WHO Environmental Noise Guidelines for the European Region: A Systematic Review on Environmental Noise and Permanent Hearing Loss and Tinnitus

Mariola Śliwińska 1,* and Kamil Zaborowski 2

1. Inclusion and Exclusion Criteria for Individual Studies

Table S1. Individual studies had to meet the following criteria in order to be included in the evidence review. If the criteria were adjusted, a justification is given detailing the reasons.

<table>
<thead>
<tr>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Population:</strong> general population in settings (hospitals, residences, public venues, educational facilities)</td>
<td>- Does not meet inclusion criteria</td>
</tr>
<tr>
<td>- Studies including members of the general population</td>
<td>- Studies including participants exposed to high levels of environmental noise from various noise sources</td>
</tr>
<tr>
<td>- Studies including specific segments of the population particularly at risk, such as children or vulnerable groups</td>
<td>- Noise exposure levels either measured or calculated and expressed in decibel values. They should aim to be representative of the individual exposure of the study participants.</td>
</tr>
<tr>
<td>- Studies including participants exposed to noise in occupational settings if relevant with combined exposure to environmental noise only</td>
<td>- Does not meet inclusion criteria</td>
</tr>
<tr>
<td><strong>Exposure:</strong> exposure to high levels of environmental noise from various noise sources</td>
<td>- Studies using hearing loss or defective hearing as a proxy for (previous) noise exposure</td>
</tr>
<tr>
<td>- Noise exposure levels either measured or calculated and expressed in decibel values. They should aim to be representative of the individual exposure of the study participants.</td>
<td>- Surveys assessing noise exposure on the basis of subjective ratings, as given by the subjects in a questionnaire</td>
</tr>
<tr>
<td><strong>Comparator:</strong> no noise exposure or lower levels of noise exposure</td>
<td>- Does not meet inclusion criteria</td>
</tr>
<tr>
<td>- Should have comparator group (corresponding to no exposure or lower level exposure)</td>
<td>- Does not meet inclusion criteria</td>
</tr>
<tr>
<td><strong>Confounding:</strong> adjusted for confounding</td>
<td>- No inclusion criteria applied; however, for every study, we will assess which possible confounders have been taken into account</td>
</tr>
<tr>
<td>- No inclusion criteria applied; however, for every study, we will assess which possible confounders have been taken into account</td>
<td>- No exclusion criteria applied</td>
</tr>
<tr>
<td><strong>Outcome:</strong> assessment of outcome</td>
<td>- Does not meet inclusion criteria</td>
</tr>
<tr>
<td>- Permanent threshold shift measured with pure-tone audiometry and permanent tinnitus assessed with the questionnaire;</td>
<td></td>
</tr>
<tr>
<td>- Relative risks (RR) or odds ratios (OR) as primary outcome measures</td>
<td></td>
</tr>
</tbody>
</table>
### Table S2. The template for assessment of quality and risk of bias.

