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Audiometric data analysis for prevention of noise-induced hearing loss: A new approach

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Abstract

Compliance with noise regulations in the past three decades has significantly reduced workplace noise exposures, particularly in the loudest industries and occupations. However, the overall effectiveness of hearing conservation programs in preventing occupational noise-induced hearing loss remains uncertain and unquantified, while the incidence and cost of occupational hearing loss remain inexplicably high. This review/commentary critically explores this paradox by examining why the *billions of* annual audiograms conducted worldwide have not been aggregately utilized or applied to predict early NIHL in groups of workers or to measure the efficacy of exposure controls. Principal contributory reasons include regulation of noise as a safety standard rather than as a health standard, the inherent complexity of audiometric data, and the lack of a standardized method of interpretation for audiograms. The unsuccessful history of efforts to develop and adopt methods and tools to analyze aggregate audiometric data is described. Consequently, the Standard Threshold Shift—a regulatorily defined, lagging indicator of individual, irreversible hearing loss that is not an effective preventive metric—remains the de facto standard of care. A population-based Best Practices approach is proposed to leverage the raw audiometric data already available and turn it into actionable data for effective secondary prevention to strategically manage and reduce occupational hearing loss risk. This approach entails statistical methods and information management tools necessary to transform audiometry from a compliance-driven, individual screening test with limited preventive capability into a medical surveillance process directly linked to aggregate corrective and prevention actions.

KEYWORDS
audiometric database analysis, audiometry, noise induced hearing loss, occupational hearing loss, standard threshold shift

1 | THE CONTEXT

Occupational noise-induced hearing loss (NIHL) from chronic workplace noise exposure is one of the most prevalent occupational diseases in the industrialized world. NIHL is the most common nonmusculoskeletal occupational disease (illness) reported in the United States, and the second leading cause of sensorineural hearing loss after age-related hearing loss (presbycusis).[1–3] The profound social and economic impacts of NIHL occur as a result of miscommunication, productivity decrements,

[Correction added on 22 March 2022, after first online publication: In Table 3, "AOHC" has been changed to "AOEC" in the "Occupational Medicine and Nursing" row and in the abbreviations list.]

and stress and social isolation both in the workplace and in personal lives.[1,2,4]

An estimated 22 million workers in the USA are exposed to hazardous levels of noise at work and are at risk for, or already have, NIHL.[4,5] A majority of workers are employed by small- to medium-sized companies in a wide range of industries and occupations in the private and public sectors.[4–6] Mining represents the highest risk industry, with as many as 61% of workers exposed to hazardous levels of noise.[3,4] The global annual incidence of occupational NIHL is estimated at 1.6 million cases, which account for 16% of all causes of disabling adult hearing loss.[1,7,8]

Occupational NIHL is a largely, if not completely preventable disease.[1,2,9] NIHL has a relatively rapid progression from onset of exposure within 4–10 or more years to irreversible impairment, and disproportionately affects younger workers.[10] Currently available treatments (hearing aids) can ameliorate impairment, but do not reverse the disease. Occupational NIHL is significantly underreported or undiagnosed in relation to specific work employment.[9–14]

Both primary prevention of noise exposure and secondary prevention of NIHL through early detection and intervention before irreversible injury occurs "are critical to preserve worker quality of life."[1] As with many other occupational diseases, the genetic, biomolecular, and pathophysiological mechanism(s) of NIHL do not need to be completely or perfectly understood to effectively prevent it.[3,10]

Noise regulations intended to prevent occupational NIHL are enforced in the USA, Canada,[15] Australia,[16] United Kingdom,[17] the European Union,[18] and many other industrialized nations. In the USA, the Occupational Safety and Health Administration's (OSHA) Noise Standards for General Industry (29 CFR 1910.95) and Construction (29 CFR 1926.52) of 1984, and the comparable Standards for mining (Mine Safety and Health Administration MSHA 30 CFR 62, 2000) and railroad (Federal Railroad Administration, 2007), regulate occupational noise exposure. These regulations (collectively, the "Noise Standards") require covered employers to implement "continuing, effective" hearing conservation programs (HCPs, sometimes known as hearing loss prevention programs), which include noise reduction controls, hearing protective devices (HPDs), worker training, noise exposure monitoring, and baseline and annual audiograms for workers. In Canada, by contrast, audiograms are not a mandatory component of noise regulations.[19]

There is universal agreement that the primary prevention focus of exposure control mandated by noise regulations has significantly reduced workplace noise exposures, especially in the loudest industries and occupations.[1] Yet, after more than 30 years with over $100 billion spent by industry on HCPs for regulatory compliance and with the *hundreds of millions* of audiograms in the USA[1] and more than *one billion* audiograms that have been conducted worldwide[20] to measure each worker's hearing loss progression over time, the overall effectiveness of HCPs in preventing NIHL remains uncertain and unquantified, and the incidence and cost of occupational NIHL remain unacceptably and inexplicably high.[4,21,22] Substantial uncertainty exists as to whether and to what extent exposure controls such as HPDs, training, and other interventions are effective in the early detection and secondary prevention of NIHL.[23,24]

Recently, comprehensive state-of-the-art reviews of NIHL prevention have reiterated what has been widely recognized for decades: "[t]he economic consequences of occupational hearing loss—in individual workers, employers, and society as a whole—are vast…."[4] However, accurate measurements of employers' direct and indirect costs of compliance with noise regulations are scarce in published research or governmental statistics. The average annual HCP cost per worker in the USA in 2019 has been estimated at $308 (range $203–$438).[4] Conservatively estimating 15 million workers in the USA are enrolled in an HCP, businesses spend over $4.5 billion ($3.0–$6.5 billion) annually on noise compliance. Assuming each worker has one audiogram per year, audiogram collection and administration probably accounts for over $1 billion annually.[22] These billions of dollars are consumed by an entire industry of stakeholders that support and operate HCPs: professional services (occupational medicine physicians and nurses, otolaryngologists, audiologists and audiometry technicians, mobile and other workplace testing services, industrial hygienists, safety professionals, engineers, and other consultants); and products (manufacturers and distributors of HPDs, audiometers, noise dosimeters and sound level meters, noise containment, training videos, software, and hearing aids).

An inordinate, albeit poorly quantified amount of time and resources is expended by companies on enforcement of HPD assignments, usage, and training. Beyond what companies directly spend on HCPs, indirect costs of NIHL and HCPs extend to workers' compensation claims, including adjudication, disputes about causation and liability, disability payments, and lost productivity.[25] Government agencies, academic institutions, and nonprofit sector organizations also expend significant public and private resources on enforcement, research, and HCP training and compliance.[4,5] Accidents, errors, and lost productivity of hearing-impaired workers probably represent the largest unmeasured cost that impacts business profitability and economic competitiveness.

2 | THE REGULATIONS

With regulation and compliance programs in place, and with vast resources expended over many decades, why has occupational NIHL not been effectively "outlawed?" Why are audiometric data and indicators not applied to understand when, where, how, and why NIHL develops in workers, with or without hearing protection? Why have regulated industries not measured their "return on investment" for HCPs—similar to the justification for other essential business expenditures? Why have government agencies or the key stakeholders not utilized audiometric data to predict early NIHL, identify workplace and individual risk factors, measure the efficacy of exposure controls, and manage risk accordingly?

The disease characteristics that make occupational NIHL amenable to primary and secondary prevention are summarized in Table 1.

