

# ***Proposal on guidelines for the collection and analysis of routine occupational health data***

by

Moens G<sup>1,2</sup>; Mylle G<sup>1</sup>, Johannik K<sup>1</sup>; De Raeve H<sup>1,2</sup>;  
Stragier Y<sup>1</sup>; Viaene B<sup>1</sup>; Lahaye D<sup>1,2</sup>; Jacques P<sup>1,2</sup>

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## **Abstract**

*A research project financed by the Federal Services for Scientific, Technical and Cultural Affairs (SSTC-project ST/93/003) proved that it is meaningful to routinely register data about health and exposure, that is if a number of guidelines are followed for the optimal and qualitative registration and analysis of these data pertaining to health in the workplace.*

*An important aim of the subsequent project (SSTC-project PS/93/06) is to put these guidelines together and to distribute them.*

*These guidelines relate, among others, to the following aspects:*

- defining the goals of the registration,*
- standardising (a.o. internationally),*
- assuring quality and quality-control,*
- epidemiological methodology and applicability,*
- privacy.*

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<sup>1</sup> IDEWE, External Service for Prevention and Protection at Work, Leuven (Belgium)

<sup>2</sup> Catholic University of Leuven, Faculty of Medicine, Department of Occupational, Environmental and Insurance Medicine, Leuven (Belgium)

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## **Introduction and situation**

The Belgian External Service for Prevention and Protection at Work, IDEWE, has been storing a database since 1987 containing data which are recorded at the moment of medical examinations among all the employees subject to medical supervision. Annually, data are thus recorded for over 200,000 employees. The registration deals with potential determinants of health damage – e.g. exposure to physical and chemical agents, psychosocial factors and work organization – but also with health effect variables such as complaints and clinical events. The occupational physicians and nurses record this information onto optically readable registration forms. These forms are scanned into a database at the Central Research Unit.

A research project has been set up (ST/93/003) in order to evaluate the usefulness of routinely collected data within the occupational health care system in detecting health problems in the workplace. The results of this project proved that the characteristics of health and exposure problems can be traced by means of aggregated-level analyses of these data. Extensive reports and publications have been issued on this matter, and a number of reports and publications are still in preparation (1-27).

In the project, it was demonstrated that the registration of health and exposure data is meaningful, on the condition that a number of guidelines are followed relating to the registration and the analysis of these data. The design and distribution of these guidelines is one of the goals set by a subsequent project (PS/93/06), which aimed to further assess the value of the registration instrument. In order to substantiate this value, initiatives have also been taken to set up user groups. These groups consist of representatives of the potential users (internal and external). In addition, the registration instrument will be followed up, readjusted and restructured on the basis of the analyses and of substantial guidelines.

In recent years, the international interest for the registration of occupational health data has increased. An indication of this was the publication by the International Labour Organization (ILO) in 1998 of technical and ethical guidelines for health surveillance of employees (28).

Further, the 'Good Practices in Health Environment and Safety Management in Enterprises' (GP-HESME) programme was started up in

2000 by the World Health Organization Europe (WHO/EURO). The design of standardized health indicators is a crucial part of this programme (29).

Recently, OSHA (30), WHO-ILO (31) and European Community funded project Work health (32) publications have addressed the same issue.

As a matter of fact this text is not meant to cover the entire field of data registration in occupational health. It must be seen as a discussion document and is only one element in the large discussion regarding this matter. At the same time it is the summary of experiences with research about this matter. Others in the field can profit from this experience if they want to set up a registration in their work setting.

This text is in the first place directed at professionals in the occupational health field, but also to interested parties who are confronted with or interested in the use of registered data: scientific institutes, professional institutions, the government and others.

## **DESIGN OF GUIDELINES**

The guidelines for a qualitative collection of routine data pertaining to health in the workplace relate, a.o., to the following aspects:

- 1) defining the goals of the registration,
- 2) choice and standardization of variables (e.g. internationally),
- 3) assuring quality and quality-control,
- 4) epidemiological methodology and applicability:
  - the type of data (e.g. reported complaints versus clinical conclusions or laboratory results),
  - the role of the latency period between exposure and health outcome,
  - the prevalence of the exposure and health outcome,
  - the role of selection phenomena when interpreting the signals.
- 5) privacy.

### **1. Defining the goals of the registration:**

When setting up a registration system, it is crucial to clearly state the goals beforehand. Each user of the system should, at the moment of recruitment, and at regular intervals later on, be informed about these goals. Through questioning, remarks about the feasibility and suggestions for readjustment of the goals can be collected.

