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*

Rationale: General Stress Model

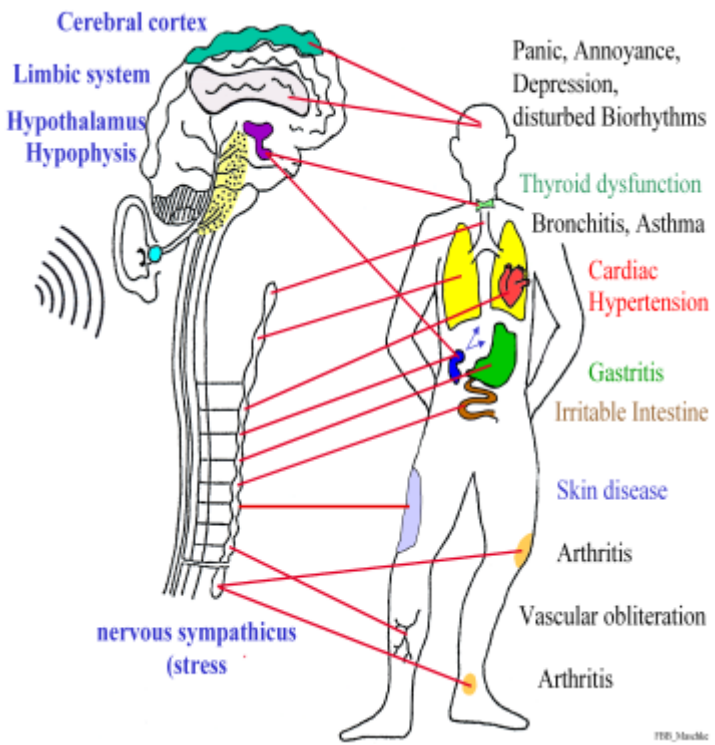


Figure: Maschke (2004)

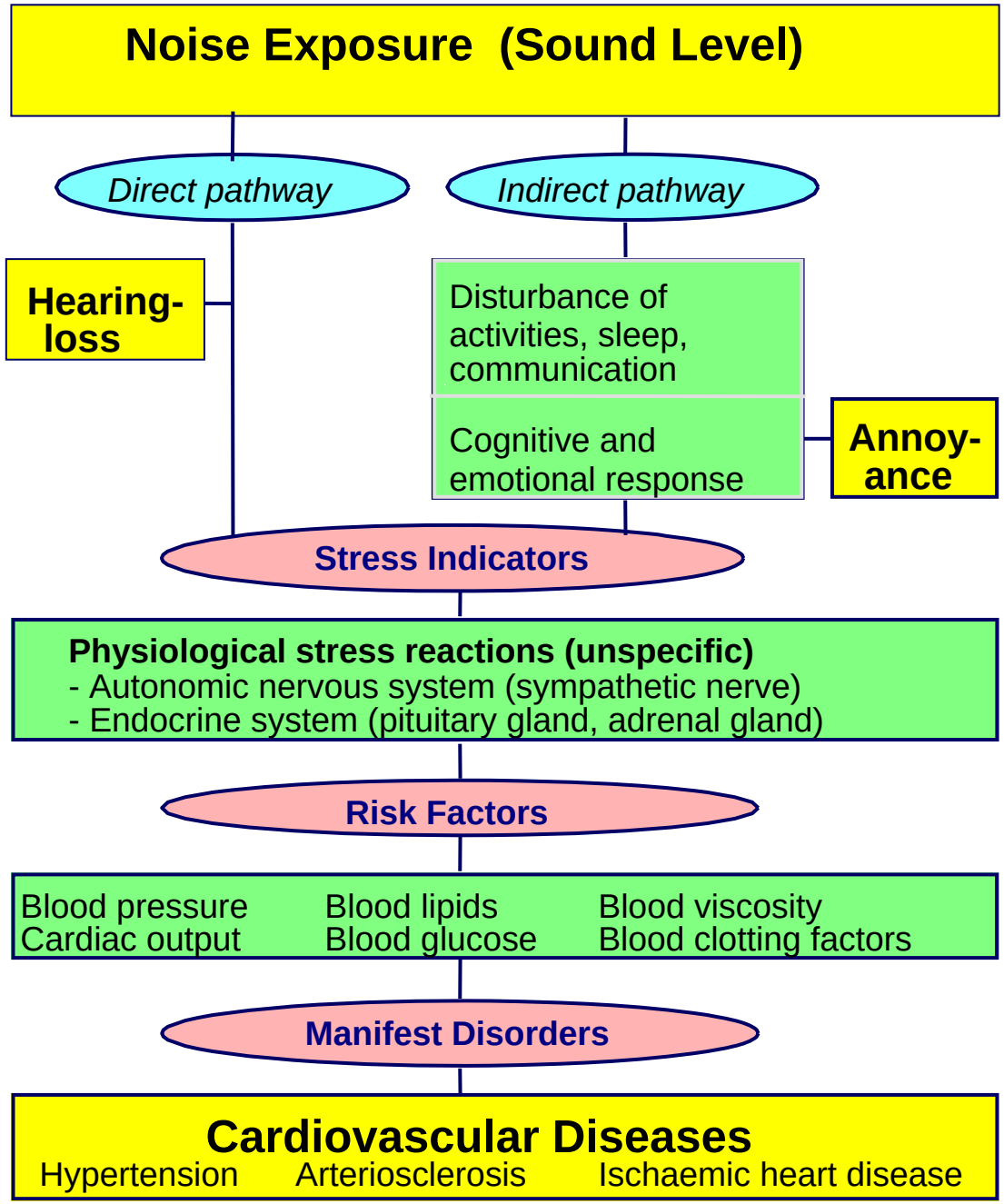
Laboratory studies:

- 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

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?

