Respiratory Syncytial Virus — Continued

RSV can be controlled with strict attention to contact-isolation procedures (*6*). Although vaccines are under development, none have been demonstrated to be safe and effective in preventing RSV-associated disease. RSV intravenous immune globulin and a recently licensed, humanized murine anti-RSV monoclonal antibody are available as prophylaxis for serious RSV infections in some high-risk infants and young children (e.g., those born prematurely or with chronic lung disease) (*7*). Ribavirin is the only available antiviral agent for treating RSV infection and may be considered for some patients (*8*).

References

1. Institute of Medicine. [Appendix N]: Prospects for immunizing against respiratory syncytial virus. In: Institute of Medicine. New vaccine development: establishing priorities. Vol II. Disease importance in developing countries. Washington, DC: National Academy Press, 1986:299–307.
2. Gilchrist S, Török TJ, Gary HE Jr, Alexander JP, Anderson LJ. National surveillance for respiratory syncytial virus, United States, 1985–1990. J Infect Dis 1994;170:986–90.
3. Dowell SF, Anderson LJ, Gary HE Jr, et al. Respiratory syncytial virus is an important cause of community-acquired lower respiratory infection among hospitalized adults. J Pediatr 1996;174:456–62.
4. Wang EEL, Law BJ, Stephens D, et al. Pediatric Investigators' Collaborative Network on Infections in Canada (PICNIC): prospective study of risk factors and outcomes in patients hospitalized with respiratory syncytial viral lower respiratory tract infections. J Pediatr 1995;126:212–9.
5. Whimbey E, Couch RB, Englund JA, et al. Respiratory syncytial virus pneumonia in hospitalized adult patients with leukemia. Clin Infect Dis 1995;21:376–9.
6. CDC. Guideline for infection control in health care personnel, 1998. Am J Infect Control 1998; 26:289–354.
7. Committee on Infectious Diseases, Committee on Fetus and Newborn, American Academy of Pediatrics. Prevention of respiratory syncytial virus infections: indications for the use of palivizumab and update on the use of RSV-IGIV. Pediatrics 1998;102:1211–6.
8. Committee on Infectious Diseases, American Academy of Pediatrics. Reassessment of the indications for ribavirin therapy in respiratory syncytial virus infections. Pediatrics 1996;97: 137–40.

Laboratory Performance Evaluation of N95 Filtering Facepiece Respirators, 1996

In 1995, CDC's National Institute for Occupational Safety and Health (NIOSH) introduced a new classification scheme for particulate air-purifying respirators (*1*). Most health-care workers use type N95 half-mask filtering facepiece respirators (i.e., N95 respirators) to prevent occupational transmission of tuberculosis.* As a result, NIOSH received inquiries about how well N95 respirators fit, whether they need to be fit tested, and whether they can be quantitatively fit tested.† In response to these inquiries, NIOSH evaluated the performance of 21 N95 respirator models on a 25-person panel. This report summarizes the results of this evaluation, which indicate that fit

*There are nine classes of filters (three classes of filter efficiency [95%, 99%, and 99.97%] each with three categories of resistance to filter efficiency degradation [N, R, and P]). N-category filters are the least resistant to degradation by oil aerosols. An N95 filter is an N-category filter that is at least 95% efficient.

†Fit testing is a procedure used to evaluate how well a given respirator fits a given person by assessing leakage around the face seal; fit testing can either be qualitative (i.e., relying on a subjective response of the wearer) or quantitative (i.e., using a measurement of actual leakage).

Laboratory Performance Evaluation — Continued

testing is needed to ensure at least the expected level of protection (i.e., the concentration of airborne contaminants inside the respirator is ≤10% of ambient levels).

The panel comprised 15 women and 10 men (all experienced in wearing respirators and fit testing); the distribution of face lengths and face widths approximated that of the general population (*2*). The 21 respirator models were the only respirators commercially available in July 1996, when the evaluation began.

Each respirator model was assessed by 1) the 25-person panel without fit testing and 2) removing from the panel those persons for whom a model failed a surrogate fit test. For each model, total penetration (i.e., direct penetration through the filter and leakage around the face seal[§] combined) was measured with each person on the panel using the TSI 8020 Portacount Plus™[¶], a fit-test instrument that uses ambient air particles as the challenge agent (*3*). In a previous study, fit factors (the reciprocal of face-seal leakage) measured by this instrument correlated with actual exposure (*4*).

For each test, the person donned the respirator and performed a user seal check (i.e., pressure-tightness test, fit check, or negative/positive pressure check) according to the manufacturer's instructions; when respirator models were available in multiple sizes, the size with the best subjective fit was used. Each person then performed a six-exercise** test during which total respirator penetration was measured. These exercises, each lasting approximately 80 seconds, simulate facial movements during normal use and typically are included in fit testing protocols. After removing the respirator, three identical repeat tests were performed. Total penetration was measured during each test; thus, four total penetration measurements were obtained with each respirator for each of the 25 persons.