Both safety and health standards require engineering and work practice controls including personal protective equipment (PPE) as well as employee training and recordkeeping requirements, but important distinctions exist between these two types of regulations with regard to their outcomes and basis of prevention[29]:

TABLE 1 Prevention characteristics of NIHL as an occupational disease

Characteristic	Description
Exposure	Risk of NIHL is directly related to cumulative exposure to noise that exceeds 85 dB.[1] The higher the dose (exposure), the higher the risk of disease.
Timing	Onset of NIHL begins in 4–10 years of initial continued noise exposure, often regardless of the use of hearing protective devices.[26,27]
Progression	NIHL is a disease that develops gradually in response to cumulative exposure to excessive levels of noise. Significant, irreversible hearing damage often occurs before the speech range (0.5–2 kHz) is affected, at which point impairment in hearing becomes clinically evident to the worker.[28] Noise-induced changes thereafter decelerate over time.[13]
Susceptibility	All individuals exposed to certain levels and types of noise are susceptible to NIHL, but only some of those exposed develop the disease.[3]

Abbreviation: NIHL, noise-induced hearing loss.

- Safety standards (e.g., Electrical, Fall Protection, Confined Spaces) are *specification-based* regulations designed to prevent acute injuries. A static checklist of requirements (specifications) must be fulfilled. Injuries are outcomes that can be counted, recorded on a list (e.g., the OSHA 300 log), and tabulated annually. A single, one-size-fits-all safety standard applies to every company or organization regardless of industry. In theory, if a safety regulation is fully and correctly implemented (i.e., "compliance"), accidents or injuries should not occur.[29] Compliance enforcement, therefore, emphasizes scheduled inspections of the facility and fulfilment of the checklist. Extensive recordkeeping requirements for injuries are collected by the government to statistically assess the efficacy of the regulations and target areas of enforcement emphasis. Serious safety-related injuries or fatalities commonly draw media attention and/or trigger reactive regulatory penalties.
- Health-based standards (e.g., asbestos, formaldehyde, lead), in contrast, are exposure-driven, *performance-based* regulations designed to prevent *occupational diseases* that result from acute, chronic or cumulative exposure to a chemical or physical hazard.[29] An occupational exposure limit is intended to prevent the disease from occurring, in most cases gradually or insidiously over time. Exposure monitoring must be conducted initially and thereafter at regular, recurring frequencies. Each covered company must develop and continuously update its own compliance plan that addresses its particular work processes and environment, and how it controls the employees' health risks related to exposure to the hazard. Medical screening requirements typically include medical examinations, biological or physiological tests, and minimum requirements for medical removal. Ultimately, the determination of compliance is based on outcomes (performance), that is, how effectively the exposure is controlled and whether or not its employees develop the disease. Unlike injuries, individual occupational disease diagnoses and statistics are rarely in the public or regulatory eye.

The regulation of noise risk primarily as a *safety standard* paradoxically diminishes the "continuing, effective" regulatory objective of preventing NIHL as an *occupational disease*. As safety-based regulations, the Noise Standards contain only the most basic exposure-based features of a health-based regulation: permissible exposure limits (PELs) and "action levels" that trigger audiometric testing requirements and reporting. In all other respects, however, the Noise Standards do not conform to health-based standards. From an exposure standpoint, the Noise Standards only require the employer to conduct initial noise dosimetry sampling, and thereafter only when conditions "change." Because noise exposures are typically complex, variable, and dynamic, they are often not accurately characterized by a single, time-weighted average (TWA) noise dosimetry measurement.[11] The relationship between magnitude and duration of noise exposure, and the risk for development of NIHL is dose- and time-dependent, but determinants of individual susceptibility and disease progression remain poorly characterized.[4] OSHA's PEL for noise of 90 dBA TWA represents an exposure that is known to increase the risk of NIHL. Job duties, assignments, and exposures in many industries are commonly variable, even without changes in the work process itself. The creation and use of Similar Exposure Groups (SEGs)—a standard industrial hygiene method for risk stratification—is neither required nor recommended by noise safety regulations.[30]

From a population health perspective, regulatory agencies do not specify the methods or provide the tools employers need for the ongoing collection, organization, analysis, or reporting of compliance data on an individual or aggregate basis.[29] As long as regulated employers fulfill the checklist of the Noise Standard's requirements (specifications) and adequately maintain the requisite recordkeeping (i.e., training, HPD provision, audiograms, and recording threshold shifts on their OSHA 300 log), employers can conflate being "in compliance" with effectively reducing the risk of NIHL in their employees.[25] The consequence of this paradox from an occupational medicine and medical surveillance perspective is that:

> [i]f health and exposure information, such as from medical monitoring, is collected merely to satisfy 'compliance' recordkeeping requirements but nothing substantive is done with this information beyond making individual health determinations, surveillance efforts in many cases are ultimately ineffective.[29]

Audiometric testing requirements for the Noise Standards contain no substantive clinical determination of the early risk of NIHL. In contrast, most health-based standards for specific chemical substances or physical or biological hazards mandate medical surveillance examinations and/or biological or other physiological monitoring to identify occupational disease in its early phase and to intervene through temporary removal, PPE, or other exposure controls. Medical surveillance has been defined as the "process of identifying, quantifying, and removing causative factors that increase the risk of occupational diseases or injuries."[29] Because employees are literally moving targets (i.e., they are hired, their job duties may or may not change, PPE use may be variable, and they are terminated, reassigned, or rehired), medical surveillance entails more than merely conducting medical monitoring at the individual employee level. Consequently, medical surveillance generates large quantities of employee-specific, dynamic, inter-related data. Each organization with a health-based compliance program is responsible for tracking the requisite results, managing its data, and documenting decisions and interventions. Regulations mandate individual employee determinations such as temporary removal based on the results of individual medical exams or testing.

Some employers (and employees) falsely believe they are conducting effective medical surveillance by administering nonmandatory "hearing health questionnaires" and by having audiologists perform otoscopic examinations of the external ear canal—services commonly performed by medical clinics and mobile testing services in conjunction with audiograms. The questionnaires typically comprise questions about pre-existing sources of noise exposure, other hearing loss conditions, or conditions that predispose to hearing loss. Otoscopic inspection of ear canals for cerumen and tympanic membrane (eardrum) patency may identify causes of conductive hearing loss—which have a different audiometric pattern from sensorineural hearing loss—but this information does not affect risk for NIHL. Employees' responses to these questionnaires and otoscopic exam findings are often reported to the employer along with the audiometric results (a violation of employees' privacy that contravenes most OSHA health-based standards). Neither of these sources of data is systematically utilized to interpret clinical findings; rather, they are used by employers to deny hearing loss claims as pre-existing or to interpret threshold shifts (see below) as nonwork-related for purposes of OSHA recordability.

PPE plays a significant role in both safety and health regulations. The effectiveness of PPE in preventing exposure and disease can be objectively demonstrated by measuring health-based outcomes. For noise exposure, HPDs are the major form of exposure control in most industries. Because the effectiveness of HPDs remains uncertain, the value of merely collecting individual audiograms and reporting on individual results is not a performance-based outcome unless the aggregate data are effectively analyzed. Meaningful interpretation of serial audiograms in a single worker, or among groups of similarly exposed workers, requires a much more sophisticated process akin to medical surveillance rather than a specification-based checklist.

3 | AUDIOMETRIC DATA INTERPRETATION

The methodology and technical requirements for workplace audiometry are codified by regulations, texts, and other widely adopted sources.[5,6,31,32] Audiogram test administration and collection, along with threshold shift reporting, consumes most of the hearing professionals' attention. It is what is (or is not) done with the audiometric data *after* it has been collected, both at an individual level and at an aggregate level, that remains problematic and unanswered.

