

ENVIRONMENTAL **NOOSE** GUIDELINES for the European Region





Abstract

Noise is an important public health issue. It has negative impacts on human health and well-being and is a growing concern. The WHO Regional Office for Europe has developed these guidelines, based on the growing understanding of these health impacts of exposure to environmental noise. The main purpose of these guidelines is to provide recommendations for protecting human health from exposure to environmental noise originating from various sources: transportation (road traffic, railway and aircraft) noise, wind turbine noise and leisure noise. They provide robust public health advice underpinned by evidence, which is essential to drive policy action that will protect communities from the adverse effects of noise. The guidelines are published by the WHO Regional Office for Europe. In terms of their health implications, the recommended exposure levels can be considered applicable in other regions and suitable for a global audience.

Keyword

NOISE – ADVERSE EFFECTS, PREVENTION AND CONTROL ENVIRONMENTAL EXPOSURE – ADVERSE EFFECTS, PREVENTION AND CONTROL GUIDELINES EUROPE

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Foreword

Noise is one of the most important environmental risks to health and continues to be a growing concern among policy-makers and the public alike. Based on the assessment threshold specified in the Environmental Noise Directive of the European Union (EU), at least 100 million people in the EU are affected by road traffic noise, and in western Europe alone at least 1.6 million healthy years of life are lost as a result of road traffic noise.

At the request of Member States at the Fifth Ministerial Conference on Environment and Health in Parma, Italy, in March 2010, the WHO Regional Office for Europe has developed these guidelines, based on the growing understanding of the health impacts of exposure to environmental noise. They provide robust public health advice, which is essential to drive policy action that will protect communities from the adverse effects of noise.

These WHO guidelines – the first of their kind globally – provide recommendations for protecting human health from exposure to environmental noise originating from various sources. They not only offer robust public health advice but also serve as a solid basis for future updates, given the growing recognition of the problem and the rapid advances in research on the health impacts of noise. The comprehensive process of developing the guidelines has followed a rigorous methodology; their recommendations are based on systematic reviews of evidence that consider more health outcomes of noise exposure than ever before. Through their potential to influence urban, transport and energy policies, these guidelines contribute to the 2030 Agenda for Sustainable Development and support WHO's vision of creating resilient communities and supportive environments in the European Region.

Following the publication of WHO's community noise guidelines in 1999 and night noise guidelines for Europe in 2009, these latest guidelines represent the next evolutionary step, taking advantage of the growing diversity and quality standards in this research domain. Comprehensive and robust, and underpinned by evidence, they will serve as a sound basis for action. While these guidelines focus on the WHO European Region and provide policy guidance to Member States that is compatible with the noise indicators used in the EU's Environmental Noise Directive, they still have global relevance. Indeed, a large body of the evidence underpinning the recommendations was derived not only from noise effect studies in Europe but also from research in other parts of the world – mainly in Asia, Australia and the United States of America.

I am proud to present these guidelines as another leading example of the normative work undertaken in our Region in the area of environment and health. On behalf of the WHO Regional Office for Europe and our European Centre for Environment and Health in Bonn, Germany, which coordinated the development of the guidelines, I would like to express my gratitude to the large network of experts, partners, colleagues and consultants who have contributed to this excellent publication. I would also like to thank Switzerland and Germany for providing financial support to this complex project, and look forward to following the influence of the guidelines on policy and research in the years to come.

Dr Zsuzsanna Jakab WHO Regional Director for Europe

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The WHO Regional Office for Europe, through its European Centre for Environment and Health, coordinated the development of these guidelines. The project was coordinated by Marie-Eve Héroux and Dorota Jarosinska, under the overall supervision of Elizabet Paunovic, Head of the European Centre for Environment and Health.

The members of the Steering Group were: Shelly Chadha, Carlos Dora, Rokho Kim, Jurgita Lekaviciute, Srdan Matic, Julia Nowacki, Poonum Wilkhu and Joerdis Wothge (see Annex 1 Table A1.1 for affiliations).

The members of the Guideline Development Group were: Stephen Stansfeld (Chair), Wolfgang Babisch, Goran Belojevic, Mark Brink, Sabine Janssen, Peter Lercher (2013–2014), Marco Paviotti, Göran Pershagen, Kerstin Persson Waye, Anna Preis, Martin van den Berg and Jos Verbeek (methodologist) (see Annex 1 Table A1.2 for affiliations).

The Systematic Review Team comprised the following experts: Mathias Basner, Lex Brown, Charlotte Clark, Payam Dadvand, Maria Foraster, Rainer Guski, Sarah McGuire, Mark Nieuwenhuijsen, Katarina Paunovic, Göran Pershagen, Gordana Ristovska, Maribel Casas Sanahuja, Dirk Schreckenberg, Rudolf Schuemer, Mariola Sliwinska-Kowalska, Kamil Rafal Zaborowski, Irene Van Kamp and Elise van Kempen (see Annex 1 Table A1.3 for affiliations).

The project's External Review Group had the following members: Gunn Marit Aasvang, Bernard Berry, Dick Botteldooren, Stephen Conaty, Yvonne de Kluizenaar, Ulrike Gehring, Truls Gjestland, Mireille Guay, Ayse Güven, Anna Hansell, Stelios Kephalopoulos, David Michaud, Arnaud Norena, Enembe Okokon, Dieter Schwela, Daniel Shepherd, Mette Sörensen, Rupert Thornley-Taylor and David Welch (see Annex 1 Table A1.4 for affiliations).

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Abbreviations

%HA	percentage of the population "highly annoyed"
%HSD	percentage of the population "highly sleep-disturbed"
BMI	body mass index
Cl	confidence interval
CNG	WHO guidelines for community noise
DALY	disability-adjusted life-year
dB	decibel
DW	disability weight
EC	European Commission
EEA	European Environment Agency
END	European Union Directive 2002/49/EC relating to the assessment and management of environmental noise (Environmental Noise Directive)
ERF	exposure-response function
EU	European Union
GDG	Guideline Development Group
GRADE	Grading of Recommendations Assessment Development and Evaluation
ICBEN	International Commission on Biological Effects of Noise
IHD	ischaemic heart disease
JRC	Joint Research Centre [of the European Commission]
mmHg	milimeters of mercury
NNG	WHO night noise guidelines for Europe
OR	odds ratio
PECCOS	population, exposure, comparator, confounder, outcome and study [framework]
PICOS	population, intervention, comparator, outcome and study [framework]
PLD	personal listening device
RANCH	Road traffic and aircraft noise exposure and children's cognition and health [study]
RCT	randomized control trial
RR	relative risk
SCENIHR	Scientific Committee on Emerging and Newly Identified Hazards and Risk

Glossary of acoustic terms

A-weighting	A frequency-dependent correction that is applied to a measured or calculated sound of moderate intensity to mimic the varying sensitivity of the ear to sound for different frequencies
C-weighting	A frequency-dependent correction that is applied to a measured or calculated sound of moderate intensity to mimic the varying sensitivity of the ear to sound for different frequencies – C-weighting is usually used for peak measurements
FAST	Fast response has a time constant of 125 milliseconds on a sound level meter
$L_{\rm Aeq,T}$	A-weighted, equivalent continuous sound pressure level during a stated time interval starting at t_1 and ending at t_2 , expressed in decibels (dB), at a given point in space ¹
L _{A,max}	Maximum time-weighted and A-weighted sound pressure level within a stated time interval starting at t_1 and ending at t_2 , expressed in dB ¹
L _{AF}	A-weighted sound pressure level with FAST time constant as specified in IEC 61672-11
$L_{\rm AF,max}$	Maximum time-weighted and A-weighted sound pressure level with FAST time constant within a stated time interval starting at t_1 and ending at t_2 , expressed in dB
$L_{\rm AS,max}$	Maximum time-weighted and A-weighted sound pressure level with SLOW time constant within a stated time interval starting at t_1 and ending at t_2 , expressed in dB
L _E	Sound energy density level is the logarithmic ratio of the time-averaged sound energy per unit volume to the reference sound energy density $Eo = 10-12 \text{ J/m}^3$.
L _{ex,8h}	$L_{_{ m eq}}$ (equivalent continuous sound level) corrected for the length of the working shift, in this case 8 hours
L _{day}	Equivalent continuous sound pressure level when the reference time interval is the day ¹
L _{den}	Day-evening-night-weighted sound pressure level as defined in section 3.6.4 of ISO 1996-1:2016 ¹
L _{dn}	Day-night-weighted sound pressure level as defined in section 3.6.4 of ISO 1996-1:2016 ¹
L _{evening}	Equivalent continuous sound pressure level when the reference time interval is the evening ¹

¹ Source: ISO (2016).

L _{night}	Equivalent continuous sound pressure level when the reference time interval is the night ¹
L _{peak,C}	Level of peak sound pressure with C-weighting, within a specified time interval
$L_{\rm peak,lin}$	Level of peak sound pressure with linear frequency weighting, within a specified time interval
Sound pressure level	the logarithm of the ratio of a given sound pressure to the reference sound pressure in dB is 20 times the logarithm to the base ten of the ratio.
SLOW	Slow response has a time constant of 10 000 milliseconds on a sound level meter

Executive summary

Environmental noise is an important public health issue, featuring among the top environmental risks to health. It has negative impacts on human health and well-being and is a growing concern among both the general public and policy-makers in Europe.

At the Fifth Ministerial Conference on Environment and Health in Parma, Italy, in 2010, WHO was requested by the Member States in the European Region to produce noise guidelines that included not only transportation noise sources but also personal electronic devices, toys and wind turbines, which had not yet been considered in existing guidelines. Furthermore, European Union Directive 2002/49/EC relating to the assessment and management of environmental noise (END) and related technical guidance from the European Environment Agency both elaborated on the issue of environmental noise and the importance of up-to-date noise guidelines.

The WHO Regional Office for Europe has therefore developed environmental noise guidelines for the European Region, proposing an updated set of public health recommendations on exposure to environmental noise.

Objectives

The main purpose of these guidelines is to provide recommendations for protecting human health from exposure to environmental noise originating from various sources: transportation (road traffic, railway and aircraft) noise, wind turbine noise and leisure noise. Leisure noise in this context refers to all noise sources that people are exposed to due to leisure activities, such as attending nightclubs, pubs, fitness classes, live sporting events, concerts or live music venues and listening to loud music through personal listening devices. The guidelines focus on the WHO European Region and provide policy guidance to Member States that is compatible with the noise indicators used in the European Union's END.

The following two key questions identify the issues addressed by the guidelines.

- In the general population exposed to environmental noise, what is the exposure-response relationship between exposure to environmental noise (reported as various indicators) and the proportion of people with a validated measure of health outcome, when adjusted for confounders?
- In the general population exposed to environmental noise, are interventions effective in reducing exposure to and/or health outcomes from environmental noise?

In light of these questions, the guidelines set out to define recommended exposure levels for environmental noise in order to protect population health.

Methods used to develop the guidelines

The process of developing the WHO guidelines followed a rigorous methodology involving several groups with separate roles and responsibilities. Throughout the process, the Grading of

Recommendations Assessment, Development and Evaluation (GRADE) approach was followed. In particular, the different steps in the development of the guidelines included:

- formulation of the scope and key questions of the guidelines;
- review of the pertinent literature;
- selection of priority health outcome measures;
- a systematic review of the evidence;
- assessment of certainty of the bodies of evidence resulting from systematic reviews;
- identification of guideline exposure levels; and
- setting of the strength of recommendations.

Based on the defined scope and key questions, these guidelines reviewed the pertinent literature in order to incorporate significant research undertaken in the area of environmental noise and health since the community noise guidelines and night noise guidelines for Europe were issued (WHO, 1999; WHO Regional Office for Europe, 2009). In total, eight systematic reviews of evidence were conducted to assess the relationship between environmental noise and the following health outcomes: cardiovascular and metabolic effects; annovance; effects on sleep; cognitive impairment; hearing impairment and tinnitus; adverse birth outcomes; and guality of life, mental health and wellbeing. A separate systematic review of evidence was conducted to assess the effectiveness of environmental noise interventions in reducing exposure and associated impacts on health.² Once identified and synthesized, the quality of the evidence of the systematic reviews was assessed by the Systematic Review Team. Subsequently, the Guideline Development Group (GDG) formulated recommendations, guided by the Systematic Review Team's assessment and informed by of a number of additional contextual parameters. To facilitate the formulation of recommendations, the GDG first defined priority health outcomes and then selected the most relevant health outcome measures for the outcomes. Consecutively, a process was developed to identify the guideline exposure levels with the help of the exposure-response functions provided by the systematic reviews. To reflect the nature of the research (observational studies) underpinning the relationship between environmental noise and health, the GRADE procedures were adapted to the requirements of environmental exposure studies where needed.

Noise indicators

From a scientific point of view, the best noise indicator is the one that performs best in predicting the effect of interest. There are, however, a number of additional criteria that may influence the choice of indicator. For example, various indicators might be suitable for different health end-points. Some considerations of a more political nature can be found in the European Commision's Position paper on EU noise indicators (EC, 2000).

² All systematic reviews are publicly available online in the *International Journal of Environmental Research and Public Health*. A detailed list of links to the individual reviews is provided in section 2.3.2 and in Annex 2 of these guidelines.

The current guidelines are intended to be suitable for policy-making in the WHO European Region. They therefore focus on the most used noise indicators L_{den} and/or L_{night} (see the glossary of acoustic terms for further details). They can be constructed using their components (L_{day} , $L_{evening}$, L_{night} and the duration in hours of L_{night}), and are provided for exposure at the most exposed façade, outdoors. The L_{den} and L_{night} indicators are those generally reported by authorities and are widely used for exposure assessment in health effect studies.

Recommendations

Specific recommendations have been formulated for road traffic noise, railway noise, aircraft noise, wind turbine noise and leisure noise. Recommendations are rated as either strong or conditional.

Strength of recommendation

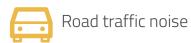
- A strong recommendation can be adopted as policy in most situations. The guideline is based on the confidence that the desirable effects of adherence to the recommendation outweigh the undesirable consequences. The quality of evidence for a net benefit – combined with information about the values, preferences and resources – inform this recommendation, which should be implemented in most circumstances.
- A **conditional** recommendation requires a policy-making process with substantial debate and involvement of various stakeholders. There is less certainty of its efficacy owing to lower quality of evidence of a net benefit, opposing values and preferences of individuals and populations affected or the high resource implications of the recommendation, meaning there may be circumstances or settings in which it will not apply.

Alongside specific recommendations, several guiding principles were developed to provide generic advice and support for the incorporation of recommendations into a policy framework. They apply to the implementation of all of the specific recommendations.

Guiding principles: reduce, promote, coordinate and involve

- Reduce exposure to noise, while conserving quiet areas.
- Promote interventions to reduce exposure to noise and improve health.
- Coordinate approaches to control noise sources and other environmental health risks.
- Inform and involve communities potentially affected by a change in noise exposure.

The recommendations, source by source, are as follows.



Recommendation	Strength
For average noise exposure, the GDG strongly recommends reducing noise levels produced by road traffic below 53 decibels (dB) <i>L</i> _{den} , as road traffic noise above this level is associated with adverse health effects.	Strong
For night noise exposure, the GDG strongly recommends reducing noise levels produced by road traffic during night time below 45 dB <i>L</i> _{night} , as night-time road traffic noise above this level is associated with adverse effects on sleep.	Strong
To reduce health effects, the GDG strongly recommends that policy- makers implement suitable measures to reduce noise exposure from road traffic in the population exposed to levels above the guideline values for average and night noise exposure. For specific interventions, the GDG recommends reducing noise both at the source and on the route between the source and the affected population by changes in infrastructure.	Strong



Railway noise

Reco	mmen	dation
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Recommendation		Strength
	For average noise exposure, the GDG strongly recommends reducing noise levels produced by railway traffic below 54 dB <i>L</i> _{den} , as railway noise above this level is associated with adverse health effects.	Strong
	For night noise exposure, the GDG strongly recommends reducing noise levels produced by railway traffic during night time below 44 dB <i>L</i> _{night} , as night-time railway noise above this level is associated with adverse effects on sleep.	Strong
	To reduce health effects, the GDG strongly recommends that policy- makers implement suitable measures to reduce noise exposure from railways in the population exposed to levels above the guideline values for average and night noise exposure. There is, however, insufficient evidence to recommend one type of intervention over another.	Strong



Recommendation	Strength
For average noise exposure, the GDG strongly recommends reducing noise levels produced by aircraft below 45 dB <i>L</i> _{den} , as aircraft noise above this level is associated with adverse health effects.	Strong
For night noise exposure, the GDG strongly recommends reducing noise levels produced by aircraft during night time below 40 dB <i>L</i> _{night} , as night-time aircraft noise above this level is associated with adverse effects on sleep.	Strong
To reduce health effects, the GDG strongly recommends that policy-makers implement suitable measures to reduce noise exposure from aircraft in the population exposed to levels above the guideline values for average and night noise exposure. For specific interventions the GDG recommends implementing suitable changes in infrastructure.	Strong



Recommendation	Strength
For average noise exposure, the GDG conditionally recommends reducing noise levels produced by wind turbines below 45 dB <i>L</i> _{den} , as wind turbine noise above this level is associated with adverse health effects.	Conditional
No recommendation is made for average night noise exposure L_{night} of wind turbines. The quality of evidence of night-time exposure to wind turbine noise is too low to allow a recommendation.	
To reduce health effects, the GDG conditionally recommends that policy- makers implement suitable measures to reduce noise exposure from wind turbines in the population exposed to levels above the guideline values for average noise exposure. No evidence is available, however, to facilitate the recommendation of one particular type of intervention over another.	Conditional

Leisure noise

Recommendation	Strength
For average noise exposure, the GDG conditionally recommends reducing the yearly average from all leisure noise sources combined to 70 dB <i>L</i> _{Ae} as leisure noise above this level is associated with adverse health effects The equal energy principle ³ can be used to derive exposure limits for othe time averages, which might be more practical in regulatory processes.	s,
For single-event and impulse noise exposures, the GDG conditionally recommends following existing guidelines and legal regulations to limit t risk of increases in hearing impairment from leisure noise in both childre and adults.	
Following a precautionary approach, to reduce possible health effects, the GDG strongly recommends that policy-makers take action to prever exposure above the guideline values for average noise and single-event and impulse noise exposures. This is particularly relevant as a large num of people may be exposed to and at risk of hearing impairment through use of personal listening devices. There is insufficient evidence, however recommend one type of intervention over another.	nber the

Target audience

The guidelines are published by the WHO Regional Office for Europe. In terms of their health implications, the recommended exposure levels can be considered applicable in other regions and suitable for a global audience, as a large body of the evidence underpinning the recommendations was derived not only from European noise effect studies but also from research in other parts of the world – mainly in America, Asia and Australia.

³ The equal energy principle states that the total effect of sound is proportional to the total amount of sound energy received by the ear, irrespective of the distribution of that energy in time (WHO, 1999).

1. Introduction

Environmental noise features among the top environmental risks to physical and mental health and well-being, with a substantial associated burden of disease in Europe (WHO Regional Office for Europe & JRC, 2011; Hänninen et al., 2014). It has negative impacts on human health and well-being and is a growing concern among both the general public and policy-makers in Europe.

WHO published community noise guidelines (CNG) and night noise guidelines (NNG) for Europe in 1999 and 2009, respectively (WHO, 1999; WHO Regional Office for Europe, 2009). Since then, significant new evidence has accumulated on the health effects of environmental noise.

The need for updated health-based guidelines originates in part from commitments made at the Fifth Ministerial Conference on Environment and Health in Parma, Italy, in 2010, where Member States asked WHO to produce appropriate noise guidelines that would include additional noise sources such as personal electronic devices, toys and wind turbines (WHO Regional Office for Europe, 2010). Furthermore, European Union (EU) Directive 2002/49/EC relating to the assessment and management of environmental noise (the END – EC, 2002a) and related technical guidance from the European Environment Agency (EEA) both elaborated on the issue of environmental noise and the importance of up-to-date noise guidelines (EEA, 2010).

The WHO Regional Office for Europe has therefore developed environmental noise guidelines for the European Region, proposing an updated set of public health recommendations on exposure to environmental noise. The main purpose of these guidelines is to provide recommendations for protecting human health from exposure to environmental noise originating from various sources: transportation (road traffic, railway and aircraft) noise, wind turbine noise and leisure noise. The guidelines focus on the WHO European Region and provide policy guidance to Member States that is compatible with the noise indicators used in the EU's END.

The following two key questions identify the issues addressed by the guidelines.

- In the general population exposed to environmental noise, what is the exposure-response relationship between exposure to environmental noise (reported as various indicators) and the proportion of people with a validated measure of health outcome, when adjusted for confounders?
- In the general population exposed to environmental noise, are interventions effective in reducing exposure to and/or health outcomes from environmental noise?

1.1 The public health burden from environmental noise

Exposure to noise can lead to auditory and nonauditory effects on health. Through direct injury to the auditory system, noise leads to auditory effects such as hearing loss and tinnitus. Noise is also a nonspecific stressor that has been shown to have an adverse effect on human health, especially following long-term exposure. These effects are the result of psychological and physiological distress, as well as a disturbance of the organism's homeostasis and increasing allostatic load (Basner et al., 2014). This is further outlined in the WHO narrative review of the biological mechanisms of nonauditory effects (Eriksson et al., 2018).

The evidence of the association between noise exposure and health effects is based on experimental work regarding biological plausibility and, in observational studies, consistency among study results, presence of an exposure–response relationship and the magnitude of the effect. Environmental noise risk assessment and risk management relies on established exposure–response relationships (Babisch, 2014).

In 2011 the WHO Regional Office for Europe and the European Commission (EC) Joint Research Centre (JRC) published a report on the burden of disease from environmental noise that quantified the healthy years of life lost in western Europeam countries as a result of environmental noise (WHO Regional Office for Europe & JRC, 2011). The burden of disease is calculated, in a single measure of disability-adjusted life-years (DALYs), as the sum of the years of life lost from premature mortality and the years lived with disability for people living with the disease or health condition or its consequences in the general population (WHO, 2014a).

Sufficient information was deemed available to quantify the burden of disease from environmental noise for cardiovascular disease, cognitive impairment in children, sleep disturbance, tinnitus and annoyance. The report, based on a limited set of data, estimated that DALYs lost from environmental noise in western European countries are equivalent to 61 000 years for ischaemic heart disease (IHD), 45 000 years for cognitive impairment in children, 903 000 years for sleep disturbance, 22 000 years for tinnitus and 654 000 years for annoyance (WHO Regional Office for Europe & JRC, 2011). These results indicate that at least one million healthy years of life are lost every year from traffic-related environmental noise in western Europe. Sleep disturbance and annoyance, mostly related to road traffic noise, constitute the bulk of this burden. Available assessments place the burden of disease from environmental noise as the second highest after air pollution (WHO Regional Office for Europe & JRC, 2011; Hänninen et al., 2014; WHO 2014b). However, a lack of noise exposure data in the central and eastern parts of the WHO European Region means that it is not possible to assess the burden of disease from environmental noise for the whole Region.

1.2 The environmental noise policy context in the EU

The EU has been working to develop a harmonized noise policy for more than two decades. 1993 saw the start of the EC's Fifth Environment Action Programme, which stated that "no person should be exposed to noise levels which endanger health and quality of life" (EC, 1993). This was followed by a Green Paper on future noise policy (EC, 1996), which reinforced the importance of noise as one of the main environmental problems in Europe and proposed a new framework for noise policy development.

The Sixth Environment Action Programme had as one of its objectives: "to achieve a quality of environment where the levels of man-made contaminants do not give rise to significant impacts on, or risks to, human health" (EC, 2002b). This paved the way for the Commission to adopt and implement the END in 2002 (EC, 2002a). The main aim of the Directive is "to define a common approach intended to avoid, prevent or reduce on a prioritized basis the harmful effects, including annoyance, due to exposure to environmental noise".

The END obliges the EC to adapt its Annexes I–III (I on noise indicators in addition to L_{den}^{4} and L_{night}^{5} , II on noise assessment methods and III on methods for assessing harmful effects of noise) to technical and scientific progress. While work on revising Annex II was finalized in 2015 and common noise assessment methods were introduced (EC, 2015), revisions of Annex III to establish methods to assess the harmful effects of noise only started in 2015. Annex III would primarily define what exposure–response relationships should be used to assess the effect of noise on populations. EU Member States have already expressed the view that the recommendations from these environmental noise guidelines for the WHO European Region will guide the revision of Annex III. Beside this main directive, few other legislative documents cover different noise sources and other related issues in the EU (EEA, 2014: Annex I).

The Seventh Environment Action Programme, which guides European environment policy until 2020 (EC, 2014a), is committed to safeguarding the EU's citizens from environment-related risks to health by ensuring that by 2020 "noise pollution in the Union has significantly decreased, moving closer to WHO-recommended levels". A particular requirement for achieving this is "implementing an updated EU noise policy aligned with the latest scientific knowledge, and measures to reduce noise at source, and including improvements in city design".

In addition to the EU's END, several national governments also have legislation and/or limit values that apply at national and/or regional levels (WHO Regional Office for Europe, 2012). The EEA, through its European Topic Centre on Land Use and Spatial Information, gathers noise exposure data and maintains the Noise Observation and Information Service for Europe, based on strategic noise maps provided by Member States (EEA, 2018). A total of 33 EEA countries, in addition to six cooperating countries in south-eastern Europe, report information on noise exposure to the EEA, following the requirements of the END. The quality and availability of noise exposure assessment differs between EU and non-EU Member States where, even if noise legislation has been harmonized with the Directive, noise mapping and action plans are still at the planning stage (EEA, 2014; 2017a; WHO Regional Office for Europe, 2012).

1.2.1 Definition of indicators in the END

The END specifies a number of noise indicators to be applied by Member States in noise mapping and action planning. The most important are L_{den} and L_{night} .

The L_{den} indicator is an average sound pressure level over all days, evenings and nights in a year (EEA, 2010). This compound indicator was adopted by the EU in the END (EC, 2002a). The L_{den} in decibels (dB) is defined by a specific formula, where:

- L_{day} is the A-weighted long-term average sound level as defined in ISO 1996-1: 2016, determined over all the day periods of a year;
- L_{evening} is the A-weighted long-term average sound level as defined in ISO 1996-1: 2016, determined over all the evening periods of a year; and
- L_{night} is the A-weighted long-term average sound level as defined in ISO 1996-1: 2016, determined over all the night periods of a year (ISO, 2016).

⁴ Day-evening-night-weighted sound pressure level as defined in section 3.6.4 of ISO 1996-1:20161 (ISO, 2016).

⁵ Equivalent continuous sound pressure level when the reference time interval is the night.

The L_{night} , according to the definition in the END, is an equivalent outdoor sound pressure level, measured at the most exposed façade, associated with a particular type of noise source during night time (at least eight hours), calculated over a period of a year (WHO Regional Office for Europe, 2009).

Annex I of the END gives technical definitions for L_{den} and L_{night} , as well as supplementary noise indicators, which might be useful for monitoring special noise situations. For example, in the case of noisy but short-lived noise like shooting noise or noise emitted by trains, $L_{A,max}$ is often used. This is a measure of the maximum sound pressure reached during a defined measurement period. It is used to set noise limits and is sometimes considered in studies to determine certain health effects (such as awakening reactions).

1.3 Perceptions of environmental noise in the WHO European Region

1.3.1 Trends at the regional level

The general population greatly values the benefits of clean and quiet environments. In Europe, people perceive noise as an important issue that affects human health and well-being (EC, 2008; 2014b). In recent years, several Europe-wide surveys have examined the perception of noise as an issue among the population. Overall, these surveys ask about generic noise, referring to "neighbourhood noise" or "noise from the street". This type of noise differs significantly in its definition from what is considered "environmental noise" in these guidelines. Nevertheless, in the absence of specific large surveys on perceptions of environmental noise as defined in these guidelines, the results provide insight into the public perception of this issue.

The European quality-of-life surveys, carried out every four years, are unique, pan-European surveys examining both the objective circumstances of lives of European citizens and how they feel about those circumstances and their lives in general. The last (fourth) survey was conducted in 2016–2017, involving nearly 37 000 citizens from all EU Member States and the five candidate countries (Albania, Montenegro, Serbia, the former Yugoslav Republic of Macedonia and Turkey). Respondents were asked whether they had major, moderate or no problems with noise in the immediate neighbourhood of their home. Almost one third (32%) reported problems with noise (ranging from 14% to 51% in individual countries), mainly in cities or city suburbs (49%) (Eurofound, 2017).

A 2010 survey of the then 27 countries in the EU, requested by the EC, showed that 80% of respondents ($n = 26\ 602$) believed that noise affects their health, either to some or to a great extent (EC, 2010).

A Eurobarometer report on attitudes of European citizens towards the environment (EC, 2014b) compiled opinions on various environmental risks from almost 28 000 respondents in 28 EU countries. Results showed that for 15% of respondents, noise pollution is one of the top five environmental issues they are worried about. Furthermore, 17% of respondents said that they lack information about noise pollution.

1.3.2 Trends at the national level

Data on perception of specific sources of environmental noise as a problem are not available for the entire WHO European Region. Nevertheless, some countries – including France, Germany, the Netherlands, Slovakia and the United Kingdom – conduct national surveys on noise annoyance, either regularly or on demand (Sobotova et al., 2006; Lambert & Philipps-Bertin, 2008; van Poll et al., 2011; Centraal Bureau voor de Statistiek, 2012; Notley et al., 2014; Umweltbundesamt, 2017).

According to these large-scale surveys, road traffic noise is the most important source of annoyance, generally followed closely by neighbour noise. Aircraft noise can also be a substantial source of annoyance. Railway noise and industrial noise are enumerated less frequently. Only limited data are available on the population's perception of newer sources of noise, such as wind turbines.

While perception surveys do not provide information on actual quantitative relationships between noise exposure and health outcomes, it is important to note that the results of such surveys represent people's preferences and values regarding environmental noise. Despite limitations and an incomplete picture, the available data on perception of environmental noise as a public health problem show concern in Europe. People are not always aware of the health impacts of noise, especially of those related to long-term noise exposure at lower levels. Greater awareness of the issue may further increase positive values and preferences.

1.4 Target audience

The environmental noise guidelines for the European Region serve as a reference for an audience made up of different groups, with varied areas of expertise including decision-making, research and advocacy. More specifically, this covers:

- various technical experts and decision-makers at the local, national or international levels, with responsibility for developing and implementing regulations and standards for noise control, urban planning and housing, and other relevant environment and health domains;
- health impact assessment and environmental impact assessment practitioners and researchers;
- national and local authorities responsible for developing and implementing relevant measures and for risk communication;
- nongovernmental organizations and other advocacy groups involved in risk communication and general awareness-raising.

These guidelines are published by the WHO Regional Office for Europe. In terms of their health implications, the recommended exposure levels can be considered applicable in other regions and suitable for a global audience, as a large body of the evidence underpinning the recommendations was derived not only from European noise effect studies but also from research in other parts of the world – mainly in America, Asia and Australia.

2. Development of the guidelines

2.1 Overview

The process of developing WHO guidelines follows a rigorous methodology and involves several groups with well defined roles and responsibilities (WHO, 2014c). These include: formulation of the scope and key questions of the guidelines; review of the pertinent literature; selection of priority health outcome measures; a systematic review of the evidence; an assessment of certainty of the bodies of evidence resulting from systematic reviews; identification of guideline exposure levels; and setting of the strength of recommendations. Throughout the process, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach was followed (Morgan et al., 2016).

The development of environmental noise guidelines started in 2013. Following WHO's procedures, the WHO Regional Office for Europe, through its European Centre for Environment and Health in Bonn, Germany, obtained planning approval and established a Steering Group and a Guideline Development Group (GDG). The former was primarily involved in initiating, structuring and executing the guideline development process; the latter was composed of leading experts and end-users, responsible for the process of scoping the guidelines and developing the evidence-based recommendations. During the initiation meeting in October 2013 in Bonn, the GDG members defined the scope of the guidelines, decided on the key questions to be addressed, prioritized health outcomes and set a timeline for completion of the work. Furthermore, authors were appointed for background papers, systematic reviews and different guideline background chapters.

In October 2014 a main evidence review meeting was held between the GDG and the Systematic Review Team in Bern, Switzerland, to discuss the evidence review drafts. In October 2014 and May 2015 the GDG met in Bern and Bonn, respectively, to refine the scope and draft recommendations. The revision and finalization of the systematic reviews of evidence was completed in early 2017. Through a series of remote meetings and teleconferences, the GDG discussed and addressed the remaining outstanding issues and feedback from the peer review of the draft guidelines, and decided on the final formulation of the recommendations. The following sections describe the steps of the guideline development process in detail.

2.2 Scope of the guidelines

Defining the scope of the guidelines included the selection of noise sources to be considered, as well as situations in which people are exposed, and noise indicators used for the formulation of recommendations. These guidelines separately consider outdoor exposure to environmental noise from road traffic, railway traffic, aircraft, wind turbines as well as outdoor and indoor exposure during leisure activities (such as attending nightclubs, pubs, fitness classes, live sporting events, concerts or live music venues and listening to loud music through personal listening devices). The guidelines are source specific and not environment specific. They therefore cover all settings where people spend a significant portion of their time, such as residences, educational institutions, workplaces and public venues, although hospital noise is exempted from the list of public institutions owing to the unique characteristics of the population involved.

The GDG agreed not to develop specific recommendations for occupational and industrial noise. Industrial noise can affect both people working at an industrial site and those living in its vicinity. The guidelines do not consider workers' exposure to noise in industrial environments, as these are regulated by workplace standards and may, in some cases, require the wearing of protective equipment or application of other preventive and protective measures. Further, the guidelines do not explicitly consider industrial noise as an environmental noise source, affecting people living in the vicinities of industrial sites. This is mainly due to the large heterogeneity and specific features of industrial noise, and the fact that exposure to industrial noise has a very localized character in the urban population.

Likewise, the current guidelines do not provide specific recommendations for the prevention of health effects linked to neighbourhood noise. Neighbourhood noise may stem from various potential sources of noise (such as ventilation systems; church bells; animals; neighbours; commercial, recreational and occupational activities; or shooting/military). As the sources may be located in close proximity to where people live, they can cause considerable concern even at low levels (Omlin et al., 2011). Several of these sources can also produce low-frequency noise, and as such, require indoor measurements for proper exposure assessment. In general, little scientific research is available on exposure and health outcomes related to neighbourhood noise.

Moreover, the guidelines do not include recommendations about any kind of multiple exposures. In everyday life people are often exposed to noise from several sources at the same time. In Germany, for example, 44% of the population are annoyed by at least two and up to five sources of noise (Umweltbundesamt, 2015). For some health outcomes, such as obesity, new evidence indicates that combined exposure to noise from several means of transportation is particularly harmful (Pyko et al., 2015; 2017).

Research indicates that, alongside exposure to more than one source of noise, combined exposure to different factors – for example, noise and vibration or noise and air pollution – has gained increasing relevance in recent years (Sörensen et al., 2017). The EC estimates that the social cost of noise and air pollution is up to €1 trillion every year (EC, 2016a). WHO acknowledges the need to develop comprehensive models to quantify the effects of multiple exposures on human health. As the main body of evidence on environmental noise still focuses on source-specific impacts of noise on health outcomes and does not incorporate combined exposure effects of multiple noise sources or other pollutants, however, the current guidelines provide recommendations for each source of noise specifically. No attempt has been made to combine noise from multiple sources for any particular health outcome.

2.2.1 Key questions

The environmental noise guidelines for the WHO European Region seek to address two main questions, which define the issues addressed by the guideline recommendations.

- In the general population exposed to environmental noise, what is the exposure-response relationship between exposure to environmental noise (reported as various indicators) and the proportion of people with a validated measure of health outcome, when adjusted for confounders?
- In the general population exposed to environmental noise, are interventions effective in reducing exposure to and/or health outcomes from environmental noise?

2.2.2 Environmental noise indicators used in the guidelines

From a scientific point of view, the best noise indicator is the one that performs best in predicting the effect of interest. There are, however, a number of additional criteria that may influence the choice of indicator because, for example, various indicators might be suitable for different health end-points and some indicators are more practical to use or easier to calculate than others. Some of these considerations are of a more political nature, as mentioned in the EC's Position paper on EU noise indicators (EC, 2000).

The current guidelines are intended to be suitable for policy-making primarily in the WHO European Region. They are therefore based on the most frequently used average noise indicators in Europe: L_{den} and L_{night} . These are often reported by authorities and are used widely for exposure assessment in health effect studies and noise impact assessments in the Region. The L_{den} (also referred to as "DENL") indicator can be calculated as the A-weighted average sound pressure level, measured over a 24-hour period, with a 10 dB penalty added to the average level in the night (23:00–07:00 or 22:00–06:00), a 5 dB penalty added to the evening (19:00–23:00 or 18:00–22:00) and no penalty added to the daytime period (07:00–19:00 or 06:00–18:00). The penalties are introduced to indicate people's extra sensitivity to noise during the evening and night. The L_{night} indicator is the A-weighted average sound pressure level, usually between 23:00 and 07:00 (EC, 2002a).

In these guidelines, L_{den} and L_{night} refer to a measurement or calculation of noise exposure at the most exposed façade, outdoors, reflecting the long-term average exposure. Thus, L_{den} and L_{night} represent all the single noise events due to a specific noise source that occur over a longer period of time, such as during a year. Moreover, most health outcomes considered in these guidelines are expected to occur as a result of long-term exposure. It is generally accepted that the most relevant parts of the whole day or night, which especially account for the time when a person is at home, are correctly attributed when using average indicators like L_{den} or L_{night} .

