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## Example of a Study Protocol for training A

### Evaluation of health problems and prevalence of hearing loss in garbage collectors compared with street cleaners

Study in Germany and comparison of study results with Ecuador

Study protocol as Part of the Summer school

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## Table of content

1 Title .....	4
2 Summary .....	4
3 Study Objectives .....	4
4 Background: .....	<b>Error! Bookmark not defined.</b>
4.1 Garbage Collectors .....	<b>Error! Bookmark not defined.</b>
4.2. Street Cleaners .....	7
4.3 Aim of Study .....	7
5 Methods: .....	<b>Error! Bookmark not defined.</b>
5.1 Study Design .....	<b>Error! Bookmark not defined.</b>
5.2 Subjects .....	8
5.3. Organisation of the Study .....	8
5.4 Data Management .....	10
5.5 Ethical Aspects .....	10
5.6 Analysis of Results .....	11
5.6.1 Primary Variables .....	11
5.6.2 Secondary Variables .....	11
5.7 Advantages/Disadvantages .....	11
6 Instruments .....	12
7 Timing .....	14
8 Literature .....	<b>Error! Bookmark not defined.</b>
9 Attachment .....	17

## **1 Title**

Evaluation of health problems and prevalence of hearing loss in garbage collectors compared with street cleaners.

## **2 Summary**

Every five years street cleaners as well as garbage collectors are medically examined in the city of . This medical examination includes an audiometry. Based on these examinations, there are indications that garbage collectors are affected more often by hearing loss than other employees of the city of who are working in public places. The aim of this study is to objectify this preliminary finding as well as to evaluate hearing impairment and other health problems by a comparison with street cleaners. The study is conducted using a validated "questionnaire on working conditions and health". This questionnaire was created by BENAVIDES et al. The study results of this survey will be compared to the situation of street cleaners and garbage collectors in Ecuador.

## **3 Study Objectives**

- Evaluation of health problems in relation to the working conditions of street cleaners and garbage collectors
- Assessment of the prevalence of complaints of the musculoskeletal system and assessment of hearing impairment by audiometry.
- Evaluation of differences in complaints of the musculoskeletal system as well as in hearing loss between street cleaners and garbage collectors

## **4 Background**

### **4.1 Garbage Collectors**

Work conditions and health problems of garbage collectors have been investigated in several studies. For example in a work physiology field study the work flow and the electrocardiogram were recorded (LUTTMANN et al, 1992), the mechanical load of low back and shoulders during pulling and pushing a two-wheeled container was compared with the load during lifting and carrying the same amount of waste (SCHIBYE et al, 2001),

and the effect of different surfaces on biomechanical loading of shoulder and lumbar spine during pushing and pulling of two-wheeled containers was described (LAURSEN, SCHIBYE, 2002). In other studies the mechanical load on the low back was compared in three methods of refuse collecting (DE LOOZE et al, 1995), the mechanical and perceived workload when working with a redesigned two-wheeled container was compared to working with a standard two-wheeled container for refuse collecting (KUIJER et al, 2003) and a study was completed on the physical and physiological workload of garbage collectors (KEMPER et al, 1990).

It is shown that municipal solid waste workers have a risk of fatal occupational injuries that is much higher than for the general workforce, non-fatal injuries are mainly musculoskeletal. Other common injuries are fractures, ocular trauma and bites and diseases include skin and gastrointestinal disorders (DOREVITCH, MARDER, 2001). A study in Taiwan showed that household waste collection presents a risk for the development of chronic respiratory symptoms, musculoskeletal symptoms and injuries caused by sharp objects (YANG et al, 2001), a study in Brazil demonstrated that the age of the garbage collectors does not necessarily have an association with the occurrence of accidents at work (ALMEIDA et al, 2009), while a study in Denmark found a decreased number of injuries with increasing seniority and age. Most often injured was the back, followed by the knees, hands and feet (IVENS et al, 1998).

The literature search shows that a lot of studies focus on the musculoskeletal problems of garbage collectors (POULSEN et al, 1995). To reduce physical workload, KUIJER et al (1999) investigated the effect of job rotation. After the introduction of job rotation, every employee was allowed to alternate between two or three possible jobs during the day, i.e. refuse collecting/street sweeping, refuse collecting/driving or street sweeping/driving. The results indicate that the total amount of work performed by means of job rotation resulted in an overall reduced physical workload of the employees of the refuse collecting department. Another study compared the work demands, workload and recovery among truck driving, refuse collecting and rotating between these two jobs, between days and during the day. Job rotation between driving and collecting is an effective measure to reduce physical workload as compared with collecting only and to decrease mental workload as compared with driving only. However, job rotation resulted in increased physical workload as compared with driving only. Job rotation did not increase mental workload as compared with collecting only. No effects were seen on recovery. No

