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Commentary

Toward Better Exposure Assessment Strategies—The New NIOSH Initiative

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NIOSH has embarked on a project to update its exposure sampling strategies manual. The current NIOSH strategy has a number of limitations. This is an opportunity to develop a robust and comprehensive exposure assessment strategy. Some of the key features of such a strategy are outlined. The importance of accurate professional judgment and exposure modeling is discussed. Bayesian statistics offers a rational approach to integrating sampling data, professional judgments, and the outputs of exposure models in a comprehensive framework.

Keywords: Bayesian statistics; comprehensive exposure assessment; exposure assessment strategies; NIOSH strategy; professional judgment; task-based exposure assessment

INTRODUCTION

About a year and a half ago, National Institute for Occupational Safety and Health (NIOSH) embarked on a long-overdue initiative to update its Occupational Exposure Sampling Strategies Manual (OESSM) (Leidel *et al.*, 1977). This manual, published in 1977, has been the basis of the US Occupational Safety and Health Administration's (OSHA's) compliance enforcement strategy. However, it has outlived its usefulness to the larger occupational hygiene community that has developed several alternative sampling strategies based on new research over the past 30 years. The new NIOSH initiative offers an opportunity to examine the state of knowledge regarding exposure assessment and to help develop a modern, robust exposure assessment strategy. To this end, NIOSH organized a workshop in Washington, DC in November 2007 and sought inputs from a broad-array of stakeholders including academics, independent consultants and representatives from industry and government. I describe below some of the topics that were discussed and my own views regarding them.

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LIMITATIONS OF THE EXISTING NIOSH STRATEGY

Exposure assessment can be carried out for a variety of reasons, and the design of the strategy should be dependent on the context. The most common reason is routine monitoring of worker exposures to chemical and physical hazards in the workplace and comparison of these exposures with an occupational exposure limit (OEL). This can be done by occupational hygienists employed by a company for routine risk management or by regulatory enforcement agencies to determine whether exposure levels meet legal standards. Another important reason might be to determine a relationship between exposure and health outcome in an occupational epidemiology study. The purpose of conducting an exposure assessment also drives the choice of the decision statistic in the analysis. For example, if the exposure assessment is done in the context of an epidemiological study, some measure of central tendency such as the arithmetic mean is appropriate. In contrast, if exposure assessment is done for routine risk management, i.e. to ensure that most of the workers have acceptable exposure levels, then some upper percentile of the exposure distribution (e.g. the 95th percentile) may be a better decision statistic. Exposure variability is one of the most important factors that should be considered while designing exposure assessment strategies. Exposures vary between workers with the same job title but with differences in the tasks that comprise the job; even for workers doing the same task, exposures vary between workers and over time, shift and location. The sampling strategy should be capable of estimating this variability. In addition, the sampling strategy should be effective (i.e. provide correct exposure decisions) and efficient (i.e. use a minimum of resources). These requirements of effectiveness and efficiency are typically at odds with each other, and any exposure strategy needs to strike a balance between these competing needs.

It is instructive to view the NIOSH strategy through the prism of the requirements described above. The OESSM describes a strategy to assess compliance on a single day for a single worker, e.g. a maximum risk employee. This is achieved typically by using one or at most two measurements. Compliance is tested by a measurement-by-measurement comparison with the OEL, thus requiring no understanding of exposure variability or the statistical calculations needed to estimate it. Therefore, only sampling and analytical variability associated with each measurement is accounted for despite the fact that this is miniscule compared to environmental variability (Nicas *et al.*, 1991). Tuggle (1981) reported that the strategy could not reliably detect poorly controlled exposures, calculating a power of only 50% to detect a clearly unacceptable exposure profile with a 25% exceedance fraction. Thus, while the NIOSH strategy is very efficient (requiring very few measurements), it is ineffective because it fails in the very task it sets out to accomplish, i.e. accurately identify work scenarios that are not in compliance. Rappaport (1984) showed that compliance status depends very strongly on the number of measurements and that the strategy perversely provides a disincentive to increasing the number of measurements. It is obvious from the vintage of the references above that these are not new criticisms and these rather major flaws in the strategy are well known. The strategy is also limited in that substances with no OELs or dermal hazards cannot be evaluated using this strategy.

In addition to not accomplishing its stated objective, the NIOSH strategy produces data that typically cannot be used for other purposes, e.g. risk management or epidemiology. For instance, by focusing sampling on 'maximum risk employees', the strategy will likely overestimate exposures and underestimate variability and be unrepresentative for epidemiological purposes. However, there are notable exceptions to this, e.g. Hall *et al.* (2002) analyzed compliance- and research-monitoring data for wood dust in British Columbia sawmills and found that compliance samples did not overestimate the mean exposure levels at the job level.

TOWARD A COMPREHENSIVE EXPOSURE ASSESSMENT STRATEGY

In recent years, there has been a substantial interest and work on developing exposure assessment strategies that evaluate health risks from all substances for all workers for all days instead of a hypothetical maximum risk worker on a single day for substances with legal exposure limits. Such a comprehensive exposure assessment strategy would characterize exposure variability and produce data that can also be used for baseline monitoring, surveillance, deciding whether to start or discontinue specific exposure control measures and for epidemiology. While there is general agreement on this goal, there is still much debate about the means of accomplishing it.

