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WHO/ILO work-related burden of disease and injury: Protocol for systematic reviews of exposure to occupational noise and of the effect of exposure to occupational noise on cardiovascular disease

Liliane R. Teixeira[a,*], Tatiana M. Azevedo[b], Alicja Bortkiewicz[c], Denise T. Corrêa da Silva[a], Wagner de Abreu[a], Márcia S. de Almeida[a], Marco A.N. de Araujo[a], Elzbieta Gadzicka[c], Ivan D. Ivanov[d], Nancy Leppink[e], Marta R.V. Macedo[f], Elvira M.G. de S. Maciel[g], Małgorzata Pawlaczyk-Łuszczyńska[h], Frank Pega[d], Annette M. Prüss-Üstün[d], Jadwiga Siedlecka[c], Gretchen A. Stevens[i], Yuka Ujita[e], José Ueleres Braga[g]

[a] Workers' Health and Human Ecology Research Center, National School of Public Health Sergio Arouca, Oswaldo Cruz Foundation, Rio de Janeiro, RJ, Brazil
[b] Workers' State Secretariat of Health, Rio de Janeiro, State Reference Center in Workers' Health, Rio de Janeiro, RJ, Brazil
[c] Department of Work Physiology and Ergonomics, Nofer Institute of Occupational Medicine, Lodz, Poland
[d] Department of Public Health, Environmental and Social Determinants of Health, World Health Organization, Geneva, Switzerland
[e] Labour Administration, Labour Inspection and Occupational Safety and Health Branch, International Labour Organization, Geneva, Switzerland
[f] Workers' Health Coordination, Oswaldo Cruz Foundation, Rio de Janeiro, RJ, Brazil
[g] Department of Epidemiology and Quantitative Methods in Health, National School of Public Health Sergio Arouca, Oswaldo Cruz Foundation, Rio de Janeiro, RJ, Brazil
[h] Department of Physical Hazards, Nofer Institute of Occupational Medicine, Lodz, Poland
[i] Department of Information, Evidence and Research, World Health Organization, Geneva, Switzerland

ABSTRACT

Background: The World Health Organization (WHO) and the International Labour Organization (ILO) are developing a joint methodology for estimating the national and global work-related burden of disease and injury (WHO/ILO joint methodology), with contributions from a large network of experts. In this paper, we present the protocol for two systematic reviews of parameters for estimating the number of deaths and disability-adjusted life years from cardiovascular disease attributable to exposure to occupational noise, to inform the development of the WHO/ILO joint methodology.

Objectives: We aim to systematically review studies on exposure to occupational noise (Systematic Review 1) and systematically review and meta-analyse estimates of the effect of occupational noise on cardiovascular diseases (Systematic Review 2), applying the Navigation Guide systematic review methodology as an organizing framework, conducting both systematic reviews in tandem and in a harmonized way.

Data sources: Separately for Systematic Reviews 1 and 2, we will search electronic academic databases for potentially relevant records from published and unpublished studies, including Medline, EMBASE, Web of Science and CISDOC. We will also search electronic grey literature databases, Internet search engines and organizational websites; hand search reference list of previous systematic reviews and included study records; and consult additional experts.

Study eligibility and criteria: We will include working-age (≥15 years) workers in the formal and informal economy in any WHO and/or ILO Member State, but exclude children (< 15 years) and unpaid domestic workers. The eligible risk factor will be occupational noise. Eligible outcomes will be hypertensive heart disease, ischaemic heart disease, stroke, cardiomyopathy, myocarditis, endocarditis and other circulatory diseases. For Systematic Review 1, we will include quantitative prevalence studies of exposure to occupational noise (i.e., low: < 85 dB(A) and high: ≥85 dB(A)) stratified by country, sex, age and industrial sector or occupation. For Systematic Review 2, we will include randomized controlled trials, cohort studies, case-control studies and other non-randomized intervention studies with an estimate of the relative effect of high exposure to occupational noise on the prevalence of, incidence of or mortality due to cardiovascular disease, compared with the theoretical minimum risk exposure level (i.e., low exposure).

Study appraisal and synthesis methods: At least two review authors will independently screen titles and abstracts against the eligibility criteria at a first stage and full texts of potentially eligible records at a second stage, followed by extraction of data from qualifying studies. At least two review authors will assess risk of bias and the

* Corresponding author at: Rua Leopoldo Bulhões, 1480, Prédio Primeiro de Maio, Laboratório do Sono e Eletrofisiologia, 21041-210 Rio de Janeiro, RJ, Brazil.
E-mail addresses: lilianeteixeira@ensp.fiocruz.br (L.R. Teixeira), tamaze@gmail.com (T.M. Azevedo), alab@imp.lodz.pl (A. Bortkiewicz), denisetorreao@gmail.com (D.T. Corrêa da Silva), abreu.wagner41@gmail.com (W. de Abreu), soalheir@ensp.fiocruz.br (M.S. de Almeida), nabuco@terra.com.br (M.A.N. de Araujo), elag@imp.lodz.pl (E. Gadzicka), ivanovi@who.int (I.D. Ivanov), leppink@ilo.org (N. Leppink), mribeiro@fiocruz.br (M.R.V. Macedo), elviramaciel@ensp.fiocruz.br (E.M.G. de S. Maciel), Malgorzata.Pawlaczyk@imp.lodz.pl (M. Pawlaczyk-Łuszczyńska), pegaf@who.int (F. Pega), pruessa@who.int (A.M. Prüss-Üstün), jadzias@imp.lodz.pl (J. Siedlecka), stevensg@who.int (G.A. Stevens), ujita@ilo.org (Y. Ujita), ueleres@ensp.fiocruz.br (J.U. Braga).

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quality of evidence, using the most suited tools currently available. For Systematic Review 2, if feasible, we will combine relative risks using meta-analysis. We will report results using the guidelines for accurate and transparent health estimates reporting (GATHER) for Systematic Review 1 and the preferred reporting items for systematic reviews and meta-analyses guidelines (PRISMA) for Systematic Review 2.

PROSPERO registration number: CRD42018092272.

1. Background

The World Health Organization (WHO) and the International Labour Organization (ILO) are developing a joint methodology for estimating the work-related burden of disease and injury (WHO/ILO joint methodology) (Ryder, 2017). The organizations plan to estimate the numbers of deaths and disability-adjusted life years (DALYs) that are attributable to selected occupational risk factors, in the first place for the year 2015. The WHO/ILO joint methodology will be based on already existing WHO and ILO methodologies for estimating the burden of disease for selected occupational risk factors (International Labour Organization, 2014; Prüss-Üstün et al., 2017). It will expand existing methodologies with estimation of the burden of several prioritized additional pairs of occupational risk factors and health outcomes. For this purpose, population attributable fractions, the proportional reduction in burden from the health outcome achieved by a reduction of exposure to the theoretical minimum risk exposure level (Murray et al., 2004), will be calculated for each additional risk factor-outcome pair and these fractions will be applied to the total disease burden envelopes for the health outcome from the WHO *Global Health Estimates* (World Health Organization, 2017).

