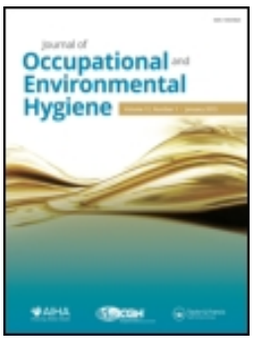

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Inward leakage variability between respirator fit test panels – Part II. Probabilistic approach

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ABSTRACT

This study aimed to quantify the variability between different anthropometric panels in determining the inward leakage (IL) of N95 filtering facepiece respirators (FFRs) and elastomeric half-mask respirators (EHRs).

We enrolled 144 experienced and non-experienced users as subjects in this study. Each subject was assigned five randomly selected FFRs and five EHRs, and performed quantitative fit tests to measure IL. Based on the NIOSH bivariate fit test panel, we randomly sampled 10,000 pairs of anthropometric 35 and 25 member panels without replacement from the 144 study subjects. For each pair of the sampled panels, a Chi-Square test was used to test the hypothesis that the passing rates for the two panels were not different. The probability of passing the IL test for each respirator was also determined from the 20,000 panels and by using binomial calculation. We also randomly sampled 500,000 panels with replacement to estimate the coefficient of variation (CV) for inter-panel variability.

For both 35 and 25 member panels, the probability that passing rates were not significantly different between two randomly sampled pairs of panels was higher than 95% for all respirators. All efficient (passing rate $\geq$80%) and inefficient (passing rate $\leq$60%) respirators yielded consistent results (probability $>$90%) for two randomly sampled panels. Somewhat efficient respirators (passing rate between 60% and 80%) yielded inconsistent results. The passing probabilities and error rates were found to be significantly different between the simulation and binomial calculation. The CV for the 35-member panel was 16.7%, which was slightly lower than that for the 25-member panel (19.8%).

Our results suggested that IL inter-panel variability exists, but is relatively small. The variability may be affected by passing level and passing rate. Facial dimension-based fit test panel stratification was also found to have significant impact on inter-panel variability, i.e., it can reduce alpha and beta errors, and inter-panel variability.

KEYWORDS
Fit test; inter-panel variability; respirator fit test panels; respirators

Introduction

A respirator fit test is a test protocol conducted to assess if a respirator is both comfortable and correctly fits its user.[1] As the sole agency responsible for approving respirators, the U.S. National Institute for Occupational Safety and Health (NIOSH) proposed new certification requirements for fit evaluation of half-mask air-purifying particulate respirators.[2] Several studies have compared different fit test methods and evaluated fit associated characteristics.[3–6] NIOSH has initiated a study to develop an up-to-date representative head and face anthropometric database, and defined two new fit test panels, including the NIOSH bivariate panel which is based on face width and length and Principal Component Analysis (PCA) panel which is based on the first two principal components calculated from facial dimensions.[7–9] Zhuang et al. proposed 25 subjects for either the bivariate or the PCA panel for certification test of respirators.[8] The Notice of Proposed Rulemaking (NPRM) proposed to use a 35-member panel for testing respirators that were intended to fit the general population.[2] Landsittel et al. found that a sample size of 35–40 yields acceptable error rates under different null and alternative hypotheses.[10] However, commenters had concerns about the variability when using this panel.

The most commonly recognized variability in fit testing includes the inter- and intra-subject variability.[11]

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NIOSH has developed respirator fit test panels to select representative subjects for IL test to address the inter-subject variability. Multiple donnings are used to address intra-subject variability. Inter-panel variability means differences in IL test results between two respirator fit test panels at two locations or even the same location. The inter-panel variability needs to be determined to adequately address the comments expressed by the stakeholders about the variability inherent in the test panel proposed by NIOSH for the IL test.

