

## **Standardization of physical measurements in European health examination surveys – Experiences from the site visits**

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## **Abstract**

**Background.** Health examination surveys (HES) provide valuable data on health and its determinants at the population level. Comparison of HES results within and between countries and over time requires measurements which are free of bias due to differences in or adherence to measurement procedures and/or measurement devices.

**Methods.** In the European Health Examination Survey (EHES) Pilot Project, 12 countries conducted a pilot health examination survey in 2010-2011 using standardized measurement protocols and centralized training. External evaluation visits (site visits) were performed by the EHES Reference Centre staff to evaluate the success of standardization and quality of data collection.

**Results.** In general, standardized EHES protocols were followed adequately in all the pilot surveys. Small deviations were observed in the posture of participants during the blood pressure and height measurement; in the use of a tourniquet when drawing blood samples; and in the calibration of measurement devices. Occasionally, problems with disturbing noise from outside or people coming into the room during the measurements were observed. In countries with an ongoing national HES or a long tradition of conducting national HESs at regular intervals, it was more difficult to modify national protocols to fulfil EHES requirements.

**Conclusions.** The EHES protocols to standardize HES measurements and procedures for collection of blood samples are feasible in cross-country settings. The prerequisite for successful standardization is adequate training. External and internal evaluation activities during the survey fieldwork are also needed to monitor compliance to standards.

**Key words:** Health survey, standardization, examination, biological sample

## **Introduction**

Health examination surveys (HESs), population-based surveys on which information is collected by questionnaires and also through physical examinations and collection of biological samples, are valuable data sources for evidence-based policy making, planning and evaluation of prevention and treatment activities and research. In Europe, the first national HESs were carried out in the late 1950s and early 1960s. The number of countries conducting a national HES has increased rapidly since the year 2000. (1)

Comparison of the HES results within countries and also between countries over time is possible if results are not biased because of differences in procedures and/or measurement devices, or bias due to non-response or differences in the coverage of sampling frames. It has been recognised that obtaining cross-country comparability of blood pressure measurements is challenging (2, 3). There is much evidence illustrating that the results of measurements, such as blood pressure (4, 5) and blood lipids (6, 7), are sensitive to deviations in the measurement procedures. For example, observed blood pressure levels are affected by posture of the subject during blood pressure measurement, and whether the back is supported or not by the backrest of the chair during the measurement. These relatively small deviations in the measurement procedures may result in up-to 15 mmHg difference in the systolic blood pressure (8). Similarly for total cholesterol, the posture of the subject during the blood drawing (sitting vs. supine) may result in up-to 0.58 mmol/l difference in the result. (9) Results of waist circumference measurement are strongly dependent on the position of the measurement tape. Observed average waist circumference varied from 89.2 cm to 90.8 cm among men and from 83.2 cm to 87.8 cm among women when using different measurement locations. (10)

Standardized measurement protocols are essential to avoid differences due to measurement bias.

For major cardiovascular and other chronic disease risk factors such as anthropometric

measurements, blood pressure and blood lipids, standardized measurement protocols have been available for decades. The 1<sup>st</sup> edition of the Cardiovascular Survey Methods (11) was published in 1968. Thereafter, standardized protocols for population surveys have been developed and published by the WHO MONICA Project (12, 13), the WHO Stepwise approach to non-communicable disease risk factor surveillance (STEPS) (14), and the Feasibility of a European Health Examination Survey (FEHES) Project (15).

Based on the demand and necessity for representative population level information about the health status and health determinants of the general population to be utilized at the national level and by the European Commission, the European Health Examination Survey (EHES) Project was launched in 2009. EHES is an initiative to set up a system of standardized health examination surveys (HES) of the adult population in Europe.

The EHES Project prepared both recommendations for planning and organizing of a national HES and standardized protocols for a set of selected physical measurements. (16-18) The feasibility of the implementation of these recommendations and standards was tested during the EHES Pilot Project (2010-2011) (19).

In this article we report how site visits were used to assess and reinforce the level of standardization obtained for the physical measurements in the survey conducted during the EHES Pilot Project and evaluate their usefulness.