Audiometric data are mathematically unique compared to other medical surveillance metrics such as blood or urinary biomarkers (e.g., blood lead level), physiological markers (e.g., pulmonary function tests), or chest radiographs (e.g., B-reading interpretations for pneumoconiosis). Table 2 summarizes the variables that contribute to audiometric data complexity. At the individual worker's hearing test level, an enormous number of permutations of audiometric results and their clinical interpretation is possible. By comparison,

TABLE 2 Audiogram complexity variables

Variable	Description
Data structure	Each audiogram contains 7 (or 8) discrete results for each ear ([0.25], 0.5, 1, 2, 3, 4, 6, and 8 kHz), representing a permutation of 14–16 frequencies in two ears. Audiometric readings are recorded in logarithmic units (dB) in interval (noncontinuous) increments of 5 dB.
Test–retest variability	The measurement at any hearing frequency has an error of ±5 dB, which equals the magnitude of minimum detectable change between audiograms.[33]
Symmetry	NIHL is typically a symmetrical disease process, but the asymmetric progression is not uncommon—for reasons that are not clearly understood.[3,9,34]
Age and health	In audiograms of older employees who may have presbycusis combined with NIHL, it may be difficult to objectively distinguish the latter from the former.[11] Certain pre-existing medical conditions and personal behaviors such as cigarette smoking (still highly prevalent in working populations) influence susceptibility to hearing loss.[4]

Abbreviation: NIHL, noise-induced hearing loss.

laboratory biomarker tests are far more straightforward to interpret: biomarkers have numerical values (vs. patterns comprised of 7–8 values for each ear) with a continuous distribution (vs. logarithmic units reported in 5 dB increments) that can be arithmetically compared; they have a lower limit of quantitation with reference ranges that demarcate unexposed, normal, or indicative of prior exposure or body burden (vs. a wide range of "normal" and other causes of hearing loss); and they measure the entire person or organ system (vs. two separate ears for one person).

Health-based standards for hazardous substances with biological monitoring requirements (e.g., lead, cadmium) require that a "physician or licensed healthcare professional" conduct required components such as medical surveillance examinations and render written physician's opinions.[29] For noise, the responsibility to interpret the audiogram, and any resultant individual or aggregate decisions that impact employees' health risk, lies with the employer. The Noise Standards authorize a technician, but do not preclude *nonmedical* personnel such as safety officers, industrial hygienists, human resources managers, or others to compare each employee's annual audiogram to the baseline audiogram and make decisions related to audiometric results (see Standard Threshold Shift section). Neither a formal interpretation nor a physician's or audiologist's written opinion of the audiograms, individually or collectively, is required unless a "threshold shift" is detected.

Physicians in primary care or specialties outside of otolaryngology or occupational medicine commonly are not trained to interpret a screening audiogram, either specifically for the diagnosis of NIHL (or early NIHL) or any other abnormality, or relate the interpretation to noise exposure measurements.[35,36] While larger organizations and certain companies utilize the services of an occupational medicine specialist, otolaryngologist or audiologist to review and interpret audiograms, the majority of regulated companies do not—and neither OSHA nor the National Institute for Occupational Safety and Health (NIOSH) tracks or analyzes these practices or their outcomes. The real-world consequence of this common practice is that:

> …[o]ften, the industrial representative will point to a stack of audiograms, saying that he hasn't the slightest idea what the reports contain or mean and that he doesn't really know if the employees are using hearing protectors properly.[37]

Audiogram interpretation for HCPs remains a subjective, nonstandardized process that varies widely even among audiologists, occupational medicine physicians, and otolaryngologists.[38] The natural history and visual audiometric progression of NIHL is well characterized and generally accepted.[28,39] Audiologists classify the extent of hearing loss from an audiogram (i.e., normal, mild, moderate, severe, profound) based upon the highest threshold value, regardless of which frequency it is or its relationship to threshold values at other frequencies. However, the pattern of the audiogram is as, if not more important as its magnitude in distinguishing the cause of hearing loss. The characteristic high-frequency "notch" pattern of NIHL is recognizable to most occupational medicine physicians and audiologists, and even to nonformally trained reviewers.[4] Even when specialists interpret screening audiograms, their clinical interpretation of the characteristic early NIHL high-frequency notch pattern has high interobserver variability, with no industry-wide or regulatorily-defined criteria.[38] The unique nature of audiometric data does not lend itself to basic summary statistics (i.e., averages, sums, maximums) that most employers or even specialists such as audiologists or physicians understand or can efficiently manage through common desktop applications such as spreadsheets. Interpretation (if any) of baseline, annual, and repeat tests typically occurs with minimal or outdated noise exposure information.

Accordingly, the standard of care for interpreting individual audiograms remains "eyeballing" them one-at-a-time, or viewing serial data in a table and manually comparing the results of the current test to a baseline test. Unless a standard threshold shift (STS) (see below) is detected and specific administrative action is required, the data are filed away until the next year's test, when this process is repeated. The majority of companies—including those which contract with physicians, clinics, audiologists, and mobile testing services to perform or manage their audiology testing—continue to utilize their audiometric data only to meet the minimum audiometry regulatory requirements.[22] Figure 1A–C contains examples of audiograms conducted over the past 9 years by occupational medicine clinics, audiologists, and mobile audiometry services that illustrate their outdated, motley "state-of-the-art" tools for managing and evaluating raw audiometric data.

While NIOSH collects audiometric information voluntarily contributed as a "convenience sample" by certain mobile audiometry providers who service larger companies, the extent to which these data represent all workers, particularly in small- to medium-sized organizations, is unknown.[40] Neither OSHA nor MSHA nor NIOSH counts how many audiograms are actually conducted annually in the USA, nor measures how the audiograms are interpreted and reported, nor checks whether threshold shifts are actually calculated correctly. Even *de minimis* compliance performance such as determining the extent to which employees are screened in a timely, consistent manner is neither monitored nor enforced by any of these agencies. Consequently, the extent to which errors and misclassification (e.g., missing/invalid tests, variable test intervals, recording errors, "cut and paste" spreadsheet errors, etc.) occur is probably large but unknown. Because such errors remain "under the radar," they may only become problematic *after* a disease is reported in one or multiple workers—almost always too late for any "corrective action" to be effective.[11]

NIHL is the only form of hearing loss for which serial audiometric screening is routinely conducted in adults. Thus, NIHL is the only

