EHES
Measuring the Health of Europeans

EHES Manual

PART B. FIELDWORK PROCEDURES

2nd edition

Hanna Tolonen (editor)

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Edited by

Hanna Tolonen

EHES MANUAL

PART B. FIELDWORK PROCEDURES

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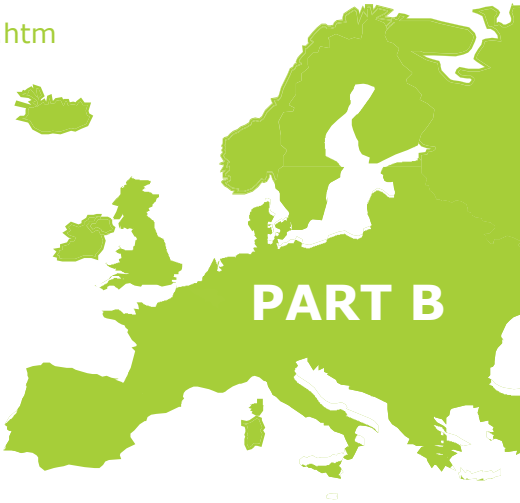

Introduction

The European Health Examination Survey (EHES) Manual provides guidelines and specifies the requirements for the implementation of standardized national health examination surveys (HES) in the European countries. Recommendations based on past experiences from national and international surveys were prepared by the Feasibility of a European Health examination Survey (FEHES) Project (Tolonen 2008). The EHES manual builds on these recommendations and on further experience obtained during the EHES Pilot Project in 2009-2012. The EHES Manual has three parts:

A. Planning and preparation of the survey
B. Fieldwork procedures
C. European level coordination

The EHES Manual is maintained by the EHES Reference Centre. This is the 2nd edition of the EHES Manual on which many topics are further clarified, providing more details and examples. The plan is to update it also in future. The latest version of the EHES Manual is available in the Internet at www.ehes.info.

This is Part B of the EHES Manual. It provides guidelines for the fieldwork procedures of a HES, including the European standard protocols for the different HES measurements. Some of the measurements are so called Core measurements, which should be included in all national HESs (see Part B, Chapter 5 and Chapter 6). The countries can also include a varying number of additional measurement in their HESs. In the beginning, agreed European standards are available only for some additional measurements. When standards for new measurements have been agreed on, they will be added to the EHES Manual. Meanwhile, if a country plans to include a measurement for which there is no European standard procedure, it should keep in contact with the EHES Reference Centre and other countries planning to include a similar measurement. A more detailed description of the criteria for HES measurements and the procedure for adopting new European standard procedures is given Part A, Chapter 5 of the EHES Manual.

As part of the planning of a national HES, each country has to prepare a national HES Manual. The procedures described in the national manual should follow the European standards specified in the EHES Manual. The national manual should be specific also in issues where the EHES manual can only give alternatives or general guidelines. The EHES

manual is unspecific in situations where the national circumstances vary and there is no common procedure which could be reasonably followed in all countries. When the European recommendation differs from the procedure used in earlier national surveys, the procedure to be adapted in the new national HES needs to be considered carefully. Sometimes there may be need to compromise between European comparability and the possibility to follow national trends from the past. The countries should prepare the national manuals in collaboration with the EHES Reference Centre.

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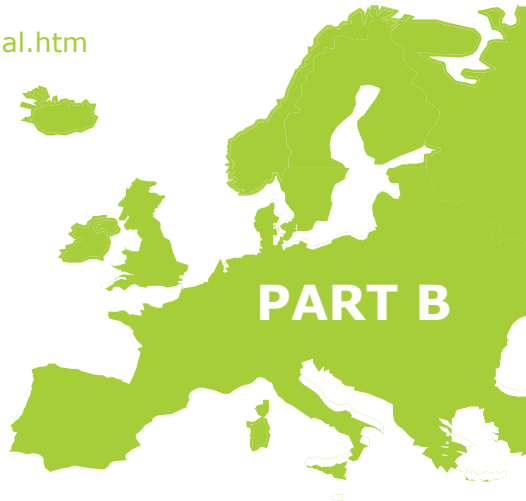

1. Coordination of the fieldwork

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The fieldwork organization usually consists of a Central office and one or several fieldwork teams. The Central office has responsibility for the overall coordination of the fieldwork. At the fieldwork team level, the team supervisor (team leader or local coordinator) is responsible for the daily coordination of the fieldwork. The specific responsibilities and division of tasks between the Central office and fieldwork team supervisors vary depending on the local survey organization. We provide here some guidelines for the division of tasks and responsibilities. This chapter considers aspects that need to be defined in the national HES manuals on

- Division of tasks and responsibilities between the Central office and the fieldwork team supervisors/local coordinator;
- Safety issues;
- Preparations at the field work sites;
- Appointment scheduling for the participants; and
- Logistics in transfer of the survey materials and travelling of the fieldwork staff.

1.1 Division of tasks and responsibilities

Figure 1.1 provides an example of the structure of the fieldwork organization. In the first example, the laboratory (National HES laboratory) is part of the Central office (at the same organization), but it can also be a separate outsourced laboratory. In this example, the different teams cover different survey sites. Close coordination of the work is needed between the laboratory, Central office and fieldwork team supervisors (Figure 1.2). This may be challenging when the laboratory is in a different organization. When examinations are carried out by

home visits, the fieldwork supervisor is often responsible for the staff at several fieldwork locations.

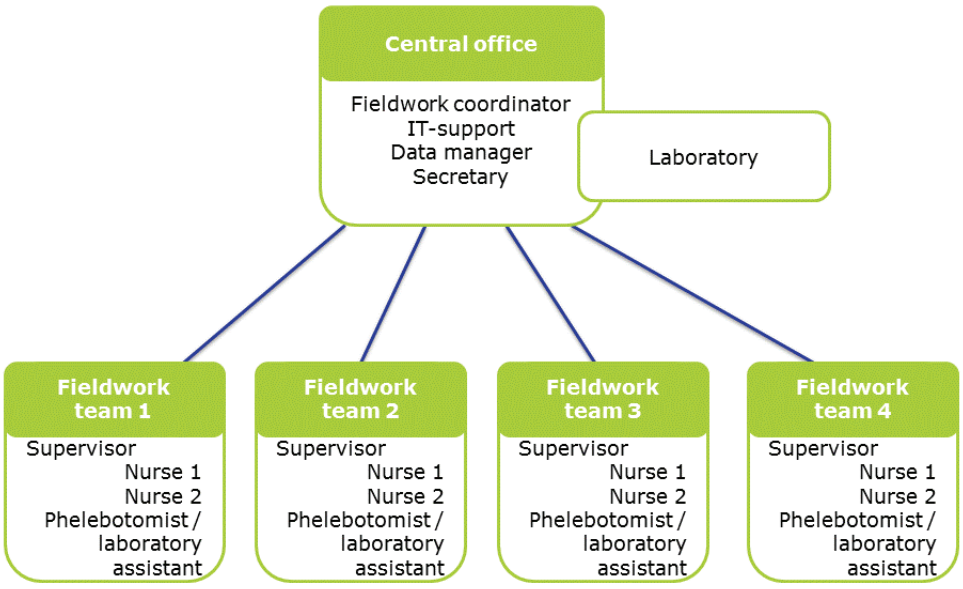

Figure 1.1. Structure of the fieldwork organization. Example 1

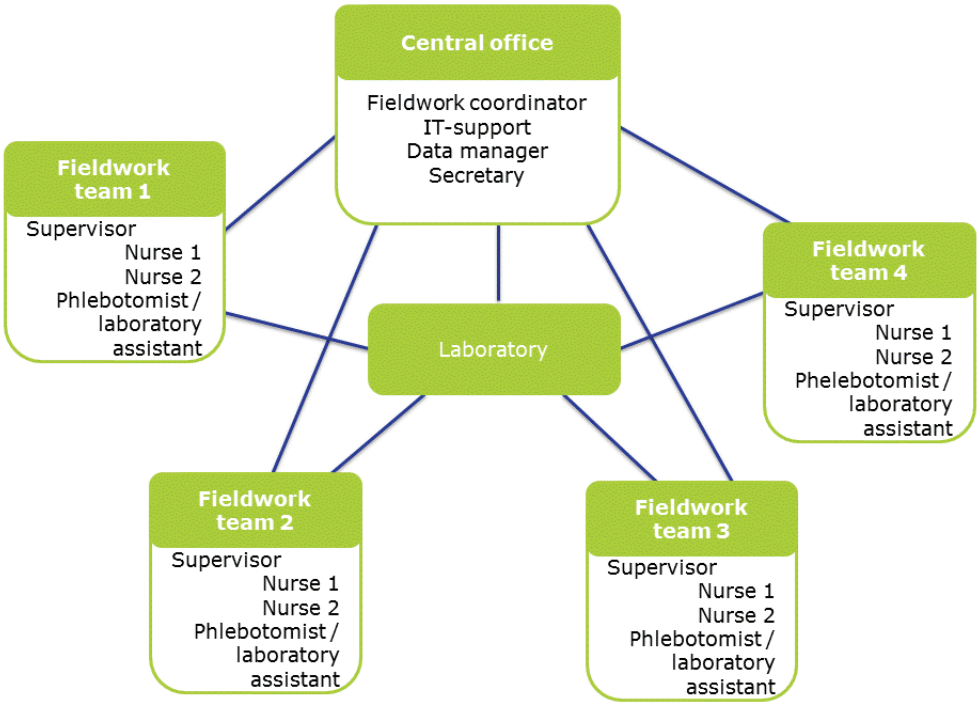

Figure 1.2. Structure of the fieldwork organization. Example 2

1.1.1 Central office

The Central office coordinates the overall fieldwork of the survey:

- Coordinating and supervising all fieldwork activities (national fieldwork coordinator).
- Survey quality control and fieldwork monitoring, with additional external auditors, if needed.
- Encouraging communication between fieldwork teams and the central office, collecting and responding to feedback from survey participants and all fieldwork team members;
- Sending survey invitations and scheduling appointments. (This may be done partly by the Fieldwork teams.)
- Selecting and agreeing on examination centres or personnel in the regions/local municipalities (if needed).
- Making sure that there are adequate personnel resources for the fieldwork (in case of sick leave and other absences or in case of staff turnover during fieldwork)
- Receiving and processing survey data from the Fieldwork teams.
- Receiving, storing and analysing blood and other samples from the Fieldwork Teams (This may be managed by an organization separate from the Central office, if the laboratory services are outsourced.).
- Keeping in contact with relevant regional/local administration and health services of the fieldwork sites. (This may be done partly by the Fieldwork teams.)
- Population level communication to raise awareness of the survey and its purposes to increase the response rate.
- Informing and reporting fieldwork progress to funders and other stakeholders

1.1.2 Fieldwork team

1.1.2.1 Structure and division of the tasks

Selection of the fieldwork staff is described in Part A, Chapter 9. The composition of the fieldwork teams depends on the type of the examination site (home visit/ local examination centre/ mobile examination unit), the core measurements and possible additional national requirements. We provide here general principles related to the fieldwork teams and examples in specific survey settings.

Each team should have a named Fieldwork team supervisor, and his/her deputy. Depending on the number of fieldwork teams and geographical coverage, several local/regional team supervisors may be needed. They need to work in close collaboration with the national fieldwork coordinator. The tasks of the field team supervisor(s) include

- Coordinating the work of the fieldwork team, consulting, solving problems and specifying guidelines when needed;
- Organizing substitutes for the fieldwork team members in case of sick leave and other absences (this can also be organized centrally from the Central office);
- Keeping in regular contact with the national survey coordination/Central office;
- Checking daily appointment schedules, checking questionnaires (if needed e.g. if built-in computer programmes not used for all data collection);
- Organizing and taking care of transfer of data and materials as well as traveling of staff members (when needed).

Depending on the organization of the fieldwork, the Field team supervisor may also carry out certain measurements.

The tasks of the members of the Fieldwork teams should be clearly defined and documented in the national Manual.

1.1.2.2 Absences

Sick leaves and other absences must be taken into account when estimating the number of survey personnel for the fieldwork (see more details in Part A, Chapter 9). There should be a specified protocol how to cover absences (expected and unexpected) during the survey fieldwork. The ways how to inform fieldwork team supervisor and/or Central office about the absences needs to be defined. Also instructions for who and how will organize substitutes for the team members needs to be defined in the national manual.

1.1.2.3 Supervision

The fieldwork supervision has two levels;

1. The national coordinator at the Central office has an overall responsibility of the fieldwork teams and fieldwork activities. She/he should visit the survey sites regularly. These visits are especially important at the beginning of the fieldwork to see how plans are working in practice. Regular visits from the Central office are also important to support and motivate the fieldwork staff as well as for quality control (see Part B, Chapter 10).
2. The fieldwork team supervisors should meet or otherwise keep in contact (e.g. by an internet discussion forum) regularly with the Central office to share up to date information from the site. The fieldwork team supervisors also bring information from the central office back to their teams, e.g. feedback from quality control. They are responsible for monitoring that team members carry out their tasks well day-to-day. If there are problems that cannot be solved within the team, the supervisors should contact the central

office and issues should be sorted out as soon as possible. It is important that the fieldwork team supervisors receive support from the central office and do not have to deal with problems alone.

Staff satisfaction is an important issue for maintaining the quality of the work. The national survey coordinator and fieldwork team supervisor have an important role in creating a positive work environment which affects staff satisfaction. A good leader should be visible, consult with staff, and provide praise and recognition (Duffield et al. 2010).

1.1.2.4 Internal communication

Sharing information between the central office and fieldwork teams as well as between and within fieldwork teams is important for the success of the work. Communication between the central office and fieldwork teams should include as a minimum issues relating to the progress of the work and to possible changes in the procedures or personnel. Sharing experiences between the fieldwork teams is an important part of internal communication. Within the fieldwork teams, communication is often focused on daily activities such as division of tasks, absences, moving to new location, etc.

Internal communication can be organized in many different ways: face-to-face meetings, video meetings, telephone meetings, extranet and internet sites, newsletters, SMS text messaging, instant messaging like Skype or even through social media. The key of communication is to make sure that every member of the team gets relevant information in timely manner.

Formal meetings are useful for disseminating important information and for making decisions. Informal meetings such as coffee breaks give the possibility to share instant issues.

It is important that the personnel are able to share their thoughts with colleagues and get advice if needed. The fieldwork staff may need extra support after unexpected incidents at the survey field site. Group discussions are usually useful and increase the feeling of belonging and support among the fieldwork personnel.

1.2 Safety issues

Safety issues during fieldwork should be considered both from the perspective of the participants and the staff. Safety issues related to each measurement should be covered in the national manual under the instructions for each measurement (see Part B, Chapter 5 and Chapter 6). Here we focus on general safety issues for the staff and for the participants. The employer and employee are both responsible for the work safety. We list here some issues relating to safely regarding the survey fieldwork but many issues depend on the survey setting. National legislation may also affect instructions required at a national level (e.g. laws on occupational health and safety).

In general, the employer is responsible for providing

- a safe work place and equipment;
- safe work processes;
- protective equipment where needed; and
- information, instructions and training.

The employee is responsible for

- following the provided safety instructions;
- using protective equipment and clothing in a correct manner;
- informing either the fieldwork team supervisor or the national fieldwork coordinator about hazards and injuries, and
- taking part to the safety training provided.

Safety instructions should include guidelines for each step of the survey fieldwork: moving to a new examination site, setting up the examination site, the measurements themselves, and personal safety of the fieldwork team members.

1.2.1 Moving to the examination site

Depending on the survey setting, these instructions should include issues relating to the moving of the survey equipment as well as travel of survey personnel. If equipment is moved by survey team members, special attention should be paid to the packing of the equipment properly both for moving containers and moving them to a vehicle, how to lift heavy equipment, and how to protect equipment from theft.

1.2.2 Setting up the examination site

For setting up the examination site, safety instructions should deal again with how to lift heavy equipment, how to place equipment at the site so that they do not cause danger to anyone, safe storage of materials, and how to make the examination place accessible for participants in a safe way. The last point may, for example, include instructions on how to make sure that the sidewalks to the examination site and floors at the building are not slippery.

1.2.3 Safety of the measurements

Each fieldwork site must have at least one person trained in first aid who is present at all times. All survey staff should be trained to make an emergency call if needed. These issues should be included in training. The safety of additional measurements must be checked (with additional health related questions), especially if there are physical fitness tests that may be too demanding for persons with health problems. Some participants, e.g. those with reduced mobility, may require

help to ensure their safety. This requires extra effort from the fieldwork personnel.

1.2.4 Safety of fieldwork staff

Safety of the fieldwork staff has several aspects: how to ensure a safe working environment, how to handle unexpected situations with participants, and how to get help when needed.

When the fieldworkers come to the new examination site, they should check the location of the fire exits, where to find fire extinguishers and what emergency procedures are possible. The location of the first aid kit should be checked. Local police officers should be informed about the survey, if the participants want to confirm with them e.g. whether it is safe to let the staff members enter their homes.

Instructions for the ergonomics at work should be provided for the fieldwork team for both measurements and when working on computer. Everyone should keep their working area clean. If liquids or other materials are spilled on the floor, they should be cleaned up immediately.

Unexpected situations may occur at the examination site or during a home visit. Even though in most cases participants are co-operating and safety issues do not seem to be a main concern, safety instructions should be offered to the fieldwork teams. A difficult situation may come up with a participant who is not co-operating (e.g. hasa mental problems) or who is under the influence of alcohol or drugs. The fieldwork team members should be advised how to act in these situations. In threatening or otherwise difficult situations, the examination has to be stopped or cancelled. The fieldwork member should report these incidents to the team supervisor and the central office. Then it must be considered whether or not it is relevant to offer a new examination time. If the participant was not co-operating or seemed to be intoxicated, it should always be recorded, as with other observations relevant to the survey.