The WHO/ILO joint methodology may include a methodology for estimating the burden of cardiovascular disease from exposure to occupational noise if feasible, as one of the additional prioritized risk factor-outcome pairs. To optimize parameters used in estimation models, a systematic review is required of studies on the prevalence of exposure to occupational noise (‘Systematic Review 1’), as well as a second systematic review and meta-analysis of studies including estimates of the effect of exposure to occupational noise on cardiovascular disease (‘Systematic Review 2’), respectively. In the current paper, we present the protocol for these systematic reviews, in parallel to presenting systematic review protocols on other additional risk factor-outcome pairs elsewhere (Descatha et al., 2018; Godderis et al., 2018; Hulshof et al., in press; Li et al., 2018; Mandrioli et al., 2018; Paulo et al., Accepted; Rugulies et al., Accepted; Tenkate et al., Accepted). To our knowledge, this is the first protocol of its kind. The WHO/ILO joint estimation methodology and the burden of disease estimates are separate from these systematic reviews, and they will be described and reported elsewhere.

We refer separately to Systematic Reviews 1 and 2, because the two systematic reviews address two different objectives and therefore require different methodologies. The two systematic reviews will however be harmonized and conducted in tandem. This will ensure that – in the later development of the methodology for estimating the burden of disease from this risk factor-outcome pair – the parameters from studies on the risk factor prevalence are optimally matched with the parameters from studies on the effect of the risk factor on the designated outcome. The findings from Systematic Reviews 1 and 2 will be reported in two distinct journal articles.

1.1. Rationale

To consider the feasibility of estimating the burden of cardiovascular disease from occupational noise and to ensure that potential estimates of burden of disease are reported in adherence with the guidelines for accurate and transparent health estimates reporting (GATHER) (Stevens et al., 2016), WHO and ILO require a systematic review of studies on the prevalence of relevant levels of exposure to occupational noise (Systematic Review 1), as well as a second systematic review and meta-analysis of studies with estimates of the relative effect of exposure to occupational noise on the prevalence of, incidence of or mortality from cardiovascular disease, compared with the theoretical minimum risk exposure level (Systematic Review 2). The theoretical minimum risk exposure level is the exposure level that would result in the lowest possible population risk, even if it is not feasible to attain this exposure level in practice (Murray et al., 2004). These prevalence and effect estimates should be tailored to serve as parameters for estimating the burden of cardiovascular diseases from occupational noise in the WHO/ILO joint methodology.

To our knowledge, five systematic reviews have been conducted on the effect of occupational noise on morbidity and/or mortality from cardiovascular disease. A 2002 systematic review and meta-analysis of 43 epidemiologic studies published between 1970 and 1999 concluded that a 5 dB(A) noise increase led to a moderate increase in hypertension (relative risk 1.14, 95% CI 1.01 to 1.29, 9 studies, I^2 unclear), but it did not identify any evidence on the effect of occupational noise on other cardiovascular diseases (van Kempen et al., 2002). A 2012 systematic review (Hwang and Hong, 2012) and two 2016 systematic reviews (Domingo-Pueyo et al., 2016; Dzhambov and Dimitrova, 2016) concluded that occupational noise impacts cardiovascular disease, with the Dzhambov one finding elevated ischaemic heart disease from occupational noise among women, but not among men. A 2016 systematic review included 12 prospective cohort studies from high-income countries published between 1999 and 2013, most of which were judged to be of high quality, but with some methodological shortcomings in exposure assessment (Skogstad et al., 2016). Meta-analyses from this review found that exposure to high occupational noise (generally measured as > 85 dB) was associated with a large, clinically meaningful increase in the incidence of hypertension (hazard ratio (HR) 1.68; 95% confidence interval (CI) 1.10 to 2.57, 4 studies, I^2 = 88%) and cardiovascular disease (HR 1.34, 95% CI 1.15 to 1.56, 3 studies, I^2 = 0%), as well as with an increase in the risk of dying from any cardiovascular disease (HR 1.12; 95% CI 1.02 to 1.24, 5 studies, I^2 = 5%).

These previous systematic reviews did not always adhere with standard requirements outlined in the PRISMA guidelines (Liberati et al., 2009). They did not use two or more reviewers for study selection, data extraction, risk of bias assessment, and/or quality of evidences assessment; did not always specify their eligibility criteria based on PICOS (or, as promoted in the *Navigation Guide* (Woodruff and Sutton, 2014) PECO); did not always search grey and unpublished literature; and often did not specify key methods (e.g., no search strategy presented and/or data extraction process not described). We are not aware of a previous systematic review of exposure to occupational noise. To the best of our knowledge, this is also the first systematic review of parameters required for estimating the global and national burden of morbidity and mortality from cardiovascular diseases attributable to occupational noise.

Work in the informal economy may lead to different exposures and exposure effects than does work in the formal economy. The informal economy is defined as “all economic activities by workers and economic units that are – in law or in practice – not covered or insufficiently covered by formal arrangements”, but excluding “illicit activities, in particular the provision of services or the production, sale, possession or use of goods forbidden by law, including the illicit production and trafficking of drugs, the illicit manufacturing of and trafficking in firearms, trafficking in persons and money laundering, as defined in the relevant international treaties” (p. 4) (104th International Labour Conference, 2015). Therefore, we will consider the formality of the economy studied in studies included in both systematic reviews.

1.2. Description of the risk factor

The definition of the risk factor, the risk factor levels and the theoretical minimum risk exposure level are presented in Table 1. Occupational noise is a well-established occupational risk factor (Skogstad et al., 2016). For health effects, measures of exposure to occupational noise would ideally include measurement of duration of the exposure, how systematic the exposure is (Guida et al., 2010), the sound pressure levels and frequency (Branco and Alves-Pereira, 2004) and other relevant risk factors for the health outcome among the population exposed to occupational noise. However, while such cumulative exposure to occupational noise may be the most biologically relevant exposure metric in theory, we here prioritize a dichotomous exposure metric in practice, because we believe that global exposure data on agreed cumulative exposure measures do not currently exist.

Table 1
Definitions of the risk factor, risk factor levels and the minimum risk exposure level.

Concept	Definition
Risk factor	Occupational noise is the exposure at the workplace to an unpleasant or unwanted sound
Risk factor levels	1. High: ≥85 dB(A) 2. Low: < 85 dB(A)
Theoretical minimum risk exposure level	Low: < 85 dB(A)

Initially, the Global Burden of Disease Study classified occupational noise into three categories: minimum exposure (< 85 dB(A)), moderately high exposure (≥85–90 dB(A)) and high exposure (> 90 dB(A)) (Murray et al., 2004). More recently, the study has defined occupational noise as a dichotomous variable, "Proportion of the population ever exposed to noise greater than 85 dB at work or through their occupation" versus the theoretical minimum risk exposure level being "Background noise exposure" (p. 1362) (G. B. D. Risk Factors Collaborators, 2017). We will adopt the two risk factor levels of the latter approach.

At this point, we assume a theoretical minimum risk exposure level of low exposure to occupational noise: < 85 dB(A). Since the theoretical minimum risk exposure level is usually set empirically based on the causal epidemiological evidence, we will change the assumed level as evidence suggests. If several studies report exposure levels differing from the two standard levels we define here, then, if possible, we will convert the reported levels to the standard levels and, if not possible, we will report analyses on these alternate exposure levels as supplementary information in the systematic review.

