Vibration Injury Network

Research Network on Detection and Prevention of Injuries due to Occupational Vibration Exposures

Protocol for epidemiological studies on vascular, neurological and musculoskeletal disorders or complaints associated with hand-transmitted vibration

Appendix H2A to Final Report

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Introduction

Under the BIOMED 2 – Vibration Injury Network concerted action research project, five laboratories specialized in hand-arm vibration are sharing experience and data in order to make the synthesis of the present knowledge concerning the physiological disorders associated with this risk factor and, when possible, finalize common tools and procedures to use in future investigations.
One of the key items of this project was the elaboration of recommendations for the design of an epidemiological study aiming at investigating the possible relationship between exposure to hand-arm vibration and different types of disorders or complaints - vascular, neurological and musculoskeletal -, taking into account as many confounding factors as possible.

This document reviews the different choices to which the user is confronted. It describes and discusses, when needed, the main items that have to be included in the protocol of a study. It lists its major components, draws the attention on the consequences of the different choices that have to be made and lists the preferred tools and procedures (questionnaires, tests, measuring techniques...) that should be used to collect the information in an epidemiological study of a certain type with specific objectives.

Cross sectional vs. longitudinal epidemiological study

The first choice, often dictated by time and economic requirements, is between a cross sectional study and a longitudinal study.
Without attempting here to define precisely and comprehensively the two approaches, it is useful to restate that cross sectional studies consist in observing the exposures and the "effects" in a given population at a given time, while, in a longitudinal study, the development of new "effects" or the evolution of existing ones is observed and the exposure is quantified during a given period, prospectively or retrospectively.

For a cross sectional study, the statistical analysis can establish the strength of the concomitancy between "exposure" and "effects" at that point in time, taking into account the "confounding" factors, and makes it possible to formulate hypotheses concerning a possible "cause-effect" relationship.

In the case of a longitudinal study, the statistical analysis can demonstrate the strength of the concomitancy between "exposure" and the evolution of the "effects", and, if all other "confounding" variables are taken into account, inferences can be made about a “cause-effect” association.

The strength of these studies depends upon the size of the sample and the comprehensiveness of the protocol.

For longitudinal studies, the strength also depends upon the duration of the observation period. Obviously, a longer period makes it possible to observe the development of a greater number of “effects” or of more important “effects”. In practice however, the loss of subjects, modifications in the exposure conditions, unavoidable alterations of the epidemiological procedure tend to offset the advantages of a longer observation period, so that the user must make the best compromise, taking into account comprehensively all the different aspects.

The type of effects to consider

The epidemiological study can focus on one or several "effects": neurological and/or vascular and/or musculoskeletal. The "effects" taken into consideration can be:

- Disorders authenticated by clinical tests and/or a clinical examination;
- Complaints expressed by the subjects.

Obviously, studies based on complaints are easier to conduct, and on larger number of subjects. Studies on disorders are much more sophisticated, more costly, often based on more limited numbers of subjects, but much more significant to conclude that a cause-effect relationship exists. Once this relationship is established however, studies based on complaints are needed to detect the early signs, usually subjective, of the disorders.

Groups of subjects to consider

- **Musculoskeletal** disorders/complaints are associated with heavy and repetitive work and might be aggravated by the exposure to vibration. Therefore any study concerning this type of "effects" must at least consider:
  - A group of ‘blue-collar’ workers using vibrating tool (GV).
  - A group of ‘blue-collar’ workers not using such tools but performing "heavy work" (Ghw), that is, work requiring arm efforts and postures similar to those adopted by the workers from the first group.
  - Ideally, a third group of ‘blue-collar’ workers not using vibrating tools and not performing heavy work as defined above, but still working in the same type of industries (Glw).

  Additionally, one might also be interested in the comparison of the GV group to the population of ‘white-collar’ workers (Gwc).

- For epidemiological studies concerning **neurological** effects, the same considerations apply to some extend, as some “effects” such as tingling, numbness and loss of dexterity might also be associated with heavy work.

