

Upper Limits for Exceedance Probabilities Under the One-Way Random Effects Model

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In this article, we propose statistical methods for setting upper limits on (i) the probability that the mean exposure of an individual worker exceeds the occupational exposure limit (OEL) and (ii) the probability that the exposure of a worker exceeds the OEL. The proposed method for (i) is obtained using the generalized variable approach, and the one for (ii) is based on an approximate method for constructing one-sided tolerance limits in the one-way random effects model. Even though tolerance limits can be used to assess the proportion of exposure measurements exceeding the OEL, the upper limits on these probabilities are more informative than tolerance limits. The methods are conceptually as well as computationally simple. Two data sets involving industrial exposure data are used to illustrate the methods.

Keywords: between- and within-worker variability; generalized confidence interval; generalized *P*-value; tolerance interval

INTRODUCTION

Applications of the one-way random effects model for assessing personal exposure level for a job group have been well demonstrated in the industrial hygiene literature for the past two decades. Many authors have postulated this model for analysing exposure data; among others, see Kromhout *et al.* (1993), Rappaport *et al.* (1995) and Lyles *et al.* (1997a,b). If multiple measurements exist for each worker, and both between- and within-worker variability are significant and need to be accounted for, then one should use the random effects model. After postulating the model, personal exposure levels can be assessed based on (i) the probability that the mean exposure of an individual worker exceeds the occupational exposure limit (OEL) and (ii) the probability that an individual exposure measurement exceeds the OEL. At the outset, we need to acknowledge that there is disagreement in the occupational hygiene field about whether one should interpret the OEL as a limit that the mean exposure should not exceed, or a limit that some upper percentile of the

exposures should not exceed (Lyles *et al.*, 1997b; Letters to the Editor, 1998). Our goal here is to present a methodology that will work in both cases.

Let θ denote the probability that the mean exposure of a worker exceeds the OEL. Consider testing the hypotheses

$$H_0 : \theta \geq A \text{ versus } H_a : \theta < A, \quad (1)$$

where A is a specified probability, usually between 0.01 and 0.1. Notice that if the null hypothesis is rejected, then we can conclude that the exceedance probability is at most A . Using the one–one relation between the cumulative probability and the quantile, it can be shown that the above testing problem is equivalent to testing if the $(1 - A)$ th quantile of the distribution of the mean exposures is less than the OEL; brief details of this appear in the next section. For example, if $A = 0.1$, then testing if $\theta < 0.1$ is equivalent to testing if the 90th percentile of the mean exposure distribution is less than the OEL. In this context, this testing problem is addressed in Lyles *et al.* (1997a) for the case of balanced data, and in Lyles *et al.* (1997b) for unbalanced data. The problems that come up in this context are somewhat complex as the parameter in the above

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hypotheses is a function of all the parameters in the one-way random effects model: the mean, as well as the two variance components. Lyles *et al.* (1997a,b) proposed large sample tests (Wald, likelihood ratio and score-type tests). These authors also suggested suitable modifications to control the type I error probability of the tests. Krishnamoorthy and Mathew (2002) proposed a test procedure based on the generalized variable approach for the case of balanced data, and Krishnamoorthy and Guo (2005) extended the results for unbalanced data. The generalized variable test is simple to use and is applicable for small samples.

Exposure level in a work environment can also be assessed by testing the probability η that an individual measurement exceeds the OEL. That is,

$$H_0 : \eta \geq A \text{ versus } H_a : \eta < A. \quad (2)$$

Note that η is the probability of an exposure measurement exceeding the OEL. Again, as in the preceding testing problem, testing equation (2) is equivalent to testing about the $(1 - A)$ th quantile of the distribution of the exposure measurements, and the quantile testing can be carried out by comparing an appropriate upper tolerance limit with the OEL; see the next section for an explanation of this. The problem of constructing one-sided tolerance limits in a one-way random effects model is also complex, and only approximate methods are available, e.g. Mee and Owen (1983); Bhaumik and Kulkarni (1991); Vangel (1992); and Krishnamoorthy and Mathew (2004). Among these approximate methods, Krishnamoorthy and Mathew's (2004) approach seems to be simple as it does not require any special table values or interpolation. These authors showed, by extensive simulation studies, that their approach is accurate as long as the intraclass correlation coefficient is not very small. In other words, their approach produces accurate results as long as the assumed one-way random model is well-fitted for the exposure data.

Hypothesis testing about an exceedance probability is useful to decide if the personal exposures for a job group are acceptable; however, an upper bound on the probability is more informative than the results based on a significance test. For example, if a significance test indicates that $\theta < 0.10$ at the level of 5%, then we can conclude that the data provide evidence to indicate that the exceedance probability is $<10\%$; but this is not the least upper bound, and the actual 95% upper limit on θ could be much $<10\%$ (see the example section).

Hewett and Ganser (1997) have provided a method for estimating 90% confidence intervals around the point estimate of the exceedance probability when the exposure sample is assumed to be a simple random sample from a lognormal distribution. This is based on an established procedure for estimating confidence

intervals around an estimate of the proportion of observations that fall in one tail of a normal distribution. The Z-value corresponding to the OEL is calculated first, followed by a look-up table or graph that allows the calculation of the 90% confidence intervals for a given sample size. It should be noted that Hewett and Ganser's approach is applicable if the exposure measurements form a simple random sample from a lognormal distribution. This means that Hewett and Ganser's approach is valid only when the between worker variance component is zero, a strict condition which may not be met in many instances.