For each respirator model, the resulting 100 total penetrations were used to calculate the 95th percentile of the total penetration, using the geometric mean (GM) and the geometric standard deviation (GSD) of these measures, as $GM \times GSD^{1.645}$ (*5*). These results summarize the performance of these 21 models without fit testing. Values for the 95th percentile ranged from 6% to 88% total penetration. Five respirator models had 95th percentiles of ≤10% total penetration (Table 1). The computed figure indicates that 95% of wearers of that model can expect a total respirator penetration less than this value and is used to indicate overall respirator performance (*6*).

For each person-respirator model combination, the first total penetration measurement then was used as a surrogate fit test to estimate N95 respirator performance when fit testing is conducted before use. Because fit tests are intended to assess only face-seal leakage, the measured total penetration was adjusted by subtracting the filter penetration,[††] measured separately on each respirator by using the Portacount™ with a specially designed fixture. Each respirator having face-seal leakage >1%[§§] during the first trial was considered to have failed the fit test for that person,

§ $P_T = P_{fp} + P_{fsl}$, where P_T is the total penetration, P_{fp} is filter penetration, and P_{fsl} is face-seal leakage.

¶ Use of trade names and commercial sources is for identification only and does not imply endorsement by the U.S. Department of Health and Human Services or CDC.

** Normal breathing, deep breathing, moving head side to side, moving the head up and down, reading a prepared text aloud, and normal breathing.

†† $P_{fsl} = P_T - P_{fp}$.

§§ The 1% criterion is the standard value used by the Occupational Safety and Health Administration and the American National Standards Institute to assess face seal leakage and is intended to provide a 10-fold safety factor between laboratory-based assessments of leakage and leakage during actual working conditions (i.e., <1% leakage in the lab should assure <10% leakage in the field).

Laboratory Performance Evaluation — Continued

TABLE 1. Performance testing data for 21 N95 filtering facepiece respirators for 25 persons, 1996

Respirator model	Total penetration* (95th percentile)†	Respirators passing surrogate fit test	
		No. passing	Total penetration* (95th percentile)†
1	6%	14	3%
2	7%	8	2%
3	18%	16	1%
4	88%	4	1%
5	31%	0	NA§
6	11%	15	4%
7	10%	5	2%
8	6%	9	2%
9	18%	0	NA§
10	12%	8	2%
11	33%	3	16%
12	41%	3	3%
13	21%	8	4%
14	26%	0	NA§
15	19%	3	3%
16	13%	9	4%
17	50%	11	1%
18	7%	20	2%
19	32%	3	4%
20	61%	1	2%
21	24%	6	5%
All	**33%**	**146**	**4%**

*Total penetration is the sum of the filter penetration and face seal leakage. For example, a total penetration of 25% corresponds to an exposure equal to ¼ of the exposure without a respirator. Total penetration is expected to be ≤10% for this class of respirators.

†Ninety-five percent of wearers are expected to have total respirator penetration less than the stated value. For this class of respirators a value of ≤10% is expected.

§This model failed the fit test (i.e., had a first-donning face fit leakage ≤1%) with all 25 persons; therefore, the 95th percentile total penetration could not be computed.

and data for that person's trials were then removed from the data set for that respirator model (*2*). For respirators passing this criterion, total penetrations measured for trials 2, 3, and 4 were used to calculate the 95th percentile of the total penetration. These values summarize the performance of the respirators after a fit test was used to screen out respirators that have face-seal leakage >1% (Table 1). The total penetrations ranged from 1% to 16%. For three models, none of the respirators passed the fit test (i.e., none had a first-donning face fit leakage ≤1%); therefore, the 95th percentile could not be computed. By applying the surrogate fit test, 17 of the 21 models had total penetration values ≤10%, a substantial increase in protection. Many models had a high fit test failure rate; 17 had acceptable fit tests for fewer than half of the panel members (Table 1).

Reported by: Laboratory Investigations Br, Div of Respiratory Disease Studies, National Institute for Occupational Safety and Health, CDC.

Editorial Note: The findings in this report indicate that fit testing N95 respirators is essential in programs employing these respirators and can eliminate poorly fitting

Laboratory Performance Evaluation — Continued

respirators, ensuring at least the expected level of protection. Without surrogate fit testing, average exposure for the 25-person panel was reduced to 33% of the ambient level, which is much less protection than expected of this class of respirators (i.e., exposure reduced to ≤10% of ambient levels). However, when fit tested first, the panel received substantially greater protection than normally expected (the average exposure was reduced to 4% of the ambient level). Without fit testing, persons unknowingly may have poor face seals, resulting in excessive leakage and exposure. For example, the respirators in this study had high fit test failure rates, with 20%–100% of panel members unable to achieve a satisfactory fit with a given respirator model.