- As **vascular** effects have never been associated to heavy work alone, an epidemiological study concerned solely by these effects might compare a vibration-exposed group GV with either Ghw or Glw or even Gwc.

The groups might either be:

- Matched as well as possible concerning some factors. This assumes that hypotheses can be made *explicitly* concerning the factors that influence the "effects". The groups will then not be matched for other factors and the researcher hopes generally that the statistical analysis will be able to eliminate, reduce, "control" the influence of these factors. This might complicate and restrict strongly the selection of the groups, without guaranteeing a significant reduction of the influence of the confounding factors.
- Chosen at random from grossly defined populations. In this more commonly used procedure, it is expected that all possible combinations of unknown or/and uncontrollable confounding factors will be encountered and that the statistical analysis will reduce or eliminate their influence. The groups are easier to form and larger studies can be conducted, with, in some cases, a lower statistical power, depending upon the range of conditions randomly encountered.

Collection of data on symptoms and personal characteristics

Whatever the type of epidemiological study, data must be collected concerning personal identification, present and past exposure, social characteristics, medical history and symptoms.

In the framework of the VINET research project, a set of four questionnaires was developed for health surveillance (Bovenzi 2000). These four questionnaires are:

- Q1: Health Surveillance - Initial Assessment: Self-Administered Questionnaire
- Q2: Health Surveillance - Initial Assessment: Questionnaire and Clinical Assessment
- Q3: Health Surveillance - Follow-up Assessment: Self-Administered Questionnaire
- Q4: Health Surveillance - Follow-up Assessment: Questionnaire and Clinical Assessment.

Table 1 compares the contents of these four questionnaires.

These lists of questions were developed essentially to record information at the time of a medical examination in occupational medicine and its layout does not correspond to what is normally necessary in epidemiological questionnaires: coded data, no open questions... Nevertheless, they provide the aspects that can be investigated and the formulation to use in the final questionnaire.

The Institute of Sound and Vibration Research of Southampton University designed a computer programme making it possible to encode and retrieve the information for the 4 questionnaires.

Obviously, Questionnaires Q1 and Q2 should be used at the beginning of a longitudinal study or for a cross sectional study and Q3 and Q4 will be used, as indicated, for the follow-up or at later stages of the longitudinal study.

In any epidemiological study, explicit decision will have to be made about:

- The number of people to include in the study.
- The way personal data will be collected.
- The number of data to collect.

Large epidemiological studies (few hundreds or thousands of subjects) usually rely on self-administered questionnaires with a limited number of items. The questionnaires are sent by mail or distributed without direct contact with the subjects. The rate of return might be low, and therefore the representativeness might be low and the data not always reliable.

Table 1 – Comparison of the 4 questionnaires designed by Bovenzi (2000)

N°	Sections	Q1	Q2	Q3	Q4
		Initial	**Initial**	**Follow-up**	**Follow-up**
	Total number of questions:	**196**	**392**	**142**	**242**
I	**Personal Identification:**	**16**	**16**	**12**	**12**
	▪ Name, age, weight… marital status, education level, ethnic group...	16	16	12	12
II	**Occupational History:**	**62**	**62**	**23**	**23**
	▪ Present occupation: work description, vibrating machines, and exposure durations…	10	10	9	9
	▪ Past occupations with HA vibration exposure: jobs titles, descriptions, hobbies, machines, exposure duration,	15	15	7	7
	▪ Present muscular workload: postures, material handling, forces, repetitiveness,	19	19	7	7
	▪ Past and present exposure to chemicals: solvents, metals, pesticides, types of industries, durations,	18	18	-	-
III	**Social History:**	**12**	**12**	**4**	**4**
	▪ Smoking and drinking habits	12	12	4	4
IV	**Medical History**	**23**	**111**	**6**	**6**
	▪ Existence of serious diseases and injuries: **cardiovascular, nerves, osteoarticular, …**	23			
	▪ Detailed descriptions and treatments		111	6	6
V	**Symptoms:**	**93**	**120**	**97**	**126**
	▪ Whiteness: extend, history, frequency, family history, leisure and work interference	**18**	**21**	**19**	**22**
	▪ Tingling: extend, history, leisure and work interference	**18**	**20**	**19**	**23**
	▪ Numbness: extend, history, leisure and work interference	**8**	**10**	**9**	**11**
	▪ Musculoskeletal disorders: nature (pain, stiffness, weakness, swelling, numbness), body zone affected, history, interference with daily activities	**49**	**69**	**50**	**70**
VI	**Clinical examination :**	**-**	**69**	**-**	**69**
	▪ Appearance of hands and arms, vascular, neurological and functional assessment	-	69	-	69
VII	**Diagnostic staging**: Stockholm scales for vascular and sensorineural symptoms	**-**	**2**	**-**	**2**