The purpose of this paper is to bring to the attention of industrial hygienists some simple methods that can be used for constructing tolerance limits in the one-way random effects model, and constructing upper confidence limits for the exceedance probabilities mentioned in the preceding paragraphs. Although the method of Hewett and Ganser (1997) does not consider between- and within-worker variability, the methods we consider do take into account such variances, and our methods are also applicable to small samples with balanced or unbalanced data. As the concept of the generalized variable method is relatively new, we first explain this approach with applications to normal and lognormal parameters in the following section. Then, we describe the one-way random effects model in the context of this problem, and then identify the probabilities of interest in terms of the model parameters. We apply the generalized variable approach given in Krishnamoorthy and Mathew (2004) and Krishnamoorthy and Guo (2005) for constructing one-sided confidence limits for θ . A confidence interval procedure for η is obtained by transforming the approximate tolerance interval procedures given in Krishnamoorthy and Mathew (2004). As the details of constructing generalized variables for various parameters in the one-way random effects model, and that of constructing tolerance limits, are given in the aforementioned papers, we merely outline the basic methodology in the following section. Finally, we illustrate the interval estimation procedures for the exceedance probabilities using two data sets given in Lyles *et al.* (1997b).

THE GENERALIZED PIVOTAL QUANTITY (GPQ) AND THE GENERALIZED TEST VARIABLE

The generalized P -value approach for hypothesis testing has been introduced by Tsui and Weerahandi (1989) and the generalized confidence interval by Weerahandi (1993). The concepts of generalized P -values and generalized confidence intervals have turned out to be extremely fruitful for obtaining tests and confidence intervals for complex problems where

standard procedures are difficult to apply. In particular, the generalized variable approach is useful to develop a *generalized pivotal quantity* (GPQ) based on which inferential procedures for a parameter of interest can be easily obtained. The classical *pivotal quantity* is a function of a random sample and the parameter of interest, and its distribution does not depend on any unknown parameters, whereas the GPQ is a function of a random variable, its observed value (the known measurements after a sample has been drawn), the parameter of interest and other parameters. The GPQ is constructed so that, for a given sample, its distribution is free of any unknown parameters. However, the frequentist properties of generalized P -values and generalized confidence intervals could depend on unknown parameters. For example, the actual coverage probability of a generalized confidence interval could be different from the assumed confidence level. However based on numerical results, it has been noted that for a wide variety of problems, generalized P -values and generalized confidence intervals do meet the usual requirements in terms of type I error probability and coverage probability; see Krishnamoorthy and Mathew (2003) for results concerning the lognormal distribution, and see also the book by Weerahandi (1995) for a variety of other applications. An attractive feature of many solutions based on generalized P -values and generalized confidence intervals is that the procedures are applicable to small samples, whereas conventional approaches based on, for example, the likelihood method, do require large samples. This will be clear, for example, from the generalized variable solution for the lognormal mean discussed later.

We shall first explain the generalized variable inferential procedure as given in Krishnamoorthy *et al.* (2006). Let X be a random variable whose distribution depends on a scalar parameter of interest θ and a nuisance parameter (parameter that is not of direct inferential interest) ω . Let x denote the observed value of X . That is, x represents the data that has been collected. To obtain a generalized confidence interval for θ , we need a GPQ, denoted by $T_1(X;x,\theta,\omega)$, that is a function of the random variable X , the observed data x , and the parameters θ and ω , and satisfying the following two conditions:

- Given x , the distribution of $T_1(X;x,\theta,\omega)$ is free of the unknown parameters θ and ω ;
- The value of $T_1(X;x,\theta,\omega)$ at $X = x$, namely, $T_1(x;x,\theta,\omega)$ is equal to θ . (3)

The percentiles of $T_1(X;x,\theta,\omega)$ can then be used to obtain confidence intervals for θ . Such confidence intervals are referred to as the generalized confidence intervals. For example, if $T_{1-\alpha}$ denotes the $100(1-\alpha)$ th percentile of $T_1(X;x,\theta,\omega)$, then $T_{1-\alpha}$ is a generalized upper confidence limit for θ . A lower

confidence limit, or two-sided confidence limits can be similarly defined.

Now suppose we are interested in testing the hypotheses

$$H_0 : \theta \geq A \text{ versus } H_a : \theta < A, \quad (4)$$

where θ_0 is a specified quantity. Suppose we can define a *generalized test variable* $T_2(X;x,\theta,\omega)$ satisfying the following conditions:

- i. For a given x , the distribution of $T_2(X;x,\theta,\omega)$ is free of the nuisance parameter ω ;
- ii. The value of $T_2(X;x,\theta,\omega)$ at $X = x$, namely, $T_2(x;x,\theta,\omega)$ is free of any unknown parameters;
- iii. For a given x and ω , the distribution of $T_2(X;x,\theta,\omega)$ is stochastically monotone in θ i.e. stochastically increasing or decreasing in θ . (5)

In general, for a given x and ω , we can take $T_2(X;x,\theta,\omega) = T_1(X;x,\theta,\omega) - \theta$, which is stochastically decreasing in θ . In this case, the generalized P -value for testing equation (4) is given by

$$\begin{aligned} \sup_{H_0} P(T_2(X;x,\theta,\omega) \geq 0) &= \sup_{H_0} P(T_1(X;x,\theta,\omega) \geq \theta) \\ &= P(T_1(X;x,\theta,\omega) \geq \theta_0). \end{aligned}$$

Because the distribution of $T_1(X;x,\theta,\omega)$ is free of any unknown parameters, the generalized P -value at θ_0 can be obtained using a numerical method or estimated using Monte Carlo simulation.

It should be noted that the generalized confidence intervals are not guaranteed to have exact frequentist coverage properties with respect to the distribution of X , and the distribution of the generalized P -values under a null hypothesis of interest may not be uniform $(0, 1)$. However, a number of simulation and numerical studies suggest that the coverage probabilities are very close to the nominal level, and the Type I error rates are close to the nominal level of significance. Hanning *et al.* (2006) showed that the generalized variable procedures are asymptotically exact in many situations.