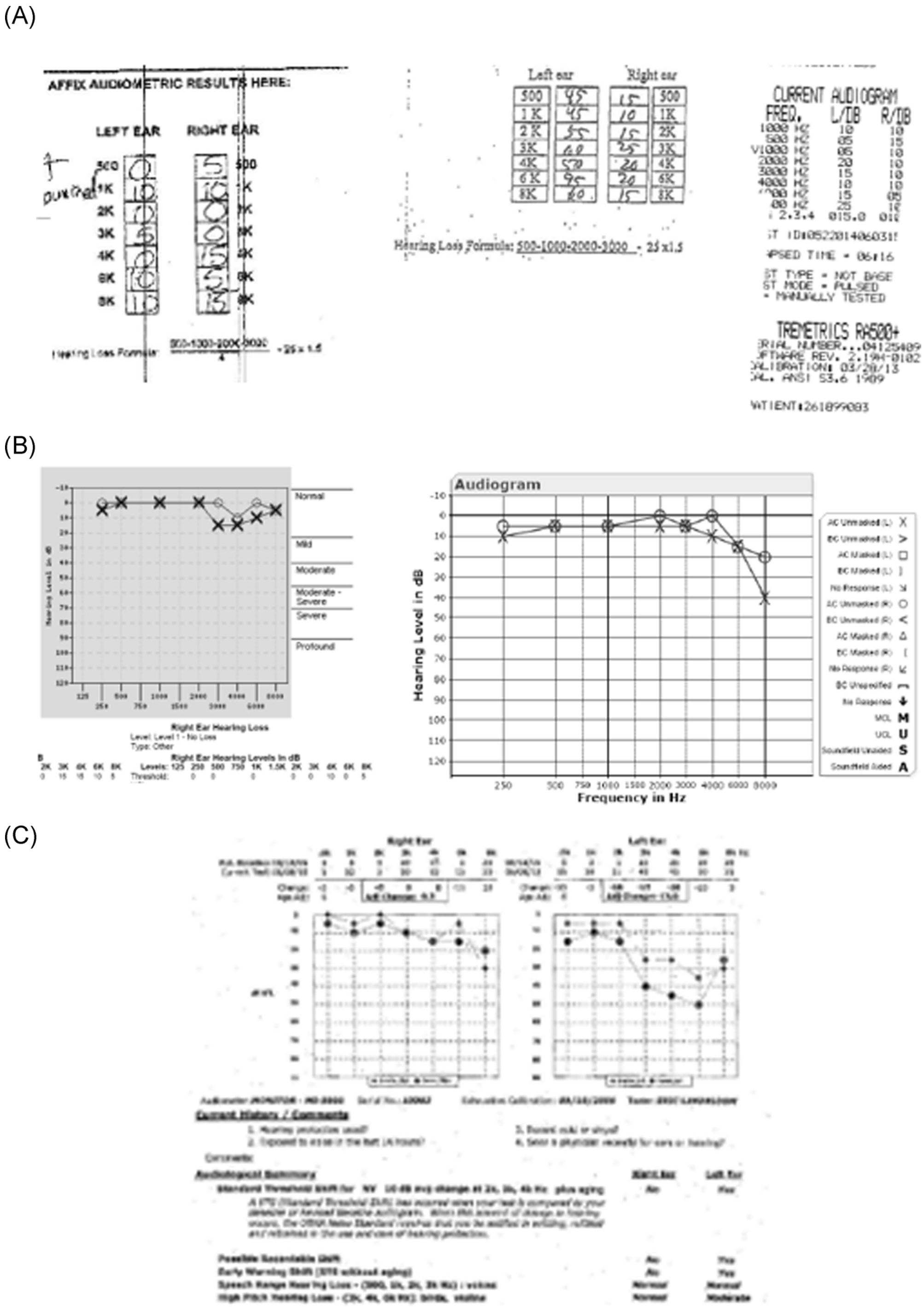

FIGURE 1 Audiogram examples (2013–2021). (A) Occupational medicine clinics, (B) audiologists, and (C) mobile audiology vendors

cause of hearing loss for which its audiometric temporal progression is very well characterized: from normal to preclinical loss to clinical hearing loss to impairment. Systematic interpretation of changes in employees' serial audiograms over time, and differentiation of NIHL from other causes of high frequency or mixed (conductive and sensorineural) hearing loss in individual audiograms and progression, is much more complex than current practice affords.[10,36] The following characteristics of NIHL and audiometric patterns underscore the need for a systematic approach to clinical audiogram interpretation:

- Definition of unexposed/normal: A universally accepted definition of “normal” or “unexposed” versus early or “mild” NIHL does not exist.[37] Some audiologists consider hearing loss thresholds ≤15 or 20 dB to be within the normal range. Other audiologists, organizations and regulatory agencies do not consider hearing to be "abnormal" or "recordable" for compliance purposes until at least one frequency or an average of frequencies (i.e., 2, 3, and 4 kHz) is ≥25 dB. Various arbitrary definitions of NIHL have been published, for example, ≥25 dB at one or more frequencies[41] or ≥20 dB for either ear at 1, 2, 3, and 4 kHz,[42] but none has been universally validated or adopted.

- Control data: Regulated companies are not required to collect nonexposed (i.e., "control") audiometric data. Few, if any companies, therefore, do so—particularly because of cost concerns and potentially unwanted liability. Since every company and job is unique in terms of its noise exposure profile, and audiometric changes over time are the outcome of interest, a comparative normative data set does not exist within or among industries or occupations to guide collective audiometric interpretation.
- Pattern: NIHL in its early stages differs from the audiometric patterns and progression of other common and uncommon causes of hearing loss. While an audiometric high-frequency notch pattern of hearing loss is characteristic of NIHL,[3] no specific criterion or threshold defines the specific notch pattern or progression, or distinguishes where the normalcy ends and disease begins.[38] Various methods have been proposed to standardize the interpretation of serial changes based on diagnostic criteria for a "notch progression" of NIHL, but none has been validated or widely adopted.[43,44] In fact, while the 8 kHz threshold is critical to the observation of a diagnostic notch, the OSHA Noise Standard still does not formally require measurement at 8 kHz, though it is rare for this omission to occur in current clinical practice.
- Progression: An individual worker may have small, seemingly minor year-to-year changes that result in a large overall audiometric change from baseline that is not detectable until a point where some irreversible hearing loss has already occurred. A universally accepted absolute or relative (e.g., percent) criterion for a significant year-to-year (test-to-test) change does not exist. Because the test–retest variability (±5 dB at any frequency) is the same as the interval increment of measurement, test-to-test changes may not reliably distinguish normal variability from true positives.
- Test interval: Noise regulations typically require baseline and annual audiograms. As a disease (NIHL) that can progress from normal to irreversibility within as few as four years, the test intervals may be too long to accurately measure and identify significant incremental, early changes.
- Symmetry: NIHL is typically bilateral (both ears) for most occupations, but its progression as measured by audiograms is rarely perfectly symmetrical.[2,9,13]
- Nonoccupational or toxicological factors: The effect or contribution of sources of nonoccupational noise (e.g., firearms, loud music, motorcycles, lawnmowers, power equipment), lifestyle behaviors (e.g., cigarette smoking), or (uncommon) oto-toxicant exposures (occupational or nonoccupational) cannot be quantitatively distinguished from occupational sources in their relative contribution to general or specific causation or progression of work-related NIHL.[42,44]

4 | STANDARD THRESHOLD SHIFT

An STS is defined by the OSHA and MSHA Noise Standards as an increase of ≥10 dB in the difference between the current test and the baseline test in the arithmetic mean (average) of hearing levels at 2, 3, and 4 kHz frequencies. An STS is deemed "recordable" if the current test's average is ≥25 dB. Either or both ears can have an STS, and more than one STS can occur over a worker's employment with an employer. The Canadian Standards Association (CSA) Standard Z107.6-16's STS has a similar definition, but also includes an isolated change versus baseline of ≥15 dB at 3 or 4 kHz.[19]

In the USA, the advent of a recordable STS in either ear constitutes the criterion for reporting and counting cases of hearing loss (29 CFR 1904.10). As previously discussed, neither the OSHA and MSHA Noise Standard, nor the CSA Standard, contains a requirement or specifies a method for any person—either company personnel, or a physician who understands NIHL, or an audiologist—to actually interpret screening audiograms beyond the determination of whether an STS from the initial (baseline) test has occurred.

OSHA and MSHA consider the regulatorily defined STS to be an "early indicator of permanent hearing loss."[11] However, no scientific evidence has been published to demonstrate how this regulatorily defined calculation is an effective preventive metric.[33] The characteristic notch pattern of NIHL with a peak loss in either the 3, 4, and/or 6 kHz range and recovery at 8 kHz is often present in early stages, but as the disease advances to the point where an STS occurs, the pattern sometimes cannot be differentiated readily from common diseases such as presbycusis (in older workers) or other less prevalent diseases associated with high-frequency hearing loss.[10] NIOSH has recommended medical surveillance for audiometry by proffering an "improved criterion for an STS" defined as an increase of 15 dB at *any* frequency except 8 kHz in either ear, based on two consecutive audiometric tests.[45] NIOSH claimed in 1998 this new criterion had the advantage of a "high identification rate and a low false-positive rate," but no research since that time has corroborated these claims, and this nonspecific method has been largely unutilized in real-world practice.

