ADJUSTING RETROSPECTIVE NOISE EXPOSURE ASSESSMENT FOR USE OF HEARING PROTECTION DEVICES

by

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Abstract

Rationale: Earlier retrospective noise exposure assessments for use in epidemiological research were not adequately characterized because they did not properly account for use of hearing protection devices (HPD) which would result in potential misclassification. Exposure misclassification has been shown to attenuate exposure-outcomes relations. In the case of already subtle relationships such as noise and cardiovascular diseases, this would potentially annihilate any association.

Objective: We investigated two approaches using Workers' Compensation Board (WorkSafe BC) audiometric surveillance data to (i) re-assess the noise exposure in a cohort of lumber mill workers in British Columbia using data on the use of HPD and the determinants of their use available through WorkSafe BC, and (ii) test the validity of the new exposure measures by testing their predictions of noise-induced hearing loss, a well-established association.

Methods: Work history, noise exposure measurements, and audiometric surveillance data were merged together, forming job-exposure-audiometric information for each of 13,147 lumber mill workers. Correction factors specific to each type and class of HPD were determined based on research and standards. HPD-relevant correction factors were created using 1) deterministic methods and self-reported HPD use after filling gaps in the exposure history, or 2) a model of the determinants of use of HPD, then adjusting noise estimates according to the methods' predictions and attenuation factors. For both methods, the HPD-adjusted and unadjusted noise exposure estimates were cumulated across all jobs each worker held in a cohort-participating lumber mill.

Finally, these noise metrics were compared by examining how well each predicted hearing loss. Analyses controlled for gender, age, race as well as medical and non-occupational risk factors.

Results: Both methods led to a strengthening of the noise-hearing loss relationships compared to methods using noise estimates unadjusted for HPD use. The method based on the modeling of HPD use had the best performance with a four-fold increase in the slope compared to the unadjusted noise-hearing loss slope.

Conclusion: Accounting for HPD use in noise exposure assessment is necessary since we have shown that misclassification did occur and led to an attenuation of exposure-response relationships. Exposure-response analyses subsequent to exposure reassessment provide predictive validity and gives confidence in the exposure adjustment methods.

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Glossary

BC	British Columbia.
dB (A)	decibel, a logarithmic unit measuring the ratio of a measured sound pressure level to a reference sound (20 μPa) further scaled to an A filter.
HCP	Hearing Conservation Programs
HPD	Hearing Protection Devices
Leq	Average sound level for a measurement period based on a 3dB exchange rate
NIHL	Noise-Induced Hearing Loss

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Co-authorship Statement

Chapters 2, 3, and 4 are manuscript prepared for scientific publication. All co-authors participated in the design and implementation of the research program

I prepared and merged the data needed to undertake the research agenda. I performed all data analyses. Ying MacNab overviewed the analyses pertaining to chapter 3; Kay Teschke contributed to the design of chapter 2. Hugh Davies supervised all chapters of this thesis, and provided me with the noise exposure, and cohort demographics and work history data.

I discussed the plan of the manuscript with Hugh Davies and performed the redaction of all chapters. All committee members provided me with feedback for concepts that needed further clarification, and with helpful suggestions for the editing of the manuscript.

1 Introduction & literature review

Noise

Today, we find ourselves assaulted almost constantly by noise - often defined as an 'unwanted sound' - from both community (planes, traffic, etc…) and at work. In spite of the fact that the issue of noise and hearing has been investigated for decades by various disciplines such as medicine, engineering, audiology, and psychology, it remains a problem.

In the occupational realm, high noise levels is likely the most ubiquitous of hazardous exposures. While the number of Canadians exposed to noise is not well characterized, Hetu et al showed that, in Quebec, 56 percent of workers in a sample of 5,000 heavy-industry plants were found to have exposures exceeding 85 dBA, the regulatory permissible level, a level associated with hearing loss [1]. Most people recognize that noise can be a health hazard because of its effect on hearing sensitivity. Unfortunately, even this significant known effect of hearing loss remains underappreciated because of other consequences, often unaddressed, that severely impact the lives of exposed workers. Moreover, only a minority of employers try to actively control noise exposure and go beyond the implementation of a hearing conservation program - the benefits of which are far from clear [2].

Both at the high levels impacting hearing and at lower levels often observed in environmental exposures, the harmful effects of noise on human health go beyond hearing damage. Many of these adverse health effects, including cardiovascular diseases, are mediated by noise as a source of stress. Biological models describing the relation between stress and coronary heart disease already exist [3], and have been adapted to include noise more recently.

This combination of highly ubiquitous noise exposure and the societal burden of cardiovascular disease, one of the leading causes of death in Canada, increases the magnitude of the problem our society faces, and begs for the consideration of noise in a more comprehensive framework where exposure, hearing loss, physiological disorders, psychosocial responses and their interactions are integrated. In order to conduct adequate research, not only all health outcomes must be fully appreciated, but the exposure characterization need to be rigorous.

My thesis research investigated approaches to better characterize occupational noise exposure by addressing research gaps identified in retrospective noise exposure assessment in occupational cohort studies.

Retrospective noise exposure assessment

Retrospective exposure assessment is typically a difficult task to undertake because of the paucity of available historical data. Compared with more “traditional” chemical agents, relatively few attempts have been made to estimate retrospectively physical agents in general, and noise in particular, for epidemiological studies [4].

Crude methods such as ‘never/ever’ exposed cannot be adopted given the noise prevalence both in the workplace and in the community. The case of noise exposure assessment is potentially more complicated to perform because of the nature of this agent: the intensity of noise generation varies greatly with the type of noise source at hand which is seldom available information in retrospective assessment. The retrospective noise exposure assessment necessitates more sophisticated approaches based on quantitative assessments.

To determine the parameters associated with hearing loss in a cohort of industrial workers exposed to noise De Almeida *et al.* (2000)[5] used duration of employment as a surrogate for exposure in a retrospective study of 222 subjects with occupational hearing loss. Burgess *et al.* [4] chose a mixed approach where, rather than grouping homogeneous exposure groups by job title or task, the assessors first used historical sampling data to estimate average area noise levels in each workplace where a survey had been performed. The noise levels were then estimated in the work area and, finally, individual estimates of exposure were further refined based on job title. Estimates were extrapolated to areas where noise surveys were not performed. Despite a common agreement that quantitative exposure estimates are more appropriate for retrospective exposure assessment, Reeb-Whitacker *et al.* [6] demonstrated that qualitative exposure assessment could also be used when calling upon workers' memory. These authors evaluated the accuracy of task recall for epidemiological exposure assessment to construction noise using a cohort of 25 construction workers and comparing their evaluation to weekly dosimetry measurements. They showed that, six months later, workers were able to correctly recall the percentage time they spent at various tasks and to estimate with relatively high accuracy – overestimating by 2dB on average - their noise exposure compared with dosimetry measurements. However, the use of models contributes to quantitative methods that are objective, valid and robust. Especially with advancements in regression techniques, historical exposure can be modeled in the presence of scarce data at the individual level as commonly found in recent retrospective cohort-based studies.

Challenges associated with noise REA

The vast majority of epidemiological cohort-based studies investigating adverse health effects of occupational noise face a common additional complicating factor for accurate estimation of noise exposure: the use of hearing protection devices. This degree of measurement error introduced by HPD may be very important where there are only weak associations between exposure and outcome to begin with.

Regardless of the approach adopted (i.e. modeling, expert-based, or qualitative assessment), retrospective noise exposure assessment is generally prone to measurement bias due to the use of hearing protection devices which attenuate the noise level. When determining the causality of a disease using a historical cohort study design, reliable and valid retrospective exposure assessment is a key element of a good epidemiological study[7].

It appears that the use of hearing protection devices is very likely to alter significantly the noise exposure experienced by workers as this would cause systematic overestimation of noise exposure. When a worker wears hearing protection devices, the odds of misclassification are certain since the measurement is taken at the shoulder with the measurement device being attached to his/her lapel and therefore, the actual dose of energy transmitted to the ear of the worker is not properly captured. The device, generally a personal dosimeter, is recording a level of sound higher than what the worker is truly exposed to.

By assigning levels of exposure that were higher than what was truly experienced, the dose-response relationship is distorted and likely to be attenuated [8].

Errors introduced in the assessment of exposure are important to reduce because a small amount of error can affect risk estimates when investigating causality of diseases [9]. This last point is crucial as the reviewed studies failed to properly account, either by completely omitting or not successfully adjusting for HPD use, which results in both cases to underestimation of the risks associated with overestimation of noise exposure, in a manner that is expected to be both differential and non-differential with respect to underlying exposure level. Both the overestimation of exposure of those with high exposures (who systematically wear hearing protection more often) and the non-differential component of misclassification are expected to lead to underestimation of the risks associated with exposure to noise

The motivation of this thesis is to improve estimates of true noise exposure by reducing the measurement error introduced by use of HPD.

For this thesis, I used a sub-sample of the cohort of lumber mill workers for which quantitative measurements were estimated and for which information on the use of hearing protection devices was available.

The original cohort consisted of approximately 27,500 lumber mill workers. Davies *et al.* [10] retrospectively assessed individual noise exposure estimates using noise sampling data from different sources (dosimetry, industry and regulatory agencies) combined with exposure determinant data gathered from interviews and mills' documentation to build models allowing the prediction of exposure levels for all jobs and time periods. An accurate historical reconstruction of noise exposure is essential especially when the relationship between exposure and health outcome is expected to be weak like in the case between noise and cardiovascular diseases (CVD).

Noise and Cardiovascular outcomes: a weak association

The contribution of psychosocial stressors to the etiology of coronary disease has been well established both in workers with and without pre-existing conditions [11]. Noise, viewed as a potent stressor, is therefore thought to adversely affect cardiovascular conditions [12]. It is hypothesized that noise leads to perturbation in hormonal balance and autonomic nervous system, which lead to chronic disease, and many studies testing different aspects of the biological model, exists in both occupational and community based studies have examind these so-called ‘non-auditory’ effects [11, 13-16], however, the evidence remains inconclusive.

Among the ‘non-auditory’ health effects of noise, cardiovascular disorders have received the bulk of the attention of researchers. The epidemiological evidence for chronic heart disease is still sparse and studies have had generally inconsistent findings. Most positive studies have found only weak associations between noise exposure and ischemic heart disease, with relative risks of 1.1 – 1.3 [17, 18]. Other studies have reported no associations [19], leading to van Kempen et al’s conclusion that the relation between noise and ischemic heart disease was still inconclusive[20]. Since then, more recent studies have shown positive associations. As an example, Davies et al., conducted a longitudinal study of heart disease mortality in a cohort of 27,464 sawmill workers [10] and showed elevated risks of acute myocardial infarction for those who were highly exposed to noise. An additional more recent study investigated the joint effects of shift work, noise and physical workload [21] where the authors demonstrated an excess risk for coronary heard disease with shift work and continuous noise exposure in the working population. However, a relatively recent study found mixed results between noise and ischemic heart disease when conducting a case control study nested within a British cohort of nuclear power workers [22].

Several factors may account for the divergence of results on the investigation of noise and cardiovascular disease, including inadequate study design and control of confounding. Even in the case of studies rigorously executed with large sample size and an appropriate adjustment for several potential confounders, information bias was an important limitation leading to misclassification (e.g. classifying exposed subjects as unexposed) and resulting in the potential attenuation of the exposure-response relationships [23]. Such a bias occurs in the noise exposure assessment phase. It reflects that the adequacy of exposure assessment was in fact the major limitation of virtually all epidemiological studies on noise and coronary heart diseases conducted so far. Non-differential exposure misclassification due to inaccuracy of exposure measurement would occur, for example, if the protection provided by the usage of personal protective equipment is omitted.

Hearing Protection Devices

In British Columbia, where hazardous levels of noise exist, workplaces are required by the provincial Worker's Compensation Board to implement a Hearing Conservation Program (HCP). These programs have seven components, of which noise control at source where practicable, the use of hearing protection devices and annual audiograms, which are performed to identify "early warning" signs of noise-induced hearing loss, are relevant to the research questions tackled in this work. Hearing protection devices are widespread and very popular mean to protect workers compared with other HCP requirements such as noise control at source, deemed to be too expensive or not practicable [24].

In the vast majority of observational studies investigating adverse health effects of noise, quantitative noise estimates use an A-weighting. This scale substantially discounts low-frequency components of the noise signal. The attenuation of the sound signal with an A-weighted filter corresponds to the fact that the human ear does not respond equally to all frequencies (more sensitive to higher frequencies between 1 to 4 kHz).

HPD can either be earplugs or ear muffs and the protection they provide vary between types of devices. Selection of HPD is influenced by the attenuation they provide. Manufacturers usually report laboratory hearing test results consisting of attenuation and standard deviations at different frequencies in one single number: the Noise Reduction Rating (NRR). While, over ten different methods to compute NRR exist, they usually relate poorly to the "real-world" performance [25]; consequently NRR have been the source of controversy. Many reasons contribute to the mismatch between the manufacturers NRR, called 'labeled' NRR, and the 'true' noise attenuation. For instance, earplugs inserted into the ear canal eliminate the natural open ear natural resonance (a peak of approximately 17 dB at 2700 Hz) which reinforces the popularity of HPD as a noise control tool in working population exposed to noise. The loss of canal resonance when an earplug is inserted, in addition to the unbalanced attenuation they provide (attenuation for high frequencies greater than for low frequencies), results in muffled voices and unclear communication. If the user already has some high frequency hearing loss, as usually observed in noise-exposed populations, hearing protection that muffles high frequencies further reduces the ability to communicate in noise. Workers are, therefore, prone to remove their HPD which adds further variability to their field performance. Other reasons for which labeled NRR do not mirror the field performance of

HPD are related to the fact that their attenuation is function of many aspects difficult to control for in laboratory settings, such as their fit, their removal during exposure (e.g. for ease of communication), and pre-existing personal protective equipment (e.g. hard hat).

Despite the gap between labeled and 'true' NRR, this rating has a great appeal compared with multiple number ratings, which necessitate octave band computational procedure. NRR require a single number for the sound level, thus offering a simplified way to (a) quantify the protection the manufacturer claims the HPD provides on their labels; and (b) to approximate the "true" sound level experienced by workers.

HPD attenuation in noise exposure assessment

Few studies of noise exposure have addressed the effect of HPD despite a general consensus that it is the primary, and often the only tool for noise control.

Adjustment for HPD in other noise exposure assessment studies

With respect to cardiovascular outcome, it has been shown, using quasi-experimental field studies, that the use of HPD is associated with reduced cardiovascular effects in noise-exposed population [26, 27]. Therefore, taking into account the use of HPD would improve the accuracy of the noise exposure assessment.

The primary objective of this dissertation work is to re-calculate noise exposure estimates by integrating the use of hearing protection devices in estimates of noise exposure levels for individual subjects working in the BC lumber mills.

In occupational cohort-based studies, use of HPD was either entered as variable in the regression equation of noise and the adverse health effect investigated or was taken account into via heuristic algorithms ref?

In a British cohort study of industrial nuclear workers, ad-hoc adjustments were made after estimating noise exposure for potential bias such as the use of hearing protection devices [4]. Davies et al used arithmetic modifiers based on observed prevalence of use of HPD to adjust retrospectively assessed individual quantitative noise measures. In both studies where historical noise estimates were used to examine cardiovascular mortality, results were mixed [10, 22]. In the mortality study that was subsequent to the exposure assessment conducted by

Burgess *et al*, findings were not robust as noise exposure did not show a positive association with ischemic heart disease in the two sites that were assessed. Furthermore, they did not predict consistently noise-induced hearing loss where the exposure assessment was conducted.

Of particular interest to the work addressed in this thesis, Davies et al [10] found a stronger effect when restricting their analyses to a sub-cohort of 8,668 workers who terminated cohort employment before 1970. As reported by Davies [28] following interviews with senior sawmill workers, HPD were not worn during that period. The authors attributed this strengthening of the exposure-response relationship in this group to reduction in exposure misclassification achieved by restricting the study group to those who never used hearing protection.

Both studies used single number rating [4, 10] because octave band measurements (required for multiple number ratings) are seldom gathered or available, especially in retrospective cohort investigations. Only a study of noise exposures on fishing vessels, octave band and A-weighted sound pressure levels were measured along with full-shift dosimetry measurements on all crew members, yet the attenuation provided by HPD was computed using a single number rating [29].

