

# Tuberculosis control through respirator wear: Performance of National Institute for Occupational Safety and Health-regulated respirators

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**Background:** In 1995 the National Institute for Occupational Safety and Health issued new rules for personal respirators. All nine new respirator categories are authorized in health care facilities for the prevention of the transmission of tuberculosis (TB). The new N95 respirator category is the most frequently used for this purpose. Data are presented on their efficiency for collecting TB-size bacteria and their potential for reaerosolizing collected bacteria.

**Methods:** All measurements of bacterial penetration were performed with dynamic aerosol size spectrometers at flow conditions corresponding to normal wear and respirator certification conditions. The reaerosolization tests were performed at conditions ranging from normal breathing to violent coughing or sneezing.

**Results:** The tested N95 respirators collected 0.1 to 0.3  $\mu\text{m}$  particles with efficiencies of 95% or higher, as specified by the regulations. TB-size bacteria of 0.8  $\mu\text{m}$  and larger, however, were collected with 99.5% or higher efficiencies; that is, the penetration of these bacteria through the filter material was 0.5% or less, much less than the required maximum penetration of 5% for the smaller particle sizes. No bacteria were reaerosolized during normal exhalation. Some reaerosolization (0.1% or less) was observed only at low humidity and extremely high air flow through the respirator, corresponding to violent coughing or sneezing.

**Conclusions:** The filter materials of N95 respirators provide good protection against TB bacteria. Thus, a significant number of bacteria can enter the respirator-wearer's breathing space only through spaces where the respirator inadequately seals to the wearer's face.

Reentrainment and reaerosolization of mycobacteria is not a problem when normal work practices are observed in health care facilities. (AJIC Am J Infect Control 1998;26:139-42.)

Since the appearance of multidrug-resistant tuberculosis (TB), health care workers have had increasing concerns about becoming infected from *Mycobacterium tuberculosis*, which led the Centers for Disease Control and Prevention (CDC) to publish in 1994 guidelines for preventing the transmission of *Mycobacterium tuberculosis* in health care facilities.<sup>1</sup> In 1995 the National Institute for Occupational Safety and Health (NIOSH) issued regulations on the per-

formance of respirators.<sup>2</sup> These regulations, generally referred to as 42 C.F.R. Part 84, replace the previous regulations under 30 C.F.R. Part 11.<sup>3</sup> All of the nine new respirator categories created under 42 C.F.R. Part 84 satisfy the 1994 CDC guidelines and are, therefore, authorized in health care facilities. The nine respirator categories consist of three levels of minimum filtration efficiency and three aerosol test procedures simulating different work environments. The three filtration efficiency levels are 95%, 99%, and 99.97%. The N95 respirator appears to be the most frequently used respirator in health care facilities because it is the least expensive respirator that satisfies the new regulations. The N95 respirator is required to have a minimum efficiency at the "most penetrating particle size" (approximately 0.1 to 0.3  $\mu\text{m}$ ) of 95%, when tested with NaCl aerosols at a flow rate of 85 L/min.<sup>2</sup> Previous tests with respirator filters have shown the efficiency to increase with particle size for particles above the most penetrating size.<sup>4,5</sup>

Airborne bacteria are generally in the size range of 0.6 to 1.5  $\mu\text{m}$ ,<sup>6</sup> larger than the most penetrating particle size. Therefore, the filtration efficiencies of N95

