28,000 patients admitted during 1992. During the previous four years, 51 patients with tuberculosis were admitted (mean, 12.8 per year). From June 1992 through May 1993, 76 patients were kept in isolation rooms during 82 admissions, for a total of 611 days (7.5 days per admission). An average of 25 health care workers visited each isolation room each day, making an average of 50 visits per room per day. The health care workers who entered a particular room differed from day to day.

There were eight newly positive PPD tests in 1992 among 3852 health care workers (0.2 percent) (Table 1), but six of these conversions occurred among employees hired the previous year who had had only one previous negative PPD test (i.e., at the time of their hire). These persons (mean age, 42 years) were considered unlikely to have entered an isolation room. Five conversions were considered most likely to be due to the booster phenomenon; one worker (who was 39 years old) had a conversion on his second PPD test, five months after he was hired, but this occurred after exposure to a patient not yet in isolation and may have represented a true conversion. Two conversions occurred in employees with at least two negative PPD tests previously; neither person had worked with a patient isolated for possible tuberculosis. One worked on a surgical unit, and the other worked on an outpatient dialysis unit. No patient with known tuberculosis was cared for on those units during the year before the PPD conversions of these employees.

The absence of conversions attributable to transmission in the isolation rooms of this hospital during 1992 suggests that with additional measures such as HEPA respirators, more than one year would be required to prevent conversion of even a single PPD test to positive status. We assume, however, that one conversion could be prevented each year with the use of these respirators. We also take as givens that disease would develop in only about 10 percent of health care workers after the appearance of a positive PPD test if they were not given prophylactic therapy,[23] that isoniazid therapy has 93 percent efficacy in preventing subsequent disease after exposure to isoniazid-sensitive strains,[24] and that 81 percent of patients with tuberculosis at this hospital in 1991 and 1992 had isoniazid-sensitive strains. Therefore, if it is assumed that there is one conversion per year, the number of cases of active tuberculosis can be calculated as follows:

$$0.10 \times [0.19 + (0.07 \times 0.81)] = 0.02467.$$

The number of years needed to prevent a single case of occupational tuberculosis would then be the inverse of 0.02467, or 41 years. The only such case recognized at this hospital during the past two decades would not have been prevented by the use of HEPA respirators, because the exposure occurred before tuberculosis was suspected.

A simple isolation mask costs $0.06. A dust–mist respirator costs $0.92. Costs for HEPA respirators in 1993 ranged from $7.51 for disposable models to $9.08 for respirators with replaceable filters (3M Health Care, St. Paul, Minn.). Minimal and maximal estimates of the annual cost of each type of mask (Fig. 1) were based on these prices. For simple isolation masks, the figure of $1,833 (i.e., 50 room visits per day times 611 days of isolation per year times $0.06 per mask) represents both the minimal and the maximal estimate, because these masks are not reusable.

For dust–mist respirators, a minimal amount of $1,886 would be required if the same worker cared for each patient throughout the course of hospitalization and the respirator was discarded only when it no longer fit adequately. This figure was obtained by multiplying 25 (the number of workers caring for each patient in isolation) by 82 (the number of admissions) by the unit cost of $0.92. A maximal amount of $28,106 would be required if the respirator was discarded after each use (50 visits × 611 days × $0.92). Since the implementation of policies requiring the use of dust–mist respirators on June 18, 1993, the hospital had spent $12,623 for them as of December 1993 (i.e., about $25,000 for an entire year). This shows that health care workers frequently discard dust–mist respirators after a single use, despite efforts to educate the workers to keep the respirators until they no longer fit adequately.

At least $15,396 would be required to purchase disposable HEPA respirators if the same 25 workers cared for each patient throughout the entire hospitalization and discarded their respirators only when necessary (25 × 82 × $7.51). A maximum of $114,715 would be required if different workers cared for each

Table 1. Rates of Conversion to a Positive PPD Test among Health Care Workers at the Study Hospital.

| Year | No. of Conversions | No. Tested* | Rate (%) |
|---|---|---|---|
| 1968–1969 | 24† | 1253 | 1.92 |
| 1972–1973 | 13‡ | 2497 | 0.52 |
| 1986 | 10 | 2857 | 0.35 |
| 1990–1991 | 15§ | 7258 | 0.21 |
| 1992 | 8¶ | 3930 | 0.20 |

*Numbers shown for 1986 through 1992 are estimates because some subjects were tested more than once.

