Practical approaches for cardiovascular risk assessment

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Noise and Health Indicators
Results of WHO Pilot Study 2004

Noise indicators recommended for ECHI*

- **Noise_Ex1**
  Population exposed to various noise levels ($L_{den}$, $L_{night}$) by different sources

- **Noise_A1**
  National regulations on maximum sound levels for indoor and outdoor leisure events

Noise indicators recommended for ENHIS**

- **Noise_E1**
  Attributable fraction of risk of cardiovascular morbidity/mortality to noise exposure

- **Noise_E2**
  Self-reported noise health effects: Annoyance and sleep disturbance

Other noise indicators

- **Noise_A2**
  Existence and effectiveness of urban or national action plans to solve noise problems

- **Noise_A3**
  Willingness to enforce and implement the environmental noise EU Directive and to apply noise abatement measures

* ECHI = European Community Health Indicators  ** ENHIS = European Environment and Health Information System
Epidemiological studies:
- Do these changes observed in the laboratory habituate or do they persist under chronic noise exposure?
- If they habituate, what are the physiological costs; if they persist, what are the long-term health effects?

Laboratory studies:
- Sound/noise is a psycho-social stressor that activates the sympathetic and endocrine system
- Acute noise effects do not only occur at high sound levels in occupational settings, but also at relatively low environmental sound levels when certain activities such as concentration, relaxation or sleep are disturbed

Rationale: General Stress Model

Figure: Maschke (2004)
Noise Exposure (Sound Level)

Direct pathway

Hearing-loss

Indirect pathway

Disturbance of activities, sleep, communication

Cognitive and emotional response

Annoyance

Stress Indicators

Physiological stress reactions (unspecific)
- Autonomic nervous system (sympathetic nerve)
- Endocrine system (pituitary gland, adrenal gland)

Risk Factors

Blood pressure
Cardiac output
Blood lipids
Blood glucose
Blood viscosity
Blood clotting factors

Manifest Disorders

Cardiovascular Diseases
Hypertension
Arteriosclerosis
Ischaemic heart disease

Source: Babisch (2002)
Epidemiological Reasoning

- Biological model
- Laboratory experiments on humans (acute effects)
- Animal experiments (long-term effects)
- Epidemiological studies (long-term effects on humans)
  - Occupational (high levels of exposure)
  - Environmental (moderate levels of exposure)
Evidence 2008

International Agency for Research on Cancer [IARC, 1987]:
„no – inadequate – limited – sufficient“

- **Biochemical Changes**
  “Inadequate - Limited”

- **Hypertension**
  “Limited - Sufficient”

- **Ischaemic Heart Diseases**
  “Limited - Sufficient”
Risk Evaluation

- Hazard identification
- Exposure assessment
- Exposure-response assessment
- Risk characterization
  - Attributable risk concept
- Risk management
  - Regulatory options
WHO Global Burden of Disease Studies

• Ischaemic heart disease (IHD) is the leading cause of death in developed (22.8%) and developing countries (9.4%).
• 12.6% of deaths are caused by IHD – worldwide.
• 13.5% of deaths are attributable to high blood pressure (HBP) – worldwide.

Source: Lopez et al. (2006)
## CVD Incidence (Germany)