In this project the following (non-limiting) goals have been retained:

*1.1 Optimizing the epidemiological usefulness of the collected data:*

- The items registered by the occupational physician should be well-standardized and reliable: these supply general indicators of health, but also data which can lead to a better insight into the relation between work and health. Therefore, a link should be established between objective exposure data, collected through the risk analysis, and subjective exposure data, obtained through medical examinations. ILO guidelines as well mention a necessary link with environmental surveillance (28). The registration of objective exposure data can, in the long run, lead to a detailed inventory of the distribution of risks across various sectors and occupations. The measuring instruments for collecting data needed here, as well as the measuring techniques to be applied and the proceeding of the registration of these data, are being developed at this moment, based on the findings in project ST/93/003.
- On the basis of the signals collected through the system, focused analytic studies can then be conducted in a controlled research environment.
- Finally, the system should also allow for primary preventive actions and interventions to be evaluated, again in a controlled research environment.

The criteria for epidemiological use itself are discussed in point 4 of this draft. There, the choice of the measuring instruments is discussed, e.g. a questionnaire for self-reporting or a registration instrument operated by the occupational safety and health advisor (e.g. a paper or electronic form).

*1.2 Better focusing of the medical examination:*

The medical examination should be focused rather on a situation and a problem context. Therefore, specific modules should be developed, e.g. sector- or occupation-specific.

*1.3 Increasing the practical usefulness in relation to the follow-up of the individual employee:*

This presumes:

- Longitudinal follow-up of the evolution of the health of the individual employee.

- Linking the results of the medical examination to:
  - \* The results of the visit of the work place (28)
  - \* The results of the risk evaluation and monitoring of the working environment (28)
  - \* The results of biological monitoring

A problem with goals 1.2 and 1.3 could be the validity of a comparison of individual data with baseline data, especially in sectors or occupations in which the workload is already high. Also at group level this could be a problem. This will also be discussed in point 4.

#### *1.4 Improved standardization of occupationally related risks:*

It is useful to construct risk profiles per industrial sector and per occupation by linking the data on sector and occupation (NACE/ISCO-code) to the results of the visits of the work place, and to those of the risk evaluation and of the biological monitoring. The draft of a job exposure matrix (JEM) for each individual, in which intensity, duration and nature of the exposure will be noted in a timeframe, will give a quantitatively better assessment of the real exposure in occupations and sectors. This JEM will also prove to be useful in the epidemiological use of the data.

#### *1.5 Optimizing and simplifying the administrative aspects:*

These aspects are obviously important, but are left out of the goals of the registration system for data on health in the workplace.

#### *1.6 Policy consequences and social use:*

Registration can claim a certain representativity (e.g. for groups of sectors or professions), so that data can be used not only for internal policy and priority determinations of the registering service, but have a broader social importance as well.

In addition, the registered data should support at least three interests:

1. Offer relevant information for the individual follow-up of the employee.
2. Offer relevant information for follow-up and reporting on the micro-group level about the status and evolution in health indicators, and in exposure and risk indicators (e.g. at professional, sector and company level).
3. Offer relevant information for follow-up and reporting on the macro-group level (epidemiological processing, timely signals) about the status and evolution in health indicators, and in exposure and risk indicators (e.g. at professional, sector and company level).

## **2. Choice and standardization of variables (national and international):**

If the registration system is efficient and user-friendly, the focus should be on arrangements for the registration of a basic set of health and risk variables within a national and possibly international context. Within the scope of the project, a proposal was formulated to define sets of variables which can be recorded or not, according to the situation. Thus, certain characteristics could be registered mandatorily (e.g. age, sex, profession, weight, length, industrial accident, sick leave, sporting and smoking habits, decision regarding capacity for work). Other situational variables could vary (e.g. assessment of working conditions, therapy, clinical complaints and findings).

ILO guidelines (28) mention 4 criteria which determine the choice of the variables to register: necessity, relevance, scientific validity and effectivity (in directing preventive actions).

Several organizations are devoting efforts in finding international agreement in this matter: among others, the Dutch Foundation for Quality in Occupational Health Care (SKB) in Amsterdam, the ICOH-Scientific Committees 'Occupational epidemiology' and 'Occupational health services research and evaluation', the 'European Agency for Safety and Health at Work' (Bilbao) and the 'European Foundation for the Improvement of Living and Working Conditions' (Dublin), the WHO/EURO in the frame of the HESME (29) and other programmes (30-32), and the ILO (28).

As a matter of fact, the comparability with important existing health registrations or surveys on federal and regional level is also important (e.g. Health Interview Survey (33)).

## **3. Assuring quality and quality control:**

Quality control of registration takes an important place in the ILO guidelines (28). By quality promotion and control we understand the range of procedures that allow:

- a) A systematic evaluation and control of the validity of the collected data, linked to focused actions for improvement. To this purpose, focused studies for the role and extent of selection bias can be performed (external validity) as well as focused validity studies of specific registered characteristics (internal validity). An illustration of such an approach is the validation of the registration of sick leave by the occupational physicians by comparing it to the

self-reporting and to the registration by the human resources department of a company or an institution (3).

