

Quantification of the burden of disease for tinnitus caused by community noise

Background paper

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FROM ENVIRONMENTAL NOISE

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ABSTRACT

Tinnitus caused by excessive noise exposure has long been described. Noise can lead to temporary or permanent hearing impairment (noise-induced hearing loss (NIHL)) and is frequently associated with tinnitus. Nevertheless, tinnitus may be experienced by a small percentage of persons exposed to excessive noise without measurable hearing loss. Because 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, this document presents key elements for the development of a valid method for quantifying specifically the burden of disease for tinnitus caused by community (environmental) noise exposure. This paper is the Background document used for a presentation at the World Health Organization Second technical meeting on Quantifying Disease from Environmental Noise held on December 15-16, 2005, at the Hotel Ambassador in Bern, Switzerland.

The proposed case definition is a sound perception that cannot be attributed to an external sound source and that causes some annoyance and/or disability. A noise exposure sources typology is suggested. The pathophysiology of tinnitus is revised and a causal web is presented. A thorough review of the epidemiological literature identified 23 studies meeting selection criteria. Prevalence of tinnitus varies from 3 to 36% due to variations in the cross-sectional study designs. Only two studies report incidence data. The natural history as well as age and sex distribution are revised. The literature on exposures causing tinnitus is discussed. Exposure-response relationship, causality, population attributable portion of tinnitus caused exclusively by community noise exposure, disability weights, cross-cultural issues as well as pending uncertainties are addressed.

RÉSUMÉ

On sait depuis longtemps que l'exposition excessive au bruit peut causer des acouphènes. Une telle exposition peut induire une perte auditive temporaire ou permanente, laquelle est fréquemment associée à des acouphènes. Cependant, un faible pourcentage d'individus peut souffrir d'acouphènes sans perte auditive après une exposition excessive au bruit. Puisque que l'histoire naturelle, la gêne et les incapacités, les approches cliniques pour le diagnostic et le traitement ainsi que les conséquences des acouphènes diffèrent significativement de ces mêmes éléments chez les personnes avec une perte auditive due au bruit, il est pertinent d'approcher séparément le calcul du fardeau de la maladie (charge de morbidité) des acouphènes causés par l'exposition au bruit communautaire (environnemental). La présente publication a servi de document de base à la présentation faite dans le cadre de la deuxième rencontre du comité technique de l'Organisation mondiale de la santé pour la quantification du fardeau de la maladie causée par le bruit environnemental. Celle-ci a été tenue à l'hôtel Ambassador de Berne, Suisse, les 15 et 16 décembre 2005.

La définition de cas proposée d'acouphène est la perception d'un son qui ne peut être attribué à une source sonore externe et qui cause de la gêne (nuisance) ou des incapacités. Une typologie des sources d'exposition au bruit est suggérée. Un état des connaissances sur la pathophysiologie des acouphènes est présenté ainsi qu'un modèle conceptuel. Une revue exhaustive de la littérature épidémiologique identifie 23 études rencontrant les critères de sélection. La prévalence des acouphènes y varie de 3 à 36% principalement à cause de la variabilité dans le devis des études transversales. Seules deux études présentent des résultats d'incidence. L'histoire naturelle de la maladie ainsi que la distribution selon l'âge et le sexe sont révisées. La littérature pertinente sur les types d'expositions causant les acouphènes est discutée. La relation exposition-réponse, la relation causale, la fraction des acouphènes dans la population générale attribuable exclusivement à l'exposition au bruit communautaire, les poids de l'incapacité (« severity weight »), la question de l'applicabilité des données de fréquence entre les cultures et pays ainsi qu'une liste des sujets nécessitant un approfondissement sont abordés.

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LIST OF INITIALS AND ABBREVIATIONS

Initials	Definition
CI	Confidence interval
DALY	Disability Adjusted Life Year
DW	Disability weight
ER	Exposure response
I	Number of incident cases
ICD	International classification of diseases
IR	Incidence
L	Standard life expectancy at age of death (in years)
Lm	Mean levels
MDS	Minimal data set
N	Number of deaths
NIHL	Noise-induced hearing loss
NIOSH	National Institute for Occupational Safety and Health
NIT	Noise-induced tinnitus
NOAEL	Non-observable adverse effect level
P	Prevalence
PAF	Population attributable fraction
PR	Prevalence rate ratio
PST	Prolonged spontaneous tinnitus
PTS	Permanent hearing threshold shift
RR	Relative risk
TQ	Tinnitus Questionnaire
YLD	Years lived with disability
YLL	Years of life lost due to premature mortality

1 INTRODUCTION

Tinnitus caused by excessive noise exposure has long been described (Holt, EE., 1882; Sataloff, J., 1952; Vernon, JA., 1995). Noise can lead to temporary or permanent hearing impairment with or without tinnitus. Excessive noise exposure is the major modifiable cause of permanent hearing impairment worldwide and an important public health priority because the estimated cost of noise in developed countries range from 0.2% to 2% of the gross domestic product (WHO-Report, 1997). Between 12 and 50% of persons with noise-induced hearing loss report having tinnitus (Sindhusake *et al.*, 2004; Kähäri *et al.*, 2003; Palmer *et al.*, 2002; Nondahl *et al.*, 2002). Tinnitus is very often found to be present concomitantly with hearing loss. This is also true for noise-induced tinnitus and noise-induced hearing loss (Vio, MM., Holme, RH., 2005; Eggermont, JJ., 2005). Nevertheless, tinnitus may be experienced by persons exposed to excessive noise without measurable hearing loss (Jones *et al.*, 1998). 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) ICD-9 (388.3) and ICD-10 (H93.1).

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 elements in persons with noise-induced hearing loss (NIHL). For instance, insomnia reported by tinnitus sufferers is not a consequence of NIHL. Therefore, the authors consider it justified that tinnitus be analyzed *per se* as an independent outcome of noise-related burden of disease.

The scope of this document is to present the results of the working groups' recent work basically around steps 1 to 4 of the method proposed by Mathers *et al.* (2001). Further work will be needed to ultimately propose a method for quantifying the burden of disease for tinnitus caused by community noise-exposure.