Inter-panel variability can be measured using several parameters in IL tests, including passing rates, passing or failing a respirator, coefficient of variation (CV), etc. These parameters can be well evaluated using resampling techniques, such as bootstrapping.[12] This study aimed to determine the variability between different anthropometric panels used to determine the IL of N95 filtering facepiece respirators (FFRs) and elastomeric half-mask respirators (EHRs) using probabilistic approaches in addition to the deterministic approach (e.g., comparing geometric mean IL values for three specific subject panels) used in Part I of this work.[13] We evaluated: (1) the probability that passing rates were not significantly different between two panels; (2) probabilities that a respirator passed the IL test (e.g., at least 26 subjects passing the IL test) in both panels, passed in either panel, and failed in both panels; (3) probabilities that a respirator would pass the IL test estimated by both binomial distribution and simulation; (4) the CV for inter-panel variability; and (5) the impact of sample size on the above estimates using 25- and 35-member panels.

Methods

Study subjects

For this study, we recruited a total of 144 subjects. Sixty-two of the subjects had previously participated in fit testing for other NIOSH-approved protocols or certification testing and had been medically cleared for fit testing. All other study candidates completed a health history questionnaire and were medically cleared to conduct fit tests, with exclusion criteria including a history of uncontrolled chronic asthma, pneumonia, and high blood pressure. All study candidates who chose to participate signed a consent form. Head and face anthropometric measurements were performed for each candidate to check if he/she would fall within the NIOSH bivariate respirator fit test panel.[8] Distribution of the study subjects, by the bivariate panel cell, is shown in Table 1.

Table 1. Number of all study subjects, 35- and 25-member panel subjects by NIOSH bivariate panel cell.

Bivariate panel cell	Number of all study subjects	Number of subjects for a 35-member panel	Number of subjects for a 25-member panel
1	12	2	2
2	12	2	2
3	12	4	2
4	27	9	5
5	12	2	2
6	12	2	2
7	21	7	4
8	12	3	2
9	12	2	2
10	12	2	2
Total	144	35	25

Respirators

We randomly selected five N95 FFRs and five N95 EHRs models from among those previously tested in our laboratory. The FFRs included 3M 1860/1860S (cup-shaped, TC-84A-0006, 3M Company, St. Paul, MN), Gerson 1730 (cup-shaped, TC-84A-0160, Louis M. Gerson Co., Inc, Middleboro, MA), Kimberly Clark Tecnol PFR95 (flat, TC-84A-0299, Kimberly Clark, Roswell, GA), Willson N9510F (flat, TC-84A-1165, Willson, Santa Ana, CA), and Sperian HCNB295F (flat fold, TC-84A-4371, Sperian Respiratory Protection USA, LLC, Santa Ana, CA), while the EHRs included MSA Comfo with 816291 filters (TC-84A-1514, Mine Safety Appliances, Cranberry, PA), Moldex 8000 with 8910 N95 filter (TC-84A-1343, Moldex-Metric, Inc, Culver City, CA), Sperian Respiratory Protection USA, LLC Premier Plus T-Series with 1060N95 filter (TC-84A-1426), 3M 7500 with 5N11 filter (TC-84A-0376) and North Safety Products 7700 with 7506N95 filters (TC-84A-1099, North Safety Products, Cranston, RI).

The five FFRs were randomly assigned labels as FFR-A, FFR-B, FFR-C, FFR-D, and FFR-E; while the five EHRs were randomly assigned labels as EHR-F, EHR-G, EHR-H, EHR-I, and EHR-J. A new FFR was provided to each subject for fit testing. Only one EHR of each size (small, medium, and large) was procured, therefore, they were cleaned and disinfected per the manufacturer's instructions before being used by the next subject.

IL measurement

In this study, IL was measured using a PortaCount Plus Model 8038 (TSI, Inc., Shoreview, MN), which is accepted by the OSHA standard for quantitative fit testing. The PortaCount uses laser technology to quantitatively measure particle concentrations outside and inside the test respirator when worn, and compute their ratio as a fit factor.