- b) A systematic evaluation and control of the **reliability** of the collected data, linked to focused actions for improvement. To this purpose, focused studies for the role and extent of observation bias can be performed. Also the statistical method for the estimation of the 95% confidence interval of the registration prevalence for each variable and each observer (corrected for selection bias), as performed in the scope of the project (5,35) can give a rough idea of the interobserver variability.

This statistical method has the following rationale:

If more than one observer records the same kind of data, one can ask how reliable these data are. To what extent do these observers consistently record the same for the same observations?

The method used is the calculation of the 95% Confidence Interval (CI) per physician/nurse and per variable. Each observer is situated in relation to the global IDEWE recording proportion. If registration is reliable, and assuming a random sample, it can be estimated that the 95% CI of each observer will enclose the population proportion. If this is not the case for a certain observer and a certain variable, we can conclude that the recording proportion of this observer differs significantly from the population recording proportion. The more observers there are with a significantly different recording proportion, the worse the consistency and reliability of the registration will be.

However, selection bias can lead to the wrong conclusions. It is possible that an observer for whom an over- or underreporting is noted, is observing a selected group for which the proportion indeed is lower or higher than the proportion in the population. By means of multivariate techniques (e.g. logistic regression), we can standardize for possible selection factors such as age and profession. In this way, influences from age and profession on the recording proportion of a certain variable can be corrected for. After correction, differences in proportion can therefore be ascribed to systematic errors. The origin of these errors can then be investigated.

The 95% confidence interval (CI) is calculated with following formula:

$$95\%CI(\pi) = p \pm 1,96 \sqrt{\frac{p(1-p)}{n}}$$

for each observer is  $\pi$  = population recording proportion  
p = sample recording proportion  
n = number in sample

This means that with 95% confidence, this interval will enclose the observers' proportion. If this interval encloses the population proportion as well, we can conclude that the observers' proportion does not differ significantly from the population proportion.

Through calculation of the percentage of observers for whom the CI encloses the population proportion, we can detect the variables for which selection problems (other than age or profession) probably occur.

Table 1 gives an illustration of the method, displaying the number of observers per variable for which the CI encloses the population proportion (noted as "matching CI").

Two trends become clear from this table:

- 1) For some variables, we find a limited number of matching CIs and an agreement between genders for observers with a deviating CI. This leads to the assumption of a systematic over- or under-reporting.
- 2) Some physicians score for the different clinical variables always higher or lower than the mean score. Since scores have been corrected for possible confounders such as age and profession, this also suggests a systematic over- or underreporting as compared to colleagues.

Finally, the flow of information should be optimal in order to promote the validity and the reliability of the registration system. This actually comes down to an improved way of valorization of the recorded data by informing people about the use of these data, and to a better support of the users of the registration system.

These guidelines are therefore related to:

- 1) setting up and maintaining an optimal flow of information and feedback;
- 2) evaluating, promoting and guarding the reliability;
- 3) evaluating, promoting and guarding the validity.

These points are explained hereafter.



TABLE 1: Number of observers per variable  
for whom the CI encloses the population proportion

Qualitative variables, measured by the occupational nurse.

Variable	MEN			WOMEN		
	Total CI number	Matching CI number	%	Total CI number	Matching CI number	%
Industrial accident	66	44	67	74	45	61
Sick leave	67	32	48	74	27	36
Smoking habits	67	41	61	74	45	61
Sporting habits	66	22	34	74	35	47
Urine tests	66	31	47	74	24	32

Qualitative variables, measured by the occupational physician.

Variable	MEN			WOMEN		
	Total CI number	Matching CI number	%	Total CI number	Matching CI number	%
Job assessment	57	39	69	63	44	70
Conflict situations	58	40	68	66	45	68
Discomfort	50	24	48	50	13	26
General impression	75	30	40	75	30	40
Treatment	69	33	48	71	28	39
Locomotor system	76	18	24	73	21	29
Nervous system	74	28	38	75	23	31
Respiratory system	75	32	43	75	35	47
Coronary system	75	52	69	74	44	59
Vascular system	72	42	58	72	32	44
Hormonal system	73	20	27	73	24	33
Lymph nodes	58	32	55	64	42	66
Digestive system	75	37	49	74	40	54
Urogenital system	68	50	74	63	20	32
Skin	75	30	40	70	25	36
Mouth and teeth	73	11	15	73	17	23
Nose and throat	71	27	38	73	29	40
Hearing	75	32	43	71	27	38
Load	66	33	50	62	27	44
Decision on work ability	76	30	40	76	26	34

