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## Towards the quantification of the burden of disease of environmental noise induced tinnitus

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### ABSTRACT

The World Health Organization (WHO), in its Environmental Burden of Disease series, is in the process of quantifying the burden of disease caused by environmental noise. Tinnitus, defined as a sound perception that cannot be attributed to an external sound source, is one of the significant health effects that may be caused by environmental noise exposures. As a contribution to WHO's project, the authors developed a method which is in validation to quantify the burden of disease of Environmental Noise Induced Tinnitus (ENIT). Three different approaches were identified to quantify disease occurrence. The authors developed the one based on random samples based survey studies using a case definition of tinnitus with comorbidity. A population attributable fraction of 3% for tinnitus exclusively caused by environmental noise (excluding occupational or mixed exposures) was derived from expert's opinion. A disability weight of 0.120 is proposed. An example of Disability Adjusted Life Year calculation is presented for WHO epidemiological Euro-A region using WHO methodology. This method to quantify ENIT will eventually allow for national burden of disease calculations.

### 1 INTRODUCTION

The World Health Organization (WHO) is in the process of developing a method to quantify the burden of disease (BoD) caused by environmental noise exposure using the Disability Adjusted Life Years (DALY) unit as a summary measure. Summary measures of population health are measures that combine information on mortality and non-fatal health outcomes to represent the health of a particular population as a single number (1). One of the fundamental goals in constructing summary measures is to identify the relative magnitude of different health problems, including diseases, injuries and risk factors (2).

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Based on an expert committee lead by Bonn's Office of the WHO European Center for Environment and Health, tinnitus was identified as one of the seven outcomes for which sufficient scientific evidence of a causal link with environmental noise exposure was found. It was therefore retained for further work on developing the technical aspects of the method to quantify the BoD. The other outcomes to be included in the BoD are hearing loss, cardiovascular diseases, sleep disturbance, accidents, cognitive impairment and annoyance.

This paper presents the current state of our work in developing a valid method to quantify the BoD for environmental noise induced tinnitus (ENIT). Some examples of calculations are given to illustrate the method, but should not be used as valid estimates as some elements of the method are in a validation process.

## **2 BACKGROUND ISSUES**

### **2.1 Disease description**

Several authors consider tinnitus as a symptom of the auditory system and not as a disease per se. On the other hand, tinnitus is a diagnosis in the International classification of diseases (ICD-9) (388.3) and ICD-10 (H93.1). Tinnitus is often found to be present concomitantly with hearing loss. This is also true for noise-induced tinnitus and noise-induced hearing loss (NIHL) (3-4). Between 12 and 50% of persons with noise-induced hearing loss report having tinnitus (5-8). Nevertheless, tinnitus may be experienced by persons exposed to excessive noise without measurable hearing loss (9). The natural history, the annoyance and disability, the clinical approaches for diagnosis and treatment as well as the consequences of tinnitus differ significantly from these same elements in persons with NIHL. For instance, insomnia reported by tinnitus sufferers is not a consequence of NIHL. Therefore, it is justified that tinnitus be analyzed per se as an independent outcome of environmental noise-related BoD.

Tinnitus is the general term for sound perception (for instance roaring, hissing or ringing) that cannot be attributed to an external sound source. To put it in terms of auditory abilities, tinnitus is the inability to perceive silence when no external sound stimulus is present (10). Tinnitus defined in such broad terms is rather prevalent. It is widely believed that mild, occasional tinnitus is experienced by nearly everybody at some time or another in their lifetime (11). There is considerable variation in tinnitus expression, its etiology, and its effects on patient's lives (12).

Tinnitus may be classified according to its different attributes: duration of a single episode (seconds, minutes; intermittent, continuous), longitudinal duration (days, months, years), severity (degree of annoyance, interference with daily living, comorbidity), patient's abilities and quality of life (12-13). There is no unique internationally recognized classification. The BoD takes the perspective of the disabilities caused by tinnitus in terms of functional health.