<table>
<thead>
<tr>
<th>Risk of Bias Check List for Studies on Noise and Health Outcomes</th>
<th>Study Name:</th>
<th>Assessor Name:</th>
<th>Date Assessed:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Study Design</strong></td>
<td>Cohort</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Case-control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cross-sectional</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Domain</strong></td>
<td>Description of criteria for judgment</td>
<td>Quote from article on which the judgment is based</td>
<td>Judgment of risk of bias</td>
</tr>
<tr>
<td>Noise Exposure assessment leading to information bias</td>
<td>The noise level (in decibel) is expressed in Lden and Lnight or its components (Lday, Levening, Lnight and the duration in hours of Lnight) AND: For long term average noise level: A. is based on a noise map using as input the actual traffic volume, composition and speed per 24 h per road/railway/airport, or the type and sound power of an industrial installation and the size in terms of either production volume or persons employed OR B. is based on measurements for a minimum of 1 week by qualified staff, and adjusted for data under point A. as well as meteorological conditions when necessary OR C. is based on a noise map reported in a separate publication but which fulfils conditions A or B For short-term noise level: D. is based on measurements for a sufficient time by qualified staff The noise level is not expressed in decibels OR is not expressed in Lden and Lnight or its components OR: For long term average noise level: A. is based on a map that does not use as input the actual traffic volume, composition and speed per 24 h per road/railway/airport, or the type and sound power of an industrial installation and the size in terms of either production volume or persons employed OR B. is based on measurements of less than 1 week OR not adjusted for data under point A. or meteorological conditions when necessary OR by unqualified staff OR C. is based on a noise map reported in a separate publication but which does not fulfils conditions A or B For short-term noise level: D. is based on measurements for an insufficient time OR by unqualified staff</td>
<td>Low</td>
<td></td>
</tr>
<tr>
<td>Bias due to confounding</td>
<td>If not enough information reported, to judge the above</td>
<td>Unclear</td>
<td></td>
</tr>
</tbody>
</table>
At least the following confounders should be incorporated for a valid assessment for the relation between noise and XXX outcome: 1...2...3...4... 

All important confounders taken into account either through matching, restriction or in the analysis 

Only 1 or no confounder taken into account OR Subjects in exposed and unexposed groups differ for one or more important confounders and there is no adjustment in the analysis 

Less then all to >1 important confounders taken into account OR Insufficient information to decide on one of the above 

<table>
<thead>
<tr>
<th>Bias due to selection of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants randomly sampled from a known population AND response rate higher than 60% AND attrition rate less than 20% in follow up studies</td>
</tr>
<tr>
<td>No random sampling OR response rate less than 60%</td>
</tr>
<tr>
<td>No information to judge the above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health outcome assessment leading to information bias I</th>
</tr>
</thead>
<tbody>
<tr>
<td>The health outcome of interest is objectively measured OR taken from medical records OR taken from questionnaire or interview using a known scale or validated assessment method</td>
</tr>
<tr>
<td>The health outcome of interest is self-reported and not assessed using a known scale or validated assessment method</td>
</tr>
<tr>
<td>Not sufficient information reported to assess the above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Health outcome assessment leading to information bias II</th>
</tr>
</thead>
<tbody>
<tr>
<td>The health outcome of interest is assessed blind for exposure information in cohort and cross-sectional studies or exposure is assessed blind for being a case in case-control studies</td>
</tr>
<tr>
<td>The health outcome and/or exposure assessment is not blinded</td>
</tr>
<tr>
<td>Not sufficient information reported to assess the above</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total Risk of Bias in Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>At least 4/5 at low risk of bias, including for domains 1, 2 and 3</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Any other</th>
</tr>
</thead>
<tbody>
<tr>
<td>Low</td>
</tr>
</tbody>
</table>

| High |

<table>
<thead>
<tr>
<th>Unclear</th>
</tr>
</thead>
</table>

| Low |

| High |

| Unclear |
Table S3. GRADE for quality of evidence from personal listening devices associated with hearing impairment and tinnitus.

