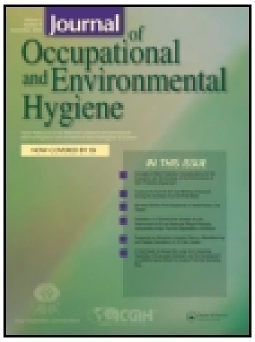

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Variability in Respiratory Protection and the Assigned Protection Factor

Mark Nicas[1] and John Neuhaus[2]

[1]Center for Occupational and Environmental Health, School of Public Health, University of California, Berkeley, California
[2]Department of Biostatistics and Epidemiology, University of California, San Francisco, California

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The workplace protection factor (WPF) for a given respirator wearer shows substantial variability from wearing to wearing; this variability is commonly assumed to be lognormal in nature. Further, when multiple WPFs are measured for each of multiple wearers, the aggregated WPFs appear to follow a lognormal distribution. However, the analysis typically applied to WPF data does not apportion variability within versus between wearers. We present an analytical framework based on a normal random effects model of log-transformed penetration P values (P = 1/WPF). Data from seven studies of negative-pressure air-purifying half-mask respirators, and from two studies of hemlet-and-visor type powered air-purifying respirators were analyzed by the method of maximum likelihood in the context of the model. More specifically, analyses were performed for log-transformed P values and for logit-transformed P values. Parameter estimates included within-wearer and between-wearer variance components. In general, the within-wearer component dominated the between-wearer component. We also propose a method for establishing an assigned protection factor, APF, that properly accounts for these variance components. Our method provides an APF satisfying two criteria: (1) for a given wearer, an acceptable WPF distribution has no more than 5% of WPFs below the APF value; and (2) for a wearer population, no more than 5% of wearers have unacceptable WPF distributions. The method incorporates an one-sided confidence limit to account for sampling variability. Alternative confidence limits were computed based on large sample variance estimates of random effects model parameters versus a bootstrap method. In general, there was good agreement between the APF values based on log-transformed versus logit-transformed P data, and between APF values based on the large sample variance estimates versus the bootstrap method. Based on large sample variance estimates for the logit-transformed P data from the seven half-mask studies, estimated APFs ranged from 1.4 to 250, with 5/7 studies yielding an APF ≤ 5.3. Given these results and related considerations, we recommend that the current half-mask APF be reduced from 10 to 5.

Keywords assigned protection factor, protection factor variability, respiratory protection

Address correspondence to: Mark Nicas, Center for Occupational and Environmental Health, School of Public Health, 771 University Hall, University of California, Berkeley, CA 94720; e-mail: mnicas@uclink4.berkeley.edu.

INTRODUCTION

The protection afforded by a respirator can be measured by the workplace protection factor, WPF, defined as the ratio of the average contaminant concentration measured outside the respirator, C_O, to the average contaminant concentration measured inside the respirator, C_I, while the respirator is worn in the workplace. Strictly, the ratio is considered a WPF only if the wearer has been properly fitted and trained in respirator use. A common observation is that when multiple WPFs are measured for a single respirator wearer, the WPFs vary substantially; this within-wearer variability is assumed to be lognormal in nature. Further, if multiple WPFs are measured for each of multiple wearers, the WPFs aggregated across wearers appear to follow a lognormal distribution. However, the analysis typically applied to WPF data does not quantify the relative degrees of within-wearer and between-wearer variability. Two related aims of this article are to investigate the within/between components of variability in WPF data, and properly account for these components in specifying an assigned protection factor, APF, for a given respirator class. Although most respirator literature uses the WPF variable, it is mathematically preferable to analyze the penetration value P, equal to 1/WPF, because C_I is directly related to P via the relationship: $C_I = C_O \times P$. We use both P and WPF terminology in this discussion. We begin by briefly summarizing past WPF research and efforts to establish APFs.

BACKGROUND

Early Work

In 1976, the National Institute for Occupational Safety and Health (NIOSH) published a Respirator Decision Logic with

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"protection factor" ratings for different classes of respirators.(1) These protection factors would now be termed APFs, and were based on quantitative fit testing studies conducted at Los Alamos National Laboratory in the period 1969–1972.(2) In general, an anthropometrically-selected panel of subjects each wore the different brands of respirator of a given class (e.g., negative-pressure air-purifying half-masks) commercially available at the time, and one quantitative fit test was performed for each subject.

For the same brand of respirator, the fit factor (FF) values typically varied across subjects. If ≥95% of the subjects achieved a FF value greater than or equal to some value X for all respirators in the class, X was equated with the APF for that class. However, FF data were not collected for all respirator classes (e.g., powered air-purifying respirators [PAPRs]), and for the latter APFs were recommended based on analogy to respirator classes that had been tested, and on the professional judgment of the researchers. For negative-pressure air-purifying half-mask respirators for which FFs had been measured, an APF of 10 was recommended; note that most respirator use involves negative-pressure air-purifying half-masks. For PAPRs for which FFs had not been measured, an APF of 1000 was recommended.(2) In the 1970s, no distinction was drawn between WPFs and FFs.

Given the above method of using FF data to derive an APF, the latter was interpreted as the minimum WPF value that would be experienced by 95% of wearers and, in general, a respirator's maximum use concentration was equated with the product of the APF and the applicable occupational exposure limit (OEL). Caveats were attached regarding respirator use in atmospheres considered immediately dangerous to life or health and, if applicable, atmospheres exceeding the use limitations of air-purifying elements.

In the early 1980s, NIOSH investigators began measuring WPFs on wearers of PAPRs due to concerns that inward leakage of contaminant exceeded the amount anticipated given the original APF rating.(3–5) In one study on two brands of loosely-fitting, helmet-and-visor type PAPR devices, the investigators attempted to measure 4 full-shift WPFs for each of 12 subjects.(4) In addition, FFs were measured for the same subjects prior to the shifts during which the WPFs were measured. In general, a subject's WPFs varied considerably and were described by lognormal distribution parameters (the geometric mean, GM, and the geometric standard deviation, GSD). When the 46 WPFs actually obtained were aggregated, they were reasonably described by a two-parameter lognormal distribution. The point estimate of the 5th percentile of the aggregate WPFs was 25, which was far below the APF = 1000 value for these PAPR models at the time; it was suggested that an APF = 25 would be more appropriate for the helmet-and-visor type PAPR. Further, it was found that a subject's FFs tended to be much higher than his/her WPFs, and that no correlation existed between the preshift FF and the subsequent full-shift WPF.

More Recent Work

In 1987, NIOSH revised its Respirator Decision Logic and updated the APF values.(6) APFs were now based on WPF data where available. However, because WPF data existed for only three classes of respirators (negative-pressure air-purifying half-mask respirators, PAPRs equipped with helmet-and-visors, and PAPRs equipped with tightly fitting facepieces), most APFs were based on quantitative fit testing data from the original Los Alamos research project(2) and from a subsequent study conducted in England.(7) For negative-pressure air-purifying half-mask respirators, the APF remained at 10. For helmet-and-visor type PAPRs, the APF was reduced to 25.