During a home visit, it is recommended that the fieldwork team members carry a mobile phone, so that it is possible to contact colleagues in case advice is needed. The fieldwork personnel should also be advised to dress appropriately (Cottrell, McKenzie 2011). Also the possibility of pairing two fieldwork members for home visits can be considered if it is needed for cultural reasons or as a precaution. It is important that fieldwork personnel feel safe and know how to act in different situations.

1.2.5 Reporting of the threatening situations and injuries

Safety instructions should also include instructions on how and to whom staff should report threatening or risky situations or injuries. Also verbal abuse of the fieldwork team members should be taken seriously and reported.

1.3 Organizing the fieldwork site

When the examinations will be carried out at clinic settings, either temporary clinics or in the premises of existing health care services, the following issues should be covered in the national manual:

- Part B, Chapter 5 and Chapter 6 provides instructions for each measurement on how the measurement site should be set up.
- How to ensure privacy during the examination.
- Where to place instructions for coming to the examination site (stands, posters with logo and arrows, etc.).
- Depending on available rooms, which may vary between locations, how to set up reception and different measurements, e.g. which measurements can be taken in the same room, where a separate room is needed, how to organize a waiting area for the participants.
- The number of rooms needed for the reception, measurements and a waiting room.
- General requirements for the rooms:
  - Easy access for the participants.
  - Privacy for the participant.
  - Quiet surroundings (e.g. no noise affecting blood pressure measurements).

In addition, collaboration with the local health care organizations and professionals need to be specified. For home visits, the field work personnel should be instructed on how to select the room and place where the examination is carried out.

1.4 Scheduling appointments with the participants

Which appointment times are offered for the participants may vary depending on the survey setting. The rules and principles for the appointment scheduling need to be specified in the national manual: time of the day and weekdays to be used, and time needed for the examination of one participant.

When scheduling appointments, the following issues should be considered:

- Fasting needed for the blood samples: for glucose (8 hours for the EHES core measurements).
- Flexibility and easy access for the participants, e.g. possibility to change and re-schedule appointments.
- Working time of the fieldwork staff.

The appointment scheduling system can be organized in many ways depending on local needs. A computerized system, which in ideal case is shared either through the internet or an external server, makes it possible to book appointments from different locations simultaneously. This is a useful feature, since appointments can be assigned or changed by the Central office and fieldwork teams, and if there is an online appointment booking system on internet, by participants themselves.

In any case, the appointment scheduling system should be built so that the history of the scheduled, changed and cancelled appointment times for each participant can be followed up. This is important information when analysing the recruitment process and timing of the examinations.

1.5 Logistics of transfer of survey materials and traveling of the fieldwork staff

Logistics is the management of the flow of materials, information and other resources between the fieldwork site, the Central office and laboratory, and between different fieldwork sites.

The following issues need to be specified in the national manual:

- Routing of measurement sites; depends on the number of fieldwork staff members and teams, and number of selected measurement sites. It needs to be specified which sites each team or staff member will cover. A system for circulation of teams or staff members between regions may be considered to minimize measurer effect on the results.
    - This routing plan will specify the number of days needed per site, the number of days needed for moving, and distances to be moved. It will also specify how the equipment will be moved from one site to another (by team members or hiring a special company to take care of the transport)
- How will the field work staff travel (using private cars, public transportation etc).
- How completed questionnaires, in case of paper questionnaires are used, and data, in case of electronic/web based data entry is used, are transferred (see Part B, Chapter 9.).
- How samples are transferred (see Part B, Section 6. on blood samples).
- Log book of sent and received equipment, questionnaires, data, samples etc.
- Possible permits needed for transfer of materials (e.g. blood samples and mercury sphygmomanometers) for example by air within the country.

Many of these issues will require different arrangements when the examinations are organized at temporary clinics, regular health care facilities or by home visits. When the fieldwork is organized at temporary clinics, the challenges in logistics lie especially in arranging the rooms and equipment when moving from one location to another. When the examinations are carried out in the regular health care settings, the challenges lie in the specific standardization requirements of the survey as compared with the regular practices. When the fieldwork is organized by home visits, the challenges lie in the transfer of questionnaires, data and especially transfer of blood samples.

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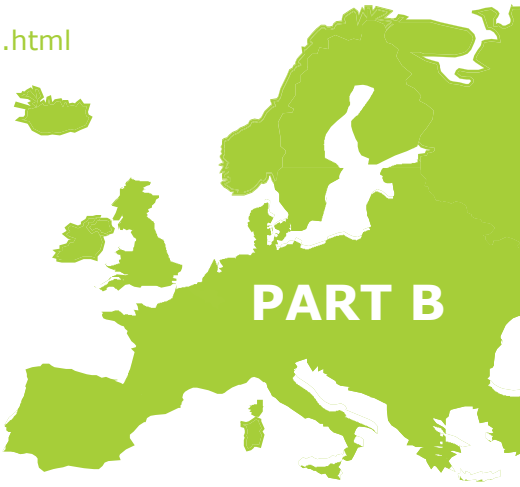

2. Instructions to participants and motivating participants

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2.1 Instructions to participants

The invitation letter can include instructions for the participants. If the invitation and the appointment are made during a phone call or home visit, the instructions can be provided verbally during the discussion. However, it is still recommended that a paper leaflet or invitation with some key issues as well as reminders of appointments and instructions are also given or sent to the participant by mail, e-mails and or text messages after the first contact. The following participant information and instructions should be adapted according to the survey setting such as home or clinic visit:

- **Contact information:** Name of the contact person, and their telephone number, address and e-mail address or a website link are given so that the participant is able to re-schedule or cancel the appointment, or ask further information on the survey.
- **Duration of the visit:** The participant can reserve enough time.
- **Travel expenses:** Rules for getting reimbursements should be specified, if they are available and needed.
- Other incentives and rules for getting these should be explained, if they are used.
- **Identification:** Everybody will be asked for a valid identification (with a picture). It may be useful to explain that a substitute for the participant is not accepted (e.g. family member or a friend).
- **Fasting:** Relates to the fasting glucose measurement, which should be done at least for those examined in the mornings. The minimum fasting time for the EHES core measurements is 8 hours, but the fasting should not exceed 14 hours. The participant needs to be informed that he/she can drink some

water and take his/her regular medicines in the morning before the visit. For those examined in the afternoon, 4 hours fasting is recommended.

- **Smoking:** The participant should abstain from smoking for one hour before the examination (it affects blood pressure measurements).
- **Vigorous physical exercise:** The participant should abstain from vigorous physical exercise for one hour before the examination (it affects blood pressure measurements and blood samples).
- **Presence of family members, significant others, interpreters:** Their presence can be allowed if needed e.g. in case of problems with understanding the language, problems in speaking, hearing or cognitive capacity.
- **Medication:** If the use of medicines will be checked and recorded during the visit, boxes of medicines/prescriptions should be taken along to the examination visit.
- At least in the northern countries and during the winter season, **instructions on clothing** may also be useful: For the EHES core measurements, light clothing is recommended. If outer layers of clothing are needed, these should be easy to take off. In some cultures undressing may be considered intimate, and mentioning this may decrease participation rates.
- Other information on what will be done in the home environment, or the possibility of home visits or visits to institutions, if these are offered for persons who are unable to attend a clinic visit, or when home visits are offered to all participants.

Adherence to these instructions should be recorded for each participant at the beginning of the examination visit, or during the measurements which are affected by the person's behaviour.

2.2 Motivating participation

Selected persons will participate only if they have enough motivation. This is why several factors in the recruitment process focus on motivation, such as communicating the importance of the survey, being flexible about schedules, and by providing incentives to participants. These issues are covered in Part A, Chapter 13. and Chapter 14.

An important issue is how to motivate those who hesitate to participate. Answers to the most common questions about the survey or reasons for not participating should be provided in national manuals to ensure that all staff members are able to give proper answers to potential participants. A list of Frequently Asked Questions and the appropriate answers may also be useful on the survey website. The following examples will help to provide quick responses for the staff recruiting participants. Additional examples are given in the Appendix at the end of this Chapter.

I'm too busy to participate.

- I can understand that you are busy, but we could organize the examination for the time most suitable for you. How about evening or weekend times … (suggest days/times)?
- It is really important for the study to be able to also include busy people like yourself, so that we can get representative information about the entire population of (specify your country).
- If the full appointment seems too time consuming, a short version with a non-participant questionnaire and only the core measurements should be offered.

I don't want to tell you my private issues, I am worried about the confidentiality of the information I have to provide.

- The information you provide will be treated in strict confidence. In the survey data, no names and ID-information are used, your data will be linked to you only for the purpose of sending you feedback on your personal results, such as the blood test results.
- If there are any questions/measurements which you feel to be too personal, you have no obligation to answer them or allow measurements to been taken.

Why have you selected me?

- You have been selected by random from … (provide sampling frame here). It is important that we include all kinds of people in the survey. This way it will most accurately represent the population of the country (specify you country).

I'm too sick to participate.

- We are interested in obtaining information from healthy and sick individuals. To be able to get a good picture of the health status and health determinants of (specify your country), it is really important to examine those with ill health, too.
- If you feel that you are not well enough to come to the examination site, could we come to you and do the examinations at your home? We will not carry out any measurement that would include any risk to your health and well-being. You have the right to refuse any measurements that you feel as too exhausting or uncomfortable.
- If the full appointment seems too exhausting, at least a non-participant questionnaire should be offered.

I don't need to do the health survey because I'm really healthy.

- We are interested in obtaining information from healthy and sick individuals. To be able to get a good picture of the health

status and health determinants of (specify your country), it is really important to examine also those with good health.

I see my doctor all the time; I don't want to talk about my health again. I have just recently had a health check at my GP.

- The survey is not just about health but also about lifestyles and other factors affecting your health.
- We cannot obtain your health information from your doctor (medical records).
- Even though there is not much personal benefit for you, we ask you to offer your information to the research and health monitoring purposes, which are needed to plan health services and other health promotion actions for future generations.

Motivation of the participants should be an ongoing process throughout the survey. Therefore, in addition to the recruitment process, motivation is also important during the examination visit to get as complete data as possible from all participants. Issues that increase motivation during the examination visit are (Clarke et al. 1990):

- An atmosphere that makes participants feel welcome and appreciated;
- The opportunity to ask questions and raise personal concerns that are taken into account and answers are given;
- Comfortable facilities e.g. privacy is important;
- Fluent change between measurements (no waiting times or minimal waiting), if the measurements are carried out by different team members. All team members should introduce themselves and welcome the participant;
- Giving encouraging feedback on the measurements.

Finally, the importance of keeping promises (e.g. giving realistic information on when the laboratory results will be mailed) and having the possibility of asking questions also after the appointment and adjusting to different situations (e.g. taking into account any special needs of the participants) are also important issues for motivation. A disappointment or frustration may accumulate unwanted attitudes towards the survey and even to future surveys. In many cultures and communities negative experiences are shared with neighbours and friends, and in the social media more often than positive.

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Appendix 2.1 FAQ - Sampling & participation

Why was I selected for the survey?

- We have drawn a representative sample of people from all over the country. It is sheer luck that you are one of them.

But I'm not representative?

- No one is representative on their own. All people are different. It is the entire sample that should be representative for the entire population, not individual participant.

How did you select me? Why did I receive an invitation?

- The answer here may differ somewhat among countries depending on what kind of sampling frame was used, but can be like: "We used a population register/postal address file/... and selected places and people at random. We first selected places and then people living at the places we selected. This is a scientifically correct way of doing it to get a representative picture of the general health status in our country."
- For this study a sample has been drawn from the .... population aged ...to .... years. By chance, your name was part of that sample. A total of .....are invited from ... municipalities.

Why do you select participants at random? How can you get a representative sample that way?

- Selecting at random is the only way we can get a representative sample, not biased by our own prejudice.

How can you learn how the health is for the entire country without asking everyone?

- We acknowledge, that we don't get exactly correct numbers but good enough to get a useful picture.

I'm too busy to participate. Can you ask my husband/neighbour/someone else instead?

- No. If we replace non-participants we end up with a sample of only people who can and want to participate. That will not be a representative sample any more. Therefore your participation is very important and your participation is very valuable.

But in opinion polls they replace people?

- Yes, but this is a scientific survey and we have to use correct scientific methods. In commercial opinion polls that is not so important.

I'm too sick/unable to participate.

- Here each country must decide what can be offered people who are too sick or unable to attend the examination. Home visits have been recommended in the EHES manual (Part A, Section 7.2). It is very important having also sick/disabled people participating or to have at least some information (at least the non-participant questionnaire) from as many as possible. In case the person is unable to respond due to severe health problems or limitations in functional capacity, e.g. a close relative or a friend can possibly give some proxy information with the invitee's consent. If not, it can severely bias the results.

I have bad health, so I don't think you'd want me to participate.

- We are not only interested in people with good health. Then we would get a wrong picture of people's general health. Therefore it would be very important if you can participate.

What do I get in return for participating?

- The answers here may differ as different countries allow different rewards. If no direct personal rewards can be promised, the benefits to the public health research and policy should be emphasized.

How many people have been invited to participate in the survey?

- We have invited ... persons from all over the country, ... persons from your community (name of town/ municipality)

How will all documents be handled?

- (Needs to be adapted to local systems). All questionnaires and data are stored encrypted, i.e. just using participant number, without any information that can be linked to your personal data. Only on the Informed Consent Form, signed by the participant, is a document where the name of the participant is mentioned. These forms are kept in locked cabinets at the research location and later on at (name of the Institute responsible for the survey). Data on the Informed Consent Forms are handled internally. In the electronic files only the respondent number, examination date and the answers to the questions are listed.

What can I expect when participating?

- (Needs to be adapted as describing survey practices). Joining the surveys means filling in a questionnaire and participating in a physical examination of about half an hour (... hours), including the following measuremetns ... (list all). You can fill out the questionnaire at home. The physical examination takes place at a research location in your area (or in your home). You will get personal feedback on results cocerning the following measurements and laboratory tests ... (list all).

I cannot visit the research facility but I want to participate, what to do?

- (Needs to be adapted). If you are physically unable to come to the examination site, please fill in your contact information on the reply card and send it back. We will contact you to make an appointment for a home visit. Ir a possibility to fill-in the full questionnaire or at least the non-participant questionnaire should be offered. If feasible, the reason for not been able to come to the examination site can be asked.

What will be done with the results?

- Immediately after the physical examination you will receive the results of your measurements (height, weight and waist circumference) and your blood pressure. You will receive the results of the blood test by post. The results are then separated from your personal information. Anonymized data from the study, where no persons can be identified, will be used for health monitoring and in scientific research on public health.

Do I need to confirm my participation? Should I reply also when I don't want to participate?

- Yes, please inform us. You received a personal invitation and we hope that you will participate. If we don't hear anything from you, we will send you a reminder.

Why is this survey needed?

- We don't have recent figures on how common health problems are or will become in the near future in the people living in/residents of (name of the country). Do we exercise enough? How are our cholesterol levels? How many people have diabetes? These data are very important for improving health promotion actions and health care in the country. Therefore, we are performing this nationwide survey at the request of (name of the national authority e.g. the Ministry of Health).

Why should I participate?

- It is very important that you would participate, the more people participating in this study, the more we know about the health situation in the country. It also gives you the chance to get more information about your own health.

How I can respond to the invitation?

- (Needs to be adapted). If you received an invitation you can sign in using the form on this website. Your login information is given in the invitation letter. You can also register by returning the reply card you received, in the enclosed envelope. A stamp is not required.

I did not receive an invitation, can I participate anyway?

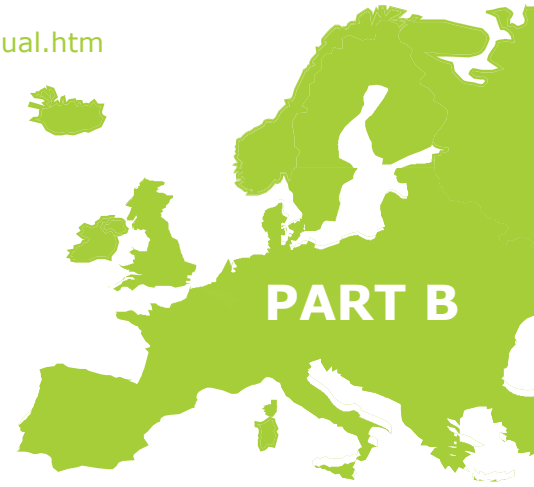
- No sorry, you can't. Only people who received an invitation can participate in this study. It is a personal invitation and not transferable. This method is the only way to collect representative data.

I cannot make it to the appointment, what should I do?

- You can make a new appointment by calling our staff: (e.g. toll free number).

Whom should I contact with other (later) questions?

- Is your question not mentioned here? Then call one of the employee(s) of the study. They are available on (add days/ times) at phone number ...(e.g. toll free number) or send your question by an e-mail to....



3. Obtaining informed consent

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The process of obtaining informed consent starts from the first contact with the survey participant (Figure 3.1). All fieldwork staff and persons working on data collection, processing or analysis need to be well informed as to why informed consent is needed, and that it is both a legal and an ethical obligation. They should also know which issues are covered in the informed consent material and why these issues are important (Manual Part A, Chapter 4 of the EHES Manual).