### Hearing Impairment

<table>
<thead>
<tr>
<th>Domains</th>
<th>Criterion</th>
<th>Assessment</th>
<th>Downgrading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Level</td>
<td>Longitudinal = high; others = low</td>
<td>All cross-sectional studies</td>
<td>Low quality</td>
</tr>
<tr>
<td>1. Study Limitations</td>
<td>Majority of studies low quality</td>
<td>All with high risk of bias</td>
<td>Downgrade one level</td>
</tr>
<tr>
<td>2. Inconsistency</td>
<td>Conflicting results; high F</td>
<td>Generally consistent results on association between environmental noise and permanent hearing loss</td>
<td>No reason for downgrading</td>
</tr>
<tr>
<td>3. Directness</td>
<td>Direct comparison; same PECO'</td>
<td>Yes, same PECO'</td>
<td>No reason for downgrading</td>
</tr>
<tr>
<td>4. Precision</td>
<td>Confidence interval contains 25% harm or benefit</td>
<td>All CI wider than 25%</td>
<td>Downgrade one level</td>
</tr>
<tr>
<td>5. Publication Bias</td>
<td>Funnel plot indicates</td>
<td>Not able to assess; too few studies</td>
<td>No downgrade</td>
</tr>
<tr>
<td>Overall judgment</td>
<td></td>
<td>Very low quality</td>
<td></td>
</tr>
<tr>
<td>6. Exposure-response</td>
<td>Significant trend</td>
<td>Not observed</td>
<td>No upgrading</td>
</tr>
<tr>
<td>7. Magnitude of effect</td>
<td>RR &gt; 2</td>
<td>Not observed</td>
<td>No upgrading</td>
</tr>
<tr>
<td>8. Confounding adjusted</td>
<td>confounding working towards the nil</td>
<td>Not observed</td>
<td>No upgrading</td>
</tr>
<tr>
<td>Overall Judgement</td>
<td></td>
<td>Very low quality</td>
<td></td>
</tr>
</tbody>
</table>

### Tinnitus

<table>
<thead>
<tr>
<th>Domains</th>
<th>Criterion</th>
<th>Assessment</th>
<th>Downgrading</th>
</tr>
</thead>
<tbody>
<tr>
<td>Start Level</td>
<td>Longitudinal = high; others = low</td>
<td>All cross-sectional</td>
<td>Low quality</td>
</tr>
<tr>
<td>1. Study Limitations</td>
<td>Majority of studies low quality</td>
<td>All studies with high risk of bias</td>
<td>Downgrade one level</td>
</tr>
<tr>
<td>2. Inconsistency</td>
<td>Conflicting results; high F</td>
<td>Contradictory results on association between environmental noise and permanent tinnitus</td>
<td>Downgrade one level</td>
</tr>
<tr>
<td>3. Directness</td>
<td>Direct comparison; same PECO'</td>
<td>Yes, same PECO'</td>
<td>No reason for downgrading</td>
</tr>
<tr>
<td>4. Precision</td>
<td>Confidence interval contains 25% harm or benefit</td>
<td>All CI wider than 25%</td>
<td>Downgrade one level</td>
</tr>
<tr>
<td>5. Publication Bias</td>
<td>Funnel plot indicates</td>
<td>Not able to assess</td>
<td>No reason for downgrading</td>
</tr>
<tr>
<td>Overall judgment</td>
<td></td>
<td>Very low quality</td>
<td></td>
</tr>
<tr>
<td>6. Exposure-response</td>
<td>Significant trend</td>
<td>Not possible to assess</td>
<td>No reason for upgrading</td>
</tr>
<tr>
<td>7. Magnitude of effect</td>
<td>RR &gt; 2</td>
<td>Not possible to assess</td>
<td>No reason for upgrading</td>
</tr>
<tr>
<td>8. Confounding adjusted</td>
<td>Effect in spite of confounding working towards the nil</td>
<td>Not observed</td>
<td>No reason for upgrading</td>
</tr>
<tr>
<td>Overall Judgement</td>
<td></td>
<td>Very low quality</td>
<td></td>
</tr>
</tbody>
</table>

* Population Exposure Comparator Outcome.
Table S4. The template for assessment of quality and risk of bias of individual studies.