Before conducting each test, the subject was asked to understand the manufacturer's selection, donning and fitting procedures for the tested respirator, and then perform a user seal check in accordance with the manufacturer's user instructions. Since we did not aim

to test the respirator fit or performance, any subject who was unable to successfully perform the user seal check was allowed to continue the fit testing. Each respirator was probed to measure concentrations inside it using a probe insertion tool. For FFRs, the commonly used sampling probe position is flush with the inside of the facepiece at the point of quadrilateral symmetry of the mouth and nose. We used an appropriate test adapter for testing EHRs.

Each subject wore the respirator for approximately five minutes before beginning the test. We used OSHA standard fit test exercises for fit testing.[14] Each individual IL was measured for 60 sec for each test subject while performing the following sequence of exercises: normal breathing, deep breathing, breathing while moving their head from side to side, breathing while moving their head up and down, reciting the rainbow passage, reaching floor to ceiling, grimacing (not included in calculations), and normal breathing. Once the subject finished the eight exercises, the PortaCount gave an overall fit factor based on results of the above eight exercises. IL was then obtained by calculating the reciprocal of the overall fit factor.

Each subject tested each of the 10 respirators in random order. Each respirator/subject combination was tested in duplicate for IL measurement, resulting in 20 IL measurements for each subject. After each fit test, the test subject removed the respirator and returned it to the test operator. The test operator returned the head straps and/or noseband to their original condition, and did not inform the subject of the results. The subject rested for two minutes and repeated the IL measurement.

Statistical analysis

We studied the inter-panel variability for both 35- and 25-member panels. Stratified by bivariate fit test panel cell, random sampling without replacement was conducted using the 144 study subjects to generate 10,000 pairs of both 35- and 25-member panels. The reason we considered two panels at a time was that in the real world, manufacturers test a respirator on a panel and a certification body tests the same respirator using another different panel to verify manufacturers' data. Required number of subjects for each panel by the bivariate panel cell is shown in Table 1. For a 35-member panel, two subjects were needed for cells 1, 2, 5, 6, 9, and 10, while cells 3, 4, 7, and 8 included four, nine, seven, and three subjects, respectively. For a 25-member panel, four and five subjects were need for cells 7 and 4, respectively, while two subjects were need for all other cells.

A subject was considered to pass the IL test if one of the two IL values was less than, or equal to, a given passing level criterion (including IL≤1%, IL≤2%, and IL≤5%). Passing rate for each respirator was calculated as the percentage of subjects who passed the IL test. As in another study to determine sample size for respirator fit test panel,[10] we considered respirators with passing rate of 80% or higher as efficient, 60% or less as inefficient, between 60% and 80% as somewhat efficient. For the 35-member panel, a respirator was considered to pass the IL test if 26 or more subjects passed the IL test (passing rate equal to or greater than 74.3%); for the 25-member panel, a respirator was considered to pass the IL test if 19 or more subject passed the IL test (passing rate equal to or greater than 76.0%), as reported by Landsittel et al.[10] These criteria could be used in possible future respirator standards.

For each pair of the sampled panels, a Chi-Square test was used to test the hypothesis that the passing rates for the two panels for each respirator were not different. We then calculated the probability that passing rate was not significantly different between the two panels for each respirator for three passing levels (IL≤1%, IL≤2%, and IL≤5%). This probability was calculated as the numbers of pairs that were not significantly different based on the Chi-square tests divided by 10,000. We also computed the probability that each respirator passed in both panels, passed in either panel, and failed in both panels. The probability of passing the IL test for each respirator was also determined from the 20,000 panels. The probability of passing the IL test was also estimated using the binomial distribution described by Landsittel et al.[10] Type I & Type II errors were then estimated for both the simulation and binomial calculation. Type II or Alpha error is the probability of rejecting effective respirators (1 – probability of passing effective respirators). Type I or beta error is the probability of passing ineffective respirators. The passing probabilities and error rates from the two approaches were then compared to see if fit test panel based simulation is an improvement from the calculation using binomial distribution.