### 3.1 Optimal information and feedback

Feedback of the results both to those who perform the registration and to the employees, the company or other interested parties, is essential in a health quality circle. Such a feedback, e.g. in the form of a report, must be easily understandable for laymen and will, in general, involve a comparison with adequate reference groups, such as the industrial sector, the professional group, the entire database or selections from it. Here are some of the initiatives for feedback realised in the project:

- \* Annually, the occupational physicians using the registration system in companies with 50 or more employees receive a survey of the prevalence figures for the main health abnormalities. Those figures are sex specific and standardized for age and are being compared to the results of the entire database or the sector. The choice of 50 employees as lower limit is statistically motivated. The statistical significance calculation of differences between index and control group turns out to be unreliable for groups smaller than 50. A clear manual, in which the legend of the survey and the interpretation of the results are explained, is joint to these surveys. Among others, it is stressed that no causal relations can be deduced from these cross-sectional data (see goal 4). The problem, as mentioned in 1.3, of the validity of a comparison of group data with baseline data especially in industrial sectors or professions with high workload is faced here.  
These standard surveys can also be generated through the computer (on line). As an example, Figures 1 and 2 show the prevalence surveys of female and male nurses in 2005.
- \* The registering professionals are informed that one person at the central research centre collects problems, questions and suggestions. These are then presented for further discussion to the guidance team, which meets at regular intervals.
- \* The registering professionals are informed regularly, through training and informative sessions, about the state of affairs regarding the registration instrument and the results of the studies conducted.

### *3.2 Evaluation and improvement of the reliability*

- \* At the central research unit an inventory of the problems and the remarks of the users of the registration instrument is made.
- \* The manual accompanying the registration system is completed with the adjustments made by the guidance team.
- \* Newly employed prevention consultants are trained in the use of the registration instrument.
- \* The reliability is evaluated systematically by means of statistical techniques, which assess the interobserver variability (see higher) (5,34).
- \* The reliability of the measuring-apparatus is guaranteed through regular gauging in a procedure of quality assurance.

### *3.3 Evaluation and improvement of the validity*

- \* An inventory is kept of the results of previous and current validation studies.

Figure 1:  
Prevalence survey of male nurses in 2005



PREVALENTIES GESTANDAARDISEERD NAAR LEEFTIJD

Jaargang 2005 - Mannen  
M.I.S.I.  
Beroep

Aantal  
115971  
3110

Table 2: Prevalence survey of male and female nurses in 2005

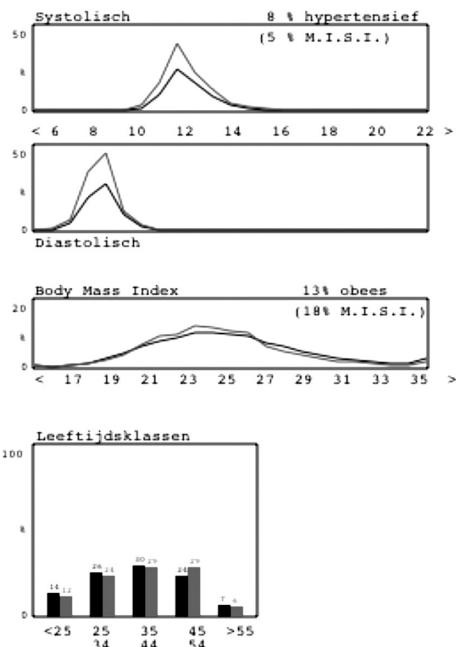
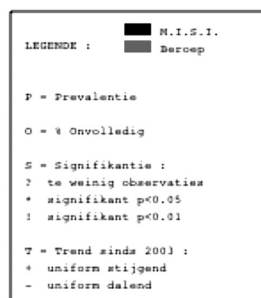
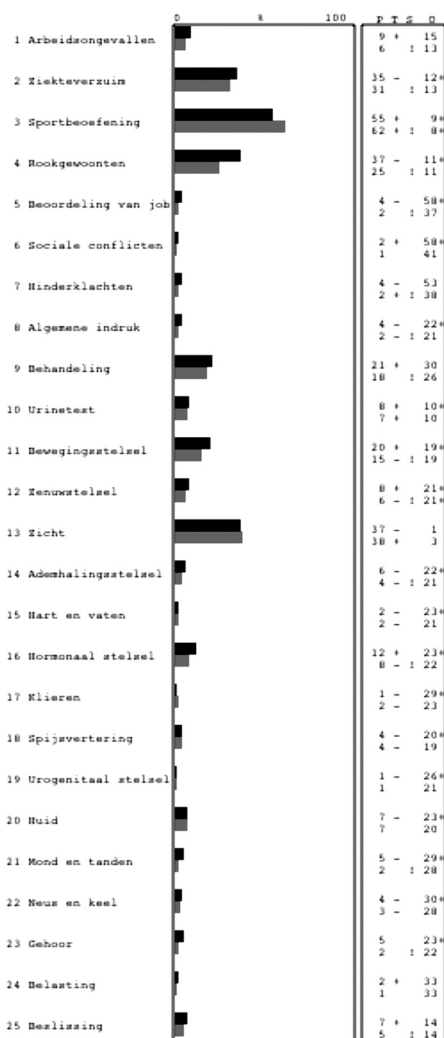