1.3. Description of the outcome

The WHO *Global Health Estimates* group outcomes into standard burden of disease categories (World Health Organization, 2017), based on standard codes from the *International Statistical Classification of Diseases and Related Health Problems, 10th Revision* (ICD-10) (World Health Organization, 2015). The relevant WHO *Global Health Estimates* categories for Systematic Review 2 are: "*II.H.2 Hypertensive heart disease*"; "*II.H.3 Ischaemic heart disease*"; "*II.H.4 Stroke"; "II.H.5 Cardiomyopathy, myocarditis, endocarditis*"; and *"II.H.6 Other circulatory disease*" (World Health Organization, 2017). Table 2 presents for each WHO *Global Health Estimates* category its inclusion in this review. We will exclude from this review cardiovascular abnormalities, cardiovascular infections and pregnancy complications (i.e., ICD-10 codes I01–09; I30; I32–33; I39–43; I47; I49–50; and I52), because an effect of occupational noise on these health outcomes is not yet sufficiently supported by evidence. Therefore, this review covers only a part of the entire disease burden of all five relevant WHO *Global Health Estimates* categories.

1.4. How the risk factor may impact the outcome

Official health estimates of the burden of disease attributable to an occupational risk factor require a sufficient level of scientific consensus that the risk factor causes the disease (World Health Organization, 2017). An assessment by WHO of the existing level of evidence on the association between occupational noise and cardiovascular diseases published in 2004 concluded that scientific consensus on causality was insufficient at that point (in 2004) to permit the production of WHO burden of disease estimates (Concha-Barrientos et al., 2004). However, scientists have recently noted that there is now sufficient evidence to reach scientific consensus that environmental noise, including occupational noise, causes cardiovascular diseases (Babisch, 2014). Mechanistic or experimental evidence suggests that occupational noise specifically also impacts morbidity and mortality from cardiovascular diseases, primarily through causing an elevated stress level and response. We are not aware of any relevant animal studies.

Fig. 1 presents the logic model for our systematic review of the causal relationship between exposure to occupational noise and cardiovascular disease. This logic model is an *a priori*, process-orientated one (Rehfuess et al., 2018) that seeks to capture the complexity of the risk factor-outcome causal relationship (Anderson et al., 2011).

Model based on (Babisch, 2014; Munzel et al., 2018; World Health Organization, 2017).

While the effect of exposure of occupational noise on morbidity and mortality from cardiovascular diseases is not fully understood in detail, there is evidence that several causal pathways operate between occupational noise and cardiovascular disease. Previous studies have concluded that the health effects of (occupational) noise depend on the duration (Guida et al., 2010), repetition (Guida et al., 2010), intensity (Branco and Alves-Pereira, 2004) and frequency of sound (Branco and Alves-Pereira, 2004). The effects may be modified by several factors, including individual susceptibility, ethnicity (Rowland, 1980), sex (Melamed et al., 2004) and other physical (Vangelova and Deyanov, 2007), chemical (Brits et al., 2012; Kirkham et al., 2011; Morata, 1998) and biological risk factors (Brits et al., 2012; Chandola et al., 2010).

The mechanism is influenced by a direct pathway composed of the synaptic nervous interactions in the reticular activating system and

Table 2
ICD-10 codes and disease and health problems covered by the WHO burden of disease categories "*II.H.2 Hypertensive heart disease*"*; "II.H.3 Ischaemic heart disease*"; "*II.H.4 Stroke*"; "*II.H.5 Cardiomyopathy, myocarditis, endocarditis*"; and "*II.H.6 Other circulatory disease*" and their inclusion in this review.

ICD-10 code or codes	Disease or health problem	Included in this review
I10–I15	Hypertensive heart disease	I10–I11, I13–I15
I20–I25	Ischaemic heart disease	I20–I25
I60–I69	Stroke	I60–I69
I30–I33, I38, I40, I42	Cardiomyopathy, myocarditis, endocarditis	I31, I38, I40, I42
I26–I28, I34–I37, I44–I51, I70–I79, I99	Other circulatory diseases	I26–I28, I49, I70–I79

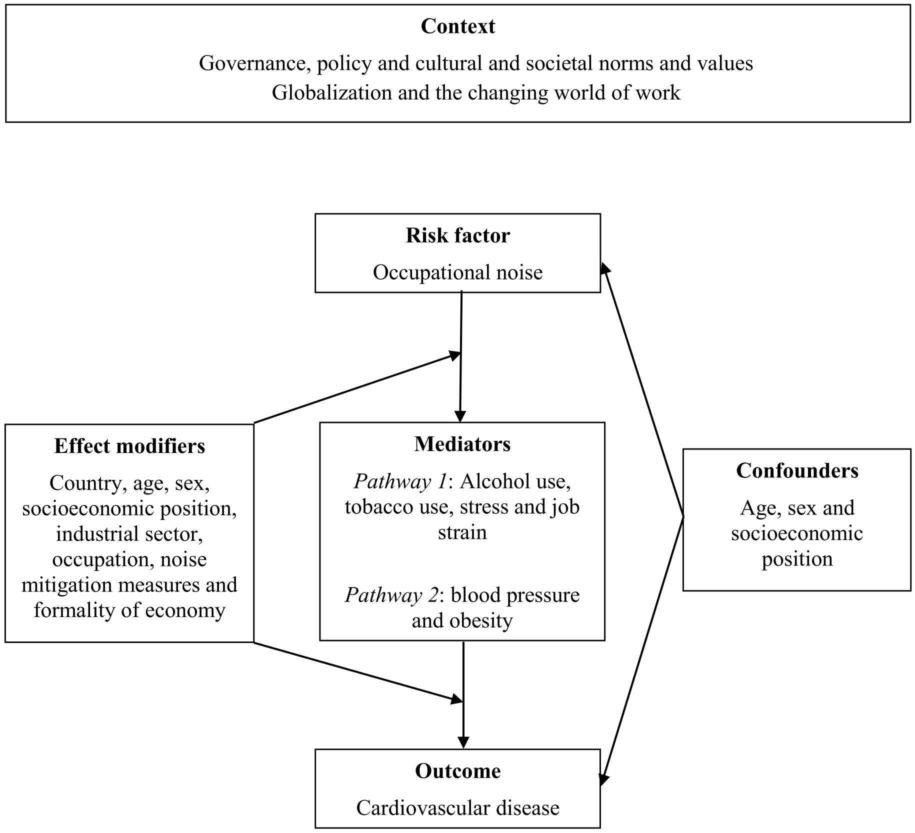

Fig. 1. Logic model of the potential causal relationship between occupational noise and cardiovascular disease.

parts of the between-brain (including the hypothalamus) and an indirect pathway composed of the emotional and the cognitive perception of the sound via the cortical and subcortical structures including the lymbic region (Andersson, 1988; Spreng, 2000).

There are three levels of physiological outcomes related to occupational noise exposure: individual characteristics, stress indicators and physiological risk factors. Evidence suggests that occupational noise causes elevated levels of stress (Munzel et al., 2018), which in turn causes cardiovascular diseases through an elevated stress response, as indicated by elevated levels of sympatho-adrenal and HPA-axis biomarkers (Skogstad et al., 2016), epinephrine, norepinephrine and cortisol, related to acute and chronic noise experiments (Babisch, 2002).

2. Objectives

1. Systematic Review 1: To systematically review quantitative studies of any design on the prevalence of relevant levels of exposure to occupational noise in the years 1970 to 2018 among working-age workers, disaggregated by country, sex, age and industrial sector or occupation.
2. Systematic Review 2: To systematically review and meta-analyse randomized control studies, cohort studies, case-control studies and other non-randomized intervention studies with estimates of the relative effect of high exposure to occupational noise on the prevalence of, incidence of or mortality from cardiovascular disease in any year among working-age workers, compared with the minimum risk exposure level of low exposure.