## **Methods**

During the EHES Pilot Project, 12 European countries (Czech Republic, Finland, Germany, Greece, Italy, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, United Kingdom/England) conducted a pilot survey. (1, 19) In four of these countries (Germany, Italy, Netherlands, United Kingdom/England) a full-size national HES was ongoing and the pilot survey was conducted as a part of that. In the other eight countries, the pilot surveys were organized as separate surveys. Most

of the pilot surveys were conducted in one or two regions/towns and covered at least 200 persons aged 25-64 years in each country. (20) EHES Manuals which included standardized measurement protocols for the core measurements to be included in all surveys were prepared and published. (16-18) These manuals were the basis for the standardization and were used during the training of the national trainers; in preparation of national HES manuals and during the site visits as 'gold standards' for the measurement procedures.

Each pilot survey included at least the core measurements and a questionnaire. These core measurements were: height, weight, waist circumference, blood pressure and collection of blood samples for analysis of lipids. The questionnaire included questions on background information (demographic and socio-economic factors); lifestyle factors such as smoking; information about previous measurements of blood pressure, cholesterol and glucose, awareness of elevated blood pressure, cholesterol and diabetes; and use of medications to treat these conditions. Questions followed the European Health Interview Survey questions as closely as possible. For these core measurements, standardized protocols were provided in the EHES Manual.(16) Countries could also include additional measurements in their pilot survey: two-thirds of the surveys had at least one additional measurement.

Centralized training in the EHES procedures was organized by the EHES Reference Centre (RC) for the national survey organizers, who were responsible for training the national survey teams. During the EHES training seminars, each standard measurement protocol was first introduced in theory followed by practical measurement training sessions (21). The national survey organizers were recommended to organize similar national training sessions for the survey personnel including both the theory and supervised practice with several members of the target population before starting the fieldwork. Such national training was organized in each country. It lasted from 8 hours to up-to six full days, depending on the number and selection of measurements, especially

additional measurements, other tasks of the fieldwork staff, and their previous experience in similar survey fieldwork. In most of the countries, the training took five full days.

The EHES RC evaluated the implementation of the surveys against the EHES protocols by conducting a site visit to each of the 12 surveys. These site visits were part of the external quality assurance. The quality assurance programme also included national actions organized by the national survey teams. During the site visit, the members of the EHES RC observed the fieldwork of the national HES, with the written consent of survey participants and fieldwork personnel, and held discussions with the survey organization/coordination team. (22) During the actual observations, EHES RC evaluators were not allowed to interfere in the measurement or ask questions. The purpose of the observation during the site visits was to check compliance with the EHES protocols and document possible deviations. For measurement performance, which brand and model of the devices were used and how devices were calibrated were checked, as well as how well measurements protocols were followed. For measurements, how the privacy of the survey participant was ensured was also evaluated. Site visits also evaluated the general conduct of the survey including: communication between fieldwork personnel and survey participants; how informed consent was obtained; and how data security was ensured in the field. For some of these, knowledge of the language spoken by the participant and fieldwork personnel was essential to make a proper evaluation of the conduct. Where EHES RC evaluators did not speak the native language(s) of the country, local survey organizers/coordinators helped with translations of the written materials and interpreted the consent request. If the survey participant spoke a language not understood by the EHEC RC evaluator, it was difficult to evaluate the informed consent process, providing the instructions and feedback for the participant and other interactions between participant and measurers.

After spending a day in the field observing the fieldwork team, the EHES RC evaluators had a meeting with the survey organizers/coordinators, and sometimes also with the fieldwork team members, to provide direct feedback on their observations. They also discussed other survey related issues such as selection of the sampling frame and sampling, recruitment of fieldwork personnel, training, data management, and the dissemination plan for the survey results.

The evaluators had a check list of the topics to be covered during the site visits (18). After each site visit, a written report was prepared to document the observations and discussions, and to provide recommendations for improvement. The site visit reports were confidential as they included photos of survey participants (with their consent), comments on the performance of the survey teams, and other confidential information.

## **Results**

Overall, the pilot surveys were well planned and the fieldwork and all core measurements were mostly conducted following the EHES protocols. Few deviations were observed during the site visits: they are summarized in Tables 1 to 3, together with relevant key points of the EHES measurement protocols.