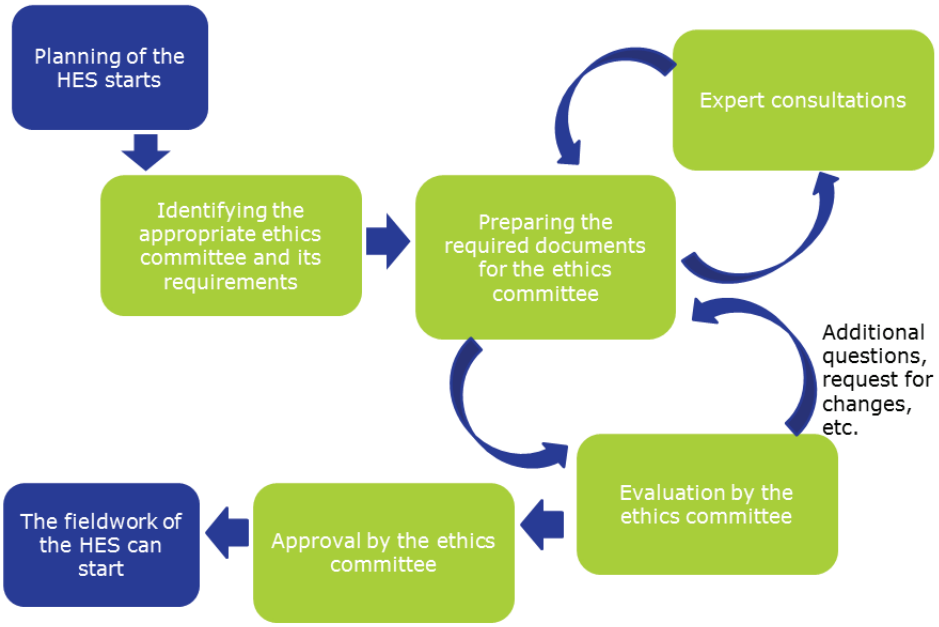

Figure 3.1. Process of obtaining informed consent

3.1 Key elements when obtaining informed consent

Key elements that must be assured when obtaining the informed consent are: information, understanding, competence and voluntariness (Caughlin et all 2009, Länsimies-Antikainen, 2010, WMA 2008).

- **Information:** All the information material that the participant has received concerning the study (including the invitation letter, the information notice or leaflet), personal communication and media campaigns , information of the web site of the survey and in social media platforms are important and they should be provided in linguistic style that is easy to understand.
- **Understanding:** To ensure understanding, the information should be provided both in writing and by personal communication.
- **Competence:** The participant's competence should also be evaluated, if there is any reason to doubt it, to make sure that he/she has adequate decision-making capacity.
- **Voluntariness:** Voluntary participation should be explicit. All participants should be able to choose freely and their decision to participate should not be influenced by coercion, manipulation or pressure. Participants should also be made aware of their right to withdraw from the study at any time and to refuse any measurement. The participants should also understand the uses of the data and the measures taken to ensure data confidentiality, so that they do not refuse to provide personal information or to undergo some measurements because they fear violations of their privacy. Both their personal gains and the public health interests should be explained. For example, taking part in measurements which do not provide information of personal interest (e.g. measuring blood lipids when these have recently been checked during a GP visit) is important to get valid results at the population level. For decision making, the participants need time and peace to read the information and to reflect on it before speaking with the field work staff and giving informed consent, and signing the consent form, as required.

3.2 Procedures for obtaining informed consent

Informed consent is a process of active communication between the fieldwork staff and the participant. The process consists of providing information and answering any questions that may arise. The consent should be obtained before carrying out any measurements. The participants should have the opportunity to ask questions at any time during the survey visit. They also need to be informed of whom they can contact for further questions, even after the examination visit.

The fieldwork staff should explain the legal aspects of the informed consent in simple words to the participant, ask them to read the information notice (or check that they have read it previously) and ensure that they have understood the key contents. Before signing the informed consent form, the participants may be asked to describe in their own words the purpose of the survey. This will ensure that they have adequately understood the information provided. A copy of the signed informed consent form may be given to the participants, to be read again later at home.

The participants may include severely ill, mentally impaired, demented or otherwise frail persons. The exclusion of such persons due to difficulties in obtaining informed consent or ability to take part in all measurements or to fill in the questionnaires, would lead to biased results. (Shepherd 2016) Thus there may be a need to identify an appropriate proxy to answer selected key questions. Also a surrogate decision maker or legal guardian may be needed for the consent. During the fieldwork, questions may arise on how to define whether a person is competent to provide the informed consent or to take part in all measurements. This problem is expected to be more common among elderly persons, especially among those who are institutionalized. In case of any concern, the fieldwork staff should be encouraged to contact their supervisor, the national fieldwork coordinator, the project leader, or other persons who are responsible for addressing issues related to the informed consent of the survey.

Standard tests of cognitive function have been used in health surveys. However, there is no consensus on the utility of such tests in the informed consent process. Moreover, there is no gold standard for formally assessing the capacity to provide informed consent in health surveys. However, there may be national rules of ethical conduct and national laws (e.g. the Mental Capacity Act in England, explained in Shepherd 2016) that need to be taken into account. In defining the fieldwork practices for persons with cognitive impairment, the national legislation has to be considered and the practices must be approved by the ethics committee. Adequate instructions also need to be given in the national fieldwork manuals. For example if a nurse sees that a participant is clearly not competent to sign the informed consent or to give accurate answers, the nurse can ask the participant if he/she has somebody who normally helps him/her with official issues (e.g. bank accounts or insurance) and another visit can be arranged with the presence of this person.

Since there are typically no major risks in health surveys, the evaluation of the competence of the person may be considered less formally than in clinical trials (GEP/IEA 2007, CIOMS 2008, Shepherd 2016). If only minor doubts concerning cognitive capacity arise and the individual is clearly willing to take part in the examination, he/she can be asked to sign the consent and the examination may be carried out.

3.3 Quality assurance of obtaining informed consent

The quality of the informed consent process is related to the quality of the information provided to the participant. The quality of the consent process can be assured by including both theoretical and practical training in the national training programme for the fieldwork staff. It should also be considered that the communication skills of the fieldwork staff may lead to differences in the process of obtaining informed consent. These skills can be observed during audit visits (see Part B, Chapter 10). Feedback during the fieldwork should also be collected to share experiences in obtaining informed consent, and problems encountered. Examples of answers to frequently asked questions concerning participation and data confidentiality, and specific explanations why the participants need to sign the informed consent, can be developed and given to all fieldwork staff to ensure that they understand the importance of informed consents and are able to provide adequate answers. If direct feedback from the survey participants can be obtained, they can be asked such questions as: Have you received adequate information, allowing you to understand the aims of the study? During audit visits, a few participants could be asked what they remember of the information provided to them before they signed the informed consent form.

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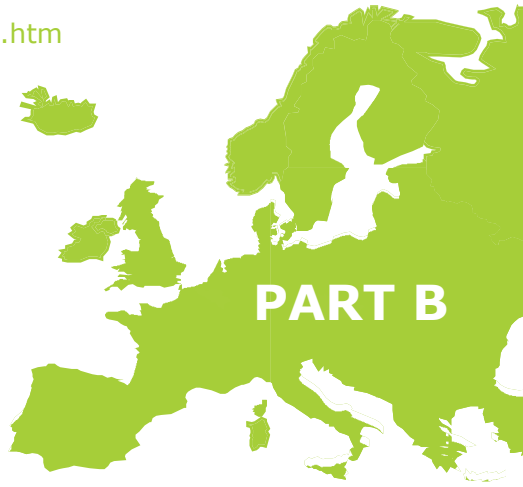

4. Interviewing and checking questionnaires

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The general principles for questionnaire administration are presented in Part A, Chapter 8. This chapter will focus on the fieldwork practices of carrying out interviews and checking self-administered questionnaires. The fieldwork personnel should be familiar with the background and meaning of the questions (see instructions for the interviewers in the EHES questionnaire, Part B, Chapter 7). The personnel should also know how their interaction with the participants and different interviewing techniques affect the reliability and quality of the data. These issues should be described during the training and specified in the national manual.

As hearing the results of the clinical measurements may affect the responses to some of the questions, the EHES core questions should be asked before carrying out the measurements. This allows the evaluation of differences between self-reports and measurements (e.g. height and weight). Some questions, e.g. those related to chronic diseases or conditions, medicine use and preventive care as well as questions on marital status and education, may be asked from proxies if the participant has severe problems in communication or cognitive capacity. However, subjective items (such as self perceived health) should not be asked from proxies. Whenever proxy respondent is used for any of the questions, this has to be documented.

4.1 Interviewing

When carrying out the interviews, follow these principles (Czaja et al 2005, Groves et al 2004):

1. Explain to the participant the possibility of stopping the interview at any time if he/she feels uncomfortable, the interview takes too much time or the participant does not wish to continue for any other reason. Stop the interview if the participant loses the ability to concentrate (e.g. is very tired or drunk) or if there are too many disturbing factors, such

as the presence of family members or other persons. Also, if you notice severe problems in the participant's communication skills, cognitive ability or hearing, stop the interview. If the interview is interrupted, explore the possibility of continuing later to finish the interview. This may require using a proxy or carrying out the interview with proxy assistance.

2. Read the survey questions and response categories exactly as they are written. If the participant does not seem to understand the question, repeat the question. If the respondent needs clarification, give additional information in a standardized way. If the participant is still unable to answer, you can give additional clarifications according to the specific instructions for the question. Where there are long lists of response categories or other complicated questions, the interview may be supported by show-cards or other visual aids.
3. Follow the order of the questions in the questionnaire: when the respondent starts talking about topics which come later in the questionnaire, instruct him/her kindly to listen to the next question.
4. Don' t comment on the responses or express any criticism (e.g. regarding participant's lifestyles) or give any other feedback during the interview than just acknowledge that you heard the answer.
5. Clarify inadequate answers in a standardized and non directive way, so that you do not affect the choice of answer categories.
6. Record the answers carefully and if open ended questions are included, record the answers verbatim.
7. Record the answers so that the participant does not focus on observing what you are writing.
8. Keep an active contact with the participant to build trust in face-to-face interviews. If computer assisted interviews are conducted, you need to keep frequent eye contact with the participant and show that you are listening and not just recording the answers by looking only at the computer.
9. It is essential that you give positive feedback on getting valuable information from the participant at the end of the interview, so that the participant feels that his/her responses and time spent with the interview were valued.
10. At the end of the interview, record all problems encountered during the interview: e.g. problems in communication skills, cognitive ability, hearing or reading, as well as the use of a proxy or the presence of family members and significant others during the interviews.This information can be used in the evaluation of the interviews.

4.2 Checking the self-administered questionnaires

If the EHES core questions are included in self administered questionnaire(s), which is(are) mailed to the respondents before the examination, they should be checked by the fieldwork staff before the physical measurements. Any additional questionnaires (with additional questions/modules) that are filled in during the examination visit, may be checked later, at the end of the examination visit.

When checking the questionnaires:

1. Be non-directive. Make sure that you will not affect the response, e.g. so that the respondent is not giving only socially desirable answers.
2. Don't comment on the responses or express any criticism (e.g. regarding participant's lifestyles).
3. Try to fill in missing items: If the respondent has not filled in all the questions because he/she has had problems in understanding the question or in choosing the answer, give further explanations as explained in the manual/during the training. If the respondent has left the question open as he/she did not want to give an answer (e.g. finds the question too intimate), record this.
4. Correct items where the respondent has selected several options in questions where only one option is allowed: ask the subject to choose the one that applies most/corresponds best to his/her situation.
5. Correct if jump rules have not been followed: help the respondent to clarify the situation.

In case of computer assisted data collection (web questionnaires, CASI) these (issues 3-5 above) can be checked within the computer program, e.g. allowing extra clarifications in wording, not allowing the respondent to select more than one option, not violating jump rules etc.

4.3 Quality assurance

Quality assurance of the interviews should include training for all interviewers with practical exercises, adequate supervision and feedback (see Part B, Chapter 10.). If feasible, additional interviews and repeated questions may be considered, as well as audit observations by fieldwork supervisors or coordinators. Data from the interviews and self-administered questionnaires should be checked at regular intervals during the fieldwork to monitor item response/non-response and identify missing data for key items. The use of response categories such as *"don't know"* or *"refusal"* (if used/allowed in the questionnaire), should be kept to a minimum. The data also needs to be checked for logical errors. In computer assisted data collection, logical checks as

well as checks for the completeness of data (answers to all key questions) can be checked within the data entry program, allowing immediate corrections. For EHIS questions, the rules in EHIS manual (EHIS 2013) and validation rules for consistency and skip rules (EHIS 2015) should be followed.

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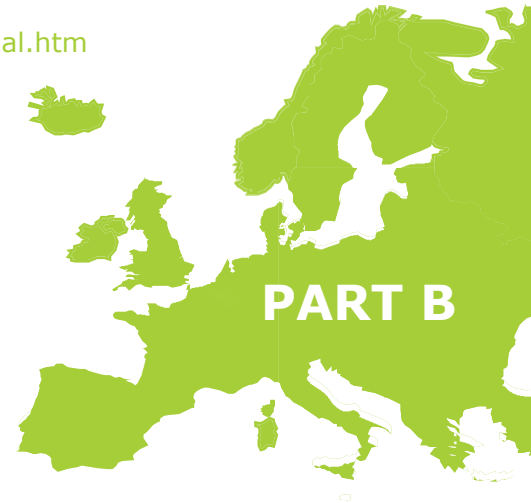

5. Physical measurements

5.1 Core measurements

5.1.1 Blood pressure

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5.1.1.1 Rationale

Both the measurers and the participants should understand the rationale of the blood pressure measurement to motivate them to take part and carry out the measurements following the protocol. A simple explanation is that blood pressure is the pressure exerted by circulating blood upon the walls of blood vessels. The blood pressure varies during day for each individual. When blood pressure results are presented, two values are given; systolic and diastolic blood pressure. Systolic blood pressure, higher of the two values, represents the pressure while the heart contracts to pump blood to the body and diastolic blood pressure, lower of the two values, represents the pressure when the heart relaxes between beats.

Elevated blood pressure is one of the key risk factors for cardiovascular diseases, dementia and some kidney diseases. Population level measurement of blood pressure is used to estimate prevalence of hypertension and to monitor changes in the blood pressure levels in the population. The proportion of the populations who's blood pressure has been measured during the past year had been 68% in Austria (Steiner 2011) and 71% in Finland (Peltonen 2008). Also awareness of high/elevated blood pressure varies considerably between countries in Europe from less than 20% up to 95% (Pereira 2009, Tolonen 2016).

Traditionally, blood pressure has been measured with the mercury sphygmomanometers. The Commission Regulation (EC) no 847/2012 has banned the sale of mercury sphygmomanometers from 10 April 2014 onwards in Europe (European Commission 2012). This, together with the development of oscillometric devices has increased the use of automated oscillometric devices in health surveys.

For the countries which have population level blood pressure trends based on mercury sphygmomanometer readings, it would be important to maintain the same instrument or at least perform a validation study to see how comparable readings with the mercury sphygmomanometer and the selected oscillometric device are.

The standardization of the blood pressure measurement procedure is important to obtain as valid readings as possible. There are many issues that affect the blood pressure levels (Table 5.1).

Table 5.1 Activities affecting the blood pressure level and the average magnitude of the effect on systolic and diastolic blood pressure

Activity	Systolic blood pressure (mmHg)	Diastolic blood pressure (mmHg)
Full bladder (Handler 2009, Campbell 1994)	Increases 10 to 15 mmHg, in case of uncomfortably distended bladder up to 50 mmHg	Increases 10 mmHg, in case of uncomfortably distended bladder up to 40 mmHg
Not resting 3 to 5 minutes before measurement (Campbell 1999)	Increases 10 to 20 mmHg	Increases 14 mmHg
Back/feet unsupported (Handler 2009)	Increases 5 to 15 mmHg	Increases 6 mmHg
Supine posture instead of sitting posture (Netea 2003, Jameison 1990)	Increases 3 to 10 mmHg	Decreases 1 to 5 mmHg
Legs crossed (Keele-Smith 2001)	Increases 5 to 8 mmHg	Increases 3 to 5 mmHg
Participant talking during the measurement (Handler 2009, Schulze 2002)	Increases 10 to 15 mmHg	Increases 6 to 10 mmHg
Arm below heart level (O'Brien 2003, Netea 2003, Netea 1999)	Increases up to 10 mmHg	Increases up to 10mmHg
Arm above heart level (O'Brien 2003, Netea 2003, Netea 1999)	Decreases up to 10 mmHg	Decreases up to 10 mmHg
Physical exercise (Campbell 1999)	Increases up to 22 mmHg	Increases 7 to 8 mmHg
Left arm instead of right arm (Gould 1985)	Decreases 1 to 3 mmHg	Increases 1 mmHg
Diaphragm of the stethoscope instead of bell (Mauro 1988)	Decreases 2 mmHg	Decreases 0 to 2 mmHg

Cuff too small (O'Brien 2003, Handler 2009)	Increases 3 to 12 mmHg, in obese persons up to 30 mmHg	Increases 2 to 8 mmHg, in obese persons up to 30 mmHg
Cuff too large (O'Brien 2003)	Decreases 10 to 30 mmHg	Decreases 10 to 30 mmHg
Cuff over clothing (Handler 2009)	Increases up to 5 mmHg	
Arm unsupported during the measurement (O'Brien 2003, Handler 2009)	Increases 1 to 7 mmHg	Increases 5 to 11 mmHg

Some persons have a tendency to have higher blood pressure levels when the blood pressure is measured in the physician's office than at home, or when measured by a physician rather than by a nurse. This is called *"white coat hypertension"*. (Frankiling 2016, Mancia 2016, Siven 2016)

5.1.1.2 Equipment

This Manual provides the measurement procedures for both the simple mercury sphygmomanometer or similar devices based on auscultation method and an automated (oscillatory) device's, as the choice needs to be done in each country.

5.1.1.2.1 Measurement by the mercury sphygmomanometer or other auscultation based devices

Figure 5.1.1 Devices when measured by mercury sphygmomanometer

Required devices are (see Figure 5.1.1):

- Simple mercury sphygmomanometer or other auscultation based device
- Stethoscope
- 3-4 cuffs of different sizes: small, medium and large cuffs. Ideally also an extra large cuff (cuff for leg) should be available for obese persons.
- Non-elastic measurement tape
- Stopwatch, digital wrist watch or watch with second hand
- Thermometer
- Watch (for recording the time of the measurement)

5.1.1.2.2 Measurement by an automated blood pressure monitoring device

Figure 5.1.2 Devices when measured by automated device

Required devices are (see Figure 5.1.2):

- An automated blood pressure monitoring device, which has passed the validation either based on the International protocol (O'Brien 2010), Association for the Advancement of Medical Instrumentation (AAMI) protocol (AAMI 2013) or the British Hypertension Society protocol (O'Brien 1993). From the British Hypertension Society web site (http://www.bhsoc.org/bp-monitors/bp-monitors/) can be found a list of validated automated blood pressure measurement devices with reference to the published validation results.
- 3-4 cuffs of different sizes: small, medium and large cuffs. Ideally also extra large cuff (cuff for leg) should be available for obese persons.
- Non-elastic measurement tape
- Thermometer
- Watch (for recording the time of the measurement)

5.1.1.2.3 Selection of cuffs for the survey

A set of 3 to 4 cuffs should be made available for the blood pressure measurement, to ensure as accurate measurement as possible. The width of the bladder of the cuff should be at least 40% of the arm circumference and the length of the bladder at least 80% of the arm circumference. Each national manual should have a table listing which cuffs are used for specific arm circumferences.