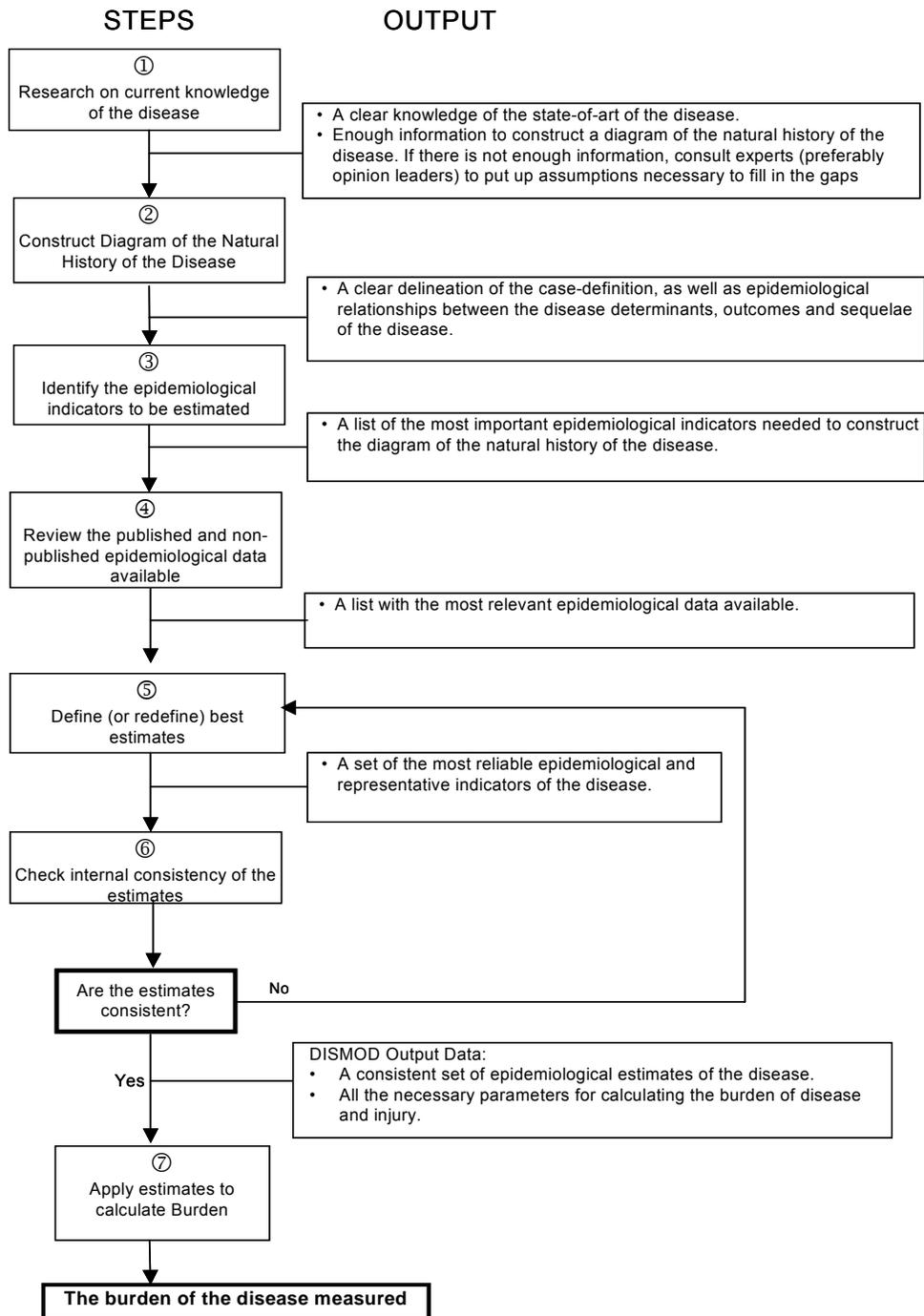


Figure 1 Developing a Reliable and Internally Consistent Epidemiological Assessment

Source: Mathers *et al.*, 2001

Although occupational noise is an important cause of tinnitus and is mentioned once but not considered as a relevant outcome in WHO document on the burden of disease for occupational noise (Concha-Barrientos *et al.*, 2004), it will only be discussed here as an aggravating factor to consider for community noise induced-tinnitus.

2 ESSENTIAL PRELIMINARY CONSIDERATIONS

2.1 DEFINITION OF TINNITUS

It is important to agree upon a working definition of tinnitus before considering its quantification in terms of burden of disease. There are several definitions of tinnitus in the published literature and according to different experts.

Tinnitus is the general term for sound perception (roaring, hissing or ringing) that cannot be attributed to an external sound source. In terms of auditory abilities, tinnitus is the inability to perceive silence, defined as the absence of external sound stimulus (Leroux *et al.*, 1993).

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 his lifetime (MacFadden, D., 1982). There is considerable variation in tinnitus expression, its etiology, and its effect on patient's lives (Tyler, RS., 2000).

The lack of a clear understanding of a unique mechanism of generation and perception of tinnitus makes a single classification difficult to envisage. 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). For longitudinal duration, tinnitus may be classified as acute (≤ 3 months), subacute 3-12 months), and chronic (> 12 months) (German ENT Society: Natl. Guidele Tinnitus, 1998: <http://www.uni-duesseldorf.de/WWW/AWMF/III/017-064.htm>). Dauman and Tyler proposed a classification according to 5 parameters of tinnitus : pathology, severity, duration, site and etiology (Dauman and Tyler *in* Tyler, 2000). Stephens and Héту proposed a classification according to patient's abilities and quality of life (Stephens and Héту, 1991). More recently, Dobie gives this interesting qualitative contour for tinnitus (Dobie, RA. *in* Tyler, 2006): «Some people who begin to notice tinnitus, whether spontaneous or induced by trauma, noise, or other insult, will experience spontaneous resolution, but many will have persistent tinnitus. For some of them, tinnitus sensation (the sound) will be joined by tinnitus suffering, with adverse effects on thinking, feeling, and other activities of daily life, including sleep».

The most often reported consequences of tinnitus or comorbidities are :

- Loss of control;
- Depressive moods, depression;
- Helplessness (despair);
- Sleep interference (difficulty getting to sleep; insomnia);
- Muscle tensions;
- Loss of attention;
- Anxiety;
- Hyperacusis;
- Headaches;
- Irritation;
- Interference with normal activities;
- Difficulty with listening;
- Difficulty with concentration.

Experts consider that tinnitus may be disturbing to such an extent that it can be a risk factor for suicide (Johnston *et al.*, 1996).

Tinnitus annoyance and experienced handicap can be measured 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.* (1994), a German translation of the tinnitus annoyance questionnaire developed by Hallam, is probably one of the most frequently used tinnitus questionnaires in Germany. As far as evaluating the severity of tinnitus, three validated tinnitus self-rating scales together with the Tinnitus Questionnaire (TQ, according to Goebel-Hiller (German) and Hallam (English)) can be employed as part of “minimal datasets” to reflect the patient’s current tinnitus status (table 1). These tests are simple and easy to use and can be completed by the patient alone. The results are easy to interpret and provide a good foundation for an effective doctor-patient dialog (Zenner *et al.*, 2006).

Table 1 Minimal data set (MDS) to be used to assess degree of tinnitus (Zenner *et al.*, 2006)

Tests	before therapy	after therapy	validity	Reliability
TQ (Hallam <i>et al.</i> 1988; Goebel <i>et al.</i> 1994).	+	+	a	A
Tinnitus Loudness (6-point response scale)	+	+	a	A
Tinnitus Annoyance (8-point response scale)	+	+	a	n.a.
Tinnitus Change (6-point response scale)	-	+	a	n. ass.

(+ = included in MDS; - = not included in MDS; a = adequate., n. a. = not adequate. n.ass. = not assessed).

Clinically important is the categorization of the tinnitus according to the resulting disability in daily life (disability weight concept). Tables 2 and 3 display details of the categorizations by Goebel *et al.* (1994) and by Biesinger *et al.* (1998).

Table 2 Categorization according to Goebel *et al.* (1994)

Compensated (Balanced) Tinnitus Goebel-Hiller/Hallam-Score

Level 1 (light)	0-30
Level 2 (medium)	31-46

Non-compensated (unbalanced) Tinnitus

Level 3 (profound)	47-59
Level 4 (severe)	60-84

Table 3 Categorization according to Biesinger *et al.*, (1998)

Compensated (Balanced) (without secondary symptoms)

The patient perceives the tinnitus but is able to cope normally without the appearance of secondary symptoms

Level I:	No disturbances
Level II:	Occurs mainly during periods of calm/stillness; is disturbing under periods of stress or strain

Non-Compensated (Unbalanced) (secondary symptoms present)

The presence of tinnitus has serious impact on the patient's life and leads to the development of psychological problems (fear, sleep disturbance, lack of concentration, depression).

Level III:	There is a constant disturbance to the private and professional life of the patient. Secondary symptoms affect the emotional, cognitive, and physical state of the patient.
Level IV:	The presence of tinnitus leads to a complete imbalance in the personal life of the patient. Employment is no longer possible.

Other countries use different questionnaires. Questionnaires that have good psychometric properties (i.e., good internal consistency and test-retest reliability) are the Tinnitus Reaction Questionnaire (developed by Wilson *et al.*, 1991), which measures emotional tinnitus-related distress, the Tinnitus Handicap Questionnaire (Kuk *et al.*, 1990) which measures the self-reported severity of tinnitus as a handicap, and the Tinnitus Handicap Inventory (Newman *et al.*, 1996), which quantifies the impact of tinnitus on everyday life. The Tinnitus Reaction Questionnaire and the Tinnitus Handicap Questionnaire have been translated and validated in French (Meric, C., Pham, E. *et al.*, 1997; Meric, C., Pham, E., & Chéry-Croze, S, 2000).

In epidemiological studies, questions are sometimes asked about tinnitus duration or severity (degree of annoyance). Psychoacoustical measurements of tinnitus can also be made. Because tinnitus is a sound perception, it can be matched in loudness and frequency with an external sound. Usually, studies that have reported such loudness-pitch matching have found that tinnitus loudness estimates usually fall between 0 and 10 dB SL (the later corresponding to more than a doubling in loudness perception) in most subjects (Vernon *et al.*, 1988; Tyler, RS., 2000). Tinnitus pitch varies somewhat more across and within subjects, but mostly corresponds to frequencies at which a hearing loss is present (Henry *et al.*, 1999). Methodological issues may contribute to this variability. A recent study found that when the procedure allows assessment of various pitch components, tinnitus is revealed to be composed of a broad frequency spectrum falling into the hearing loss range, despite feelings of unitary pitch sensation (Norena *et al.*, 2002). Yet, psychoacoustical measurements typically do not predict the psychological distress reported by patients (Møller, AR., 2000).

When considered, populational epidemiological studies usually have used simple questions about duration and the degree of annoyance rather than the tools described previously to assess the individual status.

