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Comparison of Five Methods for Fit-Testing N95 Filtering-Facepiece Respirators

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Five fit-testing methods (Bitrex, ambient aerosol condensation nuclei counter using the TSI PortaCount Plus, saccharin, modified ambient aerosol condensation nuclei counter using the TSI PortaCount Plus with the N95-Companion, and generated aerosol using corn oil) were evaluated for their ability to identify poorly fitting N95 filtering-facepiece respirators. Eighteen models of NIOSH-certified, N95 filtering-facepiece respirators were tested by a panel of 25 subjects using each fit-testing method. The penetration of the corn oil and the ambient aerosols through the filter media of each respirator was measured in order to adjust the corresponding generated and ambient aerosol overall fit factors, reflecting only face-seal leakage. Fit-testing results were compared to 5th percentiles of simulated workplace protection factors. Beta errors (the chance of passing a fit-test in error) ranged from 3 percent to 11 percent. Alpha errors (the chance of failing a fit-test in error) ranged from 51 percent to 84 percent. The ambient aerosol using the TSI PortaCount Plus and the generated aerosol methods identified poorly fitting respirators better than the saccharin, the Companion, and Bitrex methods. These errors rates should be considered when selecting a fit-testing method for fitting N95 filtering-facepieces. When both types of errors were combined as an assignment error, the ambient aerosol method using the TSI PortaCount Plus had the lowest percentage of wearers being assigned a poor-fitting respirator.

Keywords Fit-Test, Filtering-Facepiece Respirator, Simulated Workplace Protection Factor

A respirator cannot provide its optimum level of protection when it fits its wearer poorly or when it is worn improperly. Qualitative and quantitative fit-testing methods are intended to increase the likelihood that a respirator will protect its wearer. Respirator fit-testing should identify respirators that do not consistently protect their wearers at a level equal to or exceeding the assigned protection factor (APF) of the respirator class. Neither the Occupational Safety and Health Administration (OSHA), the National Institute for Occupational Safety and Health (NIOSH), nor the American National Standards Institute (ANSI) have formally developed APF values for the particulate respirators brought about by the Part 84 NIOSH certification regulations. In the past, an APF of 10 has been given to half-mask respirators and is the APF recommended by the Industrial Safety Equipment Association.[1–3]

The purpose of this study was to compare five fit-testing methods for their ability to identify poorly fitting N95 filtering-facepiece respirators. The methods included two qualitative (Bitrex [denatonium benzoate] and saccharin solutions) and three quantitative fit-testing methods (generated aerosol using corn oil, ambient aerosol condensation nuclei counter using a TSI PortaCount Plus [TSI, Inc., St. Paul, MN], and modified ambient aerosol condensation nuclei counter using the TSI PortaCount Plus with the N95-Companion). Of the available fit-testing methods, these are the only ones that can be used to fit-test N95 filtering-facepiece respirators. The other available fit-testing methods (irritant smoke and iso-amyl acetate) are not suitable for testing N95 respirators. Only high-efficiency respirators (i.e., series 100) can be used with the irritant smoke method. The iso-amyl acetate test can be used only for respirators that remove organic vapors.[4] Although N-series respirators are for use only in workplaces free of oil aerosols, a generated aerosol method was used in this study because R- and P-series respirators have similar designs to the N-series and can be fit-tested using this method.

The efficacy of the fit-tests was determined by comparing test results to a 5th percentile simulated workplace protection factor (SWPF). A PortaCount Plus measured an SWPF while a wearer performed six exercises. The results of six independent SWPF tests were used to calculate the 5th percentile. The SWPF protocol has been demonstrated to be correlated ($r^2 = 0.79$) to a measure of a respirator wearer's actual exposure. Although the results of that study suggested the Portacount Plus instrument may overestimate protection levels, no corrections were made for possible bias in this study.[5]

The differences between the SWPF testing and the ambient aerosol condensation nuclei counter method are: the number and type of exercises, the adjustment of ambient aerosol condensation nuclei counter fit factors for any filter media penetration, and the criteria for determining whether the respirator performed adequately. Comparing the measure of a respirator wearer's actual exposure to the fit-testing results was not practical for this study due to the complexity of obtaining the measure of actual exposure.[5]