Manufacturers have different cuff sizes on the market and especially for the automated devices, often only the device specific cuffs can be used. Therefore, providing specific widths for the bladder of the cuffs is difficult. The British Hypertension Society (O'Brien 1997) recommends to use 3 cuffs:

- **a small cuff:** bladder size 12 x 18 cm
- **a standard cuff:** bladder size 12 x 26 cm
- **a large cuff:** bladder size 12 x 40 cm

and the American Heart Association (Perloff 1993) recommends to use 4 cuffs:

- **a small adult cuff:** bladder size 10 x 24 cm, arm circumference 22-26 cm
- **an adult cuff:** bladder size 13 x 30 cm, arm circumference 27-34 cm
- **a large adult cuff:** bladder size 16x38 cm, arm circumference 35-44 cm
- **an adult thigh cuff:** bladder size 20 x 42 cm, arm circumference 45-52 cm.

It is important that the cuffs are selected for correct arm circumference. This can be calculated as follows:

1. Number selected cuffs as 1 = narrowest cuff, 2 = 2nd narrowest cuff, ...
2. Measure the width of the bladder of cuffs. Let them be CUFF1, CUFF2, ...
3. Calculate the optimal arm circumference (OAC_i) for each cuff as: $OACi=CUFF_i/0.4$
4. Calculate the mid-point of each pair of adjacent cuff sized (MP_{ij}): $MP_{ij}=(OAC_i+OAC_j)/2$
5. Use the mid-points of cut points for selection of different cuffs

Cuff	1	2	3
Cuff width	cuff1	cuff2	cuff3
Arm circumference	<=MP12	MP12<arm circumference (cm) < MP23	>=MP23

5.1.1.3 Exclusion criteria

Blood pressure should be measured from all participants except if a person has

- amputation of both arms,
- cast on both arms,
- open wounds/sores on both arms,
- rash on both arms,
- malformation of both arms preventing to place the cuff, or
- lymph node malfunction affecting both arms and preventing to place the cuff properly.

5.1.1.4 Measurement procedures

5.1.1.4.1 Setting up the measurement site

The measurement site should be selected so that the room in which the blood pressure is measured is quiet and has a comfortable temperature. The room temperature should be recorded for each participant. If there is any disturbance during the measurement, this should be noted on the recording form.

The measurement device should be placed on the table in front of the measurer so that she/he has a clear view on the device but that the participant cannot see the result from the device. If the mercury sphygmomanometer is used, the mercury column of the device should be at the eye level of the measurer. As the mercury is moving on

bar, looking at it from different angles (down verse or up verse) will provide different reading.

For the participant, there should be a chair which has a back-rest. For the short participants, a support for their feet should be available. The table or armrest of the chair should be on the right hand side of the participant.

5.1.1.4.2 Preparation for the measurement

General issues

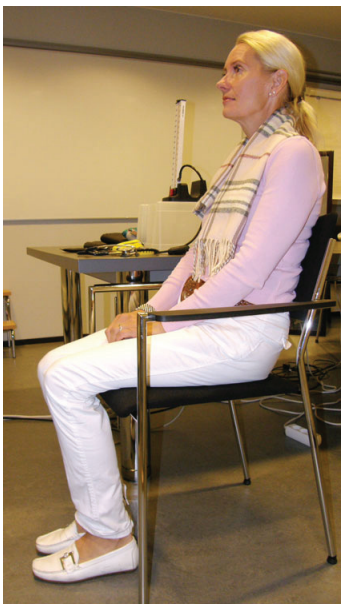
Each blood pressure measurement device used in the survey should have an individual number. This number should be recorded with each measurement.

Each measurer should have an individual identification, which is recorded with each measurement.

Instructions to the participants

Before coming to the examination, participants should be instructed to abstain from eating, drinking (except water), smoking, and heavy exercise for one hour before the measurement. The participants should also be instructed to empty their bladder, if needed, before the measurement as a full bladder affects blood pressure.

The subject should remove outer garments and all other tight clothing. Sleeves should be rolled up so that the upper arm is bare. The remaining clothing should not be constrictive, and the blood pressure cuff should not be placed over any clothing.



Position of the subject

The participant should be in a sitting position so that the arm and back are supported. The participant's feet should be resting firmly on the floor, not dangling. If the participant's feet do not reach the floor, a platform should be used to support them. If the participant cannot sit and the measurement is taken in supine posture, this should be recorded.

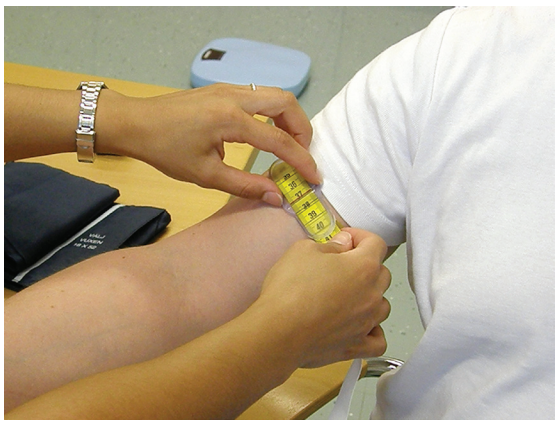
Position of the arm

The measurements should be taken on the right arm whenever possible. If not possible, e.g. the arm has been amputated or has rashes, adhesive dressing, casts, open sores, hematomas, wounds, arteriovenous shunt or any other intravenous access device, or if axillary lymph nodes have been removed, the left arm should be used. The use of left arm and reason for this should be recorded.

The arm should be resting on the desk so that the antecubital fossa (a triangular cavity of the elbow joint that contains a tendon of the biceps, the medial nerve, and the brachial artery) is at the level of the heart and palm is facing up. To achieve this position, either the chair should be adjusted or the arm on the desk should be raised, e.g. by using a pillow. The participant must always feel relaxed and comfortable.

Selection of the cuff for the participant

The greatest circumference of the upper arm is measured using a non-elastic tape, with the arm relaxed and in the normal blood pressure measurement position. The measurement should be read to the nearest centimeter and recorded. Select the correct cuff size for the arm circumference and record the size of the selected cuff.



Select the correct cuff size for
the arm circumference and record the size of the selected cuff.

5.1.1.4.3 Number of measurements

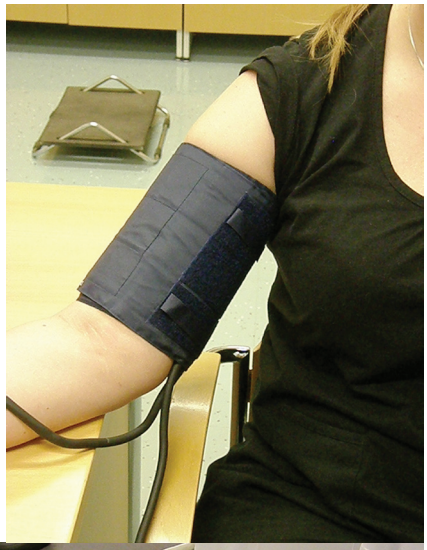
Three measurements should be taken, one minute apart.

5.1.1.4.4 Measurement protocol

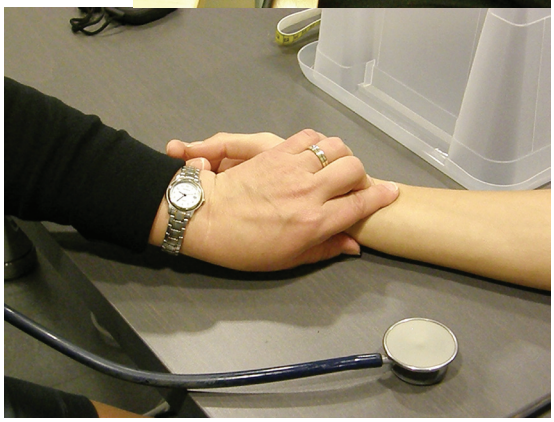
Mercury sphygmomanometer or other auscultation based device

1. The participant is asked to sit still for 5 minutes before starting the measurement. At this time the measurement pro-

cedure should be explained for the participant and emphasized that he/she should not move during and between measurements as that will increase the blood pressure.



2. The participant is asked not to talk during the measurements. It should be explained that talking during or between measurements will increase the blood pressure.
3. The arm circumference is measured and correct cuff size selected.
4. The cuff is placed on the right arm so that its bottom edge is 2-3 cm above the antecubital fossa. The top edge of the cuff should not be restricted by clothing. Make sure that the tubes from the cuff are not under the arm or otherwise tided up.



5. The radial pulse is palpated and the pulse rate is counted for 60 seconds, measured by a stop watch, a digital wrist watch or watch with a second hand.
6. Record 60-second pulse count and whether or not the pulse was regular.
7. Determine the peak inflation level:
   - The mercury column has to be at 0 level
   - The participant's radial pulse is again palpated.
   - The cuff is inflated and the level of the top of the meniscus of the mercury column is noted at the point when the radial pulse disappears. The cuff is immediately deflated by completely opening the valve.

   - The peak inflation level is determined by adding 30 mmHg to the pressure where the radial pulse disappeared.
8. The venous blood pool in the forearm is normalized by waiting at least 30 seconds or by raising the arm for 5-6 seconds.

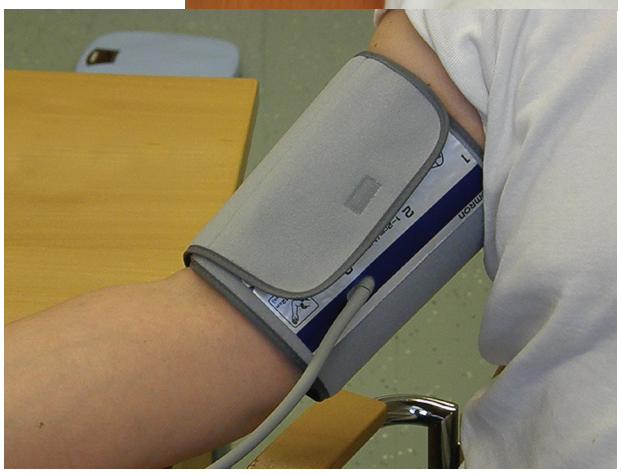
9. The brachial pulse is located and the bell of the stethoscope is placed immediately below the cuff at the point of maximal pulsation. If it is not possible to feel the brachial pulse, the bell of the stethoscope should be placed over the area of the upper arm immediately inside the bicep muscle tendon. The bell should not touch the cuff, rubber or clothing.
10. The cuff is rapidly inflated to the peak inflation level and then deflated at a rate of 2 mmHg per second.
11. The pressure should be reduced steadily at this rate until the occurrence of the systolic level at the first appearance of a clear repetitive tapping sound (Korotkoff Phase I) and the diastolic level at the disappearance of the repetitive sounds (Phase 5) have been observed. The cuff should then be rapidly deflated by fully opening the valve of the inflation bulb. Note: There may be a brief period (auscultatory gap) between systolic and diastolic pressure, when no Korotkoff sounds are heard. Thus the 2 mmHg/second deflation should be continued until the diastolic blood pressure is definitely established. If Korotkoff sounds persist until the cuff is completely deflated, a diastolic blood pressure of 0 is recorded.
12. The measurement is recorded to the nearest 2 mmHg. If the top of the meniscus falls halfway between two markings, the marking immediately above is chosen. The participant is not told his/her blood pressure at this point.
13. After waiting one minute to allow for the redistribution of blood in the forearm, a second measurement is made by repeating steps 9 to 11. The participant should not change position during this wait.
14. After another minute, the third measurement is made by repeating steps 10 to 12.

Automated (oscillatory) blood pressure measurement device

The detailed measurement protocol for the automated blood pressure measurement devices is type specific and should be adjusted for the instructions provided by the manufacturer of the specific device. Here is the generic measurement protocol.

1. The participant is asked to sit still for 5 minutes before starting the measurement. At this time the measurement procedure should be explained for the participant and emphasized that he/she should not move during and between measurements as that will increase the blood pressure.
2. The participant is asked not to talk during the measurements. It should be explained that talking during or between measurements will increase the blood pressure.
3. The arm circumference is measured and correct cuff size selected.

4. Attach the air tube of the cuff to the air jack of the machine. The cuff must be airless.
5. Make sure that the batteries are inserted or that the adapter is on.
6. The radial pulse is palpated and the pulse rate is counted for 60 seconds, measured by a stop watch, a digital wrist watch or watch with a second hand.
7. Record 60-second pulse count and whether or not the pulse was regular.
8. The cuff is placed on the right arm so that its bottom edge is 2-3 cm above the antecubital fossa. The top edge of the cuff should not be restricted by clothing. Make sure that the tubes from the cuff are not under arm or otherwise tide up.
9. Press the "ON" button: all the symbols on the display will light up in order to check the display. Note: in some models, pressing "ON" will start the measurement. In case you are using such a device, omit steps 9 and 10.
10. All the symbols then disappear and the air release symbol begins to flash.
11. Push the "START" button: the device automatically determines the correct level of inflation pressure.
12. When the target inflation values are reached, the air is automatically released. The value in the display counts downwards.
13. As soon as the monitor detects the pulse, the symbol begins to flash.
14. When the monitor no longer detects the pulse while the cuff pressure is dropping, the systolic and diastolic pressure are displayed.
15. The measurement is recorded as shown in the display. In case the device gives an error code, this is recorded. The participant is not told his/her blood pressure at this point.
16. After one minute, the second measurement is made by repeating steps 11-15. The participant should not change position during this wait. Note: some automated devices can



be programmed to take 2 or 3 measurements automatically with one minute between the measurements. If device like that is used, measurer does not need to repeat steps 11-15 manually.

17. After another minute, the third measurement is made by repeating steps 11-15.

5.1.1.5 Selection and validation of the automated (oscillatory) device

When an automated device is used for blood pressure measurement in a survey, special attention has to be paid to the selection of brand and type. The selected device should have passed at least one of the validation protocols:

- International protocol (O'Brien 2010)
- British Hypertension Society protocol (O'Brien 1993) or
- Association for the Advancement of Medical Instrumentation (AAMI) protocol (AAMI 2013)

It is also important to maintain same brand and type of the device in subsequent surveys to ensure comparability of the results between surveys and reliable estimation of time trends.

If previous surveys have been done using mercury sphygmomanometer or other brand/type of automated device, a validation study should be conducted to estimate potential differences.

5.1.1.6 Special issues when the measurement is taken at home of the participant

If the blood pressure is measured during the home visit, all the same requirements and procedures apply than for the measurements conducted at the specific examination site. Attention should be given to find a quiet place with optimal position for the participant and the measurer. All compromises in the setting and position should be recorded.

5.1.1.7 Information to be recorded

The information which should be recorded for each participant about their blood pressure measurement includes issues relating to the measurement situation: posture of the subject, activities just prior to the measurement, measurement setting and to the actual measurement. Specified issues to be recorded are given in the recording form (see Part B, Section 5.3).

5.1.1.8 Feedback to participants

The participant should be informed about his/her blood pressure levels and if their blood pressure needs to be controlled. They should receive a copy of their recordings with written instructions, when needed. There may be national differences on how this feedback needs to be provided; directly to the participant at the survey site or by the person's general practitioner.An example of the feedback form is given in Part B, Chapter 8.

5.1.1.9 Safety

When the mercury sphygmomanometer is used, special attention should be paid to handling of the device. It should be made sure that the manometer will not be dropped or treated in any way that could result in damage of the manometer.

In case of mercury spillage:

- Never use a vacuum cleaner, mob or broom to clean up a mercury spill.
- Evacuate the room and ventilate the room until the spill is cleaned up.
- When cleaning the spilled mercury
  - Remove your watch and all other jewellery to prevent mercury from bonding to the medal;
  - Use rubber gloves, protect your shoes and when ever possible use face mask and protective eye-wear;
  - Collect all the small droplets of mercury into a container (an eyedropper can be used to collect the smallest peaces), which can be sealed;
  - Use the flashlight to look all around in the areas of the spill. The light will reflect off the shiny mercury beads and make it easier to see them.
  - You can wrap tape around your fingers to collect small pieces of mercury.
  - Sprinkle sulphur powder on the spill area after cleaning up beads of mercury; a color change from yellow to brown indicates that mercury is still present and more cleanup is needed;
  - Sprinkle zinc flakes or copper flakes to amalgamate (clump together) any small amounts of mercury that remain.
  - Back all the materials used to collect the mercury and the container with mercury into zip-lock plastic bag marked with mercury waste. Dispose properly.
  - Wash your hands after cleaning the mercury.
  - Continue ventilating the room.

It is recommended that each room, where the mercury sphygmomanometer is used has a mercury spill kit. These kits can be self made or bought. The mercury spill kit usually includes:

- Rubber gloves
- Face mask
- Protective eye-wear
- Container, which can be sealed
- Eyedropper
- Tape
- Plastic bag with zip-lock
- Flashlight
- Sulphur powder
- Zinc or copper flakes

5.1.1.10 Quality assurance

Quality assurance of blood pressure measurements includes the following components:

- Training of the personnel.
- Checking the equipment and regular calibration of the devices.
- Audit visits and evaluation of the measurement data during the field work

5.1.1.10.1 Training of the measurers

Training of the blood pressure measurers should include:

1. Theory (see Section 5.1.1.1 above)
   - Why it is important to measure blood pressure in this survey.
   - Why blood pressure measurement has to be standardized.
   - What are the implications of the changes in the procedure to the blood pressure levels.
2. Practical training ideally with people with different blood pressure levels, and in the presence of a supervisor who gives feedback.