Finally, according to RS Tyler (2000), at least two elements should be included into any demographic (epidemiological) study :

- Tinnitus that lasts for five minutes or more (additionally whether it is present some or all the time);
- An assessment of the impact of the tinnitus (for example, severity or annoyance).

Given the previous elements presented, the following working definition for burden of disease purposes is proposed.

A sound perception (e.g. whistling, roaring, hissing or ringing) that cannot be attributed to an external sound source and that causes some annoyance and/or disability.

2.2 NOISE TYPOLOGY

Community noise is a rather broad category embracing many sources of noise exposure in a variety of settings. Furthermore, prevention strategies may differ considerably according to sources (regulations, policies, target populations). The following classification will be used throughout this document.

The most well-known noise sources are :

- Traffic noise (cars, planes, trains, motorcycle);
- Construction noise;
- Urban and community noise (neighbours, radio, television);
- Social/leisure noise (cassettes, fireworks, toys, rock concerts, firearms, snowmobile, motomarine).

2.2.1 The Combination of Environmental and Occupational Noise

Many adolescents and young adults work in noise-polluted environments and additionally expose themselves to social noise during their leisure, i.e. nonworking time. Because of the occupational and social noise, the rest periods needed by the hearing system are reduced. This affects particularly the 10 % subpopulation of an age group mentioned below (section "leisure noise"), since there is a higher incidence of poor schooling and low social status, unskilled occupations in noisy workplaces combined with excessive exposure to leisure noise (Plontke *et al.*, 2004a). Consequently, these people perform simple occupational tasks in a noise-polluted environment and expose themselves to more social noise as well. An individual working in a job within a noisy environment needs an aural recuperation phase of at least ten hours at below 70 dB(A) (Zenner *et al.*, 1999a). According to other authors, the ideal time for aural recuperation would be double the exposure time (e.g. for an 8 hour noise exposure, a 16 hour recuperation time). However, some authors mention that aural recuperation must be at least equivalent to exposure time. There is no general consensus about this particular point.

When evaluating individual risk for a person exposed to specific noise levels, it should not be forgotten that a limit exposure level can only provide a protective effect if hearing can recover for a sufficiently long period after the sound event (for instance after an 8-hour work day). This means that a certain recovery time (at least e.g. 10 h) with a sound level lower than 70 dB(A) is adhered to after work (Unfallverhütungsvorschrift (UVV) Lärm, Federal Republic of Germany, 1997). Protective measures are only then effective if the recovery times are adhered to and noisy recreational activities are not indulged in. The authors are not aware of

any study looking into the cumulative health effects of occupational and non occupational noise exposures.

2.3 PATHOPHYSIOLOGY

Most cases of tinnitus are of unknown origin. Among known factors such as acoustic neurinomas, presbycusis, intoxications and noise, the reported frequency of occurrence for the later is anywhere between 50 and 90% (Spoendlin, H., 1987, *in* Tyler, 2000). A very small proportion of tinnitus cases signal the presence of an underlying treatable medical condition, such as a tumor or chronic partial opening of the Eustachian tube, but the majority of cases has no apparent or treatable cause, and primarily produce psychological distress and annoyance.

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 (Eggermont, JJ., 2005). Despite those limits in understanding the pathophysiology of tinnitus, there is no doubt that noise can cause incapacitating tinnitus (Eggermont, JJ., 2005; Plontke, *et al.*, 2002)

Important principles of central neurophysiological tinnitus processing are that individual tinnitus appraisal is directly linked to neuronal networks in the brain responsible for the production of emotions, perceptions and cognitions. Among different proposed neurophysiological models, the authors briefly describe the two following: the conditioned reflex model (Jastreboff, P.J., 1990) and the sensitization model (Zenner *et al.*, 2004) (see also Llinas *et al.*, 2005; Eggermont *et al.*, 2004 for other models). The conditioned reflex model predicts that repeated temporal associations of tinnitus and emotions produce conditioned reflexes resulting e. g. in fear. According to the sensitization model, cognitive processes may be associated with a reduction in the tinnitus cognition threshold, resulting in hypersensitivity of cognition. The sensitization contributes to the extremely loud cognition of the tinnitus signal.

For noise induced hearing loss and noise induced tinnitus, it can be assumed that genesis is based on the same hearing pathophysiology (Zenner *et al.*, 2002; Pujol *et al.*, 1999; Puel *et al.*, 1995; Pujol *et al.*, 1993).

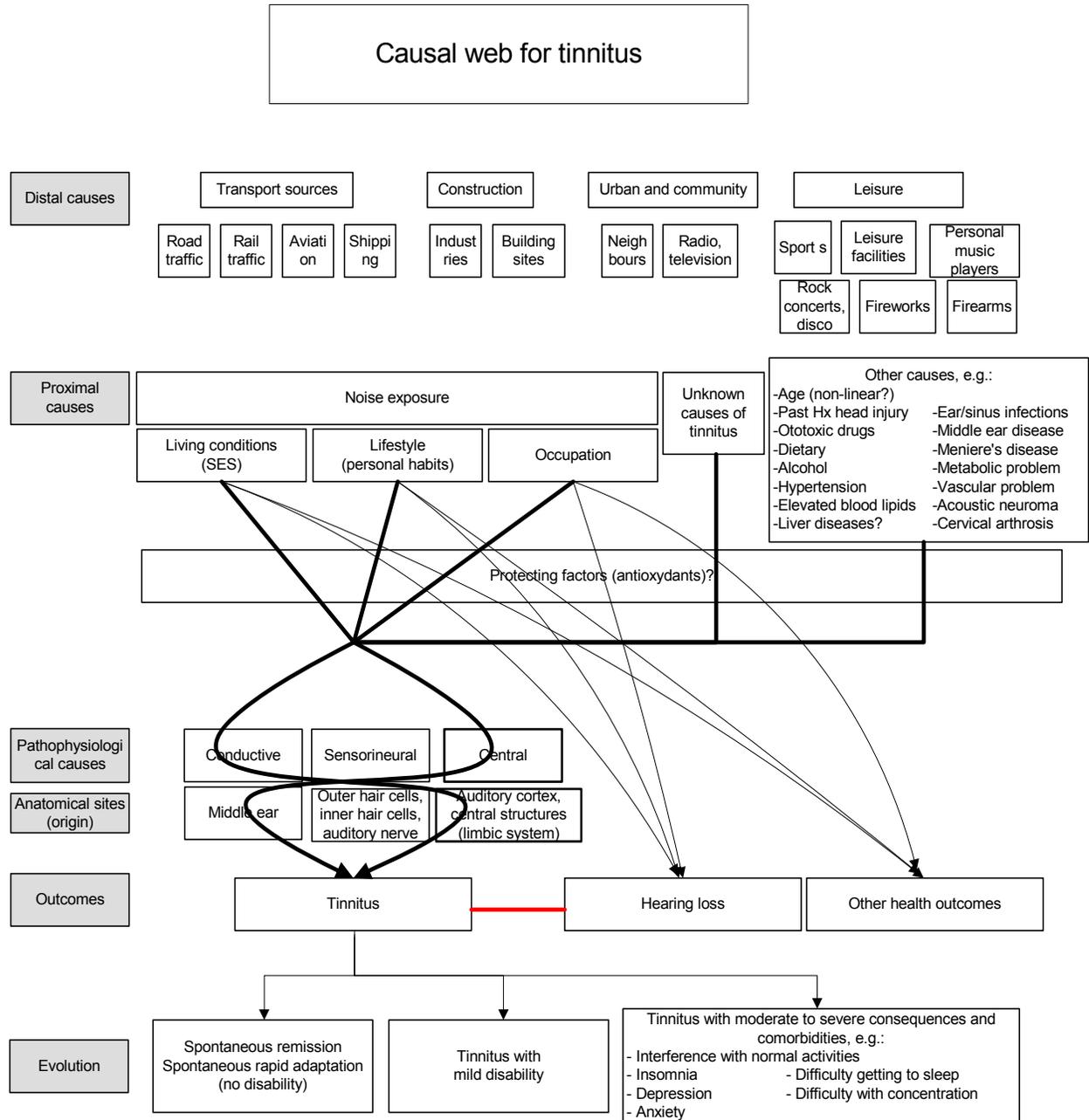
In a large study where 1 625 patients were asked to report whether their tinnitus onset was associated with some factor (circumstantial, drug-related, etc), a little less than half (N=693) reported no associated factor, about half (N=804) reported one associated factor, and a few (N=128) reported more than one associated factor. Among the ones who reported only one associated factor, 28.8% (N=468) reported a traumatic factor (as opposed to medical conditions), among which 19.9% was noise-related (11.3% long-duration noise, 3.3% brief, non-explosive noise, and 5.4% explosion such as fireworks or gunfire). Another 3.7%

mentioned a noise-related cause when more than one factor was reported (<http://www.tinnitusarchive.org/dataSets/set-1/tinnitusHistory/onsetFactorsReported>).

