Letter to the Editor: Scientific Rigor Required for a Re-Examination of Exchange Rate for Occupational Noise Measurements Re: Dobie, R.A., & Clark, W.W. (2014) Exchange Rates for Intermittent and Fluctuating Occupational Noise: A Systematic Review of Studies of Human Permanent Threshold Shift, *Ear Hear*, *35*, 86–96

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The recent article by Dobie and Clark (2014) on "Exchange rates for intermittent and fluctuating occupational noise: A systematic review of studies of human permanent threshold shift" aimed to compare the suitability of a 3-dB versus 5-dB exchange rate (ER) in predicting hearing loss from nonimpulsive intermittent or fluctuating noise exposures by reviewing studies of human noise-induced permanent threshold shift. The authors concluded that 3-dB ER systematically overestimates the risk of noise-induced hearing loss for intermittent or fluctuating noise. We contend that the authors did not arrive at their conclusions through an appropriate investigation. The article used flawed methodologies in the treatment and analysis of the data/studies and drew conclusions that were not substantiated by the cited data.

The authors indicated that their review did not aim to make recommendations for the regulation of occupational noise but suggested that their review provided evidence for a re-examination of recommendations in their concluding remarks. The National Institute for Occupational Safety and Health (NIOSH) maintains its recommendation of the 3-dB ER to provide sufficient protection for the many variations of continuous, intermittent, and fluctuating noise exposure scenarios encountered in the workplace. In view of the advances in noise measurement and the studies' other weaknesses, we question the suitability of revisiting a narrow segment of the human evidence (excluding robust animal studies and temporary threshold shift studies) based on outdated methodologies to address such an important issue.

The most appropriate ER for predicting hearing loss from noise exposure varies based on the level and duration of the noise. In fact, the 1966 and the 1993 reports by the National Research Council Committee on Hearing, Bioacoustics, and Biomechanics (CHABA) on damage-risk criteria for noise observed that ERs from 0 to 11 dB best fit the damage caused by long- versus short-duration exposures. In addition, exposures of higher frequency spectra necessitated smaller ERs (Kryter et al. 1966; National Research Council [NRC] 1993). Fluctuating and intermittent noise exposures have long been recognized as producing less hearing loss due to the physiological recovery of the auditory mechanism during quiet periods; however, a correction for intermittency has been difficult to define because the protective effect varies based on a number of variables including the spectral content of the noise, the noise level during the "quiet" period, and the interval between exposures (Suter 1992). None of these variables were available in the studies selected by Dobie and Clark nor are we aware of any studies that have sufficiently evaluated the interaction of these variables.

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METHODOLOGICAL CONCERNS

The term "systematic" review implies a well-defined, rigorous approach that includes a clearly defined question, identification of relevant studies, assessment of study quality, and synthesis of evidence through an explicit methodology designed to minimize bias (Khan et al. 2003). Several of these features are weak or lacking in the review by Dobie and Clark. Although Dobie and Clark clearly outlined their study inclusionary criteria, they appeared to selectively follow them. For example, the authors required studies to have "exposures that were sufficiently brief, intermittent, or fluctuating within a work day" that exposure estimates based on a 3-dB versus 5-dB ER "would be expected to differ by more than 1 dB" (p. 87). However, three of the included studies (Holmgren et al. 1971; Johansson et al. 1973; Thierry et al. 1978) did not provide sufficient data to estimate time-weighted averages (exposures based on the 5-dB ER). Also, one study (NIOSH 1982) did not allow estimation of the L_{Aeq8h} (exposures based on the 3-dB ER). The authors stated that the differences between the 3-dB and 5-dB exposure calculations in the Martin et al. (1975) study were "minimal," yet they included this study in Table 1 and reported its findings as "inconclusive." Another inclusion criterion specified that studies must include "hearing threshold data for workers whose ages, sexes, and career duration (in years) was [sic] specified or could be estimated" (p. 88). However, Sataloff et al. (1969) was included even though it reported that "career durations were not specified" in this study (p. 89). Career durations were not mentioned for most of the other included studies.

Applying eligibility criteria in systematic reviews always involves judgment (Higgins & Green 2011). To limit the introduction of bias through this process, two raters working independently should select studies in a review; often a third rater is required to adjudicate conflicts based on a predefined procedure. Dobie and Clark excluded at least five studies that they believe

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did not meet the eligibility criteria because of reporting issues suggesting imprecise exposure levels or insufficient data to estimate exposure. Although poor reporting in original studies is always an issue when conducting systematic reviews, Dobie and Clark could have considered additional strategies to address this problem, such as attempting to contact authors or presenting the study findings grouped by certainty of exposure level estimates.