3. Methods

We will apply the *Navigation Guide* systematic review methodology for systematic reviews in environmental and occupational health as our guiding methodological framework (Woodruff and Sutton, 2014), wherever feasible. The *Navigation Guide* applies established systematic review methods from clinical medicine, including standard Cochrane Collaboration methods for systematic reviews of interventions, to the field of environmental and occupational health to ensure systematic and rigorous evidence synthesis on environmental and occupational risk factors that reduces bias and maximizes transparency (Woodruff and Sutton, 2014). The need for further methodological development and refinement of the relatively novel *Navigation Guide* has been acknowledged (Woodruff and Sutton, 2014).

Systematic Review 1 may not map well to the *Navigation Guide* framework (Fig. 1 on page 1009 in (Lam et al., 2016c)), which is tailored to hazard identification and risk assessment. Nevertheless, steps 1–6 for the stream on human data can be applied to systematically review exposure to risk factors. Systematic Review 2 maps more closely to the *Navigation Guide* framework, and we will conduct steps 1–6 for the stream on human data, but not conduct any steps for the stream on non-human data, although we will briefly summarize narratively the evidence from non-human data that we are aware of.

We have registered the protocol in PROSPERO under CRD42018084131. This protocol adheres with the preferred reporting items for systematic review and meta-analysis protocols statement (PRISMA-P) (Moher et al., 2015; Shamseer et al., 2015), with the abstract adhering with the reporting items for systematic reviews in journal and conference abstracts (PRISMA-A) (Beller et al., 2013). Any modification of the methods stated in the present protocol will be registered in PROSPERO and reported in the systematic review itself. Systematic Review 1 will be reported according to the GATHER guidelines (Stevens et al., 2016) and Systematic Review 2 will be reported according to the preferred reporting items for systematic review and meta-analysis statement (PRISMA) (Liberati et al., 2009). Our reporting of the parameters for estimating the burden of cardiovascular diseases from exposure to occupational noise in the systematic review will adhere with the requirements of the GATHER guidelines (Stevens et al., 2016), because the WHO/ILO burden of disease estimates that may be produced consecutive to the systematic review must also adhere to these reporting guidelines.

3.1. Systematic Review 1

3.1.1. Eligibility criteria

The population, exposure, comparator and outcome (PECO) criteria (Liberati et al., 2009) are described below.

3.1.1.1. Types of populations. We will include studies of working-age (≥15 years) workers in the formal and informal economy. Studies of children (aged < 15 years) and unpaid domestic workers will be excluded. Participants residing in any WHO and/or ILO Member State and any industrial setting or occupation will be included. We note that exposure to occupational noise may potentially have further population reach (e.g. through the release of noise from the workplace into the community) and acknowledge that the scope of our systematic review will not be able capture these populations and impacts on them. Appendix A provides a briefer overview of the PECO criteria.

3.1.1.2. Types of exposures. We will include studies that define occupational noise in accordance with our standard definition (Table 1). Cumulative exposure may be the most relevant exposure metric in theory, but we will here also prioritize a non-cumulative exposure metric in practice, because we believe that global exposure data on agreed cumulative exposure measures do not currently exist. We will include all studies where occupational noise was measured, whether self-reported by the worker or workplace administrator or manager, or whether measured using other methods, including measurements by experts (e.g., scientists with subject matter expertise using sound measuring technology, such as a sound level meter). If a study presents both objective and subjective measurements, then we will prioritize objective measurements. We will include studies with measures from any data source, including registry data.

We will include studies on the prevalence of occupational exposure to the risk factor, if it is disaggregated by country, sex (two categories: female, male), age group (ideally in 5-year age bands, such as 20–24 years) and industrial sector (e.g. *International Standard Industrial Classification of All Economic Activities, Revision 4* [ISIC Rev. 4]) (United Nations, 2008) or occupation (as defined, for example, by the *International Standard Classification of Occupations 1988* [ISCO-88] (International Labour Organization, 1987) or *2008* [ISCO-08] (International Labour Organization, 2012). Criteria may be revised in order to identify optimal data disaggregation to enable subsequent estimation of the burden of disease.

We shall include studies with exposure data for the years 1 January 1970 to 30 June 2018. For optimal modelling of exposure, WHO and ILO require exposure data up to 2018, because recent data points help better estimate time trends, especially where data points may be sparse. The additional rationale for this data collection window is that the WHO and ILO aim to estimate burden of disease in the year 2015, and we believe that the lag time from exposure to outcome will not exceed 45years; so in their models, the organizations can use the exposure data from as early as 1970 to determine the burden of cardiovascular disease 45years later in 2015. To make a conclusive judgment on the best lag time to apply in the model, we will summarize the existing body of evidence on the lag time between exposure to occupational noise and cardiovascular disease in the review.

The exposure parameter should match the one used in Systematic Review 2 or can be converted to match it.

3.1.1.3. Types of comparators. There will be no comparator, because we will review risk factor prevalence only.

3.1.1.4. Types of outcomes. Exposure to the occupational risk factor (i.e. occupational noise).

3.1.1.5. Types of studies. This systematic review will include quantitative studies of any design, including cross-sectional studies. These studies must be representative of the relevant industrial sector, relevant occupation or the national population. We will exclude qualitative, modelling, and case studies, as well as non-original studies without quantitative data (e.g. letters, commentaries and perspectives).

Study records written in any language will be included. If a study record is written in a language other than those spoken by the authors of this review or those of other reviews (Descatha et al., 2018; Hulshof et al., in press; Godderis et al., 2018; Li et al., 2018; Mandrioli et al., 2018; Paulo et al., Accepted; Rugulies et al., Accepted; Tenkate et al., Accepted) in the series (i.e. Arabic, Bulgarian, Chinese, Danish, Dutch, English, French, Finnish, German, Hungarian, Italian, Japanese, Norwegian, Portuguese, Russian, Spanish, Swedish and Thai), it will be translated into English. Published and unpublished studies will be included.

Studies conducted using unethical practices will be excluded from the review.

3.1.1.6. Types of effect measures. We will include studies with a measure of the prevalence of a relevant level of exposure to occupational noise.

3.1.2. Information sources and search

3.1.2.1. Electronic academic databases. We (LRT and JUB) will at a minimum search the following seven electronic academic databases:

1. Ovid Medline (1 January 1970 to 30 June 2018).
2. PubMed (1 January 1970 to 30 June 2018).
3. EMBASE (1 January 1970 to 30 June 2018).
4. Web of Science (1 January 1970 to 30 June 2018).
5. CISDOC (1 January 1970 to 2012).
6. Toxline (1 January 1970 to 30 June 2018).
7. Health and Environmental Research Online (HERO) (1 January 2005 to 30 June 2018).
8. Scopus (1 January 1995 to 30 June 2018).
9. LILACS (1 January 1986 to 30 June 2018).

The Ovid Medline search strategy for Systematic Review 1 is presented in Appendix B. We will perform searches in electronic databases operated in the English language using a search strategy in the English language. Consequently, study records that do not report essential information (i.e. title and abstract) in English will not be captured. We will adapt the search syntax to suit the other electronic academic and grey literature databases. When we are nearing completion of the review, we will search the PubMed database for the most recent publications (e.g., e-publications ahead of print) over the last six months. Any deviation from the proposed search strategy in the actual search strategy will be documented.

3.1.2.2. Electronic grey literature databases. LRT and JUB will at a minimum search the two following electronic grey literature databases:

1. OpenGrey (http://www.opengrey.eu/).
2. Grey Literature Report (http://greylit.org/).

Internet search engines. LRT and JUB will also search the Google (www.google.com/) and GoogleScholar (www.google.com/scholar/) Internet search engines and screen the first 100 hits for potentially relevant records, as has been done previously in Cochrane Reviews (Pega et al., 2015; Pega et al., 2017).