On the opposite, longitudinal studies, with individual measurement of the constraint factors (exposure to vibration, biomechanical factors...) are inevitably concerning fewer subjects and researchers might have the possibility to collect data on longer lists of items through checked questionnaires or through personal interview.

The number of items taken into consideration in the Bovenzi questionnaires suggests that they can be used, as such, only in the second type of study.

In the first case, as well as in intermediary situations, the user must select, in these lists of items, those, which are the more relevant in his context. As an example, items about exposure to chemicals and smoking and drinking habits may be omitted in favour of other items.
Similarly, the data about musculoskeletal disorders could be limited to the last 12 month prevalence of complaints for the wrist-hand, elbow and shoulder regions, as proposed in the Nordic questionnaire (Kuorinka et al. 1987), and the information about vascular and sensorineural symptoms limited to the scores on the two Stockholm scales (Gemne et al. 1987; Brammer et al. 1987).

Collection of data about clinical disorders

Appendix III of the VINET document (Bovenzi, 2000) describes the main tests (Lewis Prusik, Allen, Phalen...) that can be used for the diagnosis of upper limb musculoskeletal disorders. Annex IV of the same document provides the criteria for clinical diagnoses of most neck and upper limb musculoskeletal disorders. This most comprehensive and recent synthesis of the main literature on this topic should guide the occupational physician or specialist performing the clinical examination.

Other documents provide the information requested to perform

- The vibrotactile threshold test and the thermal threshold test, to corroborate neurological disorders (ISO standard 13091, 2000; Lindsell and Griffin 1998)
- The rewarming test and finger systolic blood pressure test, to corroborate vascular disorders. (Lindsell and Griffin 1998; Bovenzi et al. 1995; Kurozawa et al. 1991; Bovenzi et al. 1997; Gautherie et al. 1992)

Test methods to evaluate functional hand impairment (Purdue Pegboard and Grip Strength tests) are described in many papers and summarized in a publication by Haward (1998).

Collection of data about exposure constraints

A. Evaluation of the present exposure

The evaluation of the exposure to any constraint factor raises problems of what to record and the representativeness of what is recorded.

The information requested to characterise the exposure can be

- very simple: vibration amplitudes found for similar vibrating tools in databases and durations estimated by a group of subjects....
- or very sophisticated: weighted and unweighted equivalent vibration amplitudes in the 3 axes and recorded durations.

Sophistication does not necessarily imply reliability, as these weighted amplitudes in the 3 axes might not be representative if the observation period was not selected adequately.

As was discussed briefly above for the questionnaire, the number of subjects included in a study in practice is usually inversely proportional to the time needed for the evaluation of the work constraints.

Three methods will therefore be presented, at three different levels of sophistication:
1. A simple approach, called "***Observation***", based on straightforward evaluation by the workers and the management. Obviously, the collected data will not concern individuals but groups of subjects with about the same exposure (homogeneous exposure groups HEG, Hawkins et al, 1991).

2. A very sophisticated approach, called "***Expertise***", based on measurements during representative phases to quantify the exposure of a given subject.

3. An intermediate approach, called "***Analysis***", based not on measurements, but on meticulous observation during representative phases and aiming at characterising either the mean exposure of a homogeneous exposure group, or the personal exposure of a given subject.