The majority of studies that form the body of evidence for the recommendations in these guidelines – among them large-scale epidemiological studies and socioacoustic surveys on annoyance and self-reported sleep disturbance – refer to noise exposure measured outdoors, usually at the most exposed façade of dwellings. Virtually all noise exposure prediction models in use today estimate free-field exposure levels outdoors, and most noise abatement regulations refer to outdoor levels as well. These are the practical reasons why the GDG decided not to recommend any guideline values for noise indoors. Nevertheless, in certain cases it could be helpful to estimate indoor levels based on outdoor values. The differences between indoor and outdoor levels are usually estimated at around 10 dB for open, 15 dB for tilted or half-open and about 25 dB for closed windows. When considering more accurate estimation of indoor levels, using a range of different predictors, the relevant scientific literature can be consulted (Locher et al., 2018).

The GDG was aware of the fact that many countries outside the EU are not bound by the terms of the END (EC, 2002a) and/or use noise indicators other than L_{den} or L_{night} in their noise regulations. They still can make use of these guidelines, however, because energy-based average noise indicators are usually highly correlated and "rule of thumb" transformations from one indicator to another are possible with acceptable uncertainty, as long as the conversion accounts for the long-term average

of populations, rather than individual exposure situations. Empirically derived generic conversion terms between a wide range of different noise indicators (including L_{den} , L_{dn} , L_{day} , L_{night} and $L_{Aeq,24h}$; see the glossary of acoustic terms for further details), with their uncertainty estimates, were published recently (Brink et al., 2018). The GDG encourages the use of these conversions, should the need arise.

In many situations, average noise levels like the L_{den} or L_{night} indicators may not be the best to explain a particular noise effect. Single-event noise indicators – such as the maximum sound pressure level $(L_{A,max})^6$ and its frequency distribution – are warranted in specific situations, such as in the context of night-time railway or aircraft noise events that can clearly elicit awakenings and other physiological reactions that are mostly determined by $L_{A,max}$. Nevertheless, the assessment of the relationship between different types of single-event noise indicators and long-term health outcomes at the population level remains tentative. The guidelines therefore make no recommendations for single-event noise indicators.

Different noise sources – for example, road traffic noise and railway noise – can be characterized by different spectra, different noise level rise times of noise events, different temporal distributions of noise events and different frequency distributions of maximum levels. Because of the extensive differences in the characteristics of individual noise sources, these guidelines only consider source-specific exposure–response functions (ERFs) and, therefore, formulate only source-specific recommendations.

2.3 Evidence base

Based on the overall scope and key questions the current guidelines review the relevant literature in the area of environmental noise and health in order to incorporate significant research undertaken since the publication of previous guidelines. The process of evidence search and retrieval involved several steps. These include the identification, retrieval and synthesis of the evidence, followed by a systematic review and assessment (described in section 2.4).

2.3.1 Identification, retrieval and synthesis of evidence

As a first step, the GDG identified key health outcomes associated with environmental noise. Next, it rated the relevance of these health outcomes according to the following three categories:

- critical for assessing environmental noise issues
- important, but not critical for assessing environmental noise issues
- unimportant.

The GDG rated the relevance based on the seriousness and prevalence of the outcomes and the anticipated availability of evidence for an association with noise exposure. The following health outcomes were selected as either critical or important for developing recommendations on the health impacts of environmental noise.

⁶ L_{A,max} is the maximum time-weighted and A-weighted sound pressure level within a stated time interval starting at t1 and ending at t2, expressed in dB.

Critical health outcome Cardiovascular disease Annoyance⁷ Effects on sleep Cognitive impairment Hearing impairment and tinnitus

Important health outcome Adverse birth outcomes Quality of life, well-being and mental health Metabolic outcomes

The GDG noted that research into the relationship between noise exposure and its effects on humans brings into focus several questions concerning the definition of health and the boundary between normal social reaction to noise and noise-induced ill health. As stated in WHO's Constitution: "Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" (WHO, 1946). Accordingly, documenting physical health does not present a complete picture of general health; and being undisturbed by noise in all activities, including sleep, constitutes an asset worthy of protection. Therefore, in accordance with the above definition, the GDG regarded (long-term) annoyance and impaired well-being, as well as self-reported sleep disturbance due to noise, as health outcomes.

Regarding sleep disturbance, the health outcome measures considered in these guidelines largely disregard "objective" indicators of sleep disturbance, such as the probability of awakening reactions or other polysomnography parameters. The main reason for this is the nature of the body of evidence on acute, objectively measured effects of noise during sleep. Studies of physiological effects of sleep and especially polysomnographic investigations are complex and resource-demanding; they therefore include only a small number of participants, who are often healthy young volunteers not representative of the general population. For these reasons, the majority of such studies do not meet the requirements for inclusion in the GRADE framework and full-scale meta-analysis, including adjustment for confounders. Furthermore, it is currently unclear how acute physiological reactions that affect the microstructure of sleep but are less well correlated with global sleep parameters, such as total sleep time, are related to long-term health impediments, especially considering the large interindividual differences in susceptibility to noise (Basner et al., 2011).

As sleeping satisfies a basic need and the absence of undisturbed sleep can have serious effects on human health (WHO Regional Office for Europe, 2009), the GDG set self-reported sleep disturbance, in line with the WHO definition of health, as a primary health outcome. Even though self-reported sleep disturbance might differ considerably from objectively measured parameters of sleep physiology, it constitutes a valid indicator in its own right, as it reflects the effects on sleep perceived by an individual over a longer period of time (WHO Regional Office for Europe & JRC, 2011). The importance of considering both annoyance and self-reported sleep disturbance as health outcomes is further supported by evidence indicating that they may be part of the causal pathway of noise-induced cardiovascular and metabolic diseases. This is further elaborated in the narrative review on biological mechanisms (Eriksson et al., 2018).

⁷ Noise annoyance is defined as a feeling of displeasure, nuisance, disturbance or irritation caused by a specific sound (Ouis, 2001). In the current guidelines, "annoyance" refers to long-term noise annoyance.

The second step in the evidence retrieval process constituted formulation of the key questions for the critical and important health outcomes and identification of the areas of evidence to be reviewed, following the PICOS/PECCOS approach defined in the WHO handbook for guideline development (WHO, 2014c). PICOS/PECCOS is an evidence-based technique that frames health care-related questions to facilitate the search for suitable studies that can provide answers to the questions at hand (Huang et al., 2006). The PICOS approach divides intervention questions into five elements: population, intervention, comparator, outcome and study design. In exposure studies, PICOS becomes PECCOS, which stands for population, exposure, comparator, confounder, outcome and study design. The specification of the elements of PICOS/PECCOS serves to construct the body of evidence that underpins each recommendation. Due to the complex nature of environmental noise, several distinct areas of evidence were defined to address each of the scoping questions comprehensively.

For each of the critical and important health outcomes a systematic review was conducted (see also section 2.3.2). Health outcomes regarded as important were given less weight in the decision-making process than critical ones. Inclusion and exclusion criteria to be regarded in the systematic evidence reviews were defined in accordance with the PICOS/PECCOS framework for the evaluation of evidence (see Table 1). All evidence that met the inclusion criteria was included in the systematic reviewing process. A detailed description of the types of measure for each of the health outcomes under consideration is provided in the protocol for conducting the systematic reviews (Héroux & Verbeek, 2018a). See Annex 2 for details of all background documents and systematic reviews used in preparation of these guidelines.

Category	Inclusion criteria	Exclusion criteria	
Populations	 Members of the general population Specific segments of the population particularly at risk 	Does not meet inclusion criteria	
	 (children or vulnerable groups) People exposed to noise in occupational settings (if relevant with combined exposure to environmental noise) 		
Exposure	 Noise exposure levels, either measured or calculated and expressed in dB values 	Does not meet inclusion criteria; in particular:	
	 Representative of the individual exposure of study participants (for most observational studies the dwelling location or home) 	 studies using hearing loss or hearing impairment as a proxy for (previous) noise exposure 	
	• Calculated levels for transportation noise (road, rail, air) based on traffic data reflecting the use of roads, railway lines and in- and outbound flight routes at airports	 surveys assessing noise exposure or number of listening hours based on subjective ratings given by subjects in a questionnaire 	
Confounders	 No inclusion criteria applied since the relationship between exposure to noise and a health outcome can be confounded by other risk factors; however, possible confounders taken into account were assessed for every study 	 No exclusion criteria applied; however, possible confounders taken into account were assessed for every study 	

Table 1. Inclusion and exclusion criteria for evidence reviews of health effects of environ	mental
noise	

Table 1. contd.

Category	Inclusion criteria	Exclusion criteria
Outcomes	Adverse birth outcomes	Does not meet inclusion criteria
	Annoyance	
	Cardiovascular disease	
	Cognitive impairment	
	Effects on sleep	
	 Hearing impairment and tinnitus 	
	Metabolic outcomes	
	 Quality of life, mental health and well-being 	
Study types	Cohort studies	Does not meet inclusion criteria
	Case-control studies	
	Cross-sectional studies	
	• Ecological studies (only for cardiovascular disease)	

Alongside the systematic reviews of the critical and important health outcomes, the GDG decided to review the evidence on health effects from noise mitigation measures and interventions to reduce noise levels in order to inform and complement the recommendations.

Interventions on environmental noise were defined according to five broad categories based on the available intervention literature and the experience of decades of environmental noise management (see Table 2 and Brown & van Kamp, 2017).

Table 2. Types of noise intervention

Intervention type	Intervention category	Intervention subcategory
A Source intervention		change in emission levels of sources
	 time restrictions on source operations 	
B Path intervention		 change in the path between source and receiver
	 path control through insulation of receiver/receiver's dwelling 	
C New/closed infrastructure	 opening of a new infrastructure noise source 	
	closure of an existing one	
	 planning controls between (new) receivers and sources 	
D	Other physical intervention	 change in other physical dimensions of dwelling/neighbourhood
E Behaviour cha intervention	Behaviour change	 change in individual behaviour to reduce exposure
	intervention	 avoidance or duration of exposure
		community education, communication

The GDG recognized that nonacoustic factors are an important possible confounder in both ERFs between noise levels and critical health effects and the effects of acoustic interventions on health outcomes. Whereas the inclusion criteria for confounders were not specified in PECCOS for the systematic reviews of evidence, they were considered at the stage of assessing the quality of

evidence, using the GRADE approach. Depending on the health effect under investigation, possible nonacoustic factors may include:

- gender
- age
- education
- subjective noise sensitivity
- extroversion/introversion
- general stress score
- co-morbidity
- length of residence
- duration of stay at dwelling in the day
- window orientation of a bedroom or living room towards the street
- personal evaluation of the source
- attitudes towards the noise source
- · coping capacity with respect to noise
- perception of malfeasance by the authorities responsible
- body mass index
- smoking habits.

In noise annoyance studies nonacoustic factors may explain up to 33% of the variance (Guski, 1999). The higher the quality of evidence, the lower confounding effects of nonacoustic factors may be expected. Nevertheless, as with measurement errors, confounding cannot be avoided.

Based on the retrieval and evaluation of the pertinent literature, the GDG decided to address the association of environmental noise from different sources and health outcomes separately and individually for each source of noise, and for critical and important health outcomes.

In addition to the systematic reviews of the health effects of environmental noise, a narrative review of biological mechanisms of nonauditory effects was conducted (Eriksson et al., 2018). This covers literature related to pathways for nonauditory effects and provides supporting evidence on the association between environmental noise and health outcomes in humans, especially related to cardiovascular and metabolic diseases.

2.3.2 Systematic reviewing process

After the retrieval of the evidence based on the PICOS/PECCOS approach, systematic reviews were conducted for all critical and important health outcomes. To meet the demands of the diverse and broad nature of the evidence, it was agreed that systematic reviews could vary in type. For some areas of evidence, a novel and fully fledged systematic reviewing process was needed to summarize the existing evidence; for others, the reviewing process could build upon existing (and mostly published) systematic reviews and summarise of evidence. Thus, the process consisted of two phases.

First, a comprehensive search was conducted for available systematic reviews and meta-analyses on environmental noise effects published after 2000. Each of the reviews was assessed for both relevance and quality. To be included in the evidence review process, studies from these reviews were required to meet a high quality standard, judged according to high scores of the AMSTAR checklist.⁸ In cases where quality criteria were met but the review was older than two years (published before 2012), the search of the systematic review was updated to include new papers. If no good quality systematic reviews were available, a new search for original papers was conducted. The Systematic Review Team decided how the results would affect the search strategy for individual studies as part of the second phase. This was based on the assessment of the quality of the systematic reviews and on the coherence between the main research questions of the systematic reviews and the scope of the work of the guidelines.

In the second phase a search for individual papers was conducted, with the search strategy adapted according to the outcome of the first phase. As availability of systematic reviews and meta-analyses differed for the various health outcomes considered in the guidelines, this process varied for each evidence review. The search included cohort studies, case-control studies and cross-sectional studies of people exposed to environmental noise. Where relevant – for example, for the health outcome cardiovascular disease – the search also included ecological studies.

Due to the individualized retrieval of evidence for each of the systematic reviews, the time frames of the literature included varied. An indication of the temporal coverage of the studies included in different systematic review is provided in the relevant tables in Chapter 4.

A detailed description of the methodology used to conduct the systematic evidence reviews, including individual protocols for the reviews of health effects resulting from environmental noise and from noise interventions, is available (Héroux & Verbeek, 2018b). Furthermore, all systematic reviews conducted in the guideline development process are publicly available in the open-access journal *International Journal of Environmental Research and Public Health*:

- systematic review of transport noise interventions and their impacts on health (Brown & van Kamp, 2017);
- systematic review on environmental noise and adverse birth outcomes (Nieuwenhuijsen et al, 2017);
- systematic review on environmental noise and annoyance (Guski et al., 2017);
- systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018);
- systematic review on environmental noise and cognition (Clark & Paunovic, 2018);
- systematic review on environmental noise and effects on sleep (Basner & McGuire, 2018);
- systematic review on environmental noise and permanent hearing loss and tinnitus (Śliwińska-Kowalska & Zaborowski, 2017);
- systematic review on mental health and well-being (Clark & Paunovic, in press).

⁸ AMSTAR is an instrument used to assess quality of evidence; it stands for "A MeaSurement Tool to Assess systematic Reviews" (Shea et al., 2007).

2.4 From evidence to recommendations

Once the evidence had been identified and synthesized, the Systematic Review Team assessed its quality. Subsequently, the GDG formulated recommendations, guided by this assessment and consideration of a number of other factors recognized as important. To facilitate the formulation of recommendations, it first prioritized the health outcome measures of the critical and important outcomes. A process was developed to identify the guideline exposure levels from each of the ERFs provided by the systematic reviews of evidence.

The following sections describe the assessment of the overall quality of the evidence based on the GRADE approach, selection of priority health outcome measurements, identification of guideline exposure levels and setting the strength of recommendations.

2.4.1 Assessment of overall quality of a body of evidence: the GRADE approach

As set out in the WHO handbook for guideline development (WHO, 2014c), the main framework for producing evidence-informed recommendations is the GRADE approach (Guyatt et al., 2008). This is used to assess the quality of a body of evidence synthesized in a systematic review. The assessment facilitates judgements about the certainty of effect estimates, which increases with the quality of the body of evidence. The quality can be rated high, moderate, low or very low (see Box 1).

Box 1 GRADE interpretations of quality of evidence

- High quality: further research is very unlikely to change the certainty of the effect estimate
- **Moderate quality:** further research is likely to have an important impact on the certainty of the effect estimate and may change the estimate
- Low quality: further research is very likely to have an important impact on the certainty of the effect estimate and is likely to change the estimate
- Very low quality: any effect estimate is uncertain

The original GRADE approach was developed specifically to rate the body of evidence resulting from a review of intervention studies. The initial quality level is set by study design: randomized control trials (RCTs) are considered high quality, whereas observational (nonrandomized) study designs are low quality. Then five factors are considered for downgrading the quality of the body of evidence resulting from RCTs or observational studies, and three factors are considered for upgrading the body of evidence resulting from observational studies alone.

The following five factors are used for downgrading the quality of evidence by one or two levels:

- study limitations or risk of bias in all studies that make up the body of evidence
- inconsistency of results between studies
- indirectness of evidence in the studies
- imprecision of the pooled effect estimate
- publication bias detected in a body of evidence.

The following three factors are used for upgrading the quality of evidence:

- high magnitude of the pooled effect
- direction of residual confounding and biases opposes an effect (i.e. when all plausible confounders are anticipated to reduce the estimated effect and there is still a significant effect)
- exposure-response gradient.

The GRADE approach was originally developed for application in the field of clinical medicine, where the majority of studies are randomized trials. However, to assess health effects resulting from an exposure such as environmental noise, randomized controlled trials are not applicable, as it would be unethical to expose participants deliberately to possibly harmful risk factors. The limitations of the application of GRADE to environmental health have been recognized and discussed in the literature (Morgan et al., 2016). Other types of study design dominate the evidence base in the domain of environmental noise research, so it was necessary to adapt the original GRADE approach to the subject of the current guidelines, as follows.

Instead of using the RCT study design as the starting-point for the quality rating, the study design most applicable and available for the field of research at hand was used. Thus, for evidence on the association between noise exposure and clinical health outcome measures, the rating of an evidence base consisting of cohort and case-control studies⁹ was initially rated high quality. Cross-sectional studies and ecological studies were rated low quality and very low quality, respectively. This initial point of departure was only adapted for the evidence of the association between noise exposure and annoyance and sleep disturbance. Here, cross-sectional studies were rated high quality because annoyance and sleep disturbance are regarded as an immediate effect of exposure to environmental noise. Finally, in accordance with the original GRADE approach, the starting-point for evidence on the effect of interventions was rated low quality for observational studies. After determining the point of departure, the evidence base was rated down or up whenever one or more of the criteria for downgrading or upgrading (described above) were met. Each of the systematic reviews commissioned for these guidelines includes a detailed report on the assessment of the quality of the evidence.

A detailed discussion of the adaptations of GRADE is provided in the separate methodology publication (Héroux & Verbeek, 2018b).

2.4.2 Selection of priority health outcomes

In line with the WHO handbook for guideline development (WHO, 2014c), the GDG selected the key health outcomes associated with environmental noise at the beginning of the evidence retrieval process, and the systematic reviews were commissioned accordingly. The selection of health outcomes was based on the available evidence for the association between environmental noise and the specific outcome, as well as public concern about the health outcome resulting from noise exposure. The following health outcomes were rated critical: cardiovascular disease, annoyance,

⁹ In the context of the current guidelines, "cohort studies" refer to longitudinal studies in which the occurrence of the outcome of interest in an exposed group is compared to the occurrence of that outcome in a reference group with no or lower exposure over time.

effects on sleep, cognitive impairment and hearing impairment and tinnitus. Adverse birth outcomes, quality of life, well-being and mental health, and metabolic outcomes were rated important (see also section 2.3.1).

Since all these health outcomes can be measured in various ways, the GDG evaluated each individually and prioritized different outcome measures for each in terms of their representativeness and validity. These measures were used to derive the guideline exposure levels; their prioritization was based on the impact of the disease and the disability weights (DWs) associated with the health outcome measure.¹⁰

The critical health outcomes, priority outcome measures identified and justifications for their selection are listed in Table 3.

Critical health outcome	Critical health outcome measures (priority measures marked in bold)	Justification for selection
Cardiovascular disease (L _{den})	 Self-reported or measured prevalence, incidence, hospital admission or mortality due to: ischaemic heart disease (IHD) (including angina pectoris and/or myocardial infarction) hypertension stroke 	Except for self-reports, these are objective measures of the outcome, affect a large proportion of the population, have important health consequences and can lead to more severe diseases and/or mortality. DW for IHD: 0.405. DW for hypertension: 0.117.
Effects on sleep (L _{night})	 percentage of the population highly sleep-disturbed (%HSD), self-reported, assessed with a standardized scale polysomnography measured outcomes (probability of additional awakenings) cardiac and blood pressure outcome measures during sleep motility measured sleep outcomes in adults sleep disturbance in children 	This is the most meaningful, policy-relevant measure of this health outcome. Self-reported sleep disturbances are a very common problem in the general population: they affect quality of life directly and may also lead to subsequent health impediments. Effects on sleep may be in the causal pathway to cardiovascular disease. This measure is not a proxy for physiological sleep quality parameters but is an important outcome in its own right. DW for %HSD: 0.07.
Annoyance (L _{den})	 percentage of the population highly annoyed (%HA), assessed with standardized scale percentage annoyed, preferably assessed with standardized scale 	This is the most objective measure of this health outcome. Large proportions of the population are affected by noise annoyance, even at relatively low exposure levels. Annoyance may be in the causal pathway to cardiovascular disease. DW for %HA: 0.02.

Table 3. Critical health outcomes, outcome measures identified and justifications for selection

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¹⁰ DWs are ratings that vary between 0 and 1, in which 0 indicates no disability and 1 indicates the maximum amount of disability. The rates are derived from large population surveys in which people are asked to rank a specific disease for its impact on several abilities. The DWs have been proven useful in calculating the burden of disease.

Table 3. contd.

Critical health outcome	Critical health outcome measures (priority measures marked in bold)	Justification for selection
Cognitive impairment (L _{den})	 reading and oral comprehension, assessed with tests impairment assessed with standardized tests short and long-term memory deficit attention deficit executive function deficit (working memory approxim) 	This outcome measure is the most meaningful: it can affect vulnerable individuals (children) and have a significant impact later in life. DW for impaired reading and oral comprehension: 0.006.
Hearing impairment and tinnitus $(L_{Aeq}^{11} \text{ and } L_{AF,max}^{12})$	 memory capacity) permanent hearing impairment, measured by audiometry permanent tinnitus 	This outcome measure can affect vulnerable individuals (children) and have a significant impact later in life. It is the most objective measure for which there is an ISO standard (ISO, 2013), specifying how to estimate noise-induced hearing loss. DW for mild severity level (threshold at 25 dB) for childhood onset: 0.0150.

Table 4 provides a list of the important health outcomes along with the corresponding health outcome measures included in the systematic reviews. There was no prioritization of health outcome measures leading to justification of selection, since important health outcomes had less impact on the development of recommendations.

Table 4. Important health outcomes and health outcome measures reviewed

Important health outcome	Health outcome measures reviewed			
Adverse birth outcomes	pre-term delivery			
(L _{den})	low birth weight			
	congenital anomalies			
Quality of life, well-being and	self-reported health and quality of life			
mental health	 medication intake for depression and anxiety 			
(L _{den})	 self-reported depression, anxiety and psychological distress 			
	 interviewer-assessed depressive and anxiety disorders 			
	 emotional and conduct disorders in children 			
	children's hyperactivity			
	other mental health outcomes			
Metabolic outcomes	prevalence, incidence, hospital admission or mortality due to:			
(L _{den})	• type 2 diabetes			
	• obesity			

¹¹ L_{Aeq} is an A-weighted, equivalent continuous sound pressure level during a stated time interval starting at t1 and ending at t2, expressed in dB, of a noise at a given point in space.

¹² L_{AF,max} is the maximum time-weighted and A-weighted sound pressure level with FAST time constant within a stated time interval starting at t1 and ending at t2, expressed in dB.

2.4.3 Identification of guideline exposure levels for each noise source

The GDG agreed to set guideline exposure levels based on the definition: "noise exposure levels above which the GDG is confident that there is an increased risk of adverse health effects". The identification of guideline values for each of the specific noise sources involved five distinct steps:

- 1. assessment of the validity of ERFs resulting from the systematic reviews of the effects of noise on each of the critical and important health outcomes;
- 2. assessment of the lowest noise level measured in the studies included in each of the corresponding systematic reviews;
- 3. assessment of the smallest risk or relative risk (RR) increase for each of the adverse health outcomes considered relevant;
- determination of the guideline exposure level based on the ERF, starting from the lowest level measured (see step 2) and associated with the smallest relevant risk increase for adverse health outcomes (see step 3);
- 5. comparison of the guideline exposure levels calculated for each of the critical health outcomes of one source (for example, incidence of IHD, incidence of hypertension, %HA, permanent hearing impairment and reading and oral comprehension for road traffic noise): selection of the guideline exposure level for each noise source was based on the priority health outcome measure with the lowest exposure level for that source.

To define an "increased risk" to set the guideline exposure level, the GDG made a judgement about the smallest risk or RR of the adverse health effect it considered relevant for each of the priority health outcome measures. It is important to note that the relevant risk increases are benchmark values. The GDG agreed to set them in accordance with the guiding principles it had developed, to provide guideline values that illustrate an increased risk of adverse health effects. It used expert judgements for the determination of the benchmark values; these are elaborated further in section 2.4.3.2.

The guideline exposure levels presented are therefore not meant to identify effect thresholds (the lowest observed adverse effect levels for different health outcomes). This is a difference in approach from prior WHO guidelines, like the night noise guidelines for Europe (WHO Regional Office for Europe, 2009), which explicitly aimed to define levels indicating no adverse health effects. The approach to making choices about relevant risk increases is outlined below and summarized in Table 5.

For IHD and hypertension, RR increases were considered; for annoyance and sleep disturbance, absolute risks of %HA and %HSD were considered; and for reading and oral comprehension an average delay of reading age was defined. For the cardiovascular outcomes, incidence measures were prioritized, although much of the epidemiological evidence was based on prevalence data – particularly for hypertension – where almost no longitudinal studies were available. Prevalence data are generally derived from cross-sectional studies, where the temporal aspects are difficult to determine.

Priority health outcome measure (associated DW)	Relevant risk increase considered for setting of guideline level
Incidence of IHD (DW: 0.405)	5% RR increase
Incidence of hypertension (DW: 0.117)	10% RR increase
%HA (DW: 0.02)	10% absolute risk
%HSD (DW: 0.07)	3% absolute risk
Permanent hearing impairment (DW: 0.0150)	No risk increase due to environmental noise
Reading and oral comprehension (DW: 0.006)	One-month delay in terms of reading age

Table 5. Priority health outcomes and relevant risk increases for setting guideline levels

The DWs used to rank the priority critical health outcomes measures were retrieved from the relevant literature. For cardiovascular disease as a group and for hypertension, the burden of disease from environmental noise values (WHO Regional Office for Europe & JRC, 2011) were not considered applicable by the GDG for these guidelines. Thus, for cardiovascular disease, the DW value (DW: 0.405) specifically applied to acute myocardial infarction in the publication outlining the data sources, methods and results of the global burden of disease in 2002 (Mathers et al., 2003) was retained. Since hypertension is mainly viewed as an important risk factor and not as a health outcome, no general DW has been developed. The only other available DW value available is the DW of 0.117 for hypertensive episodes in pregnancy (Mathers et al., 1999). In the absence of any general DW, the GDG agreed on a conservative approach and decided to use this value.

The DWs for high sleep disturbance (DW: 0.07), high annoyance (DW: 0.02) and impaired reading and oral comprehension (DW: 0.006) were developed in the context of calculating the burden of disease from environmental noise (WHO Regional Office for Europe & JRC, 2011). The DW for hearing impairment was not included in that publication, but it was available from the technical paper on the burden of disease from environmental noise (WHO, 2013); the DW for permanent hearing impairment ranged from 0.0031 to 0.3342, depending on severity level. Environmental noise (leisure noise) contributes to the cumulative total noise exposure throughout the life-course, which may lead to permanent hearing impairment and cause more severe disability in the later years of life. As a result, the GDG selected a DW of 0.0150 for moderate severity level ("has difficulty following a conversation in a noisy environment, but no other hearing problems"). For cognitive impairment, the DW was derived from the estimates of the burden of disease from environmental noise (WHO Regional Office for Europe & JRC, 2011). This was at a very conservative value (DW: 0.006) for noise-related impairment of children's cognition, equivalent to a DW for contemporaneous cognitive deficit in the context of a range of cognitive impairments in children ranging from 0.468 for Japanese encephalitis to 0.024 for iron deficiency anaemia (Lopez et al., 2006).

2.4.3.1 Development of ERFs

The systematic reviews of evidence provided either an ERF or other noise exposure value/metric that could be related to a risk increase of the health outcome measure. These ERFs were used to develop guideline exposure levels; however, only those functions where noise exposure demonstrated a statistically significant effect were used.

To obtain the starting level of the ERFs derived in the systematic reviews, a weighted average of the lowest exposure values measured in the individual studies included in the meta-analyses was

calculated. The weighting used the inverse of the variance of the effect estimate of the study. Thus, the lowest exposure value of studies with a small variance (usually with the largest sample size) contributed the most to the assumed onset of the ERF.

2.4.3.2 Relevant risk increase of adverse health effects

The following sections describe in detail the rationale for the selection of the relevant relative risk (RR) increase percentage for each of the priority health outcome measures considered.

Cardiovascular disease: IHD and hypertension

High-quality epidemiological evidence described in the systematic review on cardiovascular and metabolic effects of environmental noise indicates that exposure to road traffic noise increases the risk of IHD (van Kempen et al., 2018). The GDG was confident that health risks result from exposure at an RR increase in the order of 5-10% in the incidence of IHD. This is similar to the reasoning in the WHO air quality guidelines for fine particulate matter (PM25) (WHO, 2006). To determine a relevant risk increase for IHD, the GDG took as a starting-point the RR increase of 5% measured in epidemiological studies of environmental noise or air pollution. Taking into account the incidence of IHD and the seriousness of the disease, it considered lowering the RR increase for IHD to 1%, as a 5% RR increase might imply a comparatively high absolute risk from a population perspective. To decide on the final benchmark value for IHD, several aspects were considered: the number of people in a population affected by IHD; whether health risks caused by noise would make up a large part of the incidence of the disease; other examples of health risks of similar magnitude leading to preventive action. For IHD, in an average EU country with 20 million inhabitants, an RR increase of 5% for IHD would lead to several thousand extra cases attributable to noise yearly. This corresponds to a proportion of cases of IHD attributable to noise exposure of less than 10%, which is still relatively small. After extensive discussion at the very end of the guideline development process, the GDG decided to adhere to 5% as the relevant risk increase.

Hypertension is a common condition and is an important risk indicator for IHD and other cardiovascular diseases. Thus, the hypertension risk increase can be transformed into a risk increase for cardiovascular disease. To derive a relevant risk increase, the GDG focused on the incidence of hypertension, owing to the nature and quality of epidemiological evidence. Since hypertension is less serious than IHD, and not all people with hypertension will progress to cardiovascular disease, the relevant risk increase in the incidence of hypertension needed to be higher than that for IHD. Therefore, the GDG agreed on an RR increase of 10% for hypertension.

Self-reported sleep disturbance and annoyance

The GDG initially considered 5%HSD and 10%HA due to noise as relevant absolute risks, not be exceeded at the guideline level. After discussion, however, members agreed that these absolute risks were too large, since a considerable proportion of the population would still be affected; they decided to lower the relevant risk from 5% being highly sleep-disturbed to 3%. In doing so, the GDG referred to the WHO night noise guidelines (WHO, 2009), which concluded that while there was insufficient evidence that physiological effects at noise levels below 40 dB L_{night} are harmful to health, there were observed adverse health effects at levels starting from 40 dB L_{night} . At 40 dB, about 3–4%

(depending on the noise source) of the population still reported being highly sleep-disturbed due to noise, which was considered relevant to health. The GDG considered it important that this level is consistent with the previous health-based approach adopted by the WHO night noise guidelines, and agreed that the absolute risk associated with the guideline value selected should not exceed 3%HSD to be health protective.

For annoyance, which is considered a less serious health effect than self-reported sleep disturbance (as indicated by the respective DWs), the relevant risk remained at 10%HA. This means the absolute risk associated with the guideline value selected should be closest to, but not above 10%HA, to be health protective.

Cognitive impairment: reading and oral comprehension

Acquiring skills in reading and oral comprehension at a young age is important for further development: a delay in acquiring these skills can have an impact later in life (Wilson & Lonigan, 2010). This impact cannot be predicted very accurately, but the GDG considered a delay of one month a relevant absolute risk.

Permanent hearing impairment

The literature on hearing impairment as a result of occupational noise exposure is extensive. A noise exposure level beyond 80 dB during 40 years of working a 40 hour work week can give rise to permanent hearing impairment. Given that environmental exposure to noise is much lower than these levels and that noise-related hearing impairments are not reversible, the GDG considered that there should be no risk of hearing impairment due to environmental noise and considered any increased risk of hearing impairment relevant.

2.4.4 Strength of the recommendations

Finally, having determined the guideline exposure levels based on the ranking of prioritized health outcome measures, setting the strength of the recommendation was set as the final step of the guideline development process. This was also guided by the GRADE methodology (Alonso-Coello et al., 2016a; 2016b). According to this approach, strength of recommendation can be set as either strong or conditional (WHO, 2014c).

- A strong recommendation can be adopted as policy in most situations. The guideline is based on the confidence that the desirable effects of adherence to the recommendation outweigh the undesirable consequences. The quality of evidence for a net benefit – combined with information about the values, preferences and resources – inform this recommendation, which should be implemented in most circumstances.
- A **conditional** recommendation requires a policy-making process with substantial debate and involvement of various stakeholders. There is less certainty of its efficacy owing to lower quality of evidence of a net benefit, opposing values and preferences of individuals and populations affected or the high resource implications of the recommendation, meaning there may be circumstances or settings in which it will not apply.

The GRADE approach defines a number of parameters that should be assessed to determine the strength of recommendations: quality of evidence, balance of benefits and harms, values and preference related to the outcomes of interventions to exposure, resources implications, priority of the problem, equity and human rights, acceptability and feasibility (Box 2; Morgan et al., 2016).

Box 2 Parameters determining the strength of a recommendation

Quality of evidence further represents the confidence in the estimates of effect of the evaluated evidence, across outcomes critical and important to decision-making. The higher the quality of evidence, the greater the likelihood of a strong recommendation.

Balance of benefits and harms requires an evaluation of the absolute effects of both benefits and harms (or downsides) of the intervention or exposure and their importance. The greater net benefit or net harm associated with an intervention or an exposure, the greater the likelihood of a strong recommendation in favour or against an intervention or exposure.

Values and preferences related to the outcomes of an intervention or exposure set out the relative importance assigned to health outcomes by those affected by them; how such importance varies within and across populations; and whether this importance or variability is surrounded by uncertainty. The less uncertainty or variability there is about the values and preferences of people experiencing the critical or important outcomes, the greater the likelihood of a strong recommendation.

Resource implications take into consideration how resource-intensive and how costeffective and substantially beneficial an intervention or exposure is. The more advantageous or clearly disadvantageous the resource implications are, the greater the likelihood of a strong recommendation either for or against the intervention or exposure.

The priority of the problem is determined by its importance and frequency (the burden of disease, disease prevalence or baseline risk). The greater the importance of the problem, the greater the likelihood of a strong recommendation.

Equity and human rights considerations are an important aspect of the process. The greater the likelihood that the intervention will reduce inequities, improve equity or contribute to the realization of one or several human rights as defined under the international legal framework, the greater the likelihood of a strong recommendation.

Acceptability plays a prominent role: the greater the acceptability of an option to all or most stakeholders, the greater the likelihood of a strong recommendation.

Feasibility overlaps with values and preferences, resource considerations, existing infrastructures, equity, cultural norms, legal frameworks and many other considerations. The greater the feasibility of an option from the standpoint of all or most stakeholders, the greater the likelihood of a strong recommendation.

The GDG evaluated the strength of the recommendations based on these parameters, following a two-step procedure. Initially, the strength of each recommendation was set as strong or conditional based on an assessment of the quality of evidence. The GDG then identified and assessed contextual

parameters that might have a contributory role (see Box 2 above). Based on this qualitative evaluation, the initial recommendation strength was either adapted or confirmed. It is important to note that while the initial parameter "quality of evidence" was informed by comprehensive systematic reviewing processes, the remaining contextual parameters were assessed by the informed qualitative expert judgement of the GDG.

Furthermore, the GDG agreed to decision-making rules, applied when formulating the recommendations. An evidence rating of low quality or very low quality would lead only to a conditional recommendation. Setting a strong recommendation was only considered if the evidence was at least moderate quality. The final recommendations were formulated based on the consideration of all the parameters and decision rules adopted by the GDG. A detailed exploration of all the recommendations is set out in Chapter 3.

2.5 Individuals and partners involved in the guideline development process

The process of WHO guideline development is conducted by several groups with clearly defined roles and responsibilities. Comprising WHO staff members, experts and stakeholders, these are the Steering Group, the GDG, the Systematic Review Team and the External Review Group.

The **Steering Group** includes WHO staff members with different affiliations but whose work experience is relevant to the topic of environmental noise and associated health outcomes. It is involved at all stages of planning, selecting members of the GDG and External Review Group, reviewing evidence and developing potential recommendations at the main expert meetings, as well as ongoing consultation on revisions following peer review. Details of the members of the Steering Group are listed in Table A1.1 in Annex 1.

The **GDG** consists of a group of content experts gathered to investigate all aspects of evidence contributing to the recommendations, including expertise in evidence-based guideline development. This Group defined the key questions and priorities of the research, chose and ranked outcomes and provided advice on any modifications of the scope as established by the Steering Group. The members also outlined the systematic review methods; appraised the evidence used to inform the guidelines; and advised on the interpretation of this evidence, with explicit consideration of the overall balance of benefits and harms. Ultimately the GDG formulated the final recommendations, taking into account the diverse values and preferences of individuals and populations affected. It also determined the strength of the results and responded to external peer reviews. The complete list of GDG members and their specific roles, affiliations and areas of expertise are listed in Table A1.2 in Annex 1.