Thus, while the STS is useful and mandatory for regulatory reporting, from an occupational medicine and public health perspective it is a *nonspecific*, *lagging indicator* that has uncertain value as a disease prevention metric, limited to one-test (and one-ear)-at-a-time determinations. Its very definition as a marker of "injury" means that by the time an STS is detected, it is often too late to prevent or reverse the hearing loss disease process.[4] The Noise Standards require that the detection of an STS be followed by a "corrective action," but no research has been published that any such reaction in an individual worker effectively prevents progression of the disease to impairment. Individual audiometric data and STS determinations therefore do not effectively translate screening audiometry test results of *individual* workers into *aggregate*, *actionable* data for effective, population-based early detection and prediction of NIHL.

The STS's limitation as a preventive marker of early disease in individuals and in populations of workers within the same company or industry is related to the following characteristics:

- Sensitivity: The sensitivity of the STS for detection of the earliest phase of NIHL is unknown. An STS does not clearly demarcate a significant change in reversible hearing loss, either individually or in aggregate.
- Specificity: Other causes of hearing loss can produce a false-positive STS. NIHL characteristically starts in the high-frequency range, but by the time it affects the 2 kHz range, it is already advanced in many cases. The 6 kHz range, in contrast, is much more sensitive to NIHL changes but is not included in the definition.
- Asymmetry: An STS in one ear may not be matched by similar changes in the other ear, even when noise exposure is symmetrical. Nonoccupational sources of unilateral noise (e.g., gun shooting) may confound detection of a bilateral process that appears to be unilateral.[35]
- Age correction: The use of age correction formulas codified under OSHA and MSHA to adjust STS calculations for the effects of presbycusis from advancing age is of questionable validity in increasing the predictive value of the STS for early detection of NIHL.[46] Age adjustment is considered by some authorities to be an unreliable, outdated method of addressing the concomitant effects of presbycusis, and is irrelevant to the vast majority of relatively younger workers for whom age is not a significant variable.[47,48] In 1998, NIOSH revoked its recommendation for using age corrections on individual audiograms.[45]

Because neither OSHA nor MSHA collects audiometric data or verifies STS calculations for accuracy, ‘compliant' employers and their physician and audiologist vendors perceive no justification or need to do anything with the data beyond performing annual audiograms, recording the results, reacting as needed to STSs one-case-at-a-time, and recordkeeping.[37,39] In real-life practice, the potentially actionable data from audiometric results are relegated to the filing cabinet, or to the electronic equivalent of scanned faxes, audiogram reports in portable document format (PDF) stored on hard drives, or data compiled in homemade spreadsheets or safety software programs.

5 | AUDIOMETRIC DATABASE ANALYSIS

Even when employers who comply with noise regulations dutifully make efforts to reduce risk and protect their employees' hearing, they do not have the tools to go beyond minimum compliance requirements of recording individual audiometric results and STS calculations. While individual clinical diagnosis and screening for NIHL is an important component to occupational disease control, a public health or epidemiological approach “offers the possibility of altering the risk through intervention.”[49] However, for noise regulations, evidence-based methods for measuring and interpreting aggregate audiometric trends and outcomes among groups of workers have remained nonexistent.

Soon after the OSHA Noise Standard was promulgated in 1981, the need for and importance of quantitatively evaluating HCP effectiveness within a company by utilizing audiometric data was proposed. By 1987, Suter observed that:

> [s]ome noise-exposed employees are losing their hearing despite the implementation of hearing conservation programs.[50]

The explanation for this paradox was the lack of professional and regulatory guidance, in particular, the absence of a specification requiring employers to evaluate HCP effectiveness. The consequence was that:

> [e]mployers do not know how to evaluate HCP effectiveness, and audiograms are often filed away after testing.[50]

Audiology professionals advocated for statistical methods to enable employers to measure and apply aggregate audiometric data to accurately predict and identify early audiometric changes in workers. The term “audiometric database analysis” (ADBA) was developed to describe a standardized, systematic method of aggregate statistical analysis of serial audiograms in individual employees.[51] ADBA was intended to be regularly utilized by employers to identify employees with early trends to prevent threshold shifts and to apply this information to evaluate the overall effectiveness of HCPs among SEGs of workers within departments or the entire facility. The promise of analyzing aggregate audiometric data to prevent occupational NIHL was championed by this 1990 axiom: “Audiograms do not prevent hearing loss, but using ADBA results can!”[52]

Crude methods for managing audiometric data with microcomputers were proposed in the early 1990s, before the era of personal computers when data were largely recorded on paper.[53] Lipscomb observed with regard to collecting audiometric data that “great quantities of numbers on many sheets of paper can accumulate if [recordkeeping] is not streamlined.”[54]

The first coordinated effort toward developing ADBA methodology for national (USA) adoption was the 1991 draft American National Standards Institute (ANSI) S12/WG13 Standard for Evaluating the Effectiveness of HCPs (“S12.13 Standard”). The purpose of this voluntary industry standard was to define objective methods for evaluating HCP effectiveness in preventing NIHL early in the course of disease before the irreversible hearing loss has occurred.

The S12.13 Standard was directed primarily to corporate HCPs that conducted in-house audiograms. S12.13's eligibility criteria in a company required a minimum of 30 people, each with the participation of at least 4 consecutive years. The S12.13 Standard assumed no control data were available, did not rely upon the baseline test of an individual, and excluded workers with any pre-existing hearing loss. A significant year-to-year audiometric change was defined as ≥15 dB in *any* hearing frequency (0.5, 1, 2, 3, 4, or 6 kHz) in either ear. From this change, two "acceptability" metrics were defined by consensus: "% Worse sequential" <20% and "% Better or Worse Sequential" >30%. The outcomes were categorical rankings of "acceptability" or "unacceptability" based on the proportion of audiograms that met these audiometric variability criteria.

The validity and applicability of the ANSI S12.13 Standard was evaluated in several studies published in the mid-1990s.[55]

- In a study of audiograms in over 82,000 workers from the US Army's civilian database from 1968 to 1992 using four different S12.13 ADBA procedures, which compared calculated standard deviations of each single and average binaural (both ears) differences between an employee's sequential tests, only 7% of the audiograms met the eligibility criteria for ADBA analysis.[56] High-risk workers were systematically excluded from the analysis. Low levels of agreement were found between the various proposed ANSI procedures. Based on these inconsistent outcomes, and the restrictive sample size and duration requirements, the authors concluded that the S12.13 ADBA methodology had "poor validity," its adoption as a national standard was not warranted, and it "likely could not be applied to the HCPs of most small- and medium-sized businesses."[57]
- The S12.13 methodology was tested on 213 randomly selected employees' audiograms taken from within ANSI's entire database of over 140,000 audiograms.[58] This study, published in 1993, found that reporting of audiometric data in rounded up, standard 5 dB increments (as opposed to pre-1980 methodology of 1 and 2.5 dB reporting intervals) significantly biased outcomes in both directions based on the Standard's +15 dB criterion at any frequency.
- In 1995, Dobie reviewed major organizational statements "that purported to measure the effects" of workplace HCPs and concluded that no studies collectively demonstrated occupational HCP efficacy.[13] This finding was attributed to methodological flaws in measuring audiometric outcomes, rather than the impact of reducing workers' noise exposure in the workplace.
- A 1996 analysis of cross-sectional HCP data collected from a "convenience sample" from USA industries involving over 62,000 audiograms among over 15,000 workers demonstrated significant heterogeneity among databases, which in turn complicated statistical modeling analyses.[59] Pre-existing hearing loss confounded threshold variability and the resultant S12.13 outcomes.[60]
- In 1998, despite the foregoing publications, NIOSH nonetheless recommended the ANSI 12.13 draft Standard for evaluating overall HCP effectiveness. NIOSH also recommended calculating the percentage of workers having what NIOSH deemed were "significant threshold shifts"—which would require a control group (i.e., non-noise-exposed) within the same company.[45]