<table>
<thead>
<tr>
<th></th>
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<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Cardiovascular diseases (No. 390-459)</td>
<td>2,288,764</td>
<td>2,413,429</td>
<td>2,511,855</td>
<td>2,580,989</td>
<td>2,728,033</td>
<td>2,764,146</td>
</tr>
<tr>
<td>Acute rheumatic fever (No. 390-392)</td>
<td>2,038</td>
<td>1,887</td>
<td>1,515</td>
<td>1,421</td>
<td>1,391</td>
<td>1,292</td>
</tr>
<tr>
<td>Chronic rheumatic diseases (No. 393-398)</td>
<td>34,295</td>
<td>30,222</td>
<td>26,678</td>
<td>24,608</td>
<td>23,744</td>
<td>22,718</td>
</tr>
<tr>
<td>Hypertension and high blood pressure (No. 401-405)</td>
<td>148,692</td>
<td>154,640</td>
<td>159,122</td>
<td>166,656</td>
<td>185,083</td>
<td>186,922</td>
</tr>
<tr>
<td>Ischaemic heart diseases (No. 410-414)</td>
<td>703,996</td>
<td>773,538</td>
<td>794,615</td>
<td>813,294</td>
<td>855,563</td>
<td><strong>849,557</strong></td>
</tr>
<tr>
<td>Acute myocardial infarction (No. 410)</td>
<td>132,921</td>
<td>133,311</td>
<td>131,094</td>
<td>127,724</td>
<td>132,501</td>
<td><strong>133,115</strong></td>
</tr>
<tr>
<td>Diseases of the pulmonary circulatory system (No. 415-417)</td>
<td>34,898</td>
<td>34,817</td>
<td>34,497</td>
<td>34,785</td>
<td>37,758</td>
<td>38,481</td>
</tr>
<tr>
<td>Other heart diseases (No. 420-429)</td>
<td>493,463</td>
<td>522,327</td>
<td>561,507</td>
<td>582,354</td>
<td>625,543</td>
<td>638,996</td>
</tr>
<tr>
<td>Cerebral-vascular diseases (No. 430-438)</td>
<td>385,059</td>
<td>397,573</td>
<td>420,697</td>
<td>439,138</td>
<td>462,885</td>
<td>476,441</td>
</tr>
<tr>
<td>Diseases of arteries, arteriols and capillaries (No. 440-448)</td>
<td>184,437</td>
<td>189,142</td>
<td>193,638</td>
<td>198,684</td>
<td>207,743</td>
<td>215,100</td>
</tr>
<tr>
<td>Venous and other vascular diseases. (No. 451-459)</td>
<td>301,886</td>
<td>309,283</td>
<td>319,586</td>
<td>320,049</td>
<td>328,323</td>
<td>334,739</td>
</tr>
</tbody>
</table>

**IHD – 2006: 718,648 cases (ICD 10)**  
**AMI – 2006: 208,425 cases (ICD 10)**

*Source: Statistisches Bundesamt and Robert Koch-Institut (2005)*
Risk Evaluation

Hazard identification

Exposure assessment

Exposure-response assessment

Risk characterization

Attributable risk concept

Risk management

Regulatory options
WHO Expert Groups on Noise
WHO European Centre for Environment and Health

- **Noise and Health Indicators**
  "Development of Environmental and Health Indicators for EU Countries" (2002-2004)

- **Housing and Health**
  "Identifying priorities to create healthy, good quality, sustainable and affordable housing for everyone" (2002-2007)

- **Night Noise Guidelines For Europe**
  "Provide expertise and scientific advice to the Commission when developing future legislation in the area of night noise exposure, control and surveillance" (2003-2007)

- **Environmental Noise Burden of Disease**
  "Provide guidance in the estimation of burden of disease related to environmental noise, and to provide preliminary estimates of EBD from environmental noise in Europe" (2005-2008)

- **Aircraft Noise and Health**
  "Evidence review on aircraft noise and health; discuss feasible policy options for management of health risks related to aircraft noise" (2007-2008)

- **Practical Guidance for Risk Assessment of Environmental Noise**
  "Evidence review on aircraft noise and health; discuss feasible policy options for management of health risks related to aircraft noise" (2008-.....)
Exposure-response Curve

Road traffic noise – MI / IHD risk ("categorial approach")

**Exposure-response function:**
\[ OR = 1.629657 - 0.000613(L_{\text{day,16h}})^2 + 0.000007357(L_{\text{day16h}})^3, \quad R^2 = 0.96 \]

**Odds ratio**

![Graph showing the exposure-response curve with the equation provided and the categorial approach to MI/IHD risk.](image)

**Source:** Babisch (2006)
Exposure-response Curve

Road traffic noise – MI / IHD risk ("regression approach")

Exposure-response function:
OR per 10 dB(A) = 1.17, 95% CI = 0.87-1.57, p = 0.301, range = 55-80 dB(A)

Source: Babisch (2008)
Exposure-response Curve
Aircraft noise – High BP risk ("regression approach")

**Exposure-response function:**
OR per 10 dB(A) = 1.13, 95% CI = 1.00-1.28, range = 45-70 dB(A)

Source: Babisch and van Kempen (2008)

Heterogeneity: p = 0.002
Risk Evaluation

- Hazard identification
  - Exposure assessment
  - Exposure-response assessment
  - Risk characterization
    - Attributable risk concept
  - Risk management
    - Regulatory options
Traffic Noise Exposure in Europe

About 120 million people in the EU (more than 30% of the total population) are exposed to road traffic noise levels above 55 dB $L_{dn}$.