The **Systematic Review Team** includes experts in the field of environmental health, commissioned by WHO staff to undertake systematic reviews of evidence. The GDG recommended a number of authors to conduct the evidence reviews and summary chapters, based on their expertise. Details of the members of the Systtematic Review Team are included in Table A1.3 in Annex 1.

The **External Review Group** is composed of technical content experts and end-users as well as stakeholders, and is balanced geographically and by gender. The experts and end-users were selected for their expertise in the field, and the Group also included representatives of professional groups and industry associations, who will be implementing the guidelines. Members were asked to

review the material at different stages of the development process. The list of technical experts and stakeholders is provided in Tables A1.4 and A1.5, respectively, in Annex 1.

Management of conflict of interest is an integral part of WHO's guideline development procedure. All members of the GDG and authors of the evidence reviews completed WHO declaration of interest forms. These were reviewed by the WHO Secretariat for potential conflicts of interest. A number of conflicts of interest were declared in the forms, but following a standardized management review it was not found necessary to exclude any members of the GDG or authors from their respective roles. Members of the External Review Group (technical experts only) were also asked to complete the form when invited to participate.

In addition, at the start of the meeting of the GDG all members of the GDG received a briefing about the nature of all types of conflict of interest (financial, academic/intellectual and nonacademic) and were asked to declare to the meeting any conflicts they might have. No member of the GDG or the Systematic Review Team was excluded from his/her respective role. A summary of the conflict of interest management is presented in Annex 3.

The GDG set its own rules on how it would work and how contentious issues should be resolved – for instance, by means of a vote. The main decision-making mechanism involved reaching consensus; if a vote was required, the experts involved in developing the underlying evidence for the specific recommendation were excluded from voting, and an agreement was reached via a two thirds majority of the rest of the group.

2.6 Previously published WHO guidelines on environmental noise

Prior to this publication, WHO published community noise guidelines (CNG) in 1999 (WHO, 1999) and night noise guidelines for Europe (NNG) in 2009 (WHO Regional Office for Europe, 2009).

2.6.1 CNG

The scope of WHO's efforts to develop the CNG in 1999 was similar to that for the current guidelines. The objective was then formulated as: "to consolidate scientific knowledge of the time on the health impacts of community noise and to provide guidance to environmental health authorities and professionals trying to protect people from the harmful effects of noise in nonindustrial environments" (WHO, 1999). The guidelines were based on studies carried out up to 1995 and a few meta-analyses from some years later.

The health risk to humans from exposure to environmental noise was evaluated and guideline values derived. At that time WHO had not yet developed its guideline development process, on which the current guidelines are based (WHO, 2014c). The main differences in content are that the previous guidelines were expert-based and provided more global coverage and applicability, such as issues of noise assessment and control that were addressed in detail. They included a discussion on noise sources and measurement, including the basic aspects of source characteristics, sound propagation and transmission. Adverse health effects of noise were characterized, and combined noise sources and their effects were considered. Furthermore, the guidelines included discussions of strategies and priorities in the management of indoor noise levels, noise policies and legislation, environmental

noise impact and enforcement of regulatory standards; although there were no chapters on wind turbine noise and leisure noise.

2.6.2 NNG

In 2009 the WHO Regional Office for Europe published the NNG to provide scientifically based advice to Member States for the development of future legislation and policy action in the area of assessment and control of night noise exposure.

The NNG complement the previous CNG, incorporating the advancement of research on noise and sleep disturbance up to 2006. The working group of experts reviewed available scientific evidence on the health effects of night noise and derived health-based guideline values. Again, WHO had not yet introduced its evidence-based recommendations policy and the NNG were mainly expert-based. They considered the scientific evidence on the threshold of night noise exposure indicated by L_{night} as defined in the END (EC, 2002a), and the experts concluded that a L_{night} value of 40 dB should be the target of the NNG (for all sources) to protect the public, including the most vulnerable groups such as children, chronically ill and elderly people. Further, an L_{night} value of 55 dB was recommended as an interim target for countries that could not follow the guidelines in the short term for various reasons or where policy-makers chose to adopt a stepwise approach.

2.6.3 Differences from the prior noise guidelines

The current guidelines differ from the older ones, recommending levels of exposure unlike those previously outlined (especially by the NNG). The following major differences between the previous and current guidelines explain the novel set of recommended values.

- The development process for the current guidelines adhered to a new, rigorous, evidence-based methodology, as outlined in the WHO handbook for guideline development (WHO, 2014c). WHO adopted these internationally recognized standards to ensure high methodological quality and a transparent, evidence-based decision-making process in the guideline development.
- The current guidelines consider cardiovascular disease a critical health outcome measure.
- They also consider a broader set of health outcomes, including adverse birth outcomes, diabetes, obesity and mental well-being. Wherever applicable, incidence, prevalence and mortality were considered separately.
- The current guidelines cover two new noise sources: wind turbines and leisure noise.
- Critical and important health outcomes are considered separately for each of the noise sources.
- The guideline development process included the health effects of intervention measures to mitigate noise exposure from different noise sources for the first time.
- The style of recommendations differs: the current guidelines include an exact exposure value for every health outcome regarded as critical, for each noise source. Guideline recommendation values were set for each of the noise sources separately, based on the exact exposure values and a prioritization scheme, developed with the help of DWs.
- The current guidelines apply a 1 dB increment scheme, whereas prior guidelines (CNG and NNG) formulated or presented recommendations in 5 dB steps.

- In comparison to the 1999 CNG, which defined environment-specific exposure levels, the current guidelines are source specific. They recommend values for outdoor exposure to road traffic, railway, aircraft and wind turbine noise, and indoor as well as outdoor exposure levels for leisure noise.
- Except for leisure noise, all exposure levels recommended in the current guidelines are average sound pressure levels for outdoor exposure.
- The current guidelines make use of the noise indices defined in the END: L_{den} and L_{night}.

The definition of "community noise" used in the CNG in 1999 was also adapted. The GDG agreed to use the term "environmental noise" instead, and offered an operational definition of: "noise emitted from all sources except sources of occupational noise exposure in workplaces".

The current environmental noise guidelines for the European Region supersede the CNG from 1999. Nevertheless, the GDG recommends that all CNG indoor guideline values and any values not covered by the current guidelines (such as industrial noise and shopping areas) should remain valid.

Furthermore, the current guidelines complement the NNG from 2009. Two main aspects of the NNG constitute this complementarity: the different guiding principles and the comprehensive investigation of the immediate physiological effects of environmental noise on sleep. As guiding principles the NNG defined effect thresholds or "lowest observed adverse health effect levels" for both immediate physiological reactions during sleep (i.e. awakening reactions or body movements during sleep) and long-term adverse health effects (i.e. self-reported sleep disturbance). These guideline exposure levels defined a level below which no effects were expected to occur (corresponding to 30 dB L_{night}), with the aim of protecting the whole population, including – to some extent – vulnerable groups. The development of the NNG values relied on evidence-based expert judgement. In contrast, the current guidelines formulate recommendations more strictly based on a relevant risk increase of adverse health effects. Thus, the recommended guideline values might not lead to full protection of the population, including all vulnerable groups. The GDG stresses that the aim of the current guidelines is to define an exposure level at which effects certainly begin.

Secondly, the NNG comprehensively investigate the immediate short-term effects of environmental noise during sleep, including physiological reactions such as awakening reactions and body movements. They also provided threshold information about single-event noise indicators (such as the $L_{A,max}$). In contrast, the current guideline values for the night time are only based on the prevalence of self-reported sleep disturbance and do not take physiological effects into account. The causal link between immediate physiological reactions and long-term adverse health effects is complex and difficult to prove. Thus, the current guidelines are restricted to long-term health effects during night time and therefore only include recommendations about average noise indicators: L_{night} . Nevertheless, the evidence review on noise and sleep (Basner & McGuire, 2018) includes an overview of single-event exposure–effect relationships.

3. Recommendations

This chapter presents specific recommendations on guideline exposure levels and/or interventions to reduce exposure and/or improve health for individual sources of noise: road traffic, railway, aircraft, wind turbines and leisure noise. The strength of each recommendation is provided (strong or conditional) and a short rationale for how each of the guideline levels was achieved is given.

The GDG discussed extensively the best way to present guideline exposure levels – either as the exact values or in 5 dB steps – and the approach to rounding the values to the nearest integer. The 5 dB increment, rounded down from the exact exposure value to the nearest 5 dB level, was initially chosen as being commonly applied in noise legislation and used in prior guidelines (WHO, 1999; EC, 2002a; WHO Regional Office for Europe, 2009). It was also used to meet the principle of precaution, since imprecision in the exposure assessment in the field of epidemiology tends to attenuate the actual effects in the population.

Use of 5 dB increments resulted in uneven magnitude of rounding down, however, raising concerns of arbitrariness. It became apparent that inclusion of both exact values and the 5 dB roundeddown values might be confusing and could affect the applicability of the guidelines. Hence, the GDG ultimately decided that formulating recommendations based on the exact calculated values, rounded only to the nearest integer, would ensure more clarity and transparency. Furthermore, it noted that adhering to a 5 dB roster might not reflect the progress in the precision of exposure assessment methods in recent decades, which would justify application of a 1 dB step.

The GDG acknowledged that the recommendations might be presented as the exact guideline exposure levels only, leaving the use of 5 dB bands to the potential policy decisions to formulate or revise noise legislation, which are beyond the scope of this publication. The WHO guideline values are public health-oriented recommendations, based on scientific evidence on health effects and on an assessment of achievable noise levels. They are strongly recommended and as such should serve as the basis for a policy-making process in which policy options are quantified and discussed. It should be recognized that in that process additional considerations of costs, feasibility, values and preferences should also feature in decision-making when choosing reference values such as noise limits for a possible standard or legislation.

In addition to the source-specific recommendations in the following sections, a short rationale for the decision-making process by the GDG for developing a particular recommendation is provided, as well as an overview of the evidence considered. This includes a recapitulation of the specific PICOS/ PECCOS question (see section 2.3.1), along with a summary of evidence for each of the critical and important health effects from exposure to each of the noise sources, and for the effectiveness of interventions.

Furthermore, a description is provided of the other factors considered according to the GRADE dimensions for the assessment of the strength of recommendations (see section 2.4.4). While the quality of evidence is central to determining this, the process of moving from evidence to recommendations involves several other considerations. These include values and preferences, balance of benefits and harms, consideration of the priority of the problem, resource implications, equity and human rights aspects, acceptability and feasibility (WHO, 2014c).



Recommendations

For average noise exposure, the GDG **strongly** recommends reducing noise levels produced by road traffic below **53 dB** L_{den} , as road traffic noise above this level is associated with adverse health effects.

For night noise exposure, the GDG **strongly** recommends reducing noise levels produced by road traffic during night time below **45 dB** L_{night} , as road traffic noise above this level is associated with adverse effects on sleep.

To reduce health effects, the GDG **strongly** recommends that policy-makers implement suitable measures to reduce noise exposure from road traffic in the population exposed to levels above the guideline values for average and night noise exposure. For specific interventions, the GDG recommends reducing noise both at the source and on the route between the source and the affected population by changes in infrastructure.

3.1.1 Rationale for the guideline levels for road traffic noise

The exposure levels were derived in accordance with the prioritization process of critical health outcomes described in section 2.4.3. For each of the outcomes, the exposure level was identified by applying the benchmark, set as relevant risk increase to the corresponding ERF. In the case of exposure to road traffic noise, the process can be summarized as follows (Table 6).

Table 6. Average exposure levels (L_{den}) for priority health outcomes from road traffic noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Incidence of IHD The 5% relevant risk increase occurs at a noise exposure level of 59.3 dB L_{den} . The weighted average of the lowest noise levels measured in the studies was 53 dB L_{den} and the RR increase per 10 dB is 1.08.	5% increase of RR	High quality
Incidence of hypertension One study met the inclusion criteria. There was no significant increase of risk associated with increased noise exposure in this study.	10% increase of RR	Low quality
Prevalence of highly annoyed population There was an absolute risk of 10% at a noise exposure level of 53.3 dB $L_{den.}$	10% absolute risk	Moderate quality
Permanent hearing impairment	No increase	No studies met the inclusion criteria
Reading skills and oral comprehension in children	One-month delay	Very low quality

In accordance with the prioritization process (see section 2.4.3), the GDG set a guideline exposure level of 53.3 dB L_{den} for average exposure, based on the relevant increase of the absolute %HA. It was confident that there was an increased risk for annoyance below this noise exposure level, but probably no increased risk for other priority health outcomes. In accordance with the defined rounding procedure, the value was rounded to 53 dB L_{den} . As the evidence on the adverse effects of road traffic noise was rated moderate quality, the GDG made the recommendation strong.

Next, the GDG assessed the evidence for night noise exposure and its effect on sleep disturbance (Table 7).

Table 7. Night-time exposure levels (L_{night}) for priority health outcomes from road traffic noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Sleep disturbance	3% absolute risk	Moderate quality
3% of the participants in studies were highly sleep-disturbed at a noise level of 45.4 dB $L_{\rm night}$		

Based on the evidence of the adverse effects of road traffic noise on sleep disturbance, the GDG defined a guideline exposure level of 45.4 dB L_{night} . The exact exposure value was rounded to 45 dB L_{night} . As the evidence was rated moderate quality, the GDG made the recommendation strong.

The GDG also considered the evidence for the effectiveness of interventions. The results showed that:

- addressing the source by improving the choice of appropriate tyres, road surface, truck restrictions or by lowering traffic flow can reduce noise exposure;
- path interventions such as insulation and barrier construction reduce noise exposure, annoyance and sleep disturbance;
- changes in infrastructure such as construction of road tunnels lower noise exposure, annoyance and sleep disturbance;
- other physical interventions such as the availability of a quiet side of the residence reduce noise exposure, annoyance and sleep disturbance.

Given that it is possible to reduce noise exposure and that best practices already exist for the management of noise from road traffic, the GDG made a strong recommendation.

3.1.1.1 Other factors influencing the strength of recommendations

Other factors considered in the context of recommendations on road traffic noise included those related to values and preferences, benefits and harms, resource implications, equity, acceptability and feasibility; moreover, nonpriority health outcomes (the incidence of stroke and diabetes) were considered. Ultimately, the assessment of all these factors did not lead to a change in the strength of the recommendations. Further details are provided in section 3.1.2.3.

3.1.2 Detailed overview of the evidence

The following sections provide a detailed overview of the evidence constituting the basis for setting the recommendations on road traffic noise. It is presented and summarized separately for each of the critical health outcomes, and the GDG's judgement of the quality of evidence is indicated (for a detailed overview of the evidence on important health outcomes, see Annex 4). Research into health outcomes and effectiveness of interventions is addressed consecutively.

A comprehensive summary of all evidence considered for each of the critical and important health outcomes can be found in the eight systematic reviews published in the *International Journal of Environmental Research and Public Health* (see section 2.3.2 and Annex 2).

3.1.2.1 Evidence on health outcomes

The key question posed was: in the general population exposed to road traffic noise, what is the exposure–response relationship between exposure to road traffic noise (reported as various noise indicators) and the proportion of people with a validated measure of health outcome, when adjusted for main confounders? A summary of the PICOS/PECCOS scheme applied (see section 2.3.1) and the main findings is set out in Tables 8 and 9.

PECO	Description			
Population	General population	General population		
Exposure	Exposure to high levels of noise produced b	Exposure to high levels of noise produced by road traffic (average/night time)		
Comparison	Exposure to lower levels of noise produced	Exposure to lower levels of noise produced by road traffic (average/night time)		
Outcome(s)	For average noise exposure:	For night noise exposure:		
	1. cardiovascular disease	1. effects on sleep		
	2. annoyance			
	3. cognitive impairment			
	4. hearing impairment and tinnitus			
	5. adverse birth outcomes			
	6. quality of life, well-being and mental healt	th		
	7. metabolic outcomes			

Table 8. PICOS/PECCOS scheme of critical health outcomes for exposure to road traffic noise

Table 9. Summary of findings for health effects from exposure to road traffic noise (L_{den})

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)	Quality of evidence
Cardiova	scular disease				
L _{den}	Incidence of IHD	RR = 1.08 (95% confidence interval (Cl): 1.01–1.15) per 10 dB increase	53 dB	67 224 (7)	High (upgraded for dose-response)
L _{den}	Incidence of hypertension	RR = 0.97 (95% CI: 0.90–1.05) per 10 dB increase	N/A	32 635 (1)	Low (downgraded for risk of bias and because only one study was available)
Annoyan	ice				
L _{den}	%HA	Odds ratio (OR) = 3.03 (95% CI: 2.59–3.55) per 10 dB increase	40 dB	34 112 (25)	Moderate (downgraded for inconsistency)
Cognitiv	e impairment				
L _{den}	Reading and oral comprehension	Not estimated	N/A	Over 2844 (1)	Very low (downgraded for inconsistency)
Hearing	impairment and tini	nitus			
L _{den}	Permanent hearing impairment	_	-	-	_

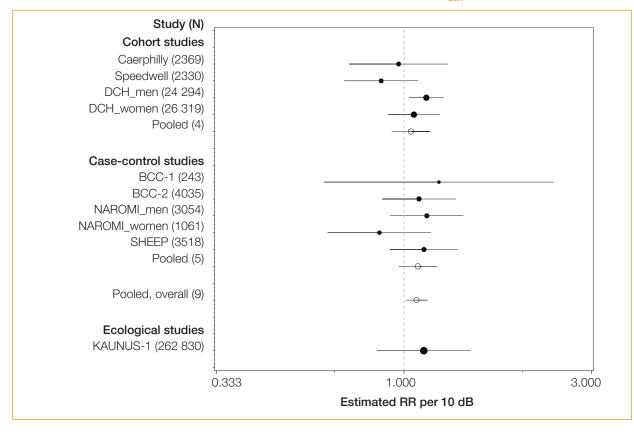
Cardiovascular disease

IHD

A total of three cohort (Babisch & Gallacher, 1990; Babisch et al., 1988; 1993a; 1993b; 1999; 2003; Caerphilly and Speedwell Collaborative Group, 1984; Sörensen et al., 2012a; 2012c) and four case-control studies (Babisch, 2004; Babisch et al., 1992; 1994; 2005a; Selander et al., 2009; Wiens, 1995) investigated the relationship between road traffic noise and the incidence of IHD. These involved a total of 67 224 participants, including 7033 cases. As identified in Fig. 1, the overall RR derived from the meta-analysis was 1.08 (95% CI: 1.01–1.15) per 10 dB L_{den} increase in noise levels, across a noise range of 40 dB to 80 dB. This evidence was rated high quality.

The data were supported by one ecological study conducted with 262 830 participants, including 418 cases, which also reported a statistically significant estimate (Grazuleviciene et al., 2004; Lekaviciute, 2007). In this study, a positive but nonsignificant association was found: RR of 1.12 (95% CI: 0.85–1.48) per 10 dB L_{den} increase in noise. This evidence was rated very low quality.

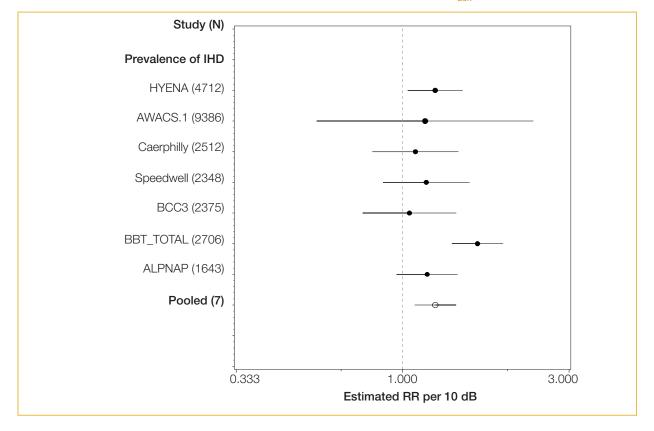
Fig. 1. The association between exposure to road traffic noise (L_{den}) and incidence of IHD



Notes: The dotted vertical line corresponds to no effect of exposure to road traffic noise. The black circles correspond to the estimated RR per 10 dB and 95% Cl. The white circles represent the pooled random effect estimates and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Furthermore, additional evidence was available from eight cross-sectional studies that investigated the relationship between road traffic noise and prevalence of IHD (Babisch & Gallacher, 1990; Babisch et al., 1988; 1992; 1993a; 1993b; 1994; 1999; 2003; 2005a; 2008; 2012a; 2012b; Caerphilly and Speedwell Collaborative Group, 1984; Floud et al., 2011; 2013a; 2013b; Heimann et al., 2007; Jarup et al., 2005; 2008; Lercher et al., 2008; 2011; van Poll et al., 2014; Wiens, 1995). These studies involved a total of 25 682 participants, including 1614 cases. The overall RR was 1.24 (95% Cl: 1.08–1.42) per 10 dB L_{den} increase in road traffic noise levels. The range in noise levels in the studies under evaluation was 30–80 dB. The results of the meta-analysis are presented in Fig. 2. This evidence was rated low quality.

Fig. 2. The association between exposure to road traffic noise (L_{den}) and prevalence of IHD



Notes: The dotted vertical line corresponds to no effect of exposure to road traffic noise. The black circles correspond to the estimated RR per 10 dB and 95% CI. The white circle represents the pooled random effect estimates and 95% CI. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Mortality from IHD was also investigated in one case-control (Selander et al., 2009) and two cohort studies (Beelen et al., 2009; Gan et al., 2012), which involved 532 268 participants, including 6884 cases. The quantitative relationship between road traffic noise and mortality from IHD was RR = 1.05 (95% CI: 0.97–1.13) per 10 dB L_{den} increase in noise levels (see Fig. 3). This evidence was rated moderate quality.

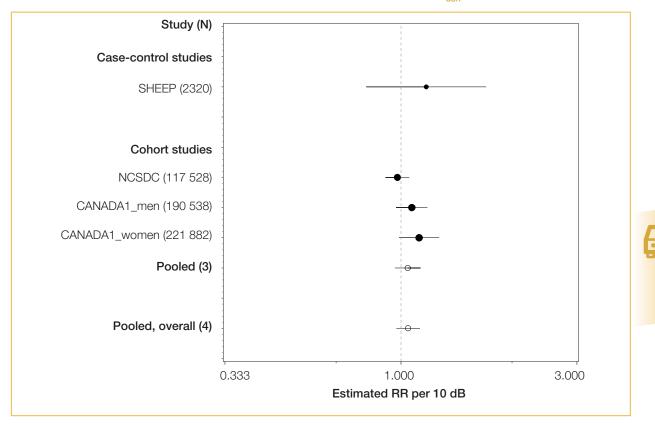


Fig. 3. The association between exposure to road traffic noise (L_{den}) and mortality from IHD

Notes: The dotted vertical line corresponds to no effect of exposure to road traffic noise. The black circles correspond to the estimated RR per 10 dB and 95% Cl. The white circles represent the pooled random effect estimates and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Hypertension

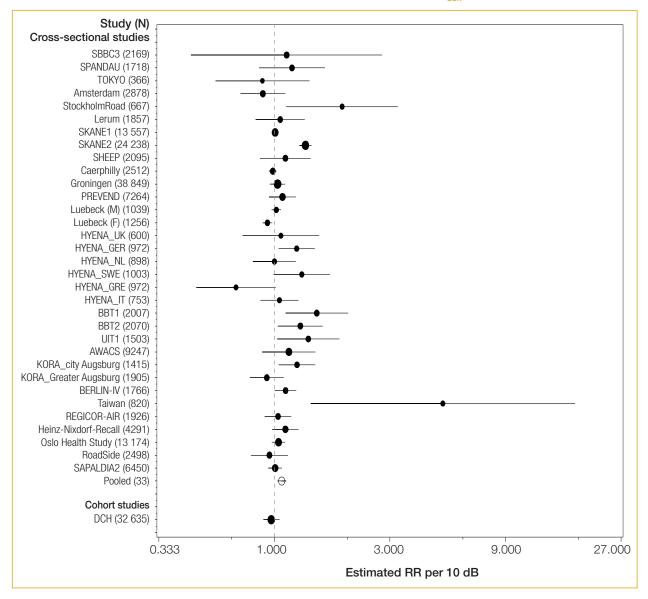
One cohort study into the relationship between road traffic noise and incidence of hypertension was identified; it involved 32 635 participants, including 3145 cases (Sörensen et al., 2011; 2012c). The study found a nonsignificant effect size of 0.97 (95% CI: 0.90–1.05) per 10 dB L_{den} increase in noise levels, which does not support an increased risk of hypertension due to exposure to road traffic noise. Because of the risk of bias and the availability of only one study, this evidence was rated low quality.

In addition, 26 cross-sectional studies were identified that looked at the association between road traffic noise and prevalence of hypertension (Babisch et al., 1988; 1992; 1994; 2005_a; 2008; 2012a; 2012b; 2013a; 2013b; 2014b; 2014c; Barregard et al., 2009; Bjork et al., 2006; Bluhm et al., 2007; Bodin et al., 2009; Caerphilly and Speedwell Collaborative Group, 1984; Chang et al., 2011; 2014; de Kluizenaar et al., 2007a; 2007b; Dratva et al., 2012; Eriksson et al., 2012; Foraster et al., 2011; 2012; 2013; 2014a; 2014b; Fuks et al., 2011; Hense et al., 1989; Herbold et al., 1989; Jarup et al., 2005; 2008; Knipschild et al., 1984; Lercher et al., 2008; 2011; Maschke, 2003; Maschke & Hecht,

2005; Maschke et al., 2003; Oftedal et al., 2011; 2014; Selander et al., 2009; van Poll et al., 2014; Wiens, 1995; Yoshida et al., 1997). In total, these studies involved 154 398 participants, including 18 957 cases. The overall RR for prevalence of hypertension was 1.05 (95% Cl: 1.02–1.08) per 10 dB L_{den} increase in noise levels. The noise range of the studies under evaluation was 20–85 dB. The overall evidence was rated very low quality.

Fig. 4 shows the association between road traffic noise and incidence and prevalence of hypertension.

Fig. 4. The association between exposure to road traffic noise (L_{den}) and hypertension



Notes: The dotted vertical line corresponds to no effect of exposure to road traffic noise. The black dots correspond to the estimated RR per 10 dB and 95% Cl. The white circle represents the summary estimate and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Stroke

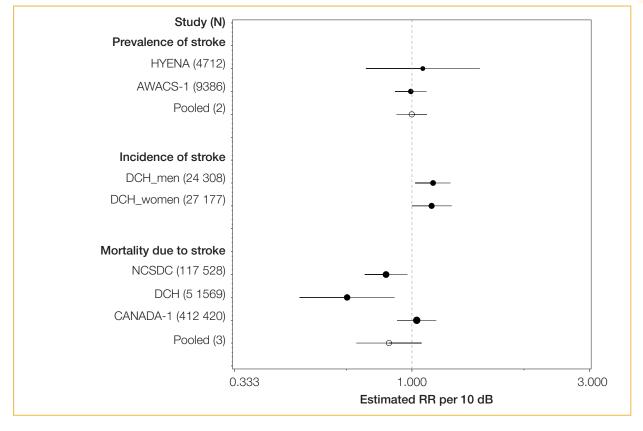
One cohort study into the relationship between road traffic noise and incidence of stroke was identified (Sörensen et al., 2011; 2012b; 2014). It involved 51 485 participants, including 1881 cases, and found an RR of 1.14 (95% CI: 1.03–1.25) per 10 dB L_{den} increase in noise levels, across a range of around 50–70 dB. The evidence was rated moderate quality.

Two cross-sectional studies on road traffic noise and prevalence of stroke involved 14 098 participants, including 151 cases (Babisch et al., 2005a; 2008; 2012a; 2012b; 2013a; Floud et al., 2011; 2013a; 2013b; Jarup et al., 2005; 2008; van Poll et al., 2014) yielded an estimated RR of 1.00 (95% CI: 0.91-1.10) per 10 dB L_{den} increase in noise levels. This evidence was rated very low quality.

Furthermore, three cohort studies investigated the relationship between road traffic noise and mortality due to stroke (Beelen et al., 2009; Gan et al., 2012; Sörensen et al., 2011; 2012b; 2014). These involved 581 517 participants, including 2634 cases, and their pooled estimate was a statistically nonsignificant RR = 0.87 (95% CI: 0.71–1.06) per 10 dB L_{den} increase in road traffic noise levels. This evidence was rated moderate quality.

Fig. 5 presents the results of the meta-analysis for road traffic noise and measures of stroke.

Fig. 5. The association between exposure to road traffic noise (L_{den}) and stroke



Notes: The dotted vertical line corresponds to no effect of exposure to road traffic noise. The black dots correspond to the estimated RR per 10 dB and 95% CI. The white circles represent the summary estimate and 95% CI. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Children's blood pressure

Six cross-sectional studies investigated the change in systolic and diastolic blood pressure in children exposed to road traffic noise in residential settings (Belojevic & Evans, 2011; 2012; Bilenko et al., 2013; Liu et al., 2013; 2014; Regecova & Kellerova, 1995; van Kempen et al., 2006). In total, 4197 children were included in these studies; the number of cases was not reported. For each increase in 10 dB L_{den} in noise levels, there was a statistically nonsignificant increase in systolic and in diastolic blood pressure of 0.08 mmHg (95% CI: -0.48-0.64) and 0.47 mmHg (95% CI: -0.30-1.24), respectively. The overall evidence was rated very low quality.

Furthermore, five cross-sectional studies investigated the association between systolic and diastolic blood pressure in children and exposure to road traffic noise in educational settings (Belojevic & Evans, 2011; 2012; Bilenko et al., 2013; Clark et al., 2012; Paunovic et al., 2013; Regecova & Kellerova, 1995; van Kempen et al., 2006). In total, 4520 children were included in these studies; the number of cases was not reported. Systolic blood pressure decreased statistically nonsignificantly, at –0.60 mm (95% CI: –1.51–0.30) per 10 dB L_{den} increase in road traffic noise levels. Diastolic blood pressure increased statistically nonsignificantly, at 0.46 mm (95% CI: –0.60–1.53) per 10 dB L_{den} increase in road traffic noise levels. For both relationships, the evidence was rated very low quality.

Annoyance

A vast amount of research proves the association between road traffic noise and annoyance. In total, 17 road traffic noise studies were identified that were used to model ERFs of the relationship between L_{den} and %HA (Babisch et al., 2009; Brink, 2013; Brink et al., 2016; Brown et al., 2014; 2015; Champelovier et al., 2003; Heimann et al., 2007; Lercher et al., 2007; Medizinische Universitaet Innsbruck, 2008; Nguyen et al., 2012a; Pierette et al., 2012; Sato et al., 2002; Shimoyama et al., 2014). These incorporated data from 34 112 study participants. The estimated data points of each of the studies are plotted in Fig. 6, alongside an aggregated ERF including the data from all the individual studies (see the black line for "WHO full dataset"). The lowest category of noise exposure considered in any of the studies, and hence included in the systematic review, is 40 dB, corresponding to approximately 9%HA. The benchmark level of 10%HA is reached at 53.3 dB L_{den} (see Fig 6).

Table 10 shows the %HA in relation to exposure to road traffic noise. The calculations are based on the regression equation %HA = 78.9270–3.1162 × L_{den} + 0.0342 × L_{den}^2 derived from the systematic review (Guski et al., 2017). Even though there is a large evidence base substantiating the association of average road traffic noise and noise annoyance, the overall evidence had to be rated low quality. The main reasons for downgrading included limitations regarding the acoustical data provided, the nature of study design (most of the studies in the realm of annoyance research follow a cross-sectional approach), the inconsistency of results and the variety in the questions asked.

Nevertheless, the general quality of the evidence was substantiated with the help of additional statistical analyses that apply classic health outcome measures to estimate noise annoyance. When comparing road traffic noise exposure at 50 dB and 60 dB, the analyses revealed evidence rated moderate quality for an association between road traffic noise and %HA for an increase per 10 dB (OR = 2.74; 95% CI: 1.88–4.00). Moreover, there was evidence rated high quality for the increase of %HA per 10 dB increase in sound exposure, when data on all sound classes were included (OR = 3.03; 95% CI: 2.59–3.55).

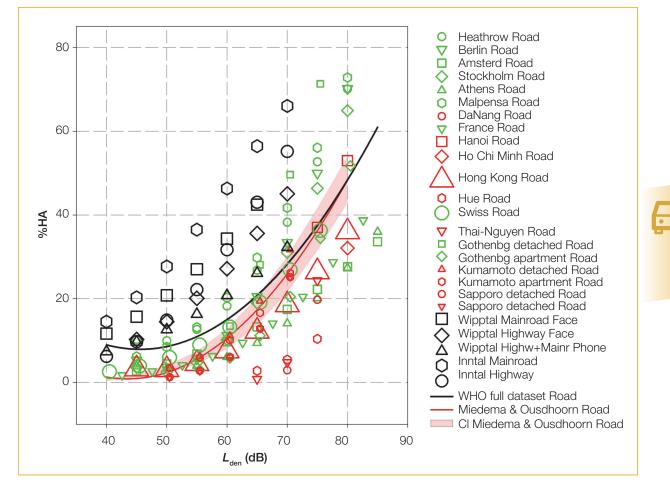


Fig. 6.Scatterplot and quadratic regression of the relationship between road traffic noise (L_{den}) and annoyance (%HA)

Notes: The ERF by Miedema & Oudshoorn (2001) is added in red for comparison.

The size of the data points corresponds to the number of participants in the respective study (size = SQRT(N)/10). If two results from different studies fall on the same data point, the last point plotted may mask the former one. The black curve is derived from aggregated secondary data, while the red one is derived from individual data. There is no indication of 95% CIs of the WHO full dataset, as a weighting based on the total number of participants for each 5 dB L_{den} sound class could not be calculated; weighting based on all participants of all sound classes proved to be unsuitable. The range of data included is illustrated by the distribution of data points. For further details on the studies included in the figure please refer to the systematic review on environmental noise and annoyance (Guski et al., 2017).

L _{den} (dB)	% HA
40	9.0
45	8.0
50	8.6
55	11.0
60	15.1
65	20.9
70	28.4
75	37.6
80	48.5

Table 10. The association between exposure to road traffic noise (L_{den}) and annoyance (%HA)

Cognitive impairment

Evidence rated very low quality was available for the association between road traffic noise and reading and oral comprehension, assessed by tests. The review identified two papers that reported the results of the cross-sectional road traffic and aircraft noise exposure and children's cognition and health (RANCH) study, which examined exposure–effect relationships (Clark et al., 2006; Stansfeld et al., 2005). The study of over 2000 children aged 9–10 years, attending 89 schools around three major airports in the Netherlands, Spain and the United Kingdom did not find an exposure–effect relationship between road traffic noise exposure at primary school, which ranged from 31 to 71 dB $L_{Aert16b}$, and children's reading comprehension.

Few studies have investigated other health outcome measures related to cognition. Evidence rated low quality was available for an association between road traffic noise and cognitive impairment assessed through standardized tests (Cohen et al., 1973; Lukas et al., 1981; Pujol et al., 2014; Shield & Dockrell, 2008). There was evidence rated very low quality for an association between road traffic noise and long-term memory (Matheson et al., 2010; Stansfeld et al., 2005). No studies examined effects on short-term memory.

There was evidence rated very low quality, however, that road traffic noise does not have a considerable effect on children's attention (Cohen et al., 1973; Stansfeld et al., 2005). Further, there was evidence rated low quality that road traffic noise does not have a substantial effect on executive function (working memory), with studies consistently reporting no association (Clark et al., 2012; Matheson et al., 2010; Stansfeld et al., 2005; van Kempen et al., 2010; 2012).

Hearing impairment and tinnitus

No studies were found, and therefore no evidence was available for the association between road traffic noise and hearing impairment and tinnitus.

Sleep disturbance

For road traffic noise and self-reported sleep outcomes (awakenings from sleep, the process of falling asleep and sleep disturbance), 12 studies were identified that included a total of 20 120

participants (Bodin et al., 2015; Brown et al., 2015; Hong et al., 2010; Phan et al., 2010; Ristovska et al., 2009; Sato et al., 2002; Shimoyama et al., 2014); these were cross-sectional studies, conducted in healthy adults. The health outcome was measured by self-reporting via general health and noise surveys that included questions about sleep in general, and other questions about how noise affects sleep (see Table 11).

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)	Quality of evidence
Effects o	n sleep				
L _{night}	%HSD	OR: 2.13 (95% CI: 1.82–2.48) per 10 dB increase	43 dB	20 120 (12)	Moderate (downgraded for study limitations, inconsistency; upgraded for dose-response, magnitude of effect)

Table 11. Summary of findings for health effects from exposure to road traffic noise (L_{ninb})

The model in the systematic review (Basner & McGuire, 2018) was based on outdoor L_{night} levels between 40 dB and 65 dB only; 40 dB was chosen as the lower limit because of possible inaccuracies of predicting lower noise levels. The range of noise exposure reported in the studies reviewed was 37.5–77.5 dB L_{night} . About 2% (95% CI: 0.90–3.15) of the population was characterized as highly sleep-disturbed at L_{night} levels of 40 dB. The %HSD at other, higher levels of road traffic noise is presented in Table 12. The association between road traffic noise and the probability of being highly sleep-disturbed was OR: 2.13 (95% CI: 1.82–2.48) per 10 dB increase in noise. This evidence was rated moderate quality.