Reaction scheme



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”

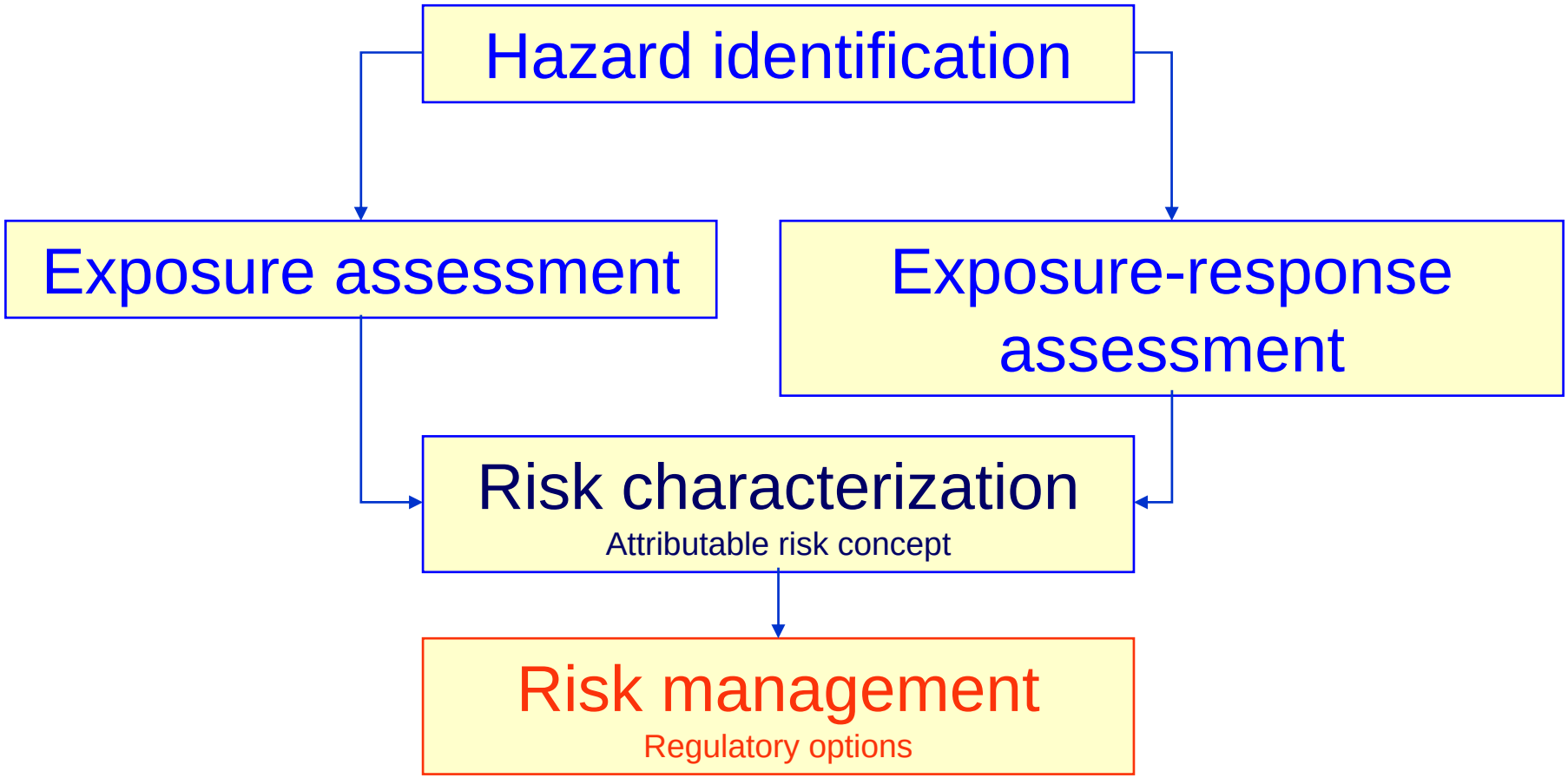
- Hypertension

  “Limited - Sufficient”