In 2002, the ANSI S12.13 Standard Committee *rejected* the adoption of its own method as a national standard, citing a variety of technical reasons, notably its lack of sensitivity and specificity, and its inability to address "failures of omission" and implementation by the employer.[61] The Committee concluded or reiterated that:

> [w]ithout evaluation procedures based on objective data, it is difficult for personnel responsible for administering the HCP to determine whether the program is actually preventing occupational noise-induced hearing loss. ...Standard threshold shifts do not provide an indicator which is amenable to standardization.[61]

The ANSI S12.13 Standard Committee concluded no alternative objective methods or criteria for population-based audiometric analysis were available to supplant "case-by-case judgments." With regard to the potential for a robust ADBA methodology to solve unmet needs, the S12.13-2002 Committee provided further insight:

> ...[v]ery few [HCPs] analyze group data to evaluate program performance except by STS rates...Therefore, the potential of the audiometric data bases to indicate HCP effectiveness is largely untapped... If ADBA procedures are used to detect and correct HCP problems early in the worker's noise exposure history, then audiometry becomes a powerful tool in preventing significant noise-induced hearing loss.... Checklist or audit approaches to evaluating HCPs are also common in use, but these approaches merely tally the observed completeness of a program, or its nominal regulatory compliance, without assessing the quality of the program elements that are present.[61]

Nearly a decade later in January 2011, the S12.13 Standard was revisited by the Committee without any additional changes.

In the two decades (1991–2011) since its inception, testing and refinements, the ANSI S12.13 ADBA methodology has never been formally adopted, nor has its utility been demonstrated for fulfilling its originally intended purpose.

6 | OTHER MODELING METHODS

Modeling studies of audiometric data have attempted to measure the effectiveness of preventive interventions. As with ANSI S12.13, these studies have not demonstrated consistent findings or produced practical applications to real-world workplace audiometric data analysis, particularly for small- or medium-sized organizations where the majority of noise-exposed workers are employed.

- In 2000, a time trend analysis method using a Cox proportional hazards multivariate regression model was suggested as an alternative to the conventional approach for measuring HCP effectiveness by calculating STS incidence compared with "a suitable reference population."[62] The methodology required specialized statistical software (SAS®) to analyze a database of 44,500 workers' audiograms over a 10-year period, with each worker having a minimum of 5 years' of participation required to detect significant trends. The authors concluded their time trends analysis is a "viable option" for hearing loss prevention program analysis "as long as one has sufficient follow-up data and an intermediate level of knowledge in statistical methods."[62]

- Longitudinal analyses of STS calculations from a single, large manufacturing company's proprietary audiometry database were performed to predict and identify "early flags" for hearing loss.[48] One method created a high-frequency "notch index" that required expert interpretation. The expert panel's audiogram interpretations had considerable variability among the experts, rendering the method impractical for surveillance purposes.[43] Even with an 8 dB age-corrected shift to minimize the probability of false-positive results, the index had a low predictive value, leading the authors to acknowledge the inherent limitation of reliance upon 2, 3, and 4 kHz values.[23]
- A study compared before versus after hearing protection interventions in reducing NIHL (defined as an STS) by monitoring daily occupational noise exposures inside HPDs.[63] Wearing HPDs reduced the risk of year-to-year STS, but numerous, plausible alternative explanations for the outcome were also identified. The authors called for controlled (randomized) trials of daily noise exposure monitoring in workers.
- A study of HCPs from three large US companies funded by NIOSH (2010) attempted to mathematically model the effectiveness of HCPs using "novel metrics."[64] The metrics were developed to model cumulative noise exposure. Bilateral audiometric hearing threshold averages (3, 4, and 6 kHz) were calculated instead of the STS triad of 2, 3, and 4 kHz. The authors attempted to quantify administrative HCP compliance components (i.e., training, medical referrals, hearing protector usage) using dichotomous ("better" vs. "poorer") quality ratings based upon group recall of whether the level of compliance was (arbitrarily) above or below 50%. The study concluded that females had less incidence of occupational NIHL than males, and that enforced use of HPDs was effective. Aside from these generalized findings, the method did *not* "specifically demonstrate differences between HCP programs and help us understand what makes HCPs more effective."[64]
- The International Standards Organization (ISO) promulgated a mathematical method for estimating worker exposure and hearing loss in 1990.[65] The applicability and reliability of the methodology has been critiqued because of its inconsistency with the known pathophysiological characteristics of NIHL.[13,66]
- Other medical technologies such as otoacoustic emissions or high-frequency (12,500–16,000 Hz) audiometry have not been demonstrated to be more sensitive or specific than audiograms in the early detection or prediction of NIHL at the individual level, and have not supplanted audiometry as a screening tool for NIHL.[4,67–69]

The collective published body of research on interventions to prevent occupational NIHL underwent a systematic review by the Cochrane Occupational Safety and Health Review Group in 2014.[70] From among nearly 2500 published studies that were identified, just 19 publications, which included 82,794 participants in HCPs, were deemed adequate for inclusion. The health outcomes of interest were STS and mean (average) total permanent hearing loss at *all* hearing frequencies. The investigators identified numerous methodological flaws and challenges in studying the impact of interventions to reduce NIHL. The review found an overall "very low-quality evidence" that the use of HPDs in well-implemented HCPs was associated with a reduction in hearing loss. The Cochrane analysis recommended studies of hearing loss prevention programs "with innovative content," particularly for industries such as construction where noise exposure is prevalent and difficult to control. No specific critique or recommendations were offered with regard to continued reliance upon the STS metric or need for aggregate, population-based analysis of audiometric data.

7 | THE DE FACTO STANDARD OF CARE

In 2009, 22 years after her initial observation that "[e]mployers do not know how to evaluate HCP effectiveness, and audiograms are often filed away after testing,"[50] Suter concluded:

> [w]e know that many more workers are having their hearing tested, but the fundamental questions of whether or not the incidence and prevalence of noise-induced hearing loss is decreasing is yet to be answered.[21]

Even with the widespread use of computerization and availability of databases, the internet, and automated information technology over the past 40 years (1981–2021), no significant advances beyond the minimum recordkeeping and one-test-at-a-time audiometric STS requirements mandated by the Noise Standards have been developed or widely adopted in the USA.[5] A similar history has occurred in other nations with comparable regulations. Aggregate audiometric data analyses have been limited to basic descriptive summary statistics of maximum hearing loss threshold values ("mild, moderate, severe"), STS incidence, and compensable disability claims.