Table 12. The association between exposure to road traffic noise (L_{night}) and sleep disturbance (%HSD)

%HSD	95% CI
2.0	0.9–3.15
2.9	1.40-4.44
4.2	2.14-6.27
6.0	3.19–8.84
8.5	4.64-12.43
12.0	6.59–17.36
	2.0 2.9 4.2 6.0 8.5

Additional analyses were conducted for other health outcome measures related to sleep, which provided supporting evidence on the overall relationship between road traffic noise and sleep disturbance. When the noise source was not specified in the question, the relationship between road traffic noise and self-reported sleep outcomes was still positive but no longer statistically significant, with an OR of 1.09 (95% CI: 0.94–1.27) per 10 dB increase (Bodin et al., 2015; Brink, 2011; Frei et al., 2014; Halonen et al., 2012). This evidence was rated very low quality.

There was evidence rated moderate quality for an association between road traffic noise and sleep outcomes measured with polysomnography (probability of additional awakenings) with an OR of 1.36 (95% CI: 1.19–1.55) per 10 dB increase in indoor $L_{AS,max}$ ¹³ (Basner et al., 2006; Elmenhorst et al., 2012). Further, evidence rated low quality showed an association between road traffic noise and sleep outcomes measured as motility in adults (Frei et al., 2014; Griefahn et al., 2000; Oehrstroem et al., 2006a; Passchier-Vermeer et al., 2007; Pirrera et al., 2014). Finally, there was evidence rated very low quality for an association between road traffic noise and both self-reported and motility-measured sleep disturbance in children (Ising & Ising, 2002; Lercher et al., 2013; Oehrstroem et al., 2006a; Tiesler et al., 2013).

3.1.2.2 Evidence on interventions

This section summarizes the evidence underlying the recommendation on the effectiveness of interventions for road traffic noise exposure. The key question posed was: in the general population exposed to road traffic noise, are interventions effective in reducing exposure to and/or health outcomes from road traffic noise? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 13 and 14.

Table 13. PICOS/PECCOS scheme of the effectiveness of interventions for expo	sure to road
traffic noise	

PICO	Description		
Population	General population		
Intervention(s)	The interventions can be defined as:		
	(a) a measures that aim to change noise exposure and associated health effects;		
	(b) a measures that aim to change noise exposure, with no particular evaluation of the impact on health; or		
	(c) a measures designed to reduce health effects, but that may not include a reduction in nois exposure.		
Comparison	No intervention		
Outcome(s)	For average noise exposure:	For night noise exposure:	
	1. cardiovascular disease	1. effects on sleep	
	2. annoyance		
	3. cognitive impairment		
	4. hearing impairment and tinnitus		
	5. adverse birth outcomes		
	6. quality of life, well-being and mental health		
	7. metabolic outcomes		

¹³ L_{AS,max} is the maximum time-weighted and A-weighted sound pressure level with SLOW time constant within a stated time interval starting at t1 and ending at t2, expressed in dB.

Type of intervention	Number of participants (studies)	Effect of intervention	Quality of evidence
Annoyance	(studies)		
Type A – source interventions (change in traffic flow rate, improved road resurfacing, truck restriction strategy, complex set of barriers, road surfaces and other measures)	6096ª (9)	 Changes in noise level ranged from around –15 dB to +15.5 dB (various noise metrics). Most studies found that the intervention resulted in a change in annoyance. 	Moderate (downgraded for study limitations; upgraded for dose-response)
Type B – path interventions (dwelling insulation, barrier construction, building intervention)	2970 (7)	 Changes in noise level ranged from -3 dB to -13 dB (various noise metrics). All studies found that the intervention resulted in a change in annoyance, as estimated by an ERF. 	Moderate (downgraded for study limitations; upgraded for dose-response)
Type C – changes in infrastructure (new road tunnel infrastructure)	1211 (2)	 Noise levels reduced by an average of -12 dB (L_{Aeq,24}). Both studies found lower annoyance responses post intervention, with no change in the controls. 	Moderate (downgraded for study limitations; upgraded for dose-response)
Type D – other physical interventions (availability of quiet side to the dwelling, existence of nearby green space)	26 786 (6)	• Because of large variability in noise levels between most and least exposed façade (quiet side), access to quiet side and/or green space resulted in less annoyance.	Very low (downgraded for study limitations)
Sleep disturbance			
 Type B – path interventions (1: façade insulation; 2: enlargement of motorway lanes but with dwelling insulation, barriers and quiet pavement) 	1158 (2)	 1: façade insulation resulted in a reduction of 7 dB for indoor noise level. 2: enlargement led to reduction in the extent of population exposure at higher noise levels (55–65 dB) with an increase in lower levels (45–55 dB) Both path interventions resulted in changes in sleep outcomes 	Moderate (downgraded for study limitations)
Type C – changes in infrastructure (new road tunnel infrastructure)	166 (2)	 Noise levels reduced by an average of -12 dB (L_{Aeq,24h}). Both studies found lower sleep disturbance indicators/ improvement in sleep post intervention, with no change in the controls. 	Moderate (downgraded for study limitations)
Type D – other physical interventions (availability of quiet side to the dwelling)	100 (1)	• An absence of quiet façade resulted in increased reporting of difficulty in falling asleep.	Very low (downgraded for study limitations, inconsistency)
Cardiovascular disease			
Type D – other physical interventions (availability of quiet side to the dwelling)	9203 (4)	• Three studies found changes (including in self-reported hypertension) with and without a quiet side. One study found no change.	Very low (downgraded for study limitations)

Table 14. Summary of findings for road traffic noise interventions by health outcome

Note: ^a This figure does not include number of participants from the studies by Langdon & Griffiths (1982) and Baughan & Huddart (1993), as the exact number of respondents was not reported.

0 0

Type A – source interventions

Most of the nine source intervention studies – Baughan & Huddart (1993), Brown (1987; 2015), Brown et al. (1985), Griffiths & Raw (1987; 1989), Kastka (1981), Langdon & Griffiths (1982), Pedersen et al. (2013; 2014), Stansfeld et al. (2009b) – showed an effect in annoyance due to changes in road traffic flow rates. In some cases these were combined with other measures like improved road resurfacing, truck restrictions or complex control measures, including barriers or road surfaces. A majority of the changes resulted in reductions of noise levels.

Regarding the strength of association between exposure and annoyance outcome, all intervention studies demonstrated that the response was of at least the magnitude estimated by a steady-state ERF. The limited available evidence on long-term effects shows that this excess response undergoes some attenuation but is largely maintained over several years. In spite of the high risk of bias in all studies, the evidence in the systematic review was initially assessed as high quality, due to an upgrade because of the dose-response effect. However, the GDG decided to downgrade this assessment in an effort to maximize consistency with the grading approach of the remaining systematic reviews. It was therefore rated moderate quality.

Type B - path interventions

Seven path intervention studies – Amundsen et al. (2011; 2013), Bendtsen et al. (2011), Gidloef-Gunnarsson et al. (2010), Kastka et al. (1995), Nilsson & Berglund (2006), Vincent & Champelovier (1993) – explored the effects on annoyance by interventions related to dwelling insulation, barrier constructions and a combination of both, as well as a full-scale building intervention. With the help of pre/post designs, the studies assessed changes in noise exposure achieved by the interventions over different periods of time. In six studies the path intervention was associated with a change in annoyance outcomes. Four of these showed that the annoyance response to the change was in the same direction and of at least the same magnitude estimated by the ERF. In spite of the high risk of bias in all studies, the evidence in the systematic review was initially assessed as high quality, due to an upgrade because of the dose-response effect. However, the GDG decided to downgrade this assessment in an effort to maximize consistency with the grading approach of the remaining systematic reviews. The evidence was therefore rated moderate quality.

Two of the studies (Amundsen et al., 2013; Bendtsen et al., 2011) assessed path interventions and sleep disturbance. The results showed a reduction in the %HSD after the interventions were conducted. One of the studies included a two-year follow-up, revealing the persistence of the effect. Risk of bias was assessed as high in both studies. The evidence was rated moderate quality.

Type C – new/closed infrastructure interventions

Two infrastructural intervention studies (Gidloef-Gunnarsson et al., 2013; Oehrstroem, 2004; Oehrstroem & Skanberg, 2000) evaluated the impact on annoyance of major reductions in road traffic flows, combined with other environmental improvements. One was a new road tunnel infrastructure, resulting in substantial traffic and noise levels reductions for residents near the previously heavy-traffic road. Both studies were pre/post designs using repeated measures of annoyance outcomes. Following the reduction in noise levels (around $-12 \text{ dB } L_{\text{Aeq,24h}}$), both studies demonstrated a statistically significant lower degree of annoyance, while there was no change in

the control group. Both also reported that the after-scores in the studies matched those estimated by the ERF, but both reported excess response, meaning that the response to change was in the direction estimated by the ERF but much steeper. In spite of the high risk of bias in all studies, the quality of the evidence in the systematic review was initially assessed as high, due to an upgrade because of the dose-response effect. However, the GDG decided to downgrade this assessment in an effort to maximize consistency with the grading approach of the remaining systematic reviews. The evidence was therefore rated moderate quality.

Two studies investigated the impact of new tunnels that removed traffic flow from surface roads on sleep disturbance (Oehrstroem, 2004; Oehrstroem & Skanberg, 2000; 2004). Subjective and objective measures of sleep quality were assessed before and after the intervention. Both studies demonstrated a statistically significant lower reporting of various sleep disturbance indicators post intervention. One study reported statistically significantly reduced time spent in bed after the intervention, which, according to the authors, could suggest increased sleep efficiency. Risk of bias was assessed as high, so this evidence was rated moderate quality.

Type D – other physical infrastructure interventions

No intervention studies were available to assess impacts on annoyance of other physical interventions. The only relevant studies (Babisch et al., 2012; de Kluizenaar et al, 2011; 2013; Gidloef-Gunnarsson & Oehrstroem 2007; van Renterghem & Botteldooren, 2012; 2010) did not provide direct evidence of an intervention. Instead, they provided indirect evidence on the magnitude of the likely effect of certain interventions (e.g. using the quiet side of the dwelling, green space in the neighbourhood) by comparing responses from groups with and without the intervention/feature of interest. All studies found an effect of the presence of the dimension investigated; in all but one, the effect was statistically significant. Risk of bias was assessed as high in all studies, so the evidence was rated very low quality.

One study investigated a subjective assessment of difficulty in falling asleep (van Renterghem & Botteldooren, 2012), before and after the intervention. The difference in the proportion of participants reporting difficulty falling asleep "at least sometimes" between homes with and without a quiet side was statistically significant. Absence of a quiet façade resulted in increased reporting of this sleep parameter. Confounding was adjusted for in the analyses of the ERFs, including noise sensitivity, window-closing behaviour and front-façade L_{den} . Risk of bias was assessed as high, so the evidence was rated very low quality.

Four studies that assessed the effect of other physical interventions on cardiovascular disease were identified (Babisch et al., 2012; 2014a; Bluhm et al., 2007; Lercher et al., 2011). Three of these found changes, including self-reported hypertension, with and without a quiet side of the dwelling; in two the difference was statistically significant. The risk of bias in these studies was generally high, so the evidence was rated very low quality.

3.1.2.3 Consideration of additional contextual factors

As the foregoing overview has shown, ample evidence about the adverse health effects of long-term exposure to road traffic noise exists. Based on the quality of the available evidence, the GDG set the strength of the recommendation on road traffic noise at strong. As a second step, it qualitatively

assessed contextual factors to explore whether other considerations could have a relevant impact on the recommendation strength. These considerations mainly concerned the balance of harms and benefits, values and preferences, equity, and resource use and implementation.

When assessing the balance of harms and benefits of interventions to reduce exposure to road traffic noise, the GDG initially noted that road traffic is the most widespread source of noise pollution, measured in terms of the number of affected people both within and outside urban areas. The EEA estimates that more than 100 million people in Europe are exposed to L_{den} levels above 55 dB; for night-time road traffic noise, over 72 million Europeans are exposed to L_{night} levels above 50 dB (Blanes et al., 2017).¹⁴ The amount of road traffic noise emitted is unlikely to decrease significantly: both transport demand, including for passenger cars (EC, 2016b), and the number of city inhabitants (Eurostat, 2016) are expected to increase. Considering the significant burden of disease attributable to exposure to road traffic noise (WHO Regional Office for Europe & JRC, 2011), the GDG expects substantial health benefits to evolve from implementing the recommendations to reduce population exposure to road traffic noise. Depending on the intervention measures used (such as restrictions of traffic), possible harms could include effects on the transportation of goods and on individual mobility of the population. Both can have impacts on local, national and international economies. Overall, the GDG estimated that the benefits gained from minimizing adverse health effects due to road traffic noise exposure outweigh the possible (economic) harms.

Considering values and preferences, it has been established that people appreciate quiet areas as beneficial for their health and well-being, especially in urban areas (Shepherd et al., 2013; Gidloef-Gunnarsson & Oehrstroem, 2007; Oehrstroem et al., 2006b). Nevertheless, the GDG recognized that the convenience of individual mobility with the help of passenger cars is valued overall by large parts of the population in the EU, as illustrated by the sustained high volume of passenger kilometres driven in Europe (EEA, 2016a; 2017a). In general, values and preferences are expected to vary throughout society, as exposure to environmental noise and continuous road traffic noise is not equally distributed: those of individuals directly affected by long-term road traffic exposure are likely to differ from those that are not affected. Individuals with a higher average sound pressure level of road traffic noise are, for example, more willing to pay to reduce their noise exposure (Bristow et al., 2014).

In light of the dimension of equity, the GDG highlighted the fact that the risk of exposure to road traffic noise is not equally distributed throughout society. People with lower socioeconomic status and other disadvantaged groups often live in more polluted and louder areas, including in proximity to busy roads (EC, 2016a). Moreover, socioeconomic factors are not only related to differences in exposure to environmental factors such as noise but are also associated with increased vulnerability and poorer coping capacities (Karpati et al., 2002).

With resource use and implementation considerations, the GDG recognized that no comprehensive cost-benefit analysis for the WHO European Region yet exists, so this assessment is based on informed expert judgement regarding the feasibility of implementing the recommendation for the majority of the population. As the systematic review of environmental noise interventions and their

¹⁴ These are gap-filled figures based on the reported data and including the situation both within and outside cities, as defined by the END.

associated impact on health shows, various effective measures exist to reduce noise exposure from road traffic and improve health (Brown & van Kamp, 2017). The resources needed to implement these measures vary as they rely on the type of intervention and the context. The GDG pointed out the following four major solutions, which are known to be cost-effective: choice of appropriate tyres, use of low-noise road surfaces, building of noise barriers and installation of soundproof windows (CSES et al., 2016). Other types of intervention include limitations of speed or type of traffic allowed on roads.

Regarding feasibility of implementation, the GDG was convinced that many of the solutions can be planned as part of regular maintenance processes and accelerated fleet and road modernization. In particular, appropriate tyres and road surfaces are only slightly more expensive than existing products, and various countries have already considered or adopted similar interventions to reduce noise levels (Ohiduzzaman et al., 2016; Sirin, 2016). This indicates that solutions to achieve recommended noise levels can be implemented and carry a reasonable cost on a societal level. The GDG noted, however, that the feasibility of implementing measures can be hindered by the fact that costs and benefits are not evenly distributed. In most cases, the health benefits gained by interventions that reduce long-term road traffic exposure accrue to citizens, whereas the costs are borne by road users, private companies and public authorities. Furthermore, the GDG expects challenges in the implementation of all long-term measures that include changes in behaviour of the population, such as increased use of car-sharing or public transport. Even though the overall costs are expected to be significant, because of the large number of people affected, the benefit of implementation of the recommendation to minimize the risk of adverse health effects due to road traffic noise for a majority of the population exceeds the resources needed.

In light of the assessment of the contextual factors in addition to the quality of evidence, the recommendation remains strong.

Other nonpriority adverse health outcomes

As an additional consideration, although not priority health outcomes and coming from a single study, the GDG noted the evidence rated moderate quality for an association between road traffic noise and the prevalence of diabetes (van Kempen et al., 2018). The noise levels in the study identified ranged from around 50 dB to 70 dB L_{den} , so the recommendation proposed is thought to be protective enough for this health outcome. Thus, it did not lead to a change in the recommendation.

Additional considerations or uncertainties

Individual noise annoyance judgements of residents are to a large extent moderated by personal variables (such as noise sensitivity and coping capacity). However, further situational factors that apply to many residents should be taken into account when analysing noise annoyance from road traffic noise, as they may moderate the relationship. These include the type(s) of road being considered (highways, urban main roads, secondary roads and so on) and the related traffic composition (share of cars, motorcycles and heavy and loud trucks) and pattern (fluctuation, frequency, intermittency). Moreover, the location of settlements and/or individual dwellings, proximity to the road, and location and availability of a quiet façade can also influence the relationship when predicting health outcomes such as annoyance.

3.1.3 Summary of the assessment of the strength of the recommendations

Table 15 provides a comprehensive summary of the different dimensions for the assessment of the strength of the road traffic noise recommendations.

Table 15. Summary of the assessment of the strength of the road traffic noise recommendation

Factors influencing the strength of recommendation	Decision		
Quality of evidence	Average exposure (L _{den})		
	 Health effects Evidence for a relevant RR increase for incidence of IHD at 59 dB L_{den} was rated high quality. Evidence for the incidence of hypertension was rated low quality. Evidence for a relevant absolute risk of annoyance at 53 dB L_{den} was rated moderate quality. Evidence for a relevant RR increase for reading and oral comprehension was rated very low quality. 		
	InterventionsEvidence on effectiveness of interventions to reduce noise exposure and/or health outcomes from road traffic noise is of varying quality.		
	Night-time exposure (L _{night})		
	 Health effects Evidence for a relevant absolute risk of sleep disturbance related to night noise exposure from road traffic at 45 dB L_{night} was rated moderate quality. 		
	 Interventions Evidence on effectiveness of interventions to reduce noise exposure and/or sleep disturbance from road traffic noise is of varying quality. 		
Balance of benefits versus harms and burdens	Health benefits can be gained from markedly reducing exposure of the population to road traffic noise; benefits outweigh the harms of interventions to reduce continuous road traffic noise.		
Values and preferences	Quiet areas are valued by the population, especially by those affected by continuous noise exposure. Some variability is possible between those who benefit from interventions to reduce road traffic noise and those who finance the interventions.		
Equity	Risk of exposure to road traffic noise is not equally distributed.		
Resource use and implications	No comprehensive cost–effectiveness analysis data are available; nevertheless, a wide range of solutions exists and several are being implemented, showing that effective interventions are both feasible and economically reasonable.		
Decisions on recommendation strength	 Strong for guideline level for average noise exposure (L_{den}) Strong for guideline value for average night noise exposure (L_{night}) Strong for specific interventions to reduce noise exposure 		

3.2 Railway noise

Recommendations

For average noise exposure, the GDG **strongly** recommends reducing noise levels produced by railway traffic below **54 dB** L_{den} , as railway noise above this level is associated with adverse health effects.

For night noise exposure, the GDG **strongly** recommends reducing noise levels produced by railway traffic during night time below **44 dB** L_{night} , as railway noise above this level is associated with adverse effects on sleep.

To reduce health effects, the GDG **strongly** recommends that policy-makers implement suitable measures to reduce noise exposure from railways in the population exposed to levels above the guideline values for average and night noise exposure. There is, however, insufficient evidence to recommend one type of intervention over another.

3.2.1 Rationale for the guideline levels for railway noise

The exposure levels were derived in accordance with the prioritizing process of critical health outcomes described in section 2.4.3. For each of the outcomes, the exposure level was identified by applying the benchmark, set as relevant risk increase to the corresponding ERF. In the case of exposure to railway noise, the process can be summarized as follows (Table 16).

Table 16. Average exposure levels (L_{den}) for priority health outcomes from railway noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Incidence of IHD No studies were available and therefore incidence of IHD could not be used to assess the exposure level.	5% increase of RR	No studies met the inclusion criteria/no studies available
Incidence of hypertension One study met the inclusion criteria. There was no significant increase of risk associated with increased noise exposure in this study.	10% increase of RR	Low quality
Prevalence of highly annoyed population There was an absolute risk of 10% at a noise exposure level of 53.7 dB L_{den}	10% absolute risk	Moderate quality
Permanent hearing impairment	No increase	No studies met the inclusion criteria/no studies available
Reading skills and oral comprehension in children	One-month delay	No studies met the inclusion criteria/no studies available

In accordance with the prioritization process (see section 2.4.3), the GDG set a guideline exposure level of 53.7 dB L_{den} for average exposure, based on the relevant increase of the absolute %HA. In accordance with the defined rounding procedure, the value was rounded to 54 dB L_{den} . As the evidence on the adverse effects of railway noise was rated moderate quality, the GDG made the recommendation strong.

Next, the GDG assessed the evidence for night noise exposure and its effect on sleep disturbance (Table 17).

Table 17. Night-time exposure levels (L_{night}) for priority health outcomes from railway noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Sleep disturbance	3% absolute risk	Moderate quality
3% of the participants in studies were highly sleep-disturbed at a noise level of 43.7 dB $L_{\rm night}$		

Based on the evidence of the adverse effects of railway noise on sleep disturbance, the GDG defined a guideline exposure level of 43.7 dB L_{night} . The exact exposure value was rounded to 44 dB L_{night} . As the evidence was rated moderate quality, the GDG made the recommendation strong.

The GDG also considered the evidence for the effectiveness of interventions. The results showed that:

- intervening at the source by applying rail grinding procedures can reduce noise annoyance;
- behavioural interventions such as informing the community about noise interventions can reduce noise annoyance.

In light of the strong evidence about the adverse health effects, the GDG followed a precautionary approach and made a strong recommendation for interventions on railway noise, as it was confident that interventions are realizable and that best practices already exist for the management of noise from railways. Since the empirical evidence on the effectiveness of different types of intervention was rated either low or very low quality, the GDG felt that no recommendation could be made on the preferred type of intervention, and agreed not to recommend any specific type of intervention over another.

3.2.1.1 Other factors influencing the strength of recommendations

Other factors considered in the context of recommendations on railway noise included those related to values and preferences, benefits and harms, resource implications, equity, acceptability and feasibility; moreover, nonpriority health outcomes were considered. The assessment of all these factors – especially the values and preferences involved in railway noise – did not lead to a change in the strength of the recommendations. Further details are provided in Section 3.2.2.3.

3.2.2 Detailed overview of the evidence

The following sections provide a detailed overview of the evidence constituting the basis for setting the recommendations on railway noise. It is presented and summarized separately for each of the critical health outcomes, and the GDG's judgement of the quality of evidence is indicated (for a detailed overview of the evidence on important health outcomes, see Annex 4). Research into health outcomes and effectiveness of interventions is addressed consecutively.

A comprehensive summary of all evidence considered for each of the critical and important health outcomes can be found in the eight systematic reviews published in the *International Journal of Environmental Research and Public Health* (see section 2.3.2 and Annex 2).

3.2.2.1 Evidence on health outcomes

The key question posed was: in the general population exposed to railway noise, what is the exposure–response relationship between exposure to railway noise (reported as various noise indicators) and the proportion of people with a validated measure of health outcome, when adjusted for main confounders? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 18 and 19.

Table 18. PICOS/PECCOS scheme of critical health outcomes for exposure to railway noise

PECO	Description			
Population	General population			
Exposure	Exposure to high levels of noise produced by railway traffic (average/night time)			
Comparison	Exposure to lower levels of noise produce	Exposure to lower levels of noise produced by railway traffic (average/night time)		
Outcome(s)	For average noise exposure:	For night noise exposure:	6	
	1. cardiovascular disease	1. effects on sleep		
	2. annoyance		7	
	3. cognitive impairment			
	4. hearing impairment and tinnitus			
	5. adverse birth outcomes			
	6. quality of life, well-being and mental he	alth		
	7. metabolic outcomes			

Table 19. Summary of findings for health effects from exposure to railway noise (L_{dan})

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)ª	Quality of evidence	
Cardiova	Cardiovascular disease					
L _{den}	Incidence of IHD	_	_	_	-	
L _{den}	Incidence of hypertension	RR = 0.96 (95% CI: 0.88–1.04) per 10 dB increase	N/A	7249 (1)	Low (downgraded for risk of bias and availability of only one study)	
Annoyan	ice					
L _{den}	%HA	OR = 3.53 (95% Cl: 2.83–4.39) per 10 dB increase	34	10 970 (10)	Moderate (downgraded for inconsistency, directness; upgraded for dose-response)	
Cognitiv	Cognitive impairment					
L _{den}	Reading and oral comprehension	-	-	-	-	
Hearing impairment and tinnitus						
L _{den}	Permanent hearing impairment	-	-	-	-	

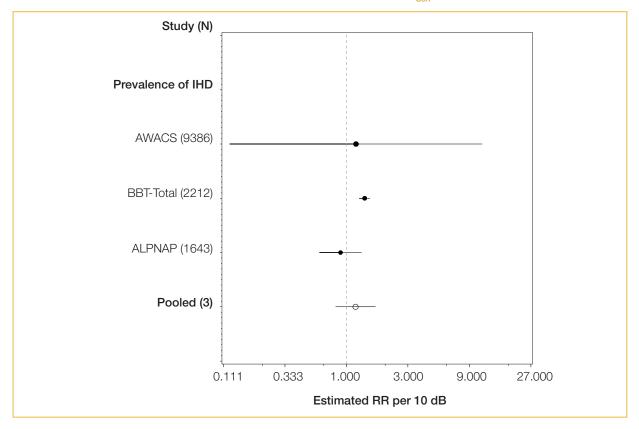
Note: ^a Results are partly derived from population-based studies.

Cardiovascular disease

IHD

No evidence was available on the relationship between railway noise and the incidence of or mortality from IHD. Four cross-sectional studies were identified, however, that assessed the prevalence of IHD in a total of 13 241 participants, including 283 cases (Heimann et al., 2007; Lercher et al., 2008; 2011; van Poll et al., 2014). The overall risk was not statistically significantly increased: the RR was 1.18 (95% CI: 0.82–1.68) per 10 dB L_{den} increase, with inconsistency across studies (see Fig. 7). The evidence was rated very low quality.

Fig. 7. The association between exposure to railway noise (L_{rien}) and prevalence of IHD



Notes: The dotted vertical line corresponds to no effect of exposure to railway noise. The black circles correspond to the estimated RR per 10 dB and 95% Cl. The white circle represents the pooled random effect estimates and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Hypertension

One cohort study on the relationship between railway noise and hypertension was identified; it assessed the incidence among people living in Denmark (Sörensen et al., 2011; 2012a). The study involved 7249 participants, including 3145 cases. The authors did not find an association between railway noise exposure and incidence of hypertension, with RR = 0.96 (95% CI: 0.88–1.04) per 10 dB L_{den} increase. This evidence was rated low quality.

In addition, five cross-sectional studies assessed the prevalence of hypertension in 15 850 participants, including 2059 cases (Barregard et al., 2009; Eriksson et al., 2012; Lercher et al., 2008; 2011; van Poll et al., 2014). The overall RR increase was not statistically significant, at 1.05 (95% CI: 0.88–1.26) per 10 dB L_{den} increase. Moreover, there was inconsistency among the results across studies. The evidence was rated very low quality.

Fig. 8 presents the studies investigating the relationship between railway noise and different measures of hypertension.

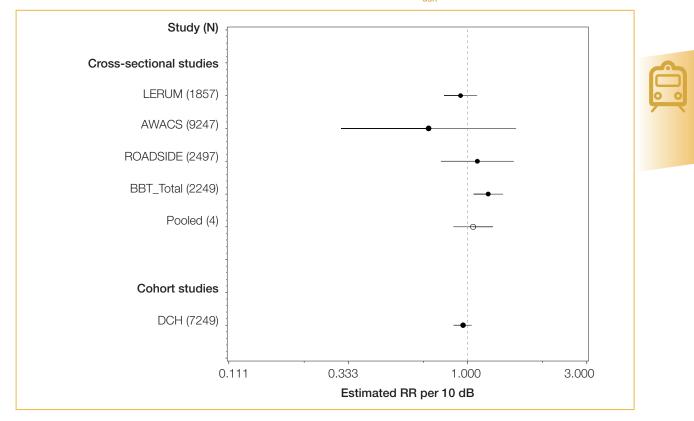


Fig. 8. The association between exposure to railway noise (L_{den}) and hypertension

Notes: The dotted vertical line corresponds to no effect of exposure to railway noise. The black dots correspond to the estimated RR per 10 dB and 95% Cl. The white circle represents the summary estimate and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Stroke

As for IHD, no evidence was available on the relationship between railway noise and incidence of or mortality from stroke. However, one cross-sectional study was identified that assessed the prevalence of stroke in 9365 participants, including 89 cases (van Poll et al., 2014). The overall risk was not statistically significantly increased, with RR = 1.07 (95% CI: 0.92–1.25) per 10 dB L_{den} increase. The evidence was rated very low quality.

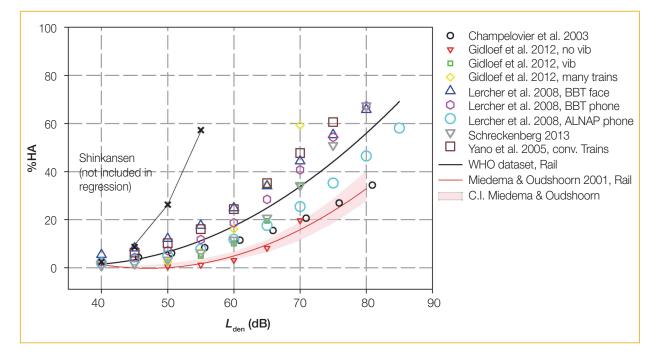
Children's blood pressure

No evidence was available for the association between railway noise and the systolic and/or diastolic blood pressure of children in residential and/or educational settings.

Annoyance

In total, 10 studies with ERFs on the association between railway noise and annoyance were included in analyses (Champelovier et al., 2003; Gidloef-Gunnarsson et al., 2012; Lercher et al., 2007; 2008; Sato et al., 2004; Schreckenberg, 2013; Yano et al., 2005; Yokoshima et al., 2008). The studies incorporated individual data from 10 970 participants. The estimated data points of each of these studies are plotted in Fig. 9, alongside an aggregated ERF including the data from all the individual studies (see the black line for "WHO dataset, Rail"). The lowest category of noise exposure considered in any of the studies, and hence included in the systematic review is 40 dB, corresponding to approximately 1.5%HA. The 10% benchmark for %HA is reached at 53.7 dB $L_{\rm den}$ (see Fig. 9).

Fig. 9. Scatterplot and quadratic regression of the relationship between railway noise (L_{den}) and annoyance (%HA)



Notes: The ERF by Miedema & Oudshoorn (2001) is added in red for comparison.

There is no indication of 95% CIs of the WHO dataset curve, as a weighting based on the total number of participants for each 5 dB *L*_{den} sound class could not be calculated; weighting based on all participants of all sound classes proved to be unsuitable. The range of data included is illustrated by the distribution of data points. For further details on the studies included in the figure please refer to the systematic review on environmental noise and annoyance (Guski et al., 2017).

Table 20 shows the %HA for railway noise exposure. The calculations are based on the regression equation %HA = $38.1596-2.05538 \times L_{den} + 0.0285 \times L_{den}^2$ derived from the systematic review (Guski et al., 2017). The overall evidence was rated moderate quality. Additional statistical analyses of annoyance outcomes supported these findings. When comparing railway noise exposure at 50 dB and 60 dB, the analyses revealed evidence rated moderate quality for an association between railway noise and %HA for an increase per 10 dB (OR = 3.40; 95% CI: 2.05-5.62). Moreover, evidence rated high quality was available for the increase in %HA per 10 dB increase in sound exposure, when data on all sound classes were included (OR = 3.53; 95% CI: 2.83-4.39).

L _{den} (dB)	% HA
40	1.5
45	3.4
50	6.6
55	11.3
60	17.4
65	25.0
70	33.9
75	44.3
80	56.1

Table 20. The association between exposure to railway noise (L_{dan}) and annoyance (%HA)

Cognitive impairment

Studies of railway noise on children's reading and oral comprehension were lacking. Nevertheless, other measures of cognition yielded evidence rated very low quality for an association between railway noise and children with poorer performance on standardized assessment tests (Bronzaft, 1981; Bronzaft & McCarthy, 1975). Evidence for the association between railway noise and children having poorer long-term memory (Lercher et al., 2003) was rated very low quality. No studies examined effects on short-term memory.

There was no clear relation between railway noise and attention in children (Lercher et al., 2003), and this evidence was rated very low quality.

Hearing impairment and tinnitus

No studies were found, and therefore no evidence was available on the association between railway noise and hearing impairment and tinnitus.

Sleep disturbance

For railway noise and self-reported sleep outcomes (awakenings from sleep, the process of falling asleep and sleep disturbance), five studies were identified that included a total of 7133 participants (Bodin et al., 2015; Hong et al., 2010; Sato et al., 2004; Schreckenberg, 2013). The studies were cross-sectional and conducted on healthy adults. The health outcome was measured by self-reporting via general health surveys and noise surveys that included questions about sleep in general, and other questions about how noise affects sleep (Table 21).

Noise metric	Priority health outcome measure	Quantitative risk for adverse health		Number of participants (studies)	Quality of evidence
Effects of	on sleep				
L _{night}	%HSD	OR: 3.06 (95% Cl: 2.38–3.93) per 10 dB increase	33 dB	7133 (5)	Moderate (downgraded for study limitations, inconsistency; upgraded for dose-response, magnitude of effect)

Table 21. Summary of findings for health effects from exposure to railway noise (L_{night})

The model in the systematic review (Basner & McGuire, 2018) was based on outdoor L_{night} levels between 40 dB and 65 dB only; 40 dB was chosen as the lower limit because of possible inaccuracies in predicting lower noise levels. The range of noise exposure reported in the studies was 27.5–82.5 dB L_{night} . About 2% (95% CI: 0.79–3.48) of the population was characterized as highly sleep-disturbed for L_{night} levels of 40 dB. The %HSD at other, higher levels of railway noise is presented in Table 17. The association between railway noise and the probability of being sleep-disturbed was OR: 3.1 (95% CI: 2.4–3.9) per 10 dB increase in noise. This evidence was rated moderate quality.

Table 22. The association between exposure to railway noise (L_{night}) and sleep disturbance (%HSD)

L _{night} (dB)	%HSD	95% CI
40	2.1	0.79–3.48
45	3.7	1.63–5.71
50	6.3	3.12–9.37
55	10.4	5.61-15.26
60	17.0	9.48–24.37
65	26.3	15.20–37.33

Additional analyses were conducted for sleep quality measures, which provided supporting evidence on the overall relationship between railway noise and sleep. When the noise source was not specified in the question, the relationship between railway noise and self-reported sleep outcomes was still positive but no longer statistically significant, with an OR of 1.27 (95% CI: 0.89–1.81) per 10 dB increase (Bodin et al., 2015; Brink, 2011; Frei et al., 2014). This evidence was rated very low quality.

There was evidence rated moderate quality for an association between railway noise and the probability of additional awakenings, measured with polysomnography, with an OR of 1.35 (95% CI: 1.21–1.52) per 10 dB increase in indoor $L_{AS,max}$ (Elmenhorst et al., 2012). Finally, evidence rated low quality was available for an association between railway noise and sleep outcomes measured as motility in adults (Griefahn et al., 2000; Hong et al., 2006; Lercher et al., 2010; Passchier-Vermeer et al., 2007), and rated very low quality for an association between railway noise and both self-reported and motility-measured sleep disturbance in children (Ising & Ising, 2002; Lercher et al., 2013; Tiesler et al., 2013).

3.2.2.2 Evidence on interventions

This section summarizes the evidence underlying the recommendation on the effectiveness of interventions for railway noise exposure (Tables 23 and 24). The key question posed was: in the

general population exposed to railway noise, are interventions effective in reducing exposure to and/ or health outcomes from railway noise? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 23 and 24.

Table 23. PICOS/PECCOS scheme of the effectiveness of interventions for exposure to railway noise

PICO	Description			
Population	General population			
Intervention(s)	The interventions can be defined as:			
	(a) a measure that aims to change noise expo	osure and associated health effects;		
	(b) a measure that aims to change noise expo health; or	re that aims to change noise exposure, with no particular evaluation of the impact on		
	(c) a measure designed to reduce health effect exposure.	sts, but that may not include a reduction in noise		
Comparison	No intervention			
Outcome(s)	For average noise exposure:	For night noise exposure:		
	1. cardiovascular disease	1. effects on sleep		
	2. annoyance			
	3. cognitive impairment			
	4. hearing impairment and tinnitus			
	5. adverse birth outcomes			
	6. quality of life, well-being and mental health			
	7. metabolic outcomes			

Table 24. Summary of findings for railway noise interventions by health outcome

Type of intervention	Number of participants (studies)	Effect of intervention	Quality of evidence
Annoyance			
Type A – source interventions (rail grinding)	81 (1)	 Changes in noise level as a consequence of the intervention ranged from around -7dB to -8 dB. Most studies found changes in annoyance outcomes, persisting more than 12 months after the intervention. 	Very low (downgraded for study limitations, inconsistency, imprecision)
Type C – changes in infrastructure (new rail infrastructure)	6000ª (1)	 A very small increase in total noise exposure was found (most had <+1 dB change; some had +2-4 dB change). Original noise from road traffic overwhelmed the train noise for effectively all participants. 	Very low (downgraded for study limitations, inconsistency, imprecision)
Type E – behaviour change interventions (informing the community about a noise intervention)	411 (1)	 Exposure levels were not reported; emission levels reduced by 1–2 dB. A reduction in annoyance of the community as a result of the intervention was reported. 	Very low (downgraded for study limitations, inconsistency, imprecision)

Note: ^a According to Lam & Au (2008), this records the number of invitation letters sent; the response rate was not reported.