Despite of the use of the same rating scheme (i.e. single number rating), the effectiveness of HPD varies greatly from one person to another [30, 31]. The performance of HPD is function of many aspects difficult to control for, such as their fit, their removal during exposure (e.g. for ease of communication), their type (e.g. custom mold earplugs), pre-existing personal protective equipment (e.g. hard hat). As pointed by Rabinowitz et al., in a longitudinal retrospective study of ambient noise exposure and hearing loss, this variability makes accurate individual noise exposure estimation in longitudinal studies virtually impossible [32]. However, in a prospective exposure assessment of construction apprentices, Seixas et al combined full-shift dosimetry, complete HPD use information, and direct measurements of attenuation from a subset of the population to adjust exposures specific to each trade. The dose-response relation showed a much stronger relation for the HPD-adjusted trades[33].

Adjustment for HPD in the B.C. lumber mill cohort

It is expected that the fact that HPD are likely the most widespread method for noise control would have an important quantitative impact on exposure assessment. This work was not only motivated by the misclassification of exposure concern but it also stem from the finding of the cardiovascular mortality study which showed that noise and ischemic heart disease relation was stronger in those who did not wear relative to the full B.C. lumber mill cohort.. We need to answer two questions:

1. Who wore HPD?
2. What attenuation did HPD provide?

In the work presented here, I used the BC lumber mill cohort for which good quality work history information was available. I will combine three data sources: (1) Work history with personal demographics for each worker in one of the 14 BC cohort sawmills, (2) Noise exposure estimates derived from a quantitative retrospective exposure assessment, (3) Audiometry data for the cohort obtained from the Workers' Compensation Board of BC, where each audiogram contains information on subjects' otological health history, occupational and leisure noise exposures, and personal hearing protector use, which includes type (plug or muff). The concurrent availability of these data sources allowed answering the first question as it became possible to determine who wore an ear protector, at what time, during which job and with what exposure level.

Alternatively, I also investigated a more general approach in which determinants of use of HPD were modeled and used to predict the likelihood of use without having to have had subjects self-report their use of HPD.

The second question was tackled by correcting theoretical attenuation provided by guidelines to approximate the effective attenuation obtained in the field using published results on how to quantify the gap between a recommended and an achieved attenuation amount.

Validation

By improving the use of exposure data, the goal is to effectively "translate a measurable quantity of exposure to an approximate, or estimate dose received by each study subject" [34] which will result in a dose response relationship closer to the "truth" (i.e. less attenuated) by reducing the likelihood of misclassification.

As noted by Stewart, improving estimation methods or equivalently testing the validity of study is a great challenge in retrospective exposure assessments [9].

Often validation relies on a set of data as a reference for comparison. Usually referred to as "gold standard" these measurement-based data are only seldom available in epidemiological studies using retrospective exposure measures. However, these measurements which are assumed to be the gold standard can be "alloyed" as measurements cannot realistically be error free [35]. Therefore expert-based evaluation has been under scrutiny. As reported by Friesen et al., results have been mixed with a few studies showing that experts based rankings were reliable. Friesen and colleagues examined the shape, goodness of fit, precision, and sensitivity of the exposure-response relationships between cumulative noise exposure and acute myocardial infarction. They used both expert- and measurement-based occupational noise estimates in the same retrospective cohort study of BC sawmill workers from which our study cohort was derived. While the goal of the study was to examine how well subjective measurements (i.e. experts) predict exposure-response relations compared to objective (i.e. quantitative) measurements, an additional result was highly relevant to my thesis. Friesen showed that the exposure protection provided by HPD made a significant contribution to noise exposure misclassification. More importantly, this study prompted the need to further test the validity of exposure measures [23].

Simulation studies represent another alternative to assess exposure measures. Seixas and Sheppard demonstrated in their investigation on the impact of random errors on exposure-response relationships that a simulation-based exercise allowed the evaluation of the precision and accuracy of different approaches to assess exposure, which consisted of different grouping schemes [36]. Simulation studies can therefore not only evaluate the performance of grouping schemes but also different exposure assessment methods.

As pointed by Stewart [37], to assess the ability of already developed exposure estimates to predict an adverse effect, predictive validity can be examined by testing their ability to predict a well established health outcome. For example Dosemeci et al tested reconstructed silica exposure estimates in metal mines and pottery factories in China, developed for the investigation of lung cancer, by examining their relationship with silicosis[38].

In the same vein, noise exposure estimates can be validated by testing their ability to predict noise-induced hearing loss (NIHL). Until now, only one study has retrospectively assessed noise exposure estimates and subsequently validated by testing their ability to predict NIHL [39].

The second objective of this thesis is to assess the reliability of the new measure by testing its predictive validity for noise-induced hearing loss in the lumber mill workers.

A model's predictions will be considered more valid, i.e. result in less exposure misclassification, if they strengthen the noise-hearing loss exposure-response relationship.

Thesis structure

In sum, use of HPD complicates the challenging task of retrospective assessment of noise exposure. This thesis work is motivated by one main question: can we improve retrospective noise exposure estimates for epidemiological studies, in light of the challenges faced when examining intrinsically weak exposure-response relation such as noise and cardiovascular diseases?

I will investigate approaches to reduce misclassification of exposure due to hearing protector use and address the following research objectives

1. What method can we adopt to take advantage of audiometric data, and more particularly the embedded information on use of HPD, to correct for the noise protection provided by HPD in unadjusted noise estimates?
2. Can we predict HPD use and then estimate HPD-adjusted noise exposure levels for individual subjects?
3. What is the validity of the new exposure measure?

In this thesis, I start with a direct linkage of self-reported use of HPD to job-exposure records in order to adjust noise exposure for each individual job record and then I compare the HPD-adjusted with the unadjusted noise metric (Chapter 2).

Second, I develop predictive models of hearing protector use from self-reports of hearing protection device use gathered on the hearing test data (Chapter 3). In this chapter,

hierarchical modeling will be utilized to take into account the repeated nature of testing within individuals and nesting of subjects within mills and to examine determinants such as mill, employer, subjects' age, department, job, exposure level, calendar year, etc.
The model can then used to predict hearing protection use for all study cohort subjects and adjust exposure accordingly. This method will be evaluated by examining the noise-hearing loss relationship using the audiometry data (Chapter 4).

In conclusion, this thesis suggests methods to reduce misclassification of historic noise exposure estimates through ways of accounting for hearing protection devices.

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2 Accounting for use of hearing protection devices in retrospective noise exposure assessment: deterministic estimation and validation.

Introduction

Most epidemiological studies investigating chronic outcomes require historical measures of exposure that are seldom complete. Noise exposure is no exception: there has been poor characterization of exposure in many aspects including the assessment of sound pressure levels [1].

Compared with more “traditional” chemical agents, a relatively modest amount of research has been devoted to retrospectively estimating noise exposure for epidemiological investigations [2]. Noise is so ubiquitous that virtually all workers are exposed to some degree both within and outside the workplace; consequently, the traditional method to characterize noise exposure as ‘ever’ or ‘never’ exposed is not appropriate. Other methods for retrospective estimation of noise exposure, such as duration of employment as a surrogate for exposure has been used [3, 4]. More recently, mixed approaches, based on past noise survey and expert judgment were developed to investigate a possible relation between noise exposure and ischemic heart disease [2].

In the present study population of blue-collar lumber mill workers, personal noise exposure estimates were quantitatively assessed using a prediction model obtained from approximately 1,900 personal dosimetry measurements to examine the relation between noise exposure and acute myocardial infarction [5]. However, this and previous studies have had a major limitation in their historical noise assessment. They have failed to adequately account for the use of

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hearing protection devices (HPD), leading to a probable over-estimation of noise exposure [5]. The result of the failure to consider HPD use is suggested in an analysis of a sub-cohort of the aforementioned lumber mill cohort. In this sub-cohort comprised of workers who never used HPD, the noise-heart disease relationship was stronger than that found in the entire cohort, supporting the hypothesis that omitting or failing to adequately account for HPD use contributes to exposure misclassification. This is particularly an issue given that the use of HPD became widespread with the implementation of "hearing conservation programs", in the 1970's, in workplaces such as lumber mills where noise exposure levels exceed the permissible limit of 85 dB(A).

Rigorous retrospective exposure assessment is a daunting task. We could adjust for HPD use if we knew which workers in the cohort used them, what type of HPD were used and when these were worn. Fortunately, a requirement of hearing conservation programs is the administration of annual hearing tests to workers, during which they self-report HPD use. We could therefore adjust exposure estimates for a cohort of Canadian lumber mill workers for whom we concurrently had demographics, job records, and quantitatively assessed noise data. The following steps were taken: (1) the gaps in the history of HPD use were imputed when individual job-exposure records did not have a coinciding hearing test, (2) a correction factor which reflected the attenuation provided by HPD was determined, and (3) the exposure was adjusted for HPD use by directly linking the correction factor associated with each self-reported use of HPD to the noise level.

Ideally, the validity of any measure should be tested before use. Yet, validation of exposure estimates remains rather unusual. While validation may require a "gold standard" set of data as a reference for comparison, one may also assess the ability of developed exposure estimates to predict an adverse effect. Predictive validity can be examined by testing their ability to predict a well established health outcome [6]. Thus, noise exposure estimates after accounting for HPD can be validated by examining the changes in noise and noise-induced hearing loss (NIHL) exposure-response relation, a long established causal relationship [7], which is well characterized [4, 8]. The strategy has been previously employed in a study of a cardiovascular disease, where estimated retrospective noise exposure [2] was validated by testing the estimates ability to predict noise–induced hearing loss [9]. We tested the validity of our noise exposure re-estimation by examining the change in association with noise-induced hearing loss using noise exposure estimates before and after adjustment for hearing protection devices.

Materials and Methods

Study population

A cohort of 27,464 lumber mill workers was initially enumerated to investigate the effects of fungicide on workers' health in 14 British Columbia lumber lumber mills selected because of the high quality of their work history data [10]. We utilized a sub-cohort linked to the audiometric data, described below, who were employed for at least one year between 1950 and 1998, and who had at least one hearing test.

Noise data

Noise exposure data was gathered from research, industry and regulatory sources. A total of 1,900 full-shift dosimetry measurements from cohort mills were used in modeling the determinants of noise exposure. The model was used to obtain the predicted A-weighted (units of dB(A) re: 20 μPa) noise exposure estimates for 3700 unique combinations of job/mill/time[11].

Audiometric data

Audiometric data was obtained from the local regulatory agency (WorkSafe BC) that coordinates hearing conservation programs, oversees the training of audiometric technicians, and archives routine audiometry surveillance data.

Approximately 90,000 hearing tests were linked to the cohort. These were administered either during the work shift or outside of work shift hours, in sound-attenuating booths where air conduction thresholds were measured for the pure tone frequencies 0.5, 1, 2, 3, 4, 6 and 8 kHz in each ear. These tests had a common questionnaire including HPD self-reports as well as a wide range of risk factors data, of which some were used in this study (see Table 2.2).

The lumber mill cohort with work history records and noise exposure (n=27,464) was linked to the audiometry data which contains audiograms and the self-reported use of HPD (Figure 2-1). Subjects with no hearing tests were excluded from the analysis. The work history period was from 1909 until 1998 whereas audiometric tests were carried out from January 1978 to December 31, 2003.

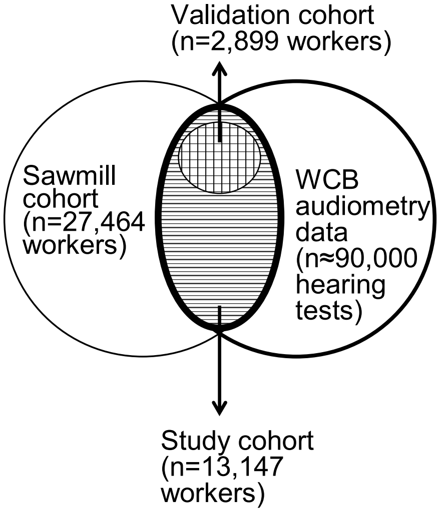

Figure 2.1 Data sources (lumber mill cohort and WCB hearing tests), study cohort (excludes subjects with no hearing test), and validation sub-cohort (includes subjects with all hearing tests performed outside work shift and with a minimum of 2 hearing tests)

Following linkage of work histories to audiometry data, we therefore had 6 categories of linked observations (see Figure 2.2): (C1) audiometric test occurred before start of work in cohort lumber mill; (C2) work history record spans period when no audiometric test was done; (C3) work history record spans period when one hearing test done; (C4) work history records spans a period when more than one hearing test performed; (C5) hearing test exists for which there is no contemporary work history record (but before termination of employment for subject); and (C6) hearing test occurs after subject’s termination of employment in cohort mill.

Categories 1, 5, and 6 occurred because hearing tests were obtained for all BC lumber mills and not exclusively for the cohort participating mills.

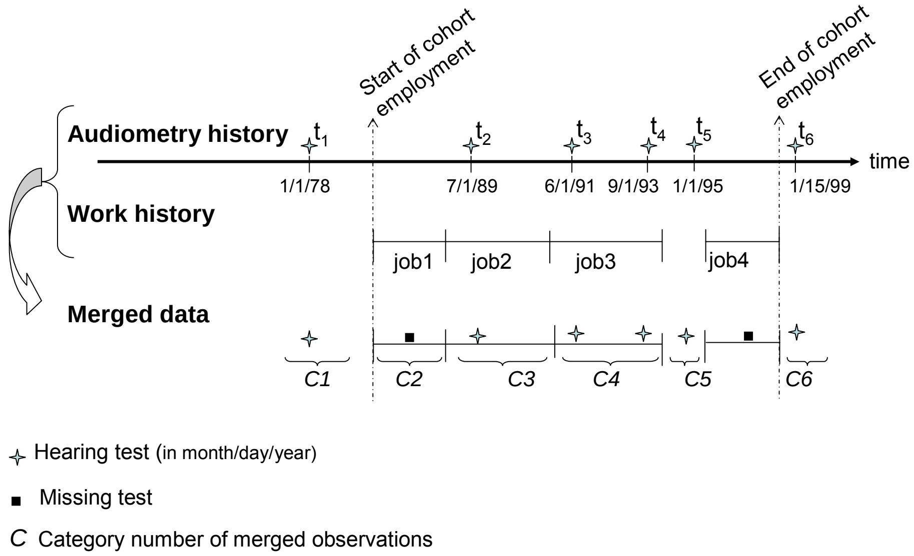

Figure 2.2 Illustration of all possible categories of linked observations in the study cohort after merging audiometry and work histories.

Step 1 – Filling gaps in the history of HPD use.

Merging the different data sets was complex because the history of HPD use has missing values, and because the self-reported HPD use is for a discrete point in time while job was the basis for assigning exposure in a given exposure over a period of time. To simplify matters, we assumed that a subject's self-reported use of hearing protectors during an audiometric test, represented usage throughout the duration of the job during which the hearing test was taken.

To handle the six different categories of observations, the following actions were taken. We excluded observations belonging to category 1 because of their very few occurrences.

For category 2, we imputed missing hearing test using the methods summarized in table 2-1, and assigned correction factors according to each imputation method.

For categories 3 and 4, we assigned a correction factor, and the mean attenuation provided by the different self-reported HPD use for each observation respectively.

Categories 5 and 6 represented about 16% of all hearing tests, and were due to audiometry testing being administered while workers were employed in non-cohort lumber mills. In order to permit the imputation methods (described fully below), all observations belonging to category 5 were all kept, while for those in category 6, only the first hearing test was kept if workers' records showed multiple hearing tests after employment in the cohort lumber mills was terminated.

To impute missed self-reported information on hearing protection use (C2), we used an approach where non-missing information [12] was used to fill gaps. Techniques vary with the types of missing data [12-14]. Our situation did not fit any typical setting of missing data since HPD "exposure" is a mix of missing and non missing information collected through repeated measurements. Weinberg *et al.* addressed this same type of missing data in a simulation study, and compared simple imputation methods [14].

We adapted this work and also developed alternative individual behavior-based and time-weighted imputation methods. The four approaches used in this study are summarized and explained in Table 2.1 below.