The proposed procedure requires in all cases the determination of the stationarity time interval STI (Malchaire and Piette 1997), defined as the time interval including all possible variations of the working conditions. This interval must be estimated on basis of production records, records of consumables, opinions of the workers, opinions of the management ... It can only be determined by or in close co-operation with the workers and their management, who know precisely the work performed, its organisation, its daily, weekly, monthly... yearly evolution...

Once the STI is determined, the selection of representative work phases requires to
1. Define the elementary operations during the STI.
2. Select at random different periods for each elementary operation during the STI.
3. Evaluate (estimate or measure) the constraints for each period.
4. Evaluate the mean constraint for the whole STI taking account of the durations.

When this mean constraint is not requested for each subject individually, but for an homogeneous exposure group, the selection at random of the different observation or measurement periods is usually performed also at random among the subjects of the group in order to merge between and within subject variances for a given operation.

The three approaches "***Observation***", "***Analysis***", "***Expertise***" will be outlined for the evaluation of the musculoskeletal constraints and the exposure to vibration.

1. Evaluation of the musculoskeletal constraints

a. "Observation" method

Many different methods were proposed in the literature to estimate, through simple observations, the risk of musculoskeletal disorders. The *RULA* method (McAtamney and Corlett 1993) makes it possible to derive a risk index for the whole body, through simple considerations of postures, forces and repetitiveness.

The *Strain Index* proposed by Moore and Garg (1995) concerns only the wrist-hand region and is based on observations of efforts (intensity, duration or frequency), wrist-hand postures, work rhythm and duration per day.

b. "Analysis" method

The technique proposed by Armstrong et al. (1982) consists in making video recordings of several work phases and analysing these videos to classify the postures of the shoulders, elbows, wrists and/or hands for each "work element". In parallel, the forces are indirectly estimated through surface EMG recordings and the duration of each "work element" is estimated. This was used by the authors in a study about musculoskeletal upper limb disorders in a poultry processing plant with rather few "work elements" and short time cycles.

The *OCRA* method proposed by Occhipinti (1998) is less sophisticated technically and draws more attention on the work organisation (durations of the cycles, rest periods... frequencies). Postures of the upper limbs segments as well as repetitiveness (number of actions per minute) are determined from video recordings while the workers, using the Borg scale, subjectively estimate forces.

Both methods use for the analysis of the video recordings the statistical principles developed and validated in the OWAS methods (Louhevaara and Suurnakki 1992).

c. "Expertise" method

At this level, the exposure evaluation will be based on continuous measurements of postures and movements through electrogoniometers and of forces indirectly through EMG recordings on the flexor muscles of the forearms. Wells et al. (1994) described such a method, including synchronized analysis of postures and forces. Malchaire et al. (2001a) used a similar approach.

2. Evaluation of the exposure to vibration

a. "Observation" method

The exposure evaluation requires the estimation of both the percentage of the time during which each vibrating machine is used and the mean weighted acceleration amplitude during this use.

The durations must be estimated from production and maintenance records, workers and management opinions, tool replacement rates... Mean amplitudes for each machine can be derived on the basis of data provided by the manufacturer or published in the literature.

During the VINET project, the web database published by Lundström at http://umetech.niwl.se grew rich of data from different sources.

As in acoustics, the personal exposure amplitude A_{PE} can then be computed as the continuous amplitude that, over 8 hours per day and 40 hours a week, would give the same exposure energy than the fluctuating and intermittent exposure met in the real life.
If $\mathbf{p_i}$ is the percentage of the time (actually of the stationary time interval) during which the machine **i**, producing the acceleration $\mathbf{A_i}$, is used, $\mathbf{A_{PE}}$ is given by:

$$A_{PE} = (\Sigma\, p_i \; A^2_i \; / \; 100)^{1/2}$$

It is worth underlining the fact that this takes into account the period without the use of vibrating tools.

b. “Expertise” method

The most sophisticated, accurate, but time consuming and costly method of evaluation of the exposure involves the strict application of the recommendations of ISO 5349. This includes

- The determination of representative sampling periods.
- The continuous recording of the vibration signals in the 3 axes X, Y, and Z on the handles of all vibrating machines.
- The determination of the weighted (and unweighted) equivalent amplitude for each axis and machine.
- The calculation of the triaxial acceleration amplitude through vectorial summation.
- The estimation - through time analysis - of the duration of use of each machine.
- The evaluation of the personal exposure amplitude as indicated before.

