REVIEW

Minimum health and safety requirements for workers exposed to hand-transmitted vibration and whole-body vibration in the European Union; a review

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In 2002, the Parliament and Commission of the European Community agreed "minimum health and safety requirements" for the exposure of workers to the risks arising from vibration. The Directive defines qualitative requirements and also quantitative requirements in the form of "exposure action values" and "exposure limit values". The quantitative guidance is based on, but appears to conflict with, the guidance in International Standards for hand-transmitted vibration (ISO 5349) and whole-body vibration (ISO 2631). There is a large internal inconsistency within the Directive for short duration exposures to whole-body vibration: the two alternative methods give very different values. It would appear prudent to base actions on the qualitative guidance (i.e. reducing risk to a minimum) and only refer to the quantitative guidance where there is no other reasonable basis for the identification of risk (i.e. similar exposures are not a suspected cause of injury). Health surveillance and other precautions will be appropriate wherever there is reason to suspect a risk and will not be restricted to conditions where the exposure action value is exceeded.

In many occupations workers are exposed to oscillatory motions (that is, vibration) of a type not encountered by living organisms prior to the industrial revolution. Vibration of powered hand-held tools and workpieces (that is, hand-transmitted vibration) and the vibration of seats and floors supporting the body (that is, whole-body vibration) can cause discomfort, interference with activities, injury, and disease.

Hand-transmitted vibration is associated with various vascular, neurological, and musculoskeletal disorders, collectively called the "hand-arm vibration syndrome". The scope of the hand-arm vibration syndrome is not clear, with different signs and symptoms recognised by different experts and in different countries. However, some disorders, especially vibration-induced white finger and neurological effects of hand-transmitted vibration, are widely recognised. Various studies have explored dose-response relations for vibration-induced white finger and some guidance has been included in standards.^{1–5}

While some effects of hand-transmitted vibration are clear, some content in the standards

rests on insubstantial foundations: the future may be expected to bring new methods for measuring, evaluating, and assessing exposures to hand-transmitted vibration with significant changes from current methods.^{6–8}

Whole-body vibration has been associated with back disorders.^{9–10} However, the extent of this problem in industry and the extent to which other disorders may also develop, are the subject of reasonable doubt. Various standards have defined means of measuring and evaluating whole-body vibration and also offered "limits" and "action levels", but there are no dose-response relations showing how the probability of any specific disorder caused by whole-body vibration is related to the magnitude, frequency, direction, and duration of exposure to vibration.^{5 11–13}

Guides and standards produced during the past 50 years have assisted the measurement of vibration (that is, the recording of relevant oscillations), the evaluation of vibration (that is, expressing measurements in simple values, so allowing comparisons of the relative severity of different sources of vibration), and the assessment of vibration exposures (that is, identifying likely effects of vibration). In recent years, concern over the health effects of vibration has led a few countries to introduce laws to limit vibration exposures.

The Commission of the European Community has been preparing for a Directive on exposure to vibration at the workplace for more than 20 years. However, it was not until 1990 that the European Parliament formally invited the Commission to draft a directive on vibration. The Directive, published on 22 June 2002, defines "the minimum health and safety requirements" for the exposure of workers to the risks arising from vibration.¹⁴ Member States of the European Union must bring into force laws to comply with the Directive by 6 July 2005.

This review summarises the requirements of the Directive and reviews the implications in relation to current understanding of the measurement, evaluation, and assessment of human exposure to hand-transmitted vibration and whole-body vibration. It is hoped that the contents of this review will be of some assistance to those considering the interpretation of the Directive within the context of national laws.

CONTENTS OF THE DIRECTIVE

The Directive contains clauses whose meaning is paraphrased in the following sections. Although

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Table 1 Exposure limit values and action values for hand-transmitted and whole-body vibration**Hand-transmitted vibration**

- The daily exposure limit value standardised to an eight hour reference period shall be $5 \text{ ms}^{-2} \text{ r.m.s.}$
- The daily exposure action value standardised to an eight hour reference period shall be $2.5 \text{ ms}^{-2} \text{ r.m.s.}$

Whole-body vibration

- The daily exposure limit value standardised to an eight hour reference period shall be $1.15 \text{ ms}^{-2} \text{ r.m.s.}$ or, at the choice of the Member State concerned, a vibration dose value of $21 \text{ ms}^{-1.75}$
- The daily exposure action value standardised to an eight hour reference period shall be $0.5 \text{ ms}^{-2} \text{ r.m.s.}$ or, at the choice of the Member State concerned, a vibration dose value of $9.1 \text{ ms}^{-1.75}$

some of the text in this section is presented exactly as in the Directive, the original text should be consulted for a precise interpretation.¹⁴

Assessment and control of the risks

The Directive says that an employer shall be in possession of an assessment of the risk and shall identify what measures must be taken in accordance with the Directive. The risk assessment shall be recorded according to national law and practice; it may include a justification by the employer that the nature and extent of the risks related to mechanical vibration make a further detailed risk assessment unnecessary. The risk assessment shall be kept up to date on a regular basis, particularly if there have been significant changes which could render it out of date, or when the results of health surveillance show it to be necessary.

Taking account of technical progress and of the availability of measures to control the risk at source, the risks arising from exposure to mechanical vibration shall be eliminated at their source or reduced to a minimum.

“Exposure limit values” and “exposure action” values are defined for both hand-transmitted vibration and whole-body vibration (see table 1). The values given in the Directive are for eight hour exposures; the values calculated for other durations are shown in table 2.

Exposure action value

On the basis of the risk assessment, once the exposure action values in table 1 are exceeded, the employer shall establish and implement a programme intended to reduce to a

minimum exposure to mechanical vibration and the attendant risks, taking into account in particular items listed in table 3.

Exposure limit value

The Directive says: “workers shall not be exposed above the exposure limit value”.

If, despite measures taken by the employer to comply with the Directive, the exposure limit value is exceeded, the employer shall take immediate action to reduce exposure below the exposure limit value. The employer shall identify the reasons why the exposure limit value has been exceeded, and shall amend the protection and prevention measures to prevent it being exceeded again.

Derogations

There are various circumstances in which Member States can allow exceptions (after appropriate consultation with both sides of industry). However, where exceptions are granted, the resulting risks must be reduced to a minimum and the workers concerned are subject to increased health surveillance.