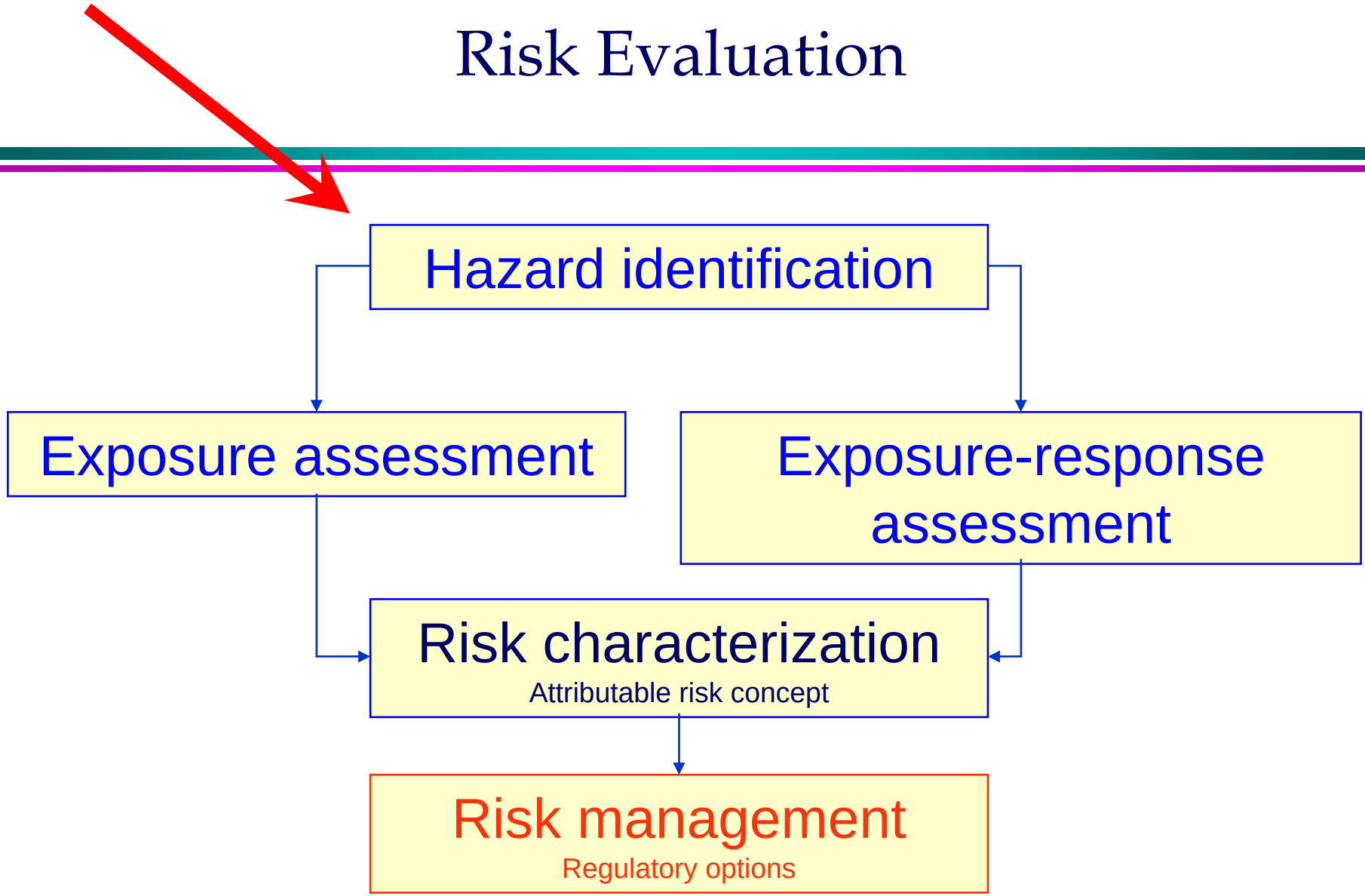
- Ischaemic Heart Diseases

  “Limited - Sufficient”

Risk Evaluation



Risk Evaluation



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)

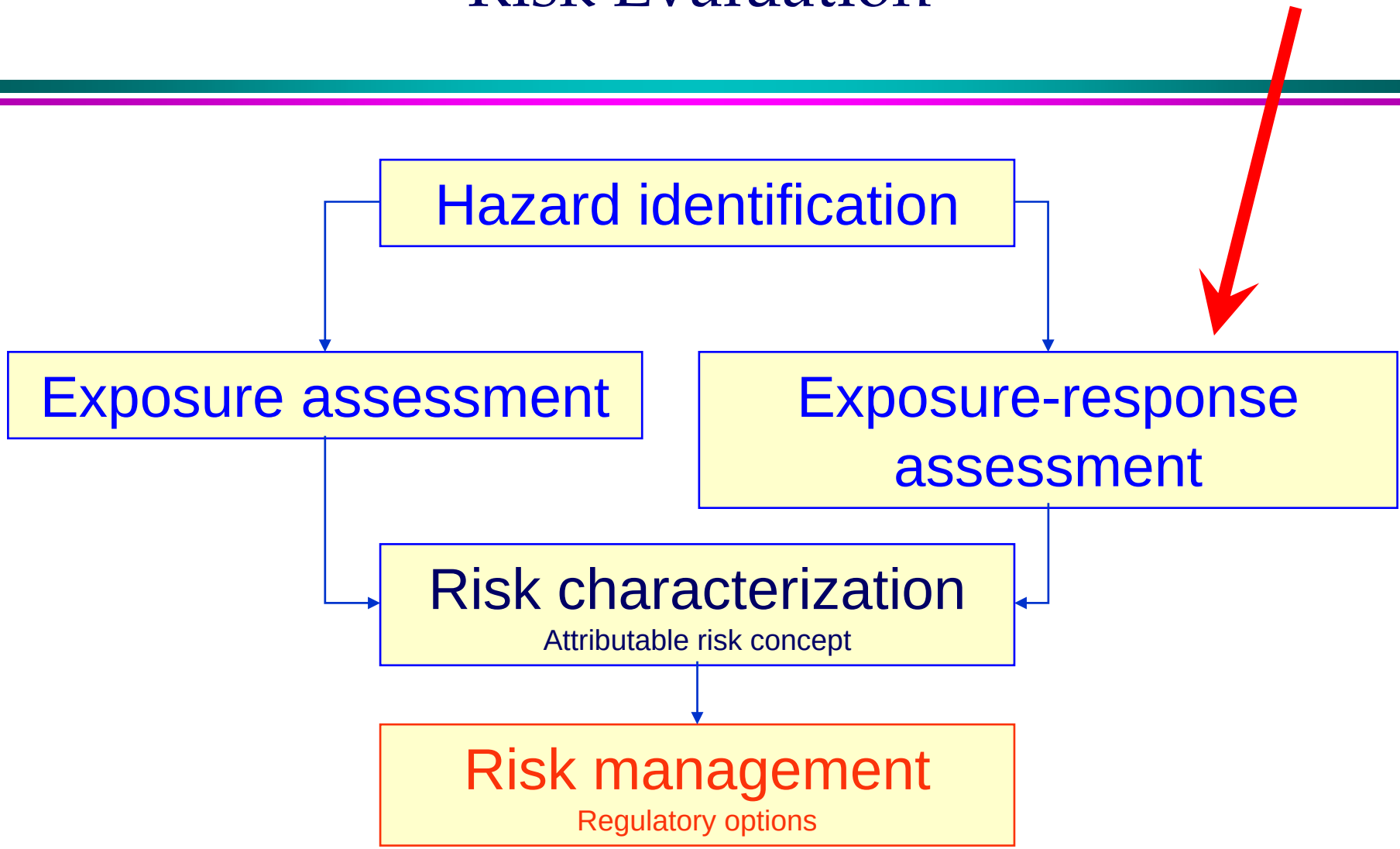
CVD Incidence (Germany)

ICD 9	1994	1995	1996	1997	1998	**1999**
Cardiovascular diseases (No. 390-459)	2,288,764	2,413,429	2,511,855	2,580,989	2,728,033	2,764,146
Acute rheumatic fever (No. 390-392)	2,038	1,887	1,515	1,421	1,391	1,292
Chronic rheumatic diseases (No. 393-398)	34,295	30,222	26,678	24,608	23,744	22,718
Hypertension and high blood pressure (No. 401-405)	148,692	154,640	159,122	166,656	185,083	186,832
Ischaemic heart diseases (No. 410-414)	703,996	773,538	794,615	813,294	855,563	**849,557**
Acute myocardial infarction (No. 410)	132,921	133,311	131,094	127,724	132,501	**133,115**
Diseases of the pulmonary circulatory system (No. 415-417)	34,898	34,817	34,497	34,785	37,758	38,481
Other heart diseases (No. 420-429)	493,463	522,327	561,507	582,354	625,543	638,996
Cerebral-vascular diseases (No. 430-438)	385,059	397,573	420,697	439,138	462,885	476,441
Diseases of arteries, arteriols and capillaries (No. 440-448)	184,437	189,142	193,638	198,684	207,743	215,100
Venous and other vascular diseases. (No. 451-459)	301,886	309,283	319,586	320,049	328,323	334,739