In general, constructing a GPQ is a non-trivial task. Knowledge about the distribution of some basic statistics involved in the problem is necessary to construct a bona fide GPQ. Assuming that the readers are familiar with the distributional results for sample statistics from a normal distribution, we shall illustrate the procedures for finding a GPQ for a normal mean.

A GPQ for a normal mean

Let X_1, \dots, X_n be a random sample from a $N(\xi, \sigma^2)$ distribution. Define

$$\bar{X} = \frac{1}{n} \sum_{i=1}^n X_i \quad \text{and} \quad S^2 = \frac{1}{n-1} \sum_{i=1}^n (X_i - \bar{X})^2,$$

and let (\bar{x}, s^2) be an observed value of (\bar{X}, S^2) . As \bar{X} and S^2 are sufficient statistics for the normal distribution, we shall construct a GPQ based on them. A GPQ for the mean is obtained, using a sequence of operations and inverse operations, as given below.

$$\begin{aligned} G_{\xi} &= \bar{x} - \frac{\bar{X} - \xi}{\sigma/\sqrt{n}} \frac{\sigma}{\sqrt{n}S} \\ &= \bar{x} - \frac{\bar{X} - \xi}{\sigma/\sqrt{n}} \frac{s}{\sqrt{n}(S/\sigma)} \\ &= \bar{x} - \frac{Z}{(\chi_{n-1}^2/(n-1))^{1/2}} \frac{s}{\sqrt{n}}, \end{aligned} \tag{6}$$

where $Z = \frac{\bar{X} - \xi}{\sigma/\sqrt{n}} \sim N(0,1)$ independently of $\frac{S^2}{\sigma^2} \sim \frac{\chi_{n-1}^2}{n-1}$. Using the result that $Z/(\chi_m^2/m)^{1/2}$ follows a t_m distribution, we can write $G_{\xi} = \bar{x} - t_{n-1} \frac{s}{\sqrt{n}}$ or $G_{\xi} = \bar{x} + t_{n-1} \frac{s}{\sqrt{n}}$, because t_m is distributed symmetrically about zero. We shall now show that G_{ξ} in equation (6) satisfies the requirements in equation (3). Using step 1 of equation (6), we see that the value of G_{ξ} at $(\bar{X}, S) = (\bar{x}, s)$ is ξ . Also, from step 3 of equation (6), we see that, for a given \bar{x} and s , the distribution of G_{ξ} does not depend on any unknown parameters. Therefore, G_{ξ} is a GPQ for the mean ξ . It is easy to see that the lower $\alpha/2$ quantile and the upper $\alpha/2$ quantile of G_{ξ} form the usual t interval for the mean. In other words, inferences on ξ based on the GPQ in equation (6) and the one based on the classical pivotal quantity $(\bar{X} - \xi)/(S/\sqrt{n})$ are the same.

An appealing feature of the generalized variable approach is that one can readily develop a GPQ for a function of several parameters provided a GPQ for each parameter is available. Specifically, if the pair $(G_{\theta_1}, G_{\theta_2})$ forms GPQs for (θ_1, θ_2) , then the GPQ for a function $f(\theta_1, \theta_2)$ is given by $f(G_{\theta_1}, G_{\theta_2})$. As will be seen in the sequel, this particular feature of the generalized variable approach enables us to construct GPQs for various functions of the variance components and the overall mean in a one-way random effects model. As an example, we shall now construct a GPQ for a log normal mean.

A GPQ for a lognormal mean

Let Y_1, \dots, Y_n be a sample from a lognormal distribution with parameters ξ and σ so that the mean is $\exp(\zeta)$, where $\zeta = \xi + \frac{\sigma^2}{2}$. As the mean is a one-one function of ζ , it is enough to find a GPQ for ζ . Let $X_i = \ln(Y_i)$, $i = 1, \dots, n$. Then, the log-transformed data X_1, \dots, X_n can be regarded as a sample from a normal distribution with mean ξ and standard deviation σ . Let \bar{X} and S^2 denote respectively the mean and variance of the sample. As we already developed a GPQ for ξ , we shall now develop a GPQ, denoted by G_{σ^2} , for σ^2 using the fact that $(n-1)S^2/\sigma^2$ has the chi-square distribution with

$df = n - 1$. Let s^2 be an observed value of S^2 . Then, a GPQ is given by

$$G_{\sigma^2} = \frac{\sigma^2}{S^2} s^2 = \frac{s^2}{\left(\frac{\chi_{n-1}^2}{n-1}\right)}.$$

We see from the above expression that the value of G_{σ^2} at $S^2 = s^2$ is σ^2 and the distribution of G_{σ^2} does not depend on any parameter when s^2 is fixed. Thus, G_{σ^2} is a bona fide GPQ for σ^2 . The GPQ for $\zeta = \xi + \frac{\sigma^2}{2}$ is given by $\left(G_{\xi} + \frac{G_{\sigma^2}}{2}\right)$, where G_{ξ} is given in equation (6). Finally, a GPQ for the log-normal mean is given by $\exp\left(G_{\xi} + \frac{G_{\sigma^2}}{2}\right)$. For a given (\bar{x}, s^2) of (\bar{X}, S^2) , the distribution of the GPQ does not depend on any unknown parameters, and so its percentiles can be estimated using Monte Carlo simulation or by numerical integration. Specifically, the $\alpha/2$ and $1 - \alpha/2$ quantiles of the GPQ form a $1 - \alpha$ confidence interval for the lognormal mean. Krishnamoorthy and Mathew (2003) showed that the results based on the GPQ are comparable to those based on the exact method due to Land (1973).