The following figure presents a causal web for tinnitus, with a particular emphasis on its relation to noise exposure.

2.3.1 Causal web for Tinnitus

Table 4 Causal web for Tinnitus



3 EPIDEMIOLOGY

3.1 OUTCOME

Published documents, experts' unpublished documents and opinions were assessed as documentary sources. The various research strategies on Medline (PubMed) retrieved more than 400 published 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 criteria by the Quebec research agent who retained 23 epidemiological publications of interest from the initial lot. The following table gives a summary of these studies.

All 23 studies have a cross-sectional descriptive part and two present incidence results (longitudinal design). One study has an analytical part with relative risk for non-occupational noise exposure. As stated before, the operational definition of tinnitus used varies greatly from one study to another. This may partly explain the variability in prevalence results.

According to a recent population based random sample study, Germany has about three million people aged 10 years or over with tinnitus (Pilgramm *et al.*, 1999). About 1.5 million have problems with tinnitus and 800 000 suffer so severely that they are in continuous medical treatment. Interestingly, the authors were able to estimate an incidence rate of tinnitus in Germany of 0.33% of the total population per annum, for an estimated 250 000 persons becoming yearly new chronic patients suffering from tinnitus (Pilgramm *et al.*, 1999).

Table 5 Summary of major epidemiological studies and results for Tinnitus

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Adams <i>et al.</i> , 1999	1996	63 402 (All ages) [Random sample]	USA	"Does anyone in the family now have Tinnitus or ringing in the ears?"	Cross- sectional descriptive	3% (P) < 45 years 1% 45-64 years 6% ≥ 65 years 9%	-	-	-	-
Axelsson <i>et al.</i> , 1989	1980s	3 600 (20-80 years) [Random sample]	Sweden	"Do you suffer from tinnitus?" (Never/Seldom/Often/Always)	Cross- sectional descriptive	14,2% (P)	-	"Plagues me all day": 2,4%	-	-
Begault <i>et al.</i> , 1998	<i>Missing data</i>	64 pilots of commercial airline (<i>missing data</i>) [<i>Missing data</i>]	USA	"Do you have a buzzing, ringing, or whistling in one or both ears (tinnitus)?" (Frequently/Occasionally/Rarely/ Never)	Cross- sectional descriptive	29,5% (P)	-	-	-	-
Chung <i>et al.</i> , 1984	<i>Missing data</i>	30 000 workers (<i>missing data</i>) [Random sample]	Canada	"Do you have ringing in your ears?" (Yes/No)	Cross- sectional descriptive	6,6% (P)	-	-	-	-

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Coles, RRA., 1984	1978-1981	Phase I: 8 069 Phase II: 7 645 (> 17 years) [Random sample]	United Kingdom	Ringing or buzzing lasting 5 minutes or more, excluding those occurring only after exposure to loud noise.	Cross- sectional descriptive	Phase I: 11% (P) Phase II: 10,6%(P)	-	5.6-7.4% interference with getting to asleep Phase I: Moderately (4%) or severely (1%) annoying: 5% Sleep disturbing: 5% Phase II: Severe effect on quality of life: 1%	-	-
Girard <i>et al.</i> , (unpublished data), 2005	1983-1996	41 631 (25-64 years) [convenience sample – blue-collar workers]	Canada	"Do you currently have continuous buzzing or whistling in one or both ears?"	Cross- sectional descriptive and analytical	5.2% (P) Adjusted PR (number of years exposed) PR(0)=1.00 PR(1)=1.03 PR(2-4)=1.11 PR(5+)=1.18 Linear trend Adjusted PR exposed/unexp. PR=1.09	0.93; 1.15 1.00; 1.23 1.03; 1.35 p=0.029 1.01; 1.19	-	-	PAF: 4.6%

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Hannaford <i>et al.</i> , 2005	1998-1999	15 788 (>13 years) [Nationwide random sample]	Scotland	"Noises in the head or ears which usually lasted more than five minutes"	Cross- sectional descriptive	17% (P)	16.4- 17.6%	Moderate annoyance: 17,4% Severe annoyance: 7,3%	-	-
Holgers, KM., 2003	<i>Missing data</i>	964 (7 years) [First 964 children of audiometric screening procedure of the ordinary school health service in Göteborg]	Sweden	(1) "After listening to loud music or other loud sound/noise, have you afterwards heard a ringing, buzzing or other sort of noise in your ears, even if the loud music or noise has been turned off?", (2) "Have you heard a ringing, buzzing or other sort of noise in your ears, without first having listened to loud music or other loud sounds?"	Cross- sectional descriptive	12% (P)	-	-	-	PAF: 2,5%
Johansson <i>et al.</i> , 2003	1998	590 (20-80 years) [Random sample]	Sweden	(1) "Do you have permanent tinnitus (permanent sounds in the ear, like pure tones or noise)?" (2) "Do you have periodically recurrent (spontaneous sounds in the ear, like pure tones or noise, that last for more than five minutes: not temporary sounds connected with alcohol consumption or very loud sound exposure)?"	Cross- sectional descriptive	13,2 % (P)	10.5- 16.0%	-	-	-

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Jokitulppo <i>et al.</i> , 2002	1996	1 323 (25-55 years) [Random sample]	Finland	<i>Missing data</i>	Cross-sectional descriptive	12% (P)	-	-	-	-
Kähäri <i>et al.</i> , 2003	<i>Missing data</i>	39 musicians (26-51 years) [convenience sample]	Sweden	Definition: Spontaneous or evoked sensation of sounds, e.g. ringing or buzzing, often combined with pure tones that occur in the absence of an external sound source. The different sounds could be uni or bilaterally located in the ears, or experienced and located somewhere in the head	Cross-sectional descriptive	48% (P)	-	-	-	-
Mercier <i>et al.</i> , 2003	2001	601 individuals attending an open concert (<i>missing data</i>) [convenience sample]	Switzerland	<i>Missing data</i>	Cross-sectional descriptive	"Post exposure tinnitus": 36% (P)	-	-	-	-
Nondahl <i>et al.</i> , 2002	1998-2000	3 737 (48-92 years) [All residents of Beaver Dam, Wisconsin]	USA	(1) "In the past year have you had buzzing, ringing, or noise in your ears?" (No/Yes/Unknown); (2) "How severe is this noise in its worst form?" (Mild/Moderate/Severe/Unknown); (3) "Does this noise cause you to have problems getting to sleep?" (No/Yes/Unknown)	Cross-sectional descriptive and 5-year follow-up	Cross-sectional 8,2% (P) 5-year follow-up 5,7% (IR)	7.4-9.1% 4.8-6.6%	-	-	-

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Olsen Widén <i>et al.</i> , 2004a	<i>Missing data</i>	1 238 (13-19 years) [Voluntary participation of students from eight schools in Göteborg and Vanesborg]	Sweden	"Permanent Tinnitus" Question: "Do you have permanent tinnitus (buzzing or ringing) in your ears all the time?" (Yes/No) "Temporary Tinnitus" Question: "Have you ever had temporary tinnitus continuing for 24 hours or longer?" (Yes/No)	Cross- sectional descriptive	8,7% (P) 21.6% (P)	-	-	-	-
Palmer <i>et al.</i> , 2002	1997-1998	12 907 (16-64 years) [Random sample]	United Kingdom	"During the past 12 months have you had noises in your head or ears (such as ringing, buzzing, or whistling) which lasted longer than five minutes?"	Cross- sectional descriptive	Global: 4,5% (P) Men 6% (P) Women 3% (P)	-	-	-	Occupational noise exposure Men 36% Women 21%
Paré <i>et al.</i> , 2000	1998	12 000 households (>15 years) [Random sample of Quebec province population]	Canada	"Do you hear ringing, buzzing or whistling noises in your ears or head that last 5 minutes or more at a time?" "How often do you hear theses noises?" "Do these noises bother you?" "Have you ever consulted a health professional for these noises?"	Cross- sectional descriptive	12,9% (P) of total population	-	Annoyance: Tinnitus that bothers moderately: 2.3% Tinnitus that bothers a lot: 1.3%	-	-