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

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

Risk Evaluation



WHO Expert Groups on Noise

WHO European Centre for Environment and Health

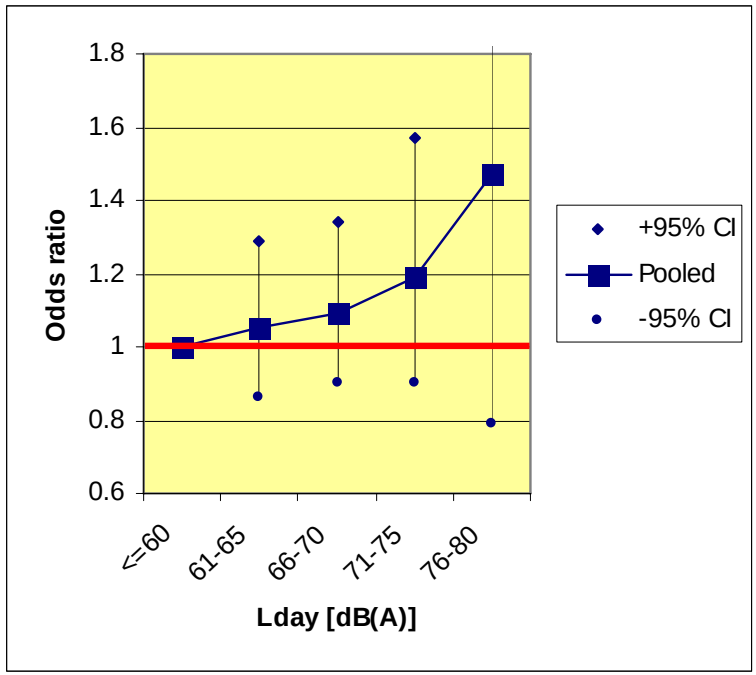
- **Noise and Health Indicators**
  "Development of Environmental and Health Indicators for EU Countries" (2002-2004)
- **Housing and Health**
  "Identifying priorities to create healthy, good quality, sustainable and affordable housing for everyone" (2002-2007)
- **Night Noise Guidelines For Europe**
  "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-.....)

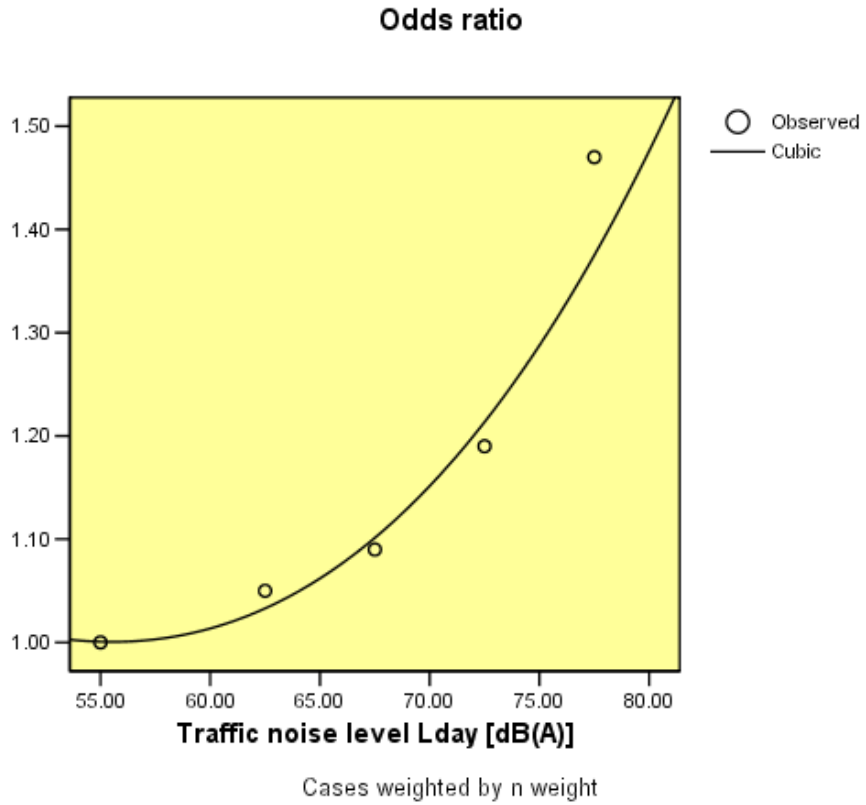
Exposure-response Curve

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

Exposure-response function:

OR = 1.629657 – 0.000613*($L_{day,16h}$)^2 + 0.000007357*(L_{day16h})^3, R^2 = 0.96





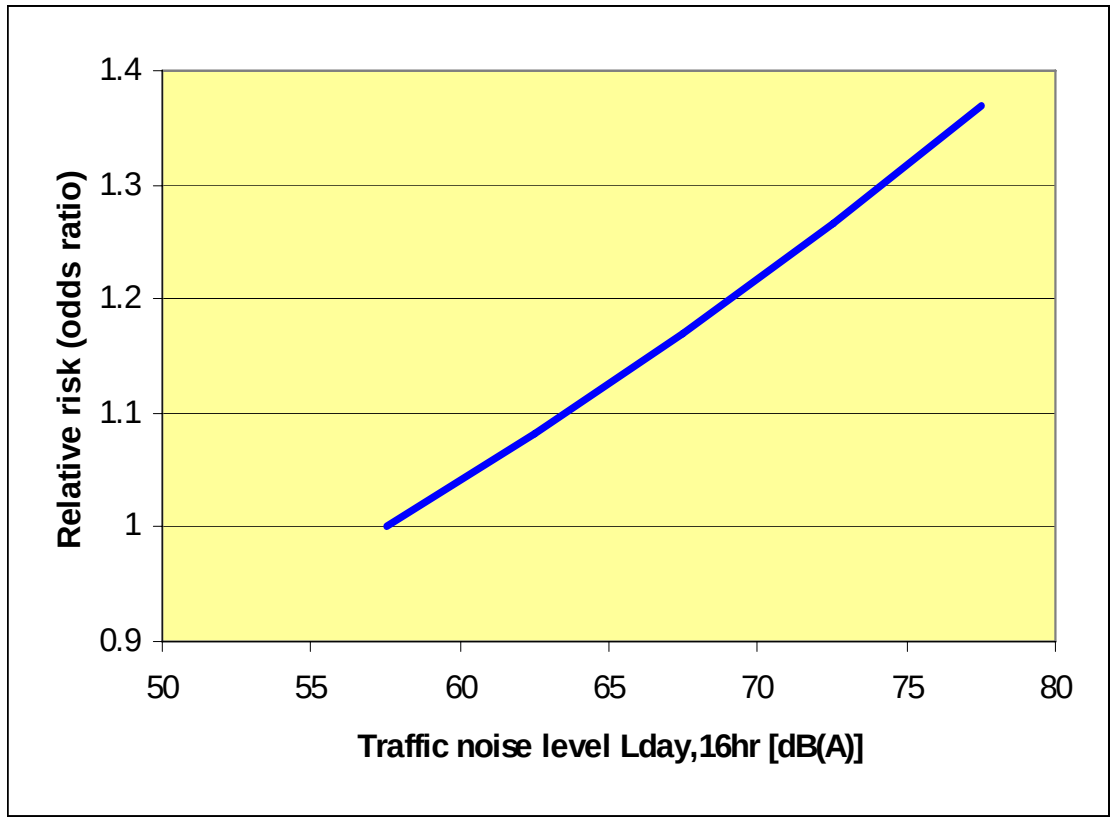
Source: Babisch (2006)