Analogous to the operational definition of the original Los Alamos APF (protection factor), the 1987 Decision Logic defined the APF as follows: "The minimum anticipated protection provided by a properly functioning respirator or class of respirators to a given percentage of properly fitted and trained users."(6, p. 29)

The "given percentage" was not specified, but the APF was equated with the point estimate of the 5th percentile of aggregate WPF data that were presumed to be lognormally distributed. Based on this derivation, the Decision Logic contained the following statement: "Thus, for a given set of data and given class of respirators, NIOSH would expect that 95% of the WPFs would exceed the calculated point estimate value."(6, p. 41)

Given the alternative APF descriptions, it is unclear whether the Decision Logic's authors believed that 95% of properly fitted and trained users would have a minimum WPF ≥ APF. However, the fact that 95% of aggregate WPFs in a wearer population exceed some value X (equated with the APF value) does not signify that 95% of wearers have a minimum WPF ≥ X. To explain, if a two-parameter lognormal model adequately described every wearer's WPF distribution, every wearer's minimum WPF would be less than the APF value. Moreover, due to between-wearer differences in the average level of protection, a substantial fraction of wearers could have more than 5% of their WPFs below the APF value, even though 95% of WPFs aggregated across wearers exceeded the APF. This seeming paradox will be illustrated at a later point.

Since the early 1980s, approximately two dozen WPF studies have been conducted, of which half have been published in the peer-reviewed literature.(3–5,8–19) Most studies adhered to the general design and data analysis used in the original NIOSH PAPR studies. That is, multiple respirator wearers were each monitored during one or more respirator use periods of varying duration to determine WPF values. All the WPFs were aggregated, and various sample statistics were computed based on the assumption that WPFs were well described by a two-parameter lognormal distribution. Quantifying the relative degrees of within- and between-wearer variability was not pursued. Special interest focused on the 5th percentile value of the aggregate WPFs, because investigators believed it was appropriate to equate the respirator's APF with this 5th percentile, or with a corresponding confidence limit computed for this estimate of the true population value.[11] In turn, the aggregate WPF 5th percentile value was interpreted as the minimum WPF value that would be obtained by 95% of respirator wearers who had been properly fitted and trained.

Note that the American National Standards Institute (ANSI) Z88.2 Committee currently defines the APF as "the expected workplace level of respiratory protection that would be provided . . . to properly fitted and trained users."[20, p. 2] This definition roughly corresponds to the 1987 NIOSH Respirator Decision Logic definition if ANSI's "expected level of respiratory protection" signifies the minimum WPF value.

A NORMAL RANDOM EFFECTS MODEL FOR PENETRATION VALUES

Because the presence of between-wearer variability in the average level of respiratory protection impacts how an APF value is determined, we offer an analysis of WPF data that quantifies the within/between variability components. The starting point is a normal random effects model for log-transformed P values.[13,21,22] The model's structure is described with reference to Figure 1. Each wearer has a lognormal P distribution with the same geometric standard deviation value, GSD_W, where the subscript W denotes within-wearer. However, each wearer has a unique geometric mean P value, which also signifies that each individual has a unique arithmetic mean P value, $\bar{P}$; the latter is the wearer's long-term average P value, or the penetration value averaged across many respirator use periods. The top panel in Figure 1 depicts lognormal P distributions for four individuals in a cohort; only four are shown to avoid clutter in the diagram. Although these distributions do not have the same variance, each has the same relative variance as measured by the GSD_W.

The arithmetic mean (and geometric mean) penetration values among different wearers are lognormally distributed. The middle panel in Figure 1 depicts the lognormal $\bar{P}$ distribution. The latter has geometric standard deviation GSD_B, where the subscript B signifies between-wearer. The arithmetic mean of the $\bar{P}$ distribution is denoted μ_P, which is the grand mean of all the individual wearer $\bar{P}$ values.

A consequence of this structure is that when the lognormal P distributions of all wearers are aggregated, the resulting total (marginal) distribution of P is lognormal, as depicted in the bottom panel in Figure 1. The total P distribution has arithmetic mean μ_P (the same arithmetic mean as the $\bar{P}$ distribution), and geometric standard deviation, GSD_T, and geometric mean, GM_T, specified by:

$$GSD_T = \exp(\sqrt{\ln^2 GSD_W + \ln^2 GSD_B}) \quad (1)$$

$$GM_T = \frac{\mu_P}{\exp(\sqrt{\ln^2 GSD_W + \ln^2 GSD_B})} \quad (2)$$

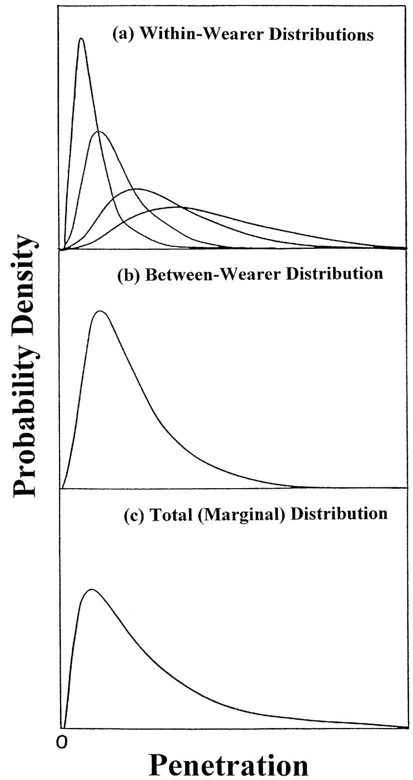

FIGURE 1. (a) The lognormal within-wearer P distributions for four individuals from the respirator wearer population. All distributions have the same geometric standard deviation value GSD_W, although their variances differ. (b) The lognormal between-wearer distribution of mean penetration values, $\bar{P}$, for the respirator wearer population. The between-wearer distribution has a mean value μ_P and geometric standard deviation GSD_B. (c) The lognormal total (marginal) distribution of P values for the respirator wearer population, formed by aggregating all the individual wearer P distributions. The total distribution has a mean value μ_P and geometric standard deviation GSD_T.

The model is most simply formulated as a linear expression in terms of ln P, which proves to have convenient statistical properties:

$$\ln P_{jk} = \mu_\ell + \beta_j + \omega_{jk} \quad (3)$$

where $\ln P_{jk}$ is the logtransformed P value for the jth randomly selected wearer during the kth randomly selected wearing period; μ_ℓ is the population mean of the log-transformed P values, $E[\ln P_{jk}]$; β_j is a random effect that converts μ_ℓ to the mean log-transformed P value for the jth wearer, and ω_{jk} is a random effect (traditionally called an "error" term) that converts the mean log-transformed P value for the jth wearer to the log-transformed P value for the wearer's kth respirator use period. The random effect β is normally distributed with $E[\beta] = 0$ and $\sigma_\beta^2 = \ln^2 GSD_B$. The random effect ω is normally distributed with $E[\omega] = 0$ and $\sigma_\omega^2 = \ln^2 GSD_W$. β and ω are treated as independent variables. That portion of total variability due to between-wearer differences is: $\sigma_\beta^2/[\sigma_\omega^2 + \sigma_\beta^2]$. With regard to

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Equations 1 and 2, $GSD_T = \exp(\sqrt{\sigma_\omega^2 + \sigma_\beta^2})$, and $GM_T = \exp(\mu_\ell)$. Note that in Equation 3, ln P is a normal variable because it is the sum of a constant, μ_ℓ, and two normal variables, β and ω. This structure permits traditional parametric statistical analysis for normally distributed log-transformed P data, and allows confidence intervals to be constructed based on the normal distribution property of the parameter estimates.