In blood pressure measurement, the most common deviations from the EHES protocol were related to instructions given to the participant before the measurement; posture of the subject during the measurement; and selection and use of the appropriate cuff. In some surveys, other deviations from the standards were identified, such as not recording the room temperature; the subject talking during the measurement; and the timing between subsequent measurements being too short (Table 1.).

The measurement of height was generally performed according the EHES protocol. A few deviations were observed. The height measurements were not always read at eye level when the

person measured was taller than the fieldwork personnel conducting the measurement. The measurement devices were not always calibrated correctly. In some surveys, deviations were observed with the position of the subject, and instability of the portable measurement device. (Table 2.)

In the measurement of weight, the most frequently observed deviation from the EHES protocol concerned clothing. In several surveys, the measurement was done without proper undressing. Similar to height measurement, shortcomings with calibration of the measurement device were observed. (Table 2.)

In the waist circumference measurement, the most frequently observed deviations were related to clothing: measurements were not taken on bare skin as recommended and there was insufficient palpation of the correct measurement place. In individual surveys, problems with the type and use of the measurement tape were also observed. For example, the measurement tape was not placed horizontally or it was twisted during the measurement. (Table 2.)

For the collection of blood samples, the most common deviations concerned the use of the right arm for drawing the sample instead of the recommended left arm and prolonged use of tourniquet. The recommendation to use the left arm for drawing the blood is linked to the recommendation to carry out the blood pressure measurement on the right arm before drawing the blood. During the blood pressure measurement, the cuff will provide pressure on the arm which may also alter plasma concentrations of analytes. In the processing of blood samples, deviations were noted in mixing of serum tubes (not turning the tube up-side-down five times) after sample drawing; in the time between blood drawing and centrifugation (exceeding the recommended one hour); and in the timing until the samples were frozen. (Table 3.)



At least a few specific measurement deviations were observed in each survey but none of the surveys had problems with all measurements. More deviations were observed in the countries with an ongoing national HES.

In addition to the measurement-specific deviations, general problems concerning the examination rooms were noted in some surveys. For example, there was too much noise in the examination rooms and people were coming in and out during the measurements. Noise may affect the measurement results (blood pressure measurement) and people coming in and out of the room risk the privacy of the measurements.

## **Discussion**

Since many of the measurements conducted in the HESs are sensitive to even minor deviations in the measurement procedures, use of standardized procedures is important to ensure comparability of the results between survey teams and over time, both within a country and also between countries. Site visits organized by the EHES RC were used to evaluate compliance with the EHES recommendations in the EHES pilot surveys. In general, only a few deviations from the standardized protocols were observed in each survey, and the training was adequate.

As differences in the population level results of blood pressure are relatively small (28), these types of deviations in the measurement procedures may cause substantial bias which can jeopardize cross-country comparisons. For example, observed deviations in the resting time before the blood pressure measurement, posture of the subject, wrong cuff size and talking during the measurement may have a significant effect on individual level measurement results. (29) One relatively new standardization issue for blood pressure measurement is the measurement device. Previously, the gold standard in population studies and clinically had been the mercury sphygmomanometer. During the EHES pilot surveys, most of the countries used oscillometric measurement devices

instead of mercury sphygmomanometers. Even though all these oscillometric devices had passed the validation test for clinical use (4), their reliability and the comparability of population survey results between different brands and models is of concern. (30) In future surveys, more attention needs to be paid to the comparability of measurements carried out with different devices, and special validation studies are needed.

If subjects are not removing jeans, sweaters, jackets, etc., the measured weight will be overestimated. For example, a regular pair of jeans can weigh 0.5 kg. It is important to conduct waist circumference measurements on bare skin. This will make it possible to palpate the correct measurement site and to check the proper placement of the measurement tape.

In some cultures and countries undressing for the measurements was problematic. When the measurements are conducted by medical or other healthcare personnel (nurses), undressing should be acceptable if the reason for undressing is properly explained and if privacy in the examination rooms can be assured. However, in some surveys, anthropometric measurements are conducted by interviewers or other non-medical survey personnel. This may create more challenges for standardization. The participants' choices should be respected and if needed, the extent of undressing should be recorded.