More than 50 million people are exposed to road traffic noise levels above 65 dB $L_{dn}$.

Environmental issue report No 12, Term 2000
Calm Network, 2004
Traffic Noise Exposure (Germany) (Probabilistic model)

Source: Umweltbundesamt (2001)
**Traffic Noise Exposure (Berlin)**

*(Noise mapping)*

<table>
<thead>
<tr>
<th>Average sound pressure level $L_{den}$ [dB(A)]</th>
<th>Exposed subjects Berlin * [%]</th>
</tr>
</thead>
<tbody>
<tr>
<td>approx. $\leq$ 60</td>
<td>87.1</td>
</tr>
<tr>
<td>&gt;60 – 65</td>
<td>4.7</td>
</tr>
<tr>
<td>&gt;65 – 70</td>
<td>4.2</td>
</tr>
<tr>
<td>&gt;70 – 75</td>
<td>3.4</td>
</tr>
<tr>
<td>&gt;75</td>
<td>0.6</td>
</tr>
</tbody>
</table>

*Source:* *Senatsverwaltung für Stadtentwicklung Berlin (2007)*
## Traffic Noise Exposure (Berlin)

(Noise mapping)

### Average sound pressure level $L_{den}$ [dB(A)]

<table>
<thead>
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<td>87.1</td>
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<tr>
<td>&gt;60 – 65</td>
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<td>15.3</td>
</tr>
<tr>
<td>&gt;65 – 70</td>
<td>4.2</td>
<td>9.0</td>
</tr>
<tr>
<td>&gt;70 – 75</td>
<td>3.4</td>
<td>5.1</td>
</tr>
<tr>
<td>&gt;75</td>
<td>0.6</td>
<td>1.5</td>
</tr>
</tbody>
</table>

*Senatsverwaltung für Stadtentwicklung Berlin (2007), Umweltbundesamt (2001)*
Risk Evaluation

- Hazard identification
  - Exposure assessment
  - Dose-response assessment
- Risk characterization
  - Attributable risk concept
- Risk management
  - Regulatory options
Attributable Fraction
Formula

\[ AF = \frac{\sum (P_i \times RR_i) - 1}{\sum (P_i \times RR_i)} \]

where:  
- \( P_i \) = Proportion of the population in exposure category i
- \( RR_i \) = relative risk at exposure category i compared to the reference level
Example: Germany
(Categorial approach)

<table>
<thead>
<tr>
<th>Average sound pressure level during the day (6-22 h) $L_{\text{day},16\text{hr}}$ [dB(A)]</th>
<th>Percentage exposed [%]</th>
<th>Relative risk of myocardial infarction [OR] *)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;= 60</td>
<td>69.1</td>
<td>1.000</td>
</tr>
<tr>
<td>&gt;60 – 65</td>
<td>15.3</td>
<td>1.031</td>
</tr>
<tr>
<td>&gt;65 – 70</td>
<td>9.0</td>
<td>1.099</td>
</tr>
<tr>
<td>&gt;70 – 75</td>
<td>5.1</td>
<td>1.211</td>
</tr>
<tr>
<td>&gt;75</td>
<td>1.5</td>
<td>1.372</td>
</tr>
</tbody>
</table>

Attributable fraction: 2.9%
Approx. 3,900 MI cases/year
Approx. 24,700 IHD cases/year
Approx. 25,300 DALYs/year

Reference year 1999
MI: 133,115 cases
IHD: 849,557 cases

*) Polynomial risk equation: $L_{\text{day},16\text{hr}}$
Example: Germany  
(Regression approach)