Table 2.1 Methods for handling missing information on use of hearing protectors (adapted from Weinberg *et al.* [14])

Acronym	Description of method	Category
OMI	Observed mean imputation. Assigned correction factor based on overall group attenuation mean weighted by the average HPD use.	**Group-based imputation method**
BBA	Behavior-based weighted average imputation. For each worker, used overall self reported use of HPD and assigned an individual mean correction factor for those who reported using HPD at least 50% of the tests ; 0 otherwise	**Individual-specific imputation methods**
TWA	Time weighted average. For each worker use neighboring tests to compute a correction factor proportional to the time weighted average of the neighboring correction factors	
CSO	Complete Subject Only; only those with complete information were considered for analysis	**Alternative method**

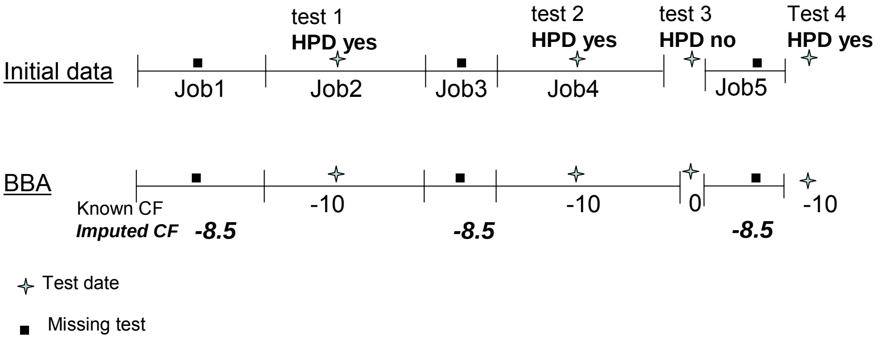

Figure 2.3 Illustration of Behavior-based Weighted Average (BBA) imputation method (see text for explanation)

Figure 2.3 displays the BBA method's mechanism for a hypothetical subject who has 5 job-exposure records, 4 hearing tests, and with 3 of the 5 job-exposure records having missed hearing test (see "Initial data" in figure). This subject consistently reports the same type and class of HPD which provides a hypothetical noise attenuation value of 10 dB (see in figure known CF=-10 dB). There is also one test when the subject reports no use of HPD. When there is a majority of positive answers in the overall self-reported use of HPD, all missing tests will be imputed a positive answer (i.e. HPD use= yes). Their correction factor (imputed CF) was the mean attenuation over all reported tests during the employment period (see "BBA")

$$\text{Imputed CF} = \frac{(-10) + (-10) + (0) + (-10)}{4} = -8.5$$

The BBA approach did not take into account the time between tests. A second approach accounting for time was used; time-weighted average (TWA) where the correction factor for a job-exposure observation with missed hearing test was derived as a time-weighted average of the adjacent previous and next) non-missing attenuation factors.

Step 2 – Estimation of attenuation and noise adjustment for HPD

Self-reported use of HPD from hearing tests gave the type (plugs, muffs) and class (A, B) of hearing protectors. For each response (Plugs or Muffs or both, Class A or B), we assigned an adjustment of the attenuation values assigned by the Canadian Standards Association (CSA Z94.2) [15], which labels the attenuation according to the class of hearing protectors. However, these values (i.e. 30dB and 24 dB for class A and B devices respectively) obtained in laboratory settings do not necessarily reflect ‘real-world’ performance. We adapted the results from Berger *et al.* on HPD field performance [16] to reflect Canadian usage patterns and concluded that field noise reduction (denoted A in equation 1) provided by earplugs and earmuffs respectively was on average 28% and 62% of the values recommended by the CSA. Erlandsson *et al.*[17] showed that workers wearing muffs were more inclined to remove their HPD than those wearing plugs for ease of communication. We adjusted the attenuation for earmuffs, using the formula proposed by Arezes *et al*[18] to take into account the fact that workers seldom wear their earmuffs during the entire shift. We then evaluated R_{3dB} only for earmuffs as

$$R_{3dB} = 10\log_{10}\left[\frac{100}{100 - p(1-10^{-\frac{A}{10}}}\right]; \tag{1}$$

where R_{3dB} is the effective attenuation using a 3 dB exchange rate for a nominal attenuation A and p percent of total noise exposure in one work shift. For records occurring before 1970, the exposure estimates were not adjusted because we know that HPD were not used [11]. For subjects reporting use of HPD we assigned the mean value of all attenuation factors after imputation if the type and class of HPD was unknown. This value was also assigned in the BBA algorithm when the number of self-reported positive answers was equal to the number of negative answers.

Step 3 – Evaluating the predictive validity of new exposure estimates

We defined our outcome variable as the average air conduction thresholds across the frequencies 0.5,1 2, and 4 kHz, further averaged across both ears. “Hearing impairment”, adapted from McNamee *et al* [9], is therefore a continuous response measuring the physiological change of hearing thresholds (in dB) over time. We further restricted the validation cohort to subjects who had their audiometric testing done after at least 16 hours of quiet (i.e. outside the work shift) (Figure 2.1).

We used a cumulative noise exposure metric to compare the adjusted with the unadjusted metric against hearing impairment. The cumulative exposure (in units of dB(A)$\times$Years) was obtained using the logarithmic addition of noise intensity (L_{eq}), adjusted and unadjusted for use of HPD, and duration (T) of employment in a given job j, for all jobs 1 to k, a worker had, as follows:

$$10\log\left[\sum_{j=1}^{k} Tj * 10^{\frac{Leq_j}{10}}\right] \tag{2}$$

The distribution of the outcome variable was first examined and log-transformed to best approximate the normal distribution. We used linear mixed effects modeling to account for within-subject correlation in repeated hearing loss measurements.

The basic model comprised non-modifiable risk factors (age, sex, and ethnic group), as well as the noise exposure metric as fixed effects variables, and had a random intercept at the worker-level. Using i and j indices for measurement occasions and worker respectively, this model can be written as

$$y_{ij}^{*} = \beta_{0j} + \beta_1 age_{ij} + \beta_2 gender_{ij} + \underline{\beta}_3 ethnicity_{ij} + \beta_4 \exp osure_{ij} + e_{0ij} \tag{3}$$

where $\beta_{0j} = \beta_0 + u_{0j}$,

and the errors are assumed to be independent with distributions $u_{0j} \sim N(0, \sigma_u^2)$ and $e_{0ij} \sim N(0, \sigma_e^2)$, and where the y^* represents the transformed hearing loss.

Data on 13 additional self-reported risk factors (from hearing tests) were grouped in four constructs (Table 2.2). Since these questions were not consistently answered, we treated them as “ever/never” variables.

Table 2.2 Potential supplemental variables from hearing tests. A ‘yes’ during any hearing tests resulted in an ‘ever’ category for that variable.

Construct	Fire arms	Otological damage	Off job noise exposure	Audiological impairment
Questions	Hunting or Trap Shooting or Hand gun use	Have you had a visit at the ear doctor in the past 5 years?	Have you been exposed to loud noise at previous job?	Do you have ringing in ears?
		Have you had an ear surgery?	Loud noise off the job?	Problems to understand speech?
		Do you have dizziness?	Were you exposed to noise in the armed forces?	
		Head Injury?		
		Blast or loud exposure?		
		Use of hearing aid?		
		Family history of hearing loss?		

In building the exposure-response models, non-modifiable risk factors (age, gender, and ethnicity) were always entered regardless of their statistical significance (equation 3). To avoid saturating the model, we selected statistically significant risk factors by examining risk factors in each construct group separately and retaining only those individual risk factors for which p-value was less than 0.05. All statistically significant risk factors were then included in a model where manual backwards selection was used (p to remain <0.05) to derive the final model (equation 4). This process was repeated for each of the exposure data sets: unadjusted exposure, OMI, BBA, TWA, and CSO.

All models were estimated using *xtreg* command and maximum likelihood estimation in STATA version 8 (STATA Corporation, College Station,TX)

Significant covariates were fitted as fixed effects and the intercept was allowed to have random effects u_{0j} among workers giving the following formulation of the final variance components model, which is an extension of the basic model described in equation 3, with P predictors.

$$y_{ij} = \beta_{0j} + \sum_{p=1}^{P} \beta_p x_{ij} + e_{0ij} \tag{4}$$

where $\beta_{0j} = \beta_0 + u_{0j}$, $u_{0j} \sim N(0, \sigma_u^2)$, and $e_{0ij} \sim N(0, \sigma_e^2)$

Results

Study cohort descriptive results

Of the 27,464 lumber mill workers enumerated at cohort inception, 13,147 workers were successfully linked to audiometric data, with a total of 221,635 records defined by job, exposure, and self-reported use of hearing protectors. Of those, 183,115 records remained for all of the 13,147 subjects, after applying the exclusion criteria. The study cohort was predominantly male (99%) and Caucasian (mostly of European descent, 89.7%), the remainder were South (mostly Sikhs, 8.8%) and East (mostly Chinese, 1.5%) Asians. Workers were highly exposed to noise; the mean HPD-unadjusted cumulative exposure was 102.7dBA×years. Table 2.3 shows main exposure characteristics of the study cohort stratified by HPD self-reported responses before their imputation, however this table does not reflect self-reported responses obtained during employment outside cohort mills for 2699 workers who had their hearing tested in non-participating cohort mills either before, during, or after employment in the cohort.

Table 2.3 Cumulative exposures in the study cohort workers, stratified by self-reported use of HPD and metrics derived based on the number of hearing tests.

		Cumulative Exposure since entry (dB(A)× year)	**Cumulative exposure since first hearing test (dB(A) ×year)**	**Cumulative duration since entry (days)**	**Cumulative duration since first hearing test (days)**
HPD Use (59,595 records)	Mean	102.7	97.5	4646.4	2051.5
	Median	103.4	99.2	3962	1673
	Standard Deviation	8.75	9.9	3420.8	1833.7
HPD no use (10,632 records)	Mean	102.2	92.8	5333.7	1521.5
	Median	103.4	95.8	4700	882
	Standard Deviation	9.45	12.0	3889	1713.6

About 68% of the study cohort population had some missing information either for use of hearing protection or in work histories (where hearing tests were taken outside employment in a cohort lumber mill). The mean unadjusted cumulative exposure throughout employment was distributed similarly between users and non-users of hearing protectors. However, the cumulative exposure starting from the date a worker's hearing was first tested was lower for those reporting not wearing hearing protection devices [92.8 dB(A)×years vs. 97.5 dB(A) ×years]. This difference was driven by the length of exposure rather than by the intensity of exposure.

Noise exposure reassessment results

To compute the effective field attenuation values for workers using earmuffs, we assumed that the total noise exposure during the work shift (p in Equation 1) was reduced by 3%.

Table 2.4: Effective protection provided by HPD by type and class.

Description of hearing protection devices	Effective Attenuation value (R_{3dB} in dB)
Muffs, class A Muffs, class B	14 12
Plugs, class A Plugs, class B	9 7
Muffs and Plugs [a]	21
Unknown [b]	See text

[a] The protection provided by both earplugs and muffs (PM) was computed by summing the average of the attenuation provided by plugs (class A and B) and muffs (class A and B).

[b] When "unknown" was reported, we assigned the overall mean attenuation of all types of hearing protectors.

The missing values in the initial data are either due to work periods in cohort mills prior to the implementation of mandatory hearing testing (non existing data), or to non-reports (truly missing data). The latter was imputed as well as those work histories occurring between 1970 and 1978 (see Table 2.5).

Table 2.5 Hearing Protection Devices use: in original cohort, following each imputation technique, and in subgroup with complete information.

	Initial data	OMI[c]	BBA[d]	TWA[e]	CSO[f]
Positive answers	59,595	138,040	129,455	124,544	3,726
Negative answers	10,632	10,510	20,793	19,559	1,250
No hearing test	112,888	34,565	32,867	39,012	9,300

c Observed Mean imputation
d Behavior-based average
e Time-weighted average
f Complete subjects only

Only 1493 workers had complete work and hearing protection use histories in the CSO sub-cohort. This subgroup was characterized by a higher mean unadjusted cumulative exposure of 106.8 dB(A)×years, which was driven by a longer job tenure. In this sub-cohort, workers had 4 hearing tests on average, with a maximum of 18 routine hearing tests, and reported using hearing protectors 75% of the tests.

The mean adjusted exposure across all hearing tests differed with each imputation method, both in the study cohorts and in the validation sub-cohorts. However, the noise metric used in the analysis of predictive validity, the cumulative noise exposure since entering the cohort (see Table 2.6), was relatively similar across the validation subgroups (between 95.1 and 96 dB(A)×year), except for the subgroup CSO characterized with higher noise levels.

Table 2.6 Mean correction factors, unadjusted and adjusted noise exposure metrics, and standard deviations (sd) in study and validation cohorts.

	Observed mean	**Behavior based average**	**Time Weighted Average**	**Complete subject only**
Mean exposure pre-adjustment	85.1	85.1	85.1	90.95
(sd) in dB(A)	(23.7)	(23.8)	(23.8)	(10.54)
Mean adjusted exposure	75.8	75.8	78.3	86.46
(sd) in dB(A)	(22.6)	(22.6)	(22.9)	(12.56)
Mean Correction factor in dB	-10	-9.8	-7.8	-10.5
Adjusted Cumulative exposure (sd) in dB(A)×year				
Study cohort	96.7	95.7	96.5	101.5
(n=13,147*)	(10.4)	(10.5)	(10.9)	(10.9)
Validation sub-cohort	96.0	95.1	96.0	99.9
(n=2899*)	(10.2)	(10.5)	(10.8)	(12.09)
Unadjusted exposure (sd) in dB(A) ×year				
Study cohort	101.4	101.4	101.4	106.8
(n=13,147*)	(8.7)	(8.7)	(8.7)	(9.3)
Validation sub-cohort	102.0	102.0	102.0	103.3
(n=2899*)	(8.7)	(8.7)	(8.7)	(9.6)

* for CSO: n= 1493 and its validation sub-cohort has a total of 424 workers.

Validation Results

Validation sub-cohort descriptive results

Of the 13,147 subjects in the initial cohort used for imputing hearing protection use, a total of 4,466 subjects met the eligibility criterion defining the validation sub-cohort. The proportion of ethnic groups remained virtually the same. With an average of 613 days, the full study cohort had much smaller average job tenure than the validation sub-cohorts (1217 days).

The number of subjects entered in the final validation model was further reduced to 2899 subjects due to missing data (see Figure 2.1).

We found that at least one variable from each risk factor group was statistically significant. Therefore, the full model included the following potential confounders: use of fire-arms, a visit at an ear doctor, experiencing dizziness, use of hearing aid, having been exposed to a loud blast, noise exposure at previous job, ringing in the ears and having difficulties understanding speech.

Validity analysis: Noise and hearing loss

Workers' hearing level was on average 14.2 dB (standard deviation 12.3 dB) and ranged between 0 and 100 dB. A linear relationship with age was assumed since the addition of a quadratic term for age did not improve the fit. Table 2.7 presents the results of the final models, as specified in equation 4, relating various risk factors including noise exposure to log-transformed hearing impairment, for each of the analyses with the adjusted exposure metrics, and for the initial data with unadjusted noise metric.

The main result of this study showed that the estimated associations between cumulative noise exposure and hearing impairment (β) after accounting for HPD use not only became significant but also increased two to three times in terms of the magnitude of the effect over unadjusted exposure.

Table 2.7 Significant Predictors and corresponding 95% Confidence Intervals (95% CI) of log transformed hearing loss, in the unadjusted dataset, and in datasets with adjustment factors accounting for HPD use (CSO not shown, n=424 subjects and results were not significant, see text).

	Exposure adjusted for hearing protection devices use via individual-based and group-based imputation methods						Non-adjusted exposure	
	OMI Observed mean β	95% CI	BWA Behavior-based weighted average β	95% CI	TWA Time weighted average β	95% CI	β	95% CI
Main effects								
Exposure	0.0034	[0.001 ;0.005]	0.0025	[0.001; 0.005]	0.0033	[0.001; .006]	0.001	[-.002; .003]
age at test	0.047	[0.04 ; 0.05]	0.047	[0.045 ; 0.05]	0.047	[0.046 ; 0.05]	0.049	[0.046; 0.05]
Female	-0.4	[-1.1 ; 0.6]	-0.44	[-1.4 ; 0.6]	-0.4	[-1.4 ; 0.6]	-0.32	[-1.4 ; 0.6]
Race								
South Asian	0.2	[0.11 ; 0.3]	0.21	[0.1; 0.31]	0.2	[0.1 ; 0.3]	0.24	[0.1 ;0.35]
Asian	-0.1	[-0.33 ; 0.09]	-0.1	[-0.32; 0.1]	-0.1	[-0.31 ; 0.1]	-0.1	[-0.3 ; 0.1]
Fire arms								
use fire arm	0.09	[0.03 ; 0.1]	0.09	[0.02 ; 0.15]	0.09	[0.03 ; 0.15]	0.06	[-0.00; 0.1]
Otology								
visit ear doctor	0.29	[.21 ; .37]	0.29	[0.21 ; 0.37]	0.29	[0.21 ; 0.37]	0.3	[0.2 ; 0.4]
use ear hearing aid	0.19	[0.03 ; 0.34]	0.18	[0.09 ; 0.34]	0.18	[0.015; 0.34]	0.2	[0.01 ; 0.34]
Exposed to blast	0.2	[0.09 ; 0.3]	0.2	[0.09 ; 0.31]	0.2	[0.09; 0.31]	0.19	[0.09 ; 0.3]
Off job noise								
Previous job	-0.12	[-.18 ; -.06]	-0.12	[-.18 ; -.06]	-0.12	[-0.18 ;-0.06]	-0.13	[-0.2 ; -0.1]
Audiology								
ringing	0.14	[0.05 ; 0.24]	0.14	[0.05 ; 0.24]	0.14	[0.05 - 0.24]	0.11	[0.03 ; 0.2]
speech	0.4	[0.31 ; 0.52]	0.4	[0.2 ; 0.4]	0.41	[0.3 - 0.51]	0.33	[0.2 0.4]

The observed mean imputation (OMI) performed best as the dose-response slope was the strongest and the confidence interval the smallest. The supplementary risk factors had the same effect on hearing impairment in all analyses, regardless of the type of imputation and whether the adjustment was performed or not. Firearm use increased hearing impairment, as did an otological condition (either a visit to an ear doctor, or the use of hearing aid, or exposure to blast), and audiology variables (i.e. understanding speech and ringing in ears). However, having previously worked in a noisy job was associated with decreased hearing impairment.