Three studies on railway noise interventions met the criteria to be included in the evidence base. All studies consisted of a pre/post design and reported annoyance outcomes at people's dwellings (Lam & Au, 2008; Moehler et al., 1997; Schreckenberg et al., 2013). They could be categorized as a source intervention, a new/closed infrastructure intervention and a communication intervention. In two of the studies, the changes in exposure after the intervention were only small, although there were significant effects on noise annoyance. The study on source interventions and annoyance revealed that a change of -10 dB in noise exposure led to a significant reduction in annoyance, which persisted over a period of 12 months after the intervention. As confounding was not addressed, and railway noise was not the dominant sound source in the studies, the evidence was rated very low quality.

3.2.2.3 Consideration of additional contextual factors

As the foregoing overview has shown, sufficient evidence about the adverse health effects of longterm exposure to railway noise exists. Based on the quality of the available evidence, the GDG set the strength of recommendation on railway noise at strong. As a second step, it qualitatively assessed contextual factors to explore whether other considerations could have a relevant impact on the recommendation strength. These contextual considerations mainly concerned the balance of harms and benefits, values and preferences, and resource use and implementation.

When assessing the balance of harms and benefits of interventions to reduce exposure to railway noise and minimize noise-associated adverse health effects, the GDG recognized that railway transportation is the second most dominant source of environmental noise in Europe. Based on EEA estimates, the number of people exposed to L_{den} above 55 dB and L_{night} above 50 dB from railway noise is 17 million and 15 million, respectively (Blanes et al., 2017).¹⁵ In light of the burden of disease from environmental noise, and railway noise in particular, the GDG agreed that the health benefits from a reduction of long-term railway noise exposure (especially during night time) to the recommended values would be significant. Considering possible harms related to adaptation of the recommended values, the GDG noted that reliance on railway transportation has increased in recent years in Europe and is expected to increase further, as an important component of the shift towards a greener economy. At a societal level, an environmental and economic benefit from the use of rail transportation is expected: trains contribute to lower environmental pollution and carbon emission than road transportation. Therefore, there is a need to balance the expected health benefits from reduced continuous railway noise exposure and the overall positive effects on the health of the population from increased reliance on the comparatively environmentally friendly mode of railway transportation. Overall, the GDG agreed that even though fewer people are exposed to railway noise than road traffic noise, it remains a major source of localized noise pollution; therefore, considerable benefits are gained by reducing exposure to railway noise.

When exploring values and preferences, the GDG acknowledged that, in general, people value rail as an alternative and more sustainable transportation method than air or road traffic (EEA, 2016a; 2016b; 2017b). Furthermore, the values and preferences in relation to implementation of the recommendation are expected to vary: those of individuals living in the vicinity of railway tracks are expected to differ from those of the rest of the population not exposed to railway noise on a long-term basis. Economic depreciation of housing and fear of adverse health effects were assumed

¹⁵ These are gap-filled figures based on the reported data and including the situation both within and outside cities, as defined by the END.

to be two main aspects influencing the evaluation of affected individuals. This especially applies to areas where new railway tracks are being built, as this results in considerable change for local inhabitants. Moreover, the GDG acknowledged that preferences might also vary in the policy-making domain across different countries as the implementation of the recommendations would mean a renunciation of the so-called "railway bonus".¹⁶

On resource use and implementation considerations, the GDG pointed out that no comprehensive cost-benefit analysis for the WHO European Region has yet been conducted, so this assessment is based on informed qualitative expert judgement regarding the feasibility of implementing the recommendation for the majority of the population. The systematic review of environmental noise interventions and their associated impact on health shows that various measures to reduce continuous noise from railway traffic exist, although knowledge about their effectiveness remains limited (Brown & van Kamp, 2017). The GDG noted that the resources needed to implement different measures may vary considerably, as they depend on the situation and the type of intervention required. Implementation of some measures is expected to be most feasible during the development of new railway tracks; such as rail pads, bi-bloc sleepers, small noise barriers and - in extreme cases - tunnels, cuttings or earthwork barriers. Other interventions include acoustic rail grinding, noise barriers built alongside the tracks, construction of guieter locomotives and wagons and replacement of brakes on freight trains. The GDG assumed that most of these solutions could be planned as part of regular maintenance or, for instance, by speeding up fleet modernization and track modernization. Even though not broadly implemented, the solutions mentioned above have already been considered or adopted to reduce noise levels from railway noise exposure. Some EU countries (such as Germany), have programmes to replace old brake blocks from freight trains with newer, guieter ones and to ban all freight trains with old brake blocks from 2020 (Umweltbundesamt, 2017). This illustrates that solutions to achieve recommended noise levels can be implemented at a reasonable cost. Overall, the GDG agreed that the benefit of implementation of the recommendation to minimize the risk of adverse health effects due to railway noise for a majority of the population exceeds the (monetary) resources needed.

In light of the assessment of the contextual factors in addition to the quality of evidence, the recommendation remains strong.

Additional considerations or uncertainties

The GDG acknowledged that the main body of evidence for the recommendations on railway noise for average exposure was based on annoyance studies, conducted mainly in Asia and Europe. Studies are few for other priority health outcomes, and the evidence was generally rated low/very low quality. There is therefore uncertainty about the effects on health outcomes. Nevertheless, as a precautionary approach, a strong recommendation is made for average exposure to L_{den} , as a broad evidence base exists for health effects from exposure to other sources of transportation noise. However, the GDG stressed the importance of further research into health effects due to long-term exposure to railway noise.

Moreover, situational factors should be taken into account when analysing annoyance from railway noise. In particular, ground-borne vibrations are sometimes an additional exposure variable in railway

¹⁶ The "railway bonus" is a correction factor commonly applied in the noise abatement policy domain in recent decades. It subsidizes the noise rating level for railway transportation by a predefined factor (Schuemer & Schuemer-Kohrs, 1991).

noise situations – especially in the case of annoyance – which may be difficult to separate from noise effects. In the set of 11 studies included in the systematic review on railway noise and annoyance, only two explicitly mentioned ground-borne vibrations as an additional source of annoyance.

Overall, the low-carbon, low-polluting nature of railway transport, especially using electric trains, means that rail is favoured over road and air traffic. However, night-time railway traffic on busy lines, including freight traffic, can be a significant source of sleep disturbance. Thus, guideline values should be set to encourage the development of rail traffic in Europe while at the same time giving adequate protection to residents from sleep disturbance.

3.2.3 Summary of the assessment of the strength of the recommendations

Table 25 provides a comprehensive summary of the different dimensions for the assessment of the strength of the railway noise recommendations.

Factors influencing the strength of recommendation	Decision
Quality of evidence	Average exposure (L _{den})
	Health effects
	 Evidence for a relevant absolute risk of annoyance at 54 dB L_{den} was rated moderate quality.
	 Evidence for a relevant RR increase of the incidence of hypertension was rated low quality. One study met the inclusion criteria but did not find a significant increase.
	Interventions
	 Evidence that different types of intervention reduce noise annoyance from railways was rated very low quality.
	Night-time exposure (L _{night})
	Health effects
	 Evidence for a relevant absolute risk of sleep disturbance related to night noise exposure from railways at 44 dB L_{night} was rated moderate quality.
	Interventions
	 No evidence was available on the effectiveness of interventions to reduce noise exposure and/or sleep disturbance from railway noise.
Balance of benefits versus harms and burdens	Railway noise is a major source of localized pollution. The health benefits of adapting the recommendation outweigh the harms. Nevertheless, it is important to consider the relevance of railways as an environmentally friendly mode of transportation.
Values and preferences	Quiet areas are valued by the population; especially by those affected by continuous noise exposure. Some variability is expected among those directly affected by railway noise and those not affected.
Resource implications	No comprehensive cost–effectiveness-analysis data are available, although a wide range of interventions exists, indicating that measures are both feasible and economically reasonable.
Decisions on	• Strong for guideline value for average noise exposure (L _{den}).
recommendation strength	• Strong for guideline value for night noise exposure (<i>L</i> _{night}).
	• Strong for specific interventions to reduce noise exposure.

Table 25. Summary of the assessment of the strength of the recommendation

3.3 Aircraft noise

Recommendations

For average noise exposure, the GDG **strongly** recommends reducing noise levels produced by aircraft below **45 dB** L_{den} , as aircraft noise above this level is associated with adverse health effects.

For night noise exposure, the GDG **strongly** recommends reducing noise levels produced by aircraft during night time below **40 dB** L_{night} , as aircraft noise above this level is associated with adverse effects on sleep.

To reduce health effects, the GDG strongly recommends that policy-makers implement suitable measures to reduce noise exposure from aircraft in the population exposed to levels above the guideline values for average and night noise exposure. For specific interventions the GDG recommends implementing suitable changes in infrastructure.

3.3.1 Rationale for the guideline levels for aircraft noise

The exposure levels were derived in accordance with the prioritization process of critical health outcomes described in section 2.4.3. For each of the outcomes, the exposure level was identified by applying the benchmark, set as relevant risk increase to the corresponding ERF. In the case of exposure to aircraft noise, the process can be summarized as follows (Table 26).

Table 26. Average exposure levels (L_{den}) for priority health outcomes from aircraft noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Incidence of IHD	5% increase of RR	Very low quality
A relevant risk increase from exposure to aircraft noise occurs at 52.6 dB L_{den} . The weighted average of the lowest noise levels measured in the studies was 47 dB L_{den} and the corresponding RR in the meta-analysis was 1.09 per 10 dB.		
Incidence of hypertension	10% increase of RR	Low quality
One study met the inclusion criteria. There was no significant increase of risk associated with increased noise exposure in this study.		
Prevalence of highly annoyed population	10% absolute risk	Moderate quality
There was an absolute risk of 10% at a noise exposure level of 45.4 dB $L_{\rm den}$.		
Permanent hearing impairment	No increase	No studies met the inclusion criteria
Reading skills and oral comprehension in children	One-month delay	Moderate quality
A relevant risk increase was found at 55 dB L_{den} .		



Based on the evaluation of evidence on relevant risk increases from the prioritized health outcomes, the GDG set a guideline exposure level of 45.4 dB L_{den} for average exposure to aircraft noise, based on the absolute %HA. It was confident that there was an increased risk for annoyance below this exposure level, but probably no relevant risk increase for other priority health outcomes. In accordance with the defined rounding procedure, the value was rounded to 45 dB L_{den} . As the evidence on the adverse effects of aircraft noise was rated moderate quality, the GDG made the recommendation strong.

Next, the GDG considered the evidence for night noise exposure and its effect on sleep disturbance (Table 27).

Table 27. Night-time exposure levels (L_{night}) for priority health outcomes from aircraft noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Sleep disturbance	3% absolute risk	Moderate quality
11% of participants were highly sleep-disturbed at a noise level of 40 dB $L_{\rm night}$		

Based on the evidence of the adverse effects of aircraft noise on sleep disturbance, the GDG defined a guideline exposure level of 40.0 dB L_{night} . It should be stressed that this recommendation for average aircraft noise levels at night far exceeds the benchmark of 3%HSD defined as relevant risk increase, but since no reliable acoustic data below this level were available, the GDG decided not to lower the guideline exposure level further, as an extrapolation of the exposure–response relationship to achieve these values would have been unavoidable. As the evidence was rated moderate quality, the GDG made the recommendation strong.

The GDG also considered the evidence for the effectiveness of interventions. The results showed that changes in infrastructure (opening and/or closing of runways, or flight path rearrangements) can lead to a reduction in aircraft noise exposure, as well as a decline in cognitive impairment in children and a reduction in annoyance. Moreover, examples of best practice already exist for the management of noise from aircraft, so the GDG made a strong recommendation.

3.3.1.1 Other factors influencing the strength of recommendations

Other factors considered in the context of recommendations on aircraft traffic noise included those related to values and preferences, benefits and harms, resource implications, equity, acceptability and feasibility; moreover, nonpriority health outcomes were considered. Ultimately, the assessment of all these factors did not lead to a change in the strength of the recommendations. Further details are provided in section 3.3.2.3.

3.3.2 Detailed overview of the evidence

The following sections provide a detailed overview of the evidence constituting the basis for setting the recommendations on aircraft noise. It is presented and summarized separately for each of the critical health outcomes, and the GDG's judgement of the quality of evidence is indicated (for a detailed overview of the evidence on important health outcomes, see Annex 4). Research into health outcomes and effectiveness of interventions is addressed consecutively.

A comprehensive summary of all evidence considered for each of the critical and important health outcomes can be found in the eight systematic reviews published in the *International Journal of Environmental Research and Public Health* (see section 2.3.2 and Annex 2).

3.3.2.1 Evidence on health outcomes

The key question posed was: in the general population exposed to aircraft noise, what is the exposure–response relationship between exposure to aircraft noise (reported as various noise indicators) and the proportion of people with a validated measure of health outcome, when adjusted for main confounders? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 28 and 29.

PECO	Description			
Population	General population			
Exposure	Exposure to high levels of noise produced by airc	raft traffic (average/night time)		
Comparison	Exposure to lower levels of noise produced by air	craft traffic (average/night time)		
Outcome(s)	For average noise exposure:	For night noise exposure:		
	1. cardiovascular disease	1. effects on sleep		
	2. annoyance			
	3. cognitive impairment	3. cognitive impairment		
	4. hearing impairment and tinnitus	4. hearing impairment and tinnitus		
	5. adverse birth outcomes	5. adverse birth outcomes		
	6. quality of life, well-being and mental health			
	7. metabolic outcomes			

Table 28. PICOS/PECCOS scheme of critical health outcomes for exposure to aircraft noise

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)ª	Quality of evidence
Cardiova	scular disease				
L _{den}	Incidence of IHD	RR = 1.09 (95% CI: 1.04–1.15) per 10 dB increase	47 dB	9 619 082ª (2)	Very low (downgraded for risk of bias; upgraded for dose-response)
L _{den}	Incidence of hypertension	RR = 1.00 (95% CI: 0.77–1.30) per 10 dB increase	N/A	4712 (1)	Low (downgraded for risk of bias and because only one study available)
Annoyan	ce				
L _{den}	%HA	OR = 4.78 (95% Cl: 2.27–10.05) per 10 dB increase	33 dB	17 094 (12)	Moderate (downgraded for inconsistency)
Cognitive	e impairment				
L _{den}	Reading and oral comprehension	1–2-month delay per 5 dB increase	Around 55 dB	(4)	Moderate (downgraded for inconsistency)
Hearing	impairment and tin	nitus			
L _{den}	Permanent hearing impairment	-	-	_	-

Table 29 .Summary of findings for health effects from exposure to aircraft noise (L_{dan})

Note: a Results are partly derived from population-based studies.

Cardiovascular disease

IHD

No cohort or case-control studies on the relationship between aircraft noise and IHD are available. However, two ecological studies were identified that provide information on the relationship between aircraft noise and incidence (hospital admission) of IHD (Correia et al., 2013; Hansell et al., 2013). These involved a total of 9 619 082 participants, including 158 977 cases. The RR was 1.09 (95% Cl: 1.04–1.15) per 10 dB L_{den} increase, and the lowest exposure range was \leq 51 dB and <45 dB. Given the weights in the meta-analysis of these two studies, the weighted average starting level was calculated as 47 dB. The evidence was rated very low quality.

Two cross-sectional studies were identified that assessed the prevalence of IHD in people living in cities located around airports in Europe. The studies involved 14 098 participants, including 340 cases (Babisch et al., 2005b; 2008; 2012a; 2012b; 2013a; Floud et al., 2011; 2013a; 2013b; Jarup et al., 2005; 2008; van Poll et al., 2014). The overall risk was RR = 1.07 (95% CI: 0.94–1.23) per 10 dB L_{den} increase. The evidence was rated low quality.

With regard to the relationship between aircraft noise and mortality due to IHD, one cohort study (Huss et al., 2010) and two ecological studies (Hansell et al., 2013; van Poll et al., 2014) were identified. The cohort study identified 4 580 311 participants, including 15 532 cases, living in Switzerland, and the authors found an RR of 1.04 (95% CI: 0.98–1.11) per 10 dB L_{den} increase in noise. The evidence was rated low quality. The two ecological studies identified a total of 3 897 645

participants, including 26 066 cases in the Netherlands and the United Kingdom. The overall RR was 1.04 (95% CI: 0.97–1.12) per 10 dB L_{den} increase in noise, and the evidence was rated very low quality.

Fig. 10 summarizes the results for the relationship between aircraft noise and different measures of IHD.

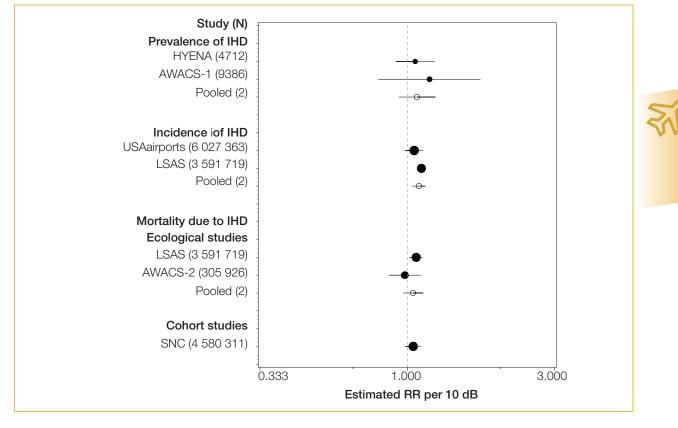


Fig. 10. The association between exposure to aircraft noise (L_{dop}) and IHD

Notes: The dotted vertical line corresponds to no effect of exposure to aircraft noise. The black circles correspond to the estimated RR per 10 dB and 95% CI. The white circles represent the pooled random effect estimates and 95% CI. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Hypertension

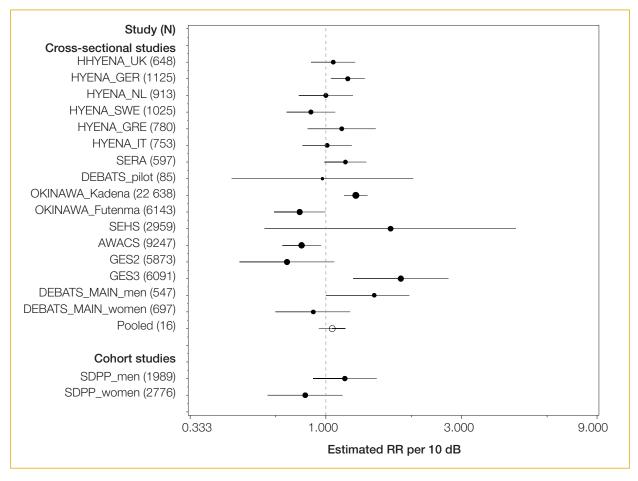
One cohort study was identified that assessed the relationship between aircraft noise and hypertension in people living in Sweden (Bluhm et al., 2004; 2009; Eriksson et al., 2007; 2010). The study involved 4712 participants, including 1346 cases. The authors found a nonstatistically significant effect size of RR = 1.00 (95% CI: 0.77–1.30) per 10 dB L_{den} increase. This evidence was rated moderate quality.

Furthermore, nine cross-sectional studies assessed the prevalence of hypertension in 60 121 participants, including 9487 cases (Ancona et al., 2010; Babisch et al., 2005b; 2008; 2012a; 2012b; 2013a; Breugelmans et al., 2004; Evrard et al., 2013; 2015; Houthuijs & van Wiechen, 2006; Jarup

et al., 2005; 2008; Matsui, 2013; Matsui et al., 2001; 2004; Rosenlund et al., 2001; van Kamp et al., 2006; van Poll et al., 2014). The overall RR was 1.05 (95% CI: 0.95-1.17) per 10 dB L_{den} increase, with inconsistency across studies. The evidence was rated low quality.

Fig. 11 summarizes the results for both prevalence and incidence of hypertension.

Fig. 11. The association between exposure to aircraft noise (L_{den}) and hypertension in cross-sectional and cohort studies



Notes: The dotted vertical line corresponds to no effect of aircraft noise exposure. The black dots correspond to the estimated RR per 10 dB and 95% Cl. The white circle represents the pooled summary estimate and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Stroke

No cohort or case-control studies on the relationship between aircraft noise and incidence (hospital admission) of stroke were available, but two ecological studies were conducted in cities around airports in the United Kingdom and United States of America, involving 9 619 082 participants, including 97 949 cases (Correia et al., 2013; Hansell et al., 2013). An overall RR of 1.05 (95% CI: 0.96-1.15) per 10 dB L_{den} increase in noise was found. The evidence was rated very low quality.

Two cross-sectional studies were identified that assessed the prevalence of stroke in 14 098 participants, including 151 cases (Babisch et al., 2005b; 2008; 2012a; 2012b; 2013a; Floud et al., 2011; 2013a; 2013b; Jarup et al., 2005; 2008; van Poll et al., 2014). The overall RR was 1.02 (95% Cl: 0.80–1.28) per 10 dB L_{den} increase. The evidence was rated very low quality.

On the relationship between aircraft noise and mortality due to stroke, one cohort study (Huss et al., 2010) and two ecological studies (Hansell et al., 2013; van Poll et al., 2014) were identified. The cohort study identified 4 580 311 participants, including 25 231 cases, living in Switzerland; the authors found an RR of 0.99 (95% CI: 0.94–1.04) per 10 dB L_{den} increase in noise. The overall evidence was rated moderate quality. The two ecological studies identified a total of 3 897 645 participants, including 12 086 cases, in the Netherlands and the United Kingdom. The overall RR was 1.07 (95% CI: 0.98–1.17) per 10 dB L_{den} increase in noise. The evidence was rated very low quality.

Fig. 12 summarizes the results for the relationship between aircraft noise and different measures of stroke.

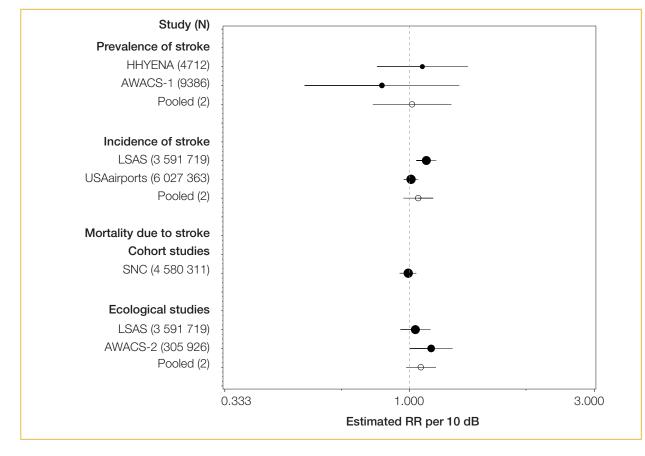


Fig. 12. The association between exposure to aircraft noise (L_{acc}) and stroke

Notes: The dotted vertical line corresponds to no effect of exposure to aircraft noise. The black dots correspond to the estimated RR per 10 dB and 95% Cl. The white circle represents the summary estimate and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

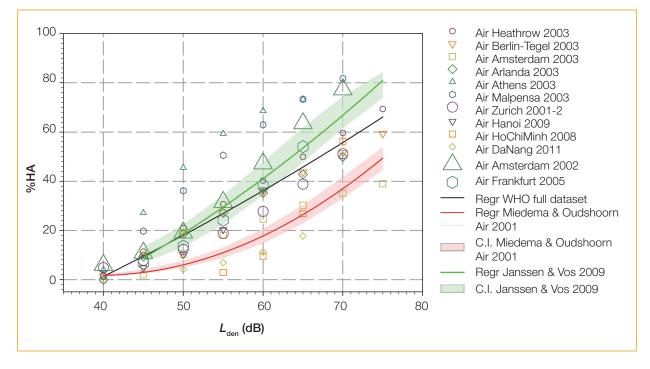
Children's blood pressure

For the association between aircraft noise and blood pressure in children, two cross-sectional studies were conducted in Australia, the Netherlands and the United Kingdom, including a total of 2013 participants (Clark et al., 2012; Morrell et al., 1998; 2000; van Kempen et al., 2006). The change in both systolic and diastolic blood pressure was assessed, in residential and/or educational settings. There was serious inconsistency in the results and therefore no overall estimate of the effect was developed. The evidence was rated very low quality.

Annoyance

A vast amount of evidence proves the association between aircraft noise and annoyance. In total, 12 aircraft noise studies were identified that were used to model ERFs of the relationship between L_{den} and %HA (Babisch et al., 2009; Bartels et al., 2013; Breugelmans et al., 2004; Brink et al., 2008; Gelderblom et al., 2014; Nguyen et al., 2011; 2012a; 2012b; Sato & Yano, 2011; Schreckenberg & Meis, 2007). These include data from 17 094 study participants. The estimated data points of each of the studies are plotted in Fig. 13, alongside an aggregated ERF including the data from all the individual studies (see the black line for "Regr WHO full dataset"). The lowest category of noise exposure considered in any of the studies, and hence included in the systematic review, is 40 dB, corresponding to approximately 1.2%HA. The benchmark level of 10%HA is reached at approximately 45 dB L_{den} (see Fig. 13).

Fig. 13. Scatterplot and quadratic regression of the relationship between aircraft noise (*L*_{den}) and annoyance (%HA)



Notes: ERFs by Miedema & Oudshoorn (2001, red), and Janssen & Vos (2009, green) are added for comparison. There is no indication of 95% Cls of the WHO dataset curve, as a weighting based on the total number of participants for each 5 dB L_{den} sound class could not be calculated; weighting based on all participants of all sound classes proved to be unsuitable. The range of data included is illustrated by the distribution of data points. For further details on the studies included in the figure please refer to the systematic review on environmental noise and annoyance (Guski et al., 2017). Table 30 shows the %HA in relation to exposure to aircraft traffic noise. It is based on the regression equation %HA = $-50.9693 + 1.0168 \times L_{den} + 0.0072 \times L_{den}^2$ derived from the systematic review (Guski et al., 2017). As the majority of the studies are cross-sectional, the evidence was rated moderate quality.

The general quality of the evidence was further substantiated with the help of additional statistical analyses that apply classical health outcome measures to estimate noise annoyance. When comparing aircraft noise exposure at 50 dB and 60 dB, the analyses revealed evidence rated high quality for an association between aircraft noise and %HA for an increase per 10 dB (OR = 3.40; 95% CI: 2.42-4.80). Moreover, there was evidence rated high quality for the increase of %HA per 10 dB increase in sound exposure, when data on all sound classes were included (OR = 4.78; 95% CI: 2.27-10.05).

Table 30. The association between exposure to aircraft noise (L_{den}) and annoyance (%HA)

L _{den} (dB)	%HA
40	1.2
45	9.4
50	17.9
55	26.7
60	36.0
65	45.5
70	55.5

Cognitive impairment

Evidence rated moderate quality was available for an association between aircraft noise and reading and oral comprehension, assessed by standardized tests. This is based on a narrative review of 14 studies that examined aircraft noise exposure effects on reading and oral comprehension (Clark et al., 2006; 2012; 2013; Evans & Maxwell, 1997; Haines et al., 2001a; 2001b; 2001c; Hygge et al., 2002; Klatte et al., 2014; Matsui et al., 2004; Seabi et al., 2012; 2013; Stansfeld et al., 2005; 2010). Of these studies, 10 were cross-sectional, and only four had a longitudinal and/or intervention design (Clark et al., 2013; Haines et al., 2001c; Hygge et al., 2002; Seabi et al., 2013). Most of the studies (10 of 14) demonstrated a statistically significant association or at least demonstrated a trend between higher aircraft noise exposure and poorer reading comprehension.

This relationship is supported by evidence on other health outcome measures related to cognition. Evidence rated moderate quality was available for an association between aircraft noise and children with poorer performance on standardized assessment tests (Eagan et al., 2004; FICAN, 2007; Green et al., 1982; Sharp et al., 2014). There was also evidence rated moderate quality on aircraft noise being associated with children having poorer long-term memory (Haines et al., 2001b). No studies examined the effects on short-term memory.

However, there was no substantial effect (evidence rated low quality) of aircraft noise on children's attention (Haines et al., 2001a; Hygge et al., 2002; Matsui et al., 2004; Stansfeld et al., 2005; 2010), or on executive function (working memory) (evidence rated very low quality), with studies consistently suggesting no association for aircraft noise (Clark et al., 2012; Haines et al., 2001a;

Haines et al., 2001b; Klatte et al., 2014; Matheson et al., 2010; Stansfeld et al., 2005; 2010; van Kempen et al., 2010; 2012).

Hearing impairment and tinnitus

No studies were found, and therefore no evidence was available on the association between aircraft noise and hearing impairment and tinnitus.

Sleep disturbance

For aircraft noise and self-reported sleep outcomes, six studies were identified that included a total of 6371 participants (Nguyen et al., 2009; 2010; 2011; 2012c; 2015; Schreckenberg et al., 2009; Yano et al., 2015). The majority of studies were cross-sectional by design and were conducted in otherwise healthy adults. The model was based on outdoor L_{night} levels between 40 dB and 65 dB only; the lower limit of 40 dB was set because of inaccuracies in predicting lower noise levels (Table 31).

Table 31. Summary of findings for health effects from exposure to aircraft noise (L_{night})

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)	Quality of evidence
Effects o	n sleep				
L _{night}	%HSD	OR: 1.94 (95% CI: 1.61–2.33) per 10 dB increase	35 dB	6371 (6)	Moderate (downgraded for study limitations, inconsistency; upgraded for dose-response, magnitude of effect)

The range of noise exposure reported in studies was 37.5–62.5 dB. Over 11% (95% CI: 4.72–17.81) of the population was characterized as highly sleep-disturbed at L_{night} levels of 40 dB. The %HSD at other, higher levels of aircraft noise is presented in Table 27. The table is derived from the regression model in the systematic review specified as %HSD = 16.79–0.9293 × L_{night} + 0.0198 × L_{night}^2 . The health outcome was measured in the studies by self-reporting, focusing on questions asking about awakenings from sleep, the process of falling asleep and/or sleep disturbance, where the question referred specifically to how noise affects sleep. The same relationship between aircraft noise and reporting being sleep-disturbed (all questions combined) can also be expressed as an OR of 1.94 (95% CI: 1.61–2.33) per 10 dB increase in noise. This evidence was rated moderate quality.

Table 32. The association between exposure to aircraft noise (L_{night}) and sleep disturbance (%HSD)

%HSD	95% CI
701102	
11.3	4.72-17.81
15.0	6.95–23.08
19.7	9.87–29.60
25.5	13.57–37.41
32.3	18.15–46.36
40.0	23.65-56.05
	15.0 19.7 25.5 32.3

Additional analyses were included in the systematic review and provided supporting evidence on the association between aircraft noise and sleep. When the noise source was not specified in the survey question, the relationship between aircraft noise and self-reported sleep outcomes was still positive, although no longer statistically significant (OR: 1.17 (95% CI: 0.54–2.53) per 10 dB increase) (Brink, 2011). This evidence was rated very low quality.

Further, there was evidence rated moderate quality for an association between aircraft noise and polysomnography-measured outcomes (probability of additional awakenings), with an OR of 1.35 (95% CI: 1.22–1.50) per 10 dB increase in indoor $L_{AS,max}$ (Basner et al., 2006). Evidence rated low quality was also available for an association between aircraft noise and motility-measured sleep outcomes in adults (Passchier-Vermeer et al., 2002).

3.3.2.2 Evidence on interventions

The following section summarizes the evidence underlying the recommendation on the effectiveness of interventions for aircraft noise exposure. The key question posed was: in the general population exposed to aircraft noise, are interventions effective in reducing exposure to and/or health outcomes from aircraft noise? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 33 and 34.

Seven studies examining different types of interventions on aircraft noise met the inclusion criteria to become part of the evidence base of the systematic review. Six of these investigated infrastructure interventions (Breugelmans et al., 2007; Brink et al., 2008; Fidell et al., 2002; Hygge et al., 2002), and one assessed a path intervention (Asensio et al., 2014). The majority of studies focused on annoyance as a health outcome, but two also included effects on sleep and one investigated the effects of path interventions on cognitive development in children.

PICO	Description		
Population	General population		
Intervention(s)	The interventions can be defined as:		
	(a) a measure that aims to change noise expo	osure and associated health effects;	
	(b) a measure that aims to change noise exposure, with no particular evaluation of the i health; or		
	(c) a measure designed to reduce health effect exposure.	cts, but that may not include a reduction in noise	
Comparison	No intervention		
Outcome(s)	For average noise exposure:	For night noise exposure:	
	1. cardiovascular disease	1. effects on sleep	
	2. annoyance		
	3. cognitive impairment		
	4. hearing impairment and tinnitus		
	5. adverse birth outcomes		
	6. quality of life, well-being and mental health		
	7. metabolic outcomes		

Table 33. PICOS/PECCOS scheme of the effectiveness of interventions for exposure to aircraft noise



Type of intervention	Number of participants (studies)	Effect of intervention	Quality of evidence
Annoyance			
Type B – path interventions (retrofitting dwellings close to airports with acoustic insulation)	689 (1)	Change in noise levels was not reported.The study found a drop in annoyance following the insulation intervention	Very low (downgraded for study limitations, inconsistency, precision)
Type C – changes in infrastructure (opening and/or closing of runways, or flight path rearrangements)	2101 (3)	 There was a wide range of changes in noise levels (from -12 dB to +13.7 dB; most between ±1 dB and 2 dB; different noise indicators used). All studies found changes in annoyance outcomes as a result of the intervention. 	Moderate (downgraded for study limitations; upgraded for dose-response)
Sleep disturbance			
Type C – changes in infrastructure (flight path changes)	1707 (2)	 Changes in noise levels were mostly between ±1 dB and 2 dB. Both studies found changes in sleep disturbance outcomes as a result of the intervention. 	Low (downgraded for study limitations)
Cognitive development of	children		
Type C – changes in infrastructure (opening and/or closing of runways, or flight path rearrangements)	326 (1)	 Changes in noise levels of +9 dB at the new airport and of -14 dB at the old airport were reported. The study found various cognitive effects on children (for both the reduction and the increase in exposure). Effects disappeared when the old airport closed, emerging after the new airport opened. 	Moderate (downgraded for inconsistency)

Table 34. Summary of findings for aircraft noise interventions by health outcome

The largest body of research concentrated on the opening and closing of runways, leading to subsequent changes in flight paths (Breugelmans et al., 2007; Brink et al., 2008; Fidell et al., 2002). It showed that changes in noise exposure as a consequence of rearrangement of flight paths, step changes or increase or removal of over-flights resulted in statistically significant changes of the annoyance ratings of residents living in the vicinity of airports. The studies investigated both increases and reductions in exposure. Moreover, all the studies provided evidence that the change in response to noise exposure was an excess response to the intervention. As all the studies either adjusted for confounding or ruled out confounding by design, and the risk of bias was high in two studies but low in one, the evidence was rated moderate quality.

Two of these studies also investigated the effects of interventions on sleep disturbance. The results indicated that the percentage of sleep disturbance changed in association with the change in noise exposure caused by flight path adaptations (Breugelmans et al., 2007; Fidell et al., 2002). Both studies adjusted for confounding, but the risk of bias was assessed as high. Thus, the evidence was rated low quality.

One study examined the impact of rearranging flight paths on the cognitive effects on children (Hygge et al., 2002), showing various effects (for both the reduction and the increase in exposure).

The study ruled out confounding by study design and the risk of bias was assessed as low. The evidence was therefore rated moderate quality.

Alongside infrastructure interventions, a Spanish study presented evidence on path interventions (Asensio et al., 2014), showing a drop in annoyance following an insulation intervention. The study did not control for confounding and the risk of bias was assessed as high. The evidence was therefore rated very low quality.

3.3.2.3 Consideration of additional contextual factors

As the foregoing overview has shown, substantial evidence about the adverse health effects of long-term exposure to aircraft noise exists. Based on the quality of the available evidence, the GDG set the strength of the recommendation of aircraft noise at strong. As a second step, it qualitatively assessed contextual factors to explore whether other considerations could have a relevant impact on the recommendation strength. These considerations mainly concerned the balance of harms and benefits, values and preferences, equity, and resource use and implementation.

When assessing the balance of harms and benefits from implementing the recommendations on aircraft exposure, the GDG acknowledged that the number of people affected was lower than for road traffic or railway noise, since aircraft noise only affects the areas surrounding airports and under flight paths. Data from the EEA show that the estimated number of people in Europe exposed to L_{den} levels above 55 dB and L_{ninht} levels above 50 dB is 3 million and 1.2 million, respectively (Blanes et al., 2017).¹⁷ Nevertheless, it remains a major source of localized noise pollution and has been predicted to increase (EASA et al., 2016). Furthermore, aircraft noise is regarded as more annoying than the other sources of transportation noise (Schreckenberg et al., 2015; Miedema & Oudshoorn, 2001); it is therefore associated with a significant burden on public health, and the GDG expects substantial health benefits for the population to evolve from implementing the recommendations to reduce exposure to aircraft traffic noise. Furthermore, the GDG noted that, depending on the intervention measure implemented (such as a night flight ban), additional health benefits could evolve, resulting from a simultaneous reduction in air pollution (EC, 2016a). The GDG also acknowledged that intervention measures like night flight bans might also reduce carbon emission, thereby positively influencing the shift towards a greener and more sustainable economy. Possible harms in relation to the applied noise abatement strategy, on the other hand, could include effects on the transportation of goods, as well as individual mobility of the population. Both could have impacts on local, national and international economies. Overall, the GDG estimated that the benefits gained from minimizing adverse health effects due to aircraft noise exposure outweigh the possible (economic) harms.