3.1.2.3. Organizational websites. The websites of the nine following international organizations and national government departments will be searched by LRT and JUB:

1. International Labour Organization (www.ilo.org/).
2. World Health Organization (www.who.int).
3. European Agency for Safety and Health at Work (https://osha.europa.eu/en).
4. Eurostat (www.ec.europa.eu/eurostat/web/main/home).
5. China National Knowledge Infrastructure (http://www.cnki.net/).
6. Finnish Institute of Occupational Health (https://www.ttl.fi/en/).
7. French National Research and Safety Institute for the Prevention of Occupational Accidents and Diseases (INRS) (http://en.inrs.fr/).
8. Italian National Institute for Insurance against Accidents at Work (Inail) (https://www.inail.it/).
9. United States National Institute of Occupational Safety and Health (NIOSH) of the United States of America, using the NIOSH data and statistics gateway (https://www.cdc.gov/niosh/data/).

3.1.2.4. Hand-searching and expert consultation. LRT and JUB will hand-search for potentially eligible studies in:

- Reference list of previous systematic reviews.
- Reference list of all study records of all included studies.
- Study records published over the past 24 months in the three peer-reviewed academic journals from which we obtain the largest number of included studies.
- Study records that have cited an included study record (identified in Web of Science citation database).
- Collections of the review authors.

Additional experts will be contacted with a list of included studies and study records, with the request to identify potentially eligible additional ones.

3.1.3. Study selection

Study selection will be carried out with Covidence (Babineau, 2014; Covidence systematic review software, n.d) and/or the Rayyan Systematic Reviews Web App (Ouzzani et al., 2016). All study records identified in the search will be downloaded and duplicates will be identified and deleted. Afterwards, at least two review authors (out of: WA, MSDA, MANDA and MRVM), working in pairs, will independently screen against eligibility criteria titles and abstracts (step 1) and then full texts of potentially relevant records (step 2). A third review author (LRT, DTCDS or JUB) will resolve any disagreements between the pairs of study selectors. If a study record identified in the literature search was authored by a review author assigned to study selection or if an assigned review author was involved in the study, then the record will be re-assigned to another review author for study selection. In the systematic review, we will document the study selection in a flow chart, as per GATHER guidelines (Stevens et al., 2016).

3.1.4. Data extraction and data items

A data extraction form will be developed and piloted until there is convergence and agreement among data extractors. At a minimum, two review authors (out of: WA, MSDA, MANDA and MRVM) will independently extract the data on exposure to occupational noise, disaggregated by country, sex, age and industrial sector or occupation. A third review author (LRT) will resolve conflicting extractions. At a minimum, we will extract data on study characteristics (including study authors, study year, study country, participants and the exposure), study design (including study type and measurements of the risk factor), risk of bias (including missing data, as indicated by response rate and other measures) and study context. The estimates of the proportion of the population exposed to the occupational risk factor from included studies will be entered into and managed with the Review Manager, Version 5.3 (RevMan 5.3) (2014) or DistillerSR (EvidencePartner, 2017) softwares.

We will also extract data on potential conflict of interest in included studies, including the financial disclosures and funding sources of each author and their affiliated organization. We will use a modification of a previous method to identify and assess undisclosed financial interests (Forsyth et al., 2014). Where no financial disclosure/conflict of interest is provided, we will search declarations of interest both in other records from this study published in the 36 months prior to the included study record and in other publicly available repositories (Drazen et al., 2010a; Drazen et al., 2010b).

We will request missing data from the principal study author by email or phone, using the contact details provided in the principal study record. If no response is received, we will follow up twice via email, at two and four weeks.

3.1.5. Risk of bias assessment

Generally agreed methods (i.e. framework plus tool) for assessing risk of bias do not exist for systematic reviews: of input data for health estimates (The GATHER Working Group, 2016), for burden of disease studies, of prevalence studies in general (Munn et al., 2014) and of prevalence studies of occupational and/or environmental risk factors specifically (Krauth et al., 2013; Mandrioli and Silbergeld, 2016; Vandenberg et al., 2016). None of the five standard risk of bias assessment methods in systematic reviews for environmental and occupational health (Rooney et al., 2016) are applicable to assessing prevalence studies. The *Navigation Guide* does not support checklist approaches, such as (Hoy et al., 2012; Munn et al., 2014), for assessing risk of bias in prevalence studies.

We will use a modified version of the *Navigation Guide* risk of bias tool (Lam et al., 2016c) that we developed specifically for Systematic Review 1 (Appendix C). We will assess risk of bias on the levels of the individual study and the entire body of evidence. As per our preliminary tool, we will assess risk of bias along five domains: (i) selection bias; (ii) performance bias; (iii) misclassification bias; (iv) conflict of interest; and (v) other biases. Risk of bias will be: “low”; “probably low”; “probably high”; “high” or “not applicable”. To judge the risk of bias in each domain, we will apply our *a priori* instructions (Appendix C).

All risk of bias assessors (WA, MSDA, MANDA and MRVM) will trial the tool until they synchronize their understanding and application of each risk of bias domain, considerations and criteria for ratings. At least two study authors (out of: WA, MSDA, MANDA and MRVM) will then independently judge the risk of bias for each study by outcome, and a third author (LRT) will resolve any conflicting judgments. We will present the findings of our risk of bias assessment for each eligible study in a standard ‘Risk of bias’ table (Higgins et al., 2011). Our risk of bias assessment for the entire body of evidence will be presented in a standard ‘Risk of bias summary’ figure (Higgins et al., 2011).

3.1.6. Synthesis of results

We will neither produce any summary measures, nor synthesise the evidence quantitatively. The included evidence will be presented in what could be described as an ‘evidence map’. All included data points from included studies will be presented, together with meta-data on the study design, number of participants, characteristics of population, setting, and exposure measurement of the data point.

3.1.7. Quality of evidence assessment

There is no agreed method for assessing quality of evidence in systematic reviews of the prevalence of occupational and/or environmental risk factors. We will adopt or adapt the latest *Navigation Guide* instructions for grading (Lam et al., 2016c), including criteria (Appendix D). We will downgrade for the following five reasons from the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach: (i) risk of bias; (ii) inconsistency; (iii) indirectness; (iv) imprecision; and (v) publication bias (Schünemann et al., 2011). We will grade the evidence, using the three *Navigation Guide* quality of evidence ratings: “high”, “moderate” and “low” (Lam et al., 2016c). Within each of the relevant reasons for downgrading, we will rate any concern per reason as "none", "serious" or "very serious". We will start at "high" for non-randomized studies and will downgrade for no concern by nil, for a serious concern by one grade (−1) and for a very serious concern by two grades (−2). We will not up-grade or downgrade the quality of evidence for the three other reasons normally considered in GRADE assessments (i.e. large effect, dose-response and plausible residual confounding and bias), because we consider them irrelevant for prevalence estimates.

All quality of evidence assessors (WA, MSDA and MRVM) will trial the application of our instructions and criteria for quality of evidence assessment until their understanding and application is synchronized. At least two review authors (out of: DTCDS, MANDA and JUB) will independently judge the quality of evidence for the entire body of evidence by outcome. A third review author (LRT) will resolve any conflicting judgments. In the systematic review, for each outcome, we will present our assessments of the risk for each GRADE domain, as well as an overall GRADE rating.