The inter-panel variability was also measured as CV of the IL. We first conducted random sampling with replacement to generate 500,000 35- and 25-member panels. With only 144 subjects, each of the 500,000 panels had to be selected with replacement. Due to the log-normal distribution of IL, we log-transformed IL as commonly done in other studies,[3–6] and calculated the mean log IL for each panel, and then calculated standardized deviation (SD) of the mean log IL for the 500,000 35- and 25-member panels, respectively. The CV was calculated by using the SD of the log IL in the following equation:[15]

$$\mathrm{CV} = \sqrt{e^{SD^2} - 1}. \quad (1)$$

The inter-panel variability of 35- and 25-member panels were finally compared using the calculated CV. All analyses were conducted using SAS version 9.3 (SAS Institute Inc., Cary, NC).

Table 2. Passing rates for the study subjects by passing level and respirator.

	All subjects (N = 144)			35-member panel subjects (N = 20,000)			25-member panel subjects (N = 20,000)		
Respirator	IL ≤1%	IL ≤2%	IL ≤5%	IL ≤1%	IL ≤2%	IL ≤5%	IL ≤1%	IL ≤2%	IL ≤5%
FFR-A	45.8%[b]	75.7%	90.3%[a]	44.5%	74.8%	88.8%	45.1%	75.1%	89.9%
FFR-B	5.6%[#]	27.1%[b]	54.9%[b]	4.8%	26.6%	54.1%	5.5%	26.8%	54.8%
FFR-C	13.2%[b]	34.0%[b]	69.4%	12.6%	33.1%	69.3%	13.0%	33.7%	69.3%
FFR-D	31.3%[b]	67.4%	88.2%[a]	31.4%	66.2%	88.3%	31.1%	67.2%	88.2%
FFR-E	11.8%[b]	29.9%[b]	59.7%[b]	12.1%	29.5%	60.8%	11.6%	29.7%	9.8%
EHR-F	86.8%[a]	97.2%[a]	98.6%[a]	85.8%	96.2%	98.1%	86.5%	97.0%	98.5%
EHR-G	34.7%[b]	73.6%	95.1%[a]	32.8%	72.1%	95.2%	34.1%	73.3%	95.1%
EHR-H	42.4%[b]	66.7%	94.4%[a]	41.0%	65.2%	93.3%	41.7%	66.2%	94.2%
EHR-I	36.8%[b]	77.8%	97.2%[a]	36.4%	77.9%	97.4%	36.4%	77.7%	97.3%
EHR-J	61.1%	84.0%[a]	94.4%[a]	60.0%	83.8%	95.7%	60.9%	84.2%	94.7%

[a] indicates efficient respirators.
[b] indicates inefficient respirators.

Results

Passing rates for the 144 study subjects were calculated by ten respirators and three passing levels (IL≤1%, IL≤2%, and IL≤5%), as shown in Table 2. For passing level of IL≤1%, EHR-F had the highest passing rate (86.8%), while FFR-A, FFR-B, FFR-C, FFR-D, FFR-E, EHR-G, EHR-H, and EHR-I all had lower passing rates (≤61.1%). For a passing level of IL≤2%, EHR-F, as well as EHR-J, could be considered as efficient respirators, while only FFR-B, FFR-C, and FFR-E were considered as inefficient respirators. For a passing level of IL≤5%, FFR-A, FFR-D, and EHR-F to J could be considered as efficient respirators, while FFR-B and FFR-E were inefficient respirators. As shown in Table 2, mean passing rates of the 10,000 pairs of sampled subjects for 35- and 25-member panel yielded very similar results compared to that of the 144 study subjects, for passing levels of IL≤1%, IL≤2%, or IL≤5%.