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)

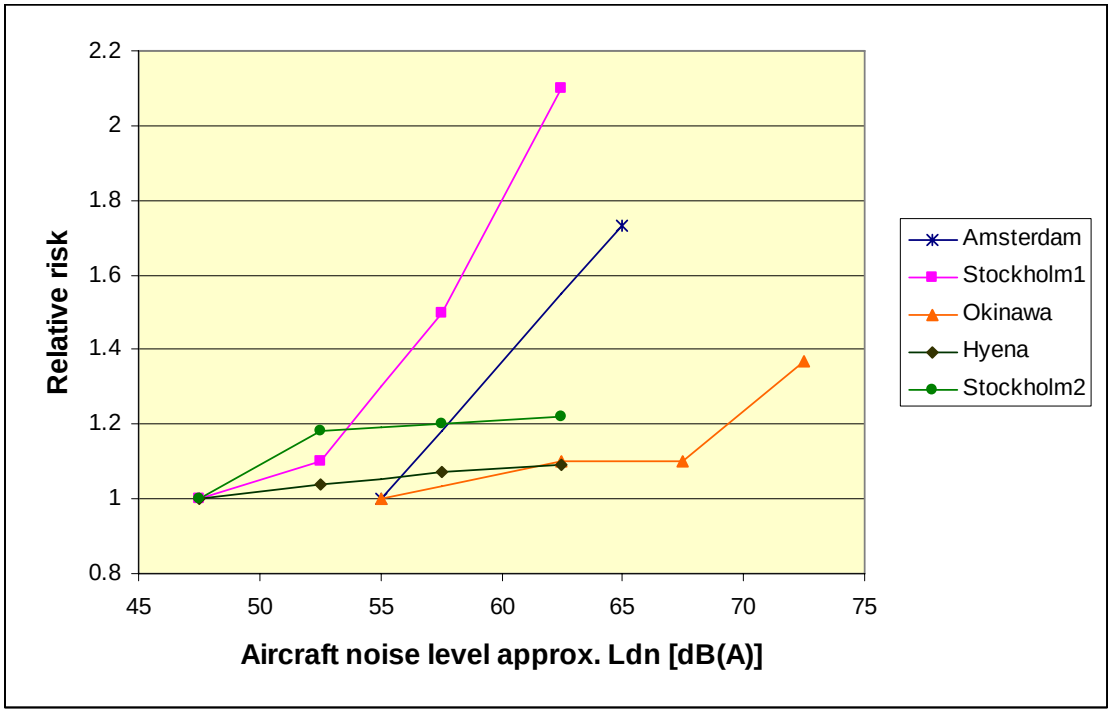


Source: Babisch (2008)

Exposure-response Curve

Aircraft noise – High BP risk ("regression approach")

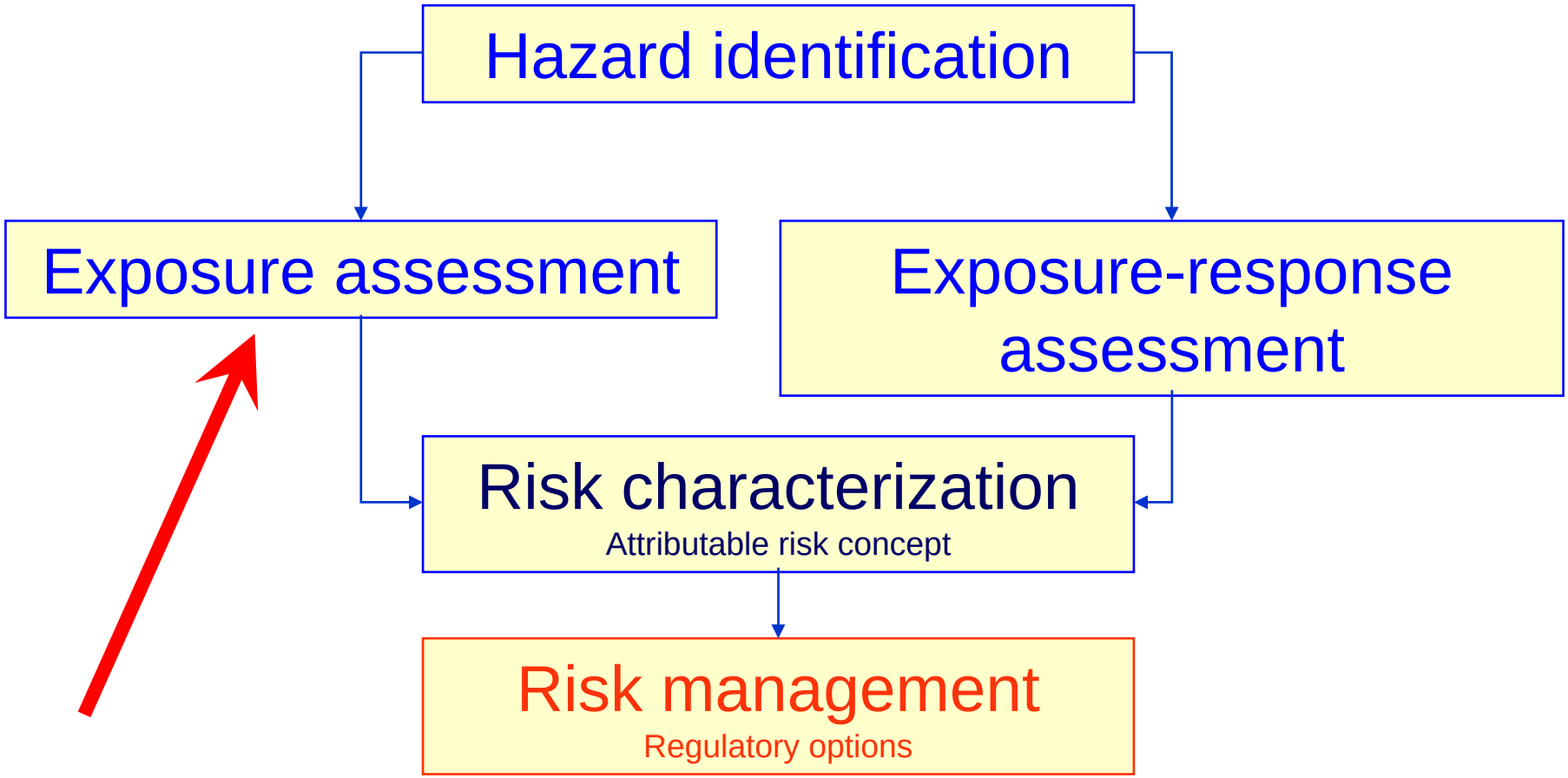
Exposure-response function:
OR per 10 dB(A) = 1.13, 95% CI = 1.00-1.28, range = 45-70 dB(A)