Tinnitus annoyance and experienced handicap can be measured in clinical or research settings on an individual basis by a variety of questionnaires. Severity grading classifications (grade I to grade IV) as measured by the Tinnitus Severity Questionnaire developed by Goebel et al. is probably one of the most frequently used tinnitus questionnaires in Germany (14). Other countries use different questionnaires that have good psychometric properties (i.e., good internal consistency and test-retest reliability) such as the Tinnitus Reaction Questionnaire (15), which measures emotional tinnitus-related distress, the Tinnitus Handicap Questionnaire (16) which measures the self-reported severity of tinnitus as a handicap, and the Tinnitus Handicap Inventory (17), which quantifies the impact of tinnitus on everyday life. Psychoacoustical

measurements of tinnitus can also be made. Yet, these measurements typically do not predict the psychological distress reported by patients (18).

Tinnitus can cause in some patients one or several of the following consequences: sleep disturbance (difficulty falling asleep or going back to sleep), cognitive effects, anxiety, psychological distress, depression (case reports of suicide), communication and listening problems (hearing problems), difficulty with concentration, frustration, irritability, tension, prevent work, reduce efficiency, restrict participation in social life

In population based survey studies, simple questions about current or past presence, duration, some consequences and the degree of annoyance are usually used rather than the tools described above to assess the individual status. There is no standardized unique questionnaire to measure these characteristics for tinnitus sufferers at a populational level. General agreement of the experts consulted (see collaborators and acknowledgements) is to focus on the degree of severity of tinnitus rather than on its duration for BoD purposes.

## **2.2 Causal factors for tinnitus**

Tinnitus caused by excessive noise exposure has long been described (19-21). A very small proportion of tinnitus cases signal the presence of an underlying treatable medical condition, such as a tumour or chronic partial opening of the Eustachian tube, but the majority of cases have no apparent or treatable cause. Among known causal factors of tinnitus, the reported frequency of occurrence of noise is anywhere between 50 and 90% (12).

There is no single pathophysiological pathway to explain the production of tinnitus. All structures of the auditory system have been suggested as possible sites of generation for tinnitus, from periphery to auditory cortex. Many explanatory models have been proposed either based on anatomical, physiological, clinical or neuropsychological approaches. Underlying mechanisms responsible for transient and chronic tinnitus are also most likely different (9). Despite those limits in understanding the pathophysiology of tinnitus, there is no doubt that noise can cause incapacitating tinnitus (9, 22). In noise induced hearing loss and noise induced tinnitus it can be assumed that genesis is based on the same hearing pathophysiology (23-27).

## **2.3 Noise typology**

Environmental noise is a rather broad category basically including all noise exposure sources in a variety of settings other than work (occupational noise). Furthermore, prevention strategies may differ considerably according to sources (regulations, policies, target populations). One possible classification for ENIT is the following classification, the most well-known noise sources being:

- traffic noise (cars, planes, trains, motorcycle),
- construction noise,
- urban and community noise (neighbours, radio, television),
- social/leisure noise (cassettes, fireworks, toys, rock concerts, bars, discos, firearms, snowmobile, motomarine, etc.).

Hearing impairment is not expected to occur at Laeq,8h levels of 75 dB(A) or below, even for prolonged occupational noise exposure. It is also expected that environmental and leisure-time noise exposure with a Laeq,24h of 70 dB(A) or below will not cause hearing impairment in the large majority of people, even after a lifetime exposure (28). Although to our knowledge, there is no empirical data to propose a non-observable adverse effect level (NOAEL) for noise-induced tinnitus, it is reasonable and plausible to use the same protective NOAEL for tinnitus as those for noise-induced hearing loss. Therefore, for ENIT BoD calculations in Euro-A and North

American countries, social/leisure noise exposure is the most relevant source of noise exposure and concern as these sources may typically exceed those protective levels.