Interestingly, the lognormality of the total (marginal) distribution of penetration values is consistent with observations in nearly all published studies. That is, when the measured P values of all subjects within a study are aggregated, the values are reasonably described by a lognormal distribution.[4,5,8−19] This observation is predicted because the aggregation of replicate P values from multiple wearers approximates the lognormal total P distribution depicted in the bottom panel of Figure 1.

The normal random effects model applied to log-transformed P values is convenient for purposes of data analysis and exposure assessment, but may not always be an adequate descriptor. One case involves a wearer group with relatively high μ_P value such that the lognormal distribution assumption leads to predicting a substantial fraction of P values greater than one. In general, $P > 1$ is physically impossible given that the ratio C_I/C_O is bound between 0 and 1, although a situation might arise in which previously absorbed gaseous contaminant emitted in exhaled breath led to measuring $C_I > C_O$. Note that $P > 1$ is the same as $WPF < 1$, so if a problem exists in applying a lognormal model to P values, the same problem pertains to applying a lognormal model to WPFs.

If μ_P is high, an alternative approach is to use a logit transform that converts P to a variable L by the operation: $L = \ln[P/(1-P)]$, such that $-\infty < L < \infty$. The inverse operation is: $P = \exp(L)/[1 + \exp(L)]$, such that $0 \leq P \leq 1$. The advantage is that when a statistic for L derived from a sample of measured P values is transformed to the P variable, the corresponding P value cannot exceed one. Further, if L has an approximately normal distribution, one can use L in the parametric random effects model that assumes normality of all variables.

STATISTICAL ANALYSIS OF PUBLISHED DATA

Estimating within/between variance components requires that specific WPF measurements be related to specific subjects. Among the WPF studies published or described at technical conferences over the past 20 years, only nine studies presented data with the requisite specificity. Seven involved negative-pressure air-purifying half-masks worn against vapors and aerosols, and two involved helmet-and-visor type PAPRs worn against aerosols. These nine studies are summarized below.

Half-Mask Respirators

Study 1, Cohen.[8] Exposure to elemental mercury vapor was determined for 7 workers in a chlorine production facility. All subjects wore the same model disposable mercury vapor respirator. Three to 4 WPFs were measured per subject, with individual WPFs based on monitoring times of 10 to 30 minutes. Measured inside-the-facepiece concentration values, C_I, were adjusted both for mercury absorption in the lungs and for exhalation of previously absorbed mercury. A total of 26 WPFs were collected.

Study 2, Galvin et al.[13] Exposure to styrene vapor was determined for 13 workers who performed spraying and non-spraying activities during fiberglass-reinforced bathtub manufacturing. All subjects wore the same model elastomeric respirator with organic vapor cartridges. Three to 6 WPFs were measured per subject, with individual WPFs based on a monitoring time of 60 minutes. Measured C_I values were adjusted for pulmonary retention of styrene vapor; no evidence for exhalation of previously absorbed styrene was reported. A total of 63 WPFs were collected.

Study 3, Reed et al.[13] Exposure to a concrete patching compound dust (as total mass) was determined for 7 workers who mixed and packaged the material. All subjects wore the same model disposable dust/mist respirator. Two to 4 WPFs were measured per subject, with most WPFs based on monitoring times of 6 hours. Measured C_I values were not adjusted for particle retention in the respiratory tract. A total of 22 WPFs were collected.

Study 4, Myers et al.[17] Exposure to particulate lead (Pb) and zinc (Zn) was determined for 25 workers in 3 brass foundries. One disposable dust/fume/mist respirator and 3 models of elastomeric respirators with dust/fume/mist filters were worn. Each subject wore 2 or more models, and 1 WPF was measured per subject per model worn. Individual WPFs were based on monitoring times of 1 to 4 hours. Measured C_I values were not adjusted for particle retention in the respiratory tract. A total of 66 WPFs were collected. The investigators statistically summarized the WPF values based on Zn. However, because the respirators were worn to protect against Pb, and because Pb appeared to be associated with smaller particles, we analyzed the WPF values based on Pb.

Study 5, Myers and Zhuang.[18] Exposure to particulate iron (Fe) was determined for 16 workers in the sinter plant and the basic oxygen process shop of a steel manufacturing plant; exposure to calcium (Ca) was determined for 1 worker. Two models of disposable dust/mist respirator and 3 models of elastomeric respirator with dust/mist filters were worn. In general, each subject wore 2 or more models, and 1 WPF was measured per subject per model worn. Individual WPFs were based on monitoring times of 1 to 4 hours; monitoring duration was not specified in the article, but was described in the general study protocol that was published separately.[11] Measured C_I values were not adjusted for particle retention in the respiratory tract. A total of 54 WPFs were collected. We analyzed the 51 WPFs based on Fe from 16 workers, and excluded the 3 WPFs based on Ca.

Study 6, Myers and Zhuang.[16] Exposure to particulate titanium (Ti) and chromium (Cr) was determined for 22 workers who spray painted aircraft. WPFs measured during spraying of a primer paint were based on Cr, while WPFs measured during

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spraying of a topcoat paint were based on Ti. Three models of elastomeric respirators equipped with combination high efficiency filter/organic vapor cartridges were worn. Twelve subjects each wore 2 models of respirator, with 1 WPF measured per subject per model worn; 1 subject had 1 and 2 WPFs measured for 2 respirator models, respectively. Nine subjects had only 1 WPF measurement. Individual WPFs were based on monitoring times of 1 to 4 hours; monitoring duration was not specified in the article, but was described in the general study protocol that was published separately.[23] Measured C_I values were not adjusted for particle retention in the respiratory tract. A total of 36 WPFs were collected.

Study 7, Weber and Mullins.[19] Exposure to styrene vapor was determined for 19 workers who performed spraying and nonspraying activities during fiberglass boat manufacturing. All subjects wore the same model elastomeric respirator with organic vapor cartridges and dust/mist filters. One to 4 WPFs were measured per subject, with individual WPFs based on monitoring times of 23 to 88 minutes. Measured C_I values were adjusted for pulmonary retention of styrene vapor. Evidence suggesting exhalation of previously absorbed styrene was reported, so the measured C_I values may have been subject to a positive bias. A total of 46 WPFs were collected.