<table>
<thead>
<tr>
<th>Average sound pressure level during the day (6-22 h) $L_{\text{day,16hr}}$ [dB(A)]</th>
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<td>1.000</td>
</tr>
<tr>
<td>&gt;60 – 65</td>
<td>15.3</td>
<td>1.082</td>
</tr>
<tr>
<td>&gt;65 – 70</td>
<td>9.0</td>
<td>1.170</td>
</tr>
<tr>
<td>&gt;70 – 75</td>
<td>5.1</td>
<td>1.266</td>
</tr>
<tr>
<td>&gt;75</td>
<td>1.5</td>
<td>1.369</td>
</tr>
</tbody>
</table>

Attributable fraction: 4.5%  
Approx. 5,990 MI cases/year  
Approx. 38,230 IHD cases/year

Reference year 1999  
MI: 133,115 cases  
IHD: 849,557 cases

*) Multiplicative model: $L_{\text{day,16hr}}$
### Example: Berlin

<table>
<thead>
<tr>
<th>Average sound pressure level $L_{den}$ [dB(A)]</th>
<th>Percentage exposed [%]</th>
<th>Relative risk of myocardial infarction [OR] * )</th>
</tr>
</thead>
<tbody>
<tr>
<td>approx. &lt;60</td>
<td>80.53</td>
<td>1.000</td>
</tr>
<tr>
<td>&gt;55 – 60</td>
<td>6.61</td>
<td>1.000</td>
</tr>
<tr>
<td>&gt;60 – 65</td>
<td>4.65</td>
<td>1.018</td>
</tr>
<tr>
<td>&gt;65 – 70</td>
<td>4.21</td>
<td>1.072</td>
</tr>
<tr>
<td>&gt;70 – 75</td>
<td>3.38</td>
<td>1.168</td>
</tr>
<tr>
<td>&gt;75</td>
<td>0.62</td>
<td>1.311</td>
</tr>
</tbody>
</table>

Attributable fraction: 1.1%

* ) Polynomial risk equation: $L_{day,16hr} = L_{den} - 2$dB(A)
Conversion

\[ L_{\text{day,16h}} \leftrightarrow L_{\text{den}} \]

\[ L_{\text{den}} \approx L_{\text{day,16h}} - 2 \times \ln\left(\frac{L_{\text{day,16h}} - L_{\text{night,8h}}}{22.4}\right) \]

Urban settings:

If \((L_{\text{day,16h}} - L_{\text{night,8h}}) \approx 7-8 \text{ dB(A)}\) then \(L_{\text{day,16h}} = L_{\text{den}} - 2 \text{ dB(A)}\)

Source: Bite and Bite (2004)
$L_{\text{day,16 hr}} \Leftrightarrow L_{\text{den}}$

### Road traffic noise

<table>
<thead>
<tr>
<th>Average sound pressure level $L_{\text{eq}}$ [dB(A)]</th>
<th>Relative risk ($L_{\text{day,16hr}}$)</th>
<th>Relative risk ($L_{\text{den}}$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>$\leq 60$</td>
<td>1.000</td>
<td>1.000</td>
</tr>
<tr>
<td>$&gt;60 – 65$</td>
<td>1.031</td>
<td>1.018</td>
</tr>
<tr>
<td>$&gt;65 – 70$</td>
<td>1.099</td>
<td>1.072</td>
</tr>
<tr>
<td>$&gt;70 – 75$</td>
<td>1.211</td>
<td>1.168</td>
</tr>
<tr>
<td>$&gt;75$</td>
<td>1.372</td>
<td>1.311</td>
</tr>
</tbody>
</table>
**Risk Communication**
(Mortality per Year - Germany)

<table>
<thead>
<tr>
<th>Category</th>
<th>Mortality Per Year (Germany)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asbestos in the environment</td>
<td>$10^{-7}$ to $10^{-6}$</td>
</tr>
<tr>
<td>Electromagnetic fields</td>
<td>$10^{-7}$ to $10^{-6}$</td>
</tr>
<tr>
<td>Carcinogenic air pollutants</td>
<td>$10^{-6}$ to $10^{-5}$</td>
</tr>
<tr>
<td>Passive smoking (lung cancer)</td>
<td>$10^{-6}$ to $10^{-5}$</td>
</tr>
<tr>
<td>Passive smoking (all)</td>
<td>$10^{-5}$ to $10^{-4}$</td>
</tr>
<tr>
<td>Traffic noise</td>
<td>$10^{-5}$ to $10^{-4}$</td>
</tr>
<tr>
<td>Air pollution (all)</td>
<td>$10^{-4}$ to $10^{-3}$</td>
</tr>
<tr>
<td>Traffic accidents</td>
<td>$10^{-4}$ to $10^{-3}$</td>
</tr>
<tr>
<td>Active smoking</td>
<td>$10^{-3}$ to $10^{-2}$</td>
</tr>
</tbody>
</table>

($10^{-5} = 1/100.000$)
Discussions
Approximation MI => IHD?