Heterogeneity: p = 0.002

Source: Babisch and van Kempen (2008)

Risk Evaluation

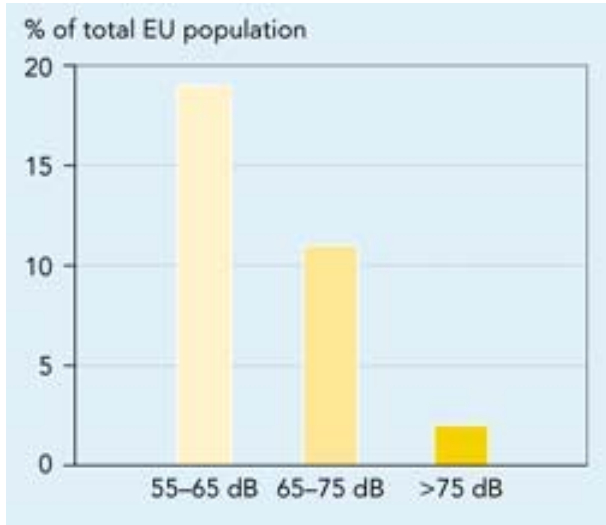


Traffic Noise Exposure in Europe

European Environment Agency
Information for improving Europe's environment

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}.

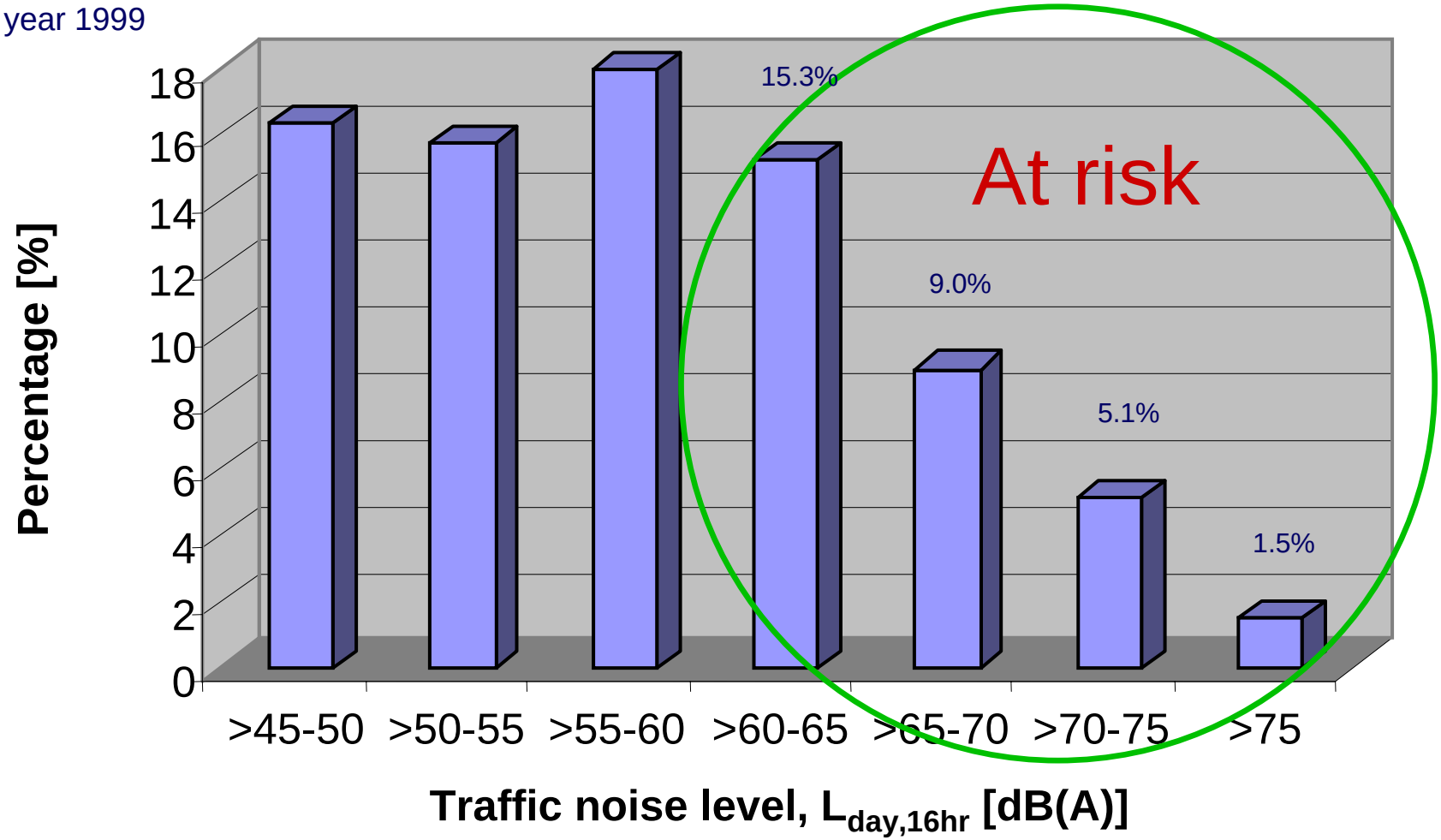
More than 50 million people are exposed to road traffic noise levels above 65 dB L_{dn}.