PAPR Studies

Study 8, Myers and Peach.[4] Exposure to particulate Pb was determined for 12 workers in a secondary lead smelter. Two models of helmet-and-visor type PAPR were worn. In general, each subject wore both models with 2 WPFs measured per model (4 WPFs per subject). Individual WPFs were based on monitoring times of 6 to 7.5 hours, in general. A total of 46 WPFs were collected.

Study 9, Myers et al.[5] Exposure to particulate Pb was determined for 12 workers in a battery manufacturing plant. Two models of helmet-and-visor type PAPR were worn (4 WPFs per subject). In general, each subject wore both models with 2 WPFs measured per model. Individual WPFs were based on monitoring times of 6 to 7.5 hours, in general. A total of 47 WPFs were collected.

Maximum Likelihood Analysis

Normal random effects models for log-transformed P values and logit-transformed P values were fit to the data in each study by the method of maximum likelihood.[22] Because the analysis focused on assessing variance components, no attempt was made to adjust the observed P values for potential measurement biases. For each type of transformed P value in each study, we estimated the within-wearer variance σ_ω^2, the between-wearer variance σ_β^2, and the population mean value μ_ℓ, using Proc Mixed in SAS. The between-wearer fraction of total variability is the ratio: $\sigma_\beta^2/(\sigma_\omega^2 + \sigma_\beta^2)$. Again, for log-transformed P values, $GSD_W = \exp(\sqrt{\sigma_\omega^2})$, $GSD_B = \exp(\sqrt{\sigma_\beta^2})$, and $GM_T = \exp(\mu_\ell)$.

Table I summarizes the findings. The two transforms generally provided similar results. Among half-mask studies 1 to 7, the estimated GSD_B values for log-transformed P values were, respectively, 1, 1.5, 2.3, 1.3, 1, 1.7. The between-wearer fraction of the total variance differed substantially. In 2/7 half-mask studies, the estimated between-wearer component was zero; observing $\hat{\sigma}_\beta^2 = 0$ will be discussed subsequently. In 5/7 half-mask studies, the estimated between-wearer component contributed, respectively, 6.5%, 11%, 23%, 46%, and 51% of the total variance (of the log-transformed P values). These findings suggest that among half-mask wearers, the within-wearer component tends to dominate the between-wearer component, and that a "typical" contribution of between-wearer variability is on the order of 10% to 20%.

In PAPR studies 8 and 9, the estimated GSD_B values from log-transformed P values were, respectively, 2.2 and 1. In Study 8, the between-wearer fraction of the total variance was 43%, while in Study 9 it was zero. Given just 2 studies, we cannot offer a "typical" value for the contribution of between-wearer variability among PAPR wearers.

The outcome $\hat{\sigma}_\beta^2 = 0$ is not unusual if a small number of replicate measurements are made per subject and the between-wearer component of the total variance is small. To illustrate, consider the following hypothetical scenario. Three replicate P values are measured for each of 12 randomly selected wearers. The true total variance corresponds to $GSD_T = 3.25$, and the between-wearer component contributes 10% of the total variance. Note that $GSD_T = 3.25$ is within the range of estimated GSD_T values in the seven half-mask studies in Table I (2.2 in Study 7, to 5.4 in Study 4). Searle[24] showed that the probability of obtaining $\hat{\sigma}_\beta^2 = 0$ is:

$$\Pr\left[\hat{\sigma}_\beta^2 = 0\right] = \Pr\left[F_{V1,V2} < \frac{\sigma_\varepsilon^2}{\sigma_\omega^2 + n \cdot \sigma_\beta^2}\right] \tag{4}$$

where $F_{V1,V2}$ is the cumulative F distribution with $V1 = k - 1$ degrees of freedom for the numerator, and $V2 = k(n - 1)$ degrees of freedom for the denominator; where k is the number of subjects; and where n is the number of replicates per subject. In the posited scenario, $k = 12$, $n = 3$, $\sigma_\omega^2 = 1.11$, and $\sigma_\beta^2 = 0.28$, for which $\Pr[\hat{\sigma}_\beta^2 = 0] = 0.32$. That is, there is a 32% chance of obtaining a zero between-subject variance estimate. For a larger between-wearer component contributing 20% of the total variance, $\Pr[\hat{\sigma}_\beta^2 = 0] = 0.17$.

DERIVING AN APF

Criteria for Acceptable Respirator Performance

The foregoing discussion of the random effects model and variance components segues to considering the derivation of an APF value. To assign a nominal level of protection, we propose two criteria for "acceptable" respirator performance that account for within- and between-wearer variability. The first criterion, which applies to an individual wearer, is the acceptable percent of WPF values that may fall below the nominal level of protection. For example, consider a half-mask respirator for which the current APF = 10. Is it acceptable for an individual wearer to experience 5% of WPFs < 10? or 1%? or some other percent? The traditional application of the

TABLE I. Estimates of Random Effects Model Parameters Based on a Maximum Likelihood Analysis of Log-Transformed Versus Logit-Transformed Respirator Penetration Data

Study (#)	# Subjects (replicates)	$\hat{\mu}_\ell$	$\hat{\sigma}^2_\beta$	$\hat{\sigma}^2_\omega$	$\hat{\sigma}^2_\beta/(\hat{\sigma}^2_\omega + \hat{\sigma}^2_\beta)$
		Log-Transformed P			
Half-Masks					
Cohen (1)	7 (26)	−3.35	0	0.95	0
Galvin et al. (2)	13 (63)	−4.38	0.15	1.15	0.11
Reed et al. (3)	7 (22)	−2.85	0.51	0.60	0.46
Myers et al. (4)	25 (66)	−4.30	0.66	2.20	0.23
Myers and Zhuang (5)	16 (51)	−5.56	0.09	1.29	.065
Zhuang and Myers (6)	22 (36)	−8.30	0	1.97	0
Weber and Mullins (7)	19 (46)	−3.63	0.30	0.29	0.51
PAPRs					
Myers et al. (8)	12 (46)	−5.13	0.59	0.78	0.43
Myers et al. (9)	12 (47)	−4.77	0	0.88	0
		Logit−Transformed P			
Half-Masks					
Cohen (1)	7 (26)	−3.30	0	1.04	0
Galvin et al. (2)	13 (63)	−4.35	0.16	1.27	0.11
Reed et al. (3)	7 (22)	−2.73	0.58	0.88	0.40
Myers et al. (4)	25 (66)	−4.26	0.65	2.40	0.21
Myers and Zhuang (5)	16 (51)	−5.55	0.09	1.31	.064
Zhuang and Myers (6)	22 (36)	−8.30	0	1.97	0
Weber and Mullins (7)	19 (46)	−3.59	0.33	0.30	0.52
PAPRs					
Myers et al. (8)	12 (46)	−5.12	0.60	0.79	0.43
Myers et al. (9)	12 (47)	−4.75	0	0.94	0

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two-parameter lognormal distribution to half-mask WPF data implies that every wearer has some percent of WPFs < 10. We are not aware of a legal or voluntary standard defining this percent, but we suggest the value 5%. That is, an acceptable WPF distribution for a wearer has no more than 5% of WPFs below the APF value; in terms of penetration, an acceptable P distribution has no more than 5% of P values above 1/APF.