MATERIALS AND METHODS

Subjects

Although 33 people (18 females and 15 males) participated in this study, a panel of only 25 subjects tested each respirator model. Panel members were recruited from respondents to an advertisement placed in a local newspaper and from participants in previous NIOSH fit-testing studies. Panel members were selected to provide a variety of facial sizes without regard to any particular facial size distribution. The subjects' lip and face lengths were measured. Female test subjects had lip lengths ranging from 43 to 55 mm and face lengths ranging from 104 to 124 mm. The male subjects had lip lengths of 44 to 59 mm and face lengths of 112 to 135 mm. All test subjects who were smokers refrained from smoking for at least 30 minutes before the tests. For at least 30 minutes after smoking a cigarette or cigar, smokers exhale particles.[6] The PortaCount Plus will detect exhaled particles and interpret them as being caused by face-seal leakage, thus causing erroneous results. All subjects abstained from eating, chewing gum, and drinking (except for plain water) for at least 15 minutes before testing.[7,8] These restrictions ensured that they would be able to detect the qualitative fit-testing agents at the lowest possible concentration.

Respirators

The 18 models of NIOSH-certified, N95 filtering-facepiece respirators used in this study are listed in Table I. The respirators were selected at random from approximately 70 models commercially available at the beginning of the study.

Fit-Testing

For the quantitative fit-tests and the SWPF testing, a sampling probe was inserted into each respirator using a TSI Fit-Test Probe Kit (P/N 8025-N95). The probe's inlet was flush with the inside of the respirator. This configuration has shown good correlation with actual exposure in previous studies.[5] The quantitative fit factors were adjusted for filter penetration (Table II).

TABLE I
List of respirators used

Manufacturer	Model number(s)	Facepiece size(s)	Type
3M	1860S/1860	Small, regular	Cup
3M	8110S/8210	Small, medium/large	Cup
3M	8212	One size fits all	Cup
3M	8512	One size fits all	Cup
AearoSafety	Pleats	Small/medium, medium/large	Folding
Gerson	2737	One size fits all	Cup
Moldex	2201N95/2200N95	Small, medium, large	Cup
Moldex	2207N95	One size fits all	Cup
Moldex	2301N95/2300N95	Small, medium, large	Cup
Moldex	2701N95/2700N95	Small, medium, large	Cup
MSA	Affinity plus	Small/medium, medium/large	Cup
MSA	Affinity ultra	Small, medium, large	Cup
North	7175N95	One size fits all	Cup
Survivair	1930	Small, medium, large	Folding
US safety	ADN95	One size fits all	Cup
Willson	1410N95	One size fits all	Cup
Willson	N9510F	Small, medium, large	Folding
Willson	N9520F	Small, medium, large	Folding

Respirators available in multiple sizes did not have instructions describing how to choose the appropriate size. Therefore, test subjects were given a respirator based on their face and lip length measurements (Table III). The respirator sizes for the corresponding face and lip length are based on recommendations by the Los Alamos National Laboratory.[9] All fit-testing was conducted in accordance with the protocol contained in the OSHA respiratory protection standard including performing a user-seal check in accordance with the manufacturers' instructions.[4] Table IV provides an overview of the fit-testing methods used in this study. The Ambient Aerosol Condensation Nuclei Counter method was chosen because it is widely used for fit-testing, and a previous study demonstrated that the fit factors obtained from this instrument during simulated healthcare workplace tests were correlated with a measure of actual exposure.[5]

Although N-series respirators are for use only in workplaces free of oil aerosols, a generated aerosol method using corn oil

TABLE II
Summary of mean filter penetration in percent by model

Model	Fit-test method		
	PortaCount Plus	Generated aerosol	Companion
Willson 1410N95	1.16	0.19	0.02
3M 1860/1860S	0.28	0.07	0.02
Survivair 1930	0.36	0.14	0.01
Moldex 2200N95/ 2201N95	0.35	0.09	0.01
Moldex 2207N95	0.90	NE[A]	0.01
Moldex 2300N95/ 2301N95	0.36	NE[A]	0.01
Moldex 2700N95/ 2701N95	0.48	NE[A]	0.03
Gerson 2737	1.43	0.94	0.07
North 7175N95	0.58	0.31	0.02
3M 8110S/8210	0.29	0.08	0.02
3M 8212	0.16	NE[A]	0.01
3M 8512	0.18	NE[A]	0.01
U.S. safety ADN95	0.24	NE[A]	0.01
Willson N9510F	0.25	NE[A]	0.01
Willson N9520F	0.36	NE[A]	0.02
AearoSafety pleats	0.34	0.38	0.20
MSA affinity plus	0.11	0.06	0.01
MSA affinity ultra	0.04	0.01	0.01