5.1.1.10.2 Checking the equipment and regular calibration of the devices

All equipment needs to be checked regularly. Each check and its outcome is recorded to the log book. If any problems are observed during

the checks, the device in question is replaced and also this is recorded to the log book.

Daily checks or when new examination place is set up

Every day, before starting the examinations, or when the examination site is set up in new place, the following issues from the equipment are checked:

- From the mercury sphygmomanometer:
  - The shape of the meniscus (top of the column of mercury) is a smooth, well-defined curve.
  - Check that the mercury raises easily in the tubing and the mercury does not bounce noticeably when inflated.
  - Disconnect the inflation system from the cuff and confirm that the meniscus of the mercury in the glass manometer tube is zero.
  - Check for cracks in the glass tube.
  - Check the screw at the top of the calibrated glass tube to make sure it is securely in place.
  - Check the coiled air tube for cracks, tears.
- From an automated device:
  - Make sure that the AC adapter cord of the device unit is securely plugged in or in case the device is operated by batteries that batteries have power.
  - Check the air tube for cracks, and confirm that the tube is securely attached to the device.

Weekly checks or when a new examination site is set up

Every week, or whenever the examination site is set up in new place, the following issues from the equipment is checked:

- From cuffs:
  - Cuff material is clean, intact.
  - Rubber tubing and inflation bulb (in mercury sphygmomanometer) is smooth, has no cracks or tears.
  - Pressure control valve opens and closes smoothly without sticking (mercury sphygmomanometer).
- From stethoscopes (mercury sphygmomanometer)
  - Stethoscope has no cracks in the tubing.
  - Earpieces of the stethoscope are securely attached.
  - Head of the stethoscope is securely attached to tubing.
  - Diaphragm is secure, no cracks.
- From mercury sphygmomanometer

- Test inflation system for air leaks:
  - Connect each cuff size to the inflation system and wrap it around the corresponding calibration cylinder;
  - Inflate to 250 mmHg;
  - Open valve and deflate to 200 mmHg and close valve; and
  - Wait for 10 seconds; if mercury column drops more than 10 mmHg, there is an air leak in the system; and
  - If a leak is detected, change the cuff, check the coiled tubing and repeat the test.

5.1.1.10.3 Quality control by coordinating office during the fieldwork

Quality control during the fieldwork includes actions to be carried out in the field by measurers regularly and keeping the log book of the regular checks as well as actions conducted by the coordinating office.

The coordinating office/fieldwork coordinators/supervisors should carry out audit visits to the fieldwork site to monitor the measurements., and/or use an external auditor In addition to the monitoring of the measurement practice, the coordinating office should monitor the quality of the measurements by checking the data. In regular intervals, which depend on the number of measurements conducted daily, the following should be checked from the data:

A) When the mercury sphygmomanometer is used for each measurer:

1. The distribution of terminal digits for systolic and diastolic measurements (separately) should be checked, to determine if
   - some measurers tend to prefer some digits over others (for example, zero preference), indicating unreliable detection of Korotkoff sounds;
   - some measurers use odd digits which, according to the protocol, should not be used.
2. The mean and standard deviation of the systolic and diastolic blood pressure measurement should be checked, to determine if the measurers are producing readings that are systematically lower or higher than the team average.
3. The proportion of identical measurements for the same participants (systolic and diastolic separately), to determine if the measurers are really doing all 3 measurements for each subject.

b) When an automated device is used:

1. For each device, the mean and standard deviation of the systolic and diastolic blood pressure measurements should

be checked, to determine if a device produces systematically lower or higher readings than the average.

2. For each measurer, the proportion of identical measurements for same participants (systolic and diastolic separately), to determine if the measurers are really doing all 3 measurements for each subject.
3. The mean and standard deviation of the systolic and diastolic blood pressure measurement should be checked, to determine if the measurers are producing readings that are systematically lower or higher than the team average. Measurer effect is also possible with automated devices: the nurses can e.g. have differences in how they make the subjects feel relaxed and comfortable.

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5.1.2 Height

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5.1.2.1 Rationale

It is important to explain to the participant the rationale and importance of the height measurement. Knowing why hight measurements are needed will motivate the participants to take part in this particular measurement. Adult height reflects the interplay of genetic endowment and various early-life experiences and exposures such as fetal, dietary, social and psychological circumstances) (The Emerging Risk Factors Collaboration 2012). Self-reports based on previous measurements of heigh may be inaccurate due to measurement bias, recall bias or due to height loss caused by morbidity and fracturs as well as by aging changes in the bones, muscles, and joints (Medline Plus 2016). People typically lose about 1 cm every 10 years after age 40. Height loss is even more rapid after age 70. Lifestyle choices may slow or speed the height loss process. It can be stressed that the measurement takes only a minute. Height will be used when calculating Body Mass Index (BMI), which is a widely used way to measure obesity. BMI is defined as the individual's body weight divided by the square of their height. Obesity is a known risk factor for many chronic diseases. There is a clear association between obesity and type 2 diabetes, hypertension and dyslipidemia. BMI is needed to estimate the prevalence of the obesity in the population (see Part A, Chapter 5 of the EHES Manual). Standardized methods in health measurement allow to follow time trends as well as comparisons between areas, population groups and countries.

5.1.2.2 Measurement protocol

5.1.2.2.1 Equipment

- Stadiometer (portable or fixed)
- Steps
- Carpenter's level
- Standardized length rods (i.e. 100 cm and 200 cm)

5.1.2.2.2 Setting up the measurement site

The measurement site should be private.

The fixed stadiometer or height rule is attached vertically to a hard flat wall surface with the base at floor level. A carpenter's level is used to

check the vertical placement of the rule. If the height rule does not have a fixed rod, it is recommended to mark with tape or a marker the straight line for the rule down to the floor.

When a portable, stand-alone stadiometer is used, the device is assembled based on the instructions of the device. A carpenter's level is used to check the vertical and horizontal placement of the stadiometer. If needed and feasible, the portable stadiometer is also fixed to the floor or wall, so that it will not move when participant steps on and off.

The floor surface under the height rule must be hard. If no such floor is available, a hard wooden platform should be placed under the base of the height rule.

5.1.2.2.3 Exclusion criteria

Height should be measured from all participants, except if a person:

- is immobile or wheelchair bound;
- has difficulties in standing straight;
- has a hairstyle or head gear (e.g. turban) which prevents the proper measurement;
- is taller than the maximum height of the stadiometer;
- refuses.

The reason for the exclusion should be recorded.

5.1.2.2.4 Measuring height

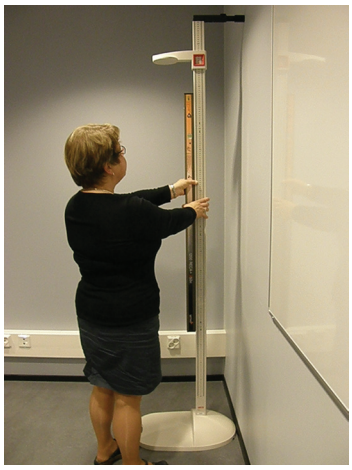
1. Ask the participant to remove his/her shoes, heavy outer garments, and hair ornaments and head dress, where culturally acceptable.
2. Ask the participant to stand with his/her back to the height rule or to the wall.
3. Check that the back of the head, shoulder blades, buttocks and heels are touching or in line with the stadiometer or the wall.
4. Ask the participant to stand in a natural straight standing po-

sition, weight evenly on both feet and arms hanging loosely by his/her side.

5. Ask the participant to look straight ahead. The 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 bony orbit (cheek bone).

6. Ask the participant to keep his/her eyes focused ahead, to breathe in deeply and to stretch to his/her full height.
7. Check the standing position from the front in order to verify that the participant is standing straight and in the middle of the stadiometer.
8. Lower the head piece of the stadiometer or the sliding part of the measuring rod so that the hair is pressed flat.
9. When the participant is taller than you are, use steps so that you can read the height rule properly.
10. Record the number of the device, and the height to the resolution of the stadiometer, preferably to the nearest millimeter. Record also, when needed, all issues affecting the measurement results (e.g. hair style).
11. Tell the participant his/her height and record it on his/her feedback form.

When the measurement is performed at the participant's home, the same protocol should be followed as closely as possible. The position of the device and the participant should be carefully checked. Any deviations from the protocol should be recorded.



5.1.2.3 Quality assurance

Quality assurance of height measurement includes the following components:

- Training of the personnel;
- Checking the equipment and regular calibration of the devices;

- Audit visits and evaluation of the measurement data during the field work.

5.1.2.3.1 Training of the measurers

See Part A, Chapter 15. on this Manual for more detailed information about the training.

Main points in the training are:

- Each measurer should understand the rational of the standardized measurement and have enough time to practice before field work, and she/he should receive supervision and feedback.
- If the survey is prolonged or when deviations are observed, refresher sessions about the measurement should be organized, at least at three month intervals.
- There should be explicit, detailed guidelines at the surveys site for performing the measurement.

5.1.2.3.2 Checking and calibration of the equipment

All equipment should be checked regularly. Each check and its outcome is recorded in the log book. If any problems are observed during the checks, the device is replaced and this is recorded in the log book.

Daily checks or when new examination site is set up

The following issues should be checked:

- The horizontal and vertical placement of the height rule is checked daily by using the Carpenter's level.
- The height of the rule is checked by using the standardized length rod when setting up a new examination site.

During the fieldwork

If the portable stadiometer can be moved during the day, the vertical and horizontal placement of the device should be checked at regular intervals, depending on the device. If it is possible that a fixed height rule moves during the day (for example it is taped on the wall) it should be checked with standardized rod at regular intervals and corrected if the error is greater than 2 mm. The results of calibration and the checking should be recorded in the survey log book.

5.1.2.3.3 Quality control by coordinating office during the fieldwork

Quality control during the fieldwork includes actions to be carried out in the field by measurers regularly and keeping the log book of the regular checks as well as actions conducted by the coordinating office.

The coordinating office will do audit visits to the field to monitor the measurements and/or organize external audits. Additional to the monitoring of actual measurements, the coordinating office will monitor the quality of the measurements based on data:

- distribution of terminal digit of the height measurement by measurer;
- mean and standard deviation of the height measurement by measurer;
- number and reasons why measurements were not done;
- daily work load (number of measurements per day by measurer).

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5.1.3 Weight

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5.1.3.1 Rationale

It is important to explain to the participant the rationale and importance of the weight measurement. This will motivate him/her to take part in this particular measurement. It can be stressed that the measurement takes only a few minutes. Weight will be used when calculating Body Mass Index (BMI), which is a widely used to measure obesity. BMI is defined as the individual's body weight divided by the square of their height. Obesity is a known risk factor for many chronic diseases and there is a clear association between obesity and type 2 diabetes, hypertension and dyslipidemia. BMI from all participants is needed to estimate the prevalence of obesity in the population. Time-trends can be followed after repeated surveys with standardized measurements.

5.1.3.2 Measurement protocol

5.1.3.2.1 Equipment

- Balanced beam scale or an electronic scale (with EC type-examination certificate for medical use) or a validated bio-impedance (body composition) scale. The scale should comply with the directive 93/43/EEC June 14 1993, updated in 2007/47*EC September 2007. There should be a a sticker at the bottom of the scale with a code and symbol to specify that the device complies with these directives (CE 09 CE 0109) and marking of precision class III, specifying that the device has been calibrated according to the EC directive.

- Calibration weights (e.g. 10 kg up to 100kg)
- A carpenter's level (if the scale does not include an in-built level)

5.1.3.2.2 Setting up the measurement site

The measurement site should be private.

The scales should be placed on a hard floor surface. The floor should not be carpeted or otherwise covered with soft material. If there is not such floor available, a hard wooden platform should be placed under the scale.

A carpenter's level (portable or included in the scales) should be used to verify that the scale is horizontal.

Device-specific instructions for setting up the scales should be followed.

5.1.3.2.3 Exclusion criteria

Weight should be measured from all participants, except if a person

- is immobile or wheelchair bound,
- has severe difficulties in standing steady,
- is heavier than the upper limit of the scale,
- refuses.

The reason for exclusion should be recorded. If the participant is pregnant, pregnancy weeks should be recorded, and self-reported weight before pregnancy should be recorded separately from the measured weight.

5.1.3.2.4 Measuring weight

Ask the participant 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. Record the clothing worn during the measurement.

Balanced beam scale

1. Ask the participant to stand in the centre of the platform, arms hanging loosely at his/her sides.
2. Check that the weight is distributed evenly on both feet.
3. Ask the participant to stand still facing ahead (not looking down).
4. Move the weights until the beam balances, meaning that the arrows are aligned.

5. Record weight to the resolution of the scales.

Electronic scale

1. Follow the device specific instructions for turning on the scales.
2. Ask the participant to stand in the center of the platform arms hanging loosely at his/her sides.
3. Check that the weight is distributed evenly on both feet. For most persons this means a small gap between the heels.
4. Ask the participant to stand still facing ahead (not looking down).
5. For the weight measurement, follow the device-specific instructions.
6. Record the weight to the resolution of the scales.

Bioimpedance device

1. Follow the device-specific instructions, check the position of the participant (see above).
2. Record the weight to the resolution of the scales.

Weight is also written on the participant's feedback form. The measurer can have a table (or this can be in the computerized data entry program) where she/he can check the BMI for the participant. The measurer can explain for example: "Your BMI means that you are classified as underweight, normal, little overweight or obese etc."

When the measurement is performed at the participant's home, the same protocol should be followed. The position of the device and participant should be carefully checked. Any deviations from the protocol should be recorded.

5.1.3.3 Quality assurance

The quality assurance of weight measurement includes the following components:

- Training of the personnel,
- Checking the equipment and regular calibration of the devices,

- Audit visits and evaluation of the measurement data during the field work.

5.1.3.3.1 Training of the measurers

See Part A, Chapter 15 of the EHES Manual for more information about training.

Main points in training:

- Each measurer should understand the rational of the standardized measurement and have enough time to practice with adequate supervision and feedback before taking actual measurements.
- If the survey is prolonged or if any deviations from the protocol are observed, refresher sessions about taking the measurements should be organized at three month intervals or more frequently.
- There should be explicit guidelines at the survey site for performing the measurement.

5.1.3.3.2 Calibration and checking the equipment

All equipment needs to be checked regularly. Each check and its outcome is recorded in the log book. If any problems are observed during the checks, the device is replaced and this is recorded to the log book.

Daily checks or when new examination site is set up

Balanced beam scale

- Check that the scale is horizontal (by carpenters level or level in the device)
- Balance with both sliding weights at zero and the balance bar aligned.
- Use calibration weights to check the scale when setting up the examination site. Place 10 kg weights one by one on the scale up to 100 kg and check that the scale works properly. If the error is greater than 0.2 kg the scale should be corrected or changed.

Electronic scale

- Check that the scale is horizontal (by carpenters level or level in the device)

- If the scale is operated with batteries, check that there is voltage on the batteries and that spare ones are on hand. Many of the electronic scales automatically inform when the voltage of the batteries is running low. Follow the device-specific instructions.
- If the scale is operated via a power cord, check that the power cord is properly attached to the device.
- Check the zero level of the scale.
- Use calibration weights to check the scale when setting up the examination site. Place 10 kg weights one by one on the scale up to 100 kg and check that the scale works properly. If the error is greater than 0.2 kg the scale should be corrected or changed.

Note: Standardized weights should be used to check the scale whenever it is feasible, both during the fieldwork and when measurements are conducted in home setting. It should be done at regular intervals (weekly or monthly) depending on the survey setting and the length of the fieldwork period.

5.1.3.3.3 Quality control by coordinating office during the fieldwork

Quality control during the fieldwork includes actions to be carried Quality control during the fieldwork includes actions to be carried out in the field by measurers regularly and keeping the log book of the regular checks as well as actions conducted by the coordinating office.

The coordinating office will do audit visits and/or organize external audits to the field to monitor the measurements. Additional to the monitoring of actual measurements, the coordinating office will monitor the quality of the measurements based on data. At regular intervals, the following should be checked from the data:

- The distribution of the terminal digit of the measurement by measurer;
- The distribution of the terminal digits for full kilograms by measurer;
- Mean and standard deviation of the measurement by measurer;
- Number and reasons why measurements were not done;
- Daily work load (number of measurements per day) by measurer.

References

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1993L0042:20071011:en:PDF
- DIRECTIVE 2007/47/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 September 2007 amending Council Directive 90/385/EEC

on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:247:0021:0055:en:PDF

5.1.4 Waist circumference

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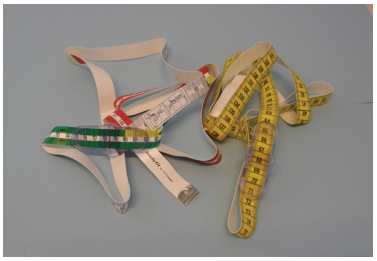
5.1.4.1 Rationale

It is important to explain to the participant the rationale and importance of the waist circumference measurement. This will motivate him/her to take part to this particular measurement. It can be stressed that the measurement takes only a few minutes. Waist circumference is used as an indicator of abdominal obesity. It is significantly associated with the risk of CVD incidence and type 2 diabetes. By measuring waist circumferences from all participants it is possible to estimate the prevalence of abdominal obesity in the population and to follow time-trends after repeated surveys with standardized measurements.

5.1.4.2 Measurement protocol

5.1.4.2.1 Equipment

- Non-elastic measurement tapes (200cm and 250cm)
- The full body length mirror, when ever feasible



5.1.4.2.2 Setting up the measurement site

The measurement site should be private.