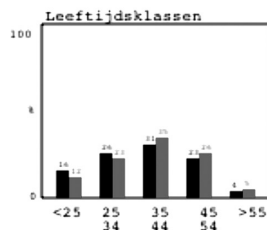
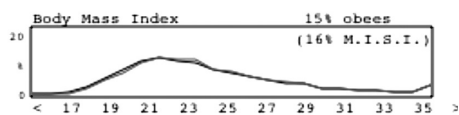
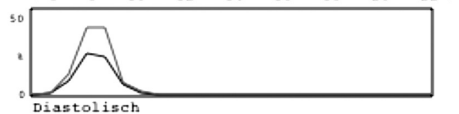
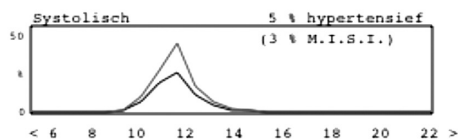
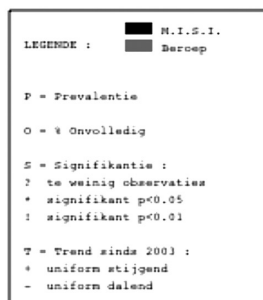
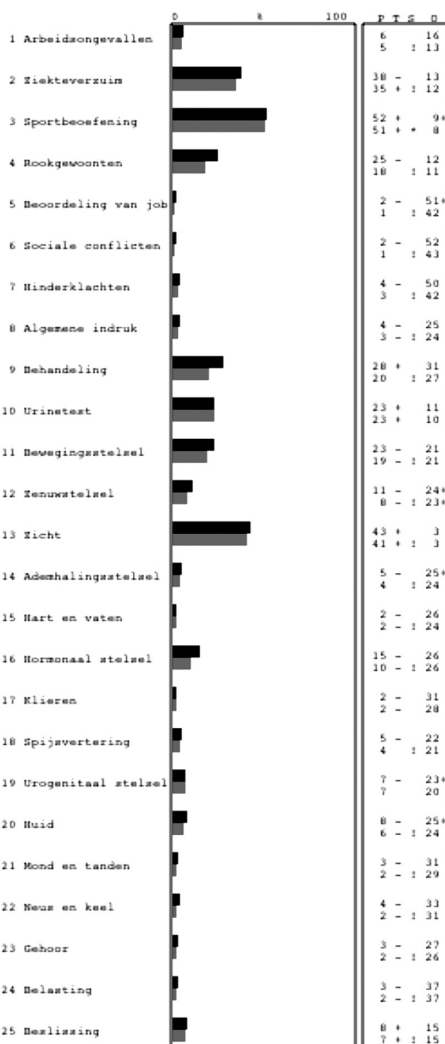
Figure 2:  
Prevalence survey of female nurses in 2005



PREVALENTIES GESTANDAARDISEERD NAAR LEEFTIJD

Jaargang 2005 - Vrouwen  
M.I.S.I. 106243  
Beroep 23244

Table 2: Prevalence survey of male and female nurses in 2005



## Legend (for Figures 1 and 2):

1. Arbeidsongeval	→ Industrial accident	P = Prevalentie	→ Prevalence
2. Ziekteverzuim	→ Sick leave	O = % onvolledig	→ % incomplete
3. Sportbeoefening	→ Practicing sports	S = significantie	→ Statistical significance
4. Rookgewoonten	→ Smoking habits	? = te weinig observaties	→ Not enough data
5. Beoordeling van de job	→ Job assessment	* = significant $p < 0,05$	→ Significant, $p < 0.05$
6. Sociale conflicten	→ Social conflicts	! = significant $p < 0,01$	→ Significant, $p < 0.01$
7. Hinderklachten	→ Hindrance complaints	<hr/>	
8. Algemene indruk	→ General impression	T = Trend sinds 2003	→ Tendency since 2003
9. Behandeling	→ Treatment	+ = uniform stijgend	→ Upward trend
10. Urinetest	→ Urinary test	- = uniform dalend	→ Downward trend
11. Bewegingsstelsel	→ Locomotor system	<hr/>	
12. Zenuwstelsel	→ Nervous system	Systolisch	→ Systolic blood pressure
13. Zicht	→ Sight	5% hypertensief	→ 5% was found hypertensive
14. Ademhalingsstelsel	→ Respiratory system	(3% MISI)	→ (3% in total IDEWE population)
15. Hart en vaten	→ Heart and blood vessels	Diastolisch	→ Diastolic blood pressure
16. Hormonaal stelsel	→ Hormonal system	Body Mass Index	
17. Klieren	→ Glands	15% obees	→ 15% was found obese
18. Spijsvertering	→ Digestive system	(16% MISI)	→ (16% in total IDEWE population)
19. Urogenitaal stelsel	→ Urogenital system	Leeftijdsklassen	→ Age categories
20. Huid	→ Skin		
21. Mond en tanden	→ Mouth and teeth		
22. Neus en keel	→ Nose and throat		
23. Gehoor	→ Hearing		
24. Belasting	→ Work load		
25. Beslissing	→ Decision		