Table 3 shows the probability that passing rates were not significantly different between two 35-member fit test panels by passing levels. The probability of passing for EHR-F reached 100% with IL≤5% for both 35- and 25-member panels, indicating no inter-panel variability. For the 35-member panel, the probabilities for all respirators were high, ranging from 97.1–98.9%, 97.7–99.6%, and 97.7–100.0% for passing levels of 1%, 2%, and 5%, respectively; for the 25-member panel, the probabilities for all respirators also were similar, ranging from 96.2–98.8%, 96.4–99.9%, and 96.2–100.0% for passing levels of 1%, 2%, and 5%, respectively. These results showed no significant inter-panel variability in passing rates for both 35- and 25-member panels.

Table 3. Probability that passing rates were not significantly different between two 35-member panels and two 25-member panels by passing levels.

	35-member panel			25-member panel		
	Passing Level					
Respirator	IL ≤1%	IL ≤2%	IL ≤5%	IL ≤1%	IL ≤2%	IL ≤5%
FFR-A	98.7%	98.3%	97.8%	96.5%	96.7%	97.1%
FFR-B	98.6%	98.3%	98.4%	98.8%	96.7%	96.2%
FFR-C	97.1%	97.7%	97.7%	96.3%	96.8%	97.1%
FFR-D	97.5%	98.1%	97.8%	96.3%	97.3%	97.4%
FFR-E	97.5%	97.8%	97.8%	96.4%	96.6%	96.6%
EHR-F	97.7%	99.6%	100.0%	96.7%	99.9%	100.0%
EHR-G	97.9%	97.8%	98.3%	96.7%	96.5%	99.1%
EHR-H	98.9%	98.2%	97.9%	96.9%	97.2%	98.4%
EHR-I	98.2%	98.7%	99.8%	96.9%	97.6%	99.9%
EHR-J	97.7%	97.7%	98.5%	96.2%	96.4%	98.7%

Table 4 gives the probability that a respirator passed in both 35-member panels, passed in either panel, or failed in both panels for each passing level. Probability of 100% for both passed or both failed means no inter-panel variability. For the passing level of IL≤1%, all 10 respirators had high probability that passing/failing a respirator was the same for the two 35-subject test panels. The only efficient respirator (EHR-F) passed both panels as high as 98.8% of the time, while 1.2% of the time, one panel passed and the other panel failed the respirator. The eight inefficient respirators failed both panels 100% of the time. EHR-J passed both panels 0.1% of the time, but failed both panels 93.1% of the time, and passed only one panel 6.8% of the time. These results indicated little inter-panel variability for a passing level of IL≤1%.

For the passing level of IL≤2%, the only two efficient respirators EHR-F and EHR-J passed the IL test for both panels 100% and 95.5% of the time, respectively, while all inefficient respirators FFR-B, FFR-C, and FFR-E failed the IL test for both panels 100% of the time, indicating little inter-panel variability. The other five somewhat efficient respirators passed one panel and failed the other panel a high percentage of the time, indicating some inter-panel variability.

For the passing level of IL≤5%, the seven efficient respirators FFR-A, FFR-D, EHR-F, EHR-G, EHR-H, EHR-I, and EHR-J passed the IL test for both panels nearly 100% of the time, while the two inefficient respirators

Table 4. Probability that a respirator passed in both panels, passed in either panel, and failed in both panels by passing levels, 35-member panel.