3.1.8. Strength of evidence assessment

To our knowledge, no agreed method exists for rating strength of evidence in systematic reviews of prevalence studies. We (LRT and JUB) will rate the strength of the evidence for use as input data for estimating national-level exposure to the risk factor. Our rating will be based on a combination of the following four criteria: (i) quality of the entire body of evidence; (ii) population coverage of evidence (WHO regions and countries); (iii) confidence in the entire body of evidence; and (iv) other compelling attributes of the evidence that may influence certainty. We will rate the strength of the evidence as either "potentially sufficient" or "potentially inadequate" for use as input data (Appendix E).

3.2. Systematic Review 2

3.2.1. Eligibility criteria

The PECO (Liberati et al., 2009) criteria are described below.

3.2.1.1. Types of populations. We will include studies of working-age (≥15 years) workers in the formal and informal economy. Studies of children (aged < 15 years) and unpaid domestic workers will be excluded. Participants residing in any WHO and/or ILO Member State and any industrial setting or occupation will be included. We note that exposure to occupational noise may potentially have further population reach (e.g. through the release of noise from the workplace into the community) and acknowledge that the scope of our systematic reviews will not be able capture these populations and impacts on them. Appendix F provides a briefer overview of the PECO criteria.

3.2.1.2. Types of exposures. We will include studies that define occupational noise in accordance with our standard definition (Table 1). We will include all studies of occupational noise, whether measured objectively (e.g. by means of technology, such as a sound level meter) or subjectively, such as studies that used measurements by experts (e.g. scientists with subject matter expertise) and self-reports by a worker or workplace administrator or manager. If a study presents both objective and subjective measurements, then we will prioritize objective measurements. We will include studies with measures from any data source, including registry data.

3.2.1.3. Types of comparators. The included comparator will be participants exposed to the theoretical minimum risk exposure level (Table 1). We will exclude all other comparators.

3.2.1.4. Types of outcomes. We will include studies that define cardiovascular disease in accordance with our standard definition of the eligible outcomes (Table 2). We expect that most studies examining exposure to occupational noise and its effect on cardiovascular disease have documented ICD-10 diagnostic codes. In the remaining cases, methods that approximate ICD-10 criteria will ascertain cardiovascular disease.

The following measurements of cardiovascular disease will be regarded as eligible:

i) Diagnosis by a physician with imaging.
ii) Hospital discharge record.
iii) Other relevant administrative data (e.g. record of sickness absence or disability).
iv) Registry data of treatment for an eligible cardiovascular disease.
iv) Medically certified cause of death.

All other measures will be excluded from this systematic review.

Objective and subjective measures of the outcome will be eligible. If a study presents both objective and subjective measurements, then we will prioritize the objective ones.

3.2.1.5. Types of studies. We will include studies that investigate the effect of exposure to occupational noise on cardiovascular disease for any years. Eligible study designs will be randomized controlled trials (including parallel-group, cluster, cross-over and factorial trials), cohort studies (both prospective and retrospective), case-control studies and other non-randomized intervention studies (including quasi-randomized controlled trials, controlled before-after studies and interrupted time series studies). We included a broader set of observational study designs than is commonly included, because a recent augmented Cochrane Review of complex interventions identified valuable additional studies using such a broader set of study designs (Arditi et al., 2016). As we have an interest in quantifying risk and not in qualitative assessment of hazard (Barroga and Kojima, 2013), we will exclude all other study designs (e.g. uncontrolled before-and-after, cross-sectional, qualitative, modelling, case and non-original studies).

Records published in any year and any language will be included. Again, the search will be conducted using English language terms, so that records published in any language that present essential information (i.e. title and abstract) in English will be included. If a record is written in a language other than those spoken by the authors of this review or those of other reviews in the series (Descatha et al., 2018; Godderis et al., 2018; Hulshof et al., in press; Li et al., 2018; Mandrioli et al., 2018; Paulo et al., Accepted; Rugulies et al., Accepted; Tenkate et al., Accepted), then the record will be translated into English. Published and unpublished studies will be included.

Studies conducted using unethical practices will be excluded (e.g., randomized controlled trials that deliberately exposed humans to a known risk factor to human health).

3.2.1.6. Types of effect measures. We will include measures of the relative effect of high exposure to occupational noise on the risk of having, developing or dying from cardiovascular disease, compared with the theoretical minimum risk exposure level (i.e., low exposure). Included relative effect measures are risk ratios and odds ratios for prevalence and mortality measures and hazard ratios for incidence measures (e.g., developed or died from a cardiovascular disease). Measures of absolute effects (e.g. mean differences in risks or odds) will be converted into relative effect measures, but if conversion is impossible, they will be excluded. To ensure comparability of effect estimates and facilitate meta-analysis, if a study presents an odds ratio, then we will convert it into a risk ratio, if possible, using the guidance provided in the Cochrane Collaboration's handbook for systematic reviews of interventions (Higgins and Green, 2011).

As shown in our logic model (Fig. 1), we *a priori* consider the following variables to be potential effect modifiers of the effect of exposure to occupational noise on cardiovascular disease: country, age, sex, socioeconomic position, industrial sector, occupation, noise mitigation measures, and formality of economy. We consider age, sex and socio-economic position to be potential confounders. Potential mediators are: tobacco smoking, alcohol use, stress, job strain, blood pressure and obesity.

If a study presents estimates for the effect from two or more alternative models that have been adjusted for different variables, then we will systematically prioritize the estimate from the model that we consider best adjusted, applying the lists of confounders and mediators identified in our logic model (Fig. 1). We will prioritize estimates from models adjusted for more potential confounders over those from models adjusted for fewer. For example, if a study presents estimates from a crude, unadjusted model (Model A), a model adjusted for one potential confounder (Model B) and a model adjusted for two potential confounders (Model C), then we will prioritize the estimate from Model C. We will prioritize estimates from models unadjusted for mediators over those from models that adjusted for mediators, because adjustment for mediators can introduce bias. For example, if Model A has been adjusted for two confounders and Model B has been adjusted for the same two confounders and a potential mediator, then we will choose the estimate from Model A over that from Model B. We prioritize estimates from models that can adjust for time-varying confounders that are at the same time also mediators, such as marginal structural models (Pega et al., 2016) over estimates from models that can only adjust for time-varying confounders, such as fixed-effects models (Gunasekara et al., 2014), over estimates from models that cannot adjust for time-varying confounding. If a study presents effect estimates from two or more potentially eligible models, then we will explain specifically why we prioritized the selected model.

3.2.2. Information sources and search

3.2.2.1. Electronic academic databases. At a minimum, we (LRT and JUB) will search the ten following electronic academic databases:

1. International Clinical Trials Register Platform (to 30 June 2018).
2. Ovid Medline (1 January 1946 to 30 June 2018).
3. PubMed (1 January 1946 to 30 June 2018).
4. EMBASE (1 January 1947 to 30 June 2018).
5. Web of Science (1 January 1945 to 30 June 2018).
6. CISDOC (1 January 1901 to 2012).
7. Toxline (1 January 1840 to 30 June 2018).
8. Health and Environmental Research Online (HERO) (1 January 2005 to 30 June 2018).
9. Scopus (1 January 1995 to 30 June 2018).
10. LILACS (1 January 1986 to 30 June 2018).