The Portacount™ fit test instrument measures the large number (several thousand per cubic centimeter) of small particles present in normal room atmospheres. The instrument counts the number of such particles that penetrate the respirator—either through face-seal leakage or directly through the filter. Previously, this instrument was recommended for use only with high-efficiency respirators that had negligible filter penetration because any particles detected inside the facepiece could be attributed to face-seal leakage. This study tested N95 respirators using the same procedure. However, because N95 filters are not 100% efficient in removing ambient air particles, two additional were steps needed: 1) separate measuring of filter penetration and 2) subtracting this filter penetration (*2*). The technique for quantitatively fit testing N95 respirators in this report is appropriate only for research purposes. The manufacturer has recently developed an accessory to test N95 respirators with the Portacount Plus™; the accessory removes the aerosols in the range that is most penetrating to the respirator filter, so filter penetration is not a concern. The approach used in this study suggests the possibility of commercial adaptation of similar fit test systems, resulting in a second, inexpensive means of quantitative fit testing N95 respirators. The availability of such a fit test system could simplify fit testing and would provide an option to persons responsible for overseeing respirator programs, especially those who already have the basic hardware for quantitative fit testing.

Although some models had (95th percentile) total penetrations ≤10% even without fit testing, these models should be fit tested. The findings in this report indicate that the models evaluated do not provide the expected level of protection for every user. Therefore, even for these models, performing a fit test has value in identifying those wearers having poor fit.

The findings in this study are subject to at least two limitations. First, specific models used do not necessarily represent the models now available; many are no longer marketed in the version tested, and continued product modifications by the respirator manufacturer may affect the fitting characteristics of specific models. Second, some models tested have been replaced with newer versions, and additional models are now available.

The fit test pass/fail level of 1% used in this report typically is recommended by respirator authorities (*7*). This criterion, however, is based on professional judgement. NIOSH will further analyze these data to determine the effect of adjusted pass/fail levels. Such analysis may provide insight into the appropriateness of that pass/fail level.

Laboratory Performance Evaluation — Continued

References

1. Office of the Federal Register. Code of federal regulations: part 84—approval of respiratory protective devices. Washington, DC: Office of the Federal Register, National Archives and Records Administration, 1996. (42 CFR part 84).
2. Coffey C. Testing of half-mask filtering facepiece N95 respirators with the TSI Portacount™. Morgantown, West Virginia: US Department of Health and Human Services, CDC, National Institute for Occupational Safety and Health, 1998.
3. TSI, Inc. Portacount Plus™ manual. St. Paul, Minnesota: TSI, Inc, 1994.
4. Coffey C, Campbell DL, Myers WR, Zhuang Z. Comparison of six respirator fit-test methods with an actual measurement of exposure: part II—method comparison testing. Am Ind Hyg Assoc J (in press).
5. Lenhart SW, Campbell DL. Assigned protection factors for two respirator types based upon workplace performance testing. Ann Occup Hyg 1984;28:173–82.
6. National Institute for Occupational Safety and Health. NIOSH respirator decision logic. Cincinnati, Ohio: US Department of Health and Human Services, Public Health Service, CDC, 1987:13–8; DHHS publication no. (NIOSH)87-108.
7. American National Standards Institute. American national standard for respiratory protection, ANSI Z88.2–1992. New York, New York: American National Standards Institute, 1992.

Progress Toward Global Measles Control and Regional Elimination, 1990–1997

In 1989, the World Health Assembly resolved to reduce measles morbidity and mortality by 90% and 95%, respectively, by 1995, compared with disease burden during the prevaccine era (*1*). In 1990, the World Summit for Children adopted a goal of vaccinating 90% of children against measles by 2000. Regional measles-elimination goals have been established in the American Region (AMR) by 2000, the European Region (EUR) by 2007, and the Eastern Mediterranean Region (EMR) by 2010. This report updates progress toward global measles control and regional elimination (*2*), and presents measles vaccination coverage and incidence for 1997* and WHO estimates of global measles morbidity and mortality in 1997 compared with the prevaccine era[†].

Reported Measles Morbidity and Routine Vaccination Coverage

In 1997, 702,298 cases were reported to WHO, a 48% decline compared with 1990 (*3*). Among the six WHO regions[§], the African Region (AFR) reported the highest measles incidence (47.5 per 100,000), and AMR reported the lowest (6.5 per 100,000). However, the 51,915 cases of measles reported from AMR in 1997 represent a 25-fold increase over the record low 2109 cases in 1996 (*2,3*). The increase resulted from a measles outbreak of >42,000 confirmed cases in São Paulo State, Brazil, that spread to other states in Brazil and to other countries in the region (*4,5*).

Vaccination coverage data were based on reports provided by member states to WHO and adjusted for the target population (annual number of infants surviving their

---

*Reported to the World Health Organization (WHO) as of July 20, 1998.

† Number of measles cases during the prevaccine era was estimated by WHO on a country-by-country basis, and assumed equivalent to 95% of the surviving infants in 1980 for most developing countries, or in 1975 for developed countries. Surviving infants were defined as all live-born infants during a 1-year period minus the number of deaths during the first year of life.

§ African, American, Eastern Mediterranean, European, South East Asian, and Western Pacific regions.