EXCEEDANCE PROBABILITIES, QUANTILES AND TOLERANCE LIMITS

To explain the relationship between exceedance probabilities and quantiles, and to describe the role of tolerance intervals, let us consider a random variable X that is distributed normally with mean μ and variance σ^2 . For a specified limit k , consider the exceedance probability $P(X > k)$. Note that $P(X > k) \geq A$ is equivalent to $P(X \leq k) < 1 - A$. The latter inequality holds if and only if k is less than or equal to the $(1 - A)$ th quantile of X , namely, $\mu + z_{1-A}\sigma$, where z_{1-A} is the $(1 - A)$ th quantile of a standard normal distribution. In other words, statements concerning an exceedance probability translate into statements concerning the quantiles. Thus, the null hypothesis $H_0 : P(X > k) \geq A$ is equivalent to $H_0 : \mu + z_{1-A}\sigma \geq k$.

To see the role of tolerance intervals, let us first recall the definition of an upper tolerance limit. Let \bar{X} and S^2 denote the sample mean and sample variance based on a sample of n observations from the normal distribution. An upper tolerance limit for the normally distributed random variable is a function of \bar{X} and S^2 , denoted by $g(\bar{X}, S^2)$, and is constructed so that at least a proportion p of the normal distribution is below $g(\bar{X}, S^2)$, with confidence, say, $1 - \alpha$. The proportion p is also referred to as the content of the tolerance interval. As we know that a proportion p of the normal distribution is less than $\mu + z_p\sigma$, the upper tolerance limit $g(\bar{X}, S^2)$ is nothing but a $1 - \alpha$ upper confidence limit for $\mu + z_p\sigma$. This is because proportion p of the normal distribution is less than $\mu + z_p\sigma$ which is less than or equal to $g(\bar{X}, S^2)$ with probability $1 - \alpha$. Therefore, at least a proportion p of the normal

distribution is below $g(\bar{X}, S^2)$ with confidence $1 - \alpha$. Thus, testing

$$H_0 : P(X > k) \geq A \text{ versus } H_0 : P(X > k) < A$$

is equivalent to testing

$$H_0 : \mu + z_{1-A}\sigma \geq k \text{ versus } H_0 : \mu + z_{1-A}\sigma < k.$$

Notice that the null hypothesis will be rejected if a $1 - \alpha$ upper confidence limit for $\mu + z_{1-A}\sigma$ (or $1 - A$ content— $1 - \alpha$ coverage upper tolerance limit) is less than k . We refer to Guttman (1970) for more details on tolerance intervals, along with the expression for $g(\bar{X}, S^2)$ given above.

For simplicity, we have presented the above results for the normal distribution, where the observations in the sample are all independent. However, the above results also hold more generally. In fact, the present article deals with observations that follow a one-way random effects model, and are not independent. The case of independent observations is already addressed in Krishnamoorthy *et al.* (2006).

THE ONE-WAY RANDOM EFFECTS MODEL

To describe the problem, let us consider the framework as given in Rappaport *et al.* (1995) and Lyles *et al.* (1997a). Let X_{ij} denote the j th shift-long exposure measurement for the i th worker, $j = 1, \dots, n_i$ and $i = 1, \dots, k$. Let us assume that X_{ij} follows a lognormal distribution so that $Y_{ij} = \ln(X_{ij})$ follows a normal distribution. Under the assumed one-way random effects model, we can write

$$Y_{ij} = \mu + \tau_i + \varepsilon_{ij}, \quad j = 1, \dots, n_i; \quad i = 1, \dots, k, \quad (7)$$

where μ is the overall mean, τ_i represents the random effect due to the i th worker, and ε_{ij} is the random deviation of the i th worker's exposure around that worker's mean. Furthermore, τ_i and ε_{ij} are mutually independent with

$$\tau_i \sim N(0, \sigma_\tau^2) \quad \text{and} \quad \varepsilon_{ij} \sim N(0, \sigma_e^2). \quad (8)$$

Notice that, conditionally given τ_i , Y_{ij} is normally distributed with mean $\mu + \tau_i$ and variance σ_e^2 . Therefore, the mean exposure μ_{x_i} for the i th worker is given by

$$\begin{aligned} \mu_{x_i} &= E(X_{ij} | \tau_i) = E(\exp(Y_{ij}) | \tau_i) \\ &= \exp(\mu + \tau_i + \sigma_e^2/2), \end{aligned} \quad (9)$$

where E denotes the expectation. Also, it follows from equations (7), (8) and (9) that unconditionally,

$$\begin{aligned} Y_{ij} &\sim N(\mu, \sigma_\tau^2 + \sigma_e^2) \quad \text{and} \\ \ln(\mu_{x_i}) &\sim N(\mu + \sigma_e^2/2, \sigma_\tau^2) \end{aligned} \quad (10)$$

Thus, the parameter θ mentioned in equation (1) is a probability that the random variable μ_{x_i} (or $\ln(\mu_{x_i})$) exceeds the OEL (or $\ln(\text{OEL})$), and the parameter η in equation (2) is a probability that the random variable X_{ij} (or Y_{ij}) exceeds the OEL (or $\ln(\text{OEL})$).

GPQS FOR THE OVERALL MEAN AND VARIANCE COMPONENTS IN THE ONE-WAY RANDOM MODEL

As the exceedance probabilities are functions of the overall mean and the variance components, we shall first provide GPQs for these individual parameters. The methods of constructing generalized variables for the mean and variance components, their validity, and the statistical properties of the inferential procedures based on them are well addressed in Krishnamoorthy and Mathew (2002, 2004) and Krishnamoorthy and Guo (2005). As we have already shown that the present problem of exceedance probabilities has one-one relation with that of constructing one-sided tolerance limits, the frequentist coverage probabilities should be similar to those for tolerance limits considered in the aforementioned papers. Specifically, the coverage probabilities of confidence limits are close to the nominal confidence level as long as the one-way random effects model is well fitted for a given sample.