This method clearly favours the accuracy of the acceleration amplitudes, to the detriment of the accuracy of the exposure durations.

In cases of workers using several machines with both hands and in several workplaces, this method proves to be totally impracticable and unrealistic.

c. “Analysis” method

A simplified method consists in

1. Identifying, as done for musculoskeletal constraints, elementary operations (“work elements”) where one of the different vibrating machines is used.
2. For each operation, measuring, according to ISO 5349, the equivalent weighted (and unweighted) acceleration during one short duration representative work phase.
3. During representative periods of work, with the normal sequence of operations, recording continuously when each machine is used, through any event recorder.

This method was used by the authors in a published study (Malchaire et al. 2001a). The determination of the machine used as a function of time was done through the qualitative analysis of the signal given by an accelerometer held, with an adaptor B & K UA0891, in the hand and against the different tools handles by the worker and the recognition of the “signature” of each machine.

B. Evaluation of the exposure history

The VINET set of questionnaires (Bovenzi 2000) described in Table 1 includes items concerning the past occupations with exposure to hand transmitted vibration. If necessary to reach the objectives of the study, the section of the questionnaire dealing with the present muscular workload can easily be repeated concerning past workstations.

In addition, some items concerning the physical constraints in the private life might be desired: sports, hobbies, practices, and leisure activities.

As the accuracy of the estimation of exposure in previous occupations is usually rather low, and in order to minimize the effect of this on the epidemiological results, it is recommended to include in the study only subjects for whom the past history appears to be negligible with respect to the present exposure, that is, subjects with a minimum seniority, at their present work situation. This minimum seniority is often dictated by circumstances and can vary as a function of the severity of the actual and past exposures as well as the latency of the symptoms or disorders. In this respect, shorter seniorities could be accepted for musculoskeletal disorders than for vascular effects associated with vibration.

C. Characterisation of the cumulated vibration exposure CVE

Different methods were used in the literature to characterise the cumulated vibration exposure. Most of the time, as suggested by ISO 5349 (1986), CVE is computed as a function of the product of the acceleration (A), the square root of the number of hours of exposure per day (d) and the number of years of exposure (T): $\mathbf{CVE = A \times \sqrt{d} \times T}$

However, this time dependency is not confirmed by all the epidemiological studies and authors are invited to test also for other types of relationships such as those used by Lunström et al. (1999) ($\mathbf{CVE = A \times d \times T}$) and Malchaire et al. (2001) ($\mathbf{CVE = A \times \sqrt{d} \times \sqrt{T}}$). This last expression follows strictly the equal-energy principle.

Collection of data about psycho-organisational factors

During the last 10 years, factors dealing with the work organisation (autonomy, requirements, controls…) and the mental constraints (mental load, responsibilities, support…) have become more and more recognized as significant risk co-factors for musculoskeletal disorders (Bongers, 1993, Malchaire et al. 2001b). Although to a lesser extend than neck disorders, hand-wrist disorders have been found in association with work situations with high stress levels. To our knowledge, the association with hand-arm vibration syndrome has never been explicitly investigated.
The Karasek questionnaire (1979) is often used to quantify the work situations in terms of decision latitude (creativity, required expertise level, self-pacing…), psychological demand (quantity of work, rhythm, concentration…) and social supports (from colleagues or supervisors…).

Some studies have questioned the Karasek model (Hellemans et Karnas 1999). In addition the Karasek questionnaire was developed typically for 'white-collar' employees and is not easily used for work situations such as those where vibrating tools are extensively used. Therefore, in order not to be limited to one single model, it is recommended to use at the same time several questionnaires describing the work situations under different angles.