The observational approach, proposed by Roach (1953), Ashford (1958) and Corn and Esmen (1979), relies on a prospective assignment of workers to groups on the basis of similarity of work, hazardous agents and environmental characteristics. Measurement data are obtained from such similarly exposed groups (SEGs) *post facto*. Kromhout *et al.* (1993) and Rappaport *et al.* (1993) correctly pointed out that such a scheme assumes that the variability in exposure between workers is small and is driven only by the variables characterized in the observational phase of the exposure assessment, i.e. within-worker variability. However, in many instances, exposure variability is driven by differences in individual work practices, i.e. between-worker variability, that is not captured by the observational approach. Rappaport *et al.* proposed classification schemes where either the entire population of workers is randomly sampled and subsequently divided into similar groups or workers in a primary building or with similar job titles are sampled and then divided into groups (Rappaport *et al.*, 1995). These sampling-based approaches require multiple measurements of every sampled worker in an SEG and mixed models to statistically estimate the between- and within-worker components of variance and fixed effects that are determinants of exposure. However, this may not always be feasible due to resource constraints. As an example, even a medium-scale manufacturing facility with ~100 exposure tasks and ~15 to 20 chemicals per task will result in >1500 chemical task combinations (i.e. SEGs) and obtaining multiple measurements from several workers in each SEG could rapidly become infeasible. An encouraging development on this front is the use of self-assessment methods that enable workers to measure their own exposures and thereby reduce the dependence on occupational hygienists for sampling (Egeghy *et al.*, 2000, 2002; Liljelind *et al.*, 2003). However, these are preliminary findings and further research is needed to establish the feasibility of such techniques in a broad range of situations.

The strategy proposed by the American Industrial Hygiene Association (AIHA) (Mulhausen and Damiano, 1998; Bullock and Ignacio, 2006) combines the observational and sampling approaches for defining SEGs. The exposure profile, or distribution of exposures, for an SEG is classified into one of five exposure categories: 0, 1, 2, 3 or 4, corresponding to trivial (or very low) exposure, highly controlled, well-controlled, controlled and poorly controlled exposures. The categories are defined on the basis of whether the 95th percentile of the exposure distribution for an SEG is <1% of the OEL, 1–10, 10–50, 50–100 or >100% of the OEL, respectively. The observational approach is used as a first step to classify workers while recognizing that a potential for misclassification exists. However, the risks of such potential misclassification are negligible for some SEGs and significant for others. The SEGs in the latter category, referred to as critical SEGs, would be monitored more thoroughly for evaluating within- and between-worker variability. Several rules of thumb can be used for identifying such critical SEGs. SEGs with exposure profiles above the OEL should not be sampled as the resources might be better spent on controlling these exposures. SEGs with exposures <10% of the OEL need not be sampled. However, sampling is appropriate for all SEGs that have exposure profiles >10% of the OEL, and the strategy recommends 6–10 measurements per SEG. The power of this strategy to detect a clearly unacceptable exposure profile with a 25% exceedance fraction is >90% for six measurements and increases to >99% for 10 measurements (Hewett, 2005). Although the AIHA strategy does not explicitly call for it, one can envision that for SEGs that have exposure profiles even closer to the OEL (e.g. between 50 and 100% of the OEL), multiple measurements per worker might be required to thoroughly characterize the components of variance. Such an approach would strike a reasonable balance between using the professional judgments of occupational hygienists to classify SEGs and obtaining sufficient measurements in situations that warrant it.

PROFESSIONAL JUDGMENT

The hybrid approach outlined above relies on the professional judgments of occupational hygienists for the initial classification of workers into SEGs. While this has been the case for a long time, there has been relatively little research into the accuracy of such subjective judgments. Even more troubling is the fact that such judgments are rarely documented and there is a lack of transparency regarding the basis of the judgments. While the use of accurate professional judgment can certainly be useful in integrating limited monitoring data and the hygienists' knowledge of the determinants of exposure, inaccuracies in the judgments could lead to inadequate levels of protection for some workers or resources being wasted on other workers. Preliminary findings from a NIOSH-funded study on professional judgments of hygienists suggest that hygienists tend to underestimate exposures, although focused training seems to remove this bias substantially (Ramachandran, 2005). This is an area where more research effort is needed to quantify the accuracy of hygienists and to develop methods to overcome systematic biases in their judgments and feedback loops for continuous improvements over time. It is also important that practitioners document every subjective exposure judgment that they make (preferably in quantitative terms) and the rationale behind it.