The derogations may include cases where exposure of a worker to mechanical vibration is usually below the exposure action values, but varies markedly from time to time and may occasionally exceed the exposure limit value. However, the exposure value averaged over 40 hours must be less than the exposure limit value and there must be evidence to show that the risks from the pattern of exposure to the work are lower than those from exposure at the exposure limit value.

Some cases of sea and air transport may also be subject to derogations where it is not possible to comply with the exposure limit value despite technical and organisation measures.

A maximum transitional period of five years from 6 July 2005 may apply where equipment is used which was given to workers before 6 July 2007 and which does not permit the exposure limit values to be respected, even taking into account technical advances and organisational measures. For agricultural and farm equipment this period may be extended by up to four years.

Worker information and training

The employer shall ensure that workers (or their representatives) who are exposed to the risks from mechanical vibration at work receive information and training relating to the outcome of the risk assessment (see table 4).

Table 2 Vibration magnitudes (in $\text{ms}^{-2} \text{ r.m.s.}$) corresponding to the hand-transmitted vibration and whole-body vibration exposure action values and exposure limit values in the 2002 Physical Agents (Vibration) Directive of the European Union

Exposure duration	Hand-transmitted vibration		Whole-body vibration			
	Exposure action value	Exposure limit value	Exposure action value		Exposure limit value	
	r.m.s. method	r.m.s. method	r.m.s. method	VDV method	r.m.s. method	VDV method
1 s	424.26	848.53	84.85	6.51	195.16	14.98
10 s	134.16	268.33	26.83	3.66	61.72	8.42
1 m	54.77	109.54	10.95	2.34	25.20	5.38
10 m	17.32	34.64	3.46	1.32	7.97	3.03
1 h	7.07	14.14	1.41	0.84	3.25	1.93
2 h	5.00	10.00	1.00	0.71	2.30	1.63
4 h	3.54	7.07	0.71	0.59	1.63	1.37
8 h	2.50	5.00	0.50	0.50	1.15	1.15
12 h	2.04	4.08	0.41	0.45	0.94	1.04
16 h	1.77	3.54	0.35	0.42	0.81	0.97
24 h	1.44	2.89	0.29	0.38	0.66	0.87

Table 3 Matters to be considered if the exposure action value is exceeded; the measures listed are in addition to health surveillance

- Other working methods that require less exposure to mechanical vibration
- Choice of appropriate work equipment of appropriate ergonomic design and, taking account of the work to be done, producing the least possible vibration
- Provision of auxiliary equipment that reduces the risk of injuries caused by vibration, such as seats that effectively reduce whole-body vibration and handles which reduce the vibration transmitted to the hand-arm system
- Appropriate maintenance programmes for work equipment, the workplace, and workplace systems
- Design and layout of workplaces and work stations
- Adequate information and training to instruct workers to use work equipment correctly and safely in order to reduce their exposure to mechanical vibration to a minimum
- Limitation of the duration and intensity of the exposure
- Appropriate work schedules with adequate rest periods
- Provision of clothing to protect exposed workers from cold and damp

Health surveillance

The text of the Directive makes it clear that workers exposed to mechanical vibration in excess of the exposure action values shall be entitled to appropriate health surveillance, but health surveillance is not restricted to situations where the exposure action value is exceeded. Health surveillance is required in other circumstances, as listed in table 5. The extent to which the three additional conditions are alternatives or a combined set is not clear. Presumably the availability of “tested techniques for detecting the harmful effects of vibration” is not intended to be a sufficient justification for health surveillance when there is no other reason to suspect a risk. However, it seems that the non-availability of such techniques is not expected to bar health surveillance.

Health surveillance, the results of which are taken into account in the application of preventive measures at a specific workplace, shall be intended to prevent and diagnose rapidly any disorder linked with exposure to vibration.

Member States shall establish arrangements to ensure that, for each worker who undergoes health surveillance, individual health records are made and kept up to date. Health records shall contain a summary of the results of the health surveillance carried out. They shall be kept in a suitable form so as to permit any consultation at a later date, taking into account any confidentiality. Copies of the appropriate records shall be supplied to the competent authority on request. Individual workers shall, on request, have access to the health records relating to them.

Where, as a result of health surveillance, a worker is found to have an identifiable disease or adverse health effect that is considered by a doctor or occupational healthcare profes-

sional to be the result of exposure to mechanical vibration at work, the matters listed in table 6 apply.

Any rights of an employee, or a prospective employee, to refuse health surveillance are not identified within the Directive.

Hand-transmitted vibration

The Directive defines “hand-arm vibration” as mechanical vibration that, “when transmitted to the human hand-arm system, entails risks to the health and safety of workers, in particular vascular, bone or joint, neurological or muscular disorders”.

Measurement and evaluation of hand-transmitted vibration

Exposure to hand-transmitted vibration may be determined by observing specific working practices and by making reference to relevant information on the probable magnitude of the vibration corresponding to the equipment, or the types of equipment, used in the particular conditions of use, including such information provided by the manufacturer of the equipment. It is stated that measurement of exposure to hand-transmitted vibration will be required in some cases but that it is not considered necessary in every case. The required method for measuring and evaluating hand-transmitted vibration is as defined in ISO 5349-1 (2001) and ISO 5349-2 (2001).^{3,4}

The evaluation of exposure to hand-transmitted vibration is based on the calculation of the daily exposure value normalised to an eight hour reference period $A(8)$, expressed as the square root of the sum-of-the-squares (so-called “total value”) of the frequency weighted acceleration values, determined in the three orthogonal axes.

Exposure action values and exposure limit values for hand-transmitted vibration

The exposure action value and the exposure limit value for hand-transmitted vibration are illustrated in fig 1 for daily exposure durations varying from 1 second to 24 hours.

Although the exposure action value and the exposure limit value are at 2.5 and 5.0 ms^{-2} r.m.s. for eight hour daily exposures, the magnitudes for shorter daily exposures are higher:

$$a_{\text{action}} = 2.5 \left[\frac{8}{t_h} \right]^{\frac{1}{2}}$$

$$a_{\text{limit}} = 5.0 \left[\frac{8}{t_h} \right]^{\frac{1}{2}}$$

where the exposure duration, t_h , is expressed in hours.