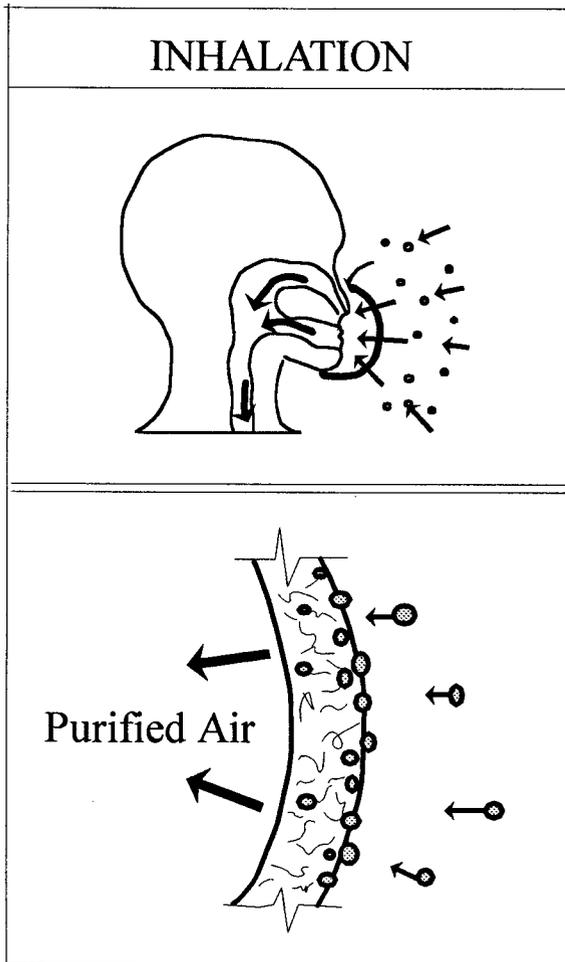
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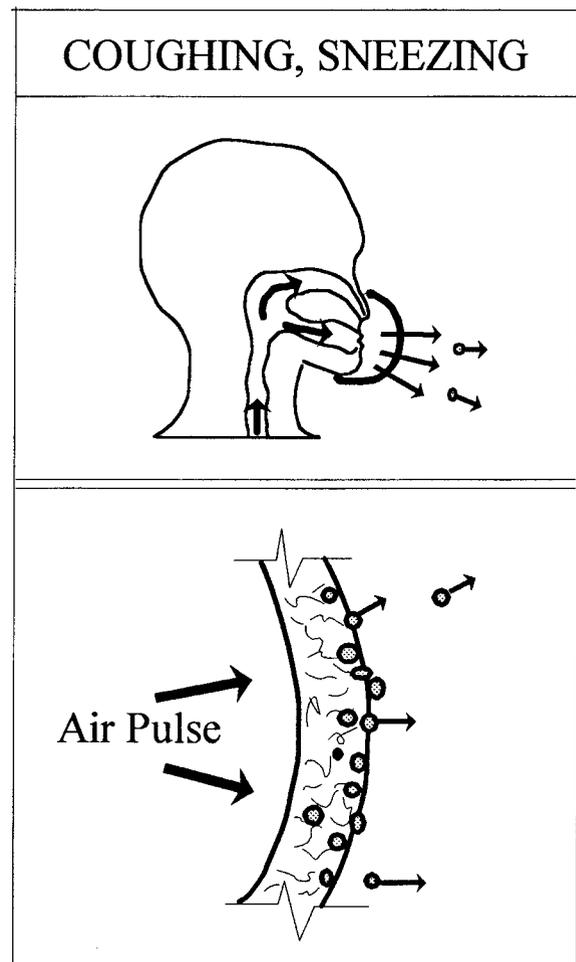
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**Fig. 1.** Collection of bacteria and other particles on a respirator filter during inhalation.

respirators for bacteria are expected to be higher than one might expect from the number 95 in the N95 name. In this study, N95 respirators were tested with surrogate bacteria simulating the size and shape of *Mycobacterium tuberculosis*. TB bacteria are rod shaped, about 0.3 to 0.6  $\mu\text{m}$  in diameter and 1 to 4  $\mu\text{m}$  in length.<sup>7</sup>

The new regulations under 42 C.F.R. Part 84 differentiate respirators by the filtration efficiency of the respirator filter media. Even if one chooses a 100% efficient respirator, airborne bacteria and other particles may pass to the wearer's breathing zone and become inhaled if there is air leakage between the respirator and the face. The air flow through a leak may be significant, because air follows the path of least resistance. The problem of face-seal leakage is not addressed in this article but is dealt with in other publications.<sup>8-11</sup> When the respirator wearer inhales, the respirator filter collects airborne bacteria and other particles mostly on or near the outer filter sur-



**Fig. 2.** Potential re-aerosolization of bacteria and other particles from a respirator filter during violent sneezing or coughing.

face, as shown in Fig. 1. Thus, the inhaled air is purified to a degree that depends on the collection efficiency of the respirator filter. When the respirator wearer exhales (Fig. 2), some of these collected bacteria may be expected to become reentrained, that is "re-aerosolized," by the exhalation air flow.