In the following, we shall provide necessary summary statistics and their distributional results that are required to construct GPQs for μ , σ_τ^2 and σ_e^2 . Let

$$\begin{aligned} \tilde{n} &= \frac{1}{k} \sum_{i=1}^k n_i^{-1}, \quad \bar{Y}_i = \frac{1}{n_i} \sum_{j=1}^{n_i} Y_{ij}, \quad \bar{\bar{Y}} = \frac{1}{k} \sum_{i=1}^k \bar{Y}_i, \\ SS_e &= \sum_{i=1}^k \sum_{j=1}^{n_i} (Y_{ij} - \bar{Y}_i)^2 \quad \text{and} \quad SS_{\bar{Y}} = \sum_{i=1}^k (\bar{Y}_i - \bar{\bar{Y}})^2. \end{aligned}$$

Note that SS_e is the usual error sums of squares (or within sums of squares). It is known that

$$\begin{aligned} \bar{\bar{Y}} &\sim N\left(\mu, \frac{\sigma_\tau^2 + \tilde{n}\sigma_e^2}{k}\right), \quad \frac{SS_e}{\sigma_e^2} \sim \chi_{N-k}^2, \quad \text{and} \\ \frac{SS_{\bar{Y}}}{\sigma_\tau^2 + \tilde{n}\sigma_e^2} &\sim \chi_{k-1}^2 \quad (\text{approximately}), \end{aligned} \quad (11)$$

and these three random variables are independent. The former two distributions are exact, and the approximate chi-square distribution associated with $\frac{SS_{\bar{Y}}}{\sigma_\tau^2 + \tilde{n}\sigma_e^2}$ is due to Thomas and Hultquist (1978). Because of this approximate chi-square distribution, some of the properties required for GPQ's will hold only approximately.

Let $(\bar{y}, ss_e, ss_{\bar{y}})$ be an observed value of $(\bar{Y}, SS_e, SS_{\bar{Y}})$. That is, $(\bar{y}, ss_e, ss_{\bar{y}})$ is the computed value of $(\bar{Y}, SS_e, SS_{\bar{Y}})$ based on a given data set.

The generalized variable for the overall mean μ can be constructed as

$$G_\mu = \bar{y} + \frac{\sqrt{k}(\mu - \bar{Y})}{\sqrt{\sigma_\tau^2 + \tilde{n}\sigma_e^2}} \frac{\sqrt{\sigma_\tau^2 + \tilde{n}\sigma_e^2}}{\sqrt{SS_y}} \frac{\sqrt{SS_y}}{\sqrt{k}}$$

$$= \bar{y} + \frac{Z}{\sqrt{\chi_{k-1}^2}} \frac{\sqrt{SS_y}}{\sqrt{k}}, \tag{12}$$

where $Z \sim N(0,1)$ independently of χ_{k-1}^2 . To get the second step, we have used the distributional properties in equation (11). In particular, we have used the approximate chi-square distribution associated with $\frac{SS_y}{\sigma_\tau^2 + \tilde{n}\sigma_e^2}$. We note that the second step in equation (12) holds only as an approximation. Let us verify that G_μ satisfies the conditions (i) and (ii) in equation (3). From step 1 in equation (12), we see that G_μ is equal to μ when $\bar{Y} = \bar{y}$ and $SS_y = ss_y$. Also, we observe from step 2 of equation (12) that, for a given \bar{y} and ss_y , the distribution of G_μ does not depend on any unknown parameters because the joint distribution of (Z, χ_{k-1}^2) does not depend on any unknown parameters.

We can construct the generalized variables for the variance components similarly. For σ_τ , we develop the generalized variable (noting that $\sigma_\tau = \sqrt{\sigma_\tau^2 + \tilde{n}\sigma_e^2 - \tilde{n}\sigma_e^2}$) as

$$G_{\sigma_\tau} = \sqrt{\left(\frac{\sigma_\tau^2 + \tilde{n}\sigma_e^2}{SS_y} ss_y - \frac{\tilde{n}\sigma_e^2}{SS_e} ss_e\right)_+}$$

$$= \sqrt{\left(\frac{ss_y}{\chi_{k-1}^2} - \frac{\tilde{n}ss_e}{\chi_{N-k}^2}\right)_+},$$

where for any number x , $(x)_+ = \max\{0, x\}$, and $N = \sum_{i=1}^k n_i$. To get the second step, we used the result that $\frac{SS_y}{\sigma_\tau^2 + \tilde{n}\sigma_e^2} \sim \chi_{k-1}^2$ independently of $\frac{SS_e}{\sigma_e^2} \sim \chi_{N-k}^2$. It is easy to verify that G_{σ_τ} satisfies the conditions in equation (3). For σ_e^2 , we have $G_{\sigma_e^2} = \frac{\sigma_e^2}{SS_e} ss_e = \frac{ss_e}{\chi_{N-k}^2}$. Again, it is easy to see that $G_{\sigma_e^2}$ satisfies the conditions in equation (3).

Finally, the generalized variable for any function $f(\mu, \sigma_\tau^2, \sigma_e^2)$ can be obtained by replacing μ , σ_τ^2 and σ_e^2 by their generalized variables.

Note that since the chi-square distribution associated with SS_y is only approximate, conditions (i) and (iii) in equation (5) will hold only approximately. However, the extensive numerical results in Krishnamoorthy and Mathew (2004), and Krishnamoorthy and Guo (2005) show that the generalized variable approach is quite satisfactory in the unbalanced case. Though not pointed out in this article, GPQ's are not unique in the unbalanced case. What we have provided is one solution that performs satisfactorily.