\* Diagnostic standard criteria, and criteria for standardized measuring circumstances, need to be put together and distributed in collaboration with representatives from the curative sector. For certain pathologies, such as occupational disorders of the superior limbs, this has already been done (35).

#### 4. Epidemiological methodology and applicability:

Goldberg and Imbernon (34) discuss in detail the purpose, the design and the epidemiological applicability of a computerised occupational health file. In what follows, the most important points are briefly discussed.

The data which have been collected through routine registration are, in principle, used in descriptive cross-sectional analyses: as a report on the state of health and, linked to it, as a signal system.

Then, focused analytical epidemiological studies can be conducted on the basis of these signals (type case-control, cohort or intervention studies).

- 1) First a criterion for prevalence is determined. This means that the health outcome, complaint or diagnosis should occur with a particular frequency in order to be formally included in the analysis. As a minimum, 1 per 1,000 can be suggested. A registration system as the one described here is not sensitive enough to trace clusters of rare health events. These clusters should be tackled through other procedures such as the 'Guidelines for investigating clusters of health events' from the Centres for Disease Control (36).
- 2) Each health related event can be registered in code (e.g. a version of ICD-9-CM or -10 (37) or the CAS-classification (38)). This will strongly enhance the processing capacity of the data (fewer corrections, no string variables). In every day practice, the accurate coding of diagnoses or complaints is only feasible by means of an 'intelligent' medium for registration, which can attribute codes automatically and quickly. Apart from the health-related classification, a useful and valid classification of working conditions, exposures and risks is needed. The Dutch CAS-classification seems to be useful to some extent. However, practice oriented research will have to confirm this.
- 3) Results can only have an adequate internal and external validity if important sources of selection and observation bias and of confounding can be assessed and reduced (see analytical studies). Decisions such as the choice of the measuring instrument (e.g. self-reports or registration by a professional) depend on this. Last of all, we recall the problem as mentioned in 1.3 of the validity of a comparison of baseline data, especially in industrial sectors and professions with high workload.

These applications can be illustrated by the figures 3 to 7:

As far as descriptive longitudinal analyses and analytical studies are concerned (cause and effect-relations), the usefulness of the system will depend on the following factors:

- 1) The possibility to assess selection bias: the healthy worker effect and other forms of selection bias, e.g. through the changes in the