	IL ≤1%			IL ≤2%			IL ≤5%		
Respirator	Both passed	Both failed	One passed and one failed	Both passed	Both failed	One passed and one failed	Both passed	Both failed	One passed and one failed
FFR-A		100.0%		40.9%	13.5%	45.6%	100.0%		
FFR-B		100.0%			100.0%			99.4%	0.6%
FFR-C		100.0%			100.0%		8.6%	48.9%	42.5%
FFR-D		100.0%		2.5%	70.9%	26.6%	99.9%		0.1%
FFR-E		100.0%			100.0%		0.2%	92.0%	7.8%
EHR-F	98.8%		1.2%	100.0%			100.0%		
EHR-G		100.0%		21.7%	29.2%	49.0%	100.0%		
EHR-H		100.0%		1.6%	76.3%	22.1%	100.0%		
EHR-I		100.0%		66.1%	3.5%	30.4%	100.0%		
EHR-J	0.1%	93.1%	6.8%	95.5%	0.1%	4.5%	100.0%		

Note: Cells without an entry had 0% probability.

FFR-B and FFR-E failed the IL test for both panels 99.4% and 92.0% of the time, respectively, indicating little inter-panel variability. FFR-C passed one panel and failed the other panel 42.5% of the time, indicating some variability.

As shown in Table 5, we compared the probability of at least 26 subjects passing the IL test in a 35-member panel, which were estimated by using the binomial distribution and simulation method. For respirators with passing probability slightly higher than 74.3% (26/35), the simulation method gave higher passing probabilities (i.e., smaller alpha error for the simulation approach as compared to the binomial calculation); while for respirator with passing probability lower than 74.3%, the simulation method yielded slightly lower passing probabilities (i.e., smaller beta error for the simulation approach as compared to the binomial calculation). For example, the alpha error from the simulation was 18.7% (1–81.3%) for Respirator EHR-I at passing level of 2% meeting the acceptable error rate of 20% or less. This was not true for the binomial calculation (alpha error of 23.5%). The beta errors from the simulation were 15.8% and 12.7% for respirator FFR-D and EHR-I at passing level of 2% which were significantly smaller than those from binomial calculation. These results showed that facial dimension based fit test panel stratification had significant impact on inter-panel variability, i.e., it can reduce inter-panel variability.

Table 5. Comparison of probabilities of at least 26 subjects passing the IL test in a 35-member panel, estimated by binomial distribution and simulation.

	Binomial distribution			Simulation		
Respirator	IL ≤1%	IL ≤2%	IL ≤5%	IL ≤1%	IL ≤2%	IL ≤5%
FFR-A	0.1%	66.3%	99.9%		63.7%	100%
FFR-B			1.5%			0.3%
FFR-C			33.6%			29.9%
FFR-D		24.9%	99.4%		15.8%	100%
FFR-E			5.4%			4.1%
EHR-F	98.7%	100%	100%	99.4%	100%	100%
EHR-G		55.2%	100%		46.2%	100%
EHR-H		22.2%	100%		12.7%	100%
EHR-I		76.5%	100%		81.3%	100%
EHR-J	7.4%	95.7%	100%	3.5%	97.8%	100%

Note: Cells without an entry had 0% probability.

The results of the 25-member panel were similar to the 35-member panel which can be seen in Tables 6 and 7. They showed little inter-panel variability for passing levels of IL≤1% and IL≤5%, but suggested some inter-panel variability for the passing level of IL≤2%. However, the FFR-E (IL≤5%), EHR-F (IL≤1%), and EHR-J (IL≤2% and ≤1%) yielded higher variability compared with that for the 35-member panel. The difference in probability of passing the IL test, alpha and beta errors between the simulation and binomial calculation decreased.

Estimates of the inter-panel variability, measured as CV of the IL, are shown in Table 8. The mean CVs for all respirators were 16.7% (ranging from 12.3–19.7%) and 19.8% (ranging from 14.9–23.2%) for the 35- and 25-member panels, respectively. Overall, the mean CV of 25-member panel was 18.6% (ranging from 14.6% for EHR-F to 23.1% for EHR-G) higher than that of the 35-member panel.