MODELING AND DETERMINANTS OF EXPOSURE

Occupational exposure data are often collected without sufficient information about the workplace to use the data effectively for exposure assessment purposes. Knowledge of these determinants of exposure can significantly improve our understanding of the variability in exposure measurements and therefore it is critical to improve the collection of appropriate data elements with exposure measurements. Details of specific recommendations for workplace data can be found in the Joint ACGIH® AIHA Task Group on Occupational Exposure Databases (1996). Exposure modeling has been a neglected area of exposure assessment, with very little emphasis on it within industry and negligible support for research from governmental funding agencies. However, this situation is expected to change dramatically with the advent of the REACh regulations in the European Union that require assessing exposures in a variety of exposure scenarios where monitoring may not be feasible. This requires quantitative knowledge of exposure determinants and mathematical exposure models that are appropriate to the scenario (e.g. see Tielemans *et al.*, 2007). Though the profession has for long paid lip service to the importance of a thorough knowledge of the determinants of exposure on the part of the hygienist, most companies do not collect such information routinely. Even basic data such as ventilation rates and pollutant generation rates are hard to come by in most situations.

However, if hygienists were required to document each exposure judgment they made along with the rationale behind it, there would be a greater incentive to systematically document the determinants of exposure and even measure them routinely. This will have two salutary effects—it will improve the hygienists' understanding of their workplace and thereby their judgments, and secondly, the knowledge of model input parameters will allow them to use some readily available exposure models which, in turn, will also improve subjective exposure judgments. There is one important caveat to this rosy scenario—most extant models have not been empirically validated. This is an important challenge for the exposure assessment community to meet. The impetus provided by REACh may help in this regard.

TASK-BASED EXPOSURE ASSESSMENT

Measuring exposures due to individual tasks and using these to estimate full-shift averages rather than measure full-shift averages directly has become a widespread practice. The rationale for such task-based exposure assessment is that allows the evaluation of the contribution of specific tasks to overall exposures and thus helps focus control efforts on the major contributors. However, Seixas *et al.* (2003) showed in a study of noise exposures that there was remarkably poor correlation between the weighted sum of task-based exposures and full-shift exposures. The method could not predict individual exposures even if the tasks performed during a shift were known.

An assumption made by proponents of task-based exposure assessment is that if exposures for each task were controlled to be within the OEL, then the full-shift exposure would also be below the OEL. This claim is interesting and, if empirically proven true, could simplify exposure assessment. There is clearly a potential research agenda to not only repeat the analysis of Seixas *et al.* (2003) in other workplaces for other pollutants but also validate the claim described above.

THE BAYESIAN FRAMEWORK

The Bayesian statistical framework has the potential for offering a unified approach to incorporating many of issues discussed above. Conceptually, Bayes theorem allows the synthesis of information from several sources in a probabilistic manner. For example, subjectively assigned exposures or exposure categories (in probabilistic format) can be refined with information obtained from more objective but limited monitoring data. The initial estimate of exposure called the prior in Bayesian parlance can also be obtained through an exposure model. The prior is then updated using monitoring data (that are used to construct a likelihood function) to yield the more refined posterior exposure estimate. The approach is generalizable for use in exposure reconstruction for epidemiological studies (e.g. Ramachandran, 2001; Wild *et al.*, 2002; Sottas *et al.*, 2005), refining exposure determinants (e.g. Ramachandran *et al.*, 2003) and routine exposure management and decision making (e.g. Hewett *et al.*, 2007). It rigorously accounts for not only the variability in exposure monitoring data but also the uncertainty in professional judgments and modeling estimates. The framework offers sufficient advantages to be considered an integral component of a comprehensive exposure assessment strategy.

WHERE DO WE GO FROM HERE?

The existing NIOSH strategy is outdated since it focuses exclusively on compliance, does not properly account for exposure variability and has a low power to detect clearly unacceptable exposure profiles (i.e. profiles with high exceedance fractions).

An updated NIOSH manual on exposure assessment strategy will be of interest to occupational hygienists worldwide. As I have argued in this commentary, a well-formulated strategy should contain the following elements.

(i) A comprehensive exposure assessment strategy, i.e. one that characterizes exposures to all substances over an extended period of time, is desirable. Such a strategy should characterize exposure variability and can be used for multiple purposes, e.g. baseline monitoring, evaluating control strategies and for epidemiology. Thus, such a strategy can be used to estimate upper percentiles of the exposure distribution (for risk management) as well as measures of central tendency (for epidemiology). The AIHA strategy is an example of such a comprehensive exposure assessment strategy.

(ii) Professional judgments made by occupational hygienists or the outputs of exposure models can be used to create SEGs and classify them into exposure categories relative to an OEL. The potential for exposure misclassification using such professional judgments can be significant for some exposure categories; for these categories, a sufficient number of monitoring data are needed to characterize the exposure profile. For critical SEGs, it may be necessary to characterize within- and between-worker variability.

(iii) The Bayesian statistical framework offers a rational and transparent approach to exposure analysis that is consistent with the way occupational hygienists intuitively combine their professional judgments with monitoring data.

Research efforts need to be devoted to more fully developing this framework for use in occupational exposure assessment. Additional issues relating to the accuracy of professional judgments, the use of models in exposure decision making, the effectiveness of training in improving professional judgments and the efficacy of task-based exposure assessments in estimating full-shift exposures also need substantial amounts of further research.

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