In this study, exhalation flows have been tested for such re-aerosolization. Because little re-aerosolization was expected during normal exhalation, tests also were performed at higher exhalation flows simulating coughing and sneezing.

#### MATERIALS AND METHODS

Single-use N95 respirators, made by two major manufacturers, were tested in this study. A nonpathogenic rod-shaped bacterium, *Bacillus subtilis*, was selected as a surrogate of *Mycobacterium tuberculosis*. *B. subtilis* is similar in size and shape to *M. tuberculosis* and has been used as a TB surrogate in previous respirator penetration studies.<sup>12,13</sup> *B. subtilis*

**Table 1.** Performance of NIOSH-certified N95 respirators

Respirator manufacturer	Filtration efficiency during normal breathing,%*		Reaerosolization of TB surrogate bacteria during violent sneezing or coughing,%†	
	NaCl certification particles, 0.2 $\mu\text{m}$	TB surrogate bacteria, 0.8 $\mu\text{m}$	RH = 22%	RH = 35%
A	96.2 $\pm$ 0.5	$\geq$ 99.5%	0.025 $\pm$ 0.015	ND
B	96.8 $\pm$ 0.5	$\geq$ 99.5%	0.022 $\pm$ 0.022	ND

RH, Relative humidity; ND, none detected by measurement system.

\*Tested at certification flow rate of 85 L/min.

†Loaded at breathing flow rate under medium work load of 50 L/min (air velocity = 8 cm/s). Reaerosolization at 300 cm/s.

cells were kept on trypticase soy agar slants at 5° C (Tryptic, Difco Laboratory, Detroit, Mich.). During the preparation for the experiments, cells were streaked on trypticase soy agar plates and incubated at 25° C for 18 hours. After incubation, cells were removed from the plates with sterile deionized water and washed with deionized water in a centrifuge operated at 2860g (Marathon 6K, Fisher Scientific, Pittsburgh, Pa.).

Because N95 respirators are certificated through tests with NaCl particles,<sup>2</sup> the first phase of this study was to test the performance of N95 respirators with NaCl particles. An NaCl aerosol with particle sizes at and above the most penetrating particle size was generated by dissolving NaCl in deionized water to a concentration of 3.5 mg/cm<sup>3</sup>, aerosolizing the solution through a Collison nebulizer (BGI Inc., Waltham, Mass.), and drying the effluent air flow of 5 L/min with clean dry air of 10 L/min. The experimental facility for the aerosol penetration portion of this study was similar to the one used before for studies with respirators certified under the previous (30 C.F.R. 11) rules.<sup>3</sup> In this facility, the aerosolized bacteria or other particles are passed through a 10 mCi <sup>85</sup>Kr electrical charge neutralizer to minimize the electrical charge on the particles. Then they enter an aerosol exposure chamber, where the test respirator is mounted on a human head mannequin. The number of airborne particles per unit volume of air (aerosol concentration) was measured outside and inside the respirator by one of two aerosol measurement devices. For the TB surrogate bacteria, an Aerosizer (Amherst Process Instruments Inc., Hadley, Mass.) measured the aerosol concentrations at an aerodynamic equivalent diameter of 0.8  $\mu\text{m}$ , and for the NaCl particles, an LAS-X laser aerosol size spectrometer (Particle Measuring Systems, Inc., Boulder, Colo.) measured the aerosol concentrations at an optical equivalent diameter of 0.2  $\mu\text{m}$ , which approximately corresponds to the most penetrating particle size. These aerosol measurement techniques have been described previously.<sup>14,15</sup>