The remaining unexplained between-worker and within-worker variance components were identical in the three analysis sub-cohorts (OMI, BBA, and TWA). In all models, 63% of the between and within worker variance was explained by the fixed effects while reducing the between worker over the within worker variance by 13%. The model fit statistic (-2 Residual log likelihood) was nearly equal across each dataset with a minor better fit for the group with time weighted average imputed data.

The performance of the data set with subject having complete information (CSO) was the worst amongst all estimation methods. Dose-response slopes for noise and hearing loss were virtually the same across adjusted and unadjusted noise metrics. The issue in using the sub-cohort with complete information (CSO) is the loss of information since only 11% of subjects have complete HPD histories. Moreover, this figure was further reduced as the restriction criterion to keep only hearing tests performed outside work shift resulted in a total of 424 workers with an average of 3.4 hearing tests. Less risk factors remained in this model compared with the analyses with OMI, BBA and TWA adjustment: no otological information was statistically significant, only firearm use, audiological risk factors and working in a previous noisy job were kept in the final model. Similar to the results following imputation, workers in the CSO group had a preventive effect for hearing loss from working in a loud previous job.

Discussion

We began with a cohort with complete longitudinal information with respect to noise exposure developed by one of the co-authors [11]. However the widespread use of hearing protection devices mean the noise estimates are biased as they reflect ambient rather than experienced noise levels. While information about type and class of hearing protection worn was available when audiometric tests were not missed, short-term field studies of HPD protection have shown that their effectiveness varied widely [19, 20] complicating accurate individual estimates of protection. Therefore, our challenge for retrospective assessment of noise exposure was twofold: handling gaps in the history of use of HPD and determining their effective attenuation. Given the availability of longitudinal information, we used existing self-reported use of HPD to fill observations where these were missing as this data feature allowed for use of simple imputation methods[13]. Thereby, a deterministic adjustment was performed and allowed computation of an adjusted noise measure. Moreover, we tested the predictive validity of both adjusted and unadjusted cumulative exposure, a metric that accounts for both the intensity and the duration of exposure, by examining their ability to predict occupational NIHL.

The resulting adjusted cumulative metric was shown to be predictive of hearing loss among workers at the BC lumber mills participating in this study cohort. Amongst the different imputation methods, the group-based imputation (OMI) performed best with 340% increase in the magnitude of the regression coefficient. This imputation has been shown to yield estimates that, when tested against a health outcome, result in unbiased dose-response relationships coefficients, good coverage of the confidence interval and good power. This good performance is due to the fact that group-based imputation produces Berkson type errors [14, 21]. The OMI technique was used despite the fact that it does not exactly fit our setting. Weinberg *et al*. imputed missing values for a cumulative residential radon exposure. The missing data in our study is not the actual exposure experienced by the subjects, but a modifier of the exposure. This distinction is important because the underlying theory for the findings by Weinberg and colleagues holds for cumulative exposure estimates. Therefore, we have empirically shown that this theory can be extended for linear models with an exposure modifier. Within the subject-specific imputation techniques, the time-weighted average (TWA) of neighboring hearing tests performed noticeably better than the behavior-based weighted average (BBA) method. One possible explanation for this result is that the behavior-based approach might have introduced a bias; an over-protection of the workers has perhaps occurred since those prone to non-use of HPD would have 0 dB attenuation throughout their work history in every missed hearing test. The validity of one approach – CSO – was weak because power and precision were considerably reduced when testing the exposure estimates in the validation study. Our validation technique was similar to that used by Mc Namee *et al.*[9] and showed better results presumably because we accounted for use of HPD.

In order to achieve the adjustment of noise exposure, we had to assume that a self-reported response - which reflects a snapshot in time - was true throughout the entire job duration within which the hearing test was taken. It is impossible to test this assumption and the possibility that a worker could have changed his behavior during job tenure in a cohort lumber mill cannot be excluded. However, an examination of the distribution of hearing loss among those reporting use and those reporting non-use of hearing protection devices showed that these two populations had the same average hearing impairment. In addition, use of HPD was not driven by the exposure level as shown in the results (see Table 2-2). We could reasonably expect then that violating our underlying assumption would have a minimal effect. Both an under- and over-protective effect would occur had the worker been erroneously, yet randomly, classified as non-compliant or overly compliant, resulting in a non-differential misclassification.

There is still controversy around how much protection is truly provided by HPD, and the only agreement is that existing laboratory assessment of HPD attenuation according to regulatory standards poorly mirrored the field attenuation and led to the standard being rescinded. After revision, the 1997 ANSI standard was devised to provide a means of calculating noise reduction values that would better correspond to real-world data [22]. We relied on the data used by the research group behind the 1997 Standard, to develop a single number representing the attenuation achieved by type and class of hearing protectors. Our method was based on the performance of HPD attenuation gathered over 90 different industries in seven countries with approximately 2900 subjects [16] and further adapted to reflect Canadian usage patterns through the exclusion of attenuation results pertaining to atypical HPD.

We also addressed the fact that our final attenuation values might be over-protecting workers. We assumed that the time an earmuff is worn during exposure to noise is systematically smaller than the work shift as several cross-sectional studies have demonstrated that workers seldom wear their hearing protectors all the time[18-20]. However, self-reports of use of hearing protection devices were demonstrated to be a good measure indicator [23]

Our study is among the few studies in which the validity of retrospectively assessed noise exposure estimates was investigated. McNamee *et al*. tested a mixed approach for assessing historical noise exposure estimates in British power plants [2] by testing their ability to predict noise induced hearing loss[9]. The audiograms used as the outcome measure may not be a perfect measure of hearing impairment, since for workers whose audiograms were obtained during shift, we did not know how well their HPD worked and consequently whether the audiometric test was measuring temporary threshold shifts. Given the size of the analysis cohort, we were able to restrict the validation exercise to those who had their hearing tests done outside shift hours (i.e. in quiet) without losing power, and to reduce the likelihood that temporary threshold shifts were inadvertently captured.

We believe that our results can be generalized to the overall cohort as the sub-cohort does reflect the overall study cohort's characteristics in terms of ranges of exposure (differences in the cumulative exposure were due to longer job tenure) and demographics traits.

We controlled for known risk factors by forcing some covariates in the models and using a careful model-building approach for others within four constructs. One concern might be that some of the otological and audiological variables might be related to noise-induced hearing loss and therefore over-adjusted the effect of cumulative exposure. Such overadjustment should mean that the coefficients for cumulative noise should be conservative estimates of their association with hearing impairment. Other approaches to handle risk factors were also possible. For example, a principal component analysis would have captured which risk factors had the most variability in explaining hearing reducing the high number of dimensions of our data to a simpler one. However, this might have led to ignoring a group of risk factors such as non-occupational noise exposure group. We favored our strategy because it allowed obtaining a very stable model. The results of the validation analyses were identical with respect to the risk factors across imputation method (i.e. OMI, BBA, TWA) and across noise metric (i.e. adjusted and unadjusted). The validation exercise was based on within-subject change in hearing level which alleviates the possibility for confounding by unobserved factors that vary between subjects and takes advantage of the availability of multiple hearing tests. Moreover, including a random intercepts at the worker level allowed accounting for the baseline hearing impairment to vary for each worker distinctly.

We did not consider trades as possible risk factors for hearing loss. Neitzel *et al.* demonstrated the high variability of use of HPD among trades [20]. Since our approach relied on self-reports, we would expect that subject-specific information reported by each worker over time would capture such variations. We are currently examining an alternative approach to account for HPD use in which individual self-reports are ignored and instead potential determinants of the use of HPD are modeled. In such a context, job and departments are crucial determinants that we incorporated in our analyses (chapter 3).

Regardless of the type of imputation used to fill gaps in the history of HPD, race behaved identically: South Asians showed significantly more hearing loss than the reference group which consisted of those of European descent. Other studies have also investigated racial differences in occupational hearing loss and hearing protection use [24-28]. One possible explanation for our results might be found in the theory proposed by Rabinowitz *et al.* [25] where migrant workers with language difficulties may be underutilizing hearing protection in the workplace and are consequently more exposed to occupational hearing loss.

In conclusion, the results we show emphasize the need for more accurate estimates, taking into account hearing protection use. These results may not be limited to noise, as they could be applied to any exposure where personal protective equipment or other control measures are is available to workers (e.g. use of respirators). Results from previous work [29] showed improvements in exposure-response relationship when using more specific measurements of exposure. Our work supports this finding and adds to the weight of evidence for the contribution of more refined quantitative exposure estimates to stronger and more precise exposure-response relationships.

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3 Determinants of use of Hearing Protection Devices in Canadian lumber mill workers

Introduction

Noise is likely the most ubiquitous of hazardous occupational exposures. The most widely applied practice to prevent exposure to high noise levels is often the use of hearing protection devices (HPD).

Failing to adequately account for the use of hearing protection devices (HPD) when assessing noise exposure, could lead to over-estimation of exposure levels, and to a non-differential misclassification of exposure threat in epidemiological studies. Poor exposure assessment is particularly a problem in retrospective studies where there is no opportunity to assess workers' HPD use directly.

The magnitude of the problem is increasing given the growing body of research relying on retrospective exposure estimates that is investigating the relationship between noise and cardiovascular diseases [1-5]. Relative risks in this association are comparatively small and more susceptible to attenuation due to crude estimators and subsequent misclassification [6]. Consequently good noise exposure assessment taking into account the often overlooked HPD use is crucial in order to avoid attenuation of a risk whose magnitude is *a priori* small. In this context, this study attempts to address the type of measurement error associated with failure to account for HPD by examining the determinants of their use.

We addressed this issue by exploiting the concurrent availability of several data resources

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that are unique to our study population. We have enumerated a cohort of industrial workers exposed to high levels of noise in BC lumber mills, including demographic characteristic and complete job histories. We also had noise exposure information retrospectively constructed by one of the co-authors [7]. Finally, we had archived routine hearing test data as required by the local regulatory agency (WorkSafe BC) for companies where noise levels are higher than 85 dBA, which contains self-reported HPD use information.

We have previously investigated approaches to reduce misclassification of exposure by accounting for hearing protector use. We have tried assigning common adjustment factors based on population-based usage characteristics [8], yet results were inconclusive. Subsequently, deterministic methods were also examined (Chapter 2). We used the hearing tests data to directly link self reported answers about the use of HPD to the existing exposure estimates and adjust them accordingly. This gave encouraging results but requires self-reported information on use of HPD from every subject in the cohort, information that is seldom available. A logical next step was to use empirical statistical modeling of the determinants of use of HPD, allowing a more generalizable predictive modeling of HPD use. Few investigators have addressed this question [9, 10]. Azeres *et al.* in studying 516 workers exposed to high levels of noise showed that individual risk perception and the outcome value for hearing preservation were the main direct predictors of the use of HPD [9]. Melamed *et al.* investigated a larger group of blue-collar male workers (n=1587) and demonstrated that the use of hearing protection devices was related to not only related to noise exposure level (odds ratio (OR) 2.94, 95% confidence interval (95% CI) 2.58--3.30], but more so to high noise annoyance (OR 3.03, 95% CI 2.77--3.29), after controlling for age, education, and ethnic origin [10].

Other investigators have used the Health Promotion Model to qualitatively explain use of HPD[11-14]. While the use of health promotion models is valuable to tailor intervention and training programs, and to promote hearing protection use in the workplace, it does not serve the purpose of epidemiological studies that need the most accurate exposure assessment given that conceptual variables such as self-efficacy, benefits, value, and barriers are seldom available.

We propose to develop predictive models of hearing protection use that allow for an objective and quantitative retrospective exposure measure and that have been extensively used in the past decades to predict historical exposures. However, most conventional regression methods assume independence of the observations on which the regression is performed. In the field of occupational exposure assessment, this assumption is conceptually violated in a wide range of situations. For example, there may be repeated measurements across time, nested within observed workers. Subjects may be nested within jobs or departments, within plants, or within industry. Ignoring such hierarchical data structures was widely practiced until recently with the advent of more sophisticated modeling tools that account for both within- and between-worker variances. To account for the effect of data hierarchies, both fixed and random effects were included in models and mixed effects modeling became more widespread for identifying determinants of exposure[15, 16]. Peretz *et al.*[15] as well as Burdorf [16] have described how this modeling tool captures correlations unaccounted for in presence of repeated measurement data.

Use of HPD have been shown to be related to factors other than exposure level, such as individual risk perceptions and company's safety climate [9], as well as social modeling [13], mixed effects model can also help account for latent (i.e. unobserved) factors and capture potential sources of variability in the HPD use outcome. When cluster-level data is available, including cluster-specific information to capture unobserved factors has only been rarely used [17]. Potential consequences of ignoring hierarchical data structures and/or latent factors include (i) a decrease in statistical efficiency and inflated standard errors (due to an incomplete use of the available information), (ii) false low standard error estimates because of the violation of the independence assumption between covariates (here measurements). For both reasons, there is a risk of incorrect inferences regarding the existence of statistical associations, and ultimately, wrong conclusions. This paper formalizes the potential relationships between different predictors including noise exposure and use of hearing protector by taking into account the repeated nature and the natural clustering of the data. In so doing, our theoretical exercise improved empirical predictions in the presence of scarce information on use of HPD, as the models will control for the correlation between workers responses over time as well as the nesting of workers within their plants. Predictions on the use of HPD will allow us to account for the protection they provide and to formulate a revised HPD-adjusted noise measure.

Methods

Data

The lumber mill cohort was previously enumerated in 14 large softwood lumber mills in British Columbia (BC, Canada) to study cancer outcomes. Complete personal work-history data was available for all workers, and employment records spanned the years from 1909 to 1998. Cohort subjects were 27,464 blue-collar workers (mainly production and maintenance) and had worked at least 1 year between January 1, 1950 and December 31, 1995.

Exposure information was obtained for earlier studies conducted by the investigators, including HPD-unadjusted noise exposure information for each unique mill/job/time combination in all 14 participating lumber mills for all time periods from 1909 until 1998 [7].

Audiometry data for the lumber mill cohort was obtained from the provincial Workers' Compensation Board (now called WorkSafe BC). Hearing tests have been mandated since 1978 for all lumber mill employees who are exposed above 85 dB(A). Each audiogram was also accompanied by a questionnaire administered by an audiometric technician that obtained information on subjects' personal hearing protector use, including type (plug or muff). This data spanned 25 years from 1978 to 2003.

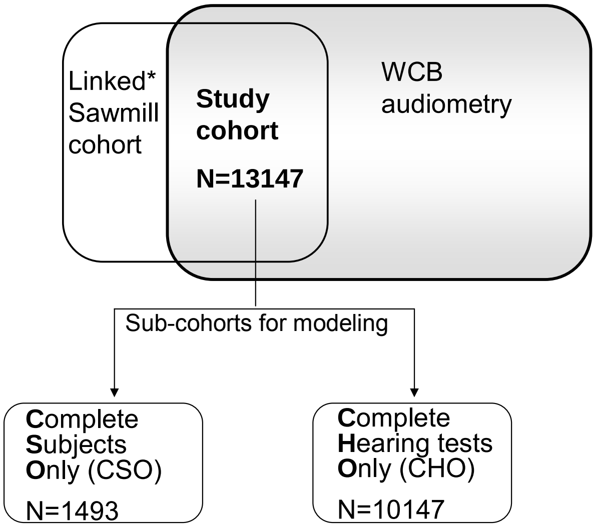
This study cohort merged the above three data sources, and resulted in a sub-sample comprised of 13147 cohort subjects having between 1 and 26 hearing tests followed longitudinally. A total of 221,635 records defined by job (title, dates of start and end), exposure, and self reported use of HPD were available for analysis.