### 3 METHOD FOR ESTIMATING ENIT BURDEN OF DISEASE

#### 3.1 General formula

The general formula for quantification of the BoD in terms of Disability Adjusted Life Years (DALY) is (29):

$$DALY = YLL + YLD$$

*where:*  
 YLL = years of life lost due to premature mortality.  
 YLD = years lived with disability.

where  $YLL = N \times L$

*where:*  
 N = number of deaths.  
 L = standard life expectancy at age of death (in years).

and where

$$YLD = I \times DW \times L$$

*where:*  
 YLD = years lived with disability.  
 I = number of incident cases.  
 DW = disability weight.  
 L = average duration of disability (years)

According to current knowledge and the data presented, the authors consider that there are no YLL caused by ENIT. Even though there are some reports of tinnitus sufferers committing suicide (30), these are likely to be already accounted for in calculations of BoD attributed to suicide.

The general formula of ENIT DALY calculation based on prevalence data becomes:

$$DALY = YLD = GP \times AF \times DW$$

GP: global prevalent cases of moderate to severe tinnitus (point or yearly prevalent cases)

AF: attributable fraction among persons with tinnitus due to environmental noise exposure

DW: disability weight

#### 3.2 Possible Approaches For Disease Occurrence

In order to be able to quantify ENIT, WHO experts suggested the following three possible approaches to estimate disease occurrence.

##### 3.2.1 Global prevalence approach

This approach would use survey-based studies to estimate the prevalence of tinnitus on a populational basis. Depending on the questions used for each individual survey, the results may represent anything from lifetime to point prevalence of tinnitus, with or without duration or severity considerations (31). In a recent review of the literature (31), prevalences varied from 3% to 36%. BoD calculations being based on an annual occurrence of the event of interest multiplied

by duration, prevalence data used must reflect a yearly prevalence. Therefore, only data of point prevalence or yearly period prevalence should be considered.

This approach has at least two limitations for calculation of a global BoD: 1- the prevalence of tinnitus may be different from one country to another; and 2- the survey questions vary from one study to another as there is no standardization of survey questionnaires. Also, cross-sectional studies have important limitations as they can't assess the evolution of the problem in terms of fluctuations in duration and severity.

With this approach, it is necessary to estimate the attributable portion of tinnitus caused by environmental noise exposure.

### **3.2.2 Exposure-specific approach**

This approach is based on studies in specific settings or noise exposure situations such as discos, bars, events using firecrackers or other specific noise exposure, and the relative risk of occurrence of tinnitus. Although there are some studies that could be used for this approach (32-35), few of them could be identified and therefore it was not possible for the authors to develop this approach at this point in time. This approach also implies having valid populational exposure data per noise source, which, to this point, is scarce and was not readily available at the time of writing this paper.

### **3.2.3 Percentage of tinnitus derived from an exposure-NIHL risk curve (36)**

This theoretical approach would be based on the existence of a valid quantitative relationship between NIHL levels and tinnitus risk. Should such a curve exist or be derived from existing data, the ISO 1999:1990 standard (ISO 1990) could be used to derive the risk of tinnitus per noise exposure level and duration.

Although we know that the prevalence of tinnitus increases with the prevalence of NIHL, to this day, according to a recent literature review by Tyler (37), we are not aware of any good quantified relationship between tinnitus prevalence and NIHL, per hearing level. Some authors do present some data about this relationship, but we are not aware of any good recent review of the literature to derive a valid curve that could readily be used for BoD calculations. Also, this approach implies having valid populational exposure data per source.

## **3.3 Global prevalence approach**

Considering the available studies and data, the authors decided, with WHO staff, to focus on the development of the first approach based on point prevalence data of tinnitus. Other experts may want to develop the two other approaches in the future.

### **3.3.1 Selection studies methodology for BoD purposes**

A comprehensive review of the literature was done using published documents as identified by PubMed's internet resource and in selected articles references, Laval's university Ariane search tool (<http://ariane.ulaval.ca>), and experts' unpublished documents and opinions. When more than one published article was based on the same target population/design, the later or updated version was used.

The various research strategies retrieved more than 400 studies in English, French, Spanish or German. From that first extraction, 99 were selected as being potentially of interest. A global quality assessment based on a pass or fail classification of the studies was done according to external validity, internal validity and data analysis on a 10 point-scale criteria grid. Once studies were selected, a data extraction form has been used. This process lead to the identification of 23

epidemiological studies of interest meeting minimal specified quality criteria that were presented in the Background paper (31).