differences were found between rotating between days and during the day (KUIJER et al, 2004). The effect of job rotation in refuse collecting on need for recovery, prevalence of musculoskeletal complaints and sick leave due to musculoskeletal complaints was evaluated. Job rotation seemed to coincide with a reduced need for recovery and was associated with an increased risk of low back complaints. No effects were found on sick leave due to musculoskeletal complaints (KUIJER et al, 2005). Whole body vibration is seen as an important risk factor for back complaints. Not only the truck driver, but also the garbage collectors are exposed to whole body vibration while sitting in the refuse truck or standing on the riding steps at the back of the truck. The exposure might be higher than in a normal truck due to the mechanical system that empties the wheeled container, the mechanical compression of the collected refuse in the cargo space and the fact that city streets are often less smooth than asphalt roads (KUIJER, FRINGS-DRESEN, 2004).

Various investigations show that garbage collectors may suffer from work-related respiratory disorders: It was shown that exposure of garbage collectors to bio- aerosols or domestic waste induced upper airway inflammation (HELDAL et al, 2003, WOUTERS et al, 2002) or exaggerated pre-existent airway inflammation during the workweek (DE MEER et al, 2007) and that bio-aerosol exposure during waste collection induced an inflammatory response in the lower airways (HELDAL et al, 2003) or can cause allergic bronchopulmonary aspergillosis (ALLMERS et al, 2000). Sanitation workers may develop lung function changes, in the first place those of FVC and FEV1 (MUSTAJBEGOVIC et al, 1994). Danish studies show that garbage handling induced a small but significant risk of occupational asthma (SIGSGAARD, 1999) and that garbage collectors had a significantly higher prevalence of flu-like symptoms and sore or itching throat compared to water-supply workers (SIGSGAARD et al, 1994). In a Swedish study it was shown that certain dusts from household waste caused airway inflammation as well as general symptoms, e.g. diarrhoea (THORN et al, 1998). Some other investigations reported that garbage collectors suffered from gastrointestinal problems. One study showed a causal relation between gastrointestinal problems and the job of waste collector. More symptoms occurred during the summer (IVENS et al 1997). An exposure-response relationship was found between nausea and endotoxin exposure and between diarrhoea and exposure to endotoxins and fungi (IVENS et al, 1999)

## **4.2. Street Cleaners**

Work condition and health problems of street cleaners also have been investigated in several studies. MARZIALE and DE CARVALLO (1989) reported that cuttings and contusion wounds were responsible for the absent time of workers in a period between zero to ten days. An increased prevalence of disorders of elbow, wrist/hand and cervical spine which could be caused by work organisation and non ergonomic tools was found in an Italian study (DE VITO et al, 2000)

It was shown that street cleaners in India had a higher risk of chronic respiratory morbidity in comparison to people working in office buildings (YOGESH, ZODPEY, 2008). In Nigeria female street cleaners working less than 2 years were examined. Compared to a control group there was a significantly higher prevalence of back pain, cough, chest pain, catarrh and sneezing (NKU et al, 2005)

## **4.3 Aim of Study**

The study has the aim to detect health problems and the prevalence of hearing loss in garbage collectors compared with street cleaners in the city of . Every five years street cleaners as well as garbage collectors are medically examined. Audiometry is part of the medical examination. There are indications that garbage collectors are affected more often by hearing loss than other employees of the city of working in public places. A potential cause could be the noise of the garbage collector trucks or the reflection of the sound in high-density areas. The aim of this study is to investigate if there are significant differences in hearing ability of garbage collectors compared to street cleaners, after correction for other causes such as potential age differences between both populations. In , the residents get a “full service”, which means that garbage collectors have to pick up the bins e.g. from the basement and that they have to carry it upstairs and cross the yard to the refuse truck. The refuse trucks have an automatic lifting device to empty two-wheeled containers or four-wheeled containers. An average work day of a refuse collector lasts about eight hours. The work is performed by male employees. Three garbage collectors are forming a team (excluding the driver). One refuse collector is running ahead of the refuse truck to collect the full dustbin and move it to the kerb, the second refuse collector is activating the automatic lifting service, the third refuse collector works behind the refuse truck to place back the empty dustbins to the respective houses. The tasks are rotated once a week between the refuse collectors. The street cleaners are cleaning the street manually, some of them also use power cleaners.