**REFERENCE No 1**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>Study Design Cross-sectional</td>
<td>Description of criteria for judgment</td>
<td>Judgment of risk of bias</td>
</tr>
<tr>
<td></td>
<td>Noise Exposure assessment leading to information bias</td>
<td>Leq (32 s) and Lex(8hr) estimates. The Leq(32 s) values were taken from the two 32-s measurements for both typical and maximum settings (corrected for transfer function of the open ear). The Lex(8 h) or daily exposure level was calculated using a 3-dB exchange rate. Daily usage was estimated by dividing subjects' self-reported weekly usage in hours by seven.</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Bias due to confounding</td>
<td>Variables included into multivariate models for audiometric frequencies and LEX(8 h)/Leq(32 s) comprised socioeconomic status, demographic factors, tubes in ears, other leisure noise exposures.</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Bias due to selection of Participants</td>
<td>237 subjects aged 10 to 17 years. Out of 35 schools invited to participate, 19 schools declined participation. Every 3rd or 4th student on their class lists were selected and distributed equally to male and female subjects in grades 5 – 12. Low participation rate – only 11% out of 2337 invitations sent.</td>
<td>Unclear</td>
</tr>
<tr>
<td></td>
<td>Health outcome assessment leading to information bias I</td>
<td>Hearing thresholds were measured by means of pure-tone audiometry.</td>
<td>Low</td>
</tr>
<tr>
<td></td>
<td>Health outcome assessment leading to information bias II</td>
<td>No information is provided about blinding the health outcome and/or exposure assessment.</td>
<td>Unclear</td>
</tr>
<tr>
<td>Total Risk of Bias in Study:</td>
<td></td>
<td>3/5 High</td>
<td>High</td>
</tr>
</tbody>
</table>

**REFERENCE No 2**

<table>
<thead>
<tr>
<th>Risk of Bias Check List for Studies on Noise and Health</th>
<th>Study Name: Hearing Risk Associated with the Usage of Personal Listening Devices among Urban High School Students.</th>
<th>Assessor Name: Mariola Sliwinska-Kowalska, Kamil Zaborowski</th>
<th>Date Assessed: 10.12.2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>Study Design Cross-sectional</td>
<td>Description of criteria for judgment</td>
<td>Judgment of risk of bias</td>
</tr>
<tr>
<td></td>
<td>Noise Exposure assessment leading to information bias</td>
<td></td>
<td>Low</td>
</tr>
</tbody>
</table>
Usual listening levels were measured while listening to initial 40 s of a pre-selected song ("Just like Heaven" by The Cure). During the test, subjects were blinded from the iPod volume setting and told to set it to their usual listening level without considering preference to the test song. Individual LAeq8h was calculated for every single person based on estimation of the level of music and hours a day of listening to the music.

Bias due to confounding

Subjects with exposure to other sources of loud noises (e.g., disco, concerts, school bands, noisy tools, home stereo) at least twice per month and prior ear problems were excluded from the study. No other confounders were taken into account (e.g., head trauma, drug ototoxicity, cigarette smoking).

Bias due to selection of Participants

Subjects aged 13-16 years were recruited from three schools selected at random from the list of high schools located within 20 km of the authors’ university. They had to be regular users of PLDs for the previous six months. Participants were probably not randomly selected, and the response rate was not provided. Eight out of 185 subjects were excluded due to ear abnormalities.

Health outcome assessment leading to information bias I

Hearing thresholds were measured by means of pure-tone audiometry and extended high frequency audiometry. Subjects were requested to refrain from listening to their PLDs for 24 h prior to the hearing test. Tinnitus was self-reported.

Health outcome assessment leading to information bias II

No information is provided about blinding the health outcome and/or exposure assessment.

Total Risk of Bias in Study: 3/5 High

REFERENCE No 3

Risk of Bias Check List for Studies on Noise and Health Outcomes

Study Name:
Sulaiman et al., 2014

Assessor Name:
Mariola Sliwinska-Kowalska
Kamil Zaborowski

Date Assessed: 10.12.2014

Study Design: Cross-sectional

Description of criteria for judgment
Noise Exposure assessment leading to information bias

Usual listening levels were measured while listening to initial 40 s of a pre-selected song ("Just like Heaven" by The Cure) in a quiet room (45-50 dBA ambient noise level). During the test, subjects were blinded from the iPod volume setting and told to set it to their usual listening level without considering preference to the song. Individual LAeq8h was calculated for every single person based on estimation of the level of music and hours a day of listening to the music.