The use of so-called “energy-equivalence” to calculate the exposure action value and the exposure limit value for durations other than eight hours means that the magnitudes

Table 4 Information to be provided to workers exposed to vibration

- Measures taken to implement this Directive in order to eliminate or reduce to a minimum the risks from mechanical vibration
- Exposure limit values and the exposure action values
- Results of the assessment and measurement of the mechanical vibration carried out in accordance with the Directive and the potential injury arising from the work equipment in use
- Why and how to detect and report signs of injury
- Circumstances in which workers are entitled to health surveillance
- Safe working practices to minimise exposure to mechanical vibration

Table 5 Matters that indicate the need for health surveillance

- Exposure to mechanical vibration in excess of the action values
OR
- The exposure of workers to vibration is such that a link can be established between that exposure and an identifiable illness or harmful effects on health
- It is probable that the illness or the effects occur in a worker's particular working conditions
- There are tested techniques for the detection of the illness or the harmful effects on health

increase in inverse proportion to the square root of the exposure duration. The Directive does not limit the exposure action value or the exposure limit value to any specific duration of daily exposure. The magnitudes for short daily durations (arising from either continuous or intermittent exposures) are extremely high (see table 2 and below).

Whole-body vibration

The Directive states that “whole-body vibration” is the mechanical vibration that, “when transmitted to the whole body, entails risks to the health and safety of workers, in particular lower-back morbidity and trauma of the spine”. The Directive applies to seated and standing postures.

Measurement and evaluation of whole-body vibration

It is stated that exposure to whole-body vibration may be determined by observing specific working practices and reference to relevant information on the probable magnitude of the vibration corresponding to the equipment, or the types of equipment, used in the particular conditions of use, including such information provided by the manufacturer of the equipment. Measurement of exposure to whole-body vibration will be required in some cases but is not considered necessary in every case. The required method for measuring and evaluating whole-body vibration is as defined in ISO 2631-1 (1997).¹²

The evaluation of exposures to whole-body vibration is based on the calculation of daily exposure $A(8)$ expressed as either: (i) an equivalent continuous r.m.s. acceleration over an eight hour period, or (ii) the vibration dose value (VDV). The evaluations use the frequency weighted acceleration, with multiplying factors applied to the fore-and-aft, lateral, and vertical axes as in ISO 2631-1 (1997) (that is, $1.4a_{wx}$, $1.4a_{wy}$, a_{wz}). With both methods (that is, the r.m.s. and the VDV), the axis giving the highest value is used in the assessment of exposure severity. In the case of maritime shipping, the evaluation may be limited to frequencies exceeding 1 Hz.

Exposure action values and exposure limit values for whole-body vibration

The exposure action value and the exposure limit value for whole-body vibration are illustrated in fig 2 for daily exposures between 1 second and 24 hours.

When using r.m.s. measures, the exposure action value and the exposure limit value are at 0.5 and 1.15 ms^{-2} r.m.s. for eight hour daily exposures; the magnitudes corresponding to shorter daily exposures are higher:

$$a_{\text{r.m.s.action}} = 0.5 \left[\frac{8}{t_h} \right]^{\frac{1}{2}}$$

$$a_{\text{r.m.s.limit}} = 1.15 \left[\frac{8}{t_h} \right]^{\frac{1}{2}}$$

where the exposure duration, t_h , is expressed in hours.

For anyone familiar with human responses to whole-body vibration, the magnitudes corresponding to short daily exposures will appear extraordinarily high when using r.m.s. measures.

When using the vibration dose value, VDV, the exposure action value and the exposure limit value are 9.1 and 21 $\text{ms}^{-1.75}$. These values appear to have been set so that they correspond to 0.5 and 1.15 ms^{-2} r.m.s. for eight hour daily exposures when the equivalence between r.m.s. and

Table 6 Matters to be considered when health surveillance indicates a health disorder arising from occupational exposure to vibration

- Workers shall be informed by the doctor, or other suitably qualified person, of the result which relates to them personally. The workers shall, in particular, receive information and advice regarding any health surveillance which they should undergo following the end of exposure
- The employer shall be informed of any significant findings from the health surveillance, taking into account any medical confidentiality
- The employer shall:
 - review the risk assessment
 - review the measures provided to eliminate or reduce risks
 - take into account the advice of the occupational healthcare professional or other suitably qualified person or the competent authority in implementing any measures required to eliminate or reduce risk, including the possibility of assigning the worker to alternative work where there is no risk of further exposure
 - arrange continued health surveillance and provide for a review of the health status of any other worker who has been similarly exposed. In such cases, the competent doctor or occupational healthcare professional or the competent authority may propose that exposed persons undergo a medical examination

VDV measures is made using the estimated vibration dose value, $eVDV$ ($eVDV = 1.4 \text{ at}^{1/4}$). The use of the “fourth power time dependency” to calculate the r.m.s. accelerations corresponding to the VDV exposure action value and the VDV exposure limit value means that the magnitudes increase in inverse proportion to the fourth root of the exposure duration:

$$a_{\text{VDV action}} = 0.5 \left[\frac{8}{t_h} \right]^{\frac{1}{4}}$$

$$a_{\text{VDV limit}} = 1.15 \left[\frac{8}{t_h} \right]^{\frac{1}{4}}$$

For daily exposures less than eight hours, these magnitudes are less than those using r.m.s. measures, with a large difference at very short durations (see table 2). For daily exposures greater than eight hours, this method allows greater vibration magnitudes. The range of magnitudes, especially those for short daily exposures, may appear more reasonable when using VDV measures than the wide range

Figure 1 Hand-transmitted vibration exposure limit value ($A(8) = 5.0 \text{ ms}^{-2}$ r.m.s.) and exposure action value ($A(8) = 2.5 \text{ ms}^{-2}$ r.m.s.).

Figure 2 Whole-body vibration exposure limit values ($A(8) = 1.15 \text{ ms}^{-2} \text{ r.m.s.}$; $\text{VDV} = 21 \text{ ms}^{-1.75}$) and exposure action values ($A(8) = 0.5 \text{ ms}^{-2} \text{ r.m.s.}$; $\text{VDV} = 9.1 \text{ ms}^{-1.75}$).

with very high magnitudes “permitted” when using r.m.s. measures.

COMPARISON WITH OTHER GUIDANCE AND THE STATE OF KNOWLEDGE

Hand-transmitted vibration

Compared with ISO 5349 (1986) and BS 6842 (1987)

A relation between years of regular exposure to vibration, E , the frequency weighted acceleration, a_{hw} , the daily exposure duration, t , and the predicted prevalence of finger blanching, C , was proposed in an Annex to International Standard 5349 (1986):²

$$C = \left[\frac{a_{hw} \cdot E}{9.5} \right]^2 \cdot \frac{t}{T_{(4)}}$$

where $T_{(4)}$ is 4 hours (in the same units as t).