†Includes 14 of 225 health care workers with documented exposure to a patient not yet in isolation.[21]

‡Includes 8 of 484 health care workers with documented exposure to a patient not yet in isolation.[22]

§Four of 15 health care workers had documented exposure to a patient not yet in isolation.

¶Five of these conversions were attributed to the booster phenomenon (see text). Of the remaining three health care workers, one had a newly positive PPD test after exposure to a patient not yet in isolation, and two had not worked with a patient in isolation.

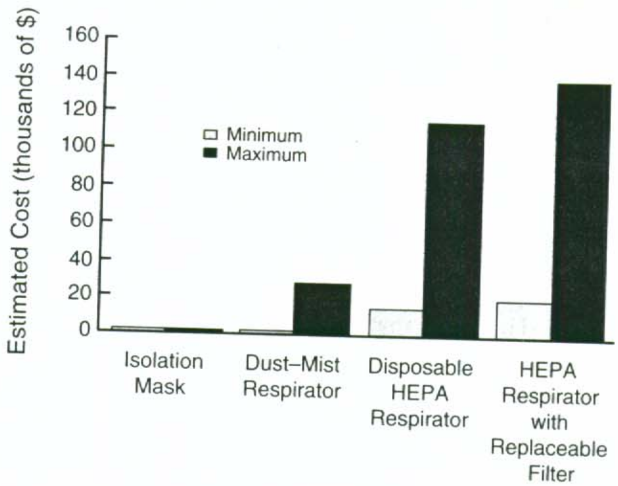


Figure 1. Minimal and Maximal Annual Cost Estimates for the Use of Several Types of Mask by Health Care Workers at the Study Hospital.

The cost of the respiratory-protection program (including medical evaluation, training, and testing of fit) is not included.

patient every day or if the workers discarded their masks each day (25 × 611 × $7.51).

For respirators with replaceable HEPA filters, the minimum cost would be $18,614 if the same workers cared for each patient throughout the patient's hospitalization (25 × 82 × $9.08). A maximum of $138,697 would be required if different workers cared for each patient every day (25 × 611 × $9.08).

As part of a personal respiratory-protection program, OSHA requires training and testing of the proper mask fit for each worker. We estimate that testing of fit will require 20 minutes to perform, plus 20 minutes of transit time for each of the 3852 health care workers at our institution with potential exposure to a patient with tuberculosis, or 2568 hours of lost time for the workers plus 1284 hours for the tester of fit. During the first year of the respiratory-protection program, this would be the equivalent of the time worked by 1.89 full-time employees at a cost of $67,462 (given that 1 full-time hospital employee works 2040 hours per year for a mean annual pay of $35,694). The cost of testing the fit of the mask for 350 new employees each year would be $6,124. Thus, testing of fit would cost $312,422 in all over a 41-year period.

Training would require 193 half-hour sessions (assuming 20 employees per session) and an additional 20 minutes of transit time per employee. This would result in 3210 hours of lost time for health care workers, at a cost of $56,166 for the first year and 96 hours, or $1,680, for the trainer. The cost of training newly hired employees would be $5,256 per year. The estimated costs of training for 41 years would be $268,086.

OSHA also suggests an annual medical evaluation.[25] Given that in the current program for maintenance workers dealing with hazardous substances a medical evaluation costs $60 and takes one hour of the employee's time, the total cost would be $231,120 and the equivalent of the time lost by 1.89 full-time employees ($67,462) for the 3852 health care workers each year ($12,241,862 for a 41-year period).

The CDC draft guideline states that screening every five years with a questionnaire should suffice to identify workers who need further evaluation. If we estimate that 10 minutes are needed for each employee to fill out a questionnaire and 5 minutes for the questionnaire to be screened in the employee health department, the cost would be $134,797 for a 41-year period.

We thus estimate that preventing a single case of occupational tuberculosis during the next 41 years by implementing the proposed requirements for HEPA respirators and a respiratory-protection program would cost this hospital between $1,333,090 and $18,508,947 (Table 2). If the number of respirators could be reduced by 50 percent because workers were caring for more than one patient, the minimal and maximal estimates would be reduced to $1,030,923 and $15,665,659, respectively.