AN UPPER LIMIT FOR θ

Using the distributional result in equation (10), we can express θ as

$$\theta = P(\mu_{x_i} > \text{OEL}) = P(\ln(\mu_{x_i}) > \ln(\text{OEL}))$$

$$= 1 - \Phi\left(\frac{\ln(\text{OEL}) - \mu - \sigma_e^2/2}{\sigma_\tau}\right), \tag{13}$$

where $\Phi(\cdot)$ denotes the standard normal distribution function. As already noted, testing hypotheses about θ is equivalent to testing about the $(1 - A)$ th quantile of the mean exposure distribution in equation (10), and the quantile is given by $\mu + \frac{\sigma_e^2}{2} + z_{1-A}\sigma_\tau$, where z_p is the p th quantile of the standard normal distribution. In particular, the hypotheses in equation (1) are equivalent to

$$H_0 : \mu + \frac{\sigma_e^2}{2} + z_{1-A}\sigma_\tau \geq \ln(\text{OEL}) \text{ versus}$$

$$H_a : \mu + \frac{\sigma_e^2}{2} + z_{1-A}\sigma_\tau < \ln(\text{OEL}).$$

For example, if $A = 0.10$, then $\mu + \frac{\sigma_e^2}{2} + z_{1-A}\sigma_\tau = \mu + \frac{\sigma_e^2}{2} + 1.282\sigma_\tau$ is the 90th percentile of the distribution of $\ln(\mu_{x_i})$. If a 95% upper confidence limit for $\mu + \frac{\sigma_e^2}{2} + z_{.90}\sigma_\tau$ is less than $\ln(\text{OEL})$, then we can conclude that $\theta < 0.10$ at the level of significance 0.05. Large sample solutions to the above testing problem are given in Lyles *et al.* (1997a,b). Tests based on the generalized variable approach are given in Krishnamoorthy and Mathew (2002) and Krishnamoorthy and Guo (2005).

Notice that θ in equation (13) is a function of $(\mu, \sigma_e^2, \sigma_\tau)$, and so we can write θ as $\theta(\mu, \sigma_e^2, \sigma_\tau)$. If G_μ , G_{σ_τ} and $G_{\sigma_e^2}$ are the generalized variables for μ , σ_τ and σ_e^2 , respectively, then a generalized variable for θ is given by

$$\theta(G_\mu, G_{\sigma_\tau}, G_{\sigma_e^2}) = 1 - \Phi\left(\frac{\ln(\text{OEL}) - G_\mu - G_{\sigma_e^2}/2}{G_{\sigma_\tau}}\right), \tag{14}$$

where

$$G_\mu = \bar{y} + \frac{Z}{\sqrt{\chi_{k-1}^2}} \sqrt{\frac{ss_y}{k}},$$

$$G_{\sigma_\tau} = \sqrt{G_{\sigma_\tau^2}} = \sqrt{\left(\frac{ss_y}{\chi_{k-1}^2} - \frac{\tilde{n}ss_e}{\chi_{N-k}^2}\right)_+} \text{ and}$$

$$G_{\sigma_e^2} = \frac{ss_e}{\chi_{N-k}^2}, \tag{15}$$

where $N = \sum_{i=1}^k n_i$ and $(x)_+ = \max\{0, x\}$. Notice that the generalized variable G_{σ_τ} could be zero; however, this does not cause any problem in computing equation (14) because the argument of the normal distribution function Φ when $G_{\sigma_\tau} = 0$ is either $-\infty$ or ∞ depending on the sign of the numerator of the

argument. In either case, the distribution function is defined and $\Phi(-\infty) = 0$ and $\Phi(\infty) = 1$.

We see from equation (15) that, for a given $(\bar{y}, ss_e, ss_{\bar{y}})$, the distributions of G_{μ} , $G_{\sigma_{\tau}}$ and $G_{\sigma_e^2}$ do not depend on any unknown parameters; so the distribution of $\theta(G_{\mu}, G_{\sigma_{\tau}}, G_{\sigma_e^2})$ is also free of unknown parameters. Even then, it is not easy to find the joint sampling distribution of all the independent random variables involved in $\theta(G_{\mu}, G_{\sigma_{\tau}}, G_{\sigma_e^2})$. However, one can use Monte Carlo simulation as given in the following algorithm to estimate the percentiles of $\theta(G_{\mu}, G_{\sigma_{\tau}}, G_{\sigma_e^2})$.

Algorithm 1

For a given data set, compute \bar{n}, \bar{y}, ss_e and $ss_{\bar{y}}$
 For $i = 1, m$
 Generate $Z \sim N(0,1)$, χ_{k-1}^2 and χ_{N-k}^2
 compute $G_{\mu}, G_{\sigma_{\tau}}$ and $G_{\sigma_e^2}$ using equation (11)
 compute $Q = \ln(\text{OEL}) - G_{\sigma_{\tau}} - G_{\sigma_e^2}/2$
 if $G_{\sigma_{\tau}} = 0$ and $Q < 0$ then
 set $T_i = 1$
 else if $G_{\sigma_{\tau}} = 0$ and $Q > 0$ then
 set $T_i = 0$
 else set $T_i = 1 - \Phi\left(\frac{Q}{G_{\sigma_{\tau}}}\right)$
 [end do loop]

The $100(1-\alpha)$ th percentile of T_i 's is a $1-\alpha$ upper limit for θ . Based on our experience, we recommend simulation consisting of at least 100 000 (i.e. the value of m in Algorithm 1) runs to get consistent results regardless of the initial seed used for random number generation. The above algorithm can be easily programmed in any programming language. A SAS program for computing one-sided limits for θ is posted at <http://www.ucs.louisiana.edu/~kxk4695>. Interested readers can download these files from this website.