The Ovid Medline search strategy for Systematic Review 2 is presented in Appendix G. To identify studies on cardiovascular disease, we adopted or adapted several search terms or strings used in a recent Cochrane Review on whole grain cereals for the primary or secondary prevention of cardiovascular disease (Kelly et al., 2017). We will perform searches in electronic databases operated in the English language using a search strategy in the English language. We will adapt the search syntax to suit the other electronic academic and grey literature databases. When we are nearing completion of the review, we will search the PubMed database for the most recent publications (e.g., e-publications ahead of print) over the last six months. Any deviation from the proposed search strategy in the actual search strategy will be documented.

3.2.2.2. Electronic grey literature databases. At a minimum, we (LRT and JUB) will search the two following two electronic academic databases:

1. OpenGrey (http://www.opengrey.eu/).
2. Grey Literature Report (http://greylit.org/).

3.2.2.3. Internet search engines. We (LRT and JUB) will also search the Google (www.google.com/) and GoogleScholar (www.google.com/scholar/) Internet search engines and screen the first 100 hits for potentially relevant records.

3.2.2.4. Organizational websites. The websites of the seven following international organizations and national government departments will be searched for both systematic reviews by LRT and JUB:

1. International Labour Organization (www.ilo.org/).
2. World Health Organization (www.who.int).
3. European Agency for Safety and Health at Work (https://osha.europa.eu/en).
4. Eurostat (www.ec.europa.eu/eurostat/web/main/home).
5. China National Knowledge Infrastructure (http://www.cnki.net/).
6. Finnish Institute of Occupational Health (https://www.ttl.fi/en/).
7. National Institute of Occupational Safety and Health (NIOSH) of the United States of America, using the NIOSH data and statistics gateway (https://www.cdc.gov/niosh/data/).

3.2.2.5. Hand-searching and expert consultation. We (LRT and JUB) will hand-search for potentially eligible studies in:

- Reference lists of previous systematic reviews.
- Reference lists of all included study records.
- Study records published over the past 24 months in the three peer-reviewed academic journals with the largest number of included studies.
- Study records that have cited the included studies (identified in Web of Science citation database).
- Collections of the review authors.

Additional experts will be contacted with a list of included studies, with the request to identify potentially eligible additional studies.

3.2.3. Study selection

Study selection will be carried out with the Covidence (Babineau, 2014; Covidence systematic review software, n.d) or Rayyan Systematic Reviews Web App (Ouzzani et al., 2016). All study records identified in the search will be downloaded and duplicates will be identified and deleted. Afterwards, at least two review authors (out of: TMA, AB, EG, EMGSM, MPL AND JS), working in pairs, will independently screen titles and abstracts (step 1) and then full texts (step 2) of potentially relevant records. A third review author (DTCDS) will resolve any disagreements between the two review authors. If a study record identified in the literature search was authored by a review author assigned to study selection or if an assigned review author was involved the study, then the record will be re-assigned to another review author for study selection. The study selection will be documented in a flow chart in the systematic review, as per PRISMA guidelines (Liberati et al., 2009).

3.2.4. Data extraction and data items

A data extraction form will be developed and trialled until data extractors reach convergence and agreement. At a minimum, two review authors (out of: TMA, AB, EG, EMGSM, MPL AND JS) will extract data on study characteristics (including study authors, study year, study country, participants, exposure and outcome), study design (including summary of study design, comparator, epidemiological models used and effect estimate measure), risk of bias (including selection bias, reporting bias, confounding and reverse causation) and study context (e.g. data on contemporaneous exposure to other occupational risk factors potentially relevant for deaths or other health loss from cardiovascular disease). A third review author (DTCDS) will resolve conflicts in data extraction. Data will be entered into and managed with the Review Manager (RevMan) (2014) Version 5.3 (RevMan 5.3) or DistillerSR (EvidencePartner, 2017) softwares, but the Health Assessment Workspace Collaborative (HAWC) (Shapiro, 2013) may also be used in parallel or to prepare data for entry into RevMan 5.3.

We will also extract data on potential conflict of interest in included studies. For each author and affiliated organization of each included study record, we will extract their financial disclosures and funding sources. We will use a modification of a previous method to identify and assess undisclosed financial interest of authors (Forsyth et al., 2014). Where no financial disclosure or conflict of interest statements are available, we will search the name of all authors in other study records gathered for this study and published in the prior 36 months and in other publicly available declarations of interests (Drazen et al., 2010a; Drazen et al., 2010b).

We will request missing data from the principal study author by email or phone, using the contact details provided in the principal study record. If we do not receive a positive response from the study author, we will send follow-up emails twice, at two and four weeks.

3.2.5. Risk of bias assessment

Standard risk of bias tools do not exist for systematic reviews for hazard identification in occupational and environmental health, nor for risk assessment. The five methods specifically developed for occupational and environmental health are for either or both hazard identification and risk assessment and they differ substantially in the types of studies (randomized, observational and/or simulation studies) and data (e.g. human, animal and/or in vitro) they seek to assess (Rooney et al., 2016). However, all five methods, including the *Navigation Guide* (Lam et al., 2016c), assess risk of bias in human studies similarly (Rooneyet al. 2016).

The *Navigation Guide* was specifically developed to translate the rigor and transparency of systematic review methods applied in the clinical sciences to the evidence stream and decision context of environmental health (Woodruff and Sutton, 2014), which includes workplace environment exposures and associated health outcomes. The guide is our overall organizing framework and we will also apply its risk of bias assessment method in Systematic Review 2. The *Navigation Guide* risk of bias assessment method builds on the standard risk of bias assessment methods of the Cochrane Collaboration (Higgins and Green, 2011) and the US Agency for Healthcare Research and Quality (Viswanathan et al., 2008). Some further refinements of the *Navigation Guide* method may be warranted (Goodman et al., 2017), but it has been successfully applied in several completed and ongoing systematic reviews (Johnson et al., 2016; Johnson et al., 2014; Koustas et al., 2014; Lam et al., 2016a; Lam et al., 2014; Lam et al., 2017; Lam et al., 2016b; Vesterinen et al., 2014). In our application of the *Navigation Guide* method, we will draw heavily on one of its latest versions, as presented in the protocol for an ongoing systematic review (Lam et al., 2016c). Should a more suitable method become available, we may switch to it.

We will assess risk of bias on the individual study level and on the body of evidence overall. The nine risk of bias domains included in the *Navigation Guide* method for human studies are: (i) source population representation; (ii) blinding; (iii) exposure assessment; (iv) outcome assessment; (v) confounding; (vi) incomplete outcome data; (vii) selective outcome reporting; (viii) conflict of interest; and (ix) other sources of bias. While two of the earlier case studies of the *Navigation Guide* did not utilize outcome assessment as a risk of bias domain for studies of human data (Johnson et al., 2014; Koustas et al., 2014; Lam et al., 2016a; Vesterinen et al., 2014), all of the subsequent reviews have included this domain (Johnson et al., 2016; Lam et al., 2016a; Lam et al., 2017; Lam et al., 2016b; Lam et al., 2016c). Risk of bias or confounding ratings will be: “low”; “probably low”; “probably high”; “high” or “not applicable” (Lam et al., 2016c). To judge the risk of bias in each domain, we will apply a priori instructions (Appendix H), which we have adopted or adapted from an ongoing *Navigation Guide* systematic review (Lam et al., 2016c)). For example, a study will be assessed as carrying “low” risk of bias from source population representation, if we judge the source population to be described in sufficient detail (including eligibility criteria, recruitment, enrollment, participation and loss to follow up) and the distribution and characteristics of the study sample to indicate minimal or no risk of selection effects. The risk of bias at study level will be determined by the worst rating in any bias domain for any outcome. For example, if a study is rated as “probably high” risk of bias in one domain for one outcome and “low” risk of bias in all other domains for the outcome and in all domains for all other outcomes, the study will be rated as having a “probably high” risk of bias overall.