At the time of writing this paper, the proposed operational case definition of tinnitus for BoD calculations is the following:

a case of sound perception (for instance roaring, hissing, ringing, noise in the ears or in the head, or alike) at the time of survey, or at most that occurred in the past year, that cannot be attributed to an external sound source, causing or inducing co-morbidity (secondary symptoms or consequences) in terms of constant disturbance of the emotional, cognitive, psychological or physical state of the patient.

This case definition excludes mild tinnitus data as the later may last much less than a year, usually causes no or little consequences and is much more subject to interpretation across authors and populations.

Some cases of tinnitus fluctuate in time from more severe to less severe and vice versa. Nevertheless, on average, it is assumed that tinnitus corresponding to this case definition will be present all year round.

The general trend for the relationship between tinnitus prevalence and age shows that tinnitus prevalence increases with age and decreases after 60 to 70 years of age (12). DALY calculations should therefore probably discount for duration through life by a factor to be determined. Also, age-specific prevalences should be used when feasible.

There are no clinically or statistically significant differences in gender for noise-induced tinnitus (12). Therefore, the authors suggest not taking gender into account for BoD calculations of ENIT.

In order to select the studies that are to be used for BoD calculations, the authors identified the ones estimating point prevalence or at the most a period prevalence covering the last year. Also, sampling had to be population based. The authors analyzed the wording of questions used in each of the 23 selected studies. There is no internationally recognized standard definition of tinnitus with comorbidity. None of the questions used in these studies answered specifically and in a standardized manner the question of comorbidity of tinnitus in terms of functional limitations. The studies estimated severity through different questions around concepts such as difficulty falling to sleep, getting one down, plaguing all day. The exact concepts to include or exclude is still a matter of debate.

### **3.4 Prevalence calculation**

Five studies have been identified to correspond to our quality criteria and to have explicit questions corresponding to some element of comorbidity from our proposed case definition. The case definition is crucial for matching the estimated prevalences to the disability weights (Mathers 2006, personal communication). The following table is presented as an example of prevalences of tinnitus causing some comorbidity. For calculation purposes in the presented example, the results used are only those reporting explicitly and unequivocally tinnitus causing sleep interference at the time of study or in the past year (bold prevalences), thus giving an estimate of only one comorbid condition caused by ENIT.

Table 1: Selected studies questions and prevalence

Study	Tinnitus Question	Severity questions (comorbidity)	Prevalence (%)
Axelsson <i>et al.</i> , 1989 (38)	“Do you suffer from tinnitus?”	Severity of tinnitus (mark the most appropriate alternative):	
		(a) Tinnitus does not bother me particularly	3.45
		(b) Tinnitus bothers me only in quiet surroundings	6.14
		(c) Tinnitus disturbs my sleep. I have difficulties in falling asleep and I am sometimes woken by tinnitus	<b>1.43</b>
		(d) Tinnitus plagues me all day	2.44
Davis, 1995 (39)	“Have you ever had noises in your head or ears?” “Does the person [in the household] get ringing or buzzing in their head or ears? Most of the time/Some of the time/Never	“Does the ringing or buzzing in their head or ears lead to difficulty getting to sleep?” Yes/No	6.9
Hannaford <i>et al.</i> , 2005 (40)	(missing exact question) [“Most questions related to current or recent (within the previous twelve months) symptoms, although several questions enquired about lifetime experience of dizziness or unsteadiness.”]	(missing question, but the authors report “tinnitus problems affected their ability to lead a normal life”)	(not reported)
		None	20.9
		Slight	7.0
		Moderate	2.2
		Severe	
Nondahl <i>et al.</i> , 2002 (6)	“In the past year have you had buzzing, ringing, or noise in your ears?” Yes/No/Unknown	“How severe is this noise in its worst form?”	
		Mild/Moderate/Severe/Unknown	1.5 (severe)
		“Does this noise cause you to have problems getting to sleep?” No/Yes/Unknown	<b>0.6</b>
		Significant tinnitus defined as “at least moderate severity [moderately severe tinnitus], tinnitus that caused difficulty in falling asleep, or both”	8.2