Statistical analysis

The nature of the statistical analysis varies greatly depending upon the type of data collected. However, it should include at the minimum

- The descriptive statistics of the groups and comparison with t-tests
- The cross correlation between independent variables
- The logistic regression with
    - as dependent variable: the fact that the subject presents symptoms or complaints
    - as independent variables: all exposure characteristics and confounding factors. As the number of such independent variables might be very large, logistic regression models must be derived iteratively.

Conclusion

The design of an epidemiological study requires a series if decisions which are a function of the objectives of the study and the financial and practical means at the disposal of the research team. Table 2 summarizes the different aspects that need decisions.

Table 2 - Elements to take into consideration in the design of an epidemiological study

Type of study	**Cross sectional**		**Longitudinal**
Effects	**Disorders**		**Complaints**
	Musculoskeletal	**Vascular**	**Neurological**
Selection of the subjects	**Matched**		**Random**
Groups (nbre of subjects)	**Gv (vibrations)**		
	Ghw (heavy work)		
	Glw (light work)		
	Gwc (white-collar)		
Data collection	**Auto questionnaire**	**Checked questionnaire**	**Interview**
Personal characteristics			
Complaints			
Clinical examination			
Diagnosis tests			
Psychosocial factors			
Exposure	**Observation**	**Analysis**	**Expertise**

Tables 3, 4, 5 and 6 summarise, as examples, four epidemiological studies published in the last 10 years.

Table 3 – Characteristics of the epidemiological study conducted by Nilsson et al. (1989)

Type of study	Cross sectional		Prospective
Effects	Disorders		Complaints
	Musculoskeletal	Vascular	Neurological
Selection of the subjects	Matched		Random
Groups (nbre of subjects)	Gv (vibration): 89		
	Ghw (heavy work)		
	Glw (light work)		
	Gwc (white-collar): 61		
Data collection	Auto questionnaire	Checked questionnaire	Interview
Data collection tools			
Personal characteristics			
Complaints			
Clinical examination			
Diagnosis tests			
Psychosocial factors			
Exposure	Observation	Analysis	Expertise

Table 4 - Characteristics of the epidemiological study conducted by Bovenzi et al. (1998)

Type of study	Cross sectional		Prospective
Effects	Disorders		Complaints
	Musculoskeletal	Vascular	Neurological
Selection of the subjects	Matched		Random
Groups (nbre of subjects)	Gv (vibrations): 68		
	Ghw (heavy work)		
	Glw (light work)		
	Gwc (white-collar)		
Data collection	Auto questionnaire	Checked questionnaire	Interview
Data collection tools			
Personal characteristics			
Complaints			
Clinical examination			
Diagnosis tests			
Psychosocial factors			
Exposure	Observation	Analysis	Expertise

Table 5 - Characteristics of the epidemiological study conducted by Lundstöm et al. (1999)

Type of study	Cross sectional	Longitudinal	
Effects	Disorders	Complaints	
	Musculoskeletal	Vascular	Neurological
Selection of the subjects	Matched	Random	
Groups (nbre of subjects)	Gv (vibrations) = 125		
	Ghw (heavy work) = 45		
	Glw (light work)		
	Gwc (white-collar)		
Data collection	Auto questionnaire	Checked questionnaire	Interview
Personal characteristics			
Complaints			
Clinical examination			
Diagnosis tests			
Psychosocial factors			
Exposure	Observation	Analysis	Expertise

Table 6 - Characteristics of the epidemiological study conducted by Malchaire et al. (2001a)

Type of study	Cross sectional	Prospective (3years)	
Effects	Disorders	Complaints	
	Musculoskeletal	Vascular	Neurological
Selection of the subjects	Matched	Random	
Groups (nbre of subjects)	Gv (vibrations): 69		
	Ghw (heavy work): 62		
	Glw (light work): 46		
	Gwc (white-collar)		
Data collection	Auto questionnaire	Checked questionnaire	Interview
Data collection tools			
Personal characteristics			
Complaints			
Clinical examination			
Diagnosis tests			
Psychosocial factors			
Exposure	Observation	Analysis	Expertise

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