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Recommendations for Organizing a Standardized European Health Examination Survey

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STANDARDIZED EUROPEAN HEALTH EXAMINATION
SURVEY**

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Discloser

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1 INTRODUCTION

Health examination surveys (HES) based on representative probability samples of the population provide information on health behaviour, health determinants (e.g., obesity, blood pressure and various blood parameters), the prevalence of various diseases, met and unmet need for health services, functional limitations and nutritional status. The information that can be obtained through HESs is complementary to that which can be obtained from different registers or from health interview surveys (HIS). Although several European Community Health Indicators (ECHI) will be made available by a HIS (EHIS), many of them can only be obtained by carrying out a HES [1]. A HES always includes a questionnaire (administered through an interview or self-administered), yet the particular strength of a HES lies in the fact that measurements, tests and assessments are performed, for example: anthropometric, physiological, clinical and/or performance measurements and tests, and blood samples. A comprehensive HES can also include numerous other measurements and examinations performed by a physicians and dentists.

The Feasibility of a European Health Examination Survey (FEHES) Project [2] has found that it is feasible to conduct standardized HESs in representative population samples in nearly all European countries [3]. The basic structure of a European HES is intended to be built on well coordinated national HESs. The FEHES Project has made recommendations on the following [4]:

- Measurements to be included in a national HES;
- Models for organizing a national HES;
- Sampling and recruitment of the participants;
- Legal and ethical issues;
- Standardized measurement protocols;
- Data management, documentation and reporting; and
- Organizing the international collaboration necessary for a system of standardized European HESs [4].

This document summarizes both the feasibility report [3] and the recommendations [4]. It also includes a recommendation for the European Commission concerning the

necessary actions for facilitating the establishment of a sustainable HES system in Member States.

2 CURRENT STATE OF HEALTH EXAMINATION SURVEYS IN EUROPE

The first national HES in Europe was carried out in the late 1950s and early 1960s, followed by an increasing number of new surveys from the 1970s to the 1990s. Since 2000, there has been a rush to start national HESs in countries where they had not been performed (Figure 1). The most comprehensive HESs in Europe have been the Mini-Finland Health Survey (1978-1980) and the Health 2000 survey (2000-2001) in Finland. Many of the earlier HES have been repeated in the current decade. Most European countries have gained expertise in conducting a HES as a result of national or regional surveys. With regard to comparisons among European countries, a major drawback is that there is no joint standardization of these surveys and thus the data are probably not comparable. This also means that most of the present health data cannot be used for comparisons among European countries.

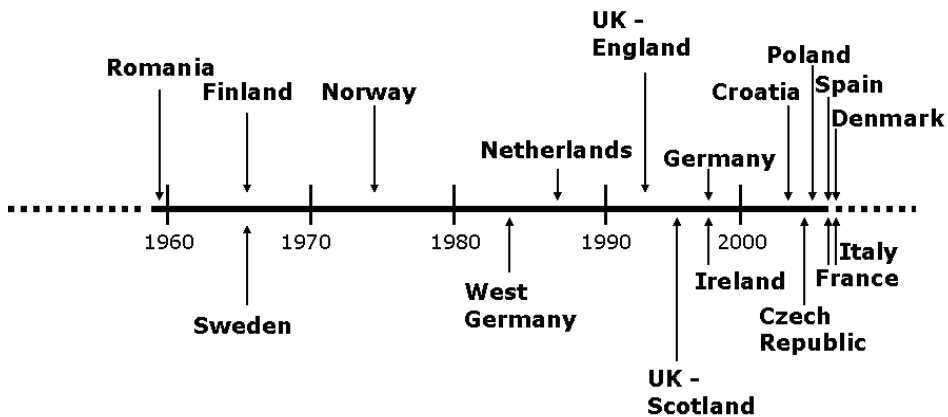


Figure 1. Time of the first national health examination survey in different European countries

In two countries (i.e., Denmark and Italy), a new HES is currently being conducted, and in 15 countries there are plans to start a national HES in the next 5 years [3].

Past experience, for example the WHO MONICA Project [5], which standardized regional cardiovascular disease risk factor surveys in 21 countries in the 1980s and 1990s, demonstrates that internationally organized standardization of the surveys is a prerequisite for international comparability, as well as for national comparability over time. This experience is supported by the national contact persons of the FEHES Project in 32 countries, nearly all of whom expressed the need for international collaboration in planning and implementing the national HESs, in particular for training personnel and standardizing and performing quality control on the measurements. [3]

Most of the HESs mentioned above concern the adult population. To date, few HESs have included children or adolescents. Since studies in these groups require modified protocols, it is recommended that a separate plan be prepared for these age groups.