Sindhusake <i>et al.</i> , 2004 (3)	“Have you experienced any prolonged ringing, buzzing or other sounds in your ears or head within the past year, that is, lasting for 5 minutes or longer?” Yes/No (Missing)	(No specific questions reported; concepts reported in publication: “becoming distressed by it [tinnitus]” “Keeps you awake at night” “Gets you down”	Very often/Often/Occasionally/Never/Unsure Very often/Often/Occasionally/Never/Unsure	18 0.2/0.7/3.6 0.3/0.7/4.4
Metaprevalence for sleep interference based on weighted prevalences of the three results in <b>Bold</b>				<b>0,75</b>

To estimate prevalent cases which are needed for calculations, the example is based on WHO epidemiological region of Euro-A countries based on population data extracted from European health for all database (HFA-DB) accessed at <http://data.euro.who.int/hfad/> on June 26, 2006.

There is some evidence that noise induced tinnitus is present in children (41). To our knowledge, there is no populational data on the prevalence of tinnitus in children. As the available prevalence data is based on population studies of 15 years and older, prevalent cases in Euro-A countries were calculated for this subpopulation.

Table 2: 2001 Population and prevalent cases of tinnitus causing sleep interference for WHO epidemiological region of Euro-A countries

Region	Total Population 2001	Population aged 15 and more	Prevalent cases of tinnitus causing sleep interference, 15 years and more
Euro-A	413 967 744	344 131 386	2 591 102

The DISMOD software developed to check the internal consistency of epidemiological estimates of incidence, prevalence, duration and case fatality for diseases (42) shall be used in the validation process.

### 3.5 Attributable fraction

All studies revised report the prevalence of tinnitus in the study population with no direct reference to causes, except for a few that don't address specifically environmental noise as a causal factor. As previously mentioned, the prevalence approach involves proposing an attributable fraction (AF) of tinnitus caused by environmental noise exposure in order to be able to calculate environmental noise induced BoD. There is no specific clinical presentation of ENIT compared to tinnitus from other causes. For BoD purposes, a case of ENIT is a case of tinnitus corresponding to the case definition exclusively caused by environmental noise exposure. Cases caused by mixed exposures such as occupational and environmental noise were excluded from the attributable fraction. This choice tends to give a conservative estimate of ENIT BoD.

Only two sources of data were readily available to estimate the attributable fraction. One is based on a large study where 1625 patients of a university research center were asked to report whether their tinnitus onset was associated with one or several factors such as specific circumstances, or taking medications or drugs. In this study, 19.9% reported noise as a single factor and another 3.7% as a combined factor with others (<http://www.tinnitusarchive.org/dataSets/set-1/tinnitusHistory/onsetFactorsReported>).

Unfortunately, the distinction between occupational and environmental noise could not be made on the basis of the available data (personal communication). The other available estimation is from Girard et al. (43) who produced preliminary results based on a large medical surveillance database of over 100 000 workers' audiometric exams. After adjustment for occupational noise exposure level and duration, hearing level and age, the estimated attributable fraction of tinnitus caused exclusively by environmental noise exposure was 4.6% for this cohort.

Because of scarcity of available data, a third source of information was used. The authors asked on an individual basis to 14 audiologist experts (clinicians, rehabilitation centers and university professors), 1 specialized psychologist and 2 Ears, Nose and Throat medical specialists, for their opinion on their estimation of the attributable portion of tinnitus caused exclusively by environmental noise exposure. The experts first gave an individual estimate of the attributable fraction with figures ranging from 1 to 15%. After discussing this issue during a meeting with a subgroup of the same experts, the consensus was for an estimated attributable fraction of 3% as a conservative, but plausible and reasonable figure.