In preface to discussing the second criterion, consider that WPF data are collected for wearers who, by definition, have been properly fitted and trained. Therefore, when a half-mask study reports WPFs < 10, or when one estimates a certain percent of WPFs < 10, these low WPFs are not due to lack of fit testing and training, and one can anticipate WPFs < 10 will be experienced in the future. Further, if all half-mask wearers do not have exactly the same WPF distribution, different wearers will experience different percents of WPFs < 10. In turn, when data from a half-mask WPF study are used to set an APF, there is no guarantee that *all* properly fitted and trained wearers will have an acceptable WPF distribution, defined as a distribution with no more than 5% of WPF values below the APF value.

The second criterion, which applies to a population of wearers, is the acceptable percent of wearers who have unacceptable WPF distributions. Is it acceptable for 5%, or 1%, or some other percent of wearers to have an unacceptable WPF distribution? We suggest the value 5%. Therefore, when using WPF data to derive an APF value, it is acceptable to set the APF such that 5% of properly fitted and trained wearers may have more than 5% of their WPFs below the APF value; in terms of penetration, it is acceptable for 5% of wearers to have more than 5% of P values above 1/APF.

An APF Defined via the Random Effects Model

Assume that variability in P is described by the random effects model, Equation 3. Let $P_{95\%,\,j}$ denote the 95th percentile of the jth wearer's lognormal P distribution. Based on the relationship between the mean, standard deviation and 95th percentile of a normal distribution, $\ln P_{95\%,\,j}$ is written:

$$\ln P_{95\%,\,j} = \mu_\ell + \beta_j + 1.645\sigma_\omega \qquad (5)$$

To explain, the sum $\mu_\ell + \beta_j$ is the jth wearer's mean penetration value on the log scale. Adding the term 1.645 σ_ω signifies that the wearer's 95th percentile P value is 1.645 standard deviations above the mean on the log scale. Again consider the right-hand side of Equation 5. The terms μ_ℓ and σ_ω are the same for all wearers, and the term β is normally distributed across wearers. Therefore, the variable $\ln P_{95\%}$ is normally distributed across wearers, which signifies that 95th percentile P values for different wearers are lognormally distributed. Given $E[\beta] = 0$

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and $\mathrm{Var}[\beta] = \sigma_\beta^2$, it follows that $E[\ln P_{95\%}] = \mu_\ell + 1.645\sigma_\omega$, and $\mathrm{Var}[\ln P_{95\%}] = \sigma_\beta^2$. The geometric mean and standard deviation for $P_{95\%}$ are:

$$\mathrm{GM}[P_{95\%}] = \exp(\mu_\ell + 1.645\sigma_\omega) = \mathrm{GM_T}\exp(1.645\ln \mathrm{GSD_W}) \quad (6)$$

$$\mathrm{GSD}[P_{95\%}] = \exp(\sigma_\beta) = \mathrm{GSD_B} \quad (7)$$

where $\mathrm{GM_T} = \exp(\mu_\ell)$. Next, let κ denote the 95th percentile of the lognormal between-wearer distribution of $P_{95\%}$ values, and let $\kappa_\ell = \ln\kappa$. For the normal distribution of $\ln P_{95\%}$, the 95th percentile is 1.645 standard deviations above the mean on the log scale, or:

$$\kappa_\ell = \mu_\ell + 1.645\sigma_\omega + 1.645\sigma_\beta \quad (8)$$

By exponentiating κ_ℓ, one can specify κ in terms of $\mathrm{GM_T}$, $\mathrm{GSD_W}$, and $\mathrm{GSD_B}$:

$$\kappa = \mathrm{GM_T}\exp(1.645[\ln \mathrm{GSD_W} + \ln \mathrm{GSD_B}]) \quad (9)$$

Because 95% of wearers have ≤5% of P values exceeding the value κ (in which case, 5% of wearers have >5% of P values exceeding the value κ), the inverse of κ is the APF value that satisfies the previous criteria for acceptable respirator performance, or:

$$\mathrm{APF} = \frac{1}{\kappa} \quad (10)$$

Statistical Estimation

Given a study in which multiple respirator wearers each have multiple P values determined, fitting the log-transformed (or logit-transformed) data to the normal random effects model via the method of maximum likelihood provides the estimates $\hat{\mu}_\ell$, $\hat{\sigma}_\beta^2$, and $\hat{\sigma}_\omega^2$, and generates a variance-covariance matrix for these estimates. The covariance structure must be considered because for unbalanced data the estimates are not typically independent. The estimate of κ_ℓ, denoted $\hat{\kappa}_\ell$, is made by inserting the appropriate parameter estimates into Equation 8. However, because $\hat{\kappa}_\ell$ is only a point estimate of the true population value, a one-sided upper confidence limit should be used to determine the APF. Standard likelihood theory[25] shows that in large samples the $\hat{\kappa}_\ell$ estimate is approximately unbiased and normally distributed. That is, $\hat{\kappa}_\ell$ may be considered normally distributed with:

$$E[\hat{\kappa}_\ell] = \kappa_\ell \quad (11)$$

$$\begin{aligned}\mathrm{Var}[\hat{\kappa}_\ell] = {} & \mathrm{Var}[\hat{\mu}_\ell] + (1.645)^2\,\mathrm{Var}[\hat{\sigma}_\beta] + (1.645)^2\,\mathrm{Var}[\hat{\sigma}_\omega] \\ & + 2(1.645)\,\mathrm{Cov}[\hat{\mu}_\ell, \hat{\sigma}_\beta] + 2(1.645)\,\mathrm{Cov}[\hat{\mu}_\ell, \hat{\sigma}_\omega] \\ & + 2(1.645)^2\,\mathrm{Cov}[\hat{\sigma}_\beta, \hat{\sigma}_\omega]\end{aligned} \quad (12)$$

Because we are primarily concerned with P values that exceed 1/APF, a one-sided 90% upper confidence limit for the κ_ℓ estimate, denoted $\mathrm{UCL}_{90\%}(\hat{\kappa}_\ell)$, is formed as follows:

$$\mathrm{UCL}_{90\%}(\hat{\kappa}_\ell) = \hat{\kappa}_\ell + 1.282\sqrt{\mathrm{Var}[\hat{\kappa}_\ell]} \quad (13)$$

where 1.282 is the z value at the 90th percentile of the standard normal distribution. For log-transformed P values, one exponentiates to obtain the one-sided 90% upper confidence limit for the κ estimate, or $\mathrm{UCL}_{90\%}(\hat{\kappa}) = \exp(\mathrm{UCL}_{90\%}(\hat{\kappa}_\ell))$. For logit-transformed P values, if we let $W = \mathrm{UCL}_{90\%}(\hat{\kappa}_{\mathrm{logit}})$, the inverse operation is used to obtain the one-sided 90% upper confidence limit, or $\mathrm{UCL}_{90\%}(\hat{w}) = \exp(W)/[1 + \exp(W)]$. The APF incorporating the confidence limit is:

$$\mathrm{APF_{UCL90\%}} = \frac{1}{\mathrm{UCL}_{90\%}(\hat{\kappa})} \quad (14)$$