Discussion

Our data demonstrate little inter-panel variability of passing rates between two randomly sampled 35- or 25-member panels for all ten study respirators. Little inter-panel variability were found for efficient (passing rate of 80% or higher) and inefficient respirators (passing rate 60% or lower), while some inter-panel variability existed for somewhat efficient respirators (passing rate between 60% and 80%). Respirators with passing rate of 80% or higher were considered effective, 60% or less were ineffective in a previous study.[9] The inter-panel variability for 35-member panel was slightly lower than that for the 25-member panel.

Table 6. Probability that a respirator passed in both panels, passed in either panel, and failed in both panels by passing levels, 25-member panel.

	IL ≤1%			IL ≤2%			IL ≤5%		
Respirator	Both passed	Both failed	One passed and one failed	Both passed	Both failed	One passed and one failed	Both passed	Both failed	One passed and one failed
FFR-A		100.0%		32.0%	18.7%	49.3%	99.4%		0.6%
FFR-B		100.0%			100.0%			97.0%	3.0%
FFR-C		100.0%			100.0%		8.0%	51.2%	40.8%
FFR-D		100.0%		4.0%	62.4%	33.6%	98.3%		1.7%
FFR-E		100.0%			100.0%		0.4%	90.1%	9.5%
EHR-F	94.6%		5.3%	100.0%			100.0%		
EHR-G		100.0%		22.8%	26.9%	50.4%	100.0%		
EHR-H		100.0%		3.1%	67.2%	29.7%	100.0%		
EHR-I		100.0%		50.2%	8.8%	41.0%	100.0%		
EHR-J	0.6%	87.2%	12.3%	86.6%	0.5%	12.9%	100.0%		

Note: Cells without an entry had 0% probability.

Our results were similar to those in Part I using the deterministic approach of this work.[13] In Part I, we found no significant difference in IL or passing rates among three randomly selected 35-member panels for the same ten studied respirators, indicating some but small inter-panel variability. We also found that passing level and passing rate might affect inter-panel variability. Similarly, the results of our analyses suggested that passing levels might affect the inter-panel variability. Based on OSHA requirements 29 CFR 1910.134 (f) (7), the passing level is a minimal fit factor of 100, which is equivalent to IL≤1%. For this passing level, eight of the ten studied respirators failed the IL test with the same probability of 100%, while one of them passed the IL test with a high probability of 98.8%, suggesting little inter-panel variability. For the passing level of IL≤5%, more respirators passed the IL test, and similarly, nine of the ten respirators yielded very consistent results. However, for the passing level of IL≤2%, only five respirators gave consistent IL test results which is not surprising since these models were in the "somewhat effective" category where inter-panel variability is highest.

Table 7. Comparison of probabilities of at least 19 subjects passing the IL test in a 25-member panel, estimated by binomial distribution and simulation.

	Binomial distribution			Simulation		
Respirator	IL ≤1%	IL ≤2%	IL ≤5%	IL ≤1%	IL ≤2%	IL ≤5%
FFR-A	0.2%	59.3%	99.2%		56.7%	99.7%
FFR-B			2.5%			1.5%
FFR-C			31.7%			28.4%
FFR-D		24.5%	97.8%		20.8%	99.2%
FFR-E			6.9%			5.2%
EHR-F	96.1%	100%	100%	97.3%	100%	100%
EHR-G		49.7%	100%		48.0%	100%
EHR-H	0.1%	22.3%	100%		18.0%	100%
EHR-I		68.9%	100%		70.7%	100%
EHR-J	9.0%	90.8%	100%	6.8%	93.1%	100%

Note: Cells without an entry had 0% probability.

We found that passing rates might be another factor that could affect the inter-panel variability. For all three passing levels, respirators with passing rates of ≤60% and ≥80% yielded consistent IL test results (pass/fail), while respirators with passing rates between 60% and 80% passed or failed the IL test with moderate probabilities. This was true for both 35-and 25-member panels. Due to the inter-panel variability for passing rates between 60% and 80%, a respirator that fails an IL test may be considered as a non-efficient respirator, while the same respirator that passes an IL test can be considered as an efficient respirator, making it difficult to make a determination.