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Parving <i>et al.</i> , 1993	1985-1986	3 387 men, (53-75 years) [convenience sample]	Denmark	"Do you experience tinnitus of > 5 minutes' duration?" (Yes/No)	Cross-sectional descriptive	17% (P)	-	Annoyance (interference with sleep, reading and/or concentration): 3%	-	-
Pilgramm <i>et al.</i> , 1999	1998-1999	7 409 (>9 years) [random sample]	Germany	(Missing data; 45 questions about tinnitus)	Cross-sectional descriptive	24.9% (ever) (P) 13% (>5 minutes) (P) 3.9% (at the time of study) (P) 0.33% population new cases per year (IR)	SD=0.35%	2.0% (moderately serious to unbearable) (P)	-	-
Roberts, J., 1968	1959-1962	6 672 (18-79 years) [Random sample]	USA	(1) "At any time over the past few years, have you ever noticed ringing (tinnitus) in your ears, or have been bothered by other funny noises in your ears?" (Yes/No); (2) "How often?" (Every few days/Less often); (3) "Do they bother you?" (Quite a bit/Just a little)	Cross-sectional descriptive	32.4% (P)	-	-	-	-
Rosenthal, U., 2003	1971-1993	1 485 (>70 years) [Random sample]	Sweden	Missing data	Cross-sectional descriptive	"Continuous tinnitus" 12% (P)	-	-	-	-

Table 5 Summary of major epidemiological studies and results for Tinnitus (suite)

Author(s) Publication year	Study year(s)	Population (age groups) [sampling]	Country	Questions / Definitions	Design	Outcome measure (type*)	CI95	Disabling tinnitus	CI95	Noise exposure OR population attributable fraction (PAF)
Sanchez <i>et al.</i> , 1999	1992-1994	1 453 (70-103) [Random stratified sample]	Australia	Wave 1 (1) "Do you have ringing or other noises in your ears and head?" (Yes/No); (2) "How often do you hear ringing or other noises?" (Occasionally - less than once per week/ Frequently - more than once per week/Constantly) Wave 3 (3) "Do you ever get noises in your head or ears which usually last longer than 5 minutes?" (No, never/Some of the time/Most or all of the time)	Cross- sectional (wave 1/1992) and 2-years follow-up (wave 3/ 1994)	Tinnitus: Wave 1 only: 10,5% (P) 2-years follow-up: 7,0% (IR)	-	-	-	-
Sindhusake <i>et al.</i> , 2004	1997-1999	2 015 (55-99 years) [all persons living in two suburban postcode areas west of Sydney]	Australia	"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)	Cross- sectional descriptive	30% (P)	-	Dizziness Severe tinnitus:61,9% Mild tinnitus:47% (P of those with tinnitus)	-	Work exposure: - None (reference) - Tolerable 9,3% - Unable to hear speech 4,3%
Williams <i>et al.</i> , 2004	<i>Missing data</i>	136 (20-65 years) [convenience sample]	Australia	<i>Missing data</i>	Cross- sectional descriptive	10% (P)	-	-	-	-

Type*: IR=Incidence; P=Prevalence; PAF=Population attributable fraction; PR= Prevalence rate ratio; RR= Relative risk; SD=Standard deviation.

Cross-sectional studies have important limitations as they can't assess the evolution of the problem in terms of fluctuations in duration and severity. The following figure presents the natural history of tinnitus annoyance over time. (Tyler, RS., 2000)

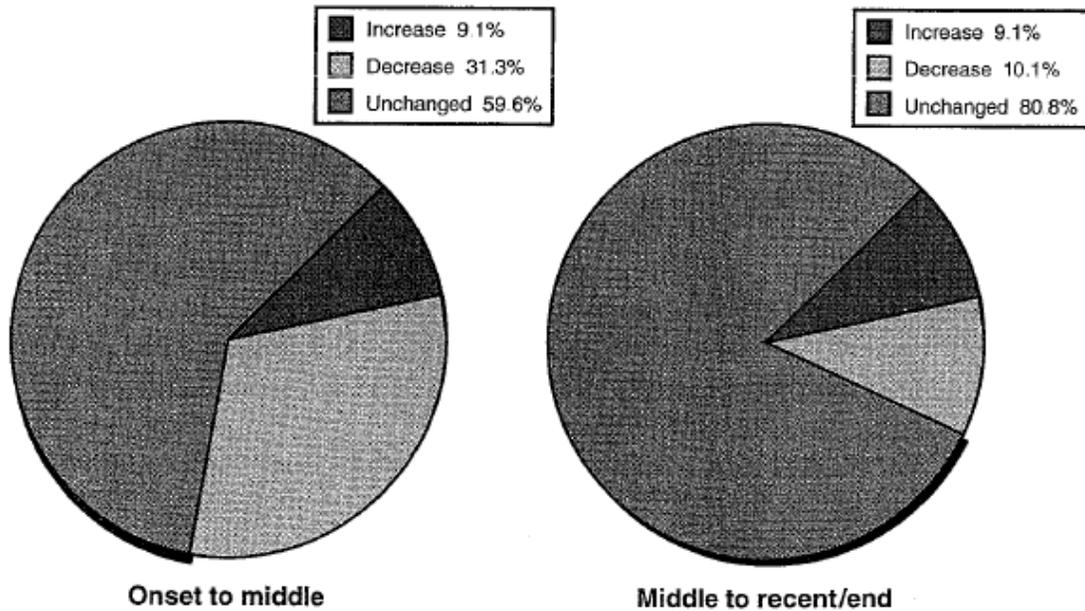


Figure 2 Tinnitus natural history, Annoyance change over time

Source: Tyler, RS., 2000, p. 18

Frequently reported difficulties experienced by tinnitus sufferers are sleep disorders (80% of 2.4 million German patients diagnosed with tinnitus). Most complaints range from being unable to fall asleep as to being woken up by tinnitus and unable to go back to sleep (Coles, RRA., 1984, Tyler *et al.*, 1983). This is followed by anxiety disorders and depressive moods characterized by the fear of an uncontrollable tinnitus. Another reported symptom is the subjective experience of difficulties with speech perception and attention. People report more problems with annoyance, irritation and the inability to relax.

From 30 patients being treated for acute acoustic trauma with acute tinnitus from new years firecrackers exposure, at least 8 (27%) were still suffering from tinnitus one year after the incident (Plontke *et al.*, 2003). These data are consistent with findings of Mrena *et al.* (2002). In this longitudinal study the authors observed 418 military recruits in Finland who were treated for acute acoustic trauma during their military service. Sixty-six (16%) still had tinnitus after 10 to 15 years. From their study, the authors concluded that in some cases tinnitus might be an even more serious threat to life satisfaction than mild hearing impairment.

3.1.1.1 Tinnitus and age

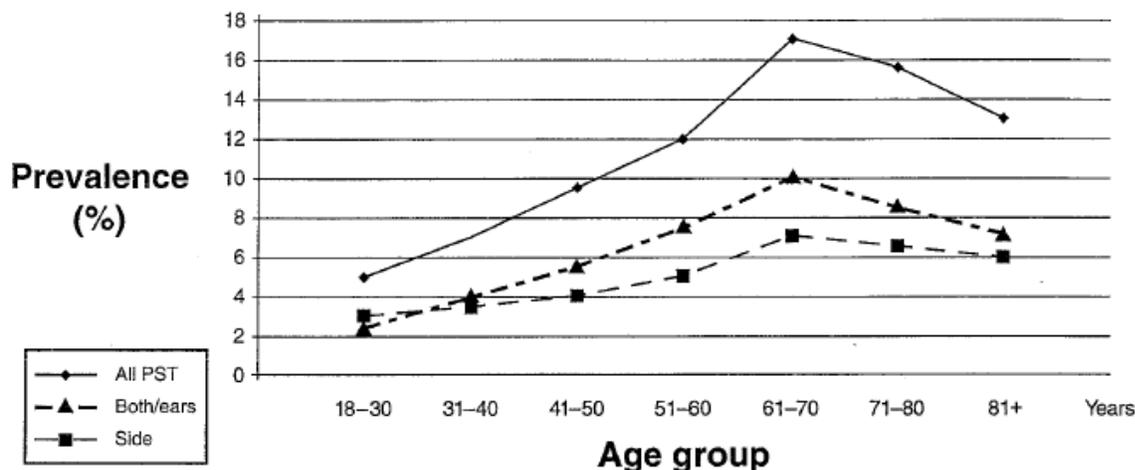


Figure 3 Prevalence of prolonged spontaneous tinnitus (PST) as a function of age and side of tinnitus

Source: Tyler, RS., 2000, p. 14

This figure shows the general trend for the relationship between tinnitus prevalence and age most often reported in studies. Some studies show a continuous increase after 60 or 70 years old.