A comparison of the exposure action value and the exposure limit value in the Directive with ISO 5349 (1986) shows that the onset of finger blanching would be expected in 10% of persons after 8.5 years at the exposure action value and after 4.2 years at the exposure limit value (fig 3). The probability of finger blanching increases rapidly with increased years of exposure, according to ISO 5349 (1986), so that 50% of persons would be expected to develop finger blanching after 19 years at the exposure action value; 50% of persons would be expected to develop finger blanching after only 9.5 years at the exposure limit value (fig 4).

It is clear that the Directive does not define “safe exposures”: according to ISO 5349 (1986) there are significant risks with exposures less than the exposure action value if exposure continues for many years, as is common in many occupations.

In ISO 5349 (1986), hand-transmitted vibration is assessed on the basis of the axis giving the highest frequency weighted acceleration. In the Directive, the evaluation of exposure is based on the root-sums-of-squares of the weighted acceleration occurring in all three axes. The comparison shown in figs 3 and 4 is therefore restricted to conditions in which there is only one dominant axis of vibration.

British Standard 6842 (1987) offered similar guidance to ISO 5349 (1986), but was restricted to a 10% prevalence of vibration-induced white finger.¹

Compared with ISO 5349 (2001)

ISO 5349-1 (2001) uses the same frequency weighting as ISO 5349 (1986), but the assessment of exposure is based on the root-sums-of-squares of the acceleration occurring in all three axes.³

A relation between the lifetime exposure to hand-transmitted vibration, D_y , (in years) and the eight hour energy equivalent daily exposure $A(8)$ is proposed for the conditions causing 10% prevalence of finger blanching:

$$D_y = 31.8[A(8)]^{-1.06}$$

Figure 5 compares the exposure action values and the exposure limit values with the conditions causing 10% finger blanching according to ISO 5349-1 (2001) for exposures up to 25 years.

According to ISO 5349-1 (2001), the onset of finger blanching would be expected in 10% of persons after 12 years at the exposure action value and after 5.8 years at the exposure limit value (fig 5). Again, the exposure action value and the exposure limit value in the Directive do not define “safe exposures” to hand-transmitted vibration according to the standard.

Compared with the EU Machinery Safety Directive

The Machinery Safety Directive of the European Community (89/392/EEC) states: “machinery must be so designed and constructed that risks resulting from vibrations produced by the machinery are reduced to the lowest level, taking account of technical progress and the availability of means of reducing vibration, in particular at source”.¹⁵ Instruction handbooks for hand-held and hand-guided machinery should specify the equivalent acceleration to which the hands or arms are subjected where this exceeds a stated value (currently a frequency weighted acceleration of $2.5 \text{ ms}^{-2} \text{ r.m.s.}$).

Assuming the Machinery Safety Directive applies to the root-sums-of-squares of the frequency weighted acceleration in all three axes, this corresponds to the eight hour exposure action level in the Physical Agents Directive. Consequently, values declared as being less than $2.5 \text{ ms}^{-2} \text{ r.m.s.}$ will not exceed the action value unless exposure is longer than eight hours in a day. However, according to ISO 5349 (1986, 2001), the eight hour value of $2.5 \text{ ms}^{-2} \text{ r.m.s.}$ could not be considered an exposure without risk.

Other observations

Some epidemiological data suggest that the evaluation methods in ISO 5349-1 (2001) are not optimum for

Figure 3 Comparison of the exposure limit value and the exposure action value with conditions in ISO 5349 (1986) associated with 10% onset of finger blanching after periods between 1 and 25 years.

Figure 4 The probability of finger blanching at the exposure limit value and the exposure action value according to ISO 5349 (1986). A 10% incidence of vibration-induced white finger is predicted after 8.5 years at the exposure action value and after 4.2 years at the exposure limit value; a 50% incidence of vibration-induced white finger is predicted after 19 years at the exposure action value and after 9.5 years at the exposure limit value.

predicting the onset of vibration-induced white finger: both the frequency weighting and the time dependency in the standard seem capable of improvement.⁸ The Directive makes it clear that vibration measurement should not be the only means of assessing a hazard: it is sufficient for there to be a “link” between exposure and an identifiable harmful effect on health. This presumably means that where tool use is known to be a potential cause of the hand-arm vibration syndrome it should be assumed that it presents a risk and that health surveillance and other precautions will be appropriate, irrespective of the measured vibration exposure.

The evaluation methods required by the Directive (that is, those in ISO 5349-1, 2001) very probably overestimate the importance of some types of vibration (for example, some frequencies) and underestimate the importance of others (for example, other frequencies). It would be unwise to assume that the duties of employers are always met if the exposure action value is not exceeded (see below).

Exposures to hand-transmitted vibration are associated with varying types and degrees of vascular, neurological and

Figure 5 According to ISO 5349 (2001), a 10% probability of finger blanching is predicted after 12 years at the exposure action value and after 5.8 years at the exposure limit value.

musculoskeletal disorders.¹⁶ The predictions of risk in ISO 5349 (1986, 2002) are limited to the onset of vibration-induced white finger but often assumed to provide some protection for other disorders, even if somewhat different types of vibration are responsible for non-vascular disorders.

Whole-body vibration

Compared with BS 6841 (1987)

British Standard 6841 (1987) defines frequency weightings and multiplying factors for the evaluation of vibration in 12 axes for the seated person: three translational and three rotational axes between the seat and the ischial tuberosities, three translational axes between the back and the backrest, and three translational axes beneath the feet.¹¹ This allows the vibration at all principal inputs to the body to be measured and evaluated in a standardised manner. However, the assessment of the health effects of whole-body vibration is restricted to the three translational axes on the supporting surface (of a seat, or the floor for a standing person) and the fore-and-aft axis for vibration on a seat backrest. There is also a tentative recommendation on how to measure and evaluate the vibration exposures of recumbent persons. The evaluation of multi-axis vibration with respect to health recommended in BS 6841 (1987) involves the calculation of the fourth root of the sum of the fourth powers of the vibration dose values in each axis. In practice, this means that if two or more axes have similar magnitudes of vibration the overall effect is increased, otherwise the “worst” axis will largely determine the vibration severity.