Figure 3:  
Mean BMI per age category in 1993 and 2005 - Females

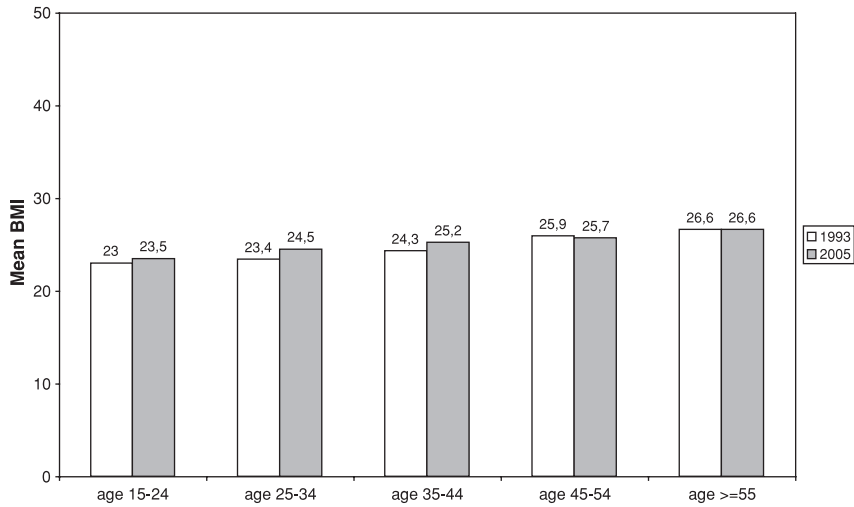


Figure 4:  
Mean BMI per age category in 1993 and 2005 - Males

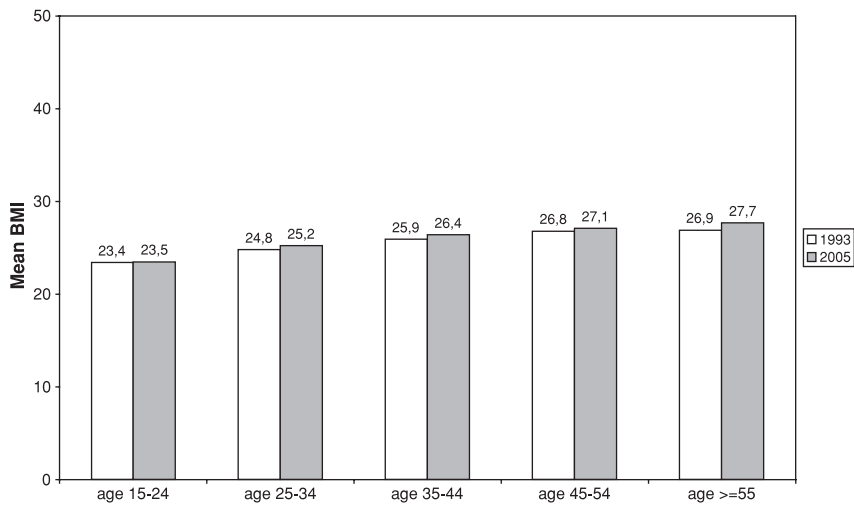


Figure 5:  
Evolution of smoking habits 1993 - 2005

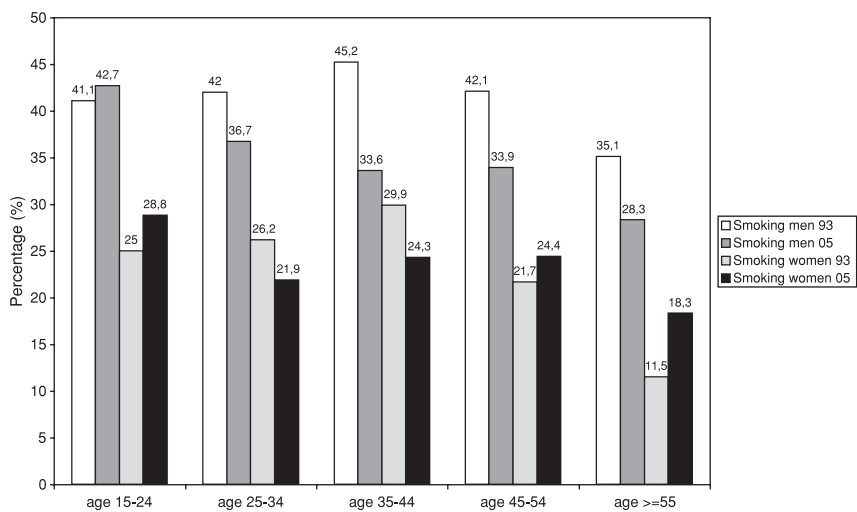


Figure 6:  
Evolution of systolic hypertension 1993 - 2005  
(systolic hypertension = systolic blood pressure > 140 mm Hg)

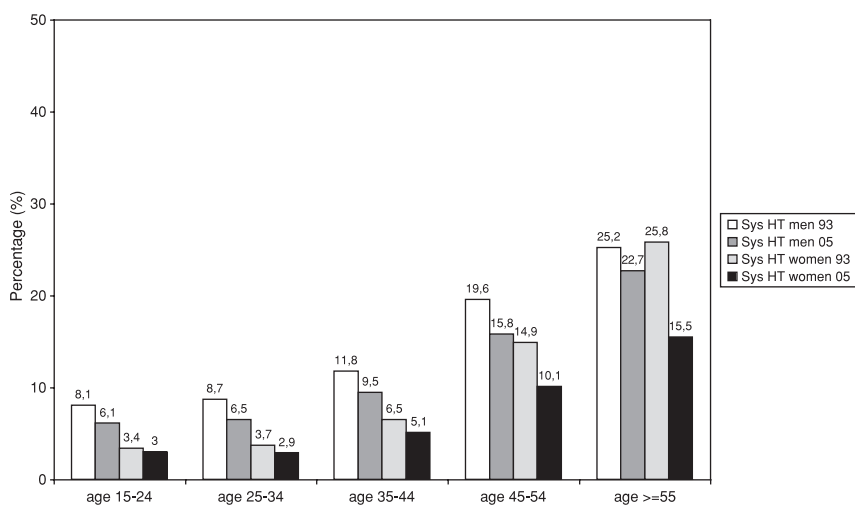
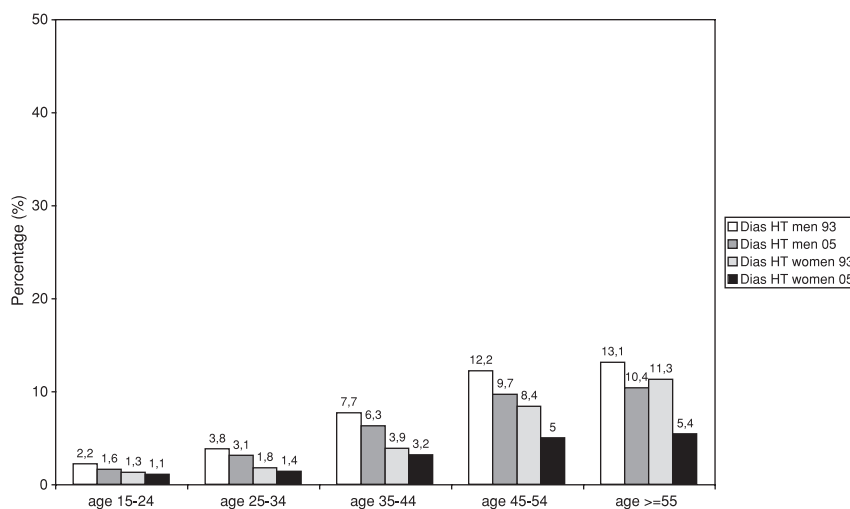




