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Statement of the Medical Society of the State of New York
 on NIOSH's Proposed Rules
 on Respiratory Protection Devices

The NIOSH announcement in the Federal Register of May 24, 1994 on Proposed Rules pertaining to Respiratory Protective Devices appears at least in part to be a federal response to the pleas of physicians and hospitals troubled by the OSHA requirement of use of the HEPA respirator originally recommended by NIOSH.

The assurance in the Register that health care institutions concerned with the nosocomial control of tuberculosis will have a broader choice of certified respirators is welcome news indeed. It is further reassuring to read the intent of NIOSH to use new particulate filter tests that will meet or exceed CDC recommendations and at the same time be substantially less expensive than the HEPA filter. That a new final rule pertaining to particulate filters will be available sometime in 1994 is also welcome news. We hope and trust that, at a later point, OSHA will be responsive to the new classification and the associated recommendations.

For the most part, this statement in the Federal Register is highly technical and is addressed mainly to manufacturers of respirators. The burden of response in complying with the new proposals is mainly on them and on the institutional users of respirators.

We speak for 27,000 physicians in New York State, some of whom are users of HEPA respirators. As a state medical society we are aware of many complaints from physicians and hospital personnel who find the HEPA respirator excessively constraining and a serious impediment to communication with patients. The present OSHA requirement of their use even in routine care is neither feasible or practical. Even pulmonologists performing special procedures report the impulse to tear off the mask with their gloved hand.

More important than the wide-spread personal reactions of individual physicians to HEPA is the fact that, when traditional control measures have been put into place and enforced, hospitals have been able to abort nosocomial TB epidemics. The implications of this observation should not be lost sight of in the quest for finding and certifying respirators with an efficiency that may even exceed the current requirements of the CDC.

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The July 1994 issue of the Annals of Internal Medicine contains an important article entitled "Tuberculosis Control Strategies: The Cost of Particulate Respirators." This is a timely and useful article on the cost and expectations of high-efficiency particulate respirators. We ask that it be included in our submission.

Respectfully submitted,

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Tuberculosis Control Strategies: The Cost of Particulate Respirators

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■ **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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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, <i>n</i>	0-60	3	95
Cases of confirmed pulmonary tuberculosis in patients in the last year, <i>n</i>	0-68	3	98
Cases of active pulmonary tuberculosis in employees in the last 5 years, <i>n</i>	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

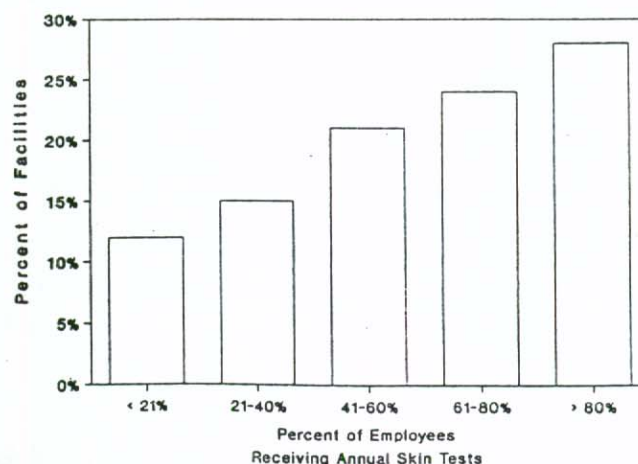


Figure 1. Percentage of employees receiving annual purified protein derivative skin tests at each facility (149 facilities providing data).

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 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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