British Standard 6841 (1987) offers an interpretation of vibration dose values which amounts to the definition of an action level: “Sufficiently high vibration dose values will cause severe discomfort, pain and injury ... vibration dose values in the region of $15 \text{ ms}^{-1.75}$ will usually cause severe discomfort ... increased exposure to vibration will be accompanied by increased risk of injury. At high vibration dose values prior consideration of the fitness of the exposed persons and the design of adequate safety precautions may be required. The need for regular checks on the health of routinely exposed persons may also be considered.”

The $15 \text{ ms}^{-1.75}$ action value in BS 6841 (1987) is mid-way between the exposure action value and the exposure limit value in the Physical Agents Directive (fig 6). However, this comparison is dependent on how many axes are included in the assessment and, particularly, whether fore-and-aft and lateral vibration influence the values: the Directive uses multiplying factors from ISO 2631 (1997) which increase the importance of fore-and-aft and lateral vibration by 40% compared with BS 6841 (1987).

Compared with ISO 2631 (1997)

International Standard 2631 (1997) is equivocal on the axes to be assessed, how they may be combined and to which postures the final assessment applies.¹² There are also various other ambiguities in the standard.¹³ One of several anomalies is that the standard includes a multiplying factor of 1.4 for vibration in the horizontal axes when considering health effects but not when considering comfort.

Annex B to the standard offers two very different “health guidance caution zones” (see fig 7). A “VDV health guidance caution zone” is defined by vibration dose values of 8.5 and $17 \text{ ms}^{-1.75}$; the corresponding r.m.s. accelerations, calculated using the “estimated vibration dose value”, are shown in fig 7. An alternative health guidance caution zone, consisting of constant acceleration from 1 to 10 minutes and then acceleration falling in inverse proportion to the square root of exposure duration from 10 minutes to 24 hours is also shown. For exposures between 1 minute and 10 minutes, the upper boundary of the r.m.s. caution zone is assumed to

be at 6.0 ms^{-2} r.m.s. and the lower boundary at 3.0 ms^{-2} r.m.s.

Referring to a health guidance caution zone, the standard says: "For exposures below the zone, health effects have not been clearly documented and/or objectively observed; in the zone, caution with respect to potential health risks is indicated and above the zone health risks are likely". An informative annex states that mainly the lumbar spine and the connected nervous system may be affected by vibration. According to this standard, to prevent a foreseeable risk of injury from vibration, the conditions should be below the health guidance caution zone. It is not clear when exposures up to the top of a health guidance caution zone might be considered acceptable.

In fig 7, the 8.5 and $17 \text{ ms}^{-1.75}$ VDV caution zone and the 3.0 and 6.0 ms^{-2} r.m.s. caution zone in ISO 2631 are compared with the 9.1 VDV exposure action value, the $21 \text{ ms}^{-1.75}$ VDV exposure limit value, the 0.5 ms^{-2} r.m.s. exposure action value, and the 1.15 ms^{-2} r.m.s. exposure limit value. It may be seen that a principal difference is the very high values "allowed" at short durations when using the r.m.s. measures in the EU Directive. While excessive magnitudes at short durations when using r.m.s. evaluation were avoided in ISO 2631 (1997), they are "permitted" in the Physical Agents Directive. In the Directive, these high magnitudes at short duration are controlled when using the VDV method of evaluation (that is, 9.1 and $21 \text{ ms}^{-1.75}$) but not when using r.m.s. measures (that is, $A(8) = 0.5$ or 1.15 ms^{-2} r.m.s.).

Compared with the EU Machinery Safety Directive

The Machinery Safety Directive of the European Community (89/392/EEC) states that instruction handbooks for machinery causing whole-body vibration shall specify the equivalent acceleration to which the body is exposed where this exceeds a stated value (currently a frequency weighted acceleration of 0.5 ms^{-2} r.m.s.).¹⁵ Assuming whole-body vibration is evaluated in the same way for the Machinery Safety Directive and the Physical Agents Directive, this corresponds to the eight hour exposure action level in the Physical Agents Directive. Consequently, if a piece of machinery is declared as having a vibration magnitude less than 0.5 ms^{-2} r.m.s. it will not exceed the action value unless either exposures last longer than eight hours or the declared vibration magnitude is not representative of vibration exposure during machinery use.

Figure 6 Comparison between the "action level" in BS 6841 (1987) ($\text{VDV} = 15 \text{ ms}^{-1.75}$) and the exposure limit values and exposure action values for whole-body vibration

Figure 7 Comparison between the health guidance caution zones in ISO 2631-1 (1997) ($3\text{--}6 \text{ ms}^{-2}$ r.m.s.; $8.5\text{--}17 \text{ ms}^{-1.75}$) and the exposure limit values and exposure action values for whole-body vibration

Health surveillance

The Directive says that, apart from exceeding the action value, there are three indications for health surveillance. One indication is that a link can be established between worker exposure to vibration and an identifiable illness or harmful effect on health. It seems probable that in many cases the exposure action value could be exceeded without evidence of a link, but the Directive requires health surveillance in such situations.

The Directive says that a second indication of the appropriateness of health surveillance is that it is "probable" that illness or harmful effects caused by vibration occur in a worker's working conditions. This presumably refers to illness or harmful effects being more likely to occur than to not occur among one or more exposed individuals, not to any one specific individual being more likely to be harmed than not harmed by vibration. Currently there is no basis for deciding on the probability of the occurrence of harm from exposures to whole-body vibration: BS 6841, ISO 2631 and the exposure action value do not indicate the risks associated with any particular vibration exposure. However, within a specific context, if it is concluded that one or more persons has been injured by whole-body vibration then it is reasonable to assume that others who are similarly exposed may also be at risk.

Another indication of the appropriateness of health surveillance is that there are tested techniques for the detection of harmful effects on health. The harmful effects of whole-body vibration are not yet established. Although "lower-back morbidity and trauma of the spine" are commonly suggested there are no proven techniques for their detection or for distinguishing any such effects from other causes of the same disorders.

Health surveillance for whole-body vibration seems problematic if looking for injury caused by vibration: the effects of whole-body vibration are not known with any certainty, they are not easily detected, and they are not unequivocally associated with vibration. Even so, health surveillance might be of assistance in identifying contraindications to jobs that may exacerbate any back injury. Irrespective of whether a lower-back or spine problem has been caused by exposure to whole-body vibration, it might be considered that a worker

who is exposed to whole-body vibration and has such problems requires special consideration. However, back problems are very common and such special consideration may be equally desirable for the very many workers with back problems who, while not exposed to whole-body vibration, are at risk from, for example, lifting tasks.