3 PROPOSAL FOR A MODEL OF A EUROPEAN HEALTH EXAMINATION SURVEY

3.1 TARGET POPULATION, CONTENT AND SIZE OF THE NATIONAL SURVEY

Conducting a national HES in the next 10 years is a realistic objective in practically all European countries. The national HES should cover at least the population of men and women between the ages of 25 and 64 years and include at least the measurements of height, weight, waist circumference, blood pressure, and the taking of a blood sample for measuring total and HDL cholesterol and fasting glucose. The questionnaire part of the HES should include at least basic socio-economic items, so that socio-economic differences in health and health determinants can be assessed, and items on general health, cardiovascular disease, hypertension, hyperlipidemia, diabetes and smoking status.

The minimum sample size is 4,000 persons per country. Every effort should be made to obtain at least a 75% response rate. The sample size should obviously be increased if a wider age group is going to be examined or if wanting to obtain more precise estimates for certain population subgroups, such as the populations of specific regions. Performing a HES is a logistical challenge and is more expensive than a HIS. A sample size of more than 8,000-10,000 would not be feasible in most countries.

Given that information on the health and health-related needs of the elderly has become increasingly important, including this population subgroup should be

considered. Additional measurements should also be considered, such as: infectious-disease markers and other measurements on the blood samples and urine, tests of physical fitness, lung function, functional capacity, cognitive function, nutrition, ankle/brachial index, ECG, bone density, and examinations of oral and mental health.

However, countries with less experience in performing a HES should not be encouraged to excessively expand their first HES and should instead be encouraged to obtain good quality data on a limited number of measurements. Attempting to cover too many measurements will result in poor quality data.

3.2 NATIONAL RESPONSIBILITIES

Given that in Europe many national HESs have been recently conducted or are being planned, it is obvious that, when possible, the responsibility of planning and conducting the future HESs should be at the national level. This increases local motivation for obtaining high quality results and is important for the selection of those measurements that are most important nationally. The national infrastructure and other national aspects such as habits, public and professional attitudes and health information needs can be taken into account. This approach also facilitates the training of national experts for the proper analysis and interpretation of the survey results.

The cost of a national HES primarily depends on the sample size, the specific measurements, and the personnel's salaries. In many countries, much of the survey work would be carried by the regular employees of national public health institutes or other organizations who would be funded directly or indirectly through the regular budget. For this reason, it may be difficult to determine the total cost of the survey. It thus seems reasonable to assume that, as a general rule, the national HESs would be funded with national sources. However, the EU should be prepared to contribute to the funding in order to make sure that the survey meets the minimum size requirements, that the core measurements that are expected from all HESs can be performed, and that the individual-level data can be transferred for international assessment and reporting (see Section 3.4 below). The EU should also be prepared to contribute financially to the testing of the extension of the surveys to cover the elderly population, as well as to the development and testing of survey methods in areas that are deemed important for consideration in future national HESs in a large number of countries.

3.3 INTERNATIONAL COORDINATION

To organize the necessary international collaboration, central coordination with sufficient expertise and resources should be established. The central coordination could

comprise a well qualified team in one or several Member States, supplemented by experts from DG Sanco and Eurostat. The main responsibility of the central coordination would be to facilitate the national surveys by performing the following:

- Creating, maintaining and disseminating the European standards;
- Providing training material and organizing training in the use of the standard procedures for the persons responsible for training the national teams;
- Coordinating external quality control and preparing guidelines for and monitoring internal quality control;
- Evaluating the success of the standardization in each survey. The results would be discussed with the organizers of the surveys and made available to all persons who using the data. Summaries would accompany the basic reports of the survey results;
- Providing advice to the countries planning a national HES and coordinating a network of the national HES organizers, in order to share experiences and expertise in organizing surveys, data collection and reporting. It is important that the experience gained by countries from earlier HESs be available to all other countries;
- Collecting individual level data from the countries for quality assessment, basic reporting and sharing with research groups. It is important that the security and confidentiality of such data be ensured. Principles and regulations for collecting, analysing and sharing these data will need to be developed and agreed upon by the countries before any data are collected. These principles and regulations must respect the rights and interests of all parties;
- Undertaking rapid basic reporting and interpretation of the results for use at the European level; and
- Managing the sharing of the data with research groups for more in-depth analyses.