In merging the data sources, a large proportion of the population had non-coinciding information with regard to audiometric and work records. Consequently, there were two categories of non-concordant linked records:

- Job-exposure histories without hearing test (112888 job-exposure records) either because audiometric surveillance did not exist before 1978 whereas jobs started as early as 1909, or due to truly missed hearing tests (e.g. worker absent).

- Hearing tests with no matching work history (49657 hearing records) because some subjects had hearing tests at non-cohort lumber mills, which were also linked.

For the modeling purposes, this partial data overlap prompted the creation of two sub-cohorts, shown in Figure 3.1, to handle the missing data problem.



* The term linked indicates that this is the sawmill cohort with linked noise exposure information for each individual, for each time period, for each job and each mill.

Figure 3.1 Definition and number of workers of the study cohort and the sub-cohorts used for modeling: (1) subject with complete information only (CSO), (2) subject with complete hearing tests information only (CHO).

Complete Subjects Only (CSO)

In this sub-cohort, each job-record must have at least one hearing test if it occurred after the date at which hearing testing became mandatory (i.e.1978).

Complete Hearing tests Only (CHO)

We also modeled the use of HPD on the cohort using all subjects, but excluding records where: (i) a job had no matching test, (ii) hearing tests were administered outside employment in a participating lumber mill, (iii) observations for which no noise exposure information was available, despite the coinciding hearing data and job history.

Modeling hearing protection use

The data consists of repeated measurements generated through the multiple hearing tests administered to workers throughout their employment period in the cohort. Workers held different jobs within different types of departments nested within each study lumber mill which confer to the data its hierarchical structure.

Random effects [18] were fitted to the lumber mill cohort data within the framework of generalized linear mixed models (GLMM) in order to handle the repeated measurements and clustered design. Using a logit link, the GLMM for the Y_{ij} binary response about use of HPD taken at the ith measurement for the jth subject, is characterized by

$$\log\left(\frac{\pi_{ij}}{1-\pi_{ij}}\right) = \operatorname{logit}(\pi_{ij}) = \beta_0 + x'_{ij}\,\beta\ + u_i\,, \qquad (1)$$

with $u_i \overset{iid}{\sim} N(0,\sigma^2_u)$, and $\pi_{ij} = P(Y_{ij} = 1 \mid x_{ij})$ denotes the probability of self-reporting use of HPD given a set of covariates (x_{ij}).

<u>Covariates selection</u>

Our covariates, which include demographics and noise exposure information, can be distinguished in three groups:

(1) Individual variables: gender, ethnicity, age at entry in the cohort, current age at measurement, and date of birth.

(2) Exposure variables: current exposure (in dB(A) re:20 microPascals), cumulative duration of exposure since entry in cohort (in dB(A)×years), job duration (in days),

(3) Contextual variables: job groups, departments, plants.

Candidate variables for inclusion in the mixed models were examined separately in univariate analyses examining the crude association between HPD use and each variable. Covariates with p-value less than 0.05 were retained for the mixed model.

Additionally, test for differences in distributions of independent categorical variables were performed using chi-square test to avoid multicollinearity. Pearson r was used to explore the correlation between continuous variables; if r was greater than 0.7, the variables that were strongly associated with use of HPD were retained.

Summary statistics, chi-square, Pearson r and simple logistic regression were obtained in Stata 8.0 (STATA Corporation, College Station, TX).

Selected covariates, excluding contextual variables, were offered sequentially in model described by equation 1. A covariate was excluded if its inclusion did not reduce the deviance significantly.

Hierarchical Analysis: modeling use of HPD

We examined different structures with increased complexity as we introduced higher nesting levels to reflect the clustering of the data.

In Model A (equation 2), a plant/subject/measurements structure was adopted where two random intercepts were included for plants and subjects. Since, we believe that department is an important factor to include in the model, we attempted to capture its mean effect on the outcome by treating it as a fixed effects variable in model A.

Using indices i, j, and k for measurements, subjects, and plants, respectively, model A, can be described as follow:

$$\text{logit}(\pi_{ijk}) = \beta_0 + \sum_{p=1}^{P} \beta_p X_{p\,ijk} + u_{jk} + v_k \; ; \qquad (2)$$

$$u_{jk} \sim N(0, \sigma_u^2),$$

$$v_k \sim N(0, \sigma_v^2),$$

where P is the number of subject-level covariates, which were defined after performing the step 1 of the analysis. We assumed that the random effects are statistically independent, with σ_u^2 representing the between-worker variability, and σ_v^2 the between-plant variability, that are not explained by the fixed effects.

In model B, we investigated whether use of HPD was best explained by the nesting of workers within departments by including workers and departments in the random part of the model (department/subject/measurement structure). We use the index d for the department cluster and describe model B as follow:

$$\text{logit}(\pi_{ijk}) = \beta_0 + \sum_{p=1}^{P} \beta_p X_{p\,ijd} + u_{jd} + v_d \; ; \qquad (3)$$

$$u_{jd} \sim N(0, \sigma_u^2),$$

$$v_d \sim N(0, \sigma_v^2),$$

Again, the same prior were postulated, that is statistically independent random effects, with σ_u^2 representing the between-worker variability, and σ_v^2 the between-department variability, not explained by the fixed effects.

Model C (equation 3) included all three clusters by fitting random intercepts for each of subjects, departments and plants (plant/department/subject/measurement structure) where their respective variance represents the between-worker (σ_u^2), between-department (σ_v^2), and between-plant (σ_ω^2) variability.

$$\text{logit}(\pi_{ijdk}) = \beta_0 + \sum_{p=1}^{P} \beta_p X_{p\,ijdk} + u_{jdk} + v_{dk} + \omega_k \;; \tag{4}$$

$$u_{jdk} \sim N(0, \sigma_u^2),$$
$$v_{dk} \sim N(0, \sigma_v^2),$$
$$\omega_k \sim N(0, \sigma_\omega^2),$$

Model D (equation 4) was considered to accommodate between-worker variations and between-plant heterogeneity while allowing the contextual variables (i.e. plants and departments) slopes to vary.

$$\text{logit}(\pi_{ijk}) = \beta_0 + \underline{\beta}_{1k} \times plant_k + \underline{\beta}_{2k} \times department_{jk} + \sum_{p=3}^{P} \beta_p X_{p\,ijk} + u_{jk} + v_k \qquad (5)$$

$$\underline{\beta}_{1k} = \underline{\beta}_1 + \underline{b}_{1k}, \underline{\beta}_{2k} = \underline{\beta}_2 + \underline{b}_{2k},$$
$$u_{jk} \sim N(0, \sigma_u^2),$$
$$v_k \sim N(0, \sigma_v^2),$$

with a Normal prior placed on the random effects b_{pk}, that is $b_{pk} \sim N(0, \sigma_p^2)$ for p=1,2.

Here, model D consisted of both the 'population average effect' of a worker-level propensity to wear HPD (via β_p), and the contextual-level variable variation effect around the average (via random effects (b_{pk})), while accounting for the between-worker and between-plant variability.

Comparison of models was carried out to choose which nesting structure and random effects selection best explained the variability in the outcome response.

Modeling HPD use used the `glme` function from the `correlatedData` library for Splus (Splus version 8.0.4, Insightful Corp., Seattle, Washington), and using the restricted penalized quasi-likelihood as estimation method for the parameters of the model. A Generalized Estimating Equations (GEE)[19] model was first fitted to the data to obtain the starting values that were entered in the final model for parameters estimation.

The data had first been visually examined to verify that underlying assumptions with respect to the normality of the random effects was not violated before interpreting any of the regression models coefficients (Table 3.2).

Time treatment

We did not expect that the factors affecting the use of hearing protection devices are linear in time. A graphical inspection and goodness of fit testing were used to decide whether second order time terms needed to be included in the models. Models with and without the quadratic time term and with different nesting structure were computed and compared. Model Fit was measured with the Akaike Information Criterion (AIC) which adjusts for the degrees of freedom in the model.

Results

The sample with complete information, CSO, had 1493 members with 4976 records. Workers had between 1 and 18 hearing tests which represented an average of 3.3 hearing tests per worker. The second sub-cohort where subjects had complete hearing tests information, CHO, comprised 10,147 subjects with 59075 hearing test measurements, with an average of 5.8 hearing tests per worker. Workers in this subgroup had between 1 and 21 tests. Both sub-cohorts were 99% male. The ethnicity breakdown was slightly different yet both study populations had a clear majority of workers from European descent.

All covariates that were examined in the univariate analysis are presented in Table 3.1 along with descriptive statistics. For discrete variables and ordinal variables, counts of number of subjects are displayed, and for continuous variables, the table shows the range, mean and standard deviations. It should be noted that the ordinal variables date of birth and calendar year were treated as continuous variables in the models to allow for higher order treatment for the calendar year variable and to decrease the number of degrees of freedom.

Table 3.1 Variables tested in the statistical models – Description and summary statistics in the sub-cohort with complete information (CSO) and sub-cohort with all hearing tests (CHO).

Variable	Descriptive Statistics	
	Sub-cohort with Complete Hearing tests only (CHO)	Sub-cohort with complete Subjects only (CSO)
Sex		
"F"	130	12
"M"	13017	1481
Race		
Chinese	1%	2%
South Asian	9%	4%
European	90%	95%
Date of Birth		
1905 until 1919	488	261
1920 until 1924	672	226
1925 until 1929	815	178
1930 until 1934	913	122
1935 until 1939	1037	92
1940 until 1944	1371	80
1945 until 1949	1856	105
1950 until 1954	2012	105
1955 until 1959	2105	180
1960 onward	1878	144

Variable	**Descriptive Statistics**	
	Sub-cohort with Complete Hearing tests only (CHO)	Sub-cohort with complete Subjects only (CSO)
age	Min = 12 Max =77 Mean = 41.03 SD = 11.6	Min = 15 Max = 77 Mean = 50.99 SD = 12.6
Age at entry	Min = 10 Max = 63 Mean = 24.77 SD = 7.8	Min = 15 Max = 63 Mean = 28.15 SD = 8.9
Exposure (dB(A))	Min:60 Max:119.77 Mean: 90.95 SD: 10.5	Min : 0 Max : 109.54 Mean : 87.77 SD : 11.82
Job duration (days)	Min: 4 Max: 17319 Mean: 1207.2 SD: 1112.6	Min : 2 Max: 17319 Mean: 1053.3 SD: 1315.9
Cumulative duration (days)	Min: 1 Max: 17871 Mean: 4103.2 SD: 3346.8	Min: 2 Max: 57791 Mean: 4831.4 SD: 4509.1
Plant (i.e. lumber mills)		
1	686	108
2	1073	252
3	1189	107
4	1034	121
5	987	112
6	1539	171
7	510	23
8	857	42
9	1021	93
10	1062	68
11	369	63
12	805	83
13	1244	111
14	1110	188
Department		
Administration	8749	87
Boom	376	87
Chip plant	527	96
Dry Kiln	492	43
Maintenance	106	519
NOS	2506	552
Planer	1827	369
Powerhouse	2509	74
Lumber milll	1827	809
Yard	2509	329

Variable	Descriptive Statistics	
	Sub-cohort with Complete Hearing tests only (CHO)	Sub-cohort with complete Subjects only (CSO)
Job groups (regrouped based on process and task similarities)		
Boom	440	74
Chip and Hog	619	107
Cleaning/labouring	3301	920
Foreman	498	100
Log yard	146	45
Lumber yard	1,271	250
Mill Maintenance	1,603	343
NOS	743	205
Non-mill Maintenance	421	129
Office	479	90
Planing	528	91
Powerhouse	175	47
Sawfiling	467	63
Sawmill – Log Processing	499	93
Sawmill – non sawing	1,378	241
Sawmill – sawing	1,123	211
Sorting and Packaging	3,624	613
Calendar year (All years before 1978 are coded 0)		
<1978	NA	1154
1978	1190	139
1979	5568	833
1980	5779	742
1981	5140	658
1982	3968	379
1983	3698	296
1984	4492	243
1985	3295	240
1986	5288	174
1987	5068	223
1988	5107	163
1989	5531	161
1990	4780	126
1991	4812	118
1992	4531	74
1993	4432	57
1994	3619	62
1995	4522	47
1996	3795	50
1997	3520	28
1998	3637	6

With the exception of age at entry, all variables were significantly associated with the use of hearing protectors in the univariate analyses. We dropped age at entry and kept date of birth since the former had a better fit (i.e. smaller log likelihood) with HPD use. The variable measuring the cumulative exposure duration since first entry in the cohort did not reduce the deviance significantly. We discarded this variable from the hierarchical model. The remaining predictors were gender, race, and date of birth, measured exposure at time of test, job duration, and departments.

To verify our assumptions with regard to the time treatment, two models (linear and quadratic expression of time) were examined. A statistical comparison using ANOVA was did not reach significance. However, the error associated with slope of the time covariate was larger when time was included as a linear predictor; we therefore chose to introduce a higher order term for the effect of time given the better visual fit and the smaller error around the estimates.

Model A (plant/subject structure) offered the best fit compared with model B (departments/subject structure) both in the sub-cohort with complete information (CSO) and in the sub-cohort with all hearing tests (CHO), as indicated by smaller AIC in model A. For instance in the sub-cohort CHO, $AIC_{model\ B} = 340555$ while $AIC_{model\ A} = 338612$. This model structure was in turn compared to the model with all three levels of nesting (model C). Here, both the standard error around the estimates coefficients and the statistical comparison of the two structures favoured Model A which was consequently chosen as the final model. Using the sub-cohort with all hearing tests, we compared, using ANOVA, the null models (i.e. model with intercepts only), and found that AIC was significantly smaller in model A than model C ($p<0.001$). We were not able to fully conduct last stage of the model building strategy because model D, which accommodates random coefficients for jobs and departments, did not converge.

Sub-cohorts prediction results are summarized in Table 3.2 showing the odds ratio with corresponding 95% Confidence Interval (95% CI), and p-values for fixed effects variables. Continuous variables were standardized for ease of interpretation such that the reported odds ratio is based on one standard deviation change.

For the group with complete information (CSO), two of the six main fixed-effects, namely current exposure and date of birth, were strong predictors for the use of hearing protectors, indicating 62% and 12% increase in the odds of using HPD per one standard deviation increase, respectively. The duration of the job was moderately significant showing a 12% decrease in odds of using HPD for one the standard deviation increase from the mean job duration (1316 days). The probability of wearing hearing protection devices was strongly and significantly associated with three of the 10 departments, namely in the *Chip Plant*, the *Planer* and the *Sawmill* department. The odds of wearing HPD for any worker randomly chosen from a Planer department were more than 11 times higher than a worker in the Administration department. In this sub-cohort (CSO) the model showed that four out of eighteen jobs strongly predicted the use of hearing protection. These jobs were *Chip and Hog*, *Log yard, Power House* and *Sawfiling* and the odds ratio for these jobs ranged from 0.08 to 12.97. A worker randomly selected in a Log Yard job would have his odds of wearing HPD decreased by 92% relative to working in a Boom job (the reference group). At the other end of the spectrum, working in a Power House job indicates close to 13 times more likely to wear hearing protectors compared with those working in a *Boom* job.

While job duration was not a significant predictor for the use of hearing protectors in the sub-cohort with complete information (CSO), the sub-cohort with all hearing tests (CHO) had all the main fixed-effects covariates strongly positively associated with the odds of using hearing protectors except gender. Moreover, jobs and departments in this sub-cohort not only showed similar results as those found in the complete information sub-cohort (CSO), both in terms of direction of effect and statistical significance, but also had additional departments and jobs displaying significant increase in odds ratio for hearing protectors use. The additional departments were the *power house* and the *sawmill* departments. The additional jobs were *maintenance*, *planning*, *non-sawing* and *sawing* jobs. Overall, the magnitude of the coefficients was smaller, yet the confidence intervals were also narrower.