Considering values and preferences, the GDG noted that negative attitudes towards aircraft noise are especially prevalent in affected individuals who can see and hear aircraft from their house, or who fear that living in proximity of airports will have an impact on their health (Schreckenberg et al., 2015) or property value (economic loss) (Bristow et al., 2014). A lack of trust in the airport and government authorities can enhance these negative attitudes towards airports and aircraft noise (Borsky, 1979; Schreckenberg, 2017). Furthermore, the GDG recognized that values and preferences of individuals living in the vicinity of different airports may vary, as the infrastructural characteristics

¹⁷ These are gap-filled figures based on the reported data and including the situation both within and outside cities, as defined by the END.

of airports have a significant effect on the evaluation of residents. Airports with a stable number of aircraft movements in the near past and no intention to change the number in the future can give rise to a different evaluation of values and preferences than airports with relatively sustained increases in the number of aircraft movements. This can result from the fact that opening new runways or increasing the number of flights usually means considerable change in the environment for inhabitants of the affected area. It has been postulated that the change of exposure itself may be an annoying factor, and this may explain why aircraft noise annoyance is generally higher than that for other sources of transportation noise at a comparable noise level (Brown & van Kamp, 2009). The GDG acknowledged that, in general, air travel is an important means of transportation relevant for businesses, the public and the economy. In Europe, aviation is projected to be the fastest-growing sector from passenger transport demand, by 2050 (EEA, 2016a). The general population tends to value the convenience of travel by air. Moreover, the GDG pointed out that exposure to aircraft noise is not equally distributed throughout society. The preferences of people living in the vicinity of airports are expected to differ from those of the general population that does not experience the same noise burden. This might facilitate variance in the values and preference of the population, as those benefiting from the services and revenues generated by an airport may regard noise reduction measures as an additional, unnecessary extra cost, while those living around an airport and affected by aircraft noise may be in favour of noise reductions, since this concerns their health and wellbeing. Despite these differences, however, the GDG was confident that a majority of the population would value the minimization of adverse health effects and therefor welcome the implementation of the recommendations.

Regarding the dimension of equity, the GDG highlighted that the risk of exposure to aircraft noise is not equally distributed throughout society. Members of society with a lower socioeconomic status and other disadvantaged groups often live in more polluted and louder areas, including in close proximity to airports (EC, 2016a). In addition to the increased risk of exposure to environmental noise, socioeconomic factors are also associated with increased vulnerability and poorer coping capacities (Karpati et al., 2002).

With resource use and implementation considerations, the GDG acknowledged that the economic evaluation of the health impacts of environmental noise is most elaborate and extensive for aircraft noise (Berry & Sanchez, 2014). Nevertheless, no comprehensive cost-benefit analysis for the WHO European Region vet exists, so this assessment is based on informed gualitative expert judgement regarding the feasibility of implementing the recommendation for the majority of the population. The systematic review of interventions and their associated impact on environmental noise and health shows that various measures to reduce continuous noise from aircraft exist. Moreover, the quality of the evidence was judged to be moderate (Brown & van Kamp, 2017). The GDG noted that the resources needed to implement different intervention measures may vary considerably, because they depend on the situation and the type of intervention required. The distribution of costs also differs from that for other modes of transportation, since exposure to aircraft noise is localized in a more applomerated way, and overall the population affected is smaller compared to other modes of transportation. The GDG furthermore recognized that multiple cost-effective intervention strategies exist (EC, 2016b). Prohibition or discouragement strategies against citizens moving to the direct proximity of airports, for example, can be implemented in the context of urban planning. Likewise, diverting flight paths above less-populated areas can lead to a reduction in exposure. In principle,

such intervention measures do not involve any direct costs, although safety concerns may limit the feasibility of these strategies. Passive noise abatement measures like the installation of soundproof windows at the dwelling were also regarded as feasible and economically reasonable by the GDG, as these are implemented at several airports already. In relation to active abatement measures, the GDG acknowledged the "balanced approach" elaborated by International Civil Aviation Organization, which states that noise reduction should take place first at the source. As indicated by the Clean Sky Programme, this could, for example, entail shifting towards the introduction of new aircraft. This broad European research programme estimates that, depending on type, the shift to newly produced aircraft could lead to a reduction of approximately 55-79% of the area affected by aircraft noise, and consequently the population exposed. As this solution has been put forward by the aviation sector, it is considered feasible. Overall, this indicates that solutions to achieve recommended noise levels can be implemented and at reasonable costs. The GDG agreed that implementation of the recommendation to minimize the risk of adverse health effects due to aircraft noise for a majority of the population would require a reasonable amount of (monetary) resources. It noted, however, that the feasibility of implementing the measures could be hindered by the fact that costs and benefits are not equally distributed. In most cases, the health benefits citizens gain from interventions that reduce aircraft exposure are borne by private companies and public authorities.

In light of the assessment of the contextual factors in addition to the quality of evidence, the recommendation remains strong.

Other nonpriority adverse health outcomes

Although not a priority health outcome and coming from a single study, the GDG noted the evidence rated moderate quality for the statistically significant association between aircraft noise and the change in waist circumference (Eriksson et al., 2014). The range of noise levels in the study identified was 48 to 65 dB L_{den} , and therefore the recommendation would also be protective enough for this health outcome.

In the context of aircraft noise, when considering the impacts of exposure on cognitive impairment in children, these guideline recommendations also apply particularly to the school setting. Noise exposure at primary school and at home is often highly correlated; however, the evidence base considered comes mainly from studies designed around sampling at school and not residences.

Additional considerations or uncertainties

There is additional uncertainty when characterizing exposure using the acoustical description of aircraft noise by means of L_{den} or L_{night} . Use of these average noise indicators may limit the ability to observe associations between exposure to aircraft noise and some health outcomes (such as awakening reactions); as such, noise indicators based on the number of events (such as the frequency distribution of $L_{A,max}$) may be better suited. However, such indicators are not widely used.

The GDG acknowledged that the guideline recommendation for L_{night} may not be fully protective of health, as it implies that around 11% (95% CI: 4.72–17.81) of the population may be characterized as highly sleep-disturbed at the recommended L_{night} level. This is higher than the 3% absolute risk considered for setting the guideline level. However, the high calculation uncertainty in predicting noise levels lower than 40 dB prevented the GDG from recommending a lower level. Furthermore,

lower levels would probably require a ban on night or early morning flights altogether, which is not feasible in many situations, given that the general population tends to value the convenience of air travel.

3.3.3 Summary of the assessment of the strength of recommendation

Table 35 provides a comprehensive summary of the different dimensions for the assessment of the strength of the aircraft noise recommendations.

Table 35. Summary of the assessment of the strength of the recommendation

Factors influencing	Decision
the strength of recommendation	
Quality of evidence	Average exposure (L _{den})
	Health effects
	 Evidence for a relevant RR increase of the incidence of IHD at 52 dB L_{den} was rated very low quality.
	 Evidence for a relevant RR increase of the incidence of hypertension was rated low quality.
	 Evidence for a relevant absolute risk of annoyance at 45 dB L_{den} was rated moderate quality.
	 Evidence for a relevant RR increase of impaired reading and oral comprehension at 55 dB L_{den} was rated moderate quality.
	Interventions
	 Evidence on effectiveness of interventions to reduce noise exposure and/or health outcomes from aircraft noise was of varying quality.
	Night-time exposure (L _{night})
	Health effects
	 Evidence for a relevant absolute risk of sleep disturbance related to night noise exposure from aircraft at 40 dB L_{night} was rated moderate quality.
	Interventions
	 Evidence on effectiveness of changes in infrastructure (flight path changes) to reduce sleep disturbance from aircraft noise was rated low quality.
Balance of benefits versus harms and burdens	Aircraft noise is a major source of localized noise pollution. The health benefits of adapting the recommendations are expected to outweigh the harms.
Values and preferences	Quiet areas are valued by the population, especially by those affected by continuous aircraft noise exposure. Some variability is expected among those directly affected by aircraft noise and those not affected.
Equity	Risk of exposure to aircraft noise is not equally distributed.
Resource implications	No comprehensive cost–effectiveness analysis data are available; nevertheless, a wide variety of interventions exist (some at very low cost), indicating that measures are both feasible and economically reasonable.
Decisions on recommendation	• Strong for guideline value for average noise exposure (L _{den})
strength	 Strong for guideline value for night noise exposure (L_{night})

3.4 Wind turbine noise

Recommendations

For average noise exposure, the GDG **conditionally** recommends reducing noise levels produced by wind turbines below **45 dB** L_{den} , as wind turbine noise above this level is associated with adverse health effects.

To reduce health effects, the GDG **conditionally** recommends that policy-makers implement suitable measures to reduce noise exposure from wind turbines in the population exposed to levels above the guideline values for average noise exposure. No evidence is available, however, to facilitate the recommendation of one particular type of intervention over another.

3.4.1 Rationale for the guideline levels for wind turbine noise

The exposure levels were derived in accordance with the prioritizing process of critical health outcomes described in section 2.4.3. For each of the outcomes, the exposure level was identified by applying the benchmark, set as relevant risk increase to the corresponding ERF. In the case of exposure to wind turbine noise, the process can be summarized as follows (Table 36).

Table 36. Average exposure levels (L_{den}) for priority health outcomes from wind turbine noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Incidence of IHD	5% increase of RR	No studies were available
Incidence of IHD could not be used to assess the exposure level.		
Incidence of hypertension	10% increase of RR	No studies were available
Incidence of hypertension could not be used to assess the exposure level.		
Prevalence of highly annoyed population	10% absolute risk	Low quality
Four studies were available. An exposure–response curve of the four studies revealed an absolute risk of 10%HA (outdoors) at a noise exposure level of 45 dB L_{den} .		
Permanent hearing impairment	No increase	No studies were available
Reading skills and oral comprehension in children	One-month delay	No studies were available

In accordance with the prioritization process, the GDG set a guideline exposure level of 45.0 dB L_{den} for average exposure, based on the relevant increase of the absolute %HA. The GDG stressed that there might be an increased risk for annoyance below this noise exposure level, but it could not state whether there was an increased risk for the other health outcomes below this level owing to a lack of evidence. As the evidence on the adverse effects of wind turbine noise was rated low quality, the GDG made the recommendation conditional.

Next, the GDG considered the evidence for night noise exposure to wind turbine noise and its effect on sleep disturbance (Table 37).

Table 37. Night-time exposure levels (L_{night}) for priority health outcomes from wind turbine noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Sleep disturbance	3% absolute risk	Low quality
Six studies were available; they did not reveal consistent results about effects of wind turbine noise on sleep.		

Based on the low quantity and heterogeneous nature of the evidence, the GDG was not able to formulate a recommendation addressing sleep disturbance due to wind turbine noise at night time.

The GDG also looked for evidence about the effectiveness of interventions for wind turbine noise exposure. Owing to a lack of research, however, no studies were available on existing interventions and associated costs to reduce wind turbine noise.

Based on this assessment, the GDG therefore provided a conditional recommendation for average noise exposure (L_{den}) to wind turbines and a conditional recommendation for the implementation of suitable measures to reduce noise exposure. No recommendation about a preferred type of intervention could be formulated; nor could a recommendation be made for an exposure level for night noise exposure (L_{night}), as studies were not consistent and in general did not provide evidence for an effect on sleep.

3.4.1.1 Other factors influencing the strength of recommendation

Other factors considered in the context of recommendations on wind turbine noise included those related to values and preferences, benefits and harms, resource implications, equity, acceptability and feasibility. Ultimately, the assessment of all these factors did not lead to a change in the strength of recommendation, although it informed the development of a conditional recommendation on the intervention measures. Further details are provided in section 3.4.2.3.

3.4.2 Detailed overview of the evidence

The following sections provide a detailed overview of the evidence constituting the basis for setting the recommendations on wind turbine noise. It is presented and summarized separately for each of the critical health outcomes, and the GDG's judgement of the quality of evidence is indicated (for a detailed overview of the evidence on important health outcomes, see Annex 4). Research into health outcomes and effectiveness of intervention is addressed consecutively.

A comprehensive summary of all evidence considered for each of the critical and important health outcomes can be found in the eight systematic reviews published in the *International Journal of Environmental Research and Public Health* (see section 2.3.2 and Annex 2).

It should be noted that, due to the time stamp of the systematic reviews, some more recent studies were not included in the analysis. This relates in particular to several findings of the Wind Turbine Noise and Health Study conducted by Health Canada (Michaud, 2015). Further, some studies were omitted, as they did not meet the inclusion criteria, including, for instance, studies using distance to the wind turbine instead of noise exposure to investigate health effects. The justification for including and excluding studies is given in the systematic reviews (Basner & McGuire, 2018; Brown et al.,

2017; Clark & Paunovic, 2018; in press; Guski et al., 2017; Niewenhuijsen et al., 2017; Śliwińska-Kowalska & Zaborowski, 2017; van Kempen et al., 2018; see Annex 2 for further details).

3.4.2.1 Evidence on health outcomes

The key question posed was: in the general population exposed to wind turbine noise, what is the exposure–response relationship between exposure to wind turbine noise (reported as various noise indicators) and the proportion of people with a validated measure of health outcome, when adjusted for main confounders? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 38 and 39.

Table 38. PICOS/PECCOS scheme of critical health outcomes for exposure to wind turbine noise

PECO	Description		
Population	General population		
Exposure	Exposure to high levels of noise produced	by wind turbines (average/night time)	
Comparison	Exposure to lower levels of noise produce	d by wind turbines (average/night time)	
Outcome(s)	For average noise exposure:	For night noise exposure:	
	1. cardiovascular disease	1. effects on sleep	
	2. annoyance		
	3. cognitive impairment		
	4. hearing impairment and tinnitus		
	5. adverse birth outcomes		
	6. quality of life, well-being and mental he	alth	
	7. metabolic outcomes		

Table 39. Summary of findings for health effects from exposure to wind turbine noise (L_{dot})

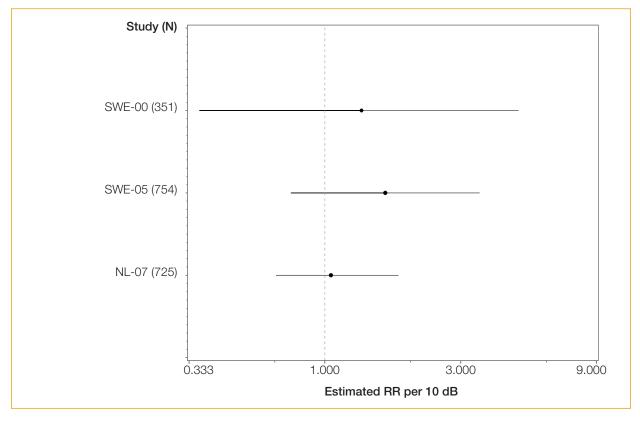
Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies	Number of participants (studies)	Quality of evidence	
Cardiova	ascular disease					
L _{den}	Incidence of IHD	-	_	_	_	
L _{den}	Incidence of hypertension	-	_	_	-	
Annoyar	ice					
L _{den}	%HA	Not able to pool because of heterogeneity	30 dB	2481 (4)	Low (downgraded for inconsistency and imprecision)	
Cognitiv	e impairment					
L _{den}	Reading and oral comprehension	_	_	_	-	
Hearing	Hearing impairment and tinnitus					
L _{den}	Permanent hearing impairment	_	-	-	-	

Cardiovascular disease

For the relationship between wind turbine noise and prevalence of hypertension, three cross-sectional studies were identified, with a total of 1830 participants (van den Berg et al., 2008; Pedersen, 2011; Pedersen & Larsman, 2008; Pedersen & Persson Waye, 2004; 2007). The number of cases was not reported. All studies found a positive association between exposure to wind turbine noise and the prevalence of hypertension, but none was statistically significant. The lowest levels in studies were either <30 or <32.5 L_{den} . No meta-analysis was performed, since too many parameters were unknown and/or unclear. Due to very serious risk of bias and imprecision in the results, this evidence was rated very low quality (see Fig. 14).

The same studies also looked at exposure to wind turbine noise and self-reported cardiovascular disease, but none found an association. No evidence was available for other measures of cardiovascular disease. As a result, only evidence rated very low quality was available for no considerable effect of audible noise (greater than 20 Hz) from wind turbines or wind farms on self-reported cardiovascular disease (see Fig. 15).

Fig. 14. The association between exposure to wind turbine noise (sound pressure level in dB) and hypertension



Notes: The dotted vertical line corresponds to no effect of exposure to wind turbine noise. The black dots correspond to the estimated RR per 10 dB and 95% CI. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

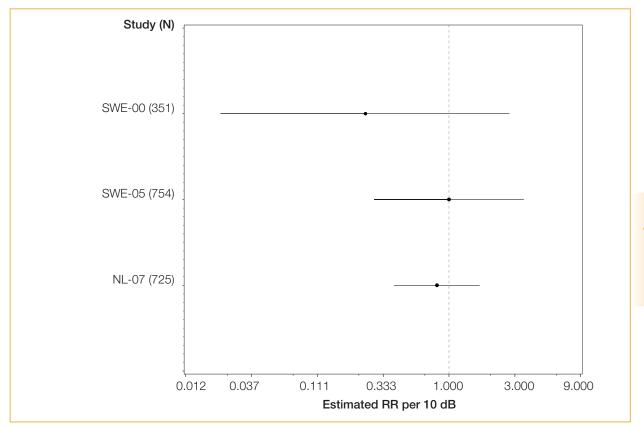


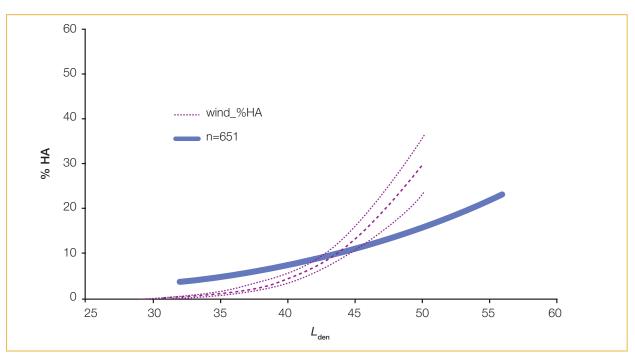
Fig. 15. The association between exposure to wind turbine noise (sound pressure level) and self-reported cardiovascular disease

Notes: The dotted vertical line corresponds to no effect of exposure to wind turbine noise. The black circles correspond to the estimated RR per 10 dB (sound pressure level) and 95% Cl. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

Annoyance

Two publications containing descriptions of four individual studies were retrieved (Janssen et al., 2011; Kuwano et al., 2014). All four studies used measurements in the vicinity of the respondents' addresses; the noise exposure metrics used in the three original studies (Pedersen, 2011; Pedersen & Persson Waye, 2004; 2007) included in Janssen et al. (2011) were recalculated into L_{den} . The noise levels in the studies ranged from 29 dB to 56 dB. Different scales were used to assess annoyance, with slightly different definitions of "highly annoyed" and explicit reference to outdoor annoyance in the data used for the Janssen et al. (2011) curve. Construction of the ERFs provided in the two publications differed and they were therefore not further combined in a meta-analysis. Fig. 16 shows the %HA from the two publications. The 10% criterion for %HA is reached at around 45 dB L_{den} (where the two curves coincide). There was a wide variability in %HA between studies, with a range of 3–13%HA at 42.5 dB and 0–32%HA at 47.5 dB. The %HA in the sample is comparatively high, given the relatively low noise levels. There is evidence rated low quality for an association between wind turbine noise and annoyance, but this mainly applies to the association between wind turbine noise and annoyance of the shape of the quantitative relationship.

Further statistical analyses of annoyance yield evidence rated low quality for an association between wind turbine noise and %HA when comparing an exposure at 42.5 dB and 47.5 dB, with a mean difference in %HA of 4.5 (indoors) and 6.4 (outdoors). There is also evidence rated moderate quality for a correlation between individual noise exposure and annoyance raw scores (r = 0.28).





Notes: Overlay of the two wind turbine outdoor annoyance graphs adapted from Janssen et al. (2011, red) and Kuwano et al. (2014, blue). The Kuwano et al. curve is based on L_{dn}; no correction for L_{den} has been applied.¹⁸ For further details on the studies included in the figure please refer to the systematic review on environmental noise and annoyance (Guski et al., 2017).

Cognitive impairment, hearing impairment and tinnitus, adverse birth outcomes

No studies were found, and therefore no evidence was available on the relationship between wind turbine noise and measures of cognitive impairment; hearing impairment and tinnitus; and adverse birth outcomes.

Sleep disturbance

Six cross-sectional studies on wind turbine noise and self-reported sleep disturbance were identified (Bakker et al., 2012; Kuwano et al., 2014; Michaud, 2015; Pawlaczyk-Luszczynska et al., 2014; Pedersen & Persson Waye, 2004; 2007). Noise levels were calculated using different methods, and different noise metrics were reported. Three of the studies asked how noise affects sleep; the other three evaluated the effect of wind turbine noise on sleep using questions that explicitly referred to noise (Table 40).

 $^{^{18}}L_{dn}$ is the day-night-weighted sound pressure level as defined in section 3.6.4 of ISO 1996-1:2016.

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of effects in studies	Number of participants (studies)	Quality of evidence
Effects of	n sleep				
L _{night}	%HSD	1.60 (95% Cl: 0.86–2.94) per 10 dB increase	31 dB	3971 (6)	Low (downgraded for study limitations, inconsistency, precision)

Table 40. Summary of findings for health effects from exposure to wind turbine noise (L_{nink})

The risk of bias was assessed as high for all six studies, as effects on sleep were measured by selfreported data. There were a limited number of subjects at higher exposure levels. A meta-analysis was conducted for five of the six studies, based on the OR for high sleep disturbance for a 10 dB increase in outdoor predicted sound pressure level. The pooled OR was 1.60 (95% CI: 0.86–2.94). The evidence was rated low quality.

3.4.2.2 Evidence on interventions

This section summarizes the evidence underlying the recommendation on the effectiveness of interventions for wind turbine noise exposure. The key question posed was: in the general population exposed to wind turbine noise, are interventions effective in reducing exposure to and/or health outcomes from wind turbine noise? A summary of the PICOS/PECCOS scheme applied is set out in Table 41.

Table 41. PICOS/PECCOS scheme of the effectiveness of interventions for exposure to wind turbine noise

PICO	Description		
Population	General population		
Intervention(s)	The interventions can be defined as:		
	(a) a measure that aims to change noise exposure and associated health effects;		
	(b) a measure that aims to change noise exposure, with no particular evaluation of the impact on health; or		
	(c) a measure designed to reduce health eff exposure.	ects, but that may not include a reduction in noise	
Comparison	No intervention		
Outcome(s)	For average noise exposure:	For night noise exposure:	
	1. cardiovascular disease	1. effects on sleep	
	2. annoyance		
	3. cognitive impairment		
	4. hearing impairment and tinnitus		
	5. adverse birth outcomes		
	6. quality of life, well-being and mental heal	th	
	7. metabolic outcomes		

No studies were found, and therefore no evidence was available on the effectiveness of interventions to reduce noise exposure from wind turbines.

3.4.2.3 Consideration of additional contextual factors

As the foregoing overview has shown, very little evidence is available about the adverse health effects of continuous exposure to wind turbine noise. Based on the quality of evidence available, the GDG set the strength of the recommendation on wind turbine noise to conditional. As a second step, it qualitatively assessed contextual factors to explore whether other considerations could have a relevant impact on the recommendation strength. These considerations mainly concerned the balance of harms and benefits, values and preferences, and resource use and implementation.

Regarding the balance of harms and benefits, the GDG would expect a general health benefit from a marked reduction in any kind of long-term environmental noise exposure. Health effects of individuals living in the vicinity of wind turbines can theoretically be related not only to long-term noise exposure from the wind turbines but also to disruption caused during the construction phase. The GDG pointed out, however, that evidence on health effects from wind turbine noise (apart from annovance) is either absent or rated low/very low quality (McCunney et al., 2014). Moreover, effects related to attitudes towards wind turbines are hard to discern from those related to noise and may be partly responsible for the associations (Knopper & Ollson, 2011). Furthermore, the number of people exposed is far lower than for many other sources of noise (such as road traffic). Therefore, the GDG estimated the burden on health from exposure to wind turbine noise at the population level to be low, concluding that any benefit from specifically reducing population exposure to wind turbine noise in all situations remains unclear. Nevertheless, proper public involvement, communication and consultation of affected citizens living in the vicinity of wind turbines during the planning stage of future installations is expected to be beneficial as part of health and environmental impact assessments. In relation to possible harms associated with the implementation of the recommendation, the GDG underlined the importance of wind energy for the development of renewable energy policies.

The GDG noticed that the values and preferences of the population towards reducing long-term noise exposure to wind turbine noise vary. Whereas the general population tends to value wind energy as an alternative, environmentally sustainable and low-carbon energy source, people living in the vicinity of wind turbines may evaluate them negatively. Wind turbines are not a recent phenomenon, but their quantity, size and type have increased significantly over recent years. As they are often built in the middle of otherwise quiet and natural areas, they can adversely affect the integrity of a site. Furthermore, residents living in these areas may have greater expectations of the quietness of their surroundings and therefore be more aware of noise disturbance. Negative attitudes especially occur in individuals who can see wind turbines from their houses but do not gain economically from the installations (Kuwano et al., 2014; Pedersen & Persson Waye, 2007; van den Berg et al., 2008). These situational variables and the values and preferences of the population may differ between wind turbines and other noise sources, as well as between wind turbine installations, which makes assessment of the relationship between wind turbine noise exposure and health outcomes particularly challenging.

Assessing resource use and implementation considerations, the GDG noted that reduction of noise exposure from environmental sources is generally possible through simple measures like insulating windows or building barriers. With wind turbines, however, noise reduction interventions are more

complicated than for other noise sources due to the height of the source and because outdoor disturbance is a particularly large factor. As generally fewer people are affected (compared to transportation noise), the expected costs are lower than for other environmental sources of noise. The GDG was not aware of any existing interventions (and associated costs) to reduce harms from wind turbine noise, or specific consequences of having regulations on wind turbine noise. Therefore, it could not assess feasibility, or discern whether any beneficial effects of noise reduction would outweigh the costs of intervention. In particular, there is no clear evidence on an acceptable and uniform distance between wind turbines and residential areas, as the sound propagation depends on many aspects of the wind turbine construction and installation.

In light of the assessment of the contextual factors in addition to the quality of evidence, the recommendation for wind turbine noise exposure remains conditional.

Additional considerations or uncertainties

Assessment of population exposure to noise from a particular source is essential for setting healthbased guideline values. Wind turbine noise is characterized by a variety of potential moderators, which can be challenging to assess and have not necessarily been addressed in detail in health studies. As a result, there are serious issues with noise exposure assessment related to wind turbines.

Noise levels from outdoor sources are generally lower indoors because of noise attenuation from the building structure, closing of windows and similar. Nevertheless, noise exposure is generally estimated outside, at the most exposed façade. As levels of wind turbine noise are generally much lower than those of transportation noise, the audibility of wind turbines in bedrooms, particularly when windows are closed, is unknown.

In many instances, the distance from a wind farm has been used as a proxy to determine audible noise exposure. However, in addition to the distance, other variables – such as type, size and number of wind turbines, wind direction and speed, location of the residence up- or downwind from wind farms and so on – can contribute to the resulting noise level assessed at a residence. Thus, using distance to a wind farm as a proxy for noise from wind turbines in health studies is associated with high uncertainty.

Wind turbines can generate infrasound or lower frequencies of sound than traffic sources. However, few studies relating exposure to such noise from wind turbines to health effects are available. It is also unknown whether lower frequencies of sound generated outdoors are audible indoors, particularly when windows are closed.

The noise emitted from wind turbines has other characteristics, including the repetitive nature of the sound of the rotating blades and atmospheric influence leading to a variability of amplitude modulation, which can be a source of above average annoyance (Schäffer et al., 2016). This differentiates it from noise from other sources and has not always been properly characterized. Standard methods of measuring sound, most commonly including A-weighting, may not capture the low-frequency sound and amplitude modulation characteristic of wind turbine noise (Council of Canadian Academies, 2015).

Even though correlations between noise indicators tend to be high (especially between L_{Aeq} -like indicators) and conversions between indicators do not normally influence the correlations between the noise indicator and a particular health effect, important assumptions remain when exposure to

wind turbine noise in L_{den} is converted from original sound pressure level values. The conversion requires, as variable, the statistical distribution of annual wind speed at a particular height, which depends on the type of wind turbine and meteorological conditions at a particular geographical location. Such input variables may not be directly applicable for use in other sites. They are sometimes used without specific validation for a particular area, however, because of practical limitations or lack of data and resources. This can lead to increased uncertainty in the assessment of the relationship between wind turbine noise exposure and health outcomes.

Based on all these factors, it may be concluded that the acoustical description of wind turbine noise by means of L_{den} or L_{night} may be a poor characterization of wind turbine noise and may limit the ability to observe associations between wind turbine noise and health outcomes.

3.4.3 Summary of the assessment of the strength of recommendations

Table 42 provides a comprehensive summary of the different dimensions for the assessment of the strength of the wind turbine recommendations.

Factors influencing the strength of recommendation	Decision
Quality of evidence	Average exposure (L _{den}) Health effects
	 Evidence for a relevant absolute risk of annoyance at 45 dB L_{den} was rated low quality.
	 No evidence was available on the effectiveness of interventions to reduce noise exposure and/or health outcomes from wind turbines.
	Night-time exposure (L _{night}) Health effects
	 No statistically significant evidence was available for sleep disturbance related to exposure from wind turbine noise at night.
	Interventions
	 No evidence was available on the effectiveness of interventions to reduce noise exposure and/or sleep disturbance from wind turbines.
Balance of benefits versus harms and burdens	Further work is required to assess fully the benefits and harms of exposure to environmental noise from wind turbines and to clarify whether the potential benefits associated with reducing exposure to environmental noise for individuals living in the vicinity of wind turbines outweigh the impact on the development of renewable energy policies in the WHO European Region.
Values and preferences	There is wide variability in the values and preferences of the population, with particularly strong negative attitudes in populations living in the vicinity of wind turbines.
Resource implications	Information on existing interventions (and associated costs) to reduce harms from wind turbine noise is not available.
Additional considerations or uncertainties	There are serious issues with noise exposure assessment related to wind turbines.
Decisions on recommendation strength	 Conditional for guideline value for average noise exposure (L_{den}) Conditional for the effectiveness of interventions (L_{night})

Table 42. Summary of the assessment of the strength of the recommendation

3.5 Leisure noise Recommendations

For average noise exposure, the GDG **conditionally** recommends reducing the yearly average from all leisure noise sources combined to **70 dB** $L_{Aeq,24h}$, as leisure noise above this level is associated with adverse health effects. The equal energy principle¹⁹ can be used to derive exposure limits for other time averages, which might be more practical in regulatory processes.

For single-event and impulse noise exposures, the GDG **conditionally** recommends following existing guidelines and legal regulations to limit the risk of increases in hearing impairment from leisure noise in both children and adults.

Following a precautionary approach, to reduce possible health effects, the GDG **strongly** recommends that policy-makers take action to prevent exposure above the guideline values for average noise and single-event and impulse noise exposures. This is particularly relevant as a large number of people may be exposed to and at risk of hearing impairment through the use of personal listening devices (PLDs). There is insufficient evidence, however, to recommend one type of intervention over another.

3.5.1 Rationale for the guideline levels for leisure noise

As specific evidence for the relationship between leisure noise and hearing loss is of insufficient quality, the GDG decided to follow a different approach for this noise source, based on knowledge regarding prevention of hearing loss in the workplace and on the CNG (WHO, 1999). There is sufficient evidence that the nature of the noise matters little in causing hearing loss, so using the existing guidelines is a justified step to prevent permanent hearing loss from leisure noise.

In accordance with the procedures for the other noise sources, the GDG would have considered evidence on exposure–response relationships for the prioritized health outcomes. However, no such ERFs could be established in the systematic reviews for any of the health outcomes (Table 43).

Table 43. Average exposure levels ($L_{Aed,24h}$) for priority health outcomes from leisure noise

	Barris and the state	and the second second second
Summary of priority health outcome evidence	Benchmark level	Evidence quality
Incidence of IHD		No evidence was
Incidence of hypertension		available
Prevalence of highly annoyed population		
Reading skills and oral comprehension in children		
Permanent hearing impairment	No increase	Very low quality/no
There is an indication that PLDs have an effect on hearing impairment and tinnitus.		evidence
There was no evidence (because no studies were found) for an		
effect of other sources of leisure noise on hearing impairment		
or tinnitus. The results of the studies could not be synthesized		
because of heterogeneity of outcome measurement.		

¹⁹ The equal energy principle states that the total effect of sound is proportional to the total amount of sound energy received by the ear, irrespective of the distribution of that energy in time (WHO, 1999).

In accordance with the evidence on the effects of PLDs on permanent hearing loss from leisure noise, the GDG recommended a guideline exposure level of 70 dB $L_{Aeq,24h}$ yearly average from all leisure noise sources combined. It was confident that there was no relevant risk increase for permanent hearing impairment below this exposure level of average leisure noise. The GDG recognized that a conversion to alternative time averages for exposure to leisure noise might be helpful for regulatory purposes; thus, a detailed table converting hourly and weekly exposure into yearly averages is provided in the subsection on additional considerations or uncertainties in section 3.5.2.3, Table 49. Furthermore, the GDG recommended sticking to the CNG recommendations for single events to limit the risk of hearing impairment from leisure noise increases for both children and adults (WHO, 1999).²⁰ Due to the nature and limited amount of available evidence, the GDG made the recommendation conditional.

Next, the GDG assessed the evidence for night noise exposure and its effect on sleep disturbance (Table 44).

Table 44. Night-time exposure levels (L_{night}) for priority health outcomes from leisure noise

Summary of priority health outcome evidence	Benchmark level	Evidence quality
Sleep disturbance	3% absolute risk	No evidence was available

Because of a lack of evidence, the GDG was not able to formulate a recommendation addressing sleep disturbance due to leisure noise at night time.

The GDG also looked for evidence about the effectiveness of interventions for leisure noise exposure. Owing to a lack of research, however, no studies were available on existing interventions and associated costs to reduce leisure noise. As no evidence was available, it was not possible to develop a recommendation on any specific type of intervention measure. However, following a precautionary approach, to reduce possible health effects, the GDG made a strong recommendation that policy-makers take action to prevent exposures above the guideline values for average noise and single-event and impulse noise exposures. This is particularly relevant as a large number of people may be exposed to and at risk of hearing impairment through the use of PLDs. There is insufficient evidence, however, to recommend one type of intervention over another.

3.5. 1.1 Other factors influencing the strength of recommendations

Other factors considered in the context of recommendations on leisure noise included those related to values and preferences, benefits and harms, resource implications, equity, acceptability and feasibility; moreover, nonpriority health outcomes were considered. Ultimately, the assessment of all these factors did not lead to a change in the strength of recommendation. Further details are provided in section 3.5.2.3.

²⁰ The GDG acknowledged the scarcity of cohort study-based evidence to define a threshold for hearing damage due to single loud exposures. It initially decided to propose $L_{AF,max} = 110$, but after much discussion it appeared that the conversion of relevant standing limits (expressed in $L_{\text{peak},C}$ and others) lacked sufficient basis.

3.5.2 Detailed overview of the evidence

The following sections provide a detailed overview of the evidence constituting the basis for setting the recommendations on leisure noise. As noted above, however, only limited evidence was available for several of the prioritized health outcomes, so it is presented and summarized for all critical and important health outcomes where possible, along with indications of the GDG's judgement of the quality of evidence. Research into health outcomes and effectiveness of interventions is addressed consecutively.

A comprehensive summary of all evidence considered for each of the critical and important health outcomes can be found in the eight systematic reviews published in the *International Journal of Environmental Research and Public Health* (see section 2.3.2 and Annex 2).

3.5.2.1 Evidence on health outcomes

The key question posed was: in the general population exposed to leisure noise, what is the exposure–response relationship between exposure to leisure noise (reported as various noise indicators) and the proportion of people with a validated measure of health outcome, when adjusted for main confounders? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 45 and 46.

PECO	Description			
Population	General population	General population		
Exposure	Exposure to high levels of noise produce	ed by leisure activities (average/night time)		
Comparison	Exposure to lower levels of noise produc	ed by leisure activities (average/night time)		
Outcome(s)	For average noise exposure:	For night noise exposure:		
	1. cardiovascular disease	1. effects on sleep		
	2. annoyance			
	3. cognitive impairment			
	4. hearing impairment and tinnitus			
	5. adverse birth outcomes			
	6. quality of life, well-being and mental health			
	7. metabolic outcomes			

Table 45. PICOS/PECCOS scheme of critical health outcomes for exposure to leisure noise

Noise metric	Priority health outcome measure	Quantitative risk for adverse health	Lowest level of exposure across studies ^a	Number of participants (studies)	Quality of evidence
Cardiova	ascular disease				
L _{Aeq,24}	Incidence of IHD	_	_	_	_
L _{Aeq,24}	Incidence of hypertension	-	-	_	-
Annoyan	ice				
L _{Aeq,24}	%HA	_	_	_	_
Cognitiv	e impairment				
L _{Aeq,24}	Reading and oral comprehension	-	-	-	-
Hearing	impairment and tin	nitus			
L _{Aeq.24}	Permanent	Not estimated	_	484	Very low
	hearing impairment			(3)	(downgraded for study limitations, precision)

Table 46. Summary of findings for health effects from exposure to leisure noise (Lagrade)

Hearing impairment and tinnitus

Several types of leisure activity are accompanied by loud sounds, such as attending nightclubs, pubs and fitness classes; live sporting events; concerts or live music venues; listening to loud music through PLDs. This recommendation is informed by a systematic review that assessed the evidence on permanent hearing loss and tinnitus due to exposure to leisure noise (Śliwińska-Kowalska & Zaborowski, 2017). The review identified two existing systematic reviews that summarized recent estimates of the risk of developing permanent hearing loss from the use of PLDs. It did not identify any studies with objective measurement of exposure to any other type of leisure noise.