[A]NE—The generated aerosol method was not evaluated using this model.

was used in this study because R- and P-series respirators have similar designs to the N-series and can be fit-tested using this method. Using only N-series respirators eliminated the need to have different respirator types, which would have introduced more variability in this study. Since fit-testing durations were brief (approximately 10 minutes), it was assumed that filter performance would be decreased only slightly and would be corrected for by measuring filter penetration of the generated aerosol immediately after each fit-test. The flush probe low flow generated aerosol method using corn oil was used in this study because it was a common facepiece sampling procedure used in the United States and was used during some workplace protection factor studies.[10–14]

TABLE III
Summary of respirator size selection based on subject facial dimensions

Face length range (mm)	Lip length range (mm)	Respirator size
93.5 to 103.5	34.5 to 52.5	Small
103.5 to 113.5	34.5 to 43.5	Small
103.5 to 113.5	43.5 to 52.5	Medium
113.5 to 123.5	34.5 to 52.5	Medium
113.5 to 123.5	52.5 to 61.5	Large
123.5 to 133.5	43.5 to 61.5	Large
103.5 to 113.5	52.5 to 61.5	Medium/large
113.5 to 133.5	34.5 to 61.5	Medium/large
93.5 to 113.5	34.5 to 52.5	Small/medium
103.5 to 113.5	43.5 to 61.5	Regular
113.5 to 133.5	34.5 to 61.5	Regular

TABLE IV
Summary of the five fit-testing methods and variations evaluated

Fit-test method	Test type	Included in 1910.134
1. Bitrex fit-test	Qualitative	Yes
2. Saccharin fit-test	Qualitative	Yes
3. Ambient aerosol fit-test		
3.1 Ambient aerosol fit-test corrected using total filter penetration	Quantitative	Yes
3.2 Ambient aerosol fit-test (uncorrected for filter penetration)	Quantitative	No
4. Ambient aerosol fit-test with the N95-Companion	Quantitative	No
5. Generated aerosol fit-test	Quantitative	Yes

For the quantitative fit-tests, subjects performed the following eight exercises: normal breathing, deep breathing, moving head side-to-side, moving head up and down, reading the rainbow passage aloud, grimacing, bending, and normal breathing. The same exercises were used for the qualitative tests, with the exceptions that grimacing was omitted and jogging-in-place replaced bending. The in-facepiece sampling for each exercise lasted one minute, except for grimacing, which lasted 15 seconds.

Before each fit-test, a subject donned a respirator per the respirator manufacturer's instructions. Once a subject believed that the respirator was donned properly, fit-testing began. After each fit-test, the subject removed the respirator and gave it to the test operator. The test operator returned the respirator to its original configuration (e.g., loosening head straps, straightening the nose-clip) and gave it back to the subject for re-donning. Subjects performed the fit-tests in random order, and there was a waiting period of at least 15 minutes between the end of one qualitative fit-test and the beginning of the other. This waiting period allowed the subjects to clear the taste of the first qualitative fit-test agent from their mouths before performing the next qualitative test.

Bitrex (Denatonium Benzoate) Solution Aerosol Fit-Test

The Bitrex test uses a person's ability to taste a bitter solution to determine whether a respirator fits properly. Each subject

was given a taste-threshold screening test to ensure that he or she could taste Bitrex. An Allegro Industries Bitrex Qualitative Respirator Fit-Test Kit, part number 2041 (Allegro Industries, Paramount, CA), was used for Bitrex screening and fit-testing. A screening test involved placing a hood approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall over a subject's head. A taste-screening aerosol (13.5 g Bitrex in 100 ml of a 5% salt solution in water) was generated in the hood using a nebulizer. All 33 subjects reported tasting Bitrex during each screening test before 10 squeezes were applied.