Unbiased, quantitative evidence that HCPs and HPDs are effective in preventing NIHL over time within companies and industries is strikingly lacking.[3] Recent reviews of the efficacy of HCPs have similarly reported conflicting results in epidemiological studies that rely upon these indirect, descriptive types of data.[9,71] A 2014 NIOSH analysis of self-reported hearing protection usage and odds ratio of STS or high-frequency (3, 4, and 6 kHz) threshold shifts in 5 years' worth of audiometric data collected from a "convenience sample" of over 19,000 subjects demonstrated no consistent relationship, leading NIOSH to question whether HPDs actually protect workers' hearing.[72]

After four decades of enforcing and fulfilling the regulatory requirement to conduct employee audiometry tests and report STSs, neither employers nor regulatory agencies in the USA or in any other nation can accurately identify and predict early NIHL from audiometric data, nor do they have an accurate estimate of HCP effectiveness as measured by audiometric population trends over time. Recent, comprehensive reviews of occupational noise exposure epidemiology do not even mention the role or need for ADBA.[3,4,73] Today, from a business and public health perspective, the magnitude and extent to which preventive measures reduce the risk of NIHL in its reversible or preimpairment stage remains uncertain.[24]

Beyond OSHA, MSHA, and NIOSH, many professional organizations and manufacturers of HPDs and audiometers have devoted extensive resources to HCPs, but neither they nor any other stakeholders provide employers with specific "best practices" tools or methods to measure audiometric aggregate trends and HCP effectiveness. Table 3 summarizes the current state of audiometric analytics.

- The American College of Occupational and Environmental Medicine (ACOEM) has issued three evidence-based statements for best practices and proficiency in early detection and prevention of occupational hearing loss (2003, 2012, and 2018).[31,73,74] ACOEM's most recent position statement asserts that "[t]he occupational and environmental medicine (OEM) physician plays a critical role in the prevention of occupational noise-induced hearing loss," and that it offers "current best practices in the diagnosis of occupational NIHL."[74] None of these evidence-based statements includes any recommendations or guidance beyond individual audiogram interpretation or action outside the scope of the OSHA Noise Standard. Specifically, there is no mention of ADBA or population-based audiometric data analytics. In 2019, ACOEM's emphasis on noise "prevention opportunities" for occupational medicine physicians remained confined to the individual audiogram level.[11]
- The American Academy of Audiology's (AAA) 2003 Position Statement advocates "protocols capable of identifying meaningful changes in hearing" and corroborates the deficiencies of the OSHA STS approach, but does not proffer any guidelines or methods beyond individual audiogram interpretation.[32] The AAA Position Statement deems two consecutive 15 dB changes at *any* frequency to be the "best practice for identifying significant noise-induced threshold shifts."
- The mission of the Council for Accreditation in Occupational Hearing Conservation (CAOHC) is to foster "best practice" in occupational hearing conservation worldwide.[75] CAOHC includes "management of the audiometric database" as one of its five professional supervisor requirements.[76] The organization expects those in charge of audiometric testing to utilize audiometric data to "identify early flags for individuals" at risk and "describe reasons for test-to-test variability." Each of these duties inherently relies upon individual judgment and knowledge for one-at-a-time audiogram interpretation. CAOHC's approach to measuring HCP effectiveness relies entirely upon OSHA's STS criteria—which makes no use whatsoever of aggregated, population-based audiometric data beyond the individual worker's test results.[77]
- The National Hearing Conservation Association's (NHCA) guidance documents for managing audiometric data include no provisions for ADBA or any use of audiometric data beyond individual, one-test-at-a-time interpretation and recording of an STS for compliance with the OSHA Noise Standard.[25,47]
- The ISO Standard 1999, Acoustics—Estimation of Noise-Induced Hearing Loss (2013, updated in 2018), provides "a method for calculating the expected noise-induced permanent threshold shift in the hearing threshold levels of adult populations due to various levels and durations of noise exposure."[78] This methodology focuses on the regulatory outcome at the individual employee level—the permanent threshold shift (equivalent to STS)—but does not measure trends among groups to assess HCP effectiveness at the population level or indicate which subgroups are at increased risk before irreversible health effects or regulatory endpoints (e.g., STS) occur. This ISO standard has not been widely adopted or tested in occupational hearing conservation practice in the USA.
- Neither of the major industrial hygiene professional organizations—the American Industrial Hygiene Association (AIHA) nor the American Conference of Governmental Industrial Hygienists (ACGIH)—has published methods or guidelines for audiometric data analysis to complement standardized methods of noise exposure.
- NIOSH's Occupational Hearing Loss Surveillance Project has amassed a "convenience sample" of over 15 million audiograms collected from the private sector, but has not conducted any longitudinal trend analyses on this data.[4] NIOSH's current hearing loss prevention research agenda appears focused on conducting cross-sectional studies exploring the magnitude of NIHL prevalence in selected industries, and estimating the extent of (non) compliance with HDPs among US workers exposed to hazardous workplace noise.[79]

8 | THE SOLUTION

NIOSH, regulatory health and safety agencies, researchers, and policymakers have recently acknowledged the need for NIHL prevention best practices by calling for new, "real-world" technologies and approaches.[4,5,80] The 2019 National Occupational Research Agenda for Hearing Loss Prevention includes objectives to improve occupational hearing loss surveillance and develop audiological tests for hearing loss prevention as part of an overarching objective to "provide scientific basis for policies and guidelines that will *inform best practices* for hearing loss prevention efforts."[81]

While reduction of noise exposure remains the primary objective for primary prevention of NIHL, the "lowest hanging fruit" for effective, secondary prevention will be the ability of employers to

TABLE 3 Current state of tools and methods available for employers to measure audiometric aggregate trends and HCP effectiveness

Stakeholder class	Stakeholder examples	Tools or methods to measure	
		Aggregate trends	HCP effectiveness
Government	OSHA, MSHA, NIOSH	No	No
Occupational Medicine and Nursing	ACOEM, AOEC, AAOHN	No	No
Audiometry and Occupational Health Services	ASI Health Services, HCI, Examinetics, Workplace Integra, Concentra	No	No
Public Health, Labor	ILO, WHO	No	No
Standards	ANSI, ISO	No	No
Audiologists, Hearing Health	AAA, CAOHC, NHCA	No	No
Industrial Hygiene, Safety	AIHA, ACGIH, ASSP	No	No
Hearing Protection manufacturers and distributors	Honeywell, Howard Leight, North Safety; 3M, Peltor	No	No
Audiometers and audiology Software	Benson, Grason Stadler, Sycle, CounselEar, HearTrak	No	No
OH/IH Software	Enablon, Intelex, Cority, Gensuite, OHM, PureSafety, HSI	No	No
Workers' Compensation insurers	AIG, Travelers, York, Zurich	No	No
Labor Unions	UAW, Teamsters, OCAW	No	No

Abbreviations: AAA, American Academy of Audiology; ACGIH, American Conference of Governmental Industrial Hygienists; ACOEM, American College of Occupational and Environmental Medicine; AIHA, American Industrial Hygiene Association; ANSI, American National Standards Institute; AOEC, Association of Occupational and Environmental Clinics; CAOHC, Council for Accreditation in Occupational Hearing Conservation; HCI, Hearing Conservation, Inc.; ISO, International Standards Organization; MSHA, Mine Safety and Health Administration; NHCA, National Hearing Conservation Association; NIOSH, National Institute for Occupational Safety and Health; OSHA, Occupational Safety and Health Administration; WHO, World Health Organization.

effectively utilize audiometric data that *has already been collected* and collectively turn it into "actionable data" on a population health level.

The routine statistical analysis of aggregate audiometric data trends among individuals and SEGs within and across organizations to predict and identify early NIHL remains a longstanding, unfulfilled need not met by noise regulations or the ANSI S12.13 Standard (1991–2011). Aggregate metrics that can accurately *summarize* audiometric trends specifically toward NIHL at *both* the individual *and* population levels, and methods to systematically apply these metrics to objectively evaluate *performance* of how HCPs impact *health-based outcomes*, have yet to be developed, defined or applied.