Gender and ethnic group of the subjects had the same effect on the odds of wearing hearing protectors relative to the base group in both sub-cohorts. Females were less likely to wear HPD and South Asians (mostly Sikhs) were the least likely amongst the three predominant ethnic groups to wear hearing protectors. These estimates were not significant with the exception of the odds for the group referred as White (mostly of European descent).

Table 3.2 Hearing Protection Devices use – Odds Ratio (OR) for fixed-effects variables in logistic regression with random intercepts for subject and plant, using the sub-cohort restricted to subjects with all hearing tests (CHO) and the sub-cohort restricted to subjects with all information (CSO)

	Sub-cohort of workers with complete information (CSO) 1493 workers,4976 records				Sub-cohort of workers with all hearing tests (CHO) 10147 workers, 59075 records			
Fixed effects Variables	**OR**	**95% CI**		**p-value**	**OR**	**95% CI**		**p-value**
(Intercept)	0.86	0.03	29.37	0.94	1.23	0.51	2.94	0.64
Race								
Chinese	1.00	ref			1.00	ref		
South Asian	0.36	0.05	2.48	0.30	0.91	0.56	1.48	0.70
European	0.22	0.04	1.15	0.07	0.46	0.29	0.73	0.00
Sex								
Female	1.00	ref			1.00	ref		
Male	2.93	0.29	29.9	0.36	1.02	0.59	1.77	0.93
Date of Birth	1.12	1.05	1.20	0.00	1.24	1.21	1.26	<.0001
Job length	0.88	0.77	1.00	0.06	1.06	1.03	1.09	<.0001
Exposure	1.62	1.38	1.89	<.0001	1.43	1.38	1.48	<.0001
Time	1.05	0.97	1.13	0.24	1.10	1.08	1.12	<.0001
Time^2	1.01	1.00	1.01	0.00	1.00	1.00	1.00	0.06
Department								
Administration	1.00	ref			1.00	ref		
Boom	0.27	0.05	1.53	0.14	0.94	0.64	1.38	0.75
Chip Plant	8.57	2.10	34.94	0.00	1.93	1.36	2.74	0.00
Dry Kiln	2.41	0.30	19.59	0.41	0.83	0.53	1.29	0.41
Maintenance	1.22	0.46	3.30	0.69	1.38	1.02	1.86	0.04
NOS	4.27	1.67	10.90	0.00	1.78	1.34	2.37	0.00
Planer	11.46	4.31	30.46	<.0001	2.77	2.08	3.68	<.0001
PowerHouse	0.81	0.15	4.43	0.81	3.94	2.26	6.87	<.0001
Sawmill	5.90	2.67	13.04	<.0001	2.19	1.67	2.87	<.0001
Yard	1.16	0.45	3.02	0.76	0.92	0.69	1.21	0.53
Job Group								
Boom	1	Ref			1	Ref		
Chip and Hog	9.80	1.34	71.85	0.02	2.98	2.09	4.23	<.0001
Cleaning/Labouring	0.63	0.10	4.09	0.63	1.16	0.85	1.58	0.35
Foreman	0.98	0.15	6.22	0.98	0.85	0.61	1.20	0.37
Log yard	0.08	0.01	0.92	0.04	1.32	0.91	1.92	0.15
Lumber yard	1.53	0.23	10.04	0.66	1.50	1.10	2.04	0.01
Maintenance	4.30	0.64	29.12	0.13	2.88	2.03	4.09	<.0001
NOS	0.79	0.10	6.53	0.83	1.79	1.26	2.52	<.0001
Non-mill maintenance	1.24	0.17	8.79	0.83	0.78	0.52	1.15	0.21
Office	1.36	0.18	10.22	0.77	0.78	0.53	1.14	0.20
Planing	3.76	0.42	33.54	0.24	5.04	3.31	7.66	<.0001
PowerHouse	12.97	1.10	152.3	0.04	1.50	0.79	2.85	0.21
Sawfiling	8.86	1.10	71.21	0.04	7.32	4.88	10.99	<.0001
Lumber milll-Log Proces	0.39	0.06	2.83	0.35	1.05	0.75	1.46	0.77
Lumber milll-nonsawing	1.40	0.18	10.93	0.75	2.73	1.96	3.81	<.0001
Lumber mill-sawing	3.75	0.52	27.24	0.19	2.71	1.94	3.77	<.0001
Sorting and Packaging	0.56	0.09	3.67	0.55	1.73	1.27	2.36	0.00

Table 3.3 shows that the higher level cluster variance was smaller in the analysis sub-cohort with all hearing tests (CHO) compared with the sub-cohort with subjects having complete information (CSO) indicating that variability in workers' behaviour toward use of hearing protection devices was slightly better explained by plants contribution in CSO than in the CHO model. However, the confidence interval around the variance components estimates was narrower in the sub-cohort with all hearing tests. The same pattern was found for the variability between subjects: the complete information subgroup captured more variability at the subject level than was unexplained by the fixed effects covariates, yet with larger confidence intervals than in the subgroup having all hearing tests.

In the CHO model, random-effects coefficients for plants varied between -0.72 to 0.92 with nine out of fourteen plants predicting a reduction in the odds of using HPD.

Table 3.3 Estimated variance components of HPD use predictions and model fit in two sub-cohorts of BC Lumber mill cohort population: Restricted to All tests (CHO) subgroup and subjects with complete information only (CSO)

	Subjects with complete hearing tests (CHO)		Subjects with complete information (CSO)	
	estimate	95% CI	estimate	95%CI
Between plant variance σ_k^2	0.55	0.36 – 0.84	0.85	0.54 – 1.33
Between subject variance σ_{jk}^2	2.18	2.13 – 2.22	2.73	2.59 – 2.88
Model fit statistic (AIC)	341089		28386	

Comparison with the null model in which no fixed effects variables were entered showed that both individual specific (age, race, and ethnicity) and job specific (department, job, exposure, job length) factors reduced the between-worker component variance by 11% and 5% in CHO and CSO sub-cohorts respectively. Furthermore, the estimated intra-cluster correlation showed that the correlation between two measurements on the same worker was decreased by 8% in the CHO sub cohort when comparing the null to the final model, and only by 2% in the CSO sub-cohort for the worker cluster level.

Discussion

The sub-cohorts used in this study showed some differences in predicting the odds of hearing protections use which naturally leads to the question of which sub-group between the one with complete information (CSO) and the one with all hearing tests data (CHO) to choose for fitting the model in the full cohort.

While all fixed effects predicted positive associations both in CSO and CHO, only the latter had all associations statistically significant. Also, performing a complete-case analysis, when using the CSO data, discards valuable information which may result into reduced power and precision. Despite the fact that the analyses with complete information captured slightly more variability at the between plant and between workers levels, we favoured using predictions from the sub-group with all hearing tests (CHO) in light of a more precise estimation indicated by the confidence intervals estimates. Moreover, the regression estimate might be artificially inflated in the complete case analysis where odds ratios are, for certain department and jobs (planer department and power house job) more than ten-fold increased compared to the reference group. In this context, the predictions of the group with complete information were perhaps spurious given the small percent decrease in the relative magnitude of the between worker and within worker variability from a null random model to the full model.

Therefore, using the model based on the group with all hearing tests is more appropriate for adjusting exposure in the full cohort for use in an epidemiological study.

The model predictions were reassuring because departments where we expect to see high noise levels, such as the Planer, Chip Plant and Sawmill, are the ones where the probability of use of HPD is significantly high. Similarly, departments that are traditionally located outside (Kilns, Boom) are less noisy and, for them the coefficients were negative. This was also true for job groups, with for example a planer job showing a five-fold increase in the odds of wearing hearing protectors compared with working in a boom job. We could hypothesize that job processes reflects more than the noise environment and postulate that we might be capturing endogenous factors inherent to the job such as attitude toward risk or social culture associated with a given job.

We standardized the random-effect estimates to compare the effects between plants. These estimates capture the group level variability inherent to working in a given plant which could be hypothesized to reflect the absence or presence of plant's safety culture toward hearing conservation and HPD use.

We found that there are differences between ethnic groups with those of European descent being at lower odds to use HPD. Other investigations have also shown that there were strong differences between other ethnic groups, namely Hispanic and non-Hispanic workers [20] and Black and White workers[21]. This result shows the importance of including race in noise related epidemiological studies. Our analyses indicated a gender difference in hearing protection use, yet without statistical significance. We think that this result is due to an extremely imbalanced predictor (99% male population) in light of the high degree of heterogeneity found between male and female in HPD use and previous findings relative to gender differences in the use of hearing protectors[22]. Age was also a strong predictor as we found that the younger population is more likely to use HPD which could be explained by the fact habits are more easily established in younger workers. Another important result is that exposure level did influence the use of hearing protectors which has been recognized by other studies [10, 23, 24].

We sought an optimal methodology to define the determinants of use of HPD and to quantify them. Given the natural clustering of the data, where subjects are nested within departments, in turn nested within plants, we examined a three-level modeling structure with random intercepts for each of workers, department and plants levels. This hierarchical model improved the precision of the predicted use of hearing protection devices, yet examination of the goodness of fit criteria showed signs of over fitting (greater AIC in model C). The model with departments as fixed effects not only provided greater simplicity but also captures the heterogeneity toward use of HPD. Including departments or jobs as random effects would have been indicated if cluster level variables were available and a clustering was *a priori* theorized. In spite of the absence of cluster level variables, we offered jobs and departments as random coefficients to borrow information from the underlying common distribution in favour of those clusters with little data. Unfortunately, we were unable to generate any results because of convergence issues. We do not think that this affected our predictions greatly except perhaps a smoothing of the regression coefficients across jobs and departments. In this context, Friesen and colleagues [22], reported that including jobs both in the fixed or random parts of the model has been criticized. Friesen compared three model structures predicting exposure to dust estimates (in the same study population that is investigated in this paper), whether job was treated as fixed and random effect, she observed no differences in the predictions of the models.

Further research should investigate the use of fully Bayesian model for this type of mismeasurement problem. Instead of predicting HPD use, a non-frequentist approach (made more available recently with the introduction of software such as WinBUGS) would allow modelling the adjusted exposure estimates by taking advantage of the a priori information provided in the self-reported use of HPD. Such an approach would have allowed quantifying the uncertainty associated with the parameters. Here, we used empirical Bayes estimates as we had not only a large dataset, but also a large number of observations per cluster. We might have not captured the unmeasured department-related determinants that could be surrogates for social modeling factors given the paucity of contextual data. However, we did obtain the fixed effects predictive estimates for each of the departments in all plants while taking into account unmeasured plant-related determinants that could for instance capture the company's safety climate.

This research provides a starting point for future research involving noise exposure. We hope that this first step answers the appeal made by investigators to use multilevel modelling for retrospective exposure assessment [15, 16, 26]. Modeling predictors of HPD use allows fitting probability estimates to each worker in the full cohort, thereby providing a method to correct exposure at the individual level according to his likelihood of wearing the hearing protectors.

As indicated earlier, we have investigated, in another study (Chapter 2), a deterministic approach to account for HPD use and adjust exposure accordingly in the same study population. We will compare estimates derived from the present probabilistic route with the deterministic approach by testing the adjusted exposure estimates against a well known noise related disease, sensorineural hearing loss.

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4 Adjusting for use of hearing protection devices: a suggested approach for historical noise exposure re-assessment and validation

Introduction

Hearing protection devices (HPD) are a complicating factor when trying to assess exposure for epidemiological studies on noise-related health effects for multiple reasons, including the fit, comfort associated with their use, compatibility, deterioration over time, and other existing personal protective equipment (e.g. hard hats). Exposure characterization needs to be accurate in order to obtain an unbiased exposure-response relationship. In the context of a retrospective study, use of hearing protection devices reduces the actual noise exposure by blocking the ear canal. Failing to take this reduction into account may lead to a serious non-differential misclassification threat, which has been shown to attenuate the exposure-response relation [1]. Previous work investigating the effect of exposure to noise on heart disease, in a cohort of British Columbia (BC, Canada) lumber mill workers from which a sub-sample was abstracted for our own study, showed a stronger relation when employment was terminated before 1970, a date we know hearing protectors were not used [2]. This finding could be explained by an improved assessment of historical noise measures (i.e. a reduction in the over-estimation of workers' exposure).

A question arises from this result and given the prevalence of protective hearing devices: how can we account for HPD use when using noise exposure estimates based on retrospective exposure assessment?

Information useful in accounting for HPD use may be found in archived surveillance data. Workplaces characterized by high levels of noise are required to implement such surveillance programs, called 'Hearing Conservation Programs'. In British Columbia (BC, Canada) these

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A version of this chapter will be submitted for publication. Sbihi H, K. Teschke, Y. MacNab, H.W. Davies. Adjusting for use of hearing protection devices in a lumber mill cohort: a suggested approach for historical noise exposure re-assessment and validation programs are mandated by the provincial regulatory agency (WorkSafe BC), and this agency archives all resulting hearing tests data. Among the required components of these surveillance programs are: noise control at source where practicable, HPD and annual hearing tests. Unfortunately, engineered noise control is perceived as expensive and deemed impracticable [3]. Consequently, there is consequently a heavy reliance on HPD. Annual hearing tests not only allow identification signs of sensorineural hearing loss during the audiometry, but also gathering ancillary information such as self-reported use of HPD.

Approaches to reduce misclassification of exposure by accounting for hearing protector use were previously investigated through assigning common adjustment factors based on population-based usage characteristics [4]. We also examined a deterministic method that used the availability of audiometry data to directly link self-reported answers about the use of HPD to the existing exposure and adjust it accordingly (Chapter 2). However, audiometric tests are seldom available and the method has intrinsic errors associated with sole reliance on self-reported information.

We have previously modeled the use of hearing protection devices in our study population, and predicted the probability of use for each cohort-participating worker (Chapter 3). We then estimated correction factors corresponding to the attenuation in decibel (dB) provided by different types of hearing protection devices (Chapter 2). In this study, we (i) apply the previously developed model combined with estimated correction factors to historically adjust for use of HPD in a cohort of Lumber mill workers in BC and (ii) validate the new exposure measures using archived audiometry data linked to our study population.

Methods and Materials

Study population

The original cohort described more in detail elsewhere [5] consisted of 27,464 workers employed for a minimum of one year between 1950 and 1995 at one of 14 lumber mills in British Columbia (BC, Canada). Cohort subjects personal identifiers and work histories were obtained from company records.

From the original lumber mill cohort, a sub-cohort of workers for whom noise exposure information was quantitatively characterized (see following section), were successfully linked to hearing tests surveillance data (Figure 4.1) from 1978 to 1998, which provided three types of information: (i) audiometry data (hearing thresholds at different pure tone frequencies from 500 Hz to 8 kHz), (ii) HPD use (self-reported answer prompted by audiometry technicians at time of test), and (iii) risk factors data (self-reported to technicians e.g. otological, non-occupational history).

Following linkage of work histories to hearing test data, we had three types of observations:

(1) Audiograms without exposure information, as audiometric testing was performed at a non-cohort lumber mill (occurred either before start or after end of work in a cohort mill);

(2) work history records during periods when no audiometric test was done;

(3) work history records during periods when one or more hearing tests were done.

The data of our study cohort was obtained by: (1) excluding observations where no exposure information was available, (2) excluding observations obtained before entering the start of employment in a cohort lumber mill, and (3) only keeping one post-employment hearing tests.

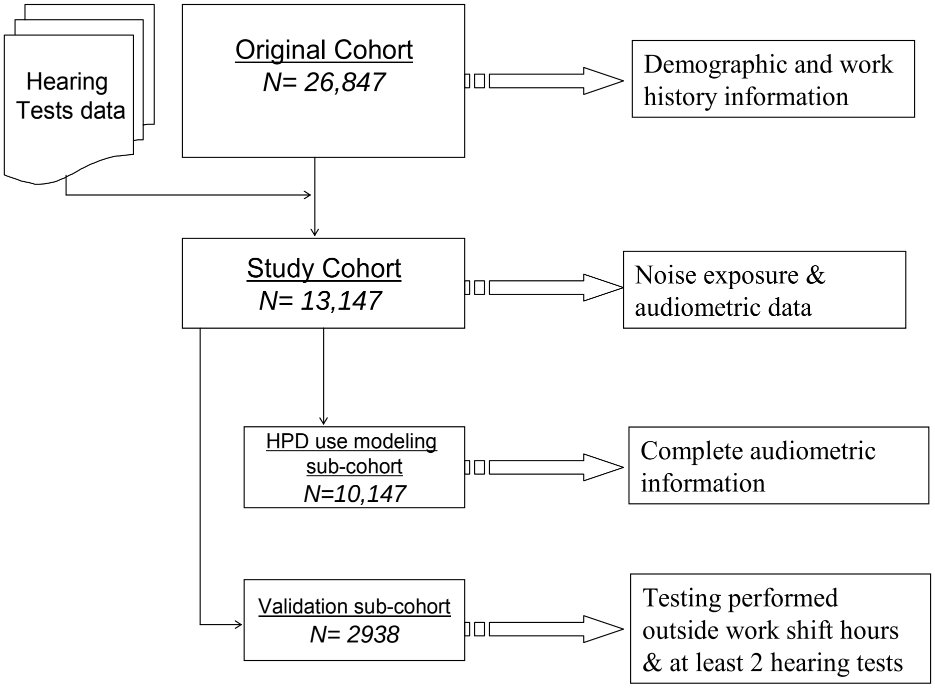

Figure 4.1 Definition of cohort and sub-cohort of BC lumber mill workers.