After a screening test, a subject left the laboratory, drank water, and rinsed his or her lips and mouth. This helped to clear the taste of the taste-screening aerosol from the mouth and eliminated the possibility of erroneous results if the subject reported the after-taste of the taste-screening aerosol as face-seal leakage during the fit-test. Then, the subject returned to the laboratory and the Bitrex fit-test was conducted. The test subject donned the respirator per the respirator manufacturer's instructions, and a test hood was placed over the subject's head. The subject was instructed to breathe only through a slightly opened mouth with the tongue extended and to report immediately if Bitrex was tasted. A fit-test aerosol consisting of 338.2 g Bitrex in 200 ml of water (12.5 times the screening concentration) was sprayed into the hood. The Bitrex concentration in the hood was replenished every 30 seconds. If the person did not taste Bitrex, the test was considered to have been passed. If a subject tasted Bitrex at any time, the test was considered to be a failure and was stopped.

Saccharin Solution Aerosol Fit-Test

The saccharin test uses a person's ability to taste a sweet solution to determine whether a respirator fits properly. As with the Bitrex test, test subjects were given a taste-threshold screening test to ensure that they could taste saccharin. A 3M Qualitative Fit-Testing Apparatus, part number FT-10/FT-10S (3M Co., St. Paul, MN), was used for both saccharin screening and the fit-testing. A screening test involved placing a hood approximately 12 inches (30.5 cm) in diameter by 14 inches (35.6 cm) tall over a subject's head. A taste-screening aerosol (0.83 g saccharin USP in 100 ml distilled water) was generated in the hood using a nebulizer. The number of squeezes (10, 20, or 30) required to elicit a response was noted. All 33 subjects reported tasting saccharin.

After a screening test, the subject left the laboratory, drank water, and rinsed his or her lips and mouth. This helped to clear the taste of the taste-screening aerosol from the mouth and eliminated the possibility of erroneous results if the subject reported the after-taste of the taste-screening aerosol as face seal leakage during the fit-test. Then, the subject returned to the laboratory, and the saccharin fit-test was conducted. The test subject donned the respirator per the respirator manufacturer's instructions, and a test hood was placed over the subject's head. The subject was instructed to breathe only through slightly opened mouth with the tongue extended and to report immediately if saccharin was detected. A fit-testing aerosol composed of 83 g saccharin in 100 ml of distilled water (100 times the screening concentration) was sprayed into the hood using the same number of squeezes based on the number of squeezes required to elicit a taste response during the screening taste. The saccharin concentration in the hood was replenished every 30 seconds using half the number of squeezes used initially. If a person did not taste saccharin, the test was considered to have been passed. If a subject tasted saccharin, the test was considered to be a failure and was stopped.

Ambient Aerosol Condensation Nuclei Counter Fit-Test (PortaCount Plus) Method

A TSI PortaCount Plus Model 8020 was used to conduct ambient aerosol fit-tests. The PortaCount Plus uses ambient particles as the challenge agent and counts the number of particles outside and inside a facepiece. The ratio of these two numbers is a fit factor. The PortaCount Plus is based on a miniature, continuous flow condensation nuclei counter, also referred to as a condensation particle counter. A condensation nuclei counter takes particles that are too small to be easily detected, grows them to a larger, more easily detectable size through the use of 2-propanol, and then counts them using a laser photometer.[6]

Ambient Aerosol Condensation Nuclei Counter Fit-Test with the N95-Companion (Companion Method)

TSI developed the N95-Companion accessory to the PortaCount Plus specifically for fit-testing N95 filtering-facepiece respirators. The N95-Companion contains an electrostatic particle classifier. The particle classifier takes advantage of the electrostatic charges on ambient particles to allow only a predetermined particle size range (0.03 to 0.05 μm) to pass through to the PortaCount Plus for counting. It is assumed that the penetration of particles in this size range through N95 filter media is so insignificant that any particles counted are due only to face seal leaks. The PortaCount Plus then compares the number of particles outside the mask to the number inside the mask in this size range. The ratio is a fit factor. In this configuration, the fit factor is obtained directly from the PortaCount Plus.[15] A TSI model 8026 Particle Generator was used to generate a sodium chloride aerosol to ensure that the ambient aerosol contained at least 100 particles/cc in the appropriate size range.