AN UPPER LIMIT FOR η

Notice that the probability that an individual exposure measurement exceeds the OEL is given by $\eta = P(X_{ij} > \text{OEL})$. Since $Y_{ij} = \ln(X_{ij}) \sim N(\mu, \sigma_{\tau}^2 + \sigma_e^2)$, we have

$$\begin{aligned} \eta &= P(X_{ij} > \text{OEL}) = P(Y_{ij} > \ln(\text{OEL})) \\ &= 1 - \Phi\left(\frac{\ln(\text{OEL}) - \mu}{\sqrt{\sigma_{\tau}^2 + \sigma_e^2}}\right). \end{aligned} \quad (16)$$

As $Y_{ij} = \ln(X_{ij}) \sim N(\mu, \sigma_{\tau}^2 + \sigma_e^2)$, its $(1-A)$ th quantile is given by $\mu + z_{1-A}\sqrt{\sigma_{\tau}^2 + \sigma_e^2}$. Therefore, testing $H_0 : \eta \geq A$ versus $H_a : \eta < A$ is equivalent to testing

$$\begin{aligned} H_0 : \mu + z_{1-A}\sqrt{\sigma_{\tau}^2 + \sigma_e^2} &\geq \ln(\text{OEL}) \text{ versus} \\ H_a : \mu + z_{1-A}\sqrt{\sigma_{\tau}^2 + \sigma_e^2} &< \ln(\text{OEL}). \end{aligned} \quad (17)$$

The null hypothesis in equation (2) will be rejected at the level α if a $1 - \alpha$ upper confidence limit for $\mu + z_{1-A}\sqrt{\sigma_{\tau}^2 + \sigma_e^2}$ is less than $\ln(\text{OEL})$.

As noted earlier, the above hypotheses can be tested by comparing an upper tolerance limit for $N(\mu, \sigma_{\tau}^2 + \sigma_e^2)$ with $\ln(\text{OEL})$, where the content of the tolerance interval is to be $1 - A$, and the confidence level is to be $1 - \alpha$. Towards this, we note that Krishnamoorthy and Mathew (2004) provided such an approximate upper tolerance limit, and is given by

$$\begin{aligned} U(A) &= \bar{y} + t_{k-1, 1-\alpha}(\delta) \sqrt{\frac{ss_{\bar{y}}}{k(k-1)}}, \text{ with} \\ \delta &= z_{1-A} \left(k + \frac{k(k-1)(1-\bar{n})ss_e}{N-k} F_{k-1, N-k, \alpha} \right)^{\frac{1}{2}}, \end{aligned} \quad (18)$$

where $t_{m,p}(\delta)$ is the p th quantile of a noncentral t distribution with $df = m$ and noncentrality parameter δ , and $F_{k-1, N-k, \alpha}$ denotes the α th quantile of an F distribution with degrees of freedoms $k-1$ and $N-k$.

A $1 - \alpha$ upper confidence bound for η can be obtained by identifying the set of values of A for which the null hypothesis in equation (17) will be accepted. Specifically, the maximum value of A for which the null hypothesis in equation (17) is accepted, or equivalently $U(A)$ satisfying $U(A) \geq \ln(\text{OEL})$, is a $1 - \alpha$ upper bound for η . Notice that δ in equation (18) is a decreasing function of A while the other quantities are fixed, because z_{1-A} is decreasing with increasing A . Furthermore, for a given m and p , it is known that $t_{m,p}(\delta)$ is an increasing function of δ . As a result, $U(A)$ in equation (18) is a decreasing function of A , and the maximum value of A for which $U(A) \geq \ln(\text{OEL})$ is the solution of the equation $U(A) = \ln(\text{OEL})$. Thus, a $1 - \alpha$ upper limit for η is the solution (with respect to A) of the equation

$$U(A) = \bar{y} + t_{k-1, 1-\alpha}(\delta) \sqrt{\frac{ss_{\bar{y}}}{k(k-1)}} = \ln(\text{OEL}). \quad (19)$$

Write

$$\begin{aligned} \delta &= z_{1-Ac}, \\ \text{where } c &= \left(k + \frac{k(k-1)(1-\bar{n})ss_e}{N-k} F_{k-1, N-k, \alpha} \right)^{\frac{1}{2}}. \end{aligned} \quad (20)$$

Then, from equation (19), we have

$$t_{k-1, 1-\alpha}(z_{1-Ac}) = (\ln(\text{OEL}) - \bar{y}) \sqrt{\frac{k(k-1)}{ss_{\bar{y}}}}. \quad (21)$$

The above equation can be solved for A using available PC calculators as shown in the example section below.

It should be noted that many other approaches are available for computing an upper tolerance limit in the one-way random model; see for example, Mee and Owen (1983), Bhaumik and Kulkarni (1996), and Liao *et al.* (2005). The first two references deal with the balanced data situation only, whereas Liao *et al.* (2005) also consider the unbalanced situation. We have chosen to use the results in Krishnamoorthy and Mathew (2004) since their approximate upper tolerance limit has an explicit expression, and hence is easy to compute. Overall, their approximation is quite accurate, as noted in Krishnamoorthy and Mathew (2004).

EXAMPLES

We shall now illustrate the methods of the preceding sections using two sets of shift-long exposure data reported in Tables D2 and D3 of Lyles *et al.* (1997b). The data in Tables D2 and D3 represent nickel dust exposure measurements on a sample of maintenance mechanics from a smelter, and on a sample of maintenance mechanics from a mill, respectively. The data were collected from samples of workers from a nickel producing facility. For these data sets, we computed the values of \bar{y} , \bar{n} , $ss_{\bar{y}}$ and ss_e as given in Tables 1 and 2. An upper limit θ can be computed by plugging these values in the generalized variables in equation (14) and then using Algorithm 1. To compute the 95% upper limits for θ , we used Algorithm 1 with $m = 100\,000$.