3.1.2 Children

Prevalence of chronic tinnitus was estimated to be 29-60% in hearing impaired children between the ages of 12 to 18 years (Graham, JM., 1987) (see also Tyler, RS., 2000, chapter 10 Tinnitus in Children).

In children with normal hearing, the prevalence of tinnitus has been reported to be between 6% and 36% and much higher in children with hearing loss. In an epidemiological study in 7 year old school children (n=964), Holgers (2003) reported a prevalence of tinnitus of 12%. In contrast to other reports, hearing loss did not correlate to the prevalence of tinnitus and no gender differences were found. Noise exposure was suggested to be the cause of tinnitus in 2.5% of the children. The author concluded that persistent tinnitus in children may have similar causes to that in adults.

Kentish *et al.* (2000) reported in a preliminary (pilot) study with 24 children presenting to the Psychology Department with troublesome tinnitus that tinnitus can have as marked an effect on children's lives as it is reported to have on adults. The authors found insomnia, emotional distress, listening and attention difficulties as the main psychological factors associated with tinnitus in children with a secondary effect upon their school performance.

3.1.2.1 Tinnitus and gender

Table 6 Data on gender difference in the prevalence of tinnitus from four studies

<i>Study</i>	<i>Population</i>	<i>Number</i>	<i>Percent Tinnitus</i>	
			<i>Male</i>	<i>Female</i>
Leske (1981)	Civilian non-institutionalized population	6,672	29.7	34.9
Office of Population Census and Survey (1983)	Sample of population in private households, United Kingdom	23,000	13	16
Chung et al. (1984)	Noise-exposed workers in the United Kingdom	30,000	6.6	5.6
National Study of Hearing Phase II 1981–1982. Davis (1995)	Random sample of adults in four big cities in the United Kingdom.	7,645	10.2	11.0

Source: Tyler 2000, p. 12

Despite the variability in the results presented in previous table, the authors are not aware of any clinically or statistically significant differences in gender for noise-induced tinnitus. On the other hand, they are not aware of any study looking specifically into this issue.

3.2 EXPOSURE

When the sound level exposure regularly reaches or exceeds 90 dB(A), noticeable hearing impairments can be expected. If measured by conventional pure tone audiometry, sound pressure levels below 85 dB(A) have statistically only a low influence on hearing over the long-term. Exceptions include individuals with a vulnerable inner ear. However, this level is still capable of inducing measurable hearing-losses in high frequency ranges. Impaired hearing can start to appear in the range between 85 and 89 dB(A), but only after long exposure periods (VDI 2058, Blatt 2, VDI 2055 Blatt 2, 1988; Dierhoff, HG., 1976), or perhaps earlier with the predisposition of greater cochlear vulnerability. From 90 dB on a clear risk to hearing must be reckoned with. Tremendous environmental stress occurs with social noise that, contrary to other environmental noise, is generally demanded by the consumers.

A new risk assessment by the (US) National Institute for Occupational Safety and Health Cincinnati, Ohio (NIOSH, revised criteria, 1998) incorporating the 4 kHz audiometric frequency in the definition of hearing impairment reaffirms support for the 85 dB(A) recommended exposure limit for occupational noise exposure (85 decibels, A-weighted, as an 8-hour time-weighted average). With a 40-year lifetime exposure at 85 dB(A), the excess risk of developing occupational NIHL is 8% considerably lower than the 25% excess risk at the 90 dB(A) level.

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 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 (Berglund *et al.*, 2000).

If one is inclined to carry out calculations with noise levels, it should not be forgotten that the decibel (dB) is a logarithmic ratio unit. Thus an increase in rating level of 3 dB (e.g. from 90 to 93 dB(A)) represents a doubling in sound pressure. In other words, a two-hour stress with 93 dB(A) engenders the same sound energy as a four hour stress at 90 dB(A). An exposure at 105 dB(A), as is frequently encountered in discos, entails the same sound pressure dosis already after 4.8 minutes as an eight-hour noise exposure at 85 dB(A).

[NOTA BENE. The authors wish to debate the following hypothesis with the WHO expert group: although at the moment of writing this paper they did not have on hand empirical data to propose a non-observable adverse effect level (NOAEL) for noise-induced tinnitus (NIT), they believe that it is reasonable and plausible to use the same protective WHO NOAEL as for NIHL, being 75 dB(A) Laeq-8h and 70 dB(A) Laeq-24h. The authors wish the expert group's input for any additional empirical studies.]

Impulse noise can cause larger lesions inside the cochlea than continuous noise (20). The important criteria for noise-induced hearing impairments are sound levels, quick and steep increase of sound levels, duration of sound levels and individual vulnerability. Upon noise exposure comprising these factors individuals typically can experience tinnitus. Permanent irreversible cochlear impairment does occur with a permanent threshold shift (PTS) after recovery time and a permanent tinnitus is also possible. The permanent damage of the cochlea occurs frequently although it cannot be assessed with current diagnostic measures.

In most cases environmental noise does not reach the sound levels of occupational noise. One exception is social noise.

3.2.1 Children's Toys

Although to our knowledge there is no prospective studies on the risk for hearing loss or tinnitus from children's toys, based on a German expert panel consensus and case reports (Maassen *et al.*, 2001), there is no doubt that noisy toys increase the risk for hearing loss and tinnitus in children. The following table presents a list of children's noisy toys, which may cause hearing impairment. Toy weapons can reach sound levels up to and greater than 135 dB(A) at a distance of 1 meter from the exposed ear. When only 2.5 cm away from the ear then acoustic peaks of up to and greater than 163 to 173 dB(A) can be reached (Zenner *et al.*, 1999b). Toys making cracking noises are held very close to the ear by children and reach sound levels up to 135 dB(A) and small trumpets up to 125 dB(A).

Table 7 Noise from children’s toys in dB(A); Results from randomly chosen German childrens’ toys

Toy	Distance from the ear; sound pressure level in dB(A)	
	2.5 cm	25 cm
Carnival plastic trumpet “Trötttrompete”	116-117	100-104
Small trumpet	123-125	100-102
Single trumpet	109-116	92-100
Double trumpet	109-124	92-106
Indian trumpet		100-110
Signalling whistle	118-124	102-108
Trill whistle	126-128	112-114
Referee’s whistle	127-129	107-109
Jumping cracker “Knackfrosch”	128-129	120-121
Other crackers “Knackfiguren”	134-135	120-122
Toy weapons		
Pistols	130-135	113-121
Pistols with caps “Streifenmunition”	>135	>135
Pistols with other ammunition “Knallplättchen”	>135	>135
Barrel revolver with cartridge “Amorces”	>135	>135
Air rifle with air compression	>135	130-135

Source : Zenner *et al.*, 1999b, European committee CENT/TC5L : « safety of toys »

The following noise pollution expected in Germany for adolescents and young adults is as follows :

- In discotheques the estimated standardized value will be $L_m=90$ dB(A); this sound level limit is much too high for a 10% subpopulation in each age group (95 dB(A)). (where L_m =median level);
- The median of $L_m=78$ dB(A) for portable cassette players and CD-players seems unproblematic but is actually a hazardous level for 10% of the population with a value of 98 dB(A).

Epidemiological studies on adolescents and young adults who have not been exposed to occupational noise have revealed an increasing amount of cases of verifiable irreversible cochlear damage. The most agreed upon plausible causes are the widespread availability of very noisy toys (pistols and fire crackers), fireworks as well as the ubiquitous availability of electro-acoustic amplifiers such as portable cassettes/CDs, music in discotheques or open air concerts (Maassen *et al.*, 2001).

Sound levels recorded in discotheques are generally between 92 and 111 dB(A) whereas headsets or earphones which can be inserted directly into the auditory canal have demonstrated maximum sound levels up to 120 dB(A) and average sound levels of 100 dB(A). This corresponds to the upper sound levels or more of a jack hammer. Another hazardous source is the loud speakers used during musical performances such as open air concerts or the like.

Maassen *et al.* (2001) presents interesting populational exposure data from Germany (see following 3 tables).

Table 8 Loud leisure noise activities of 18-19 year olds. Percentages are given in a representative group of 505 persons as well as the mean weekly and lifetime exposure.