The tests on the reaerosolization of bacteria from respirator filters were performed in two steps. First, bacteria were loaded onto the respirator filters in an experimental facility that is similar to the one used for aerosol penetration studies. In this facility, the number of particles collected on the filter was determined by measuring the aerosol concentrations upstream and downstream of the respirator during the loading cycle. The respirator then was mounted in another facility in which air was passed through the respirator in the opposite direction, and the number of reaerosolized particles was measured in the effluent airstream. The percentage of reaerosolized bacteria was thus determined as the ratio of reaerosolized bacteria to the number of bacteria previously collected by the respirator. The air velocity through the respirator was 8 cm/s during the loading cycle, which corresponds to breathing under a heavy workload at the respirator certification flow rate of 85 L/min. Reaerosolization of bacteria was recorded at reverse air velocities of 8 to 300 cm/s. The maximum reaerosolization velocity of 300 cm/s is 37 times the loading velocity and corresponds to violent sneezing or coughing.

One sample of each N95 respirator was tested in this study. The samples were taken from a supply of purchased respirators. Each data set was repeated five times, and the results are reported by their means and standard deviations.

## RESULTS AND DISCUSSION

Table 1 is a summary of the results. The first filtration efficiency column shows that the selected N95 respirators have collection efficiencies well above the required 95% level when tested with NaCl particles at the particle size for maximum aerosol penetration. The second filtration efficiency column shows that the efficiency of collecting TB surrogate bacteria, such as *Bacillus subtilis*, is equal to or higher than 99.5%, which is much higher than the required 95%. At this level, very few bacteria penetrate the filter and are detected by the aerosol instru-

ment; thus, the efficiency cannot be determined more precisely than indicated. Separate experiments confirmed that the aerosol particles measured in the bacterial size range by the aerosol spectrometer were only test bacteria.<sup>16</sup>

Bacteria usually are contained in droplets when emitted during exhalation. Thus, a TB bacterium-containing droplet may be larger in size than the bacterium itself. The efficiencies of the respirator filters tested in this study and those tested in previous studies were found to increase with particle size above the mean aerodynamic size of 0.8  $\mu\text{m}$  for TB bacteria.<sup>4,5,13</sup> Thus, the filters of N95 respirators are very effective in removing TB bacteria from the inhalation air flow of a respirator wearer.

The next column of Table 1 shows that less than 0.1%, that is, less than one out of 1000 collected bacteria, is reaerosolized at a reverse flow rate corresponding to 37 times normal breathing (violent coughing or sneezing). Reaerosolization reaches significant levels only at higher reverse air flow conditions, which do not correspond to conditions encountered during normal respirator wear. The data shown in this column were obtained with the entire test facility at a relative humidity level (RH) of 22%. When the relative humidity was raised to levels above 35%, corresponding to more normal respirator wear conditions, no reaerosolization was detected. While it still may occur at a level below the limit of detection of the test instrument, it is not significant. The decrease in reaerosolization with increasing relative humidity is attributed to liquid bridging between the bacteria and the filter fibers.

## CONCLUSION

The present study has shown that the most frequently used respirators in health care environments, satisfying the new NIOSH regulations under 42 C.F.R. Part 84, are considerably more effective in collecting bacteria the size and shape of *Mycobacterium tuberculosis* than the number 95 in the name N95 may suggest. The 95% minimum efficiency level is for the most penetrating particle size, which is well below the mean size of most bacteria. TB-size bacteria and bacteria contained in liquid droplets are collected at 99.5% or higher efficiencies. Thus, bacteria the size and shape of *Mycobacterium tuberculosis* can reach the respiratory tract of a respirator wearer in significant numbers only if there is face-seal leakage between the respirator and the face.

When the respirator wearer exhales, none of the collected bacteria is likely to be reentrained by the exhalation air flow. Only when the respirator wearer coughs or sneezes in a violent manner

does any possibility of bacterial reaerosolization exist. The reaerosolization percentage is below 0.1% at low relative humidities and less at higher relative humidities.

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