With no early prospect of an objective test for back problems caused by whole-body vibration, health surveillance will often be limited to patient reports of any symptoms. It seems possible that some may lose their job unnecessarily as a result of reporting a back problem while others may decide not to report such problems for fear of losing their job.

Vibration dose

The choice of eight hours for the equivalence between the r.m.s. and VDV exposure action value and exposure limit value seems arbitrary. Some would argue that there is greatest knowledge of any cumulative effects of whole-body vibration with exposures around four hours. Equivalence at four hours would have raised the VDV exposure action value and exposure limit value for all durations. The equivalence between the r.m.s. and VDV measures assumes the estimated vibration dose ($eVDV = 1.4 a_{rms} t^{1/4}$), but the multiplying factor of 1.4 only applies to continuous exposures not containing shocks: an eight hour exposure is unlikely to be continuous and may often contain shocks.

The vibration dose value is, arguably, more simple than r.m.s. methods of measurement. However, it is not well understood by some who have become familiar with values obtained using r.m.s. measures (but may not understand the mathematical equations or limitations of the method) and are daunted by a relatively new VDV method (with a simpler equation and different units).

The VDV can be viewed with varying degrees of sophistication. For many, it may be sufficient to assume that it merely defines a different relation between the r.m.s. vibration magnitude and exposure duration, as shown by the different slopes in fig 2: the VDV method indicates less change in vibration magnitude for a given change in exposure duration than the r.m.s. method. The vibration dose values within the Directive can be interpreted simply in this manner, so the values for any duration can be calculated as in the equations above and as listed in table 2.

The lack of understanding of vibration dose values arises because the underlying mathematical basis of the method allows it to be used for all types of vibration (not merely continuous uninterrupted exposures), including shocks. With the current paucity of knowledge of the injury mechanisms associated with occupational exposures to shocks it is not possible to say with confidence how such motions should be evaluated. However, it seems reasonable to assume that for many exposures the vibration dose value provides more appropriate guidance than r.m.s. measures which allow extremely high magnitudes of such short duration events.

The VDV is inherently a dose measure: it accumulates exposures in accord with the fourth power time dependency and so increases with increased exposure. The r.m.s. method is an averaging procedure: it averages exposures on an "energy" basis and can fall with increased exposure. (An r.m.s. measure can be reduced by including periods of low vibration within the measurement period, whereas this does not reduce the VDV.)

For either the VDV or the r.m.s. measure, an eight hour equivalent exposure can be estimated from r.m.s. values measured over shorter "representative periods". With steady state continuous exposures this may be sufficiently accurate, but with exposures that vary in magnitude, are intermittent

or contain shocks this may introduce significant errors. In practice, therefore, measures (both r.m.s. and VDV) may be best obtained over long periods, ideally a full day of exposure, although this is difficult to achieve without artefacts causing errors in the measurements.

Exposures that are either shorter or longer than eight hours can be expressed as an eight hour equivalent value (as in the Directive), or any other exposure period (for example, 1 second, as in the vibration dose value). When using r.m.s. measures, the r.m.s. exposure action value corresponds to a dose of $84.85 \text{ ms}^{-1.5}$ and the r.m.s. exposure limit value corresponds to a dose of $195.16 \text{ ms}^{-1.5}$. These two doses give values of 0.5 ms^{-2} r.m.s. and 1.15 ms^{-2} r.m.s. with eight hour exposures but different values with other exposure periods, as shown in columns 4 and 6 of table 2.

Both the VDV and r.m.s. measures as defined in the Directive are dose measures (and both have units that may seem unfamiliar: $\text{ms}^{-1.75}$ and $\text{ms}^{-1.5}$). The fundamental difference is that the VDV was developed to offer a procedure for evaluating shocks, repetitive shocks, and intermittent vibration and for comparing the severity of exposures having widely differing durations. A Member State of the European Union may choose either the r.m.s. or the VDV method. Although probably unsuitable for such motions, the choice of the r.m.s. method will allow it to be used for motions in which high acceleration may occur for a short period. Since such motions are thought to be those most likely to cause injury, the use of the r.m.s. exposure action value and the r.m.s. exposure limit value is likely to be under-protective for precisely those situations where injury from whole-body vibration is considered most likely to occur.

The minimisation of any risk associated with whole-body vibration can involve balancing exposures to vibration and shock, such as in suspension seating where improved isolation of vibration can be achieved if greater risk of "end-stop impacts" in the suspension is permitted. Where such alternatives are present, the use of r.m.s. methods will encourage a reduction in "vibration" but an increase in "shocks". As shown by the high levels permitted for short exposures in fig 2, shocks and other short-term events will not be limited to reasonable levels by r.m.s. methods.

The high magnitudes of vibration "permitted" for short durations by the r.m.s. exposure action value and the r.m.s. exposure limit value are worrying. For 10-minute exposures, the r.m.s. exposure action value is 3.5 ms^{-2} r.m.s. and the r.m.s. exposure limit value is at 8 ms^{-2} r.m.s., both being potentially unsafe exposures according to ISO 2631 (1997). For one minute exposures, the r.m.s. exposure action value is at 11.0 ms^{-2} r.m.s. and the exposure limit value is at 25.2 ms^{-2} r.m.s.—conditions that cannot be considered safe for anyone in any environment.

With 10 minute exposures the r.m.s. exposure limit value is 2.6 times the VDV exposure limit value; for one minute exposures, the r.m.s. exposure limit value is 4.7 times the VDV exposure limit value. This vast discrepancy is greater than the, admittedly large, uncertainty in knowledge as to the likely risks from different durations of exposure to whole-body vibration.

The extraordinarily high vibration magnitudes "allowed" for short durations by the r.m.s. method are so great that it must be assumed that many among the European Parliament, the European Council, and their advisors were either unaware of the magnitudes at short durations that are associated with the r.m.s. values, or unfamiliar with the severity of these magnitudes. However, although these levels may be "tolerated" by some setting the guidance, the highest magnitudes are so severe that they will not be tolerated by those being exposed to the vibration!