Bias due to confounding
No prior exposure to any loud occupational noise. None of the subjects had participated in a band, was engaged in shooting activities or had a hobby of playing musical instrument. None of the subjects was exposed to other sources of loud noises (e.g., disco, concerts, noisy tools, home stereo) more than once in a month. No prior ear disorders and currently taken medications, including ototoxic drugs.

Subjects aged 18-30 years were recruited voluntarily from the students and staff of one university, using strictly defined inclusion and exclusion criteria. Exposed group of 35 subjects (users of PLDs for at least 1 year, 1 h/day and at >50% of the maximum volume setting) was sex- and age matched to the control group of 35 subjects who never or rarely used a PLD.

Health outcome assessment leading to information bias I

Hearing thresholds were measured by means of pure-tone audiometry and extended high frequency audiometry. TEOAE and DPOAE amplitude were measured objectively. Subjects were requested to refrain from listening to their PLDs for 24 h prior to the hearing tests.

Health outcome assessment leading to information bias II

No information is provided about blinding the health outcome and/or exposure assessment.

Total Risk of Bias in Study: 3/5 High
No audiometric data. The presence of tinnitus was assessed by a questionnaire. Diagnostic criteria of tinnitus were not specified. It’s not clear whether the outcome is a permanent tinnitus or transient tinnitus after listening to music.

Health outcome assessment leading to information bias II

No information is provided about blinding the health outcome and/or exposure assessment.

Total Risk of Bias in Study:

1/5 very high

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**REFERENCE No 5**

<table>
<thead>
<tr>
<th>Risk of Bias Check List for Studies on Noise and Health Outcomes</th>
<th>Study Name: Risky Music Listening, Permanent Tinnitus and Depression, Anxiety, Thoughts about Suicide and Adverse General Health. Vogel et al., 2014</th>
<th>Assessor Name: Mariola Sliwinska-Kowalska Kamil Zaborowski</th>
<th>Date Assessed: 10.12.2014</th>
</tr>
</thead>
</table>
| Study Design Cross-sectional | Noise Exposure assessment leading to information bias  
No direct measurement of noise levels. Average weekly exposure time to MP3 players was estimated by referring the volume of the device to dB(A) value and multiplying days per week and hours per day to calculate (weekly) Permissible Exposure Limits (PEL<sub>week</sub> = music level of 89 dBA listen for 56 h a week). Bias due to confounding  
Values adjusted for age and gender  
Bias due to selection of Participants  
A total of 1228 students, aged 16-25 years of 2 Dutch secondary vocational schools were invited. No randomization. Participation rate 77.9%  
Health outcome assessment leading to information bias I  
No audiometric data. The presence of “permanent hearing-related symptoms” were categorized as “I am constantly experiencing hearing symptoms (yes, no)”. There is not clear what proportion of subjects with “permanent hearing-related symptoms” experienced permanent tinnitus. Diagnostic criteria of permanent tinnitus were not specified. No validated method of tinnitus assessment.  
Health outcome assessment leading to information bias II  
No information is provided about blinding the health outcome and/or exposure assessment. | Judgment of risk of bias  
Unclear/High?  
Low  
Low  
High  
Unclear/High |
Table S5. The list of included and excluded studies.

**Included Studies**


**Excluded Studies**


Eggemann, C.; Koester, M.; Zorowska, P. Hearing loss due to leisure time noise is on the rise. The ear also needs a rest period. MMW Fortschr. Med. 2002, 144, 30-33.


Hohmann, B.W.; Mercier, V.; Felchlin, I. Effects on hearing caused by personal cassette players, concerts, and discotheques and conclusions for hearing conservation in Switzerland. *Noise Control Eng. J.* 1999, 47, 163-165.


Ryberg, J.B. A national project to evaluate and reduce high sound pressure levels from music. *Noise Health* 2009, 11, 124-128. doi: 10.4103/1463-1741.50698.