The results for the group of maintenance mechanics from a smelter are given in Table 1. Here, we see that the 95% upper limit for θ is 0.0004. That is, <0.04% of mean exposures exceed the OEL.

To compute the 95% upper limit for η , we need to compute the value of c in equation (20). Using

the statistics in Table 1, and $F_{22,11,.05} = 0.4428$, we computed

$$c = \left(k + \frac{k(k-1)(1-\bar{n})}{N-k} \frac{ss_e}{ss_{\bar{y}}} F_{k-1, N-k, \alpha} \right)^{\frac{1}{2}}$$

$$= \left(23 + \frac{23(22)(1-0.855)}{34-23} \frac{2.699}{16.081} (.4428) \right)^{\frac{1}{2}}$$

$$= 4.9112.$$

Thus, we have from equation (21) that

$$t_{k-1, 1-\alpha}(z_{1-A}c) = t_{22, .95}(z_{1-A}(4.9112))$$

$$= 3.863 \sqrt{\frac{23(22)}{16.081}} = 20.6595. \quad (22)$$

Using the online calculator (<http://calculators.stat.ucla.edu/cdf/>), we computed $z_{1-A}(4.9112) = 15.1994$ or $z_{1-A} = 3.0948$. The last equation implies that $1 - A = \Phi(3.0948)$ or $A = 0.0010$. Thus, a 95% upper limit for η is 0.001. This means that <0.1% of exposure measurements exceed the OEL. To compute a 99% upper limit, we have to use $F_{22,11,.01} = 0.3141$. Using this value, we computed c as 4.8323. Then solving the equation $t_{22,.99}(z_{1-A}(4.8323)) = 20.6595$, we get $z_{1-A} = 13.1995/4.8323 = 2.7315$. This yields a 99% upper limit for η as 0.0032.

Note: The online calculator mentioned above or the StatCalc 2.0 by Krishnamoorthy (2006) posted at <http://www.ucs.louisiana.edu/~kxk4695> computes the missing value satisfying the equation $P(t_m(\delta) \leq x) = q$ when the other three values are given. In our case, δ is the missing value. To solve equation (22), we use $m = 22$, $x = 20.6595$ and $q = 0.95$. Using these values, we get $\delta = z_{1-A}(4.9112) = 15.1994$.

In Table 2, we present the results for the exposure data collected from a group of maintenance mechanics from a mill. The 95% (99%) upper limit

Table 1. Upper limits for $\theta = P(\mu_{x_i} > \text{OEL})$ and for $\eta = P(X_{ij} > \text{OEL})$ based on nickel exposure data in Table D2 of Lyles *et al.* (1997b); $k = 23$ and $N = 34$; OEL = 1 mg/m3

\bar{y}	\bar{n}	$ss_{\bar{y}}$	ss_e	Upper limit for θ		Upper limit for η	
				95%	99%	95%	99%
-3.683	0.855	16.081	2.699	0.0004	0.0020	0.0010	0.0032

Table 2. Upper limits for $\theta = P(\mu_{x_i} > \text{OEL})$ and for $\eta = P(X_{ij} > \text{OEL})$ based on nickel exposure data in Table D3 of Lyles *et al.* (1997b); $k = 20$ and $N = 28$; OEL = 1 mg/m3

\bar{y}	\bar{n}	$ss_{\bar{y}}$	ss_e	Upper limit for θ		Upper limit for η	
				95%	99%	95%	99%
-4.087	0.854	19.681	9.801	0.0002	0.0045	0.0028	0.0084

for θ is 0.0002 (0.0045). We also computed 95% (99%) upper limit for η as 0.0028 (0.0084).

Remark: We would like to point out that the above data were used by Lyles *et al.* (1997b) and Krishnamoorthy and Guo (2005) for testing $H_0: \theta \geq A$ versus $H_0: \theta < A$. Lyles *et al.* used a large-sample method, and Krishnamoorthy and Guo used a generalized variable approach. If $A = 0.1$, then both approaches showed that $\theta < A$, at significance level 0.05, for both sets of data. However, if $A = 0.05$, then to conclude whether or not $\theta < A$, one has to carry out the test procedures again at significance level 0.05. On the other hand, in our present setup, the computed 95% upper limits for θ enable us to conclude $\theta < 0.05$ for both problems at level 0.05. This is certainly an advantage of setting one-sided limits for θ .

CONCLUDING REMARKS

The use of a model that includes a random effect is a convenient and practically useful approach to capture the heterogeneity among the exposed group. In this article, we concentrated on a situation where the one-way random effects model is appropriate for the log-transformed exposure data. Problems of interest for the purpose of exposure monitoring now reduce to inference problems concerning the unknown parameters of the model: the overall mean and the two variance components. As opposed to standard applications of the one-way random effects model, where the problems of interest deal with the individual parameters, exposure monitoring applications require inference on parametric functions that involve all the unknown parameters. Novel approaches are required to deal with such problems, especially since small sample procedures are desired. Here, we have investigated the generalized inference idea to come up with confidence intervals and tests for two parametric functions of interest: the probability that the mean exposure of an individual worker exceeds the OEL, and the probability that the exposure of a worker exceeds the OEL. The latter parametric function also comes up in connection with the computation of tolerance intervals. We have also illustrated our methodology by applying them for the analysis of actual exposure data.

For the problems mentioned in this article, large sample confidence bounds could be easily obtained using standard methods; see Lyles *et al.* (1997a) for details. However, the numerical results in Krishnamoorthy and Mathew (2002) show that the generalized variable approach has a definite edge in terms of maintaining the type I error probability of the tests, and coverage probability of the confidence intervals. As should be clear from the computational algorithm mentioned in this article, the generalized variable approach is quite easy to

implement. Furthermore, the fact that they are also applicable to small samples make them attractive options for analysing exposure data.

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