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July 20, 1994 GARY WM. FARNES, CHIEF EXECUTIVE OFFICER

NIOSH Docket Office
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Dear NIOSH:

In response to the federal register of May 24, 1994 which addresses respiratory protective devices, we are pleased to see that NIOSH is taking the initiative to test alternative masks.

The HEPA filtered mask in hospitals presents several problems:

- they are uncomfortable to wear.
- concern about compliance issues. Employees may be fit tested, taught to wear the mask properly, but if uncomfortable or the patient can not hear them, they may move the mask.
- HEPA masks are difficult to fit on women.
- HEPA masks with the exhalation valve, if put on a tuberculosis patient, may potentially increase the transmission of tuberculosis.
- the cost of the HEPA mask is an issue in these days of health care reform and cost cuts
- a definition of use time for the reuseable HEPA mask has not been presented; long term use presents a storage problem for hospitals.

It is refreshing to see that NIOSH will begin to test alternative mask choices. A disposable mask would be preferred as it resolves the storage issue and concern about resistant organisms on the outside of masks. The type C mask, if approved for health care worker use with tuberculosis patients, would resolve many of the cost, storage issues, and we believe achieve better employee acceptance.

Will NIOSH require fit testing of the type C mask? Sources at CDC have stated that pulmonary function testing and possibly fit testing may not be required for the particulate tuberculosis use mask.

Enclosed is an article from the New England Journal of Medicine that outlines many issues in which we are agreement. Thank you for your interest in comments on this important issue.

Sincerely

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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.

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 mainte-

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nance 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 \times 611 days \times \$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 \times 82 \times \$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.

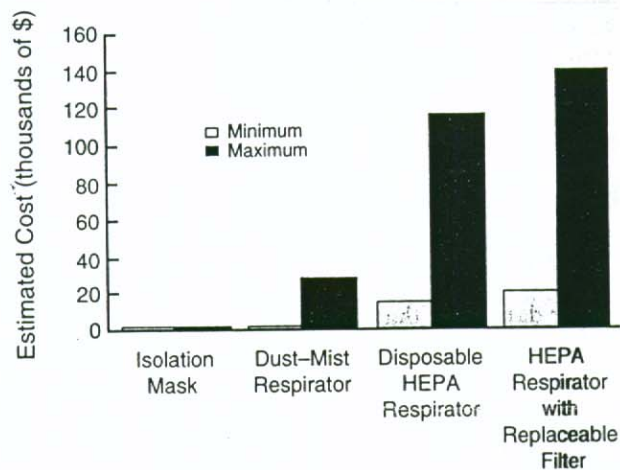


Figure 1. Minimal and Maximal Annual Cost Estimates for the Use of Several Types of Mask by Health Care Workers at the Study Hospital.

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 ($25 \times 611 \times \$7.51$).

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 ($25 \times 82 \times \$9.08$). A maximum of \$138,697 would be required if different workers cared for each patient every day ($25 \times 611 \times \$9.08$).

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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