For log-transformed P values and logit-transformed P values in each of the WPF studies, we used the estimates $\hat{\sigma}_\omega^2$, $\hat{\sigma}_\beta^2$, and $\hat{\mu}_\ell$ in Table I to compute the point estimate $\hat{\kappa}$ and the one-sided 90% upper confidence limit $\mathrm{UCL}_{90\%}(\hat{\kappa})$. These results are summarized in Table II. The $\mathrm{UCL}_{90\%}(\hat{\kappa})$ values based on Equation 13 are listed under the column heading "Analytical". The two transforms generally provided similar results, except for studies 3 and 4. In the latter, naive computation

TABLE II. Point Estimates and One-Sided 90% Upper Confidence Limits for κ Based on Parameter Estimates via Maximum Likelihood Analysis of Log-Transformed Versus Logit-Transformed Respirator Penetration Data

Study (#)	$\hat{\kappa}$	$\mathrm{UCL}_{90\%}(\hat{\kappa})$ Analytical	$\mathrm{UCL}_{90\%}(\hat{\kappa})$ Bootstrap
Log-Transformed P			
Half-Masks			
Cohen (1)	0.18	0.26	0.20
Galvin et al. (2)	0.14	0.21	0.22
Reed et al. (4)	0.67	1[a]	1[A]
Myers et al. (4)	0.58	0.97	1[A]
Myers and Zhuang (5)	0.04	0.06	0.08
Zhuang and Myers (6)	0.0025	0.004	0.006
Weber and Mullins (8)	0.16	0.21	0.28
PAPRs			
Myers et al. (8)	0.09	0.15	0.17
Myers et al. (9)	0.04	0.05	0.13
Logit-Transformed P			
Half-Masks			
Cohen (1)	0.17	0.29	0.22
Galvin et al. (2)	0.14	0.20	0.25
Reed et al. (4)	0.52	0.69	0.71
Myers et al. (4)	0.40	0.53	0.72
Myers and Zhuang (5)	0.04	0.06	0.08
Zhuang and Myers (6)	0.0025	0.004	0.006
Weber and Mullins (8)	0.15	0.19	0.24
PAPRs			
Myers et al. (8)	0.09	0.15	0.15
Myers et al. (9)	0.04	0.05	0.08

[A]The computed value exceeded one, which is assumed to be impossible for penetration; therefore, the computed value was set equal to one.

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of $UCL_{90\%}(\hat{\kappa})$ based on the log-transformed P values would yield 1.31 and 0.97, respectively; note that we report 1.0 when Wald-type confidence limits exceed 1.0. In contrast, the logit-transformation yielded respective $UCL_{90\%}(\hat{\kappa})$ values of 0.69 and 0.53. Study 3 involved the highest P values overall with $\hat{\mu}_P = 0.10$, and Study 4 involved the greatest overall variability in P values with an estimated $GSD_T = 5.4$. In the context of a lognormal distribution model, both factors could lead to predicting a nontrivial fraction of P values exceeding one.

If the sample size is "large" in the context of statistical sampling, the normal distribution assumption for the estimate $\hat{\kappa}_\ell$ is reasonable, and Equations 8, 12, and 13 are adequate for computing $UCL_{90\%}(\hat{\kappa})$. However, the number of WPF measurements in each of the nine WPF studies is not "large," in which case the normal distribution assumption may be suspect. Therefore, we examined an alternative method termed the bootstrap[26] for computing a 90% one-sided upper confidence limit for the $\hat{\kappa}$ estimate. The method is explained using the data from half-mask Study 2.

In that study, there were k = 13 subjects, and 3 to 6 replicate P measurements per subject. Ten thousand (10,000) iterations of the following sampling experiment were performed. A sample of 13 subjects was randomly selected *with replacement* from the k = 13 subjects in the study. In any given sample, some subjects may appear two or more times. A maximum likelihood analysis based on the random effects model of the transformed P values was performed for each sample, and estimates of μ_ℓ, σ^2_β, and σ^2_ω were obtained. Using these estimates, a $\hat{\kappa}$ estimate was computed. The 10,000 iterations of the sampling experiment provided a distribution of 10,000 $\hat{\kappa}$ estimates. The 90th percentile value of this distribution is a 90% one-sided upper confidence limit for $\hat{\kappa}$.

The right-hand column of Table II reports bias-corrected and accelerated (BC_a) bootstrap confidence limits. Efron and Tibshirani[26] show that the BC_a method yields more accurate confidence limits. In general, the $UCL_{90\%}(\hat{\kappa})$ values based on the bootstrap method agree with the large sample variance estimates.

DISCUSSION

The Five Percent Paradox

We previously asserted that although only 5% of WPF values aggregated across all wearers might be less than the APF value, a substantial fraction of wearers could have more than 5% of their WPFs below the APF value. This seeming paradox is easily illustrated in the context of the random effects model for ln P. Consider the model parameters $\mu_P = .025$, $GSD_B = 1.7$ and $GSD_W = 3.0$, which are consistent with the estimated parameters for half-mask respirators in Table I. The total (marginal) P distribution has $GM_T = .012$ by Equation 3, and $GSD_T = 3.4$ by Equation 2, such that only 4% of P values in the wearer population exceed 0.1 (only 4% of WPF values are less than 10). Next, $GM[P_{95\%}] = .0724$ by Equation 6, and $GSD[P_{95\%}] = 1.7$ by Equation 7, such that 27% of $P_{95\%}$ values exceed 0.1. That is, 27% of wearers each have more than 5% of P values above 0.1, which is to say, 27% of wearers each have more than 5% of WPFs less than 10. This result illustrates the flaw in equating the APF with the 5th percentile of WPF values aggregated across all wearers. Rather, one needs to account for both between- and within-wearer variability in WPFs.

The Half-Mask APF

We proposed that an APF be set such that 95% of wearers experience less than 5% of their WPFs below the APF value, and that a confidence limit be used such that: $APF_{UCL90\%} = 1/UCL_{90\%}(\hat{\kappa})$. For overall consistency, we consider half-mask APFs corresponding to the $UCL_{90\%}(\hat{\kappa})$ values in Table II based on the logit-transformed P values. Among the seven half-mask studies, the $UCL_{90\%}(\hat{\kappa})$ values in increasing order are: .004, .06, 0.19, 0.20, 0.29, 0.53, 0.69. The inverses represent estimated half-mask APF values of, respectively: 250, 17, 5.3, 5.0, 3.4, 1.9, 1.4. If one uses just the point estimates $\hat{\kappa}$ absent the confidence limits, the inverses represent estimated half-mask APF values of, respectively: 400, 25, 7.1, 6.7, 5.9, 2.5, 1.9. Clearly, different WPF studies provide a substantially different idea of a half-mask's nominal level of protection. Overall, we believe these results support reducing the current APF for the negative-pressure air-purifying half-mask respirator class to APF = 5.