Estimation of the attenuation provided by hearing protectors.

During audiometric testing, subjects were asked to self-report their HPD use by class (A and B) as per the Canadian Standards Association (CSA), and by type, that is either plugs, muffs or both. In Canada, the minimum attenuation that is required to be provided by class A and B devices is 30dB and 24 dB respectively whether plugs or muffs. Since the Canadian Standard for hearing protectors (CSA Z90.4)[6] reflects the laboratory attenuation, we applied performance data from Berger et al. [7] to the noise reduction rating (NRR) recommended by the CSA to derive the protection level more likely to reflect "real-world" conditions. We adapted the results from the review study by Berger et al. to reflect Canadian usage patterns and found that field noise reduction for earplugs cover on average 28% of the labeled values, and earmuffs field performance yield on average 62%. By weighting the protection values for each class of HPD by the proportion of real-world performance for each type of HPD, we obtained the nominal attenuation ('A' in equation 5). We adjusted the attenuation for earmuffs, using the formula proposed by Arezes and colleagues [8], to take into account the fact that workers seldom wear their HPD for the entire shift, particularly earmuffs [9]. We obtained the effective attenuation R_{3dB}.

$$R_{3dB} = 10\log_{10}\left[\frac{100}{100 - p(1-10^{-\frac{A}{10}})}\right] \tag{1}$$

Where A is the nominal attenuation, p the proportion of total noise exposure duration in a work shift, and R_{3dB} is derived based on a 3dB exchange rate.

Table 4.1 Effective attenuation provided by Hearing Protection Devices by type and class.

Description of type and class of hearing protection devices reported by workers	**R_{3dB} : Effective Attenuation value (dB)**
Muffs, class A	14
Muffs, class B	12
Plugs, class A	9
Plugs, class B	7
Muffs and Plugs combined	21

Noise exposure

HPD-unadjusted noise estimates

Retrospective noise exposures of study cohort members were quantitatively assessed, based on a predictive model created using approximately 1,900 personal noise measurements from cohort lumber mills. These measurements were gathered from regulatory agencies, research and industry data for the period 1970 to 1997[4].

HPD-adjusted noise estimates using the determinants of HPD use model

To adjust these noise exposures for use of HPD, we conducted a probabilistic re-assessment of noise exposure accounting for HPD using a prediction model, a noise correction factor, and data on the prevalence of use of hearing protectors. The methodology used is described fully elsewhere (Chapter 3). In brief, for the modeling, we used a subgroup of 10,147 lumber mill cohort workers, for whom we had complete audiometry data (Figure 4.1).

A predictive model for the binary response of HPD use or not, where π_{ijk} denotes the probability of reporting use of HPD, was obtained using generalized linear mixed models framework to handle the natural clustering of the data. Using indices i, j, and k for measurement occasions, subjects, and mills, respectively, and a logit link, the model we used can be described as follow:

$$\log\left(\frac{\pi_{ijk}}{1-\pi_{ijk}}\right) = \text{logit}(\mu_{ijk}) = \beta_0 + \sum_{p=1}^{P} \beta_p X_{p_{ijk}} + u_{jk} + v_k \;; \quad (2)$$

$$u_{jk} \sim N(0, \sigma_u^2)$$

$$v_k \sim N(0, \sigma_v^2)$$

Here, p, the number of subject-level predictors, were age, sex, ethnic group, noise exposure, date of birth, calendar year, job duration, job titles, and departments. The model assumptions were that the random effects were statistically independent; with σ_u^2 representing the between-worker variability and σ_v^2 the between-mill variability that are not explained by the p fixed effects. The study cohort records, originally structured by job-exposure observation, were split by calendar year to allow for the new exposure measure estimates to be predicted according to the model (equation 2).

In this study, the predicted probability of HPD use, p_{jmn}, for each worker j, for each job-exposure record m, and for each year n, were obtained by fitting the model's prediction to the 13,147 lumber mill workers. For workers with no exposure information, the mill-level predicted probability of hearing protection use was assigned if the worker's employment did not terminate before 1978, the year audiometry became mandatory.

Upon obtaining the individual predicted probabilities of hearing protection use, an algorithm was devised to assign to each probability a noise attenuation value resulting in a correction factor. The correction factor (CF) represents the decibel attenuation of the hearing protector. It is given by

$CF_{jmn} = p_{jmn} * W_n$ (2);

where W_n is a time-varying attenuation value. For each year n, we calculate W_n as the weighted average of HPD-specific attenuation values (see table 4.1) described in details below.

$W_n = 14\ AM_n + 12\ BM_n + 9\ AP_n + 7\ BP_n + 21\ PM_n$ (3);

where the weights represent the proportion of the lumber mill population using each type and class of hearing protectors. Using the yearly HPD-specific (i.e. type and class) prevalence of HPD use from the existing audiometric data in participating lumber mills:

AM_n is the proportion of workers using class A muffs

BM_n represents the proportion for those wearing class B muffs

AP_n equals the proportion of those using class A earplugs

BP_n the proportion of class B earplugs users

PM_n, the proportion of workers using both plugs and muffs users.

Cumulative exposure (in units of dB(A)×years) was estimated as time-weighted average exposure and was computed using the logarithmic addition of (both HPD adjusted and non-adjusted) noise intensity (Leq) and duration (T) of employment in a given job j, for all jobs held 1 to k. This was computed using the following formula

$$10\log\left[\sum_{j=1}^{k} Tj * 10^{\frac{Leq_j}{10}}\right] \qquad (4)$$

Validation analysis

Noise Induced Hearing Loss (NIHL)

Standardized auditory testing was carried out by audiometric technicians whose training was supervised by the Workers' Compensation Board. Air conduction thresholds were measured for the pure tone frequencies 0.5, 1, 2, 3, 4, 6 and 8 kHz in each ear.

We defined hearing loss as the average air conduction thresholds across the frequencies 0.5 2, 4, and 6 kHz, in both ears. This definition was consistent with McNamee *et al.*[10]. The outcome variable was therefore a continuous response measuring the physiological hearing level over time. We applied a log transformation for our response variable to follow approximately a normal distribution

Tests were either during the work shift or outside work hours, in sound-attenuating booths. The validation sub-cohort included subjects who had their testing in quiet conditions, at least 16 hours outside work hours to minimize the effect of temporary threshold shift and for whom a minimum of two hearing tests were available (Figure 4.2).

Other risk factors

Additional information was gathered by audiometric technicians, including potential confounders for the noise-NIHL association such as otological information. We grouped potential hearing loss risk factors in four constructs: (1) Use of firearms, (2) otological history, (3) non-occupational noise exposure, and (4) audiological disorders. We aggregated one construct of risk factors into one single response item because Cronbach's alpha was greater than 0.8 (use of firearms). Risk factors questions were treated as "ever/never" information to handle missing responses.

Predictive validity of HPD-adjusted estimates of noise exposure

The analyses conducted to evaluate the HPD-adjusted exposure estimates were performed using the following model where only the intercept was allowed to have random effects u_{0j} among workers, giving the following general formulation:

$$y^{*}_{ij} = \beta_{0i} + \beta_1 age_{ij} + \beta_2 gender + \underline{\beta}_3 ethnicity_{ij} + \beta_4\, cumulative\ \exp osure_{ij} + e_{0ij} \quad (6)$$

$$\beta_{0i} = \beta_0 + u_{0i}\,;\ u_{0ij} \sim N(0,\sigma^2_u)\,;\ e_{0ij} \sim N(0,\sigma^2_e)$$

$$i = 1,\dots,N;\ j = 1,\dots,N_i;$$

Where there are N workers, N_i hearing tests corresponding to the i^{th} worker, and y^* is the log transformation applied to y (NIHL) to approximate a Gaussian distribution. In this model σ^2_u represents the between-worker variance, and σ^2_e the within-worker variance.

The model building strategy began with examining an initial model which had non-modifiable risk factors entered as fixed effects, namely age, gender, and ethnicity, regardless of their statistical significance in the univariate analysis, and either adjusted or non-adjusted noise exposure (referred to as 'basic'). We then extended the basic model by examining separately groups of variables for each of the four risk factor constructs and selecting those significantly associated with hearing loss. Finally, using manual backwards stepwise regression, from previously retained risk factors, only significant variables ($p\text{-value} < 0.05$) were selected while keeping non-modifiable risk factors. Using the same indices for the basic model definition, the final model can be described by

$$y_{ij}^{*} = \beta_0 + \sum_{p=1}^{P} \beta_{pij} x_{ij} + e_{0ij} \qquad (7)$$

$$\beta_{0i} = \beta_0 + u_{0i}, u_{0i} \sim N(0,\sigma_u^2), e_{0ij} \sim N(0,\sigma_e^2)$$

The βs here are fixed effects for P predictors (age, sex, ethnicity, noise exposure, significant risk factors), and var(u_{0i}) and var(e_{0ij}) are two variance parameters to be estimated.

The slopes (β) of the relationship between hearing loss and the adjusted or unadjusted metric were compared to determine whether adjustment for HPD use improved the exposure-response relation. All models were estimated using *xtreg* command and maximum likelihood estimation in STATA version 8 (STATA Corporation, College Station,TX)

Results

The study and validation sub-cohorts

After applying the exclusion criteria, the study cohort was comprised of 13,147 workers with a total of 183,115 records defined by job, exposure, and self-reported use of HPD.

The study cohort was predominantly male (99%) and composed of three major ethnic groups with 8.8% South Asians (mostly Sikhs), 1.5% Chinese, and the remaining majority being Caucasian, mostly of European descent (89.7%). Workers were highly exposed to noise: the average measured exposure was 90.6 dB(A) and the mean unadjusted cumulative exposure was 101. 4dB(A) × years.

The majority of workers had a least one observation with missing HPD use data (n=8749). Among 2944 workers who had all their audiometric testing performed while working in non-cohort lumber mills, 126 workers terminated their employment before 1978 and were consequently not attributed any probability of use of HPD. Hence, we excluded these workers from the cohort study.

The validation sub-cohort had 2938 workers with all hearing tests performed after at least 16 hours outside the occupational noise exposure (i.e. work shift) and with all potential risk factors informed. This validation sub-cohort had a slightly lower exposure than in the study cohort with a mean adjusted cumulative exposure of 99.7 dB(A) × year. This difference was driven by the job length as workers in the validation subgroup had shorter job tenure (716 days on average) than in the study cohort (894 days on average). In this subgroup, workers had between 2 and 16 hearing tests (on average 4.3 hearing tests).

Predicted hearing protector use.

The mean predicted probability of using hearing protection was 0.82 (standard deviation 0.27). For workers assigned mill-level predicted probabilities, the odds were slightly higher (mean=0.86, standard deviation = 0.11). Table 4.2 shows the yearly proportion of hearing protection devices users by type and class; each cell represents the weights applied in equation 3.

After adjusting the exposure to account for the attenuation provided by HPD (mean correction factor 9.7dB), the mean adjusted exposure was 84.6dB(A), and the mean adjusted cumulative exposure since first entry in the study cohort was 98.26dB(A)× year.

Table 4.2 Proportion of hearing protection devices users by class and type in the study cohort.

Year	Proportion of HPD users	Proportion of HPD specific users (in %)			
		Muffs Class A	Plugs Class A	Muffs Class B	Plugs Class B
1978	71.6	43	45	8	4
1979	76	51	37	6	6
1980	76.9	45	47	6	2
1981	78.5	46	47	5	2
1982	78.6	34	39	11	15
1983	80.2	46	44	2	5
1984	83.7	44	49	2	4
1985	85.3	51	39	1	6
1986	83.8	53	35	1	9
1987	86.1	44	47	1	5
1988	85.8	43	50	1	2
1989	87.3	31	46	1	2
1990	88.2	31	50	1	1
1991	88.9	40	55	1	1
1992	91.4	37	59	1	1
1993	92.2	38	57	1	2
1994	91.9	41	53	1	2
1995	92	36	59	1	3
1996	92.6	36	60	1	2
1997	91.8	30	66	1	1
1998	93.7	33	62	2	1

Predictive validity results: Hearing loss and noise exposure

Table 4-3 presents the results of the final model, as specified in equation 6, relating various risk factors including noise exposure to hearing level. The slopes of all confounding variables that we controlled for were stable across the validation sub-group and the study cohort.

The estimated regression slope (β) of the association between hearing loss and cumulative noise exposure became statistically significant after accounting for HPD use and increased by four-fold in terms of the magnitude of the effect. According to the model's prediction, a doubling of exposure intensity or a doubling of duration of exposure given a 3 dB exchange rate, would reduce the average hearing across both ears at frequencies 0.5, 1, 2 and 4 kHz, by *exp*(0.004*3 dB), or 1.01 dB, while all other model covariates are held constant. Our results also demonstrate an increase in hearing threshold of 1.13 dB for an interquartile increase in adjusted exposure.

Table 4.3 Validation results – Noise and log transformed hearing loss with and without adjustment for hearing protection use.

	Validation subgroup with exposure adjusted for hearing protection use			Validation subgroup with unadjusted exposure		
	β	95% CI		β	95% CI	
Fixed Effects						
exposure (dB(A)*Year)	0.004	0.001	0.007	0.001	-0.003	0.005
Sex						
female	0.25	-0.9	1.5	0.29	-0.9	1.5
Ethnicity						
Chinese	0.27	0.1	0.4	0.27	0.15	0.4
East Indian	-0.12	-0.4	0.1	-0.13	-0.39	0.12
Age (years)	0.050	0.05	0.06	0.053	0.05	0.056
Risk Factors						
Use of firearm	0.1	0.02	0.18	0.1	0.02	0.17
Ear doctor visit	0.4	0.3	0.49	0.4	0.3	0.5
Exposed to blast	0.2	0.08	0.33	0.2	0.08	0.33
Exposed to noisy previous job	-0.11	-0.19	-0.041	-0.11	-0.19	-0.044
Problems understanding speech	0.39	0.27	0.5	0.39	0.28	0.6
Random effects						
between worker variance	0.92	0.89	0.95	0.92	0.89	0.95
within-worker variance	0.8	0.79	0.81	0.8	0.79	0.81

Subjects of Chinese descent were significantly more at risk of developing hearing loss due to occupational noise exposure than the baseline group (i.e. those of European descent).

At least one variable from each risk factor construct was controlled in the validity analysis. The majority of risk factors were positively associated with hearing loss with a hearing threshold level between 1.1 dB and 1.5 dB (use of firearms, visit to an ear doctor, past exposure to a blast, or having problems understanding speech). However, exposure to a previous noisy job reduced the hearing loss.

Discussion

Previous work investigating the effect of exposure to noise on heart disease in the cohort of workers used in this study showed a stronger relation when employment was terminated before 1970, before which we know hearing protectors were not used [2]. The purpose of this study was to adjust for hearing protection device use in the more recent cohort members. The results showed that adjusting for hearing protection device use led to a stronger and more significant noise-hearing loss relationship than exposure estimates with no adjustment. A plausible explanation of the strengthening effect observed in the study by Davies *et al.* might be the reduction in exposure misclassification, since it has been extensively shown that non-differential misclassification attenuates epidemiological relationships [11].

Testing the validity of predictive models examines whether the predictions can be generalized. Therefore, we can expect that the new noise estimates will likely result in stronger exposure-response slopes; especially important when used to investigate an inherently 'weak' relationship like noise and ischemic heart disease.

Few studies have tried to account for HPD [12], and the majority had a cross sectional design[13]. For cross sectional studies where HPD was taken into account, the focus was not in adjusting historical noise estimates. We only know of one study where retrospective noise exposure assessment was subsequently examined through a validation analysis [10]. While this study aimed at testing historical noise exposure estimates obtained to examine the relation between noise and cardiovascular disease [14], it did not *per se* account for use for hearing protection devices.