	Percentage %	hour/week	Lifetime exposure in months
Visits to discotheques	79.7	6.2	30.6
Listening to loud music	71.9	11.4	44.3
Playing musical instruments	7.5	9.7	49.2
Motorbike, motor scooter	21.5	8.3	20.3
Other kinds of motor sports	2.5	9.5	12.8
Shooting sports	2.0	3.7	16.3
Others	2.6	7.4	40.2

Table 9 Mean levels L_m per year of occupational and non-occupational sound exposure and mean levels L_m per year for different exposure conditions

Source/exposed persons	Number of exposed persons in Great Britain	Yearly L _m [dB(A)]
Discotheques		
(different estimations)	2 400 000	80-95
	600 000	>95
Industrial workers	2 600 000	>80
	600 000	>90

Source	L _m dB(A)* 10%	L _m dB(A)* 50 %
Discotheques		
highest estimation	95	87
lowest estimation	90	85
live Rock-concerts	91	83
Rock musicians	122	102
Listeners to PCP	86	77
Motorbike	81	
* Energy equivalent continuous sound level calculated for 1 year		

Source: Maassen *et al.*, 2001, pages 5 and 9

The clinical suspicion that many young people have exposed themselves to situations hazardous to their hearing has been verified in a survey. In 1814 young German males 2/3 reported to have had tinnitus at least once. More than 2/3 of people who had gone to the discotheque reported that they experienced temporary tinnitus or a numbness of the ears (Babisch *et al.*, 1988). The correlation between occurrence of tinnitus and discotheque variables was statistically significant. Two other studies by Meyer-Bisch, C. (1996) and Mori, T. (1985) demonstrated that 2/3 of the adolescents reported tinnitus after exposure to loud music.

In Canada, the authors found only one study of leisure exposure done on 269 students (Cheesman *et al.*, 2001). These authors questioned duration of exposure for the past seven days for 32 leisure activities capable of producing sound levels of 80 dB(A) or greater. Results are presented in the following table.

Table 10 Mean number of activities and total duration of participation in noisy leisure activities for the three student groups for the one week reporting period

	high school	college	university	all
number of activities	6.6	5.3	4.2	5.1
total duration (hrs)	24.4	20.2	19.5	20.7

Source: Cheesman *et al.*, 2001, page 42.

[Nota bene. We are currently in contact with US experts, but have been unable to gather populational data for this meeting; further work will be needed to cover this gap. The same applies for other countries.]

3.2.2 Exposure response (ER)-relationship

Analytical studies on community noise and tinnitus are very scarce. The authors only found the published studies cited in table 8 of Maassen *et al.* (2001). The results show the relationship between community noise exposure and permanent hearing threshold shift (PTS). We are in the process of verifying for similar analysis for tinnitus in the cited references of that table.

Table 11 Studies showing a correlation between music exposure and PTS

Author (year)	Comparison	Age (years)	Effect
Taylor (1976)	Music exposed/control	School leavers	PTS at 6 kHz 6.3 dB
Fearn (1981)	Music exposed /control	9 - 12 13 - 16 18 - 25	PTS (at 3 - 6 kHz) 1.5 dB “ “ 2 dB “ “ 3.3 dB “ “
Fearn (1981)	Music exposed /control (1 year)	9 - 25	Relative risk for PTS ≥ 5 dB doubled
Fearn and Hanson (1984)	“	18-25	rel. risk of PTS ≥ 10 dB at 4 kHz proportionally increasing with the number of music events
Mori (1985)	Noise workers with music/ without music	20 - 24	PTS at 4 kHz = 5 dB PTS at 6 kHz = 9 dB
Babisch et al. (1988)	Disco Visitors/controls (4 times per month) Listening to music/control (≥3h/ day)	Boys 13 - 19 Girls 13 - 19 Boys 13 -19 Girls 13 - 19	PTS at 4 kHz = 5 dB PTS at 4 kHz = 4 dB PTS at 4 kHz = 3 dB PTS at 4 kHz = 4 dB
West and Evans (1990)		Young people	Correlation between music exposure and slight PTS
Struwe et al. (1996)	Disco visitor/ control Loud PCP/control	Recruits	rel. risk of PTS ≥ 20 dB RR = 1.3 (CI: 1.0 - 1.6)* RR = 1.8 (CI: 1.1 - 3.1)*
Meyer-Bisch (1996)	Disco /controls Rock concerts/controls PCP/control	15 -25	no difference PTS at 3 - 6 kHz PTS at 3 - 6kHz
Ising and Babisch (1998)	Disco + PCP / control	13 - 18	PTS at 3 -6 kHz depending on dosis, increasing to 8 dB (extreme exposure)
Mercier et al. (1998)	Music exposure $L_{m} \geq 85$ dB(A)for 5 years / $L_{m} < 85$ dB(A)	Pupils at trade school	rel. risk = 1.57 (CI 1.18 - 2.1)

Source: Maassen *et al.*, 2001, page 11

Girard et *al.*, very recently produced (2005) interesting preliminary results based on a large surveillance database of over 100 000 workers audition, labouring almost exclusively in industrial sectors, gathered through the occupational medical surveillance programs done by the Quebec Public Health Directions. In addition to individual hearing threshold levels, the database contains information from a questionnaire, applied shortly before auditory tests are performed, on individual occupational and extra-professional noise exposures, demographic and medical variables, including tinnitus. The questions for extra-professional noise exposure are :

- In a military setting, have you ever participated in firing exercises: YES/NO/UNCERTAIN-DONOTKNOW; if YES, how many firing sessions have you done?
- Have you ever done sport shooting? YES/NO/UNCERTAIN-DONOTKNOW; if YES, for how many years? On average, how many cartridges per year?
- Are you actually or have you been in the past been exposed for 4 hours or more per week to each of the following (number of years): snowmobile/motorcycle-“Quad”-VTT/farm vehicles/snowblower/hand power tools/loud music (disco, stereo, walkman)/chainsaw/others?

The question for tinnitus is :

- Do you currently have :
 - ...
 - continuous buzzing or whistling in one or both ears?
 - ...

This preliminary analysis was done on a subset of 44 320 male individuals aged 25-64 years tested between 1983 and 1996 who either had normal hearing or whose hearing loss was exclusively due to occupational noise. 2 689 (6.07%) workers had an unusable answer for tinnitus, leaving 41 631 workers for analysis. The prevalence of tinnitus is 5.2% (2173/41 631). The main adjusted results for different factors obtained with a Log-binomial regression model approach are presented in the following tables.

Table 12 Regression model #1* for the risk of tinnitus

Variables	Prevalence rate ratio	95% confidence interval
0 expo extra-professional	1,00	
≥ 1 year expo extra-professional	1,09	1.00707; 1.18671
Normal hearing	1,00	
Threshold of detectable (16 – 30 dB)	1,55	1.35756; 1.76675
Mild loss (31 - 40 dB)	2,35	2.01465; 2.75264
Moderate loss (41 – 50 dB)	3,72	3.18941; 4.32783
Severe loss (51 dB et plus)	6,58	5.73743; 7.54035
Occ. noise (< 90 dB(A))	1,00	
Occ. noise (≥ 90 dB(A))	0,99	0.91790; 1.08151
25 – 34 years old	1,00	
35 – 44 years old	0,87	0.76937; 0.98580
45 – 54 years old	0,83	0.71405; 0.97256
55 years old and over	0,87	0.71843; 1.04890
Occ. noise exposure duration (continuous)	1,01	1.00382; 1.01532

* Extra-professional noise exposure as a dichotomous variable

Table 13 Regression model #2* for the risk of tinnitus

Variables	Prevalence rate ratio	95% confidence interval
0 expo extra-professional	1,00	
≥ 1 year expo extra-professional	1.03	0.92688; 1.15314
2-4 years expo extra-professional	1.11	0.99820; 1.22892
≥ 5 years expo extra-professional**	1.18	1.03485; 1.35350
Normal hearing	1,00	
Threshold of detectable (16 – 30 dB)	1,55	1.35883; 1.76845
Mild loss (31 - 40 dB)	2,35	2.01507; 2.75322
Moderate loss (41 – 50 dB)	3,72	3.18601; 4.32350
Severe loss (51 dB et plus)	6,58	5.74449; 7.54941
Occ. noise (< 90 dB(A))	1,00	
Occ. noise (≥ 90 dB(A))	0,99	0.91820; 1.08186
25 – 34 years old	1,00	
35 – 44 years old	0,87	0.77200; 0.98937
45 – 54 years old	0,83	0.71971; 0.98082
55 years old and over	0,87	0.72334; 1.05644
Occ. noise exposure duration (continuous)	1,01	1.00363; 1.01513

* Extra-professional noise exposure in 4 categories.