The Scientific Committee on Emerging and Newly Identified Hazards and Risk (SCENIHR) (EC, 2008b) report concluded that prolonged exposure to sounds from PLDs may result in temporary hearing threshold shift, permanent hearing threshold shift and tinnitus, as well as poor speech communication in noisy conditions. However, based on the data available, there was no direct evidence for an effect of repeated, regular daily exposure to music through PLDs on development of permanent noise-induced hearing loss. Data on tinnitus were inadequate and therefore inconclusive. No meta-analysis was provided for any of the hearing effects; nor were the exposure-effect curves reported. The SCENIHR report was based on a narrative review of 30 original papers with over 2000 participants and exposure to music sounds that covered a range of 60–120 dB. Studies included in the review were carried out between 1982 and 2007.

In 2014 a second systematic review was published by Vasconcellos et al. (2014). Although the objective of this publication was to determine threshold levels of personally modifiable risk factors for hearing loss in the paediatric population, specific thresholds analyses were limited. Based on the descriptive overview of original papers, the authors identified exposure to loud music (including use of PLDs) and working on a mechanized farm as the main risk factors for hearing loss in children

and teenagers. Thresholds of exposure to music, significantly associated with hearing loss in youth, were:

- more than four hours per week or more than five years of personal headphone usage;
- more than four visits per month to a discotheque.

The evidence review identified five new cross-sectional studies on noise from PLDs since the publication of the SCENIHR report (Feder et al., 2013; Levesque et al., 2010; Sulaiman et al., 2013; 2014; Vogel et al., 2014). Direct measurement of hearing thresholds with pure tone audiometry was performed only in three studies – by Feder et al. (2013) and Sulaiman et al. (2013 and 2014). In total, audiometric data from 484 subjects were analysed; among them, 449 were exposed and 35 were not exposed to PLD music. Two other studies by Levesque et al. (2010) and Vogel et al. (2014) did not perform audiometric measurement but reported on tinnitus in a total of 1067 participants.

Noise from PLDs was estimated based on direct measurement of equivalent sound pressure levels (in dB) in four studies (Feder, 2013; Levesque et al., 2010; Sulaiman et al., 2013; 2014) and based on converting volume-control setting levels of PLD into dB levels in one study (Vogel et al., 2014). The resulting exposure levels (L_{Aeq} values) had a mean of between 72 dB and 91 dB, although in two studies these data were not provided. In all studies, individual $L_{Aeq,8h}$ value was calculated based on an estimated level of music and the number of hours a day listening to the music through the PLD declared by an individual in the questionnaire. Resulting $L_{Aeq,8h}$ mean values were between 62 dB and 83 dB when provided.

Potential confounding was controlled by excluding the subjects with exposure to other sources of high-level noise or prior ear problems (Sulaiman et al., 2013), by excluding those with these factors and ototoxic drug intake (Sulaiman et al., 2014) or by controlling for these confounders by accounting for them in the statistical models. The confounders comprised socioeconomic status, demographic factors, tubes in the ear and leisure exposures in one study (Feder, 2013), and age and sex in one study (Vogel et al., 2014). One of the studies did not adjust for confounding factors (Levesque et al., 2010).

Data on permanent hearing loss were taken from audiometric measurements (Feder, 2013; Sulaiman et al., 2013; 2014), while data about permanent tinnitus were taken from self-reported responses to questionnaires (Levesque et al., 2010; Vogel et al., 2014). In one case, the outcome was defined as "permanent hearing-related symptoms", but it is not clear what proportion of subjects experienced permanent tinnitus (Vogel et al., 2014).

For permanent hearing loss, there is no pooled effect size, because the authors of the original studies either did not report data or reported in different formats. However, these studies indicate a harmful effect of listening to PLDs. For permanent tinnitus, there is no pooled effect size because the effects of noise from PLDs on permanent tinnitus were contradictory. These results are generally consistent with previous reviews by SCENIHR (EC, 2008b) and Vasconcellos et al. (2014).

The risk of bias was assessed as high for all five studies. The overall evidence for an effect of PLDs on hearing impairment and tinnitus was rated very low quality.

3.5.2.2 Evidence on interventions

The following section summarizes the evidence underlying the recommendation on the effectiveness of interventions for leisure noise exposure. The key question posed was: in the general population exposed to leisure noise, are interventions effective in reducing exposure to and/or health outcomes from leisure noise? A summary of the PICOS/PECCOS scheme applied and the main findings is set out in Tables 47 and 48.

Table 47. PICOS/PECCOS	scheme	of	the	effectiveness	of	interventions	for	exposure	to
leisure noise									

PICO	Description				
Population	General population				
Intervention(s)	The interventions can be defined as:				
	(a) a measure that aims to change noise expe	osure and associated health effects;			
	(b) a measure that aims to change noise exposure, with no particular evaluation of the impact on health; or				
	(c) a measure designed to reduce health efference exposure.	cts, but that may not include a reduction in noise			
Comparison	No intervention				
Outcome(s)	For average noise exposure:	For night noise exposure:			
	1. cardiovascular disease	1. effects on sleep			
	2. annoyance				
	3. cognitive impairment				
	4. hearing impairment and tinnitus				
	5. adverse birth outcomes				
	6. quality of life, well-being and mental health	6. quality of life, well-being and mental health			
	7. metabolic outcomes				

Table 48. Summary of findings for interventions for leisure noise

Type of intervention	Number of participants (studies)	Effect of intervention	Quality of evidence
Hearing impairment			
Type E – behaviour change interventions (education programme/campaign)	4151 (7)	None of the studies involved measurement or estimation of exposure levels or health outcomes.	-
		Most studies found a significant effect of change in knowledge or behaviour.	

Seven individual studies on PLDs, attendance at music venues and participation in other recreational activities where there was risk of hearing damage and/or tinnitus were included in the systematic review (Dell & Holmes, 2012; Gilles & Van de Heyning, 2014; Kotowski et al., 2011; Martin et al., 2013; Taljaard et al., 2013; Weichbold & Zorowka, 2003; 2007). All studies examined interventions directed at changes in knowledge or behaviour and hearing impairment.

The studies all sought evidence on the effectiveness of some form of educational programme or campaign aimed at children, adolescents or college students. These addressed perceptions and

knowledge of the risk of high levels of noise – generally, but not exclusively, from PLD sources or from attendance at music events – and actual or intended changes to hearing damage risk behaviours, including avoidance, frequency or duration of exposure, regeneration periods when in high noise, or playback levels.

The outcome assessed in all intervention studies was the change in knowledge and behaviours towards hearing damage risk. The health outcome measures varied widely and included measurements on the youth attitude towards noise scale, participants' knowledge about hearing damage, participants' PLD usage patterns, participants' attitudes to wearing hearing protection (some in general; some at discotheques) and frequency of discotheque attendance. A majority of the studies found a significant effect of change in knowledge or behaviour. No indication on the persistence of knowledge and behavioural change was given, though.

None of the studies included objectively measured outcomes or a measured change in noise level exposure; thus, the effectiveness of the interventions could not be assessed, and the quality of the evidence was not rated according to GRADE.

3.5.2.3 Consideration of additional contextual factors

Based on the quality of the available evidence discussed in the foregoing overview, the GDG set the strength of recommendation of leisure noise to conditional. As a second step, it qualitatively assessed contextual factors to explore whether other considerations could have a relevant impact on the recommendation strength. These considerations mainly concerned the balance of harms and benefits, values and preferences, and resource use and implementation.

When assessing the balance of benefits and harms, the GDG recognized that exposure to leisure noise is widespread and frequent. In particular, as many as 88–90% of teenagers and young adults report listening to music through PLDs earphones (Pellegrino et al., 2013; Vogel et al., 2011). In 2015 WHO estimated that 1.1 billion young people worldwide could be at risk of hearing loss due to unsafe listening practices (WHO, 2015a). Furthermore, among young people aged 12-35 years in middle- and high-income countries, nearly 50% listen to unsafe levels of sound through personal audio devices (mp3 players, smartphones and others), and around 40% are exposed to potentially damaging levels of sound at nightclubs, bars and sporting events. Noise-induced hearing loss can be prevented by following safe listening practices, so the GDG concluded that health benefits can be gained from markedly reducing population exposure to leisure noise, including through actions to promote safe listening practices. A reduction of leisure noise is also assumed to reduce nuisance that can be caused to other people than those who enjoy leisure activities, such as neighbours. Furthermore, specifically for PLDs, it can reasonably be expected that a reduction of noise exposure could also lead to a reduction in accidents, injuries and other potential safety risks. In relation to possible harms and burdens, the GDG could not identify any harms (except economic costs, which are addressed in the paragraph on resource use and implementation) arising from implementation of the recommended guideline values.

Considering values and preferences, the GDG recognized that listening to music with the help of a PLD, going to concerts and attending sport events are activities regarded as enjoyable and therefore assumed to be valued by the overall population. Furthermore, it is expected that values and preferences might vary in particular with respect to the use of PLDs and embracing leisure activities involving loud noise, like concerts, and that some population groups – especially younger individuals – might voluntarily expose themselves to high levels of sound during these activities. Despite this, the GDG was confident that recommendations to lower noise levels for the prevention of hearing damage from leisure noise would be welcome by a majority of the population. Recommendations are expected to be particularly welcome when it comes to protecting the hearing of young children and teenagers, as these vulnerable groups often do not have control over their environment and the noise levels to which they are exposed, such as from noisy toys or at school.

With resource use and implementation, the GDG noted that interventions exist to reduce exposure to leisure noise from PLDs, attendance at music venues and participation in recreational activities, as aggregated by the systematic review on environmental noise interventions and their associated impacts (Brown & van Kamp, 2017). As most of these relate to implementation of a behaviour change, the reduction of exposure to leisure noise is expected to be technically feasible and cheap. None of the empirical investigations objectively measured outcomes or a measured change in noise level exposure, so the effectiveness of such measures cannot be assessed. Nevertheless, it is important to note that there is ample evidence from the occupational health field that high noise levels cause hearing damage, and that occupational interventions to reduce noise exposure are effective at lowering the risk of hearing problems or hearing damage (EC, 2003; Garcia et al., 2018; ISO, 2013; Maassen et al., 2001). In conclusion, resources needed to reduce exposure to leisure noise are not expected to be intensive, but implementation and long-term success of measures might be challenging, owing to cultural factors, as changes in behaviour are expected to be tricky to implement.

In light of the assessment of the contextual factors in addition to the quality of evidence, the recommendation remains conditional.

Additional considerations or uncertainties

The GDG considers the noise levels selected for this recommendation to be reasonable precautionary measures, in view of the rating of very low quality for the available evidence on an effect of leisure noise on permanent hearing impairment and tinnitus identified in the systematic review.

Extensive literature shows hearing impairment in populations exposed to specific types of nonoccupational environments, although these exposures are generally not well characterized. There are no studies with objective measurement of exposure to any other type of leisure noise (except PLDs) and permanent hearing impairment or tinnitus. Nevertheless, this recommendation generally applies to all leisure noise exposures, such as events in public venues (concerts halls, sports events, bars and discotheques) and educational facilities, and use of PLDs. The recommendation also applies to exposure to impulse sounds, such as those in shooting facilities or from the use of toys and firecrackers.

Hearing loss is the resultant value of combined exposures to different sources of leisure noise including, but not limited to, PLDs. Therefore, the recommendations apply to the combined noise levels from all sources.

Noise-induced hearing loss develops very slowly over years of exposure, giving rise to challenges in the assessment of the health impacts from prolonged use of PLDs and exposure to leisure noise. The induction period for the development of hearing impairment and tinnitus is long, and varying

exposure conditions and changing lifestyle habits (including confounding noise sources), particularly among young people, will have an impact. Therefore, recommendations regarding leisure noise have often been inferred from the occupational field, where exposure conditions are more stable over time.

Indeed, long-term exposure to noise, objectively assessed and at levels measured in occupational settings for various professions, can lead to permanent hearing loss and tinnitus. This evidence, while not reviewed systematically as part of the work related to these guidelines, can be used as supportive evidence and justification for the need to develop a recommendation for leisure noise, given that many people could be at risk of developing hearing loss and/or tinnitus from exposure to lower levels of environmental noise. Similar otobiological mechanisms must also be considered for environmental noise.

To date, no commonly accepted method for assessing the risk of hearing loss due to environmental exposure to noise has been developed. One of the main challenges is to conduct a long-term objective exposure assessment of environmental noise and relate this to the development of permanent hearing impairment and tinnitus. The GDG underlined the strong need for research to develop a comprehensive methodology. In the absence of a method, and as long as no other tools are available, the equal energy principle outlined in the ISO standard for the estimation of noise-induced hearing loss (WHO, 1999) can be used as a practical tool for protecting public health from exposure to leisure noise. As a result, the relationship between leisure noise exposure and auditory effects can be quantified for a variety of exposure levels, duration and frequency.

Several organizations have established regulations for the protection of workers from risks to their health and safety arising from exposure to noise, and in particular risk to hearing. Of particular relevance is EU Directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers to the risks arising from physical agents (noise) (EC, 2003). Based on the ISO 1999 standard (ISO, 2013), the Directive sets limits of exposure depending on equivalent noise level for an eight-hour working day and obliges the employer to take suitable steps if the limits are exceeded. It recommends three action levels for occupational settings, setting the lowest, most conservative value at $L_{ex,Bhr} = 80$ dB. According to the Directive, no consequences of exposure to occupational noise are expected at this level. While exposure patterns and certain characteristics of occupational and leisure noise exist, knowledge of the hearing impairment risks and preventive interventions can be used to assess health risks associated with leisure noise (Neitzel & Fligor, 2017).

The CNG recommend a limit of $L_{Aeq,24h} = 70$ dB(A) for preventing hearing loss from industrial, commercial shopping and traffic areas, indoors and outdoors (WHO, 1999). Health and safety regulations are usually based on an exposure profile of a typical worker (eight hours per day, five days per week). Using the existing knowledge from the ISO standard and established health and safety regulations, it is possible to use the equal energy principle to derive the resulting noise exposure level for an exposure profile more appropriately suited for leisure noise. Converting 40 hours at 80 dB to a continuous exposure to noise (24 hours per day, seven days per week), this leads to a yearly average exposure of 71 dB for lifelong exposure.²¹ This is the same value as the WHO recommendation of

²¹ 71 dB = 80 dB (derived from ISO standard) – 6.2 dB (conversion of yearly average of 40 working hours divided by continuous exposure to noise: (10 log (2080hrs/8760 hrs)) – 3 dB (extrapolation of 40 working years to lifelong exposure).

70 dB (WHO, 1999). Table 49 presents the noise levels per hour for various time averages in order to keep within the recommended yearly average exposure, and assuming that exposure to other noise sources generally does not contribute significantly. For example, for specific events taking place for one-, two- or four-hour averages, once a week (such as visiting a discotheque or watching a loud movie), an hourly noise level of 85 dB would lead to an average yearly exposure of 63 dB, 66 dB and 69 dB, respectively. However, the same hourly exposure of 85 dB for an activity taking place for 14 hours per week (two hours per day, seven days a week) would lead to a yearly exposure of 74 dB, which exceeds the recommendations.

Table 49. Combination of hourly	exposure and number of	f hours per week to	arrive at a yearly
average L _{Aeq}			

Hours of exposure per week	One-hour exposure level (L _{Aeq})						
	70	75	80	85	90	95	100
1	48	53	58	63	68	73	78
2	51	56	61	66	71	76	81
4	54	59	64	69	74	79	84
14 (2 hours per day, 7 days per week)	59	64	69	74	79	84	89
28 (4 hours per day, 7 days per week)	62	67	72	77	82	87	92
40 (8 hours per day, 5 days per week)	64	69	74	79	84	89	94
168 (24 hours per day, 7 days per week)	70	75	80	85	90	95	100

Note: green = combinations of exposure/duration below current guideline level; red = combinations of exposure/duration above current guideline level; blue = input parameters.

The equal energy principle cannot be used to derive single-event limits because at high levels the ear starts to respond with nonlinear behaviour. The CNG provides several values, in different units: $L_{AF,max} = 110 \text{ dB}$ for industrial noises (no distance stated), $L_{peak,lin} = 140 \text{ dB}$ for adults and $L_{peak,lin} = 120 \text{ dB}$ for children (measured at 100 mm) (WHO, 1999). EU Directive 2003/10/EC on the minimum health and safety requirements regarding the exposure of workers recommends a lower action level of $L_{peak,C} = 135 \text{ dB}$ (at 100 mm). In a recent overview Hohmann (2015) provided an ERF for hearing damage caused by shooting noise, from which it appears that a safe level of $L_E = 120 \text{ dB}$ can be derived.

Although it is clear that high noise levels cause acute hearing damage, there is no agreement on a safe level. Further research is highly recommended. In the mean time, existing guidelines should be applied.

3.5.3 Summary of the assessment of the strength of recommendation

Table 50 provides a comprehensive summary of the different dimensions for the assessment of the strength of the leisure noise recommendations.

Factors influencing the strength of recommendation	Decision
Quality of evidence	Average exposure (L _{Aeq.24h})
	Health effects
	• Evidence of an effect from PLDs on hearing impairment and tinnitus, in the absence of evidence for other health outcomes and absence of evidence on hearing impairment and tinnitus from other types of leisure noise besides PLDs, was rated very low quality.
	Interventions
	 No evidence was available on the effectiveness of interventions to reduce noise exposure and/or health outcomes from leisure noise.
Balance of benefits versus harms and burdens	The general benefit from reduction of leisure noise outweighs any potential harms.
Values and preferences	There is variability in the values and preferences of the general population.
Resource implications	The resources needed to reduce exposure to leisure noise are not expected to be intensive, but implementation and the long-term success of measures may be challenging, mainly due to cultural factors.
Decision on strength of	• Conditional for guideline level for average noise exposure $(L_{Aea,24h})$
recommendation	Conditional for single-event and impulse noise
	Strong for interventions to reduce noise exposure

Table 50. Summary of the assessment of the strength of the recommendation

3.6 Interim targets

An interim target was proposed in the NNG (WHO Regional Office for Europe, 2009), "recommended in situations where the achievement of NNG is not feasible in the short run for various reasons". The NNG emphasized that an interim target is "not a health-based limit value by itself. Vulnerable groups cannot be protected at this level".

The GDG discussed whether to propose interim targets as part of the current guidelines, and if so, what process would be needed to derive those values. The current recommendations are health-based and already provide guideline values per noise source (for both L_{den} and L_{night}). They also include information on exposure–response relationships for various health outcomes, which can be used by policy-makers or other stakeholders to inform the selection of different values, if needed. Further, interim targets may work differently in different countries and for different noise sources, and it may not be optimal to propose them Europe-wide. As a result, there was consensus among members of the GDG not to provide interim targets.

4. Implications for research

The development of these environmental noise guidelines for the WHO European Region has made evident some key knowledge gaps and research needs. The main ones specific to the guideline recommendations are presented as implications for research in the sections that follow.

4.1 Implications for research on health impacts from transportation noise

For the assessment of health effects from the main sources of transportation noise (road traffic, railways and aircraft), the various evidence reviews show the following knowledge gap: there is a need for longitudinal studies on the health impacts from exposure to environmental noise, to inform future recommendations properly (Table 51).

Current state of the evidence	Limited evidence is available on health impacts from transportation noise from large-scale cohort and case-control studies, with objective measurement of both noise exposure and health outcomes.	
Population of interest	Research is needed into effects of exposure on children and adults exposed to environmental noise from transportation sources.	
Exposure of interest	Objective measurement or calculation of transportation noise exposure is required; in particular, from studies of health effects related to combined exposure to different noise sources.	
Comparison of interest	The data should be compared to the effects of lower levels of transportation noise.	
Outcomes of interest	Measures of the following health outcomes is required, assessed objectively and harmonized where possible – for example, according to common protocols:	
	annoyance	
	effects on sleep	
	 cardiovascular and metabolic effects 	
	adverse birth outcomes	
	cognitive impairment	
	 mental health, quality of life and well-being 	
	 hearing impairment and tinnitus 	
	any other relevant health outcome.	
Time stamp	The systematic review included studies between October 2014 and December 2016.	

Table 51. Implications for research on health impacts from transportation noise (air, rail, road)

4.1.1 Specific implications for annoyance

To predict absolute %HA at the full range of levels (and the corresponding CIs), an integrated analysis of the original raw data from all of individual studies would be necessary. The evidence review conducted as part of the guidelines focused only on secondary data handling and therefore does not replace a full meta-analysis of all individual data. The development of a generic exposure-response relationship (from a full meta-analysis based on all individual data) is suggested as a priority research recommendation (see Table 52).

Current state of the evidence	The evidence review on annoyance conducted as part of the guidelines does not provide a generalized ERF but points to significant differences compared to the curves used in the past. It shows that the available generalized ERFs are in need of adjustment, preferably as a result of undertaking a full meta-analysis. This is especially the case for the sources aircraft and railway noise, which new data show are more annoying than previously documented.	
Population of interest	Research is needed into effects of exposure on children and adults exposed to air, rail and/or road traffic noise.	
Exposure of interest	Objective measurement of transportation noise exposure is required.	
Comparison of interest	The data should be compared to the effects of lower levels of transportation noise.	
Outcomes of interest	······································	
Time stamp	The systematic review included studies up to October 2014.	

Table 52. Recommendation for research addressing the exposure-response relationship

4.2 Implications for research on health impacts from wind turbine noise

Further research into the health impacts from wind turbine noise is needed so that better-quality evidence can inform any future public health recommendations properly. For the assessment of health effects from wind turbines, the evidence was either unavailable or rated low/very low quality. Recommendations for research addressing this priority are proposed in Table 53.

Table 53. Implications for research on health impacts from wind turbine noise

Current state of the evidence	The current evidence on health outcomes related to wind turbine noise is unavailable or of low/very low quality and mainly comes from cross-sectional studies. Methodologically robust longitudinal studies with large samples investigating the quantitative relationship between noise from wind turbines and health effects are needed.
Population of interest	Research is needed into effects of exposure on children and adults exposed and living near sources of wind turbine noise. Studies should assess subgroup differences in effects for vulnerable groups such as children, elderly people and those with existing poor physical and mental health.
Exposure of interest	Exposure to noise at a wide range of levels and frequencies (including low-frequency noise), with information on noise levels measured outdoors and indoors (particularly relevant for effects on sleep) at the residence is needed. The noise exposure should be measured objectively and common protocols for exposure to wind turbine noise should be established, considering a variety of noise characteristics specific to wind turbine noise.
Comparison of interest	The data should be compared to the effects in similar areas without wind turbines. Pre/ post studies of new wind turbine installations are needed, especially if "before measures" unbiased by the stress and knowledge of potential wind turbine farm development need to be developed.
Outcomes of interest	Measures of health outcomes are required, assessed objectively – for example, according to common protocols (ICBEN scale for annoyance and self-reported sleep disturbance). The studies should include the most important situational and personal confounding variables, such as negative attitudes towards wind turbines, visual impact, economic gain and other socioeconomic factors.
Time stamp	The systematic review included studies between October 2014 (review on annoyance) and December 2016 (review on cardiovascular disease).

Alongside the defined needs for research on wind turbine noise it should be noted that research regarding industrial noise in general is required. More specifically, there is a need to investigate stationary sources (including heat, ventilation and acclimatization devices) and their impacts on health. Studies on hearing disorders from impulse and/or intermittent sounds are also needed; these would enable assessment of adverse effects created by one or several sounds of short duration with a high maximum sound level or impulse sound level.

4.3 Implications for research on health impacts from leisure noise

For the assessment of effects from leisure noise, the evidence to make a recommendation on the ERF to use for health risk assessment, or of a threshold for effects, was either unavailable or rated very low quality. This is a research gap: longitudinal studies with longer follow-up are needed; these should measure noise objectively, not only from PLDs but also from other types of leisure noise.

There is uncertainty in the measurement of early hearing disorders among young people using the tonal audiometry commonly applied. Precise methods to identify early hearing impairment and other hearing disorders are needed. Owing to long induction periods, however, adequate research may be difficult to perform, particularly among young people who change their exposure in terms of sound level and frequency as they age (for example, changing their music listening habits and venue visits). As a result, the recommendations refer to the results derived from stationary noise sources in the occupational field, in conjunction with the equal energy principle (see Table 54).

Current state of the evidence	Currently, no evidence is available on hearing impairment and tinnitus from large-scale cohort and case-control studies, with objective measurement of noise exposure and using a suitable method to assess hearing impairment in young people.	
Population of interest	Research is needed into effects of exposure on children and adults exposed to environme noise from different sources and in different settings.	
Exposure of interest	Objective measurement of leisure noise exposure is required.	
Comparison of interest	The data should be compared to the effects of no leisure noise exposure from these sources.	
Outcomes of interest	The primary outcomes identified are:	
	 hearing loss measured by audiometry; 	
	 specific threshold analyses focused on stratifying the risk of permanent hearing loss according to clearly defined levels of exposure to leisure noise, such as music through PLDs; 	
	 concise methods to identify early hearing impairment and other hearing disorders; 	
	 temporary threshold shift after exposure to leisure noise, as it may be reasonably predictive of future permanent threshold shift; 	
	 age-related hearing loss progression depending on early-age exposure to leisure noise, such as to loud music; and 	
	 tinnitus, measured objectively and subjectively. 	
Time stamp	The systematic review included studies up to June 2015.	

Table 54. Implications for research on health impacts from leisure noise

4.4 Implications for research on effectiveness of interventions to reduce exposure and/or improve public health

The quality of the evidence on the effectiveness of interventions to reduce exposure to and health outcomes from environmental noise was variable. Further studies directly linking noise interventions to health outcomes are required, particularly for sources other than road traffic noise, and for human health outcomes other than annoyance.

Most studies involved road traffic noise (63%), followed by aircraft noise (13%) and railway noise (6%). The remaining interventions were for leisure noise (13%) and noise in hospital settings (4%). No interventions were identified that either addressed wind turbine noise or focused on educational settings.

Exposure-related interventions were mainly associated with a reduction in environmental noise exposure. However, in five studies (four road traffic noise studies and one aircraft noise study) some or all of the participants experienced noise exposure increases.

There is no clear evidence with respect to thresholds, which are defined as:

- the smallest change in exposure levels that results in a change in outcome; and
- the minimum before-level, regarding changes in health outcomes as a result of interventions.

The limited evidence base on the health effects of environmental noise interventions is thinly spread across different noise source types, outcomes and intervention types. Diversity exists between studies even within intervention types in terms of study designs, methods of analysis, exposure levels and changes in exposure experienced as a result of the interventions. For these reasons, carrying out a meta-analysis across studies examining the association between changes in level and changes in outcome was not possible.

To remedy this main research gap, longitudinal studies assessing noise exposure and health outcomes objectively should be developed, taking into account the most relevant confounders. The establishment of common protocols for future research is warranted (see Table 55).

Authorities should include significant funding for the design and implementation of studies to evaluate the effectiveness of interventions to reduce noise and their impact on health.

Current state of the evidence	The current evidence on effectiveness of interventions to reduce health outcomes is limited and of varying quality. Few longitudinal studies have been done that take into account the most relevant confounders and measure the noise exposure and the outcomes objectively.
Population of interest	Research is needed into effects of interventions on defined populations exposed to and/or living near sources of environmental noise.
Intervention of interest	Research into any noise intervention at various points along the system pathway between source and outcome, for a variety of noise sources, is required.
Comparison of interest	The data should be compared to:
	 a steady-state control group, in similar areas with various exposure gradients from environmental noise sources;
	 the noise exposure in the same population, through a series of sequential measurements assessing the change before and after the intervention, preferably with multiple after measurements.
Outcomes of interest	Future intervention studies should use validated and, where possible, harmonized measures of exposure and outcome, as well as of moderators and confounders.
	The studies should use measures of exposure including noise exposure at a wide range of levels and frequencies (including low-frequency noise), with information on noise levels outdoors and indoors (particularly relevant for effects on sleep).
	They should also use measures of health outcomes, including the following outcomes assessed objectively – for example, according to common protocols (ICBEN scale for annoyance) – with consideration that the change in human response for some health outcomes from a step change in exposure may have a different time course to that of the change in exposure:
	annoyance
	effects on sleep
	 cardiovascular and metabolic diseases
	adverse birth outcomes
	cognitive impairment
	 mental health, quality of life and well-being
	hearing impairment and tinnitus
	 any other relevant health outcome.
	Further, they should use measures of moderators and confounders, including repeated measurements of situational and personal variables such as activity interference, potential confounders such as noise sensitivity, coping strategies and a range of other attitudinal variables.
Time stamp	The systematic review included studies up to October 2014.

Table 55. Implications for research on effectiveness of interventions to reduce exposure and/ or improve public health

5. Implementation of the guidelines

5.1 Introduction

These guidelines focus on the WHO European Region and provide guidance to Member States that is compatible with the noise indicators used in the EU's END (EC, 2002a). They provide information on the exposure-response relationships between exposure to environmental noise from different noise sources and the proportion of people affected by certain health outcomes, as well as interventions that are considered efficient in reducing exposure to environmental noise and related health outcomes.

The WHO guideline values are evidence-based public health-oriented recommendations. As such, they are recommended to serve as the basis for a policy-making process in which policy options are considered. In the policy decisions on reference values, such as noise limits for a possible standard or legislation, additional considerations – such as feasibility, costs, preferences and so on – feature in and can influence the ultimate value chosen as a noise limit. WHO acknowledges that implementing the guideline recommendations will require coordinated effort from ministries, public and private sectors and nongovernmental organizations, as well as possible input from international development and finance organizations. WHO will work with Member States and support the implementation process through its regional and country offices.

5.2 Guiding principles

Four guiding principles provide generic advice and support when incorporating the recommendations into a policy framework, and apply to the implementation of all the recommendations.

The **first principle** is to reduce exposure to noise, while conserving quiet areas. The recommendations focus on reduction of population exposure to environmental noise from a variety of sources, in different settings. The general population can be exposed regularly to more than one source of noise simultaneously (including, in some cases, occupational noise), as well as to other nonacoustic factors that can modify the response to noise (such as vibration from railways, air pollution from traffic or visual aspects of wind turbines). Thus, overall reduction of exposure from all sources should be promoted. Furthermore, noise exposure reduction in one area should not come at the expense of an increase in noise elsewhere; existing large quiet outdoor areas should be preserved.

The **second principle** is to promote interventions to reduce exposure to noise and improve health. The evidence from epidemiological studies on adverse health effects at certain noise levels, used as a basis to derive the guideline values proposed in the recommendations, supports the promotion of noise interventions. The potential health impacts from environmental noise are significant, especially when considering the widespread exposure to environmental noise across the population and the high baseline rates for various health outcomes associated with environmental noise.

There are challenges in assessment of the effectiveness of interventions to reduce noise exposure and/or improve health, as there is often a significant time lag between the intervention and a measurable change in exposure and related health benefits. The lack of – or limited direct evidence

for – quantifiable health benefits of some specific interventions does not imply that measures to achieve population exposure according to the proposed guidelines should be ignored.

Given the different factors that determine noise exposure, a single measure alone may not be sufficient to reduce exposure and/or improve health significantly, and a combination of methods may be warranted. Nevertheless, it is widely acknowledged that the most effective actions to reduce exposure tend to be those that reduce noise at the source. Such actions have the biggest potential, whereas other measures can be less effective or sustained over time, especially when they depend on behaviour change or noise reductions inside houses.

The **third principle** is to coordinate approaches to control noise sources and other environmental health risks. Considering the common transport-related sources of environmental noise and air pollution, and in particular the evidence of independent effects on the cardiovascular system, a coordinated approach to policy development in the sectors related to urban planning, transport, climate and energy should be adopted for policies with an impact on environmental noise, air quality and/or climate. Such an approach should yield multiple benefits through increased commitment and financial resources; increased attention to securing health considerations in all policies; and use of policy to control noise and other environmental risks such as air pollutants, including short-lived climate pollutants. There is wide consensus on the value of pursuing coordinated policies that can deliver health and other benefits, such as those associated with the local environment and economic development. Furthermore, coordinated policy-making is potentially cost-saving.

The **fourth principle** is to inform and involve communities that may be affected by a change in noise exposure. In planning new urban and/or rural developments (transport schemes, new infrastructures in less densely populated areas, noise abatement and mitigation strategies), bringing together planners, environmental professionals and public health experts with policy-makers and citizens is key to public acceptability and involvement and to the successful guidance of the decision-making proces. Potential health effects from environmental noise should be included as part of health impact assessments of future policies, plans and projects, and the communities potentially affected by a positive or negative change in noise exposure should be well informed and engaged from the outset to maximize potential benefits to health. Introducing measures incrementally may help with acceptance.

5.3 Assessment of national needs and capacity-building

National needs, including the need for capacity-building, differ between Member States in the WHO European Region. They depend on the existence and level of implementation of national and/ or European and international noise policies; these are more likely to be implemented fully in EU countries thanks to the legally binding provisions of the EU's END (EC, 2002a). In most countries in the Region noise is perceived as a major and growing environmental health and public health problem. Noise mapping and action plans are carried out in accordance with the END in EU Member States, and in south-eastern European countries noise legislation has mainly been harmonized with the END. Nevertheless, significant differences still exist in the completeness and regular updating of noise exposure assessment between countries. Noise exposure assessment is a required input for noise health impact assessments, along with exposure–response relationships and population baseline data.

WHO has identified some common needs for knowledge transfer and capacity-building for health risk assessment of environment noise in the Member States that joined the EU after 2003, the newly independent states and south-eastern European countries (WHO Regional Office for Europe, 2012):

- implementation of the END and its annexes, especially in the preparation of strategic noise mapping and action plans;
- human resources development through education and training in health risk assessment and burden of diseases stemming from environmental noise;
- methodological guidance for health risk assessment of environmental noise.

These guidelines mostly recommend exposure–response relationships related to the exposure indicators L_{den} and L_{night} . They are therefore of particular relevance to EU countries and those applying the END. In countries that do not use these indicators, users of the guidelines need to convert their noise indicators into L_{den} and L_{night} before being able to apply the recommendations. Conversion between indicators is possible, using a certain set of assumptions (Brink et al., 2018).

5.4 Usefulness of guidelines for target audiences

The provision of guideline values as a practical tool for guiding exposure reduction and the design of effective measures and policies is widely seen as useful. The WHO guidelines equip policy-makers and other end-users with a range of different needs with the necessary evidence base to inform their decisions. As indicated in section 1.4, these guidelines serve as a reference for several target audiences, and for each group they can be useful in different ways.

- For technical experts and decision-makers, the guidelines can be used to provide exposureresponse relationships that give insight into the consequences of certain regulations or standards on the associated health effects. They also can be useful at the national and international level when developing noise limits or standards, as they provide the scientific basis to identify the levels at which environmental noise causes a significant health impact. Based on these recommendations, national governments and international organizations can be better informed when introducing noise limits, to ensure protection of people's health.
- For health impact assessment and environmental impact assessment practitioners and researchers, these guidelines provide exposure-response relationships that give insight into the expected health effects at observed or expected noise exposure levels. They offer recommendations on the maximum admissible noise levels for some sources and provide important input to assit in deriving the health burden from noise; in that sense, they can be used when producing studies such as noise maps and action plans to obtain an evaluation of the magnitude of the health problem. The systematic reviews developed in support of these guidelines allow practitioners to raise awareness of the credibility of the issue of noise as a public health problem and to use the recommended exposure-response relationships uniformly. Researchers will also benefit from the guidelines as they clearly identify critical data gaps that need to be filled in the future to better protect the population from the harmful effects of noise.
- The guideline recommendations provide a useful tool for national and local authorities when deciding about noise reduction measures, as they provide data to estimate the health burden on the population and therefore allow comparison among different policy options. These options

can include measures to reduce the noise emitted by the sources, measures aimed at impeding the transmission of noise from the sources to people and measures aimed at better planning the location of houses (urban planning).

• The guideline recommendations can also be used by civil society, patients and other advocacy groups to raise awareness and encourage actions to protect the population, including vulnerable groups, from exposure to noise.

Regarding noise abatement and mitigation of noise sources, practical exposure-response relationships for various noise sources are useful quantitative input to determine the impact of noise on health. They can be valuable information to use in cost-effectiveness and cost-benefit analyses of various policies for noise abatement. In this respect, the guideline recommendations can be an integral part of the policy process for noise reduction by various institutions; they are of great value for communicating the health risks and potential cost-effective solutions to reduce noise.

National and local authorities and nongovernmental organizations responsible for risk communication and general awareness-raising can use these guidelines for promotion campaigns and appropriate risk communication. The guidelines provide scientific evidence on a range of health effects associated with noise and facilitate appropriate risk communication to specific vulnerable groups. They therefore need to be promoted broadly to citizens, national and local authorities and nongovernmental organizations responsible for risk communication.

5.5 Methodological guidance for health risk assessment of environmental noise

A health risk assessment is the scientific evaluation of potential adverse health effects resulting from human exposure to a particular hazard – in this case, environmental noise. The main purpose of the assessment is to estimate and communicate the health impact of exposure to noise or changes in noise in different socioeconomic, environmental and policy circumstances.