Prolonged use of a tourniquet causing for example occlusion for 120 seconds has been shown to increase blood total cholesterol levels by 2-5%. (31) Qualified phlebotomists are usually quick in drawing the blood sample and can minimize the effect of a tourniquet on the sample. It was easier to follow the EHES recommendations in pilot surveys, which were not part of an ongoing national HES or were conducted in countries where there was no tradition of HES. Changing the protocols in ongoing surveys or those focusing on national trends requires considerable effort in estimating and correcting the effects of deviations in measurement procedures. Most countries with long traditions for organizing national HESs found it more important to be able to follow their national

trends than to ensure high comparability with other countries. Solving these threats to national trends would require validation studies, needing extra funding.

Most of the observed deviations in the measurement procedures can be corrected with training and supervision during the fieldwork. On many occasions the local protocols were clarified and missing details of the EHES recommendations were added after the site visits. Usually the correct procedures for the observed issues had already been included in the national manuals and training, but the importance of compliance with all details in the procedures had not been sufficiently understood by fieldwork personnel. On-site supervision is needed during the first days, and also later during the fieldwork period to ensure good quality data. When the survey is prolonged for more than a few months, refreshing training sessions may be needed.

Observation of the measurements during site visits or through video recordings is the only way to check that the measurement protocols are being followed correctly. EHES RC site visits were one-time visits during the entire survey period. An internal audit system is needed to assess quality periodically. This could include periodic audit visits either by the national coordinating team or some external body. An internal audit system can reveal problems early in the survey process which can be corrected immediately, preventing adverse effects on quality and comparability of collected survey data.

Site visits were also important for evaluating the feasibility of the EHES protocols. Since EHES pilot surveys were the first surveys applying these protocols, site visits provided valuable information about their cultural acceptability and feasibility in different types of survey settings. For example, recommending undressing for the anthropometric measurements was found to be difficult in some southern European countries. This resulted in adding a question to the recording form about level of clothing (underwear vs. light clothing).

The site visits demonstrated that cross-country standardization of the EHES core measurements is feasible but it requires sufficient training both at the international and national level. Even though the EHES core measurements are simple and require only simple equipment, there are many challenges in standardization. Internal and external quality assurance procedures, including site visits and national audit visits, will help to identify deviations from the standard procedure and other possible problems during the fieldwork so that they can be corrected immediately. Positive feedback will also help to encourage adherence to the standards.

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### **Conflicts of interest**

None declared.

### **Keypoints (3-5 points)**

- Cross-country standardization of physical measurements for major chronic disease risk factors is challenging but feasible.
- Training is essential for successful standardization of the measurement procedures both within and between countries.

- Site visits and internal audit visits help to identify deviations from the standard procedures during the fieldwork so that they can be corrected immediately.

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**Table 1.** EHES protocol for blood pressure measurement and observed deviations

<b>EHES protocol for specific point (23)</b>	<b>Observed deviations (number of surveys with deviation) §</b>
The participant is asked to sit still for 5 minutes before starting the measurement.	Resting time before the measurement less than 5 minutes (4)
The arm circumference is measured and correct cuff size selected.	The arm circumference was not measured (3)
The cuff is placed on the right arm so that its bottom edge is 2-3 cm above the antecubital fossa.	The placement of the cuff in the arm was incorrect (3)
The participant should be in a sitting position where the arm and back are supported. The participant's feet should be resting firmly on the floor, not dangling.	Incorrect sitting position (4)
Three subsequent measurements are taken, 1 minute between each measurement.	Time between subsequent measurements was less than 1 minute (1)
The participant should remain silent during the entire measurement process, including all three subsequent measurements and the time between them.	Participant was talking during the measurements (1)
Room temperature should be recorded.	Room temperature was not recorded (1)
<i>Minimum number of deviations per survey</i>	0
<i>Maximum number of deviations per survey</i>	3
<i>Average number of deviations per survey</i>	1.5