Other observations

The scientific evidence is not yet sufficient to define a dose-response relation between whole-body vibration and back disorders. There is not even unanimity among researchers that whole-body vibration is always a risk. However, this is implied in the Directive where whole-body vibration is defined as: "mechanical vibration that, when transmitted to the whole body, entails risks to the health and safety of workers, in particular lower-back morbidity and trauma of the spine". It is possible for whole-body vibration to cause other disorders and, obviously, whole-body vibration can occur without evidence of morbidity.

Effects of whole-body vibration are highly dependent on body posture. Whole-body vibration, posture, and other factors are likely to combine in a complex manner to cause any morbidity. If the exposure action value and the exposure limit value are appropriate in one situation they may not be good indicators of risk for other situations.

Epidemiological studies to investigate any relation between whole-body vibration and the risks of back problems are difficult to design, and no study is immune from criticism. Some reviews have identified criteria for the inclusion of studies based on the adequacy of the design, investigation, and reporting of findings. From one review of 19 selected studies it was concluded there is "strong evidence of a positive association between exposure to whole-body vibration and back disorder".¹⁰ Similarly, a review of epidemiological studies selected to meet specific criteria defined by Bovenzi and Hulshof (2000), concluded that in both cross-sectional and cohort studies there was "evidence that occupational exposure to whole-body vibration was associated with an increased risk of low back pain, sciatic pain, and degenerative changes in the spinal system, including lumbar intervertebral disc disorders".⁹ Counter-arguments to these conclusions may raise concerns about the involvement of sitting posture, other activities causing increased risk, the effects of aging, inadequate knowledge of the type and extent of vibration exposure, etc. Some of these factors (for example, sitting posture, lifting tasks, and vibration exposure) may have influenced risk in the past, so correcting for their influence by statistical means at the time of the study may not be sufficient. The suitability of control populations against which the findings are judged is also a concern.

A proportionate response to any increased risk of back disorders associated with whole-body vibration should consider the extent to which vibration increases risk within the context of all other risks. Other factors (especially lifting) are more clearly associated with back disorders. One recent study implies that, irrespective of the evidence for whole-body vibration being a potential cause of harm, it is not a major cause of lower back morbidity in the working population in Britain.¹⁷

Epidemiological studies alone cannot determine the formula in which vibration magnitude, vibration frequency, vibration direction, exposure duration, posture, and other factors should be combined to predict lower back morbidity. For some of these factors (for example, vibration frequency), the variation in risk is currently based on laboratory studies of biodynamic, subjective, or physiological responses (giving, for example, frequency weightings). Such studies cannot be expected to produce precise methods of evaluating vibration, yet these evaluation methods are used to determine whether there are correlations between morbidity and vibration exposure (in epidemiological studies) and also to prevent risk (in the Physical Agents Directive). It is possible that in epidemiological studies some correlations are missed because exposure measures are inappropriate. It is also possible that the Physical Agents Directive is controlling inappropriate motions because the methods of quantifying motions are not

optimum. This applies not only to the vibration "evaluation" procedure (that is, obtaining a single value from a sample vibration measurement), but also to a vibration "measurement", which may not be typical of past exposures (contributing to morbidity in epidemiological studies) or typical of current exposures (being assessed according to the Physical Agents Directive). This is especially a problem with occasional extreme exposures, including shocks.

GENERAL DISCUSSION

Degree of protection

The Directive does not indicate the degree of protection that is provided by the exposure action value or the exposure limit value. The risk of injury will presumably rise with increased exposure: with more days, months, and years of exposure. For exposures to hand-transmitted vibration, the current International Standard suggests the risks of vibration-induced white finger might be estimated as 10% after about 12 years at the exposure action value and after 5.8 years at the exposure limit value. Is it sensible to suppose that the risks of "lower-back morbidity and trauma of the spine" are similar and, if so, is this reasonable? In fact, current knowledge cannot provide answers to such questions. With hand-transmitted vibration, the influence of vibration magnitude, vibration frequency, vibration direction, exposure duration, and some other factors are insufficiently known to make accurate estimates of the probability of injury: the risks are probably much greater than 10% in some conditions and much less in others. With whole-body vibration, it would be rash to make any estimate of risk solely from knowledge of the vibration: while understanding is at an embryonic stage, estimates of what is likely to be safe or unsafe will benefit from experience of the various conditions and not blind reliance on formulae.

Exposure duration

The use of the "energy" time-dependency (that is, r.m.s. methods) means that the corresponding exposure action values and the exposure limit values for both hand-transmitted vibration and whole-body vibration have very high magnitudes with short daily exposures. Such magnitudes might arise briefly during continuous exposures, or from intermittent exposures to high magnitudes, or from isolated or repeated shocks. Although knowledge of the effects of these high magnitudes is limited, it is reasonable to assume that they are undesirable. For many tools and machines, such high vibration magnitudes are now also unnecessary.

When vibration is usually below the exposure action value, but varies markedly from time to time and occasionally exceeds the exposure limit value, a Member State may allow an exception provided the exposure averaged over 40 hours is less than the exposure limit value and there is evidence that the risks are lower than those from exposure at the exposure limit value. This is vaguely worded and may allow many exceptions. The method of averaging is not specified, and very different conclusions will be reached by linear averaging, by r.m.s. averaging, and by fourth power averaging over 40 hours. It is not stated which 40 hours should be averaged: is this a single 40 hour period or five successive working (or non-working) days of eight hours? It is not clear what is meant by "usually below the exposure action value": this may apply during a day (but very many exposures to vibration are below the action level for long periods, or could be made to be usually below the exposure action value by the addition of exposures at a low level!), or it may apply to days of the week (for example, three days out of five). In the latter case, this may allow exposures at very high magnitudes on

some days. In order to be restricted to reasonable exposure conditions, the method requires a more precise definition.

The Directive does not specifically mention exposures that only occur for a few weeks or a few months. It is assumed that the exposure action values and exposure limit values apply to individual days (apart from derogations related to 40 hours as mentioned above). Exposures arising from, for example, seasonal work for a few weeks or months will therefore be treated equally with the same daily exposures that continue throughout the year. This seems reasonable, not least because an employer who is responsible for the working conditions during a few weeks or months may not be able to predict whether future employment of the worker will be of lesser risk.