Further justifying our recommendation requires defining "acceptable" overexposure for an individual worker. Given variability in C_O and P, it is likely impossible to prevent some proportion of C_I values from exceeding the OEL. Denote this exceedance proportion by $Pr[C_I > OEL]$. But what is the acceptable value of this proportion? Nelson et al.[27] suggested that $Pr[C_I > OEL] \leq .05$ is acceptable because it is consistent with the overexposure criterion used by NIOSH in its exposure assessment manual,[28] although it was noted that the Occupational Safety and Health Administration (OSHA) defines its OELs as "limits not to be exceeded."[27] For this discussion, we also use $Pr[C_I > OEL] \leq .05$ as the acceptable overexposure criterion for an individual.

Computing $Pr[C_I > OEL]$ requires specifying the wearer's distributions of C_O and P. Assume that C_O and P are independent lognormal variables. Given that $C_I = C_O \times P$, it follows that C_I is a lognormal variable for which:

$$GM[C_I] = GM[C_O] \times GM[P] \quad \textbf{(15)}$$

$$GSD[C_I] = \exp\left(\sqrt{\ln^2 GSD[C_O] + \ln^2 GSD_W}\right) \quad \textbf{(16)}$$

where GSD_W is the GSD of the wearer's P distribution. Under the assumption that half-mask penetration values are well described by the random effects model, and that all wearers experience the same lognormal C_O distribution, the proportion of wearers who each have $Pr[C_I > OEL] > .05$ is found as follows. For any wearer, $GSD[C_I]$ is specified by Equation 16. The wearer's 95th percentile C_I value, denoted $C_{I,95\%}$, can be written as a function of the wearer's mean C_I value, $\overline{C_I}$, and

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GSD[C_I] value:

$$C_{I,95\%} = \overline{C_I} \times \left[\frac{(GSD[C_I])^{1.645}}{\exp(0.5\ln^2 GSD[C_I])}\right] \quad (17)$$

Consider the right-hand side of Equation 17. Because the GSD[C_I] value is the same for every wearer, the bracketed expression is constant across wearers. However, the parameter $\overline{C_I}$ is lognormally distributed across wearers because $\bar{P}$ is lognormally distributed across wearers. It follows that $C_{I,95\%}$ is also lognormally distributed across wearers. As derived in Appendix 1, the GM and GSD of $C_{I,95\%}$ are specified by:

$$GM[C_{I,95\%}] = \mu_{C_O} \times \mu_P \left[\frac{(GSD[C_I])^{1.645}}{\exp(0.5(\ln^2 GSD[C_I] + \ln^2 GSD_B))}\right] \quad (18)$$

$$GSD[C_{I,95\%}] = GSD_B \quad (19)$$

where μ_{C_O} is the population mean C_O level, and μ_P is the population mean P value. In turn, the proportion of wearers who each have more than 5% of their C_I values above the OEL, denoted Pr[$C_{I,95\%}$ > OEL], is determined by:

$$Pr[C_{I,95\%} > OEL] = 1 - \Phi\left(\frac{\ln OEL - \ln GM[C_{I,95\%}]}{\ln GSD[C_{I,95\%}]}\right) \quad (20)$$

where $\Phi(z)$ is the cumulative standard normal distribution function evaluated at z.

Because estimates of μ_P, GSD_B and GSD_W are available for the Table I half-mask studies, Equations 18–20 can be applied if the C_O distribution is specified. In general, a respirator's maximum use concentration (maximum C_O level) is: MUC = APF × OEL. Because a maximum C_O level is difficult to determine, and might be much higher than the vast majority of C_O values, it is arguably more reasonable to substitute the 95th percentile C_O level for the MUC term in the previous equation. In that case, it would be acceptable to wear a half-mask respirator with APF = 10 in an environment for which the 95th percentile C_O level was 10 × OEL, because (95th percentile C_O)/10 = OEL. This view of the MUC is nominally consistent with the previous idea that Pr[C_I > OEL] = .05 is acceptable.

Next, consider a lognormal C_O distribution with GM[C_O] = 4.2 × OEL and GSD[C_O] = 1.7. The value GSD[C_O] = 1.7 is chosen because it is the median within-worker GSD[C_O] value found in 69 employee groups performing "indoor work".[29] Given GSD[C_O] = 1.7, the value GM[C_O] = 4.2 × OEL is chosen so that the 95th percentile C_O level is 10 × OEL. Note that in this C_O distribution, 32% of the values fall in the range 5 × OEL to 10 × OEL. For each half-mask study, Table III lists the computed value of Pr[$C_{I,95\%}$ > OEL] under the column heading "95%ile C_O = 10 × OEL". Pr[$C_{I,95\%}$ > OEL] values range from zero to 57%. In 3/7 studies, the exceedance percentages are 4% or greater; that is, 4% or more of wearers each has more than 5% of C_I levels above the OEL. All Pr[$C_{I,95\%}$ > OEL] values would be higher for GSD[C_O] < 1.7, and lower for GSD[C_O] > 1.7. Note that the listed exceedance percentages are based on the best estimates of the random effects model parameters, and not on upper confidence limits. The right-hand column in Table III shows the effect of lowering the half-mask APF to 5, which has the effect of lowering the MUC such that the 95th percentile C_O level is equal to 5 × OEL given GSD[C_O] = 1.7. Halving the current APF would reduce Pr[$C_{I,95\%}$ > OEL] by more than 50%.

TABLE III. The Proportion of Half-Mask Respirator Wearers Who Each Have More than 5% of C_I Levels Exceeding the OEL Given C_O Distributions with a 95th Percentile at 10 × OEL Versus 5 × OEL, and with GSD[C_O] = 1.7

Study (#)	95th Percentile C_O = 10 × OEL	95th Percentile C_O = 5 × OEL
Cohen (1)	0^A	0^A
Galvin et al. (2)	0.0056	0
Reed et al. (4)	0.57	0.21
Myers et al. (4)	0.37	0.12
Myers and Zhuang (5)	0	0
Zhuang and Myers (6)	0^A	0^A
Weber and Mullins (8)	0.040	0.0013

Note: Exceedance proportions were computed for each study by Equations 18–20 of the main text.

^{A}The estimated between-wearer variance for penetration values was zero. For the within-wearer GM[P] and GSD_W estimates, less than 5% of C_I levels exceed the OEL. Because there is no estimated variability between wearers, no wearer has more than 5% of C_I levels above the OEL.

Related Considerations

We foresee two objections to reducing the current half-mask APF: (1) several studies show high WPFs that do not warrant an APF = 5; and (2) half-mask wearers are usually exposed to C_O levels that do not approach the current MUC defined here as 95th percentile C_O = 10 × OEL. We address each issue.