Generated Aerosol Method

The generated aerosol method used a (4 foot [1.2 m] $\times$ 4 foot [1.2 m] $\times$ 7 foot [2.1 m]) laboratory chamber (Dynatech Frontier Corporation, Model 222-6, Albuquerque, NM) in which an air concentration of approximately 16 milligrams per cubic meter of corn oil aerosol was generated. A Dynatech Frontier Model 260 Respirator Fit-Testing System was used to generate the aerosol. The method of detection for the corn oil was a light-scattering photometer (Air Techniques Inc., Model TDA-2GF

aerosol fit-test photometer, Owings Mills, MD), which could determine fit factors to approximately 100,000. An in-facepiece sampling flow rate of 2 L/min was used since this was the flow rate used in the past for the generated aerosol method utilizing a flush probe.[5] The other forms of the generated aerosol method (e.g., exhalation valve discharge, continuous high flow, deep probe) were used primarily in research applications and would be very difficult to adapt to fit-test filtering-facepiece respirators.

Simulated Workplace Protection Factor Testing

The SWPF testing using the PortaCount Plus was used to determine whether an acceptable level of protection was obtained. The six-donning, six-exercise SWPF procedure used in this study has been demonstrated, in a simulated healthcare workplace test, to provide fit factors that have a high correlation with a wearer's actual exposure.[5] Before starting an SWPF test, a subject donned the respirator per the respirator manufacturer's instructions including performing a user-seal check. After the respirator was donned, SWPF testing began.

An SWPF test consisted of a test subject performing the following six exercises for one minute each: 1) normal breathing, 2) deep breathing, 3) moving head side to side, 4) moving head up and down, 5) reading the rainbow passage out loud, and 6) normal breathing.[5] An overall SWPF factor was obtained. An SWPF is a measure of the protection received from a respirator and includes both filter penetration and face-seal leakage. After completing the first test, a subject removed the respirator and gave it to the test operator. The test operator returned the respirator to its original configuration (e.g., loosening head straps, flattening nosepiece). The subject then donned and user-seal checked the same respirator again per the manufacturer's instructions. A second test, identical to the first, was conducted. This procedure was repeated four additional times for a total of six SWPF tests for each subject and respirator combination.

The six SWPF tests for each subject and respirator combination were used to calculate the 5th percentile SWPF value (the value at which 95% of the SWPFs will be greater than or equal to this number) for each respirator model and subject combination. The 5th percentile was calculated using the geometric mean (GM) and the geometric standard deviation (GSD) as $GM/GSD^{1.645}$.[12]

This is a different protocol than the one-donning eight-exercise OSHA fit-testing protocol described in the previous section even though both protocols use the TSI PortaCount Plus. In addition, the required values for determining a poorly performing respirator from a properly performing one are different. For the PortaCount Plus method, the fit factors reported by the PortaCount Plus were adjusted to correct for any filter penetration. The target value for a properly performing respirator was a fit factor of 100. For the simulated workplace protection factor protocol, the fit-factors reported by the PortaCount Plus were not corrected for filter penetration. They were used as total protection factors (consisting of both filter penetration and face-seal leakage). The required value for this protocol was 10.

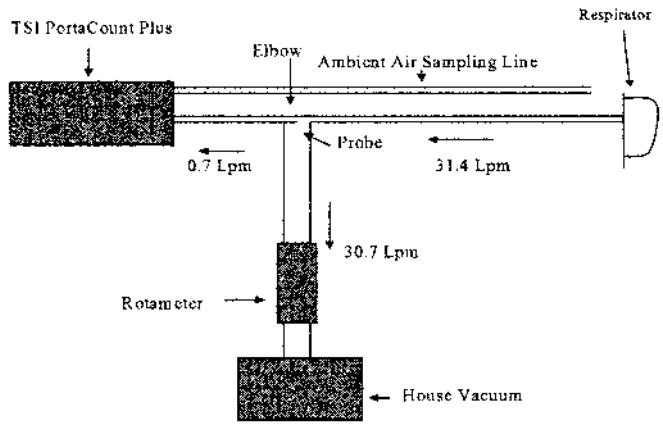

FIGURE 1
Filter penetration measurement system schematic.

Adjusting for Filter Penetration

A fit factor is a measure of face-seal leakage only. It has been demonstrated that ambient particles can have significant penetration (greater than 0.03%) through N95 filter media.[16] The fit factors reported by the PortaCount Plus by itself, therefore, were not "true" fit factors (a measure of the face-seal leakage only) but were total protection factors (a measure of face-seal leakage and filter penetration). Thus, filter penetration needed to be measured in order to convert the total penetration to face-seal leakage.