Quantitative versus qualitative guidance

With hand-transmitted vibration the limited knowledge of the dependence of risk on vibration magnitude, vibration frequency, vibration direction, daily and yearly exposure duration, together with hand-grip, position and posture of the hands, temperature, and other factors does not allow the probability of vibration-induced white finger to be predicted with any precision. Knowledge of the factors influencing other disorders (for example, neurological and musculoskeletal) is even less substantial. For example, in the case of vibration-induced white finger, some studies suggest that the frequency weighting W_h used in current standards provides a less accurate prediction than obtained with no frequency weighting. The difference between the two is very large (for example, the relative importance of vibration on a tool dominated by 31.5 Hz and one dominated by 125 Hz varies by a factor of four with and without the weighting). If there is an error of four (or more) due to the frequency weighting, and also errors due to other factors, it follows that the exposure action value and the exposure limit value correspond to very different degrees of risk with different tools.

With whole-body vibration, the large divergence between the r.m.s. and VDV measures (with short duration exposures) is one indication of the lack of knowledge of what types of vibration cause injury. However, the uncertainty is great for all durations of exposure: there is no substantial body of knowledge showing what type of injury, the probability of injury, or the severity of injury that occurs with any duration of exposure to whole-body vibration. It may be logical to expect that whole-body vibration can cause injury but it is currently not logical to assume that injury will be prevented by any particular exposure action value or exposure limit value.

Current understanding of the effects of hand-transmitted vibration and whole-body vibration indicates it is unwise to assume that the exposure action value defines the boundary of safe exposures. For example, it seems certain that some exposures to hand-transmitted vibration below the exposure action value can cause a high incidence of vibration-induced white finger if exposures are continued for a sufficient number of years. Those seeking to prevent disorders will heed the exposure action value but will not assume that controlling exposures to levels below the action value is sufficient to prevent foreseeable risks of injury.

A potential hazard from hand-transmitted vibration can be identified if: (i) it is known that broadly similar vibration exposures carry a risk of injury (for example, injury has been reported at the same workplace or with similar work elsewhere), or (ii) even though injury has not been reported with similar exposures, the vibration magnitudes and exposure durations are sufficient to anticipate a risk of injury from the guidance in relevant standards. Knowledge of vibration magnitudes and exposure durations are not the best means of predicting risk because the frequency

weighting, time dependencies, and other features of current standards are inaccurate. It is therefore not sufficient to reduce the vibration magnitude and exposure duration to some more or less arbitrary value in current standards or directives.

It may be argued that the Directive is based on standards that, in some areas, are not soundly based on an established relation between vibration and injury. Yet it may also be argued that the Directive conflicts with these same standards in that they suggest a high probability of injury for some exposures below the exposure action value and far below the exposure limit value. These two criticisms highlight the inevitable weakness of quantitative guidance in the Directive. The qualitative guidance (that is, "the risks arising from exposure to mechanical vibration shall be eliminated at their source or reduced to a minimum") applies irrespective of whether the action value is exceeded and is consistent with knowledge. This implies that an employer is responsible for the effects of vibration exposures greater than the minimum achievable exposures, and not only responsible for the effects in excess of the exposure action value. The "magic numbers" (2.5 and 5 ms^{-2} r.m.s. for hand-transmitted vibration; 0.5 and 1.15 ms^{-2} r.m.s. or 9.1 and $21 \text{ ms}^{-1.75}$ for whole-body vibration) will have a high visibility over coming years, but the underlying message is that where a vibration exposure might be harmful it should be minimised.

The Directive specifies "minimum requirements", allowing Member States to adopt more protective measures, including lower exposure action values and lower exposure limit values. It also says that employers should make adjustments in the light of technical progress and advancing scientific knowledge with a view to improving the health and safety protection of workers. The emphasis is on the minimisation of risk and what employers are doing to minimise risk, not merely on whether the exposure action value or the exposure limit value are exceeded.

CONCLUSIONS

The 2002 European Physical Agents Directive for vibration gives guidance that will have a large impact on considerations of the severity of occupational exposures to hand-transmitted vibration and whole-body vibration within the European Union. Countries outside the European Union may follow some of the principles in the Directive.

Neither the "exposure action values" nor the "exposure limit values" in the Directive define safe exposures to hand-transmitted vibration or whole-body vibration.

Exceeding an exposure action value is one indication of the need for health surveillance. Health surveillance and other precautions will also be appropriate for some conditions below the exposure action value. The exposure limit value restricts the maximum permissible daily exposures to hand-transmitted vibration and whole-body vibration.

Some of the exposure action values and exposure limit values (those based on r.m.s. acceleration according to ISO 5349-1 and ISO 2631) appear to allow unreasonably high magnitudes of vibration for short daily exposures. After many years, a high incidence of vibration-induced white finger may be expected for some exposures to hand-transmitted vibration below the exposure action value. It is therefore concluded that for both hand-transmitted vibration and whole-body vibration the quantitative guidance (that is, the "exposure action value" and the "exposure limit value") are insufficient to identify vibration hazards, and that the qualitative guidance (that is, reducing risk to a minimum) is the key message.

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ECHO.....

Air pollution and birth weight

Please visit the *Occupational and Environmental Medicine* web-site [www.occenvmed.com] for a link to the full text of this article.

Studies in several countries have suggested an association between air pollution and low birth weight. In São Paulo, Brazil, a city with high levels of air pollution, an association was shown between air pollution and intrauterine mortality and late fetal loss, and umbilical cord blood concentrations of carbon monoxide correlated with ambient levels. Now another study in São Paulo has related air pollution to low birth weight.

Clinical and other data concerning all singleton, full term, live births in São Paulo during 1997 were collected from official certificates. Air pollution data were available from the São Paulo environmental agency. Maternal exposure to air pollutants was estimated for each trimester of pregnancy using city wide measurements. Of a total of 214 973 live births in the city in 1997 data were analysed for 179 460. The mean birth weight for singleton pregnancies was 3186 g and 5% were of low birth weight (<2500 g). Birth weight was affected by infant sex, maternal age, maternal education, number of antenatal visits, parity, and type of delivery. The effect on birth weight of exposure to air pollutants (respirable particles (PM₁₀), sulphur dioxide, carbon monoxide, nitrogen dioxide, and ozone) was calculated for each trimester with adjustment for the other factors affecting birth weight. Low birth weight was related to higher levels of exposure to PM₁₀ and carbon monoxide in the first trimester. A 10 µg/m³ increase in exposure to PM₁₀ was associated with a 13.7 g reduction in birth weight and a 1 ppm increase in carbon monoxide exposure was associated with a 23.1 g reduction.

Exposure to air pollutants in the first trimester of pregnancy may have an adverse effect on fetal weight gain.

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