It is true there are studies that support setting a half-mask APF > 10; among these are studies 5 and 6 analyzed in this article. However, one cannot consider these studies in isolation from the entire set of WPF studies, and among the larger set are findings that support reducing the current APF. We believe the wide discrepancy among WPF studies is due in large part to the physical nature of the measured contaminant. Studies involving gas-phase contaminants[8,13,19] and small particle contaminants[14] tend to yield relatively low WPFs, while studies involving large particle contaminants[16,18] tend to yield relatively high WPFs. In turn, differential contaminant penetration through faceseal leak paths based on aerodynamic size is consistent with this observation, that is, a higher fraction of gas-phase contaminants and small-particle contaminants penetrate the leak paths.[30–32]

A valid question arises. If a respirator provides high WPFs against large nonrespirable particles, shouldn't the respirator have a high APF when worn in atmospheres containing

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similarly sized particles? In theory, the answer is yes, with the caveat that the same respirator should have a lower APF when worn in atmospheres containing respirable particles and gas-phase contaminants (assuming that the appropriate air-purifying elements are used). In practice, it would likely prove confusing to implement a dual APF policy, particularly if a respirator with a combination filter and cartridge is simultaneously worn against particulate and gas-phase contaminants. At the same time, implementing a dual APF based on the contaminant's aerodynamic size is a policy option that might be considered by OSHA and NIOSH.

The second objection involves the ambient exposure levels in half-mask respirator applications. We previously posed a "worst case" scenario in which C_O levels were high overall such that 5% exceeded 10 × OEL. The argument has been made that in most half-mask use situations, C_O levels seldom approach 10 × OEL.[33] We agree that most half-mask use likely involves C_O levels that are only several-fold the OEL, but we also believe situations exist (or can arise) in which a substantial percentage of C_O levels are in the 5 × OEL to 10 × OEL range such that half-mask use is inadequate. This circumstance segues to another policy question. If one concludes it would be best not to use a half-mask when $C_O = 10 \times$ OEL, should one legally permit half-mask use at $C_O = 10 \times$ OEL because it seems unlikely that the situation will arise? In our view, the answer is no. The problem is akin to posting a speed limit at a school crossing. Most persons would agree that the limit should not be posted at 30 mph just because most drivers keep their speed down to 15 mph or less.

A practical consideration is that if most half-mask applications *do* involve C_O levels that seldom exceed 5 × OEL, reducing the current APF to 5 would have little impact overall on existing half-mask respirator programs. Further, combined with setting APF = 5, the new MUC can be explicitly defined as follows—a half-mask may be used if the proportion of the wearer's C_O levels (or the probability of a random C_O level) exceeding 5 × OEL is 5% or less. This definition acknowledges that C_O levels are variable and cannot be instantaneously determined (except in unusual circumstances), and that permitting half-mask use in situations where a small proportion of C_O levels exceed 5 × OEL is acceptable.

CONCLUSIONS

We examined seven published half-mask respirator studies and two published PAPR studies via a maximum likelihood analysis in the context of a normal random effects model. These studies were chosen because they provided WPF data that were suitable for estimating within-wearer and between-wearer variance components; that is, WPFs were identifed with specific subjects and, in general, two or more WPFs were measured per subject. We did not attempt to adjust WPF data for potential measurement bias, although we believe that in 6/9 studies involving particulate contaminants, there was a positive bias overall such that WPF values were overestimated.

For the half-mask studies, based on the $UCL_{90\%}(\hat{\kappa})$ values for the logit-transformed P data, we estimated APFs ranging from 1.4 to 250, with 5/7 studies yielding an APF ≤ 5.3. Based on these results and related considerations, we recommend that the current half-mask APF be reduced from 10 to 5. For the two PAPR studies, the estimated APFs were, respectively, 7.1 and 20. The latter results suggest that the current APF = 25 for the helmet-and-visor type PAPR class also be reduced, but we do do not offer a number given the paucity of data; further, the design of helmet-and-visor PAPRs may have changed in the 18 plus years since the two studies were conducted.

In discussing the appropriate APF for the half-mask respirator class, we considered the C_I levels that might be experienced by persons who wore the respirators in highly contaminated environments such that a substantial proportion of C_O levels exceeded 5 × OEL, as currently permitted. In Table III, we used the best estimates of the random effects model parameters for each study, and posited a C_O distribution with $GSD[C_O] = 1.7$ and a 95th percentile at 10 × OEL. In 3/7 studies that had the largest between-wearer variance estimates, 4% or more of wearers were predicted to experience more than 5% of their C_I levels above the OEL. Although most half-mask applications likely involve C_O levels that are only several-fold the OEL, that circumstance per se does not justify permitting half-mask use in more highly contaminated environments; further, the same circumstance would mitigate the impact of reducing the APF on existing half-mask respirator programs.

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APPENDIX 1

The Derivation of Main Text Equations 18 and 19

For a respirator wearer's lognormal C_I distribution with mean $\overline{C_I}$ and $GSD[C_I]$, the 95th percentile value $C_{I,\,95\%}$ can be written as:

$$C_{I,\,95\%} = \overline{C_I} \times \left[\frac{(GSD[C_I])^{1.645}}{\exp(0.5\ln^2 GSD[C_I])}\right] \quad \textbf{(A1)}$$

Consider the wearer's mean inhalation concentration $\overline{C_I}$. This parameter is the product of the wearer's mean ambient contaminant level μ_{C_O}, and mean penetration value $\bar{P}$, or:

$$\overline{C_I} = \mu_{C_O} \times \bar{P} \quad \textbf{(A2)}$$

Assume that μ_{C_O} is the same for all wearers. According to the random effects model, $\bar{P}$ is lognormally distributed across wearers. It follows that $\overline{C_I}$ values are lognormally distributed across wearers with:

$$\begin{aligned} GM[\overline{C_I}] &= \mu_{C_O} \times GM[\bar{P}] \\ &= \mu_{C_O} \times \frac{\mu_P}{\exp(0.5\ln^2 GSD_B)} \quad \textbf{(A3)} \end{aligned}$$

$$GSD[\overline{C_I}] = GSD[\bar{P}] = GSD_B \quad \textbf{(A4)}$$

Next, consider Equation A1, which relates a wearer's $C_{I,\,95\%}$ value to $\overline{C_I}$ and $GSD[C_I]$. Because $GSD[C_I]$ is constant across wearers, the bracketed term involving $GSD[C_I]$ is a constant. Because $\overline{C_I}$ is lognormally distributed across wearers, it follows that:

$$GM[C_{I,\,95\%}] = GM[\overline{C_I}] \times \left[\frac{(GSD[C_I])^{1.645}}{\exp(0.5\ln^2 GSD[C_I])}\right] \quad \textbf{(A5)}$$

$$GSD[C_{I,\,95\%}] = GSD[\overline{C_I}] = GSD_B \quad \textbf{(A6)}$$

By substituting the Equation A3 identity for $GM[\overline{C_I}]$ into Equation A5 and combining the denominator's exponential terms, one obtains Equation 18 of the main text. Equation A6 is the same as Equation 19 of the main text.

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