## **5 Methods**

### **5.1 Study Design**

The study will be conducted according to a transversal study design. A transversal study allows to measure the exposure and the prevalence of a disease simultaneously. This type of study design allows to obtain information on the prevalence of a disease or of healthy complaints at a particular time and to get first information on a relationship between exposure and disease. The study design has the following advantages:

- the study is simple and quick and allows to get a quick overview
- multiple aspects of exposure and disease can be measured at the same time
- the time needed for the study participants is acceptable
- there are no high costs for the implementation of the study
- the study design is in particular suitable to detect the prevalence of chronic health conditions and diseases such as problems of the musculoskeletal system or hearing loss, unless these conditions strongly correlate with outflow from the occupational population studied

The study is descriptive.

### **5.2 Subjects**

In the city of 223 garbage collectors and 208 street cleaners are employed. At least 100 employees of each group will be entered into the study. People who quitted the job of garbage collectors or street cleaners within the last year will also be entered. A written informed consent is needed before entering the study.

The study results will be compared with the study results of garbage collectors and street cleaners in Ecuador.

### **5.3. Organisation of the Study**

Before starting with the study, all subjects will be informed orally about the study and its aims. All subjects who have given written informed consent will be handed out a questionnaire. We decided not to perform a personal interview because a study with Danish garbage collectors indicates that caution should be exercised when pooling data collected by self-administered questionnaires and telephone interviews in epidemiological



research. Some types of questions may be sensitive to the data collecting method (VAN OOIJEN et al, 1997).

The standardized and validated “questionnaire on working conditions and health” (BENAVIDES et al) will be used (translated into German). The questionnaire has the following advantages:

- this questionnaire has been shown in previous studies to be useful
- the questions are useful for a survey of working conditions in international comparative studies
- a comparison between different countries is possible, nevertheless cultural and other differences between countries and subpopulations within countries should be kept in mind.

This standardized questionnaire will be completed by the Standardised Nordic questionnaires for the analysis of musculoskeletal symptoms (KUORINKA et al), some questions from the European Community Respiratory Health Survey (BURNEY et al) and the following questions:

- Before starting your work as garbage collector or street cleaner, how many years did you work in a place, at which communication at a distance of one meter was only possible by loud talking during at least two hours a day?
- Do you feel to hear less? Did you therefore visit an audiologist or a physician?
- Did you use hearing protection at your previous job always or nearly always?
- How many hours a week are you listening to loud music?
- Before starting your work as garbage collector/ street cleaner, how many years did you work in a place or did leisure activities where you carried regularly more than 20 kg or worked in extreme posture (overhead activities, kneeling activities, activities with extreme flexion of the trunk)?
- If you are not working as a garbage collector or street cleaner any more: Did you leave the job primarily for health reasons
- If you are not working as a garbage collector or street cleaner any more: Did you leave the job because of your age that caused too much problems in functioning at work?

The questionnaires will be provided with a study number and will be anonymous. The written informed consent will have the same study number as the questionnaires. With the help of the name of the participant in the written informed consent the questionnaire will be associated with the audiometry which was done in the department of the Occupational Health Service of the city of . The link of the name of a participant to the questionnaire is only possible by the investigator, the written informed consent will be kept in a security container; the questionnaires will be kept in another place that is locked.

Only audiometries which have been carried out within the last five years will be included in the study. If a participant has not completed an audiometry during the last 5 years, an audiometry will be completed during the study. The dates of the audiometries will be noted for the study.

Two weeks after handing out the questionnaires, the employees will be reminded by mail to return the questionnaires. After two more weeks, the participants who have not returned the questionnaire will be reminded again and they will be handed out a new questionnaire. After two more weeks, participants will be asked by telephone to return the questionnaire. After another 2 weeks, the participants one last time will be asked by telephone to return the questionnaire or to tell about the reasons for the non-participation.

As a first assessment of the noise exposure, at random chosen participants will obtain a noise-dosimeter during a working day, also chosen at random. Dosimeters are used for employees who work in downtown as well as for employees who work in the suburbs. Four employees who work in downtown and four employees who work in the suburbs will obtain a noise-dosimeter for one day to get a first impression.

#### **5.4 Data Management**

The questionnaires are numbered. Part of the data will be entered twice into the data base by independent persons. The results will be sent to the CIH Centre in Munich. There, both versions are compared for errors. The data are entered at Epiinfo. The data will be saved each day and in addition they will be stored separately to an external hard disk that will be stored in a separate place. The questionnaires are kept locked in a safe place.

#### **5.5 Ethical Aspects**

The study will be conducted according to the protocol. The subjects will be given comprehensive verbal information about objectives and procedures. Written informed

consent must be obtained prior to the start of the study. Subjects have the right to withdraw from the study at any time, even without giving the reasons.

The study includes an anonymous questionnaire and an audiometry. Invasive procedures are not performed. The subjects receive the results of the study by mail. Additionally, the study results will be presented and explained in a staff meeting. The employer will be informed about the overall results of the study, the results of individual questionnaires and results of small groups (less than 15 persons) are fully confidential.