All risk of bias assessors (TMA, DTCDS, AB, EG, EMGSM, MPL, JS and JUB) will jointly trial the application of the risk of bias criteria until they have synchronized their understanding and application of these criteria. At least two study authors (out of: TMA, AB, EG, EMGSM, MPL AND JS) will independently judge the risk of bias for each study by outcome. Where individual assessments differ, a third author (DTCDS) will resolve the conflict. In the systematic review, for each included study, we will report our study-level risk of bias assessment by domain in a standard ‘Risk of bias’ table (Higgins et al., 2011). For the entire body of evidence, we will present the study-level risk of bias assessments in a ‘Risk of bias summary’ figure (Higgins et al., 2011).

3.2.6. Synthesis of results

We will conduct meta-analyses separately for estimates of the effect on incidence and mortality. Studies of different designs will not be combined quantitatively. If we find two or more studies with an eligible effect estimate, two or more review authors (out of: JUB, LRT, DTCDS and EMGSM) will independently investigate the clinical heterogeneity of the studies in terms of participants (including country, sex, age and industrial sector or occupation), level of risk factor exposure, comparator and outcomes. If we find that effect estimates differ considerably by country, sex and/or age, or a combination of these, then we will synthesise evidence for the relevant populations defined by country, sex and/or age, or combination thereof. Differences by country could include or be expanded to include differences by country group (e.g. WHO region or World Bank income group). If we find that effect estimates are clinically homogenous across countries, sexes and age groups, then we will combine studies from all of these populations into one pooled effect estimate that could be applied across all combinations of countries, sexes and age groups in the WHO/ILO joint methodology.

If we judge two or more studies for the relevant combination of country, sex and age group, or combination thereof, to be sufficiently clinically homogenous to potentially be combined quantitatively using quantitative meta-analysis, then we will test the statistical heterogeneity of the studies using the I^2 statistic (Figueroa, 2014). If two or more clinically homogenous studies are found to be sufficiently homogenous statistically to be combined in a meta-analysis, we will pool the risk ratios of the studies in a quantitative meta-analysis, using the inverse variance method with a random effects model to account for cross-study heterogeneity (Figueroa, 2014). The meta-analysis will be conducted in RevMan 5.3, but the data for entry into these programmes may be prepared using another recognized statistical analysis programme, such as Stata. We will neither quantitatively combine data from studies with different designs (e.g. combining cohort studies with case-controls studies), nor unadjusted and adjusted models. We will only combine studies that we judge to have a minimum acceptable level of adjustment for confounders. If quantitative synthesis is not feasible, then we will synthesise the study findings narratively and identify the estimates that we judged to be the highest quality evidence available.

3.2.7. Additional analyses

If we source micro-data on exposure, outcome and potential confounding variables, we may conduct meta-regressions to adjust optimally for potential confounders.

If there is evidence for differences in effect estimates by country, sex, age, industrial sector and/or occupation, or by a combination of these variables, then we will conduct subgroup analyses by the relevant variable or combination of variables, as feasible. Where both studies on workers in the informal economy and in the formal economy are included, then we will conduct sub-group analyses by formality of economy. Findings of these subgroup analyses, if any, will be used as parameters for estimating burden of disease specifically for relevant populations defined by these variables. We will also conduct subgroup analyses by study design (e.g. randomized controlled trials versus cohort studies versus case-control studies).

We will perform a sensitivity analyses that will include only studies judged to be of "low" or "probably low" risk of bias from conflict of interest; judged to be of "low" or "probably low" risk of bias; and with documented or approximated ICD-10 diagnostic codes. We may also conduct a sensitivity analysis using an alternative meta-analytic model, namely the inverse variance heterogeneity (IVhet) model (Doi et al., 2017). We may also conduct a sensitivity dose-response meta-analysis of studies that report categorical risk estimates, which would enable us to investigate potential threshold effects (Xu and Doi, 2017).

3.2.8. Quality of evidence assessment

We will assess quality of evidence using a modified version of the *Navigation Guide* quality of evidence assessment tool (Lam et al., 2016c). The tool is based on the GRADE approach (Schünemann et al., 2011) adapted specifically to systematic reviews in occupational and environmental health (Morgan et al., 2016). Should a more suitable method become available, we may switch to it.

At least two review authors (out of: LRT, EMGSM and DTCDS) will assess quality of evidence for the entire body of evidence by outcome, with any disagreements resolved by a third review author. We will adopt or adapt the latest *Navigation Guide* instructions (Appendix D) for grading the quality of evidence (Lam et al., 2016c). We will downgrade the quality of evidence for the following five GRADE reasons: (i) risk of bias; (ii) inconsistency; (iii) indirectness; (iv) imprecision; and (v) publication bias. If our systematic review includes ten or more studies, we will generate a funnel plot to judge concerns on publication bias. If it includes nine or fewer studies, we will judge the risk of publication bias qualitatively. To assess risk of bias from selective reporting, protocols of included studies, if any, will be screened to identify instances of selective reporting.

We will grade the evidence, using the three *Navigation Guide* standard quality of evidence ratings: "high", "moderate" and "low" (Lamet al. 2016c). Within each of the relevant domains, we will rate the concern for the quality of evidence, using the ratings "none", "serious" and "very serious". As per *Navigation Guide*, we will start at "high" for randomized studies and "moderate" for observational studies. Quality will be downgrade for no concern by nil grades (0), for a serious concern by one grade (−1) and for a very serious concern by two grades (−2). We will up-grade the quality of evidence for the following other reasons: large effect, dose-response and plausible residual confounding and bias. For example, if we have a serious concern for risk of bias in a body of evidence consisting of observational studies (−1), but no other concerns and there are no reasons for upgrading, then we will downgrade its quality of evidence by one grade from "moderate" to "low".

3.2.9. Strength of evidence assessment

We (LRT, EMGSM and DTCDS) will apply the standard *Navigation Guide* methodology (Lamet al. 2016c) to rate the strength of the evidence. The rating will be based on a combination of four criteria: (i) quality of body of evidence, (ii) direction of effect, (iii) confidence in effect and (iv) other compelling attributes of the data that may influence certainty. The ratings for strength of evidence for the effect of exposure to occupational noise on cardiovascular disease will be "sufficient evidence of toxicity/harmfulness", "limited of toxicity/harmfulness", "inadequate of toxicity/harmfulness" and "evidence of lack of toxicity/harmfulness" (Appendix I for summary and definition of ratings).

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Conflict of interest

None declared.

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Author contributions

IDI, NL, FP and AMPŰ had the idea for the systematic review. IDI, NL, FP and YU gathered the review team. FP led and all authors contributed to the development of the standard methodology for all systematic reviews in the series. FP led and all authors contributed to the development and writing of the standard template for all protocols in the series. LRT is the lead reviewer of this systematic review. LRT wrote the first draft of this protocol, using the protocol template prepared by FP, and all authors made substantial contributions to the revisions of the manuscript. The search strategy was developed and piloted by JUB in collaboration with a research librarian. LTR and FP are experts in epidemiology, AB is an expert in occupational cardiovascular disease, and FP and JUB are experts in systematic review methodology. FP coordinated all inputs from the World Health Organization, International Labour Organization and external experts and ensured consistency across the systematic reviews of the series. LRT is the guarantor of the systematic reviews.

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Appendices. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.envint.2018.09.040.

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