Figure 7:  
Evolution of diastolic hypertension 1993-2005  
(diastolic hypertension = diastolic blood pressure > 90 mm Hg)



work force over the years, or switches to another company or external prevention service, the loss of sick employees, etc... At any rate, we must have a good idea about the representativity of the study group for the population for which we want to generalize our findings.

- 2) The possibility to assess observation bias. Earlier we mentioned the importance of standardization and the assessment and adjustment of interobserver variability and of calibration of measuring instruments.
- 3) The possibility to register health outcomes and exposure parameters, and changes herein in a reliable and valid way (e.g. results of biomonitoring). The design of a JEM could be an important aid here. Goldberg and Imbernon give suggestions about the construction of such a matrix (34).

The registered data can best be limited to exposure and health data which are well known and measurable. In this way, the results of molecular biological tests can only be registered if the validity is reasonably well known (e.g. predictive validity). If not, the results of the registration will be very difficult to interpret and will raise more questions than it will solve. Such test results can

of course be registered in the scope of a specific prospective study design in which we indeed try to assess the predictive value of these tests. In this case however, the ethical consequences must be fully considered and an Ethics Committee should be asked for advice (see point 5).

- 4) The possibility to evaluate the influence of confounding variables. Even though some confounding factors, such as age, sex, smoking-habits, are, as a standard, included in the analysis, confounders often depend on a specific research-problem, and are therefore not routinely measured.
- 5) The latency period between exposure and outcome (health event), and the severity of the outcome: the shorter the latency period, and the less the outcome will urge the employee to quit his work situation (through disease or disability), the more longitudinal analyses could be considered. Obviously, the four preceding conditions should also be fulfilled.

As no acceptable solution has yet been found for these problems, the following point of view is taken:

- 1) Analytical studies on a group-level urge for a specific design, through which stricter control can be exercised on the quality of the data and on the sources of bias. This applies in particular for intervention studies, in which the effect of occupational health interventions on specific health outcomes is assessed. This type of study is seen as a priority to found the social relevance of occupational health care in the future.
- 2) Longitudinal analyses are only possible for the follow-up of the evolution of specific health and exposure parameters on the individual level. This refers to the practical usefulness of the registering instrument.

Still the ILO argues for the creation of the possibility to realise the long term follow-up of employees with disorders with a long latency period (28). This obviously requires organizational and logistic conditions (e.g. a unique identification and the linkage of the data to other databases in which data of the same employee are recorded).

## **5. Ethics and privacy:**

At this moment, in our organization, a study-protocol has to be written for each study design, and for each time the processed data, that are not related to the own company, have been obtained by means of the

registering instrument. This protocol is presented to an Ethics Committee that gives its advice before the study is conducted.

The processing of the data should be done according to the current privacy legislation (39). In this respect, employees whose personal data are collected should be informed about who is in charge of the processing procedures, and about the aims of the data processing (included in the research protocol). These persons can check their personal data, that are recorded about them, at any time they want, and they can obtain additional information about the processing procedures by consulting the public register as intended by Article 18 of the Law regarding the processing of personal data.

In the ILO guidelines as well, much attention is paid to the aspects of protection of personal privacy in the different stages of the design and use of a surveillance system (28).

## **Conclusion**

The guidelines described above can be considered as a draft, issued by the experiences in registration and research of an External Service for Prevention and Protection at Work. These guidelines need to be adjusted according to advices given by the users, in the broadest sense of the word, going from those recording the data and using the data for an optimal performance of their job to employers, employees, governments and other institutions in the field, experts and other persons concerned.

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