Environmental issue report No 12, Term 2000
Calm Network, 2004

Traffic Noise Exposure (Germany)
(Probabilistic model)

Reference year 1999



Source: Umweltbundesamt (2001)

Traffic Noise Exposure (Berlin)
(Noise mapping)

Average sound pressure level L_{den} [dB(A)]	Exposed subjects Berlin * [%]
approx. ≤60	87.1
>60 – 65	4.7
>65 – 70	4.2
>70 – 75	3.4
>75	0.6

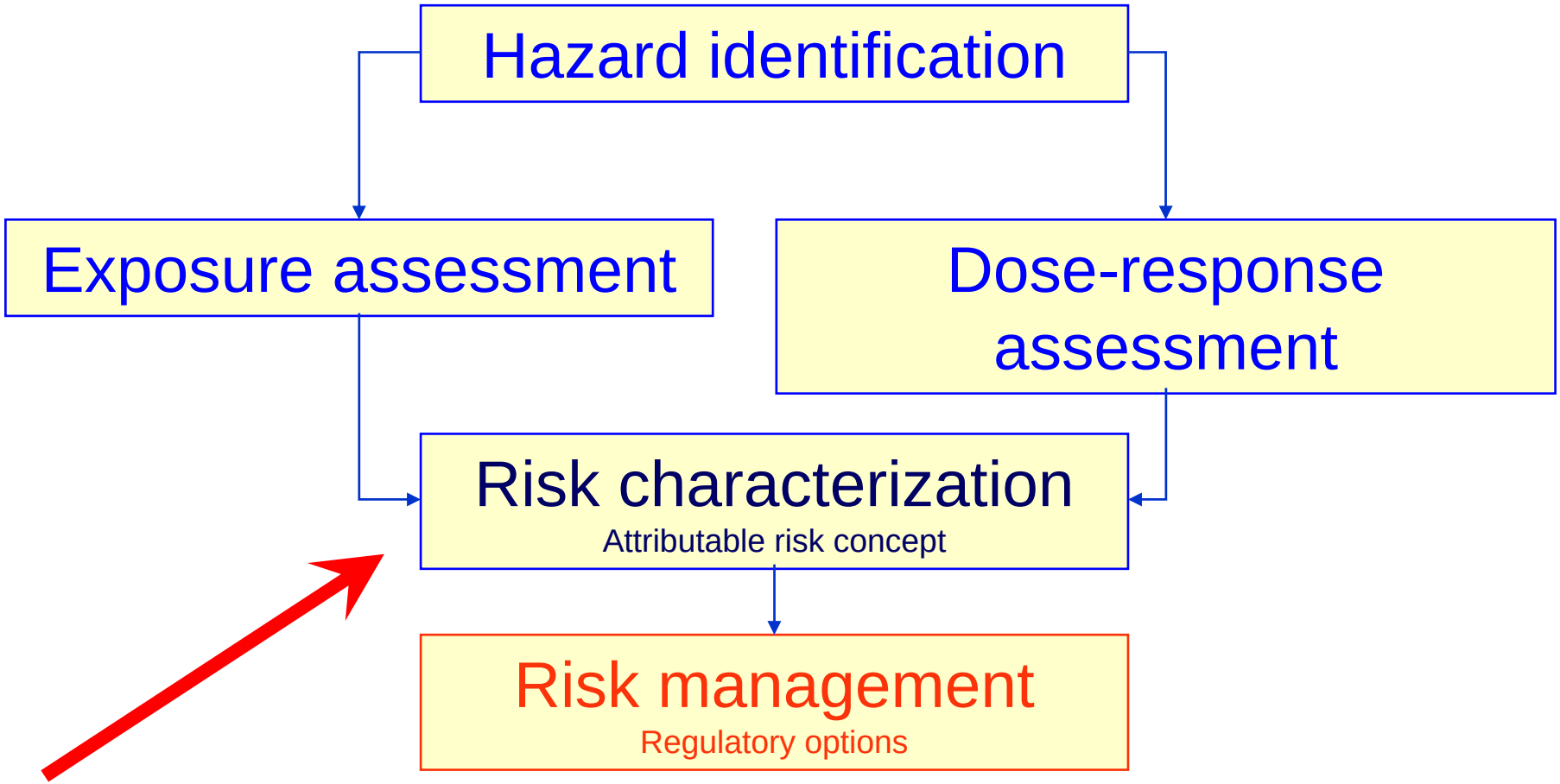
Source: * Senatsverwaltung für Stadtentwicklung Berlin (2007)

Traffic Noise Exposure (Berlin)
(Noise mapping)

	2005	1999
Average sound pressure level L_{den} [dB(A)]	**Exposed subjects Berlin * [%]** Major road network	**Exposed subjects Germany ** [%]**
approx. ≤60	87.1	69.1
>60 – 65	4.7	15.3
>65 – 70	4.2	9.0
>70 – 75	3.4	5.1
>75	0.6	1.5

Source: * Senatsverwaltung für Stadtentwicklung Berlin (2007), ** Umweltbundesamt (2001)

Risk Evaluation



Attributable Fraction
Formula

$$AF = \{\Sigma(P_i * RR_i) - 1\} / \Sigma (P_i * RR_i)$$

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)

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

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: $L_{day,16hr}$

Example: Germany
(Regression approach)

Average sound pressure level during the day (6-22 h) $L_{day,16hr}$ [dB(A)]	Percentage exposed [%]	Relative risk of myocardial infarction [OR] *)
<= 60	69.1	1.000
>60 – 65	15.3	1.082
>65 – 70	9.0	1.170
>70 – 75	5.1	1.266
>75	1.5	1.369