Dobie and Clark did not conduct a formal assessment of study quality nor did they evaluate the risk of bias. No criteria were defined to determine the validity and generalizability of the results of the included studies. Modern systematic reviews make use of evaluation tools to appraise the quality of included studies and assess the strength of inferences drawn from them (Higgins & Green 2011). Quality should be assessed across multiple domains, including the risk of bias (study limitations from an internal validity perspective), precision (sample size, effect size), consistency (direction and magnitude of effect), and generalizability (AHRQ 2002; IOM 2011). To evaluate the risk of bias, careful consideration must be given to the specific design of included studies, which Dobie and Clark do not provide in their review. No systematic attempt to evaluate study quality is reported related to the control of confounding variables, subject selection criteria, suitability of exposure assessment, quality of the audiometry, or statistical power. Only one study included more than 1000 subjects and three studies included less than 100 workers. Dobie and Clark did not include study quality as a criterion for eligibility, and studies were therefore not excluded from the review solely for poor quality. Studies of poor quality or high risk of bias are not typically excluded from a review; however, the impact of these studies ought to be explored (IOM 2011). While the authors acknowledged that all the studies included in their review "had significant weaknesses," they simply noted that their conclusions "must be tempered by an appreciation" of these weaknesses (p. 94).

In addition, the review by Dobie and Clark did not address the issue of publication bias. For example, studies may not be published in peer-reviewed journals because of negative results. Searching MEDLINE alone is not considered sufficient for a systematic review. Although Dobie and Clark did attempt to contact other investigators, presumably for unpublished studies, their methods would not be judged as a comprehensive gray literature search by modern standards (Higgins & Green 2011; IOM 2011).

EXPOSURE ASSESSMENT CONCERNS

Exposure assessment is a critical component of assessing the suitability of various ERs. Dobie and Clark made broad assumptions about the duration of exposure essentially based on the average age of the study samples. This is a particularly weak component of their analysis, especially in the context of forestry workers (Holmgren et al. 1971) and immigrant guest workers (Pressel & Freudenstein 1970), whose work was likely significantly less than full-time. In addition, calculation of time-weighted average and L_{Aeq8hr} at the time that the reviewed studies were conducted (30 to 40 years ago) was accomplished without the aid of instruments capable of integrated measurements. The authors' conclusions do not reflect that the overprediction of hearing loss could have resulted from inaccurate estimates of actual exposure, due to a prediction error from methodological/instrumentation differences (Earshen 1980, 1994). More recent research has shown that the adequacy of the ER depends on both noise intensity and noise kurtosis (Lataye & Campo 1996; Davis et al. 2009) and that the accuracy of L_{eq} predictions of hearing loss risk depends on duration (hours per day), intensity, and type (continuous versus intermittent) of noise exposure (Danielson et al. 1991; Hamernik et al. 2007). Alternative metrics have been demonstrated to more accurately assess risk than L_{eq} metrics and even allow the integration of impulse exposures (Davis et al. 2009; Zhao et al. 2010). The uncertainty in exposure levels within the original studies should have been reflected more clearly in their summary of findings.

STATISTICAL CONCERNS

Dobie and Clark indicated that "the available data did not permit meta-analysis" due to the lack of variance estimates necessary for pooled analysis in all but one selected study (p. 88). The Methods proposed no statistical analyses, and the Results presented no statistical findings from the review. However, in the midst of the Discussion, the authors presented a probability calculation based on a "simple two-tailed sign test" (pp. 93–94) in support of their conclusions. The authors did not mention that such a probability calculation assumes that the six studies included in the analysis were randomly chosen and independent. The assumption of random selection is clearly not met based on the design of the review. Furthermore, when probability estimates are based on such a small sample, judgments of which studies to include become extremely critical. For example, if just one of the six studies had favored the 3-dB ER, the two-sided probability calculation would have been 0.219 instead of 0.03, as reported by Dobie and Clark. If only five studies had been included and all five favored the 5-dB ER, the calculation would have been 0.0625. Thus, in an analysis of this size, the result of the probability calculation is highly dependent on judgments regarding study inclusion.

CITED LITERATURE

The review by Dobie and Clark also omitted or misrepresented important facts in the presentation of background material relevant to the question of ERs. For example, the authors mentioned that the Occupational Safety and Health Administration, Mine Safety and Health Administration, and Federal Railroad Administration use the 5-dB ER, but only mentioned one organization (NIOSH) that recommends the 3-dB ER. In fact, many more organizations currently support the 3-dB ER over the 5-dB alternative, including the U.S. Environmental Protection Agency, the U.S. Department of Defense, the U.S. Department of Interior, the U.S. Department of Energy, the National Aeronautics and Space Administration, the American Conference of Governmental Industrial Hygienists, the American Academy of Audiology, and the American National Standards Institute. In reporting results of a 2006 review by Humes (2006), the authors stated that several U.S. military branches "had all used a 4-dB exchange rate" (p. 86); however, they neglected to mention that the same document (Humes 2006, Table 5-1) indicates that the U.S. Army and Air Force currently use the 3-dB ER and that the Department of Defense "strongly encouraged" this ER. The recent recommendation by the National Research Council was also not reported: "The U.S. Department of Labor should adopt the 85-dB(A)/3-dB limit

for exposure to hazardous noise. This would replace the current 90-dB(A)/5-dB requirement" (*Technology for a Quieter America*, Recommendation 4-1, NRC 2010).