The central coordination should be funded by the EU and operate in collaboration with the EU, WHO, OECD and other agencies. The required expertise for such central coordination is primarily available at the national public health institutes of a number of European countries with past experience with national HESs. For this reason, we propose that for the time being the central coordination be set up as a consortium of several such institutes and European actors. In the longer term, a good solution might be to establish a permanent capacity, which would cover the work needed for HESs and

possibly health monitoring at large. Whatever the organizational solutions, it is clear that there is a need for high quality expertise in the area of health monitoring at the EU level.

3.4 OWNERSHIP OF THE DATA AND MATERIALS COLLECTED IN THE SURVEYS AND THE PRINCIPLES FOR SHARING THEM

The collection of individual level data in a centralized database is necessary for assessing data quality, the success of the standardization, and country-specific characteristics of the data. These are a prerequisite for meaningful comparisons of the survey results among countries. Past experience has shown that many of the shortcomings in the data can still be remedied at this stage. Collection of the data in one database also facilitates the joint analysis and reporting of data.

It is proposed that blood samples and possibly other material collected in the surveys be stored nationally. If in some countries this is not feasible, alternatives should be considered.

Ownership of the data and the material collected in the HESs should remain at the national level. Extensive use of the data for public health and research purposes in the countries should be strongly encouraged.

The countries should have an obligation to provide, free of charge, data to the central coordination database, in particular:

- the individual level data on the compulsory and optional measurements specified for the European HESs;
- information on the quality status, sampling unit and sampling weight of each survey respondent;
- data on non-respondents: information on reason for non-response, age and sex, which can be used for weighting the survey for non-response and for assessing the effect of non-response on the results.

The central coordination should use these data to assess and document the success of the standardization and comparability of the data, the basic reporting of the surveys results, and the overall evaluation of how the surveys were conducted.

Assessment of the success of the standardization involves analytical investigation of the actual survey procedures used, the data generated in the surveys and the data and information generated through external quality control. The documented assessment reports are an essential prerequisite for the analysis and interpretation of the survey data.

Basic reporting involves the basic descriptive results from the HES, taking the results of the data assessment into account. Priority should be placed on the indicators in the ECHI list.

Overall HES evaluation involves collecting and documenting the experience with conducting the survey as a whole: what went well, what difficulties were encountered, what the overall cost of the survey was, how well the survey plan covered the actual needs, situations encountered in the survey, etc. The instruments and procedures for collecting the data needed for this evaluation have to be developed by the central coordination, and each country will be asked to provide data for the evaluation.

The central coordination should prepare a system for, and assist the countries in, transferring their data to the central database. This system should allow the data variables to be checked for accuracy and consistency and the data to be packed and encrypted for transfer via Internet. The data transfer and management system has to ensure the security and confidentiality of the data. One prerequisite is that it should not be possible to identify individual persons from the transferred data.

Collection of the data in the central database will also facilitate the sharing of the data with research groups and possible other third parties. The principles and regulations for sharing individual level HES data with third parties need to be developed and should respect national regulations and the rights and interests of all parties concerned.

4 SETTING UP THE EUROPEAN HEALTH EXAMINATION SURVEY

Because of the large number of national HESs already being planned for the next five years and the countries' high motivation for joint standardization, there is now a unique opportunity to lay the foundation for a European HES. Taking into account the fact that "To implement a pilot European Health Examination Survey" is listed in the Work Plan for 2008 of EU's Health Programme [6], we propose that the European HES be set up in two phases.

4.1 PHASE I

The first phase would involve:

- a) setting up the central coordination with the tasks specified in Section 3 above; and
- b) planning and preparing a national HES in 8-12 countries.

4.1.1 PLANNING AND PREPARATION OF THE NATIONAL HEALTH EXAMINATION SURVEYS

The preparation of the national HESs would start with the conceptualization of local aims and purposes and decisions on how the HES should be organised and operated. A common core module of measurements should be covered by all countries; the selection of additional measurements will depend on local interests and resources (see Section 3 above) [4]. The planning and preparation should also cover the duration and timing of local pilots and full scale surveys, personnel needs, fieldwork logistics, survey sampling, legal and ethical issues, laboratory analyses, possible translation of measurement protocols and instruments into local language(s), training and certification of the survey teams, data management, quality control, data quality assessment, basic reporting and survey evaluation. The local budget would be prepared and local funding sought for the full scale survey. Emphasis should be placed on strategies for contacting and motivating the persons selected for inclusion in the sample, in order to achieve a high response rate.