If a mirror is used, it is placed against the wall or if the mirror stands on its own feet, it is placed next to the measurement place. The measurer should have a chair with wheels to sit on when checking the correct position of the tape.

5.1.4.2.3 Exclusion criteria

The waist circumference should be measured from all participants, except when the person:

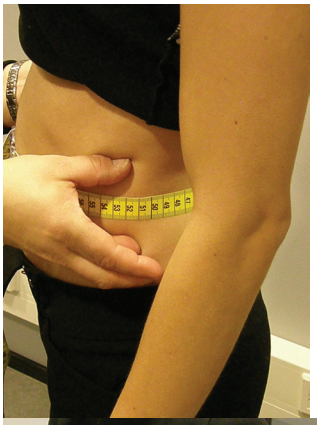
- is immobile or wheelchair bound,
- has difficulties standing straight,
- pregnant women (over 20 pregnancy weeks) may be excluded.
- has a hernia, a colostomy or ileostomy (wears a stoma bag/ostomy bag), recent abdominal surgery or other problems/devices which prevent the proper measurements,
- refuses.

The reason for exclusion and pregnancy status (in weeks) should be recorded.

5.1.4.2.4 Measuring waist circumference

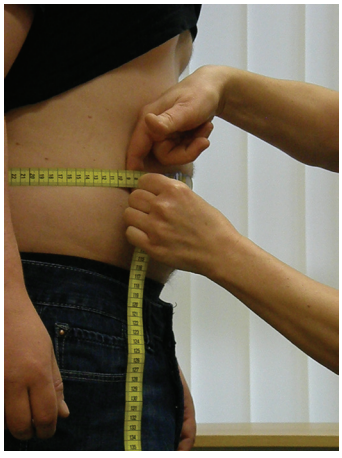
1. Ask the participant to reveal the waist, by loosening the belt, lowering the pants/skirt and lifting the shirt. Nothing should strain the waist. The measurement is done on bare skin. If the participant feels uncomfortable or refuses to undress, take the measurement over light clothing and record this.

2. Ask the participant to stand in front of you, while you are sitting. If a mirror is used, check that you have a clear view of it.
3. Ask the participant to stand with his/her weight evenly balanced on both legs, a small gap between the legs.



4. Check that the participant's hands are hanging loosely beside the body.
5. Palpate the waist to find the right measurement place: midway between the lower rib margin and the iliac crest. Check the position from both the right and left sides of the body.
6. Position the measuring tape at the participant's waist or ask him/her to pass the tape around.

7. Check that the measuring tape is horizontal for example by moving with the chair to see to the back of the participant, asking the participant to turn around or checking from the mirror.
8. Hold the measuring tape firmly, ensuring the horizontal position is maintained. Check that the tape isn't too tight or too loose. You should be able to place one finger between the tape and the subject's body.



9. Ask the participant to breathe normally; take the reading at the end of light exhalation.
10. Record the waist circumference to the nearest millimeter.

11. Record the waist circumference also on the participant's feedback form. The recommended maximum waist circumference for men and women can also be given.

In some cultures and for some persons undressing may not be acceptable. This should be respected, but no tight garments intended to alter the shape of the body should be kept on. The waist circumference can be measured over light underwear, like a thin shirt. Any exceptions on dressing should be recorded.

When the measurement is performed at the participant's home, the protocol should be followed as closely as possible. Any deviations from the protocol should be recorded.

Self-reported waist circumference is not acceptable.

5.1.4.3 Quality assurance

The quality assurance of waist circumference measurement includes the following components:

- Training of the personnel;
- Checking the equipment;
- Audit visits and evaluation of the measurement data during the field work.

5.1.4.3.1 Training of the measurers

All measurers should receive training before the fieldwork. The main points in the training are:

- Each measurer should understand the rational of standardized measurement and have enough time to practice, including with overweight and obese persons, and with adequate supervision and feedback.
- If the survey is prolonged or when deviations from the standards are observed, refresher sessions about the measurement should be organized, e.g. at three month interval.

For more detailed information, see Part A, Chapter 15. Training programme.

5.1.4.3.2 Checking and calibration of the equipment

All equipment needs to be checked regularly. Each check and its outcome is recorded in the log book. If any problems are observed during the checks, the tape is replaced and this is also recorded in the log book.

Daily checks and when a new examination site is set up

- the condition of the measurement tape is checked visually. If there are cracks or the tape is torn, it should be replaced.

Monthly checks

- The length of the measurement tape should be measured by using calibrated length rods. If the measuring tape is stretched, it should be replaced.

5.1.4.3.3 Quality control by coordinating office during the field work

Quality control during the fieldwork includes actions to be carried out in the field by measurers regularly and keeping the log book of the regular checked as well as actions conducted by the coordinating office.

The coordinating office will do audit visits to the field to monitor the measurements and/or organize external audits. In addition to monitoring actual measurements, the coordinating office will monitor the quality of the measurements based on data:

- The distribution of terminal digit of the measurements by measurer.
- Mean and standard deviation of the measurements by measurer.
- Reasons why measurements are not done.
- Daily work load (number of measurement per day by measurer).

5.2 Additional measurements

5.2.1 Hip circumference

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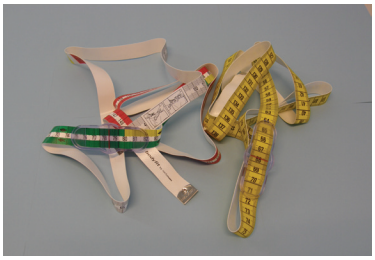
5.2.1.1 Rationale

It is important to explain to the participant the rationale and importance of the hip circumference measurement. This will motivate him/her to take part in this particular measurement. It can be stressed that the measurement takes only a few minutes. Hip measurement is used in combination with waist circumference when calculating waist-to-hip ratio (WHR). WHR is useful to evaluate the abdominal body fat distribution, as compared to the gluteofemoral one (relating to the buttocks and thighs) one. Abdominal adiposity distribution is associated with an increased risk of cardiovascular disease (CVD) risk factors, events and morbidity. (Huxley 2010)

According to the World Health Organization, a WHR threshold >= 0.90 in men and >= 0.85 in women increases the risk to develop cardiometabolic complications (WHO 2008)

5.2.1.2 Measurement protocol

5.2.1.2.1 Equipment



- Non-elastic measurement tapes (200 cm and 250 cm)
- The full body length mirror whenever feasible

5.2.1.2.2 Setting up the measurement site

The measurement site should be private.

If a mirror is used, it is placed against the wall or if the mirror stands on its own feet, it is placed next to the measurement place. The measurer should have a chair with wheels to sit on when checking the correct position of the tape.

5.2.1.2.3 Exclusion criteria

The hip should be measured in all participants, except when the person:

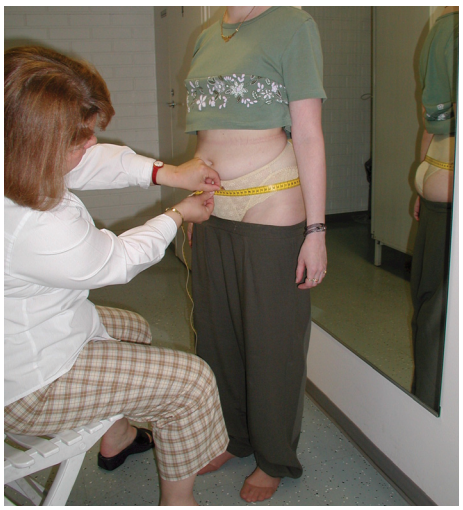
- is immobile or wheelchair bound
- has difficulties standing straight

- pregnant women (over 20 pregnancy weeks) may be excluded
- refuses

The reason for exclusion should be recorded. If the participant is pregnant, pregnancy weeks should be recorded.

5.2.1.2.4 Measuring hip circumference

- Ask participant to show the hip. The measurement is done over underwear. If the participant feels uncomfortable or refuses to undress, take the measurement over light clothing and record this.
- Ask the participant to stand in front of you while you are sitting. If a mirror is available, you should have a clear view of it.
- Ask the participant to stand with his/her weight evenly balanced on both feet, feet close together.
- Check that the participant's hands are hanging loosely beside the body.
- Place the measuring tape at the participant's hip or ask him/her pass the tape around.



- Place the measuring tape over the buttock at the maximal circumference.
- Check that the measuring tape is horizontal for example by moving with the chair to see the back of the participant, asking the participant to turn around or by checking from the mirror.
- Hold the measuring tape firmly, but not too tight, ensuring the horizontal position. The tape should not be too tight or too loose.
- Record the hip circumference to the nearest millimeter.

In some cultures and for some persons undressing may not be acceptable. This should be respected, but no tight garments intended to alter the shape of the body should be kept on. Any exception on dressing should be recorded.
When the measurement is performed at the participant's home the protocol should be followed as closely as possible. Any deviations from the protocol should be recorded.

Self-reported hip circumference is not acceptable.

5.2.1.3 Quality assurance

The quality assurance of hip circumference measurement includes the following components:

- Training of the personnel ;
- Checking the equipment;
- Audit visits and evaluation of the data during the fieldwork

5.2.1.3.1 Training of the measurers

All measurers should understand the importance of standardized measurements and receive training before the fieldwork. The main points in the training are:

- Measurers should have enough training with persons of different sizes.
- If the survey is prolonged or when deviations from the standards are noticed, refresher sessions about the measurement should be organized. e.g. at three month intervals.

For more detailed information, see Part A, Chapter 15. Training programme.

5.2.1.3.2 Checking and calibration of the equipment

All equipment needs to be checked regularly. Each check and its outcome are recorded in the log book. If any problems are observed during the checks, the tape is replaced and this is also recorded in the log book.

Daily checks and when a new examination site is set up

- The condition of the measurement tape is checked visually. If there are cracks or the tape is torn, it should be replaced.

Monthly checks

- The length of the measurement tape should be measured by using calibrated length rods. It the measuring tape is stretched, it should be replaced.

5.2.1.3.3 Quality control by coordinating office during the field work

Quality control during the fieldwork includes actions to be carried out in the field by measurers regularly and keeping the log book of the regular checked as well as actions conducted by the coordinating office.
The coordinating office will do audit visits or organize external audits to the field to monitor the measurements. In addition to monitoring

actual measurements, the coordinating office will monitor the quality of the measurements, based on data:

- The distribution of terminal digit of the measurements by measurer.
- Mean and standard deviation of the measurement by measurer.
- Reasons why measurement are not done.
- Daily work load (number of measurement per day by measurer)

References

- Huxley R, Mendis S, Zheleznyakov E, Reddy S & Chan J. Body mass index, waist circumference and waist:hip ratio as predictors of cardiovascular risk—a review of the literature. European Journal of Clinical Nutrition (2010) 64, 16–22.
- World Health Organization, Waist circumference and waist-hip ratio: Report of a WHO Expert Consultation. Geneva, 8-11 December 2008. 2011

5.2.2 Handgrip test

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[1] National Institute for Health and Welfare (THL), Helsinki, Finland

5.2.2.1 Rationale

It is important to explain to the participant the rationale and importance of the chair stand test. This will motivate him/her to take part to this particular measurement. It can be stressed that the measurement takes only 3 to 5 minutes.

Handgrip strength is an indicator of upper body strength, but it is also used as an indicator of overall muscle strength in population studies. It correlates with overall physical fitness and is also a predictor of mortality (e.g. Rantanen ym. 1994, Bohannon 2008).

5.2.2.2 Measurement protocol

5.2.2.2.1 Equipmet

- A straight-backed chair, preferably without arm rests
- Dynamometer

5.2.2.2.2 Exclusion criteria

Handgrip test is conducted for all participants, except if a person has:

- has swelling, inflammation, severe pain or injury in both hands preventing to squeeze the device;
- has undergone surgery to both hands in the previous 6 months;
- has in both hands bad arthritis or rheumatic diseases preventing the squeezing of the device;
- does not understand the instructions due to dementia or some other cognitive problem;
- refuses.

Reason for the exclusion should be recorded.

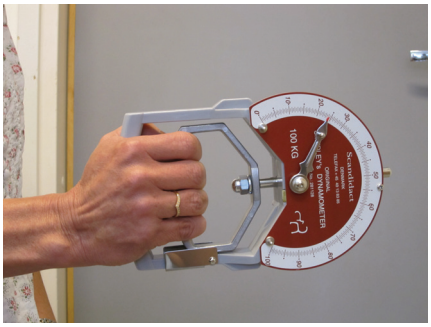
5.2.2.2.3 Posture of the subject

It is recommended to use the standard position by American Society of Hand Therapist (Innes 1999, Roberts ym. 2011). The participant should sit in a chair with straight back, the feet flat on the floor, the shoulders adducted and neutrally rotated (upper arm aligned with the trunk), elbow flexed at 90 degrees, forearm in a neutral position, and the wrist between 0 and 30 degrees

extension and between 0 and 15 degrees ulnar deviation (a similar position as when shaking someone's hand). Arms should be unsupported.

5.2.2.2.4 Adjustment of the device

The device should be adjusted to fit the size of the participant's hand so that the second joint of the forefinger is in 90 degree flexion. Before starting the test, the participant should be asked whether the grasp feels as it is easy squeeze.



5.2.2.2.5 Conducting hand grip test

The measurement is performed on the participant's dominant hand (the hand the participant prefers to use to perform fine and gross motor tasks such as writing), if feasible. If not, this should be recorded.

The detailed measurement protocol depends on the device. The following generic instructions are same for all devices:

1. Ask the participant to sit as instructed in 5.2.2.2.3.
2. Illustrate the use of the instrument to the participant.
3. Adjust the dynamometer before the measurement to fit the hand of the participant according to the instructions of the manufacturer. (see 5.2.2.2.4)
4. Ask the participant to squeeze the dynamometer with as much force as possible. The squeezing should last from 3 to 5 seconds. Encourage the participant to do his/her best during the measurement. "The test starts, ready, begin! Squeeze! Squeeze! Squeeze! Good, you can stop now and rest".

5. Have a 30-60 seconds pause to avoid the effects of muscle fatigue.
6. Repeat the step 4 for the second measurement.
7. If the difference between the first and second measurement is large (more than 10%), conduct a third measurement after a 30-60 seconds rest. Otherwise the test can be finished.
8. Repeat the step 4 for the third measurement.

5.2.2.3 Quality assurance

Quality assurance of the handgrip test includes the following components:

- Training of the personnel;
- Checking the equipment and regular calibration of the equipment;
- Audit visits and evaluation of the measurement data during the fieldwork.

5.2.2.3.1 Training of the measurers

All measurers should receive training before the fieldwork. The main points of the training are the proper orientation to the dynamometer and performance guidelines.

- Each measurer should understand the meaning of standardization and have enough time to practice with adequate supervision and feedback before performing actual tests with the survey participants.
- If the survey is prolonged or if any deviations from the protocol are observed, refresher sessions about conducting the test should be organized at three monthly intervals or more frequently.
- For more detailed information, see Part A, Chapter 15. of the EHES Manual

5.2.2.3.2 Checking and calibration of the equipment

Dynamometers need to be calibrated according to the instructions of the manufacturer and checked regularly.

References

- Bohannon RW. Hand-grip dynamometry predicts future outcomes in aging adults. Review. J Geriatric Phys Ther 2008;31(1):3-10
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- Rantanen T, Era P, Kauppinen M, Heikkinen E. Maximal isometric muscle strength and socioeconomic status, health, and physical activity in 75-year-old persons. J Aging Phys Act 1994; 2: 206-220.
- Roberts HC, Denison HJ, Martin HJ, Patel HP, Syddall H, Cooper C, Sayer AA. A review of the measurement of grip strength in clinical and epidemiological studies: towards a standardized approach. Age Aging 2011:40;423-429.

5.2.3 Timed chair stand test

Johanna Mäki-Opas[1], Hanna Tolonen[1]. Hali Valkeinen[1], Päivi Sainio[1]

[1] National Institute for Health and Welfare (THL), Helsinki, Finland

5.2.3.1 Rationale

It is important to explain to the participant the rationale and importance of the chair stand test. This will motivate him/her to take part to this particular measurement. It can be stressed that the measurement takes only a few minutes.

Timed chair stand test is a functional test which measures ability to rise from a chair. It is a test of lower extremity and central strength, especially muscle strength, balance and coordination but other functional domains are also involved, such as endurance.

5.2.3.2 Measurement protocol

5.2.3.2.1 Equipment

- Stopwatch.
- Firm, armless, straight-backed, chair without stuffing. Height of the chair: 43-45 cm.

5.2.3.2.2 Instructions to the participant

Participants should be instructed to wear steady shoes without high heels or slippery soles.

5.2.3.2.3 Setting up the measurement site

The measurement site should be private.

The chair is placed against a firm table so that it cannot move during the test. If the chair is placed against a wall, the participant is reminded to take care that her/his head does not hit on the wall while sitting down during the test.

5.2.3.2.4 Exclusion criteria

The single chair stand test is conducted for all participants. The repeated chair stand test is conducted for those able to rise up once without using hands to help, and the exclusion criteria for the repeated test are:

- if the blood pressure is 180/110 or higher AND the person has ever had myocardial infarction (heart attack), coronary heart disease or angina pectoris or stroke (cerebral haem-

orrhage, cerebral thrombosis). (These diseases are asked in the EHES questionnaire, see Part B, Chapter 7.);

- if the blood pressure is 200/120 or higher;
- if the person has had myocardial infarction (heart attack) or stroke (cerebral haemorrhage, cerebral thrombosis) less than three months ago. (This needs to be specified if the person has answered 'yes' to these questions in the EHES questionnaire.);
- is immobile or in a wheelchair and is unable to stand up without help, or is otherwise unable to stand up without help (walking aids are not allowed);
- if the person does not understand the instructions due to dementia or some other cognitive problem;
- if the person refuses.

Reason for the exclusion should be recorded.

5.2.3.2.5 Conducting timed chair stand test

Posture of the subject

The participant should be sitting feet touching the floor (e.g. the chair should not be too high) with small gap between the legs, and back touching the chair. The participant is asked to fold his/her arms across his/her chest.