§ A total of 12 surveys evaluated

**Table 2.** EHES protocol for anthropometric measurements and observed deviations

<b>Anthropometric measurement</b>	<b>EHES Protocol for specific point</b>	<b>Observed deviations (number of surveys with deviation) §</b>
Height (24)	<p>The participant is asked to stand with his/her back to the height ruler or to the wall (head, shoulder blades, buttocks and heels touching or in line with the stadiometer or the wall).</p> <p>The participant's head should be positioned so that the Frankfort Plane is horizontal: the top of the external auditory meatus (ear canal) is in line with the inferior margin of the bone orbit (cheek bone).</p>	Posture of the participant was incorrect (1)
		Correct posture could not be ensured due to the device (1)
	The standing position of the participant is checked in the front in order to verify that the participant is standing straight and in the middle of the stadiometer.	Posture of the participant was not checked properly (1)
	When the participant is taller than the measurer, steps should be used in order to read the height rule properly.	The reading was not taken at eye level (3)
	The measurement device should be stable.	The measurement device was moving during the measurement (2)
	Equipment should be checked and calibrated regularly with a standard rod.	Calibration of the equipment was not done correctly (3)
	<i>Minimum number of deviations per survey</i>	0
	<i>Maximum number of deviations per survey</i>	3
	<i>Average number of deviations per survey</i>	0.9

<b>Anthropometric measurement</b>	<b>EHES Protocol for specific point</b>	<b>Observed deviations (number of surveys with deviation) §</b>
Weight (25)	The participant is asked to undress to his/her underwear. If the participant refuses or feels uncomfortable undressing, ask him/her to take off the shoes, heavy garments such as jacket, pullover, belts, heavy jewellery and to empty his/her pockets.	The participants were not asked to remove any clothes (1)
		The weight was not measured in underwear (4)
	Standardized weights should be used to check the scale whenever it is feasible.	Calibration of the scale was not done properly (4)
	<i>Minimum number of deviations per survey</i>	0
	<i>Maximum number of deviations per survey</i>	3
Waist circumference (26)	The participant is asked to show the waist, by loosening the belt, lowering the pants/skirt and lifting the shirt.	Participant was not asked to loosen the belt and trousers (1)
	The measurement is done on bare skin.	The measurement was not done on bare skin (3)
	The participant is asked to stand with his/her weight evenly balanced on both legs, and hands hanging loosely beside the body.	Hands were up during the measurement (1)
	The waist is palpated to find the right measurement place: midway between the lower rib margin and the iliac crest.	Right measurement place was not palpated (4)
	It is checked that the measuring tape is horizontal and not twisted.	Measurement tape not in horizontal level (1)

<b>Anthropometric measurement</b>	<b>EHES Protocol for specific point</b>	<b>Observed deviations (number of surveys with deviation) §</b>
		Measurement tape twisted during the measurement (1)
	Non-elastic measurement tape should be used.	Did not use recommended measurement tape (2)
	<i>Minimum number of deviations per survey</i>	<i>0</i>
	<i>Maximum number of deviations per survey</i>	<i>3</i>
	<i>Average number of deviations per survey</i>	<i>1.3</i>

§ A total of 12 surveys evaluated

**Table 3.** EHES protocol for blood sample collection and observed deviations

<b>EHES Protocol for specific point (27)</b>	<b>Observed deviations (number of surveys with deviation) <sup>§</sup></b>
The blood sample should usually be drawn from the left arm (not the arm from which the blood pressure was measured).	Arm used for the sample drawing varied between participants (1)
	Blood sample drawn from right arm (3)
The use of a tourniquet should be minimized. The tourniquet should be released before the flow of blood begins. In any case, the use of a tourniquet should be limited to less than one minute.	The tourniquet was not opened before blood flow (4)
For serum, EDTA and fluoride-citrate tubes, the tube should be adequately mixed 5 times immediately after the sample has been taken by inverting the tube completely top-down	Blood tubes were not mixed adequately after sample collection (1)
The time from phlebotomy to centrifugation should be 30-60 min.	Blood samples were not centrifuged within one hour (3)
Samples should be frozen without delay.	Blood samples were not frozen straight after centrifugation (1)
<i>Minimum number of deviation per survey</i>	0
<i>Maximum number of deviations per survey</i>	4
<i>Average number of deviations per survey</i>	1.1

<sup>§</sup> A total of 12 surveys evaluated