Local pilot surveys of 200 subjects should be included in this phase. The countries should be able to start the full-size HES immediately after they have completed Phase I. It is possible that some countries can start a full-size HES already during Phase I. In these countries, the HES will be used to test external quality control and central data management and assessment procedures.

4.1.2 SELECTION OF THE PILOT COUNTRIES

The 8-12 pilot countries for Phase I should be those that plan to start their national HES first and those that have very recently started their HES and will continue to conduct it for most of Phase I. It will be important for Phase I to include countries with various degrees of experience in performing a HES. For countries with little recent experience, the main focus should be on preparing the HES and testing the fieldwork. For countries with an existing HES system, the aim should be to find an optimal

strategy to integrate the European standards, so as to facilitate international comparability, without excessively compromising the ability to follow national trends from the past. These countries should also play an important role in sharing their experiences with the less experienced countries.

4.1.3 SETTING UP THE CENTRAL COORDINATION

The FEHES Project has defined the measurement standards for the core measurements that should be included in each national HES [4]. The central coordination should organize training for the national trainers on the use of these standards. If a country wishes to include in its HES measurements for which there are no agreed upon standards, the country and the central coordination should jointly assess available standards and possibly develop new standards, with the objective of developing a recommendation for a new European HES standard. However, it should be kept in mind that, in Phase I, it is much more important to prepare focused surveys which will be successful and provide timely information than to use the available resources for developing new standards.

The central coordination should also undertake external quality control of the core measurements. This will be conducted through the review of the manuals of the national surveys, site visits during the local pilot surveys, assessment of the local survey and quality control procedures, and assessment of the data obtained from the surveys. A specific task for the central coordination is to set up external quality control for the laboratory analyses of serum lipids and plasma glucose. There has been no external quality control for these in Europe since the activity of WHO Regional Lipid Reference Centre [5] ceased in 1997.

Some of the important tasks of the central coordination in Phase I also include providing professional support for establishing the sampling design for the full size HES in each country and guidelines for calculating the weights for the estimates and the analyses of the final data from each HES. They also include providing professional support to the countries on legal and ethical issues and data confidentiality, to ensure that these are in line with current and foreseeable national and international legislation and principles. Finally, the evaluation of Phase I is of paramount importance.

4.1.4 IMPLEMENTATION AND FUNDING OF PHASE I

Phase I should take two years, and the topic “implementation of a pilot European Health Examination Survey” of the Work Programme 2008 [6] of the Health Programme should be devoted to this.

The central coordination should be funded by the EU. Once the central coordination is in place, it will also lower substantially the threshold of obtaining national funding for the national HES in most countries. Nevertheless, to speed up the piloting of the European HES, it is proposed that a central contribution, which would cover a part of the national activities, would be available also for the piloting countries (see Chapter 9 of the Recommendations [4]). A tentative two years' budget for the EU's contribution, which should be sufficient for setting up the central coordination and for completing Phase I involves:

Personnel for central coordination: 60,000.00 € × 17 person years	1,020,000.00 €
Project manager	
Administrative secretary	
2 researchers for HES standardization and evaluation	
Survey statistician	
Laboratory standardization (1.5 persons)	
Professional advice on legal and ethical issues	
Data/ web manager	
EU contribution to piloting countries: 50,000.00 € × 12 countries	600,000.00 €
The rest of the national costs would be covered locally	
Two training seminars, 30 persons each	100,000.00 €
One for planning the surveys, and other one for the measurement procedures	
Four Pilot coordinators' meetings, 25 persons each	100,000.00 €
Participation in six meetings for the Health Programme at the Commission	6,500.00 €
Site visits: 2 visits per country (12 countries)	50,000.00 €
Investments, consumables and shipment of reference samples in external quality control laboratory	80,000.00 €
Total	1,956,500.00 €

4.2 PHASE II

In Phase II, which would immediately follow Phase I, the full size HESs in the 8-12 Phase I countries should be conducted. These surveys would complete the piloting of the “European HES”. Another task for Phase II would be to plan and conduct a national HES in the remaining countries.

Phase II would take 5-7 years. Because of the involvement of the large number of countries and the demanding fieldwork, substantially more funding will be required than for Phase I. Phase II should involve a gradual change to the sustainable European HES system, where the Phase I countries would start planning their second surveys and there would be ongoing support from the central coordination. This support should include:

- Maintenance of the network of the organizers of national HESs;
- Planning, quality assurance and evaluation of the national HESs;
- Timely data analysis and reporting;
- Assessment and development of survey methods; and
- Assessment of priorities for HES measurements and the development of the European HES system.

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