** Only the 5 years and above extra-professional exposure category shows a significant CI95. The significant test for linear trend (p (linear-trend)=0,029) indicates a clear relationship between the risk of tinnitus and the number of years exposed to extraprofessional noise.

The highlights of this unheard of preliminary study are the following :

- There is a 10% risk of having tinnitus for individuals exposed to extra-professional noise for one year or more compared to those unexposed (<1year), after adjustment for occupational noise exposure level and duration, hearing level and age;
- There is a statistically significant linear relationship (dose-response curve) between duration of extra-professional noise exposure and the risk of having tinnitus, after adjustment for occupational noise exposure level and duration, hearing level and age;
- The calculated population attributable portion (PAP) for extra-professional noise-induced tinnitus in Quebec blue collar workers is 4.6% (55.8% of workers were exposed to non-occupational noise);
- These results probably underestimate the relative risk and therefore the PAP as the selection criteria exclude exposed workers that have mixed hearing loss.

NOTA BENE. One possible alternative approach the authors wish to discuss at the WHO expert meeting to get around this apparent paucity of direct analytical studies is the following: use the very well known dose-response relationship between occupational noise exposure and hearing loss; infer similar dose-response relationship for community noise exposure at equivalent dosis; estimate the percentage of tinnitus sufferers by level of NIHL; infer from there the risk of community noise tinnitus by noise-exposure level (per source).

Some elements for discussion are presented here. It is possible to estimate the proportion of the noise-exposed population that will acquire noise-induced hearing loss based on long-term exposure. The following table (Table 4) below indicates that a hearing loss (hearing thresholds averaged over 0.5, 1, 2 and 4 kHz) of 30 dB HTL will affect 9 % of the population after 40 years of exposure at 77 dB(A) for Laeq-8hours. If one consider a larger auditory impairment of 50 dB HTL, 0 % of the population will be affected at that same exposure level. The proportion of the population affected by a noise-induced hearing loss will increase with the sound level pressure.

Table 14 Hearing loss of 30 dB and 50 dB over 40 years as percentage of the population

	Noise level						
	77 dB(A)	82 dB(A)	87 dB(A)	92 dB(A)	97 dB(A)	105 dB(A)	115 dB(A)
% of population with 30 dB htl after 40 years	9	19	31	49	70	92	100
% of population with 50 dB htl after 40 years	0	1	4	9	17	37	73

Source: Robinson *et al.*, 1994

Tinnitus is a common experience following exposure to noise. Data from Jones *et al.* (1998) suggests that at least 25% of those people who report noise-induced hearing loss also report having tinnitus. A further 10% reported tinnitus in the absence of hearing loss.

3.2.3 Causality

Revised tinnitus literature seems to assume *de facto* a causal relationship between noise exposure and tinnitus. There seems to be little doubt among the experts about this causal relationship. Nevertheless, it is worthwhile to very briefly review Sir Austin Bradford Hill's criteria of causality (1965) :

- Strength [of the association]: based on available analytical studies, the strength of association between community noise exposure and tinnitus is not very high;
- Consistency [of the findings]: (this criteria is not applicable, as too few analytical studies are available);
- Specificity [of the association]: tinnitus is not a specific consequence of noise exposure; also, tinnitus is often of unknown origin;
- Temporality [lack of temporal ambiguity]: the acute nature of tinnitus appearance after acute exposures such as disco music or rock concerts gives good evidence of the temporal relationship, at least for acute exposure;
- Biological gradient [dose-response curve]: there is some evidence for a dose-response effect of occupational noise induced tinnitus (Sindhusake *et al.* 2004, others) and of a dose-response effect for community noise induced tinnitus (Girard *et al.*, 2005);
- [Biological] plausibility: although the exact pathophysiological pathway of tinnitus induced by noise exposure is not known, it is plausibly similar to the pathway for NIHL, at least for the onset of tinnitus, through damage to cochlear nervous cells; maintenance of tinnitus is still a matter of debate (brain cortex);
- Coherence [of the evidence]: the observation that noise can induce tinnitus is coherent with actual scientific knowledge;
- Experiment: experimental animal models tend to confirm that noise can induce ear damage that can generate tinnitus (Wallhäusser-Franke *et al.*, 1999; Mahlke *et al.*, 2004 ; Zhang *et al.*, 2003; Wallhäusser-Franke *et al.*, 2003);
- Analogy: the analogy with occupational noise induced hearing loss, the strong concomitant occurrence of hearing loss and tinnitus, makes analogies possible for community-noise induced tinnitus.

3.3 DISABILITY WEIGHTS

The authors are not familiar with disability weight (DW) methodology. According to their judgment, DW's should be determined with similar methodologies as those used for conditions such as chronic pelvic pain and low back pain, as tinnitus could be comparable to these conditions. Therefore, the following elements should be interpreted with caution as they propose preliminary DW's according to our understanding of this issue.

The DW proposed by the working group are based on their own expert judgment, using analogies with the available DW's sent to the group by WHO Bonn's office. They have not

been discussed thoroughly. Therefore, the proposed DW should be seen as a first draft. Validation of these suggested DW need to be done in the future through validated processes.

The group recommends two DW to match with which ever data is available for calculation: one for general tinnitus prevalence data, one for annoying (disabling) tinnitus to match the proposed working definition.

For moderate to severely annoying tinnitus, the analogy is made with chronic pain. Chronic pelvic pain has a DW of 0.122 (GBD 1990 *in* Annex A, WHO document) whereas low back pain caused by chronic intervertebral disc has a DW of 0.121 (range 0.103-0.125) (GBD, 1990 or Netherlands weights *in* Annex A, WHO document). Primary cases of insomnia 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 is suggested. One could argue that this DW could be used for any annoying (disabling) tinnitus, including mildly annoying tinnitus.

For global prevalence of tinnitus without reference to its severity, a global disability weight of 0.012 is suggested as a majority of people declaring tinnitus in surveys will either have spontaneous remission or adapt easily. Globally, the group believes that it should not be a null disability weight, as it is for mild adult onset hearing loss. On the other hand, only a small proportion of persons reporting ever having tinnitus will be disabled. Based on an estimated 10% who become moderate to severe sufferers, a DW of 0.012 seems logical.

3.4 UNCERTAINTIES:

NB. All uncertainties have been discussed elsewhere :

- Uncertainties with tinnitus definition;
- Uncertainties with consequences of tinnitus and quantification;
- Uncertainties with attributable portion of noise induced tinnitus;
- Uncertainties with exposure-response curves;
- Uncertainties with transcultural aspects of tinnitus;
- Uncertainties with severity weight estimations.

3.5 CONSIDERATION OF CROSS-CULTURAL GENERALIZABILITY OF DERIVED ER CURVE

Can we infer similar prevalence and natural history for tinnitus 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.

3.6 EXAMPLE OF CALCULATION OF THE BURDEN OF DISEASE FOR EUROPE

[Might be completed at the meeting by Prof. Zenner *et al.*, if data available].

3.7 CONCLUDING REMARKS

No direct curative medical tinnitus treatments are available at this time. Some forms of treatment for chronic tinnitus are instrumental and cognitive behavioural methods which cannot heal tinnitus but teach individuals how to influence tinnitus cognition or perception. (see also Tyler, RS., 2006).

The burden of disease caused by community noise induced tinnitus had probably been so far largely underestimated. The data presented demonstrate that it is paramount medically, politically, and economically to implement effective preventive measures for noise pollution, particularly for the protection of minors and young adults.

3.8 PENDING ISSUES

The general formula for quantification of the burden of disease in terms of Disability Adjusted Life Year (DALY)s is:

$$DALY = YLL + YLD$$

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 community noise-induced tinnitus.

In terms of YLDs, the following methodological questions will have to be addressed :

- Prevalence measures available versus incidence measures used for YLDs; very few published articles have studied the incidence of tinnitus;
- NOAEL : a final consensus is necessary to estimate a valid NOAEL;

- Exposure per noise source : which noise sources are likely to cause tinnitus; for instance, should populations exposed to traffic noise >70 dB(A) be included? Do we have valid data for exposures to different leisure noises?
- ER-relationship and population attributable fraction: at this point, there is very scarce literature giving direct measures; the well-known occupational noise-NIHL relationship could be used under certain conditions;
- DW: the suggested DWs are a first proposal based on DWs for analogous conditions; a validation process by an expert panel or other valid approach should be performed;
- Cross-cultural issues: only expert opinions were available at the time this document was written; this issue will have to be addressed further.

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