Single chair stand test

The single chair test is conducted for all participants. If the person is not able to perform the test due to disability (e.g. the participant is immobile, or wheelchair bound and not able to stand up, or has difficulties to maintain an upward posture, or needs help to stand up), the ability to rise up once is recoded accordingly.

1. Explain and demonstrate the single rise to the participant.
2. Ask the participant to sit on the chair as described under *Posture of the subject*
3. Ask the participant to stand up from the chair one time. If the participant cannot rise without using his/her arms, say "Try to stand up using your arms".
4. Record the outcome of the single chair stand. If the participant refuses to try the single chair stand or is unable to stand up on his/her own without using the arms, do not attempt the repeated chair stand. If the single stand succeeds without using hands, the repeated chair stand test can be conducted.

Repeated chair stand test

1. Explain that now the participant needs to stand up 10 times as quickly as possible. Demonstrate the test by doing a few fast rises on your own chair, so that the participant understands that she/he needs to stand up as quickly as he/she can. Tell that it is important to straighten up properly the knees and the upper body and when sitting down, the back should touch the back rest. In the demonstration important factors are: correct starting position, correct standing position, back touching the chair when sitting down, and speed.
2. Check that the starting posture of the participant is correct. Ask the participant to resume the sitting position, with the feet resting on the floor, back touching the chair, and the arms folded across the chest.
3. Ask the participant to stand up 10 times (30-69 years old)/5 times (70+ years old) as quickly as he/she can without break. Knees and upper body need to be straighten up properly and when sitting down, the back should touch the back of the chair.
4. When the participant is properly seated, say "Ready, begin" and start the stopwatch.
5. Count out loud each time the participant rises up.
6. When the participant completes the 5th rise, press the split timer on the stopwatch (when split time is taken, it is possible to get results for also those who are unable to finish 10 repetitions but succeed to do 5).
7. Stop the stopwatch when the participant has stood up for the 10th time (the time is taken when the participant is in standing position even if she/he still sits down).

If it is considered to improve acceptability of the test, age specific instructions can be used; for those ager 30-69 to stand up 10 times, and for those aged 70 and over to stand up 5 times.

If it seems that the participant is not conducting the test as fast as he/she could, repeat the instructions immediately at the early phase of the test: "as quickly as possible". Note, that the measurer should be near the participant to support him/her if needed.

If the participant stops and appears to be fatigued before completing the 10 stands, ask "Can you continue?". If the participant says "Yes", continue timing until 1 minute has elapsed. If he/she says "No", stop the stopwatch and record the number of completed stands without using arms.

The test is repeated only if some external factor disturbs the performance or if the timing fails.

The test is stopped if

- the participant becomes too tired or severely short of breath;
- the participant uses his/her arms;

- the participant has not completed all of the rises after 1 minute;
- the measurer is concerned for the participants safety.

5.2.3.2.6 Specific issues when the test is conducted at home of the participant

If the chair stand test is conducted during a home visit, the same measurement procedure applies. Since the chair used for the test is usually one from the participant's home, the characteristics of the chair should be recorded, and chairs without stuffing should be selected whenever possible.

5.2.3.3 Safety issues

The measurer monitors performance and stands close enough in order to provide assistance if needed.

5.2.3.4 Quality assurance

Quality assurance of the timed chair stand test includes following components:

- Training of the personnel;
- Checking the equipment;
- Audit visits and evaluation of the measurement data during the fieldwork.

5.2.3.4.1 Training of the measurers

All measurers should receive training before the fieldwork. The main points in the training are:

- Each measurer should understand the meaning of standardization and have enough time to practice with adequate supervision and feedback before performing actual tests with the survey participants.
- If the survey is prolonged or if any deviations from the protocol are observed, refresher sessions about conducting the test should be organized at three monthly intervals or more frequently.

For more detailed information, see Part A, Chapter 15. of the EHES Manual.

5.2.3.4.2 Checking the equipment

The chairs and the stopwatch (for battery charge) need to be checked regularly. Each check and its outcome are recorded in the log book. If any problems are observed during the checks, the device in question is replaced and this is recorded to the log book.

Especially the condition of the chair, stability, is checked daily. Batteries for the stopwatch should be available.

5.3 Recording forms for measurements and their quality control

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On the field there are several different recording forms:

- measurement recording forms,
- quality control log books, and
- material transfer log books.

The recording forms can be paper forms or electronic forms. In addition detailed recording of information on participation and all contacts with selected persons is needed either in computerized logistics programmes or paper forms.

5.3.1 Measurement recording forms

Actual measurement results as well as circumstances on which the measurements are taken and other issues possibly affecting the measurements are recorded in the measure recording forms in a pre-defined format. Depending on the organization of the fieldwork, there may be one measurement form which includes all the measurements of the survey or each measurement may have its' own recording form.

In each measurement form, the participants identification code has to be the first item or a bar code label on top of the form, if paper forms are used.

Specification of issues which should be recorded for each EHES core measurement are listed under specific measurement protocols:

- Blood pressure measurement (Part B, Section 5.1.1)
- Height measurement (Part B, Section 5.1.2)
- Weight measurement (Part B, Section 5.1.3)
- Waist circumference measurement (Part B, Section 5.1.4)
- Hip circumference measurement (Part B, Section 5.2.1)
- Hand grip test (Part B, Section 5.2.2)
- Timed chair stand test (Part B, Section 5.2.3)

An example of the EHES core measurements recording form for blood pressure, anthropometric measurements (height, weight, and waist and hip circumferences) and functional capacity tests (hand grip and timed chair stand) are in the Appendix 5.1, Appendix 5.2, Appendix 5.3 and Appendix 5.4.
It should be noted, that if for example the information on room temperature is needed for more than one measurement and measurements are conducted in different rooms, there should be a place for room temperature in the recording form for each measurement for which this information is needed. If all measurements are conducted in the same room, it is enough to have one place for the room temperature in the recording form.

5.3.2 Quality control log books

The documentation of the quality control actions taken on the field (see Part B, Chapter 10), require quality control log books. In the quality control log books, all quality control actions should be recorded with date and time when action was taken, who did it, and what was the outcome. Also possible correction actions has to be recorded.

The quality control log book should include at least following issues.

Log book for daily quality control

- Height rule checked with standardized rod
  - Error less than 2 mm
  - Error greater than 2 mm.
  - If error greater than 2 mm, specify actions taken
- Vertical placement of the height rule should be checked with carpenter's level
  - In line
  - Out of line, actions taken:
- Checking the weight scale using the standardized weights daily if digital devices are used, if balanced beam scales are used, weekly
  - Error less than 0.2 kg
  - Error greater than 0,2, specify actions taken
- Checking of the horizontal placement of the weight scale
  - In line
  - Out of line, actions taken:
- Checking of the zero level of the balanced beam scale
  - In line
  - Out of line, specify actions taken
- Checking the waist measurement tape
  - No disruptions or other visible faults
  - Faults detected, tape changed

- Checking the length of the waist measurement tape (frequency depending of the number of measurements)

5.3.3 Material transfer log books

Every time when material (questionnaires, devices, samples, etc.) is transferred from one location to other, type of the material, quantity, serial numbers of devices or samples, data of dispatch and person sending material out should be recorded. On the other end, the sample information should also be recorded by person receiving the material. This way it can be checked that no material is lost during the transfer.

Appendix 5.1 Blood pressure recording form

Measuring the Health of Europeans

Blood pressure recording form

Participant id: ☐☐☐☐☐☐

Measurer id: ☐☐☐☐☐☐

Measurement time and room temperature

Date of the measurement (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

Time of the day (hh:mm): ☐☐☐☐

Room temperature (^{O}C): ☐☐

Has participant done one hour before measurement

Vigorous physical exercise	☐ Yes	☐ No
Smoked	☐ Yes	☐ No
Eaten	☐ Yes	☐ No
Drank anything else than water	☐ Yes	☐ No
Emptied his/her bladder	☐ Yes	☐ No

Reason if not measured at all

- ☐ Medical reason preventing the measurements
  - ☐ Amputation of both arms
  - ☐ Cast on both arms
  - ☐ Open wounds/sores on both arms
  - ☐ Rash on both arms
  - ☐ Malformation of both arms preventing to place the cuff
  - ☐ Lymph node malfunction in both arms, e.g. caused by breast cancer and preventing to place the cuff
  - ☐ Other
- ☐ Refusal
- ☐ Other, specify: ☐☐☐☐☐☐☐☐☐☐

Type of the measurement device

- ☐ Mercury sphygmomanometer
- ☐ Automated device
- ☐ Other, specify: ☐☐☐☐☐☐☐☐☐☐

Number of the measurement device ☐☐☐

Arm used for the measurement

- ☐ Right
- ☐ Left

Reason for use of left arm

- ☐ Medical reason
  - ☐ Paralized and/or spastic right arm
  - ☐ Amputation of right arm
  - ☐ Cast on right arm
  - ☐ Rash on right arm
  - ☐ Intravenous access device on right arm
  - ☐ Malformation of right arm preventing to place the cuff
  - ☐ Lymph node malfunction in right arm, e.g. caused by breast cancer and preventing to place the cuff
- ☐ Other, specify: ☐☐☐☐☐☐☐☐☐☐

Posture of the subject during the measurement

- ☐ Sitting
- ☐ Supine

Reason for supine posture

- ☐ Bed driven
- ☐ Other, specify ☐

Selection of the cuff

Arm circumference (cm):

Used cuff size:

- ☐ Small (arm circumference 17-21 cm)
- ☐ Medium (arm circumference 22-31 cm)
- ☐ Large (arm circumference 32-41 cm)
- ☐ Extra large (arm circumference 42- cm)

Blood pressure measurement results

	1st measurement	2nd measurement	3rd measurement
Systolic blood pressure (mmHg)			
Diastolic blood pressure (mmHg)			
Error code of the device			
Observations by measurer			

Pulse rate (60 sec.) ☐

Was the pulse regular?

- ☐ Yes
- ☐ No

Appendix 5.2 Anthropometric recording form

EHES Measuring the Health of Europeans

Anthropometric recording form

Participant id: ☐☐☐☐☐☐

Measurer id: ☐☐☐☐☐☐

Measurement time

Date of the measurement (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

Time of the day (hh:mm): ☐☐☐☐

If participant is woman, is she pregnant

☐ No

☐ Yes, pregnancy weeks: ☐☐

Height

Reason if not measured at all

- ☐ Hairstyle or head dress prevents mesurement (not possible to undress)
- ☐ Wheelchair bound or immobile
- ☐ Unsteady stand
- ☐ Height exceeds the upper limit of the stadiometer. Specify, the upper limit of the stadiometer: ☐☐☐ cm
- ☐ Refusal
- ☐ Other, specify: _____

Height measurement

Number of the measurement device: ☐☐☐

Height (cm) ☐☐☐

Observations by measurer affecting the measurement result:

Weight

Reason if not measured at all

- ☐ Weelchair bound or immobile
- ☐ Unsteady stand
- ☐ Weight exceeds the upper limit of the scale. Specify, the upper limit of the scale: ☐☐☐ kg
- ☐ Refusal
- ☐ Other, specify: _____

Weight measurement

Number of the measurement device: ☐☐☐

Weight ☐☐☐ kg

Measurement was done in

- ☐ Light underwear
- ☐ Without heavy outer garments
- ☐ Other, specify: _____

Other observations by measurer affecting the measurement results:

Waist circumference

Reason if not measured at all

- ☐ Wheelchair bound or immobile or cannot stand
- ☐ Unsteady stand
- ☐ Circumference exceeds the maximum length of the tape. Specify, the maximum lenght of the tape: ☐☐☐
- ☐ Large hernia, stomage bag or other device on measurement area
- ☐ Refusal
- ☐ Pregnant (over 20 weeks)
- ☐ Other, specify: ☐

Waist circumference measurement

Waist circumference (cm) ☐☐☐

Measurement was done over

- ☐ Bare skin
- ☐ Light underwear
- ☐ Without thick outer garments
- ☐ Other, specify: ☐

Other observations by measurer affecting the measurement results:

☐

Hip circumference

Reason if not measured at all

- ☐ Wheelchair bound or immobile or cannot stand
- ☐ Unsteady stand
- ☐ Circumference exceeds the maximum length of the tape. Specify, the maximum lenght of the tape: ☐☐☐
- ☐ Refusal
- ☐ Pregnant (over 20 weeks)
- ☐ Other, specify: ☐

Waist circumference measurement

Waist circumference (cm) ☐☐☐

Measurement was done over

- ☐ Underware
- ☐ Light clothing
- ☐ Without thick outer garments
- ☐ Other, specify: ☐

Other observations by measurer affecting the measurement results:

☐

Appendix 5.3 Hand grip recording form

EHES Measuring the Health of Europeans

Hand grip recording form

Participant id: ☐☐☐☐☐☐

Measurer id: ☐☐☐☐☐☐

Measurement time

Date of the measurement (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

Dominant hand:

- ☐ Right
- ☐ Left

Hand used in the measurement:

- ☐ Right
- ☐ Left

Reason why dominant hand was not used:

- ☐ Swelling or inflammation
- ☐ Severe pain or injury
- ☐ Surgery to the hand in the past 6 months
- ☐ Bad arthritis or rheumatic disease preventing to squeeze the device

Test results:

1st measurement ☐☐ kg
2nd measurement ☐☐ kg
3rd measurement ☐☐ kg

Reason why the test was not done:

- ☐ Amputation of both arms
- ☐ Swelling or inflamation on both arms
- ☐ Severe pain or injury on both arms
- ☐ Surgery to both hands in past 6 months
- ☐ Bad arhritis or rheumatic disease on both hands preventing to squeeze the device
- ☐ Refuse
- ☐ Other, specify: ☐☐☐☐☐☐☐☐☐☐

Appendix 5.4 Timed chair stand test form

Timed chair stand test

Participant id: ☐☐☐☐☐☐

Measurer id: ☐☐☐☐☐☐

Measurement time

Date of the measurement (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

One chair stand:

- ☐ Succeeded without arm
- ☐ Succeeded with help from arms
- ☐ Un-succeeded (bed-driven, unable to rise up without help)
- ☐ Not conducted, why:
  - ☐ Refused
  - ☐ Other, specify: ☐

Repeated chair stand:

Time for 5 chair stands:

☐☐ seconds

only ☐ stands completed

Time for 10 chair stands:

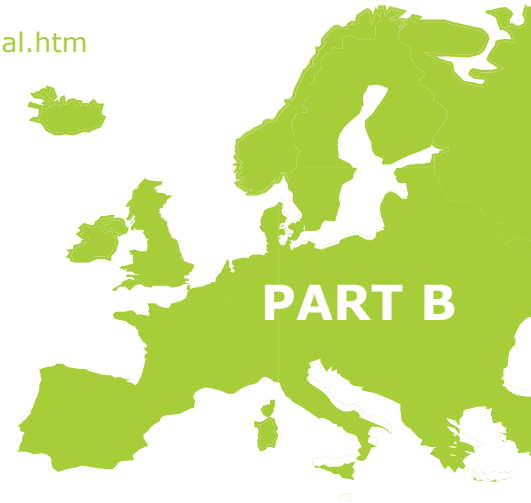
☐☐ seconds

only ☐ stands completed

Reason why the repeated test was not conducted or was discontinued:

- ☐ High blood pressure or cardiovascular disease
- ☐ Unable to rise up several times without help
- ☐ Difficult to stand (unsafe to conduct the test)
- ☐ Refuses
- ☐ Other, specify: ☐

6. Collection of biological samples



6.1 Core measurements

6.1.1 Blood sample collection

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6.1.1.1 Rationale

The purpose of a European health survey is to collect data and biological samples from a random population. The main goal is made up of the core measurements but additional measurements will probably be done in each country and also at a later phase. Therefore special attention is paid to pre-analytical conditions more demanding than those needed for the core measurements.

- The core measurements are serum total cholesterol, HDL-cholesterol and plasma glucose.
- Potential additional measurements covered by this manual are whole blood HbA_{1c} and DNA extraction from whole blood.
- All serum and plasma aliquots as well as the whole blood tubes are frozen at site.

Generally at least one nurse/laboratory technician/phlebotomist is needed per site. Laboratory work comprises two phases:drawing of blood and the processing of blood samples. Sample processing also includes transferring storage tubes into the storage boxes and their freezing.

- All serum and plasma aliquots in storage tubes as well as whole blood collection tubes are transferred directly after processing into a -20ºC freezer. Frozen samples are sent in

one or more batches in dry ice to the national HES (NHES) laboratory, where they are stored long term at a maximum temperature of -70ºC. The time from phlebotomy to the long term storage should not exceed 1-2 months.

6.1.1.2 Equipment and apparatus

6.1.1.2.1 Equipment for drawing of blood samples

The blood sampling tubes should all be evacuated and provided by the same national supplier. This is to ensure that the tubes, needles and holders/adapters are compatible with each other.

Equipment

- Blood sampling vacuum tubes
- Needle for vacuum tubes
- Needleholder/adapter into which the needle is pushed. It may contain an easy mechanism to release the needle.
- Needle disposal container
- Stasis
- Disinfection solution
- Swabs, gauze pads
- Skin tape
- Disposable gloves, latex and nitrite
- Centrifuge tubes for use in case of incomplete clotting of sera and re-centrifugation.
- Thin glass or plastic rods to manipulate an incomplete blood clot

Also if possible, the chair on which participant sits during the blood drawing should have arm rests and no wheels. Arm rests help to place the arm for blood drawing but also they will support participant (prevent falling sideways) in case he/she faints.