Our results suggested that inter-panel variability differed with the number of subjects in the fit test panel. The probability that a respirator passed or failed indicated that the 25 number panel yielded a little more inter-panel variability. This is consistent with the study by Landsittel et al. who reported that requiring at least 26 of 35 subjects to achieve sufficient fit nearly met the pre-specified optimal levels: Type I error rates below 1% or 5% and Type II error rates below 20% or 10% for the different null and alternative hypotheses, but the optimal cutoff of 19 for a 25-member panel yielded a Type II error over 20% for $\theta = 0.80$ and a Type I error of over 5% for $\theta = 0.60$.[10] In addition, the CV of the IL that we calculated using the bootstrap method quantitatively estimated the inter-panel variability, and also suggested that a 25-member panel was expected to yield 18.6% higher inter-panel variability, compared with that of a 35-member panel.

Variability is inherent to fit testing research. Besides the sample size and the passing criterion for respirator IL test, several other factors may contribute to the panel variability. The fitting characteristic of a respirator, such as a natural silicone facepiece vs. a natural rubber facepiece, may result in fit test results with a wide range of geometric standardized deviation.[16] Several studies demonstrated that different fit testing methods were associated with various Type I and Type II errors.[17,18]

Table 8. Inter-panel variability estimated as coefficient of variance.

	35-member panel			25-member panel			
Respirator	SD	Overall Mean Log(IL)	CV	SD	Overall Mean Log(IL)	CV	% increase of CV
FFR-A	0.169	−4.079	17.0%	0.198	−4.090	20.0%	17.5%
FFR-B	0.169	−2.825	17.0%	0.200	−2.830	20.2%	18.7%
FFR-C	0.173	−3.132	17.4%	0.202	−3.153	20.4%	17.1%
FFR-D	0.175	−3.925	17.6%	0.208	−3.917	21.0%	19.2%
FFR-E	0.195	−2.945	19.7%	0.229	−2.918	23.2%	17.9%
EHR-F	0.189	−5.320	19.1%	0.216	−5.352	21.9%	14.6%
EHR-G	0.136	−4.194	13.7%	0.167	−4.210	16.8%	23.1%
EHR-H	0.159	−4.199	16.0%	0.187	−4.220	18.9%	17.9%
EHR-I	0.123	−4.241	12.3%	0.148	−4.247	14.9%	20.5%
EHR-J	0.168	−4.593	16.9%	0.201	−4.607	20.3%	20.0%

SD indicates standardized deviation.
CV indicates coefficient of variation.

Conclusions

Our results suggested that IL inter-panel variability exists, but it is relatively small. A 25-member panel may yield slightly higher inter-panel variability than that of a 35-member panel. The inter-panel variability may be affected by passing level (IL≤1%, IL≤2%, and IL≤5%) and passing rate by causing more or fewer respirators to fall into the somewhat efficient respirator category (≥ 60% and ≤80% pass rate) where inter-panel variability is most pronounced. Respirator manufacturers and end users should have high confidence in the results of respirator fit tests done on a single 35-person panel for respirators that are either efficient (≥ 80% pass rate) or inefficient (≤60% pass rate). Results from a single 25- or 35-person panel for somewhat efficient respirators (≥ 60% and ≤80% pass rate) should be viewed cautiously. Optimization of proper passing rate, passing level and passing criterion (minimal number of subjects required to pass, e.g., 26 of 35, or 23 of 35) can be done to minimize the variability between fit test panels. Facial dimension based fit test panel stratification was also found to have significant impact on inter-panel variability, i.e., it can reduce alpha and beta errors, and inter-panel variability.

Disclaimer

The findings and conclusions in this article are those of the authors and do not necessarily represent the views of the National Institute for Occupational Safety and Health. Mention of commercial product or trade name does not constitute endorsement by the National Institute for Occupational Safety and Health.

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