### **3.6 Disability weight**

There is no disability weight (DW) readily available for tinnitus for BoD calculations. So far, an effort has been made to propose DW based on three different approaches. First, by analogy with comparable diseases for which WHO already has DW. The best comparison that was proposed by the experts was with chronic pain, as this health problem shares several characteristics with tinnitus such as ongoing unwanted internal (centrally located) stimulus; causing or inducing co-morbidity (secondary symptoms) in terms of constant disturbance of the emotional, cognitive, psychological or physical state; not so well understood pathophysiology; lack of valid objective clinical findings or confirmatory lab tests; problem that may respond to cognitive therapy. Chronic pelvic pain has a DW of 0.122 (44) whereas low back pain caused by chronic intervertebral disc has a DW of 0.121 (range 0.103-0.125) (44). Other plausible comparisons are with cases of primary insomnia which have a DW of 0.100 while a mild depressive episode has a DW of 0.140. As tinnitus may induce in some cases any of these two consequences, an interpolation in those ranges seems reasonable. Thus, a DW of 0.120 was suggested.

A second approach was developed, based on the Canadian Population Health Impact of Disease Project, as an alternative to this first approach (see <http://www.phac-aspc.gc.ca/phi-isp/index.html> for details). The preference scores were based on rating by health professionals and university experts. This attempt did not give the expected results due to unresolved methodological issues and thus was not pursued.

At this point, as a third approach, we are pending of a consensus with WHO experts, most probably using the interpolation method (similar to our first approach). To help in the process, some of the collaborating experts reached a consensus depicting the portrait of a so-called «typical median» or «average» person having tinnitus with co-morbidity in terms of the 11 domains of functional health described in the Canadian method.

### 3.6.1 Example of DALY numerical calculation

In order to illustrate better the proposed method, the following numerical example for tinnitus causing sleep interference is given.

- estimated prevalence of outcome: 0.75% (see Table 1)
- estimated prevalent cases in Euro-A countries, population 15 years and more, 2001: 2 591 102
- all these cases are assumed to be lifelong chronic cases
- population attributable fraction for environmental noise: 3%
- DW: 0.120

$2\,591\,102 \times 0.03 \times 0.120 = 9328$  DALY attributable to tinnitus causing sleep disturbance in Euro-A countries.

To help better understand this figure, in 2001, the number of DALY attributable to the following problems in the epidemiological Euro-A region were: periodontal problems 16 000, gonococemia 15 000, hepatitis B 18 000, cataract 19 000, appendicitis 16 000, syphilis 3000, malaria 2000 (45).

## 4 DISCUSSION

To our knowledge, the BoD of tinnitus or ENIT has never been estimated before. The epidemiology of functional limitations caused by tinnitus is rather scarce and even moreso for ENIT.

DALY calculation of ENIT for other countries may need some adjustments. Can we infer similar prevalences and natural history for tinnitus with comorbidity in different cultural settings? What about the risk of tinnitus from similar exposures? Can we infer similar disability weights? Possibly not... Some experts are convinced that the burden of tinnitus is influenced by the cultural situation. The burden may be higher in cultures with frequent highly demanding professional work, where tinnitus may contribute to unacceptable mistakes.

This kind of questioning has been dealt with for other health problems in the global BoD project and similar approaches for their answering could be used for ENIT.

## 5 CONCLUSION

Although we are unable at this point in time to give a final estimate of the BoD for ENIT, the approach described in this paper should soon make available a valid quantitative method to do so, as soon as the validation process ends.

The epidemiology of functional limitations caused by tinnitus is rather scarce. ENIT is even more difficult to pinpoint. Although the proposed approach with its case definition may end up underestimating the true BoD of ENIT, hopefully it will be useful as a start off to better ascertain the burden of suffering caused by tinnitus. As stated in introduction, one of the fundamental goals in constructing summary measures is to identify the relative magnitude of different health problems, including diseases, injuries and risk factors (2). Such measures, when based on sound science, are powerful tools at different levels of decision as they allow for comparisons between health problems and risk factors. Therefore, diseases such as tinnitus which are often not very well known or understood outside specific expert circles and therefore not very high on the political agenda, may benefit from a tool such as the BoD.

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