ICD-9 Code 410-414:

- 410: Acute myocardial infarction
- 411: Other acute and sub-acute forms of ischaemic heart disease
- 412: Old myocardial infarction
- 413: Angina pectoris
- 414: Coronary atherosclerosis, chronic ischaemic heart disease
Approximation Males => Females?

Males: higher *absolute* risk of CVD
Females: different *relative* risk?
Causality?

- Magnitude of effect
- Presence of dose-response relationship
- Consistency with other studies in different populations and with different methodology
- Coherence (biological plausibility)
Support ?

Effect modification

Room orientation
Window opening habits
Length of residence
Significance?

- $\alpha$-error vs. $\beta$-error
- 2-tailed vs. 1-tailed
- p-value vs. confidence interval
- individual study vs. pooled data
Exposure-response Relationship
(>10/>15 years in residence)

Exposure-response function (regression approach):
OR = 1.44 per 10 dB(A), 95% CI = 0.97-2.12, p = 0.067
Bias?

- Age
- Prevalence of diabetes mellitus
- Prevalence of hypertension
- (Prevalence of hyperlipaemia)
- Family history of MI
- Smoking
- Alcohol consumption
- Relative body weight
- School educational level
- Employment status
- Working hours per week
- Shift work
- Second job or activity
- Marital status
- Subjective noise sensitivity
Confounding with Air Pollution?

- Same source (road traffic)
- Individual assessment of noise exposure - no ecological data
- Micro-scale differences of noise exposures were considered (due to shielding) in individual exposure assessment (orientation of rooms) – In air pollution studies often only the background exposure was considered (meso-scale).
- Associations between aircraft noise and cardiovascular endpoints were shown in noise studies. However, the contribution of aircrafts to ambient concentrations of air pollutants is small.
- Associations between occupational noise and CVD endpoints were shown.
- Some noise studies show larger effects with respect to the exposure during the night (bedroom) than during the day (living room). However, concentrations of air pollutants are lower during the night.
- Closing the windows was associated with smaller effect estimates. However, concentrations of indoor pollutants are often higher than outdoor concentrations.
Environmental Noise Directive (END)

L_{den} ?

- Weighing factors derived from annoyance research.
- Not validated with respect to physiological reactions.
- Why consider $L_{\text{night}}$ in $L_{\text{den}}$ when $L_{\text{night}}$ is independently assessed, anyway? => Legislation.
- $L_{\text{eq}}$-based indicators are well correlated. However, different noise sources (air, road, rail) => $L_{\text{den}}$ values not comparable.
- Scientists prefer physical indicators (without 'mystic' weights).
- Better indicators: $L_{\text{day}}$, $L_{\text{night}}$. 
How Many Risk Curves?

- $L_{\text{den}}$ and $L_{\text{night}}$
  
  (resp. $L_{\text{day}}$ - living room, $L_{\text{night}}$ - bedroom) ?

- High BP and MI and IHD ?

- Aircraft and Road and Rail and ...? 

- Males and Females ?

- Simplifications / approximations are needed !
Epidemiological Reasoning

George Cornstock:

"The art of epidemiological reasoning is to draw sensible conclusions from imperfect data."
Horton [1998]:

“We must act on facts, and on the most accurate interpretation of them, using the best scientific information. That does not mean that we must sit back until we have 100% evidence about everything. Where the state of the health of the people is at stake, the risks can be so high and the costs of corrective action so great, that prevention is better than cure.”

“Where there are significant risks of damage to the public health, we should be prepared to take action to diminish those risks, even when the scientific knowledge is not conclusive, if the balance of likely costs and benefits justifies it.”
Thanks For Listening!

Contact:

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