To simulate the filter penetration through a complete respirator while being worn during a fit-test, the respirator was sealed to a flat plate that was connected to a flowmeter (Cole-Parmer Instrument Company, Model 32461-00, Vernon Hills, IL) and house vacuum. The PortaCount Plus was connected to the system as shown in Figure 1. The flow rate of the PortaCount is 0.7 L/min.[6] An additional 30.7 L/min was pulled through the respirator for a total of 31.4 L/min, which was estimated to be an appropriate flow rate for a person performing a fit-test.[16] The penetration obtained through the whole respirator was then subtracted from the total penetration factors obtained with the PortaCount Plus. Using the same procedure, filter penetration was also determined for the generated aerosol and the Companion methods. The purpose of conducting the filter penetration with the Companion method was to determine if the aerosol sizes that the N95-Companion let through to the PortaCount Plus did not significantly penetrate N95 filter media.

STATISTICAL ANALYSIS

Alpha and Beta Errors

To determine if a fit-test adequately screened out poorly fitting N95 filtering-facepiece respirators, a statistical approach similar to that used in biomedical applications was used.[17–19] A respirator providing adequate protection was defined as one having a 5th percentile SWPF value ≥ 10.[1–3] A two-by-two contingency table was constructed for each fit-test method

TABLE V
Parameters of two-by-two contingency table

	5th percentile of simulated workplace protection factor	
Fit-test result	<10	≥10
Pass	A (# of false passes)	B (# of true passes)
Fail	C (# of true failures)	D (# of false failures)

(Table V) using the fit-test method results and the 5th percentile SWPFs calculated for each subject and respirator combination. From these tables, alpha (α) and beta (β) errors for each method were computed. The α error, commonly called a false positive, is the fraction of subjects having a respirator that provided adequate protection (as defined by the 5th percentile SWPF) but failed the fit-test (i.e., a false inadequate protection conclusion). The β error, commonly called a false negative, is the fraction of subjects having a respirator that provided inadequate protection but passed the fit-test (i.e., a false adequate protection conclusion). A respirator's β error is more important than its α error because it may lead to overexposure of a respirator wearer. However, the α error is still important because of the burden it places on respirator users and programs. A high α error results in the unnecessary retesting of wearers who already have an adequately fitting respirator. The accuracy goals were 0.50 for the alpha error and 0.05 for the beta.[20]

Assignment Error

The assignment error, the percentage of respirator wearers mistakenly assigned an ill-fitting respirator, was calculated using the model developed by Campbell et al.[21] The assignment error was based on the alpha and beta errors computed for each method and a "fit-testing program" in which a wearer was given two tries to pass a fit-test before moving on to another respirator model.

RESULTS

Table VI contains the protection results based on the 2-by-2 contingency table analysis for the five fit-testing methods. The Bitrex method failed to meet the targets for both types of error. However, the α error was only a percentage point (51%) higher than the goal. The Bitrex method had the highest β error at 11 percent.

The ambient aerosol method met the goals for the β error. However, its α error was 75 percent. Only the generated aerosol method had a higher α error. The ambient aerosol method using the N95-Companion also failed to meet the statistical goals. Its α error was 57 percent, and its β error was 9 percent.

The generated aerosol method met the β error accuracy goal and had the lowest β error. In contrast, it had the highest α error (84%). The saccharin method did not meet the statistical goals. Its α error (56%) was the second closest to the accuracy goal, and its β error was the second highest at 9 percent. The saccharin and ambient aerosol with the Companion methods had almost identical values.

The assignment errors for the methods were: Bitrex—8.99 percent, generated aerosol—6.59 percent, ambient aerosol—5.92 percent, Companion—8.21 percent, and saccharin—8.09 percent. Although the generated aerosol test had the lowest β error, it did not give the lowest assignment error. Its high α error off-set the low β error.

DISCUSSION

Of the five methods tested, the generated aerosol method was perhaps the best in identifying respirators that fit poorly. Using the 5th percentile, it met the test criteria for the β error. The α and β errors were 84 percent and 3 percent, respectively. This means that in the generated aerosol tests, 97 percent of the subjects failed the fit-test with an SWPF <10 (true inadequate conclusion) and in only 16 percent of the subjects passed the fit-test with an SWPF ≥10 (true adequate conclusion). High α errors create an economic burden (i.e., fit-tests have to be repeated even though a respirator would have likely provided adequate protection).