## **5.6 Analysis of Results**

### **5.6.1 Primary Variables**

The primary outcome variable of the study is the hearing impairment of garbage collectors and street cleaners.

The results are influenced by the age of the subjects, years working in high noise levels at work as a garbage collector or street cleaner, total years working in jobs with noise exposure, noise exposure in their leisure time, and by substantial interindividual differences in susceptibility for noise-induced hearing loss and for presbycusis.

### **5.6.2 Secondary Variables**

The secondary outcome variable of the study is health problems referring to musculoskeletal problems.

The results are influenced by the age of the subjects, years working as in unergonomic working conditions as a garbage collector or street cleaner, total years working in physically demanding jobs or inappropriate ergonomic load in the leisure time.

## **5.7 Advantages/Disadvantages**

The study provides a quick overview of health problems in relation to musculoskeletal disorders and hearing loss in the studied populations. An investigation of a causal connection is not possible with this study design. Health problems of a short duration cannot be detected by this study design; health conditions causing many drop-outs are difficult to detect as well. It is presumed that more employees suffering from health problems will participate in the study than employees without health problems, so there could be a bias in the results of the study.

## 6 Instruments

We use a standardized questionnaire, which will be combined with already completed audiometries of the participants. In the department of Occupational Health Service of the city of        an audiometer is available:

Technical information:

Audiometer: Siemens SD 26, corresponding DIN 45620, DIN 45624

Calibration:    DIN ISO 389/389.A1 for headsets

                  DIN ISO 7566 for headsets for bone conduction

                  DIN ISO 8798 for masking noise

Service:        service and calibration each year corresponding §11 MP-BetriebV, safety-related service corresponding §6 MP-BetriebsV, done by company Dippacher, last time 25.08.2009

The audiometries are done in an extra room (internal room without windows) with little external noise. Unfortunately there is no sound booth. All the audiometries are done with at least 14 hours out of noise exposure.

There are principles for occupational health screening examinations, published by the German Statutory Accident Insurance. The audiometries will be valued according to the principle “noise” (G20-Lärm). The sum of the hearing loss at 2,3 and 4 kHz of the better hearing ear of an employee will be used and compared with the initial audiometry. The initial audiometry means the audiometry done at the beginning of a job as garbage collector or street cleaner, it is not the audiometry done before someone started working in a job with noise exposure (unfortunately these audiometries done in other companies are not available).

Only audiometries of employees working at least 5 years as garbage collector or street cleaner will be considered. Employees working less than 5 years as garbage collector or street cleaner are allowed to be included in the study, but the audiometries will not be considered.

Employees who never worked in a job with noise exposure and their hearing loss exceed the limit permitted in the table 1 are allowed to be included in the study, but the audiometries will not be considered.

The sum of the hearing loss at 2,3 and 4 kHz of a garbage collector and a street cleaner in the same age-group also will be compared (see table 1).

The sum of the hearing loss at 2,3 and 4 kHz will be correlated with the maximum permissible value of the age of an employee corresponding to table 2 (to avoid a bias caused by the age of the employees).

Employees suffering from aerotympanal conduction problems will get an audiometry with bone conduction. The audiometries will be valued according to the principle "noise" (G20-Lärm).

Age L in years	Frequency in kHz				
	1	2	3	4	6
	Hearing Loss in dB				
$L \leq 30$	15	15	20	25	25
$30 < L \leq 35$	15	20	25	25	30
$35 < L \leq 40$	15	20	25	30	35
$40 < L \leq 45$	20	25	30	40	40
$L > 45$	20	25	35	45	50

table 1: initial examination (persons who never worked in a job with noise exposure): limit of hearing loss (aerotympanal conduction)

Age L in years	Sum of hearing loss at 2,3 and 4 kHz in dB
$L \leq 20$	65
$20 < L \leq 25$	75
$25 < L \leq 30$	85
$30 < L \leq 35$	95
$35 < L \leq 40$	105
$40 < L \leq 45$	115
$45 < L \leq 50$	130
$L > 50$	140

table 2: follow-up examination (persons who already worked in a job with noise exposure): limit of hearing loss (aerotympanal conduction)

## 7 Timing

June 2010: Final protocol version

July/August 2010: Presentation of the project to the Employee Committee and small pilot study with 6 subjects: 3 garbage collectors / 3 street cleaners, with the aim of reformulating unclear issues and testing the audiometry. Submit the study to the Ethics Commission.

September 2010: start of the study

November / December 2010: arranging the missing audiometries

March 2011: statistical analysis

July 2011: Evaluation of the project, presentation of study results to participants and to the employer.

## 8 Literature

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## **9 Attachment**

written informed consent

questionnaire