A major strength of the study lies in the use of a model to predict use of hearing protection devices because the measurement errors are reduced. By defining the determinants of use of HPD, we were able to predict for each worker of the study cohort the likelihood of use of HPD. In doing so, bias related to using self-reported data is circumvented. Although, self-report about HPD use has been shown to be a good indicator, the sole reliance on a subjective source of information to achieve the adjustment carries a certain degree of error, either due to recall bias or compliance bias. Systematic measurement bias was also reduced. For instance, in a study where the adjustment for hearing protection devices relied on self-reports of use of hearing protectors, the exposure characterization suffered because it did not capture the variability of HPD use due to trade differences [13]. Here, the predictive model had both department and job groups; therefore the probability of use of hearing protectors incorporates this source of variability.

However, our study had some limitations. These were mainly concerned with different sources of measurement errors. In the exposure reassessment phase, the attenuation provided by hearing protection devices is a central concern. Rabinowitz *et al* recognized the complexities posed by the variability of the attenuation provided by HPD and stated that most studies have “shown that such effectiveness [of hearing protectors] varies widely between individuals, making accurate individual estimation of protection impossible”. We believe that while precise individual estimation is hard to achieve, the combination of a critical review on real-world performance with an objective assessment of the use of HPD alleviates this issue. This study relies on empirical findings derived from a review where data was gathered from more than 90 different industries tallying approximately 2900 individuals. Moreover, the average correction factors abstracted from this review were combined with an objective prediction model on behavior toward use of hearing protection devices. It is important to recall that despite the controversy around Noise Reduction Rating, the use of a single number to indicate performance offers the only means to account for different types and classes of hearing protectors use in the absence of longitudinal octave-band workplace noise measurements.

In the predictive validity analysis phase, our inability to test how well workers used their hearing protectors was a concern. We addressed this in two regards. First, the validation analyses were limited to subjects who had hearing tests performed outside work shift hours. Such an exclusion criterion increased the likelihood that the hearing loss definition was capturing permanent threshold shifts rather than temporary thresholds shifts. Second, to take into account the fact that workers are seldom highly compliant, we considered that they would systematically remove their earmuffs and accounted for this aspect by adjusting the estimated HPD-specific attenuation for a proportion of time exposed during a work shift. Such an adjustment helps preventing an under-estimation of noise exposure. Finally, despite the fact that data was cleaned with respect to logical errors, other sources of measurements errors could have been overlooked (e.g. hearing threshold levels not decreasing consistently for some subjects). We examined our data and found that hearing threshold levels were not differentially distributed between subjects reporting use and non-use of hearing protection devices, which minimizes the misclassification threat.

Our validation analysis results were stable for all covariates that were controlled across the data with adjusted and unadjusted exposure. The strength of such result is likely due to the model building strategy. Furthermore, performing a within-subject analysis of hearing loss with a random intercept allowed controlling for factors that vary between subjects and accounting for a varying initial hearing loss. Another approach could have been adopted for handling risk factors data. Principal component analysis would have captured which risk factors had the most variability in explaining hearing loss reducing the high number of dimensions of our data to a simpler one. However, this might have led to ignoring a group of risk factors such as the non-occupational noise exposure group or possibly to less stable results than those reported here. For instance, we found that workers exposed to a prior previous job had a decreased risk of hearing damage. This might be due a severe baseline hearing loss such that these workers hearing impairment was less relative to those who did not have a previous noisy job.

More sophisticated methods could be used, therefore further work should aim at using a fully Bayesian approach that incorporate the measurement error in the prior probabilities in order to avoid the reliance on yearly proportion of HPD use. Such methods would have characterized the effect size of the attenuation provided by the attenuation factor. However, despite the heuristic component of this approach, this study demonstrated an improved noise-hearing loss relation when accounting for hearing protectors use in a cohort of workers followed between 1909 and 1998. While the relative difference before and after adjustment for use of HPD is considerable, the magnitude of the effect is very subtle.

Finally, these results have a good external validity and we could expect the same dose-response strengthening in the entire study cohort since the exposure range of the validation sub-cohort reflects the exposures of the 13,147 workers of the study cohort.

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5 General discussion and Conclusion

Exposure assessment of historical noise exposure for occupational health studies has significantly evolved over the past two decades both with respect to the methods used and the study designs adopted. Recent published research has moved from crude expert-estimates or self-reports to estimators based on quantitative measures often via modeling technique.

In the literature on the effects of noise, early studies were devoted to noise-induced hearing loss, but the trend has been slowly moving toward the investigation of adverse health effects other than the auditory system, especially cardiovascular disease. Despite the high plausibility of a biological model linking noise to cardiovascular health effects, the strength of exposure-disease relations is expected to be weak because of the multifactorial nature of the disease. The combination of these two aspects creates a complicated problem: can retrospective exposure assessment be accurate enough to capture weak exposure-disease associations?

The research presented here was an extension of previous work investigating the effect of noise on acute myocardial infarction. In this study, the retrospective noise assessment in British Columbia (BC) lumber mills was rigorously performed using models allowing the prediction of exposure levels for all jobs and time periods [1]. In this mortality study, a sub-cohort of subjects who terminated cohort employment before 1970, showed a statistically significant increase in the relative risks of acute myocardial infarction mortality with increasing exposure, a result not replicated in the full cohort where the relationship was more mitigated. This sub-sample differs from the full cohort with respect to their non-use of HPD.

The underlying hypothesis of this work is that failing to account adequately for the use of

HPD in the full cohort led to an over-estimation of noise exposure and consequently to exposure misclassification. The results of the thesis showed that misclassification of exposure likely took place. It also addressed the question pertaining to the ability of retrospective cohort-based study to detect associations that are tenuous by nature such as noise and cardiovascular end points. The results show that it is possible to improve inadequately measured exposure variables and reduce misclassification, (a) if supplemental information is available – here self-reported HPD use and factors affecting their use, and (b) if corrections of the original exposure estimates are made using either deterministic or probabilistic models.

I started by investigating heuristic approaches to reduce misclassification of exposure due to hearing protector use. Given the lack of generalizability of such an approach I also developed predictive models of HPD use from a sub-sample of the study cohort with self-reported information about factors affecting HPD use gathered from the hearing test data. By utilizing hierarchical modeling to take into account the repeated nature of testing within individuals and nesting of subjects within mills, I estimated HPD-adjusted individual noise estimates using the determinants of use model prediction.

Key findings

Evaluation of the use of HPD modeling

Various models for the prediction of use of HPD were examined where determinants such as mill, employer, subjects' age, department, job, job length, exposure level, and calendar year were included. These models also had different nesting structure reflecting the natural clustering of subjects within mills, in turn nested within plants.

Two distinct sub-samples of my study cohort were defined and used for the modeling. The first sub-sample consisted of workers with complete information on their work and exposure history as well as complete information about the use of HPD as reported during audiometric testing (also referred to as complete case analysis). While this sample had conservative definition criteria, the method to define the second sub-sample was to keep all the hearting tests that has coincident work periods to maximize the number of HPD reports we had with corresponding information.

In both sub-samples, the final models included a random intercept for worker and a random intercept for plant. Hearing protection devices use was significantly associated with factors such as noise exposure and age. We also showed that some jobs such as sawfiling and departments (e.g. planer) were strongly associated with the use of hearing protection devices, regardless of which subset of the cohort the data was abstracted from.

One of the main findings was that the sub-cohort of subjects with excluded records where no hearing test information was available was better suited to predict use of hearing protection. This finding, which at first seemed counterintuitive, shows that discarding valuable information by using a smaller group with complete information results in reduced power and precision.

The second main finding was that interpretation of the regression estimates need careful assessment as those found in the complete case analysis sub-sample were perhaps artificially inflated. This finding emphasizes the need to compare the decrease in the relative magnitude of the between-worker and within-worker variability from a null random model to the full model.

The last main message is that a model – if validated – can be used to predict hearing protection use for cohort subjects for whom individual hearing protection use data is unavailable. This finding sheds light on the model building strategy. When building the predictive model, the epidemiological perspective had more weight than the exposure assessment lens in terms of the choice of determinants to include. Had I included information available through the hearing test questionnaires for a more accurate prediction, it would have been impossible to generalize the results and predict use of HPD to a larger sample of the study population.

Importance of testing the predictive validity of exposure measures

New exposure measures will be considered more valid, i.e. result in less exposure misclassification, if they can be shown to demonstrate a stronger noise-hearing loss relationship.

In chapters 2 and 4, both the deterministic and probabilistic methods were respectively assessed by examining the exposure-response relationship using noise-induced hearing loss, a well-characterized and long-established noise health effects.

Validity of exposure measures derived from deterministic methods

The deterministic method where self-reported use of HPD was linked to noise estimates led to an HPD-adjusted exposure measure that predicted hearing impairment more strongly and significantly than noise exposure without adjustment.

The challenge using this method was two-fold. First, linking self-reported use of HPD implies that for each job-exposure record, a hearing test carrying this information was needed. As in every retrospective cohort study, this information had gaps. Thus, different imputation methods were used to fill gaps in the history of use of HPD.

All methods used for imputing missing self-reports about the use of HPD to allow accounting for HPD when reconstructing historical noise exposure improved estimates because the new measure strengthened the noise-hearing impairment relationship.

The group-based mean imputation performed best amongst all other methods, with a threefold increase in the effect size of the noise-hearing impairment association while other imputation methods using subject-specific algorithms such as the time-weighted imputation had slightly over a two-fold increase. This is reassuring since this method of imputation is the simplest and least labour intensive.

Validity of exposure measures derived from a probabilistic method

We showed a four-fold increase in the noise exposure and hearing loss slope, after adjusting for HPD use, while controlling for gender, age, race, as well as medical and non occupational confounding variables. The improvement and strengthening of the dose-response relation with unadjusted- and adjusted-HPD exposure measures will allow generalizing these results to a larger population. The predictive validity of the noise estimates motivated the choice of the explanatory variables in the determinants of HPD use model. Both the epidemiological and exposure assessment perspectives were colliding when building the model. From an exposure assessment perspective, more explanatory variables such as initial hearing loss, and pre-existing otological conditions, included in the questionnaire during audiometric testing would lead to a more precise exposure model. However, given that this model's rationale was to predict the likelihood of use of HPD for re-estimating noise exposure in the context of epidemiological analyses of health effects of noise exposure, we chose variables commonly found and most likely to exist for larger samples of population in order to allow estimation within the broad cohort population and increase the power of epidemiological analyses.

Contributions

In this thesis, we have shown how the extensive use of HPD increases the complexity of an accurate exposure assessment because the attenuation provided to those who wear these devices which is highly variable and difficult to quantify from one worker to another [2]. Because of the weak nature of the relation in noise and CVD, mismeasurement is a crucial consideration in retrospective noise exposure assessment.

Starting with HPD-unadjusted individual noise estimates, our work investigated two methods for re-estimating noise exposures in which the attenuation provided by HPD is accounted for. These methods can be distinguished between a probabilistic method, where we modeled the behavior of workers in order to predict the likelihood of use of HPD, and a deterministic approach by which we took advantage of the availability of data about self-reported use of HPD and linked it to available HPD-unadjusted noise estimates.

This work brings an original contribution to the occupational epidemiology of health effects of noise research area as most published research papers either acknowledge the bias induced by omitting to account for use of HPD use or try to account for HPD using crude tools where group-based ad-hoc algorithms are applied to individual-level exposure estimates. The methods we used were fairly straightforward and could be adopted elsewhere. We hope these two approaches would be applicable to various industries including lumber mills. Noise exposure in sawmill is a typical industrial noise exposure that can be found in other industries. Since HCP are implemented both in Canada and the US, so we hope that audiometric surveillance is available in jurisdictions across North America. Even where information on personal use of HPD is not available, our probabilistic approach offers means to perform the adjustment in the absence of such data. In fact the probabilistic modeling approach was more successful than the deterministic approach that required more extensive data.

The strength of our work also resides in the subsequent analysis of the predictive validity of the new exposure measures, and we hope that we have shown that validation is necessary to be able to claim that the noise estimates are improved. Since we had a health outcome, NIHL, whose underlying mechanisms and effect-levels with the exposure are well understood, we had a unique opportunity to rely on this relationship and ascertain whether we did improve exposure estimates.

Finally, an important aspect of this research was to demonstrate that even if NIHL is a known and compensated claim for occupational exposure to noise, the changes are quite subtle and require a quantitative noise exposure estimation that includes accounting for HPD use. From this perspective, to account for HPD use would be far more critical for a noise-CVD relationship which is not as established and probably weaker in order to take appropriate policy changes.

Limitations and knowledge transfer opportunities

The tools used in this work could be improved

1. The deterministic method necessitated to impute a correction factor to workers with missing information. Our methods (group-based and individual-based) were simple algorithms. More sophisticated methods such as multiple imputation techniques are available. Their use would have probably led to more precise results as different types and class of HPD could have been imputed.

2. The probabilistic method could be improved by either
    a. Modeling a multinomial response
    b. Using a Bayesian approach where we would view measurement error as composed of three sub-models: (1) an outcome/disease model, (2) a measurement model, and (3) an exposure model. Adopting a prior (i.e. information on the nature and type of measurement error) when specifying the measurement model, the exposure model links the disease to a "true" exposure with some error modeled in the outcome model to obtain posterior distribution of the parameters of interest.
3. The use of noise-induced hearing loss might be an "alloyed" gold standard outcome. Throughout the research presented, both exposure assessment methods (i.e. deterministic and probabilistic) were examined while considering that noise and noise-induced hearing loss has a fully characterized exposure-response relationship. This rather strong assumption should be used with caution as the patho-physiology of the noise-induced hearing loss has still some unanswered questions and the exact evolution of the disease is yet to be elucidated.

This last limiting aspect also sheds some concern about the choice of the noise metric. We have chosen a cumulative exposure metric, which is the most adequate metric for chronic diseases where both intensity and duration of exposure have an effect. However, in the absence of a clear picture on the noise-induced hearing loss mechanism, this choice might be questionable.

Overall, this study had positive results despite simple methods. Therefore, we can project that a refinement in the approach used would likely strengthen a noise-hearing loss relation, and consequently a noise-cardiovascular endpoint association.

However, a second set of challenges relate to the real-world attenuation of HPD. The high variability of the attenuation measurement and the myriad of factors that affect their performance make the task of accurately characterizing historical exposure nearly impossible. Therefore, I would advocate for approaches such as the one demonstrated by *Seixas et al.* in their investigation of early hearing loss due to occupational exposure to noise [3] where HPD attenuation was directly measured and applied to the measured noise exposure levels. The research team started by prospectively monitoring hearing and noise exposure among a cohort of construction industry apprentices and in parallel extensively supervising HPD use during construction work tasks. The average level of attenuation achieved by a sample of construction workers on whom direct measurements of individual HPD attenuation during typical use in the field were obtained (20 dB). HPD adjusted exposure levels were calculated by subtracting 20 dB from the measured sound level for each minute during which HPD use was reported. Trade specific mean exposure levels, with and without accounting for the variable use of hearing protection in each trade, were calculated and used to group subjects by trade specific exposure level. Mixed effects models were used to estimate the change in hearing outcomes over time for each exposure group and showed how changes in hearing loss are subtle to detect through audiometric surveillance during the first years of work.

The challenges I faced in this thesis are not confined to retrospective assessment of occupational exposure to noise. While specific to the retrospective assessment of exposure, they are true for both occupational and environmental exposure and span chemical, biological and physical hazards. Savitz and colleagues faced parallel challenges as those I faced with in this thesis, when retrospectively assessing drinking water chlorination by-products ingestion. In their investigation for birth outcome effects, the retrospective exposure assessment of drinking water intake was complicated by the use of water filtration devices (in pitchers and faucets) [4]. These authors conducted the most extensive study where filtration was empirically assessed and taken into account in the exposure characterization phase using heuristic algorithms. However these authors acknowledge that "despite unprecedented efforts to accurately characterize exposure, [they] have done so incompletely". Reliance on self-reported information, for most if not for all retrospective studies, is subject to error, however this aspect should not deter from seeking accuracy of exposure estimates, particularly in presence of exposure-response relations *a priori* known to be tenuous. Finally, to evaluate errors in the exposure assessment methods should be performed not only to exposure assessment approaches such as those presented here, but also to other methodologies such as defining grouping schemes. Predictive validity was used in the work I present here, however it should be noted that using a set of gold standard measurements if available or using simulation techniques are valid and highly recommended approaches to evaluate the assessment of exposure of biological, chemical, or physical hazards.

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