POLICY IMPLICATIONS

On the basis of their review, Dobie and Clark stated that "the 3-dB ER [exchange rate] systematically overestimates the risk of NIHL [noise-induced hearing loss] for real-life workplaces with intermittent or fluctuating noise" (p. 94). We consider this an overreaching conclusion in view of the weaknesses of both the underlying studies and the review. The authors did note that "future research could correct those deficiencies" in the studies included in their review (p. 94). We wholeheartedly agree; and we believe that a call for new studies, using updated exposure assessment techniques and considering new metrics such as kurtosis, is the only valid recommendation that can be made at this time.

Dobie and Clark did note that "there may be others [real-life exposures], such as brief but uninterrupted high-level exposures, for which the 5-dB exchange rate underestimates risk" (pp. 94–95). Alluding to the totality of research evidence which has already shown that one ER does not fit all exposure situations, Dobie and Clark stated that "One can imagine a hybrid system in which different exchange rates are used for different types of noise, spectral regions, or temporal characteristics" (p. 95). However, at this point in time, implementing varying ERs in the workplace is considered prohibitively complex. The numerous publications (Kryter et al. 1966; DOL 1969; Suter 1992; NRC 1993; NIOSH 1998) on the topic acknowledge that the downside of the simplicity of a single-number ER is imprecision. This highlights the technical and policy considerations, which affect the development of exposure criteria and their application to standards and regulations. These considerations include (a) What proportion of the noise-exposed population should be protected? (b) How much hearing loss constitutes an acceptable risk? and (c) Should we protect even the most sensitive members of the exposed population against any loss of hearing, should we protect against only a compensable hearing handicap, or should we protect people against some amount of hearing impairment that lies between these two extremes? The rationale for the using the 3-dB ER has been addressed in the literature (e.g., Suter 1992; Prince et al. 1997; NIOSH 1998; Stephenson et al. 2010; Murphy & Kardous 2012; Themann et al. 2013).

Although Dobie and Clark indicated in their Introduction that the purpose of their review was "scientific" and not to make "recommendations for the regulation of occupational noise" (p. 87), they use findings for the subgroup of workers who are least exposed to hazardous noise (those exposed to intermittent and fluctuating noise versus those exposed to continuous noise) to make generalized concluding remarks on the cost and benefits of using the 3-dB versus the 5-dB ERs. While the authors noted the possibility that the 5-dB ER could underestimate risk for some workers, they make no mention of the overwhelming evidence that many workers in programs using this ER are sustaining noise-induced hearing losses. Despite the implementation of the 5-dB ER in the 1960s, occupational hearing loss has remained the most common occupational illness in the United States. The Bureau of Labor Statistics reports staggering information on the significant number of occupational hearing losses sustained each year—an estimate that only includes those hearing losses serious enough to reach the "recordability" criterion (Martinez 2012; BLS 2013). The associated economic burden is estimated to exceed $242 million annually in the civilian sector (Themann et al. 2013); military and veteran compensation constitute an additional $660 million for hearing loss and $190 million for tinnitus annually (IOM 2006). Additional societal costs—including costs associated with diagnosis, treatment, and rehabilitation and the measurable burden reflected by reduced quality of life, disability, and suffering—while harder to quantify, have also been estimated (Nelson et al. 2005; Themann et al. 2013). Many factors beyond the ER certainly contribute to this burden (Verbeek et al. 2012). Research has shown that many hearing loss prevention programs are poorly implemented, and more emphasis on noise control has the potential to contribute to the prevention of both hearing loss and other costly and serious health and safety conditions (NRC 2010). However, considering that no ER perfectly protects all workers from all types of noise exposures, a more conservative ER has the best potential to reduce noise exposures and the burden of noise-induced hearing loss.

CONCLUDING REMARKS

To conclude, we consider that the publication of Dobie and Clark offers insufficient coverage of background information and key literature, narrow focus, insufficient methodology for a systematic review, inclusion of studies of questionable quality, inadequate presentation of probability as a statistic in a qualitative paper, discussion that goes beyond the data, and conclusions that exceed the boundaries of the findings. Contributing to the scientific literature on such an important topic as regulating the effects of noise exposure on the hearing of millions of exposed workers requires a more thorough and rigorous investigation.

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