The guideline recommendations, along with the detailed information contained in the systematic evidence reviews, can be used to assess health impacts in order to answer a variety of policy questions on:

- the public health burden associated with current or projected levels of noise;
- the human health benefits associated with changing a noise policy or applying a more stringent noise standard;
- the impacts on human health of emissions from specific sources of noise for selected economic sectors (and the benefits of policies related to them); and
- the human health impacts of current policy or implemented action.

The results from a health risk assessment are usually reported as the number of attributable deaths, number of cases, years of life lost, years lost due to disability or DALYs.

The quantification of the impacts for one combination of noise source, noise exposure indicator and health outcome may to some extent include effects attributable to another. Consequently, for any particular set of combinations, consideration should be given to potential double counting.

It is also important to note the uncertainties in quantification of the health impacts. One set of uncertainties relates to the CIs associated with the recommended ERFs; these quantify the random

error and variability attributed to heterogeneity in the epidemiological studies used for health risk assessment. Other types of uncertainty include modelling/calculation of noise exposure, estimates of population background rates for morbidity and mortality, and transferability of ERFs from locations where studies were carried out or data were otherwise gathered to another location. This is especially true for noise annoyance, for which there is often considerable heterogeneity in effect sizes of studies because estimates vary between noise sources and are to some degree dependent on the situation and context. Furthermore, cultural differences around what is considered annoying are significant, even within Europe. It is therefore not possible to determine the "exact value" of %HA for each exposure level in any generalized situation. Instead, data and exposure–response curves derived in a local context should be applied whenever possible to assess the specific relationship between noise and annoyance in a given situation. If, however, local data are not available, general exposure–response relationships can be applied, assuming that the local annoyance follows the generalized average annoyance. Despite the challenges in applying a "generalized" ERF to specific local situations, the GDG believes that the percentage of high annoyance defined in section 2.4.3 is an acceptable estimate of the "average" %HA at a certain noise level – for example, in Europe.

When performing a health risk assessment of environmental noise, it is important to note several considerations. The selection of particular noise source(s), noise exposure indicator(s) and health outcome combinations to be used for estimation of the health impacts depends on the particular policies and/or measures being assessed. These guidelines propose recommendations for four types of noise source using noise indicators L_{den} and/or L_{night} (road traffic, railway noise, aircraft noise and wind turbine noise) and one recommendation using $L_{Aeq,24h}$ (leisure noise). Any population may be exposed to different noise sources associated with the same health outcome. Estimated impacts should not be added together without recognizing that addition will, in most practical circumstances, lead to some overestimation of the true impact. Impacts estimated for only one combination will, on the other hand, underestimate the true impact of the noise mixture, if other sources of noise also affect that same health outcome.

The scientific evidence reviewed and summarized in these guidelines implies that the following health outcomes can be quantified in a health risk assessment, and that their effects are cumulative:

- from road traffic noise incidence of IHD, annoyance and sleep disturbance, and potentially incidence of stroke and diabetes;
- from railway noise annoyance and sleep disturbance;
- from aircraft noise annoyance, reading and oral comprehension in children, sleep disturbance and potentially change in waist circumference and incidence of IHD;
- from wind turbine noise: annoyance.

The DWs suggested in section 2.4.3 can be used to calculate DALYs.

Data on incidence and prevalence of some health outcomes related to noise (mainly cardiovascular disease) can be found at a national level in online databases available on the WHO Regional Office for Europe website (WHO Regional Office for Europe, 2017).

General principles of relevance for environmental factors when conducting health risk assessments and quantifying the burden of disease can be found elsewhere (European Centre for Health Policy, 1999; Murray, 1994; Murray & Acharya, 1997; Murray & Lopez, 2013; Quigley et al., 2006; WHO,

2014a; 2014b; WHO Regional Office for Europe, 2016). In particular, the WHO Regional Office for Europe and JRC jointly published the first estimates of the burden of disease from environmental noise in 2011 (WHO Regional Office for Europe & JRC, 2011). The publication includes guidance on the procedure for the health risk assessment of environmental noise, exemplary estimates of the burden of the health impacts of environmental noise and a discussion of the uncertainties and limitations of the procedure to calculate the environmental burden of disease. The reader is referred to this publication for more detailed explanations on quantitative risk assessment methods for environmental noise.

5.6 Route to implementation: policy, collaboration and the role of the health sector

Preventing noise and related health impacts relies on effective action across different sectors: health, environment, transport, urban planning and so on. The health sector needs to be engaged effectively in different sectors' policy processes at national, regional and international levels. It needs to provide authoritative advice about the health impacts of noise and policy options that will bring the greatest benefits to health.

In most countries in the WHO European Region, the commitment of the health sector to engage in action to address environmental noise issues needs to be improved and better coordinated. A more coherent overall response is needed, taking into account relevant linkages with existing health priorities and concerns. Thus, some actions can be seen as aspects of the role of the health sector:

- engaging in proper communication with relevant sectors about noise exposure from different sectors and sources (environmental, urban development, transport and so on) to ensure that health issues are adequately addressed as part of international, regional, national and/or local efforts to address environmental noise – the implementation approach may differ across sectors, depending on the level of awareness of noise as a public health problem;
- promoting the guideline recommendations to policy-makers from different sectors and organizing information campaigns and awareness-raising activities in collaboration with national health authorities and WHO country offices to inform citizens and health practitioners about the health risks of environmental noise;
- using decision support instruments such as health impact and health risk assessments to quantify health risks and potential benefits associated with policies and interventions aimed at addressing environmental noise, including presenting information about the severity of the health effects (for example, with cardiovascular disease) to convey the serious impacts of noise and to try to change attitudes and behaviours of policy-makers and the general public;
- promoting the guidelines to health practitioners and physicians, especially at the community level (through associations of physicians, cardiologists and so on as part of the stakeholder group);
- supporting the establishment of national health institutions capable of initiating and developing health promotion measures, and conducting research, monitoring and reporting on health impacts from environmental noise and its different sources;

- organizing capacity-building workshops and training to increase knowledge of the guidelines as well as creating tools, skills and resources for health risk assessment and developing intersectoral collaboration, particularly in non-EU countries;
- promoting relevant research initiatives and shaping the research agenda, in part based on critical research recommendations and gaps identified in the guidelines, as well as on the impact and effectiveness of interventions and experience with their implementation;
- developing and updating guidelines and policies that influence national, regional and international benchmarks and targets related to environmental noise, as well as advocating the inclusion of the guidelines in development and shaping of national, regional and international noise policies and standards;
- working with other sectors to strengthen noise level monitoring and evaluation, particularly in non-EU countries, to ensure proper conducting of health risk assessments of environmental noise.

5.7 Monitoring and evaluation: assessing the impact of the guidelines

Exposure–response relationships and other recommendations provided by these guidelines should be incorporated into national health policies and the main related policy documents. They should be used for health impact and health risk assessments to identify health risks and potential benefits associated with policies and interventions related to environmental noise.

Population noise exposure should be monitored and assessed at a national scale, at least in urban areas. Furthermore, information on trends in occurrence of noise-related health outcomes considered in these guidelines, such as annoyance or sleep disturbance, should be gathered. These monitoring activities should be performed on a regular basis to ensure proper health risk assessments of noise.

5.8 Updating the guidelines

The progress and pace of noise and health research has intensified over the last 10 years, including new studies published after the completion of the systematic reviews done for these guidelines. This is partly related to the growing car fleet and resulting traffic, the density of urbanization, demographic changes and shifts towards renewable energy, including wind turbines, which have caused an increase in public perception and political awareness of the environmental noise problem. Noise exposure assessment has also improved, due partly to European legislation, and this has provided useful data for epidemiological studies on the health effects of environmental noise. Considering this, the recommendations proposed in these guidelines are expected to remain valid for a period of about 10 years. WHO will monitor the development of the scientific advancements on noise and health research in order to inform any updated guidance on environmental noise.

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Annexes

Annex 1. Steering, advisory and external review groups

Tables A1.1–A1.5 give details of the various teams involved in the development of the WHO environmental noise guidelines for the European Region.

Table A	1.1 W	HO Ste	ering	Group
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Name	Role	Affiliation
Shelly Chadha	Technical Officer, Office for Hearing Impairment	WHO headquarters, Geneva, Switzerland
Carlos Dora	Coordinator	WHO headquarters, Department of Public Health and Environment, Geneva, Switzerland
Marie-Eve Héroux	Technical Officer, Air Quality and Noise	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Dorota Jarosinska	Programme Manager, Living and Working Environments	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Rokho Kim	Environmental Health Specialist, Team Leader	WHO Regional Office for the Western Pacific, Division of Noncommunicable Diseases and Health through the Life-Course, Manila, Philippines
Jurgita Lekaviciute	Consultant, Noise	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Srdan Matic	Coordinator, Environment and Health	WHO Regional Office for Europe, Copenhagen, Denmark
Julia Nowacki	Technical Officer, Health Impact Assessment	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Elizabet Paunovic	Head of Office	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Poonum Wilkhu	Consultant, Noise	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany
Jördis Wothge	Consultant, Noise	WHO Regional Office for Europe, European Centre for Environment and Health, Bonn, Germany

Table A1.2. Guideline Development Group

Area of exp	ertise	Reference	Are	a of e	xper	tise					Re	ference
Noise sources measurement		1	Annoyance									6
Biological me	chanisms of effects	2	Cognitive impairment, quality of life, mental health and well-being								7	
Cardiovascula diseases	ar and metabolic	3	Adve	erse bi	rth out	come	6					8
Sleep disturbance 4		4	Envi	ronmei	ntal no	ise int	erventi	ons				9
Hearing impairment/tinnitus 5		5	Meth	nodolo	gy and	d guide	eline de	evelop	ment			10
Name Position and affiliation				(s	ee ref	erence	e num	bers	above))	opment	
Wolfgang Babisch	Senior Scientific Offic Federal Environment Germany		1	2 ×	3 X	4	5 X	6	7	8	9	10
Goran Belojevic	Professor Institute of Hygiene a Ecology Faculty of M University of Belgrade Serbia	edicine			x			x				
Mark Brink	Senior Scientist Federal Office for the Switzerland	Environment	X			х		x				
Sabine Janssen	Senior Scientist Department of Susta Mobility and Safety Netherlands Organisa Applied Scientific Res Netherlands	ation for				x		x				
Peter Lercher (2013–2014)	Professor Medical University of Austria	Innsbruck							X	х		
Marco Paviotti	Policy Officer Directorate-General f European Commissio Belgium		x								x	
Göran Pershagen	Professor Institute of Environme Karolinska Institute Sweden	ental Medicine		Х	x					х		

 \Rightarrow

Table A1.2. contd

Area of exp	pertise	Reference	Are	a of e	xper	tise					Ref	erence	
Noise sources measurement		1	Annoyance									6	
Biological me	chanisms of effects	2		nitive ir th and			quality	of life,	menta		7		
Cardiovascula diseases	3	Adve	erse bii	th out	come	S					8		
Sleep disturbance 4			Envi	ronmei	ntal no	ise int	ervent	ions				9	
Hearing impai	irment/tinnitus	5	Meth	nodolo	gy and	d guide	eline d	evelop	ment			10	
Name Position and affiliation		ation	Are	a of e						line d above)		pment	
			1	2	3	4	5	6	7	8	9	10	
Kerstin Persson Waye	Professor Occupational and En Medicine The Sahlgrenska Aca University of Gothent Sweden	ademy	X			×		x					
Anna Preis	Professor Institute of Acoustics Adam Michiewicz Ur Poland						x	x					
Stephen Stansfeld (Chair)	Professor/Head of th Psychiatry Barts and Queen Ma London United Kingdom								X				
Martin van den Berg	Senior Noise Expert Ministry of Infrastruct Environment Netherlands	ure and	X										
GRADE me	thodologist												
Jos Verbeek	Senior Researcher Finnish Institute of Oo Health Finland	ccupational	x										

Systematic review topics	Experts involved	Affiliation
Cardiovascular and metabolic diseases	Elise van Kempen	National Institute of Public Health and the Environment (RIVM), Netherlands
	Göran Pershagen	Institute of Environmental Medicine, Karolinska Institute, Sweden
	Maribel Casas Sanahuja	Institute for Global Health (ISGlobal), Spain
	Maria Foraster	Barcelona Institute for Global Health (ISGlobal), Spain and Swiss Tropical and Public Health Institute, Switzerland
Sleep disturbance	Mathias Basner	Department of Psychiatry, Perelman School of Medicine at the University of Pennsylvania, United States of America
	Sarah McGuire	Department of Psychiatry, Perelman School of Medicine at the University of Pennsylvania, United States of America
Hearing impairment and tinnitus	Mariola Sliwinska- Kowalska	Nofer Institute of Occupational Medicine, Poland
	Kamil Rafal Zaborowski	Nofer Institute of Occupational Medicine, Poland
Annoyance	Rainer Guski	Department of Psychology, Ruhr-University, Germany
	Dirk Schreckenberg	ZEUS GmbH, Centre for Applied Psychology, Environmental and Social Research, Germany
	Rudolf Schuemer	Consultant for ZEUS GmbH, Centre for Applied Psychology, Environmental and Social Research, Germany
Cognitive impairment,	Charlotte Clark	Ove Arup & Partners, United Kingdom
mental health and well- being	Katarina Paunovic	Institute of Hygiene and Medical Ecology, Faculty of Medicine, University of Belgrade, Serbia
Adverse birth outcomes	Mark Nieuwenhuijsen	Institute for Global Health (ISGlobal), Spain
	Gordana Ristovska	Institute of Public Health of Republic of Macedonia, the former Yugoslav Republic of Macedonia
	Payam Dadvand	Institute for Global Health (ISGlobal), Spain
Interventions	Lex Brown	Griffith School of Environment/Urban Research Program, Griffith University, Australia
	Irene Van Kamp	National Institute of Public Health and the Environment (RIVM), Netherlands

Table A1.3. Systematic Review Team

Table A1.4. External Review Group

Area of expertise	Reference	Area of expertise	Reference
Cardiovascular and metabolic diseases	1	Cognitive impairment, mental health and well-being	5
Sleep disturbance	2	Adverse birth outcomes	6
Hearing impairment/ Tinnitus	3	Environmental noise interventions	7
Annoyance	4	Recommendations and implementation guidance	8

		galac							
Name	Affiliation	Area of expertise sought for guideline development (see reference numbers above)							
		1	2	3	4	5	6	7	8
Gunn Marit Aasvang	Norwegian Institute of Public Health, Norway		Х						
Bernard Berry	Berry Environmental Limited, United Kingdom							Х	
Dick Botteldooren	Department of Information Technology, Ghent University, Belgium				X				
Stephen Conaty	South Western Sydney Local Health District, Australia								x
Ulrike Gehring	Institute for Risk Assessment Sciences, Utrecht University, Netherlands						Х		
Truls Gjestland	SINTEF, Department of Acoustics, Norway				Х				
Mireille Guay	Healthy Environments and Consumer Safety Branch, Health Canada/Government of Canada, Canada		X		X				
Ayse Güven	Audiology Department, Faculty of Heath Sciences, Baskent University, Turkey			Х					
Anna Hansell	Centre for Environmental Health & Sustainability, George Davies Centre, University of Leicester, United Kingdom	Х							x
Stylianos Kephalopoulos	European Commission, DG Joint Research Centre, Italy							Х	X
Yvonne de Kluizenaar	The Netherlands Organization for applied scientific research (TNO), Netherlands							Х	
David S. Michaud	Healthy Environments and Consumer Safety Branch, Health Canada/Government of Canada, Canada		X		x				
Arnaud Norena	Université Aix-Marseille, Fédération de Recherche, Laboratoire Cognitive Neuroscience, France			x					
Enembe Okokon	National Institute for Health and Welfare, Finland								Х
Dieter Schwela	Stockholm Environment Institute, University of York, United Kingdom								х
Daniel Shepherd	AUT University, Auckland, New Zealand					Х			
Mette Sörensen	Danish Cancer Society Research Centre, Denmark	Х							х
Rupert Thornley- Taylor	Rupert Taylor Ltd, Noise and Vibration Consultants							Х	X
David Welch	School of Population Health, Faculty of Medical and Health Sciences, University of Auckland, New Zealand			x				х	

Table A1.5. Stakeholders and end users that participated in the stakeholder consultation

Area of expertise/interest	Reference	Area of expertise				Reference		
Implementation of recommendations on railway noise	1	Implementati wind turbine	tions on	4				
Implementation of recommendations on aircraft noise	2	Implementati leisure noise	5					
Implementation of recommendations on road traffic noise	3	Implementati recommenda	6					
Organization						lly sought for umber above)		
		1	2	3	4	5	6	
Airlines for Europe			Х					
Airports Council International Europe (ACI)		Х						
Anderson Acoustics		Х						
Bundesverband der Deutschen Luftverkehr		Х						
European Automobile Manufacturers' Assoc			Х					
European Aviation Safety Agency			Х					
European Express Association		Х						
European Noise Barrier Federation							Х	
Flughafenverband (ADV)			Х					
International Air Transport Association (IATA)		Х					
International Civil Aviation Organization (ICA	O)		Х					
International Union of Railways		Х						
Landesamt fuer Natur, Umwelt und Verbraucherschutz Nordrhein-Westfalen							Х	
Public Health Agency of Sweden							Х	
Stephen Turner Acoustics						Х	Х	
Union Européenne Contre les Nuisances Ae	eriennes		Х					
Vie en.ro.se.							X	

Note: in total 53 organizations and institutions had been approached to participate in the stakeholder consultation.

Annex 2. Systematic reviews and background documents used in preparation of the guidelines

Annex 2 provides a detailed list of all the supplementary documents accompanying the WHO environmental noise guidelines for the European Region.²²

Systematic reviews

- Basner M, McGuire S (2018). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and effects on sleep. Int J Environ Res Public Health. 15(3):pii: E519 (http://www.mdpi.com/1660-4601/15/3/519/htm).
- Brown AL, van Kamp I (2017). WHO environmental noise guidelines for the European Region: a systematic review of transport noise interventions and their impacts on health. Int J Environ Res Public Health. 14(8). pii: E873 (http://www.mdpi.com/1660-4601/14/8/873/htm).
- Clark C, Paunovic K (2018). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and cognition. Int J Environ Res Public Health. 15(2). pii: E285 (http://www.mdpi.com/1660-4601/15/2/285/htm).
- Clark C, Paunovic K (in press). WHO Environmental noise guidelines for the European Region: a systematic review on environmental noise and quality of life, wellbeing and mental health. Int J Environ Res Public Health.
- Guski R, Schreckenberg D, Schuemer R (2017). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and annoyance. Int J Environ Res Public Health. 14(12). pii:1539 (http://www.mdpi.com/1660-4601/14/12/1539/htm).
- Nieuwenhuijsen MJ, Ristovska G, Dadvand P (2017). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and adverse birth outcomes. Int J Environ Res Public Health. 14(10). pii: E1252 (http://www.mdpi.com/1660-4601/14/10/1252/ htm).
- Śliwińska-Kowalska M, Zaborowski K (2017). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and permanent hearing loss and tinnitus. Int J Environ Res Public Health. 14(10). pii: E1139 (http://www.mdpi.com/1660-4601/14/10/1139/ htm).
- van Kempen E, Casas M, Pershagen G, Foraster M (2018). WHO environmental noise guidelines for the European Region: a systematic review on environmental noise and cardiovascular and metabolic effects: a summary. Int J Environ Res Public Health. 15(2). pii: E379 (http://www.mdpi. com/1660-4601/15/2/379/htm).

²² All references were accessed on 27 June 2018.

Background documents

- Eriksson C, Pershagen G, Nilsson M (2018). Biological mechanisms related to cardiovascular and metabolic effects by environmental noise. Copenhagen: WHO Regional Office for Europe (http://www.euro.who.int/en/health-topics/environment-and-health/noise/publications/2018/biological-mechanisms-related-to-cardiovascular-and-metabolic-effects-by-environmental-noise).
- Héroux ME, Verbeek J (2018a). Results from the search for available systematic reviews and meta-analyses on environmental noise. Copenhagen: WHO Regional Office for Europe (http://www.euro.who.int/en/health-topics/environment-and-health/noise/publications/2018/results-search-for-available-systematic-reviews-environmental-noise).
- Héroux ME, Verbeek J (2018b). Methodology for systematic evidence reviews for the WHO environmental noise guidelines for the European Region. Copenhagen: WHO Regional Office for Europe (http://www.euro.who.int/en/health-topics/environment-and-health/noise/ publications/2018/methodology-systematic-evidence-reviews-who-environmental-guidelines-forthe-european-region).

Annex 3. Summary of conflict of interest management

All external contributors to the guidelines, including members of the GDG, Systematic Review Team and External Review Group, completed WHO declaration of interest forms in accordance with WHO's policy for experts. Further, at the initial stage of the project WHO technical staff reviewed and accepted *curricula vitae* of the candidates for the GDG.

At the beginning of the GDG meetings, the participants declared any conflict of interest by submitting declaration of interest forms. Updated declarations of interest were also collected from the members of the GDG, Systematic Review Team and External Review Group at the final stage of the project.

The conflict of interest assessment was done according to WHO procedures. If a conflict was declared, an initial review was undertaken by the WHO Secretariat to assess its relevance and significance. A declared conflict of interest is insignificant or minimal if it is unlikely to affect or to be reasonably perceived to affect the expert's judgment. Insignificant or minimal interests are: unrelated or only tangentially related to the subject of the activity or work and its outcome; nominal in amount or inconsequential in importance; or expired and unlikely to affect current behaviour.

The WHO Secretariat reviewed and assessed the declarations. In one case the legal unit was consulted for advice; in another the potential conflict was reported in the updated declaration of interest at the final stage of the process and assessed unlikely to affect expert's performance; in a further case a member of the GDG was also a co-author of a systematic review owing to the need to support systematic review authors with additional expertise, but there was no remuneration for this activity.

No member of the GDG or the Systematic Review Team was excluded from his or her role in the guideline development process. The declared conflicts of interest of the External Review Group members were considered when interpreting comments during the external review process.

Annex 4. Detailed overview of the evidence of important health outcomes

As a first step of the evidence retrieval process, the GDG defined two categories of health outcome associated with environmental noise: those considered (i) critical or (ii) important, but not critical for decision-making in the guideline development process.

The GDG relied on the critical health outcomes to inform its decisions on priority health outcomes, so only these were used to inform the recommendations. Nevertheless, as the relevance of some of important health outcomes was difficult to estimate *a priori*, systematic reviews were conducted for both critical and important health outcomes.

This annex provides a detailed overview of the evidence of the important health outcomes – namely adverse birth outcomes, quality of life, well-being and mental health and metabolic outcomes – for each of the noise sources. A comprehensive discussion of all the evidence considered (both critical and important) is available in the published systematic reviews (see section 2.3.2 and Annex 2 for details).

1. Road traffic noise

1.1 Adverse birth outcomes

In total, the systematic review found five studies (two with more or less the same population) on road traffic noise and birth outcomes and three related studies on total ambient noise, likely to be mostly road traffic noise. Too few studies for each of the various measures related to adverse birth outcomes were available to undertake a quantitative meta-analysis. There was evidence rated low quality for a relationship between road traffic noise and low birth weight (Dadvand et al., 2014; Gehring et al., 2014; Hjortebjerg et al., 2016; Wu et al., 1996); however, the estimates were imprecise and in some cases not statistically significant. Further, there was no clear relation between road traffic noise and small for gestational age (OR = 1.09; 95% CI: 1.06–1.12 per 6 dB increase). The evidence for both measures of adverse birth outcomes comes from the same publications and this evidence was rated low quality (Gehring et al., 2014; Hystad et al., 2014).

This evidence was supported by one ecological time-series study published recently looking at total ambient noise and various measures related to adverse birth outcomes (Arroyo et al., 2016a; 2016b; Diaz et al., 2016).

1.2 Quality of life, well-being and mental health

Evidence rated moderate quality was found for an effect of road traffic noise on emotional and conduct disorders in childhood (Belojevic et al., 2012; Crombie et al., 2011; Hjortebjerg et al., 2015; Ristovska et al., 2004; Stansfeld et al., 2005; 2009a; Tiesler et al., 2013) and evidence rated moderate quality for an association of road traffic noise with hyperactivity in children (Hjortebjerg et al., 2015; Tiesler et al., 2013).

There was no clear relationship, however, between road traffic noise exposure and self-reported quality of life (evidence rated low quality) (Barcelo Perez & Piñeiro, 2008; Brink, 2011; Clark et al., 2012; Honold et al., 2012; Roswall et al., 2015; Schreckenberg et al., 2010b; Stansfeld et al., 2005; 2009b; van Kempen et al., 2010); medication intake for depression and anxiety (evidence rated very low quality) (Floud et al., 2011; Halonen et al., 2014); depression, anxiety and psychological distress (evidence rated very low quality) (Honold et al., 2012; Stansfeld et al., 2009b); and interview measures of depression and anxiety (evidence rated very low quality) (Stansfeld et al., 2009b).

1.3 Metabolic outcomes

1.3.1 Diabetes

For the relationship between road traffic noise and the incidence of diabetes, one cohort study was identified, which included 57 053 participants and 2752 cases (Sörensen et al., 2013). The estimate of the effect was RR = 1.08 (95% CI: 1.02–1.14) per 10 dB L_{den} increase in noise across the range of 50–70 dB, and therefore the evidence was rated moderate quality.

Furthermore, two cross-sectional studies were identified that looked at the prevalence of diabetes (Selander et al., 2009; van Poll et al., 2014). The studies included 11 460 participants and 242 cases. Both studies reported a harmful effect of noise, and one showed a statistically significant association. However, the results were imprecise and with serious risk of bias, so the evidence was rated very low quality.

1.3.2 Obesity

With regard to the association between road traffic noise and change in body mass index (BMI) and waist circumference, three cross-sectional studies were identified, with 71 431 participants (Christensen et al., 2016; Oftedal et al., 2014; 2015; Pyko et al., 2015). For each 10 dB increase in road traffic noise, there was a statistically nonsignificant increase in BMI of 0.03 kg/m² (95% CI: -0.10-0.15 kg/m²) and in waist circumference of 0.17 cm (95% CI: -0.06-0.40 cm). There was inconsistency in the results between the studies; therefore, for both associations, the evidence was rated very low quality (Fig. A4.1 and Fig. A4.2).

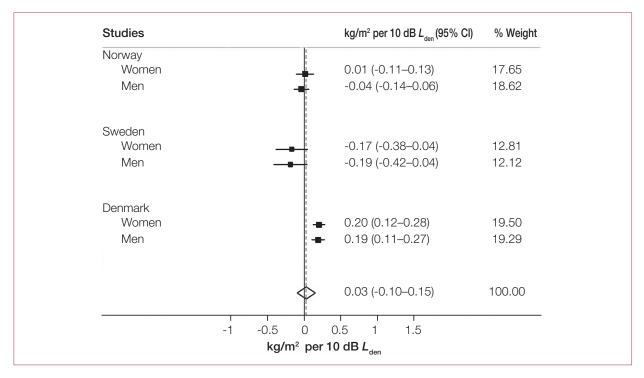


Fig. A4.1 The association between exposure to road traffic noise (L_{den}) and BMI in three Nordic studies

Notes: The black vertical line corresponds to no effect of noise exposure. The black dots correspond to the estimated slope coefficients per 10 dB for each sex in each study, with 95% Cls. The diamond designates summary estimates and 95% Cls based on random effects models. The dashed red line corresponds to these summary estimates. Heterogeneity between studies: p = 0.000; heterogeneity between genders: p = 0.360; overall (I-squared = 84.4%, p = 0.000). Weights are from random effect analysis.

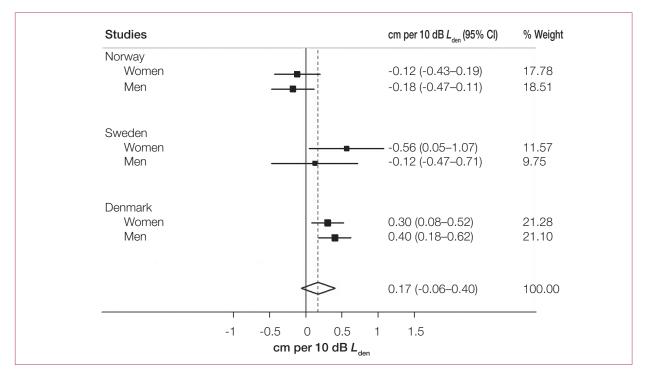


Fig. A4.2 The association between exposure to road traffic noise (L_{den}) and waist circumference in three Nordic studies

Notes: The black vertical line corresponds to no effect of noise exposure. The black dots correspond to the estimated slope coefficients per 10 dB for each sex in each study, with 95% CIs. The diamond designates summary estimates and 95% CIs based on random effects models. The dashed red line corresponds to these summary estimates. Heterogeneity between studies: p = 0.001; heterogeneity between genders: p = 0.842; overall (I-squared = 69.0%, p = 0.007). Weights are from random effect analysis.

2. Railway noise

2.1 Adverse birth outcomes

No studies were found, and therefore no evidence was available on the association between railway noise and adverse birth outcomes.

2.2 Quality of life, well-being and mental health

Evidence rated very low quality was found for a weak effect of railway noise exposure on selfreported quality of life or health, albeit from a limited number of studies (Roswall et al., 2015; Torre et al., 2007). There was evidence rated moderate quality for an effect of railway noise on emotional and conduct disorders in childhood (Hjortebjerg et al., 2015), but no clear relationship between railway noise and children's hyperactivity (Hjortebjerg et al., 2015); this evidence was rated moderate quality.

2.3 Metabolic outcomes

2.3.1 Diabetes

One cohort study was identified that looked at the relationship between railway noise and the incidence of diabetes (Sörensen et al., 2013). The cohort study of 57 053 participants, including 2752 cases, found evidence rated moderate quality that there was no considerable effect of railway noise on diabetes, with an RR of 0.97 (95% CI: 0.89-1.05) per 10 dB L_{den} increase in noise.

Furthermore, one cross-sectional study was identified that looked at the relationship between railway noise and the prevalence of diabetes (van Poll et al., 2014), including 9365 participants and 89 cases. An RR of 0.21 (95% CI: 0.05–0.82) per 10 dB L_{den} increase in noise was found, but the reasons for the beneficial effect were not immediately apparent. The evidence in the study was rated very low quality.

2.3.2 Obesity

Regarding the association between railway noise and change in BMI and waist circumference, two cross-sectional studies were identified, with 57 531 participants (Christensen et al., 2016; Pyko et al., 2015). Christensen and colleagues observed a statistically significant increase of 0.18 kg/m² (95% CI: 0.00–0.36 kg/m²) per 10 dB for BMI and 0.62 cm (95% CI: 0.14–1.09 cm) per 10 dB for waist circumference in those exposed to railway noise, at levels above 60 dB L_{den} . Pyko and colleagues found a statistically significant increase in waist circumference of 0.92 cm (95% CI: 0.06–1.78 cm) per 10 dB L_{den} . The corresponding estimate for BMI was statistically nonsignificant, at 0.06 kg/m² (95% CI: –0.02–0.16 kg/m²). The evidence was rated low/very low quality.

3. Aircraft noise

3.1 Adverse birth outcomes

Evidence rated very low quality was available for an association between aircraft noise and pre-term delivery, low birth weight and congenital anomalies, as evidenced by six studies included in the systematic review (Ando & Hattori, 1973; Edmonds et al., 1979; Jones & Tauscher, 1978; Knipschild et al., 1981; Matsui et al., 2003; Schell, 1981). The potential for risk of bias in these was high and the results tended to be inconsistent.

3.2 Quality of life, well-being and mental health

Evidence rated very low quality was available for an effect of aircraft noise on medication intake for depression and anxiety (Floud et al., 2011). There was evidence rated very low quality for an effect of aircraft noise exposure on interview measures of depression and anxiety (Hardoy et al., 2005) and rated low quality for an association of aircraft noise with hyperactivity in children (Clark et al., 2013; Crombie et al., 2011; Stansfeld et al., 2009a).

The evidence showed, however, no substantial effect of aircraft noise on self-reported quality of life or health (Clark et al., 2012; Schreckenberg et al., 2010a; 2010b; Stansfeld et al., 2005; van Kempen et al., 2010) or on emotional and conduct disorders in childhood (Clark et al., 2012; 2013; Crombie et al., 2011; Stansfeld et al., 2005; 2009a). This evidence was rated very low quality.

3.3 Metabolic outcomes

3.3.1 Diabetes

For the relationship between aircraft noise and incidence of diabetes one cohort study was identified, including 5156 participants and 1346 cases (Eriksson et al., 2014). The estimate of the effect was imprecise, with an RR of 0.99 (95% CI: 0.47-2.09) per 10 dB L_{den} increase in noise; the evidence was therefore rated very low quality.

Furthermore, one cross-sectional study was identified that looked at the prevalence of diabetes (van Poll et al., 2014), including 9365 participants and 89 cases. The RR was 1.01 (95% CI: 0.78–1.31) per 10 dB increase in aircraft noise. The evidence was rated very low quality.

3.3.2 Obesity

For the association between aircraft noise and change in BMI and waist circumference, one cohort study was identified, with 5156 participants (Eriksson et al., 2014). For each 10 dB increase in aircraft noise level, the increase in BMI was 0.14 kg/m² (95% CI: -0.18-0.45) (evidence rated low quality), and the increase in waist circumference was 3.46 cm (95% CI: 2.13-4.77) (evidence rated moderate quality). The range of noise levels in the study was 48–65 dB L_{den} . In the case of BMI, the change over the whole range in noise values was not statistically significant and was less than what could be considered clinically relevant (3–5% change in BMI); however, for waist circumference, the change was equivalent to an increase of 5.8 cm.

4. Wind turbine noise

4.1 Quality of life, well-being and mental health

Five low-quality systematic reviews of wind turbine noise effects on mental health and well-being have been carried out (Ellenbogen et al., 2012; Kurpas et al., 2013; Merlin et al., 2013; Onakpoya et al., 2015; Schmidt & Klokker, 2014). These reviews differed in their conclusions and delivered inconsistent evidence that wind turbine noise exposure is associated with poorer quality of life, well-being and mental health. Therefore, the evidence for no substantial effect of wind turbine noise on quality of life, well-being or mental health was rated very low quality.

4.2 Metabolic outcomes

4.2.1 Diabetes

For the relationship between wind turbine noise and prevalence of diabetes, three cross-sectional studies were identified, with a total of 1830 participants (Bakker et al., 2012; Pedersen, 2011; Pedersen & Larsman, 2008; Pedersen & Persson Waye, 2004; 2007; Pedersen et al., 2009; van den Berg et al., 2008). The number of cases was not reported. The effect sizes varied across studies, and only one study found a positive association between exposure to wind turbine noise and the prevalence of diabetes; therefore, no meta-analysis was performed. Due to very serious risk of bias and imprecision in the results, this evidence was rated very low quality. As a result, there is no clear relationship between audible noise (greater than 20 Hz) from wind turbines or wind farms and prevalence of diabetes (Fig. A4.3).

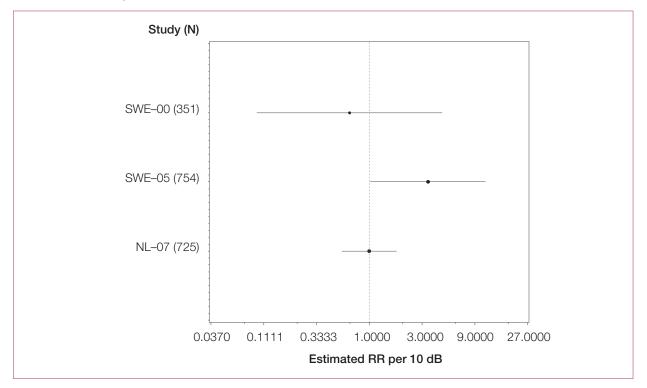


Fig. A4.3 The association between exposure to wind turbine noise (sound pressure level) and self-reported diabetes

Note: The dotted vertical line corresponds to no effect of exposure to wind turbine noise. The black circles correspond to the estimated RR per 10 dB (sound pressure level) and 95% CI. For further details on the studies included in the figure please refer to the systematic review on environmental noise and cardiovascular and metabolic effects (van Kempen et al., 2018).

5. Leisure noise

Owing to a lack of evidence meeting the critieria for systematic reviewing, no results for any of the important health outcomes can be given for exposure to leisure noise.

Annex 4 references

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The WHO Regional Office for Europe

The World Health Organization (WHO) is a specialized agency of the United Nations created in 1948 with the primary responsibility for international health matters and public health. The WHO Regional Office for Europe is one of six regional offices throughout the world, each with its own programme geared to the particular health conditions of the countries it serves.

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Noise is an important public health issue. It has negative impacts on human health and well-being and is a growing concern. The WHO Regional Office for Europe has developed these guidelines, based on the growing understanding of these health impacts of exposure to environmental noise. The main purpose of these guidelines is to provide recommendations for protecting human health from exposure to environmental noise originating from various sources: transportation (road traffic, railway and aircraft) noise, wind turbine noise and leisure noise. They provide robust public health advice underpinned by evidence, which is essential to drive policy action that will protect communities from the adverse effects of noise. The guidelines are published by the WHO Regional Office for Europe. In terms of their health implications, the recommended exposure levels can be considered applicable in other regions and suitable for a global audience.



World Health Organization Regional Office for Europe UN City, Marmorvej 51, DK-2100 Copenhagen Ø, Denmark Tel.: +45 45 33 70 00 Fax: +45 45 33 70 01 E-mail: eurocontact@who.int