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: $L_{day,16hr}$

Example: Berlin

Average sound pressure level L_{den} [dB(A)]	Percentage exposed [%]	Relative risk of myocardial infarction [OR] *)
approx. <60	80.53	1.000
>55 – 60	6.61	1.000
>60 – 65	4.65	1.018
>65 – 70	4.21	1.072
>70 – 75	3.38	1.168
>75	0.62	1.311

Attributable fraction: 1.1%

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

Conversion

$$L_{day,16h} <=> L_{den}$$

$$L_{den} \approx L_{day,16h} - 2*\ln[(L_{day,16h}-L_{night,8h})/22.4)]$$

Urban settings:

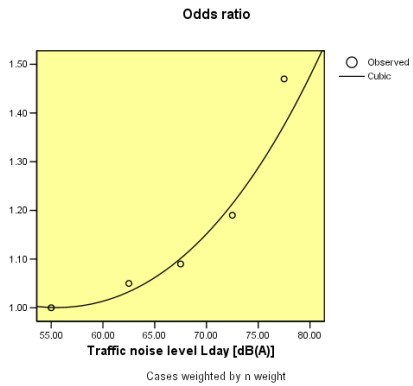
If ($L_{day,16h}$-$L_{night,8h}$ ≈ 7-8 dB(A) then $L_{day,16\ h} = L_{den}$ - 2 dB(A)

Source: Bite and Bite (2004)

$L_{day,16\ hr} \Leftrightarrow L_{den}$

Road traffic noise

Average sound pressure level L_{eq} [dB(A)]	Relative risk ($L_{day,16hr}$)	Relative risk (L_{den})
<= 60	1.000	1.000
>60 – 65	1.031	1.018
>65 – 70	1.099	1.072
>70 – 75	1.211	1.168
>75	1.372	1.311



Risk Communication

(Mortality per Year - Germany)

• Asbestos in the environment	10^{-7} to 10^{-6}
• Electromagnetic fields	10^{-7} to 10^{-6}
• Carcinogenic air pollutants	10^{-6} to 10^{-5}
• Passive smoking (lung cancer)	10^{-6} to 10^{-5}
• Passive smoking (all)	10^{-5} to 10^{-4}
• Traffic noise	10^{-5} to 10^{-4}
• Air pollution (all)	10^{-4} to 10^{-3}
• Traffic accidents	10^{-4} to 10^{-3}
• Active smoking	10^{-3} to 10^{-2}

(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

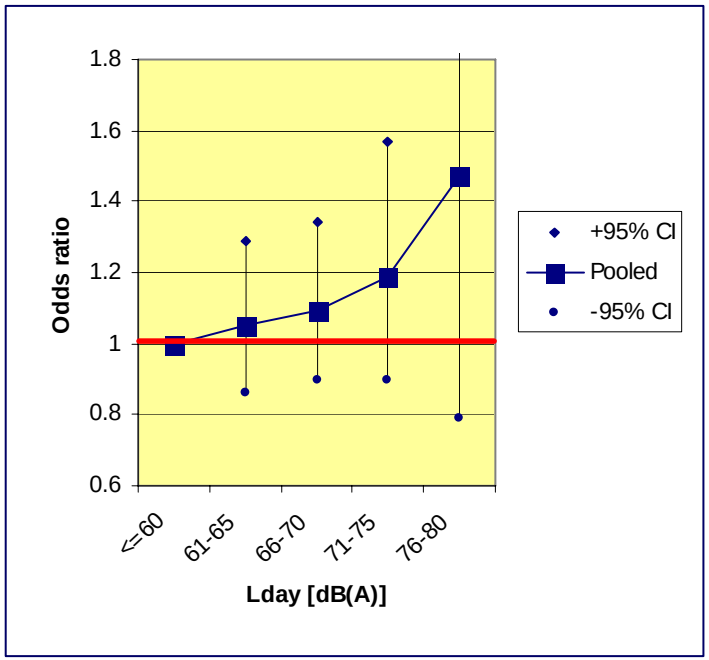
Length of residence

Significance ?

- α-error vs. β-error
- 2-tailed vs. 1-tailed
- p-value vs. confidence interval
- individual study vs. pooled data

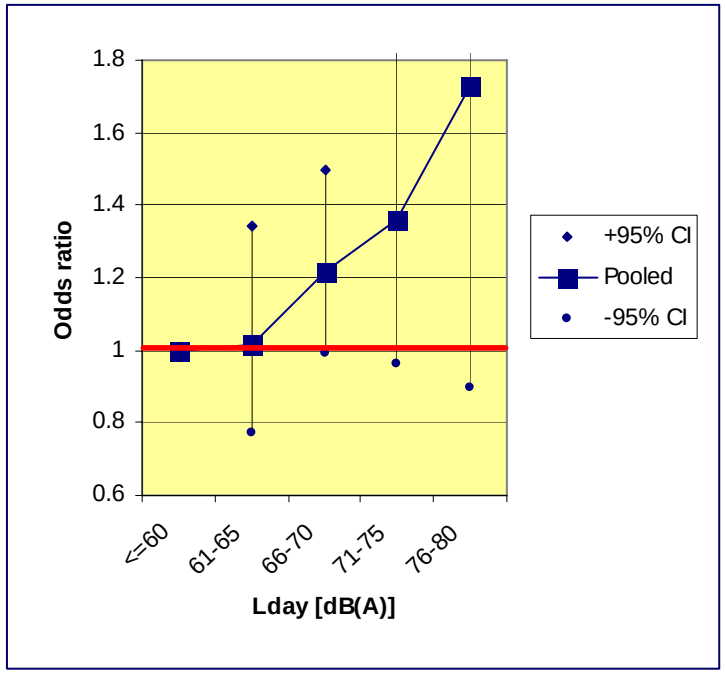
Exposure-response Relationship
(>10/>15 years in residence)

Total sample



>70 dB(A): OR = 1.25, p = 0.086

Sub-sample (long residence time)



>70 dB(A): OR = 1.44, p = 0.020

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_{night} in L_{den} when L_{night} is independently assessed, anyway? => Legislation.
- L_{eq}-based indicators are well correlated. However, different noise sources (air, road, rail) => L_{den} values not comparable.
- Scientists prefer physical indicators (without 'mystic' weights).
- Better indicators: L_{day}, L_{night}.

How Many Risk Curves?

- L_{den} and L_{night}

  (resp. L_{day} - living room, L_{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."

Precautionary Principle

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 !

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Umwelt Bundes Amt
Für Mensch und Umwelt