## Discussion

The CDC draft guideline specifies the use of HEPA respirators to prevent nosocomial tuberculosis but gives no epidemiologic data about their efficacy.[20] Recent tuberculosis outbreaks occurred in hospitals with inadequate administrative and engineering measures for control.[10-14] Each hospital had isolation rooms with positive pressure relative to the hallway.[11-14] In one outbreak, exhaust air from a sputum-induction room was recirculated into the HIV clinic.[11] In another outbreak, patients were permitted to go to common areas or group activities without keeping their masks on. When they were readmitted, patients with known tuberculosis were not always placed in isolation again.[14] In these outbreaks transmission was controlled when the 1990 CDC guidelines were implemented. HEPA respirators were not used.[10-14]

At our hospital, administrative and engineering controls have been used for decades to prevent nosocomial tuberculosis. Simple isolation masks were used until 1993, when the hospital switched to dust–mist respirators. Our PPD screening has shown declining

Table 2. Estimated Cost of Preventing One Case of Occupationally Acquired Tuberculosis with HEPA Respirators and a Respiratory-Protection Program.

| Item | Minimal Cost | Maximal Cost |
|---|---|---|
| | *dollars* | |
| Respirator | | |
| Disposable | 631,236 | — |
| With replaceable filters | — | 5,686,577 |
| Respiratory program | | |
| Testing of fit | 312,422 | 312,422 |
| Training | 268,086 | 268,086 |
| Medical evaluation | 134,797 | 12,241,862 |
| Total | 1,346,541 | 18,508,947 |

rates of new positive tests for 25 years (Table 1). Many conversions occurred in employees without known exposure and were possibly due to exposure in the community after the employee was hired or to exposure before hiring (i.e., with conversion on the second PPD test after hiring because of the booster phenomenon). In 1992, only three health care workers were considered actually to have had a conversion, one of which was due to unprotected exposure. The other two employees had not worked with a patient in isolation for tuberculosis; thus, HEPA respirators would not have prevented them from having a conversion.

The National Jewish Center for Immunology and Respiratory Medicine in Denver documented only two PPD conversions in the decade after 1983. There, employees use simple isolation masks while caring for the many patients with tuberculosis, who stay in negative-pressure rooms with ultraviolet lights (Burton LJ: personal communication).

In 1992 our hospital spent $1,833 on simple isolation masks. In 1993 dust–mist respirators were used that cost almost 14 times as much as the simple isolation masks. In turn, HEPA respirators could cost six times more than the dust–mist respirators. Implementing a respiratory-protection program would cost still more. At hospitals that treat more patients who require isolation for tuberculosis, the costs would obviously exceed our estimates.

Such costs are difficult to justify, given the lack of epidemiologic data demonstrating the effectiveness of either HEPA respirators or a respiratory-protection program and the strong epidemiologic evidence for the effectiveness of the currently recommended administrative and engineering controls. Moreover, when tuberculosis is transmitted, it is often transmitted by patients who have been given an incorrect diagnosis and who have not been isolated. HEPA respirators would not alter the risk of exposure to such patients or the risk that is present early in an outpatient visit, before a history has been taken that suggests tuberculosis (as in the only case of occupational tuberculosis documented at our hospital in the past two decades). Because the CDC specifies that the new guidelines should be followed in ambulatory care clinics, dental clinics, home health care settings, emergency medical services, and other facilities, such as treatment centers for substance abuse and medical areas in correctional facilities, the potential cost to the nation could be very high.

HEPA respirators have inconvenient aspects that are important but difficult to quantitate precisely. They are bulky and less comfortable than isolation masks. They muffle the voice and interfere with communication with the patient. They may cause respiratory compromise in some workers. Overall, HEPA respirators are cumbersome, and a requirement to use them would interfere with practical aspects of the daily delivery of health care.

In an era of cost control by the federal government, this proposal would lead to tremendous, unnecessary increases in hospital expenses. We are concerned that many hospitals may respond by eliminating other, more important parts of their infection-control programs that actually do prevent infection. This would be most unfortunate and could lead to further increases in hospital costs and excess in-hospital mortality.

## Conclusions

Our data show that current administrative and engineering controls are very effective in preventing the nosocomial transmission of tuberculosis. Hospitals that use such controls have no need for HEPA respirators or a respiratory-protection program. In our opinion, the draft guideline represents an overreaction to recent outbreaks of nosocomial tuberculosis in hospitals that were not complying with recommended control measures. Those outbreaks were controlled by the implementation of the current guidelines, without the use of HEPA respirators. Data from hospitals that comply with existing guidelines suggest that the proposed measures would add negligible protective efficacy at great price. Such costly, unproved measures should not be required unless epidemiologic data demonstrate their efficacy and cost effectiveness.

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