Best practices are determined largely by organizations that operate most efficiently and productively by managing and utilizing information effectively, including leveraging technology to minimize identified risks.[11,29] For companies and public entities, the compelling "business case" to widely adopt a best practices approach to NIHL prevention and risk management means they would need to exceed minimum regulatory compliance and recordkeeping requirements. The approach needed to accomplish this objective includes two key, inter-related components: statistical methods and automated information management technology.

1. *The statistical methods* transform raw audiometric data and patterns into metrics, from which trends specifically toward early NIHL (before STS occurs) can be measured using standardized statistical tests, both individually and collectively in groups (populations) such as SEGs. Practical analytical statistical methods and tools are automated and capable of pulling raw data directly from a live, scrubbed database without expert statistical analysis packages or extensive manual oversight.[62] Numerical criteria to evaluate HCP effectiveness by SEGs can be developed either by consensus or retrospective analysis of audiometric data endpoint benchmarks, such as the STS. Temporal trends toward NIHL, adjusted appropriately for employee-specific time intervals relative to the duration of employment or age, identify individuals and groups at the highest risk. These metrics are applied to measure the impact of preventive interventions including engineering, administrative, PPE, or other exposure controls. Challenges for the statistical methodology are summarized in Table 4.
2. An *information management platform* configurable to each organization (company, facility or other employer entity) streamlines and automates the *process* of managing dynamic audiometric data: scheduling, collection, analysis, reporting, and documentation. Expertise in audiology should not be required for these aspects of data management.

Efficiently managing complex, inter-related, time-dependent audiometric data and the related employee and workplace data requires capturing data in a relational database. A database is part of but does not in and of itself constitute a business system platform. Desktop software database applications such as Microsoft Excel® or

TABLE 4 Challenges for statistical methods for practical audiometric database analysis

Attribute	Description
Data structure	Interval (5 dB) scale of logarithmic values
	Permutation of 14 data points (0.5, 1, 2, 3, 4, 6, and 8 kHz per ear, ×2 ears)
	Two ears, one person
Population	Small to large in numbers
	Variable duration (years) or number of tests relative to test frequency
	No controls (unexposed)
Interpretation	Distinguish NIHL from other patterns
	Variable baseline, including pre-existing hearing loss
	Test-to-test variability
	Handle outliers and missing data
Applicability	Simplicity and ease of use
	Real-time data access to/from an information management system
	Automated interpretation

Abbreviation: NIHL, noise-induced hearing loss.

Access® are useful for many business applications, but they are not designed or reliably configured for automating the process of managing dynamic health and safety compliance data.

Automation of information in a health and safety business platform aggregates and integrates data into the operational workflow by rapidly performing repetitive tasks such as scheduling and tracking of tests, data entry or upload, data analysis, and reporting in a consistent, predictable manner. Modern businesses increasingly rely upon information systems that integrate data from one or more real-time systems so they can avoid moving or replacing data into and out of separate "silos." Audiometric and employee job and noise exposure data should ideally be managed seamlessly in conjunction with other health and safety data (e.g., training, respirators, medical surveillance, industrial hygiene) as well as with data from other business processes, such as human resources. The system should be easy to operate, accurate, reliable, fast, secure, and accessible. Most importantly, this technology must be affordable for organizations of any size or industry to use it continuously and consistently.

Given the inertia of the status quo, the most realistic opportunity to successfully advance risk management around noise will be a voluntary, Audiometric Data Best Practices approach—rather than attempting to modify longstanding noise regulations. Which profession(s) or stakeholder(s) (Table 3) is (are) best positioned to leverage the opportunity to lead these Audiometric Data Best Practices methods and tools? As with the introduction of any new technology, the impetus will likely be industry-specific and driven by money and perception of return on investment. The PPE (HPD) and audiometer manufacturing industries would stand to financially benefit the most from offering such technology in conjunction with their products to prove and increase their value. Audiologists are closest to the raw data collection and interpretation process; however, most audiologists presently in private practice and their audiology software platforms are disconnected from the business and methods of occupational audiology screening (Figure 1). Industrial hygienists are the most qualified to stratify workers' risk by external noise exposure measurements and utilize aggregate outcomes to evaluate the effectiveness of exposure controls, but they would need to be willing to delve into uncharted waters of medical data interpretation and handling. Finally, occupational medicine physicians and nurses, in theory, understand all of the foregoing subject matter areas, and are often in a position to collect, interpret, and manage occupational health data. However, occupational medicine (at least in the USA) remains a highly fragmented field where some practitioners have no formal occupational medicine residency training.[12,29]

Regardless of how Audiometric Data Best Practices take off, documentation of the outcomes will require several years to evolve and gain professional and business acceptance. The process will necessitate rigorous methods for properly categorizing and tracking noise exposure and PPE use (e.g., HPD fit testing) throughout employees' employment, and ensuring timely scheduling and performance of audiometric testing within each participating organization. Publication of consistent (positive) outcomes will then attract the interest and attention of authoritative standard-setting organizations (e.g., ISO or ANSI) to create evidence-based standards that, when promulgated and widely adopted, would become the de facto standard of care. Workers' compensation insurers and other risk management entities would follow suit and require 'compliance' with Audiometric Data Best Practices to offer premium discounts and attract lower risk businesses.

The widespread adoption of accessible, standardized methods and tools to accurately identify early NIHL in workers, measure the impact of exposure controls and other interventions to prevent irreversible hearing loss, and objectively evaluate the performance and outcomes of HCPs will be a major breakthrough for all stakeholders:

- *Employees* will receive useful information by which to understand their risk related to NIHL and increase their willingness to participate in all aspects of HCPs.
- *Employers* can create a benchmark for each industry to effectively protect their employees' hearing, set target levels for interventions (e.g., PPE level, temporary removal), and measure their outcomes on a continuous, real-time basis. Organizations that can objectively demonstrate the effectiveness of their HCPs could not only reduce direct costs associated with NIHL but could also potentially qualify for reductions in workers' compensation insurance premiums.
- *Industrial hygienists and safety professionals* will have the right tools to link exposure controls to performance-based health outcomes to justify, improve or trim their HCPs.
- *Regulators* could access and leverage large, representative databases of redacted or disidentified data or summary statistics for further analysis

to define the distribution and determinants of NIHL needed for exposure control and disease prevention. This capability would allow regulatory agencies to transform their traditionally reactive enforcement into a proactive, cost-saving and productivity-enhancing resource to the businesses they regulate.

- *Audiologists, occupational medicine and other physicians, and manufacturers and distributors of HPDs and audiometer hardware and software* can utilize or offer this technology in conjunction with their existing products and services, thereby increasing their value to their customers and differentiating themselves from their competitors based on quality rather than solely price.
- *Workers' compensation insurers* can utilize insured companies' data and metrics to measure HCP effectiveness, set benchmarks (e.g., by industry), and provide tangible premium incentives and reductions for companies who utilize Audiometric Data Best Practices to reduce NIHL risk.

Collectively, disrupting the status quo of regulatory compliance through implementation and widespread adoption of these Audiometric Data Best Practices among regulated companies of all sizes and across all covered industries will be a paradigm shift in solving the persistent, elusive goal of reducing the incidence of NIHL and lowering the economic and social burden associated with noise as an occupational hazard.

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CONFLICTS OF INTEREST

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AUTHOR CONTRIBUTIONS

James Craner is fully responsible for the conception, design, research, content, writing, analysis, and proposed solutions in this review/commentary. The author has approved the publication, vouches for its accuracy and integrity, and agrees to be held accountable for all aspects of the work.

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