The Bitrex method had a β error of 11 percent, which is slightly higher than the β error found in a previous study (9%).[22] In the current study, a true inadequate protection conclusion was reached in 89 percent of the tests, while in the previous study it was 91 percent. The false inadequate protection conclusion rate decreased from the 53 percent found in the previous

TABLE VI
Summary of results used in two-by-two contingency tables

Method	Number of false passes (A)	Number of true passes (B)	Number of true failures (C)	Number of false failures (D)	α error (%) (D/[B + D])	β error (%) (A/[A + C])
Accuracy goal	—	—	—	—	≤50	≤5
Bitrex	21	134	177	142	51	11
Generated aerosol	2	28	73	147	84	3
Ambient aerosol	7	69	191	207	75	4
Companion	17	120	181	156	57	9
Saccharin	11	44	112	57	56	9

study to 51 percent in the current study. The reasons for these discrepancies may be attributable to differences between study protocols and different respirators being used during the studies.

The α and β errors were computed for each respirator model for the three methods with the highest overall errors: the Companion, Bitrex, and saccharin. The errors for all three methods varied widely between the models. For the Companion method, the α errors ranged from 33 percent to 100 percent with two models having an α error of 100 percent, meaning for these models, no subjects with SWPFs >10 passed the fit-test. Having an α error of 100 percent means that all the failures were false negatives, yet some had 5th percentile SWPF values greater than 10. The Companion β errors ranged from 0 percent to 35 percent. Five models had a β of 0 percent, which means that there were no false positives (i.e., all poor-fitting respirators were correctly identified) while one model had a false positive rate of 18 percent.

The results for the Bitrex and saccharin methods were similar. These data suggest that fit-testing errors are model dependent. Since the error rates will always depend upon the underlying distribution of SWPF values, it is not surprising to see the variation from model to model; each model has a different underlying distribution of SWPF values. However, much of the variation between models is likely due to the small number of trials with each model (i.e., small numbers in the contingency tables). More research into this issue is needed.

The assignment errors provide another means of comparing the efficacy of the various fit-test methods. The assignment errors between the two qualitative fit-test methods were fairly comparable. Two of the quantitative fit-test methods (generated and ambient aerosol) had comparable assignment errors, which were at least 1.5 percent lower than those for the qualitative methods. However, the Companion method had an assignment error in the range of the qualitative methods. Further research is needed to determine why the assignment error for the Companion method is higher than those for the other quantitative methods.

The pass/fail level in a fit-test of any half-mask respirator is set at a fit factor of 100 ($10\times$ the APF). Traditionally, in a qualitative fit-test, the subject (without the respirator) is first exposed to a "taste threshold screening" concentration of the test agent that is 1 percent of that to be used in the fit-test. The 100-to-1 ratio between the two concentrations is what assures a fit factor of 100. However, the Bitrex fit-test employs only a 12.5-to-1 ratio of the two concentrations (in accordance with the OSHA regulation) indicating that passing the Bitrex fit-test only assures a fit factor of 12.5 rather than 100.[4] It is unknown whether this affected the results of this study. In a recent study, only 23 percent of the subjects wearing a full facepiece with a leaking exhalation were able to identify the taste of Bitrex.[23] A study is currently underway to determine the effect of the 12.5-to-1 ratio on the results of the Bitrex test as well as a subject's ability to detect Bitrex.

CONCLUSIONS

None of the five fit-testing methods met the criteria for determining whether a fit-test adequately screened out poorly fitting respirators. The generated aerosol method had the lowest β error (i.e., correctly identifying a poor-fitting respirator). The ambient aerosol method using the PortaCount Plus had a similar value of 4 percent but a lower assignment error of 5.92 percent. When all three factors are considered (alpha, beta, and assignment error), the ambient aerosol method using the PortaCount is perhaps the best method for identifying poorly fitting respirators.

The accuracy of fit-testing methods and the fitting characteristics of filtering-facepiece respirators need to be improved. Further research is needed to lower the percentage of subjects failing a fit-test while achieving an acceptable simulated workplace protection factor. This would decrease the economic burden of conducting fit-testing by lowering the number of repeat fit-tests.

DISCLAIMER

Mention of commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health or West Virginia University.

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