6.1.1.2.2 Other equipment

Blood collection tubes

- Serum evacuated tubes containing gel (10/8 ml) or plain serum tubes (10/9 ml)
- Fluoride-citrate plasma tube (5/2 or 5/3 ml)
- EDTA plasma tube (5/3 or 5/4 ml)
- EDTA plasma tubes (10/9 ml)

Storage tubes

- Cryotube 1.5 ml for -70 °C storage
- Plastic tube 3 ml for -20 °C storage

- Tube for pooling serum 15 ml

Storage boxes

- storage box for 1.5 ml cryotubes
- storage box for 3 ml plastic tubes
- storage box for small whole blood tubes
- storage box for large whole blood tubes

Pipets

- Pipet with disposable tip for transferring 1.5 ml. Also spare pipet should be available.
- Disposable tips
- Disposable Pasteur- pipets

6.1.1.2.3 Apparatus

Centrifuge

Adjusting speed

- Blood tubes, either with or without gel should be centrifuged using 2000-2200 g RCF.
- Depending on the centrifuge, allow 1 min extra time for it to reach maximal rate and 1 additional min for braking, together 12 min.
- The centrifuge manual should be available at the laboratory site. In case samples of several subjects are centrifuged at the same time, it must be ensured that the time from phlebotomy to centrifugation remains between 30-60 min for all tubes. Care must be taken that tubes will not get mixed by mistake.

Have a few empty blood sampling tubes ready to be used as counterbalances in case you have to centrifuge an odd number of tubes. Use tap water for balancing.
Calculation of rpm

$$rpm = 1000 \; x \sqrt{\frac{RCF}{11,18\, r}}$$

, where

- rpm = rotations per minute
- RCF = relative centrifugal force (g)
- r = radius (cm) from the bottom of a test tube to the centre of the rotor

A spare centrifuge should be available at site or arranged in advance with a health care centre, hospital etc.

Figure 6.1.1. Blood sampling tubes from one subject are awaiting centrifugation on the right side and the tube rack on the left is awaiting centrifuged tubes.

Freezer

- The temperature of the freezer is measured with a calibrated min-max thermometer. The temperature is documented daily on a form. If the temperature rises above -15 ºC and remains there for several hours, the freezer must be replaced. The samples stored at an incorrect temperature must be documented.
- The temperature forms are returned to the NHES Lab after the survey
- The nominal temperature of the freezer should be set at -20ºC to -22ºC.

6.1.1.3 Exclusion criteria

Blood samples should be collected from all participants, except if a person has

- a chronic illness which restricts taking of all or part of the blood samples according to the protocol,
- anemia (Hb below 100 g/l),
- doubts about the blood volume to be taken.

Also if a person refuses by any reason from blood sample collection, the wish of the participant must be honored.

6.1.1.4 Blood drawing procedures

6.1.1.4.1 Setting up the blood drawing site

The blood tubes are arranged in the designated tube rack according to the sampling chart, Figure 6.1.3. The tube rack is to be used for

tubes intended for only one subject. Blood tubes should not be labelled before venipuncture as tubes may have to be replaced due to vacuum failure or other defect. It is advisable to have some extra tubes available if replacing is needed.

A personal label sheet is reserved for each participant by the nurse/lab technician. The laboratory form is for documenting all events relating to blood sampling and processing, see Part B, Section 6.3 of the EHES Manual.

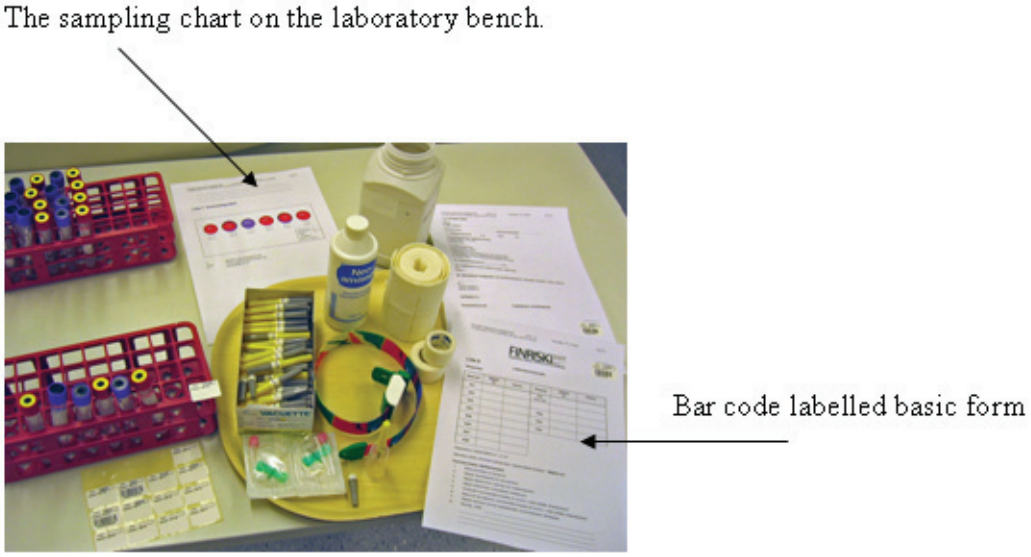


Figure 6.1.2. Site for blood drawing

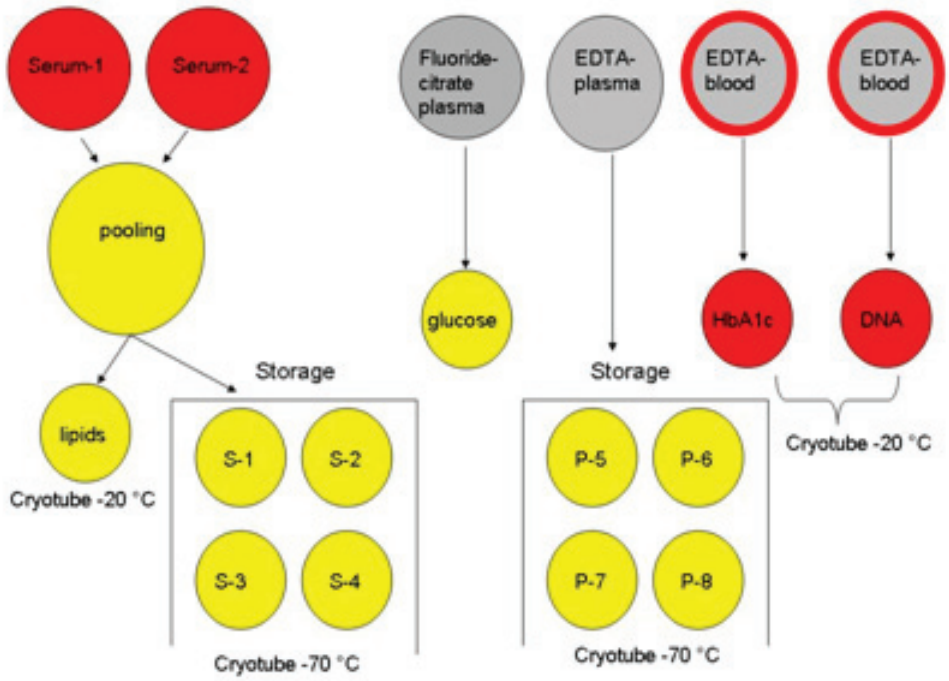


Figure 6.1.3. Blood sampling chart

6.1.1.4.2 Preparing for the blood drawing

General information

Each person participating in the health survey is expected to give blood samples at least for the core measurements including serum and plasma (two blood tubes) and one whole blood for DNA, three blood tubes altogether.

During the entire survey, the blood withdrawal, processing, storage and transport are to be maintained as uniform as possible by adhering to the manual and instructions. This ensures that the role of pre-analytical factors are as small as possible. For example, the order and type of blood tubes are to be taken for each subject according to the blood sampling chart, Figure 6.1.3.

Fasting

The serum samples for total cholesterol and HDL cholesterol can be taken at any time of the day, with the subject non-fasting. If measuring fasting glucose, lipoprotein fractions and triglycerides, the samples should be collected after a fasting period of at least 8 hours and at most 14 hours (excessively long fasting causes major changes in energy metabolism, with implications for blood triglycerides). In practice, this means that fasting must be overnight and that the samples can only be taken in the morning and can only be expected from persons who are invited to undergo the examination in the morning. In all cases the length of time from the last meal in full hours should be recorded to the blood sample collection form (see Part B, Appendix 6.1).

Posture of the subject and arm to be used

All blood samples should be drawn with the subject in a sitting position preceded by a 10-15 min rest. In case participant tells that he/she easily faints during the blood collection, the sample can be taken on supine posture due to safety of the participant. This exception should be recorded on sample collection form.

Preferably, blood should not be collected from the arm that was used for blood pressure measurement, (i.e., blood should usually be drawn from the left arm).

Use of a tourniquet

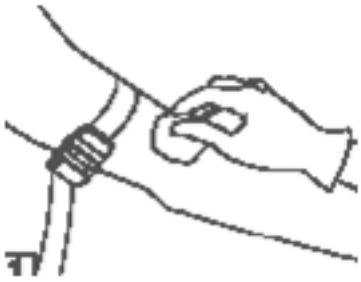
Prolonged venous occlusion can cause changes in concentrations of blood constituents. Therefore, the use of a tourniquet should be minimized. If a tourniquet is used to search for a vein, it should be released when the bloodstream runs. In any case, the use of a tourniquet should be limited to less than one minute.

6.1.1.4.3 Blood samples drawing protocol

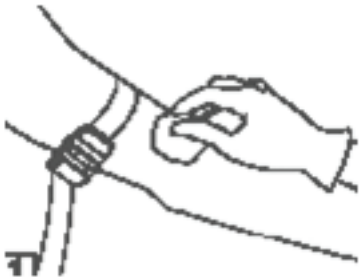
For safety reasons disposable gloves should be worn during blood sample drawing and when processing serum, plasma and blood.

1. Place the first label from the left upper corner of the sheet of labels on the participant form.
2. Gently tap (e.g. against your hand) the fluoride citrate plasma tube (grey cap) if it contains granules. This way the granules from the stopper will drop to the bottom of the tube.
3. Gently twist the sample needle to break the seal. Release the cover from the end of the needle. Leave the needle protector case still on the needle. Connect the holder and sample needle. Leave the needle protector case on the needle.

4. Apply a tourniquet around the participant's upper arm.



5. Place the arm in a downward position and disinfect the puncture site. It is more comfortable for the participant if the arm rests on a pillow.



6. Remove the protector case from the needle.

7. Perform the venipuncture using the accepted technique.

Figure 6.1.4. Collection of blood (gel serum tube is being filled and an EDTA-plasma tube awaits filling).

8. Collect blood first into the 2 plain serum tubes (red cap). Press the tube at the bottom of the holder that the needle will puncture the stopper and start filling. Support the tube during filling.

9. Remove the tourniquet when the bloodstream runs.

10. When the bloodstream stops, take the tube out of the holder. Check that the tube is filled to the accurate volume.

11. Immediately after taking the plain serum tube out of the holder it should be adequately mixed 5 times by inverting the tube completely top-down. The tubes should be stored in a vertical position until sample handling.

12. Next, introduce and fill the fluoride-citrate plasma (grey cap) tube.

13. Immediately after taking the fluoride-citrate tube out of the holder it should be adequately mixed 15 times by inverting the tube completely top-down. The tubes should be stored in a vertical position until sample handling.

14. Next introduce and fill the 3 EDTA tubes (violet cap).

15. Immediately after taking the EDTA tube out of the holder it should be adequately mixed 5 times by inverting completely top-down. The tubes should be stored in a vertical position until sample handling.

16. Remove the needle from the vein. Immediately apply pressure on the puncture site with a gauze pad until bleeding stops.
17. Label the successfully filled blood sampling tubes according to the sampling chart, Figure 6.1.3.
18. All material contaminated with blood should be considered hazardous. All needles and other sharps must be discarded into a needle dispose container and all other material into a biological waste container.

NOTE! The last 2 EDTA tubes should not be centrifuged nor the caps removed!! The HbA1c analysis is made from whole blood and blood for DNA extraction may become contaminated.

6.1.1.5 Labels

6.1.1.5.1 Requirements for the labels

The quality of labels is of utmost importance. They have to fulfill several criteria:

- The glue must have special properties to adhere on different surfaces and keep tight in a cold (-70 oC) and damp environment
- The label ink should be water resistant and possibly also to liquid nitrogen
- Use of bar codes is recommended, as most clinical chemistry analyzers use bar codes to identify samples in the automatic process

One sheet of labels per subject is recommended. This sheet contains bar code labels for:

- Blood sample collection form (see Part B, Appendix 6.1)
- Blood sample handling recording form (see Part B, Appendix 6.2)
- Blood sampling tubes
- Pooling tube
- Storage tubes
- Storage boxes
- Tube rack

The abbreviation of the survey name with the country code.

- The box shows type of sample or form or questionnaire.
- The secondary key=unique person ID number\ For survey and subject identification, this number can be generated, see Part A, Section 12.2 of the EHES Manual.
- The (bar)code with its numerical value=primary key. Each storage tube is given a unique number (Figure 6.1.5).

Figure 6.1.5. Unique number on storage tubes.

- Labels from the sheet are transfered on the blood collection tubes and storage tubes according to the blood sampling chart. The remaining blank labels are spare labels.

In case a designated label is destroyed or misplaced, blank labels should be available. The primary and secondary key numbers and sample type or other descriptor should be written in water resistant ink.

6.1.1.5.2 Labeling of storage boxes

The boxes should be labeled before placing them in the freezer. Otherwise the labels will not stick on a damp or icy surface.

Labels contain the following information:

- survey code-country code, eg. EHES-FI
- type of sample: S, P, B
- number of the box in bar code and numerical form.

The box label sheet contains 2 identical labels: one is placed on the front of the box and the other on the lid. Both labels should be visible when the lid is in place, see Figure 6.1.6.

Figure 6.1.6. Bar code labels placed on the lid and box

6.1.1.6 Blood sample processing

Sample processing includes centrifugation of blood tubes, labelling of storage tubes, pipetting aliquots into storage tubes and transferring storage tubes into freezers at the earliest convenience.

It is strongly recommended to wear protective gloves while opening the centrifuged blood tubes as well as during further handling of the blood samples.

6.1.1.6.1 Centrifugation

Before centrifugation, make sure that the blood has clotted in the plain serum tube (red cap).

Centrifugation of the clotted blood to obtain serum should be performed after making sure that the blood has clotted. The waiting for the blood to be clotted is at least 30 minutes at room temperature, 20-22 °C. Do not prolong the waiting for over 60 minutes.

Immediately after the waiting period the plain serum tube (red cap), the fluoride-citrate (grey cap) and the 1st EDTA (violet cap) plasma tubes are centrifuged.

The last two EDTA tubes designated for HbA1c and DNA extraction must not be centrifuged!

1. Place the plain serum tube (red cap) and fluoride-citrate (grey tube) and the 1st EDTA (violet cap) plasma tubes in the centrifuge. Don't remove the caps from the tubes. Before centrifugation is started check that all tubes are resting on the bottom of the centrifuge rack. The tubes should not hang on the cap as this might result in separation of the tube and cap and spilled blood and the cap will then swirl in the centrifuge head and cause severe damage. Always check that the centrifuge rotor is in balance.
2. Centrifuge the tubes 2000 g for 10 minutes at room temperature. The relative centrifugal force (RCF) can be calculated by using an empirical equation or by using a nomogram for converting RCF to rpm.

6.1.1.6.2 Sample handling after centrifugation

Immediately after centrifugation, the caps must be removed except from the last two EDTA tubes. The samples are distributed as follows:

1. Place the bar code labels properly. The code must be upright or else the reading with barcode reader is impossible, see Figure 6.1.7.

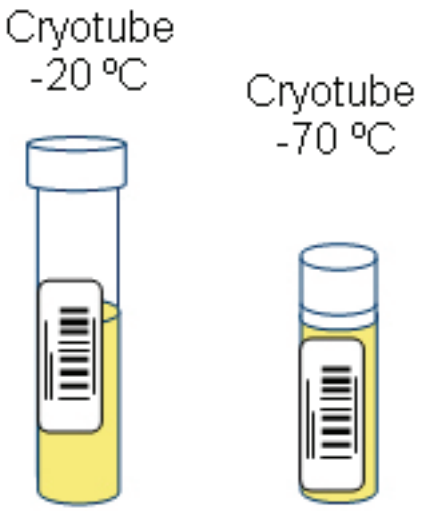


Figure 6.1.7. Correct labelling of cryotubes

2. If a bar code label is damaged, replace it with an extra label (empty ones on the sheet) and copy the bar code number and the sample type from the damaged label to the extra label with a water resistant pen.
3. Pour the serum from the 2 serum collection tubes into the pooling tube, mix gently by swirling the contents.
4. Pipette 2 x 1.5 ml serum from the pooling serum tube into the 3 ml plastic tube and 1.5 ml aliquots into the 1.5 ml storage cryotubes. Check that the serial number (person ID) is the same in the label of the serum collection tube and the labels of the cryotubes.

5. Pipette 2 x 1.5 ml from the fluoride-citrate plasma tube into two 1.5 ml cryotubes.
6. Pipette 2 x 1.5 ml from the EDTA tube into two 1.5 ml cryotubes.
7. The last two EDTA tubes are not centrifuged nor are the caps removed.
8. Close the cryotubes with caps and freeze the tubes at once. When frozen, the tubes must be kept in an upright position. Take special care in closing the tubes in order to prevent evaporation. Some tubes may be stored for decades before use.
9. Put the frozen samples in their respective boxes in the freezer to wait for the shipment. Fill an entire box before taking a new one.

10. All sheets of labels, both used and unused, should be returned to the NHES laboratory at the end of the study.

Note! It is important to pipet no more than 1.5 ml into cryotubes since serum and plasma will expand during freezing. The right volume can be checked from the scale on the tube wall.

6.1.1.6.3 Labeling of storage tubes

- The storage tubes are labeled according to a labeling scheme.
- Place the storage tubes in a tube rack according to the pipetting scheme. Place a label on the tube rack, see Figure 6.1.8.
- Remove the test tube caps a short time before pipetting, for instance when the blood tubes are being centrifuged.
- Opening of the caps with one hand is easier if the rack contains a stopper at the bottom of the tube well.
- There is no need to label all tubes if the blood collection is incomplete.

Figure 6.1.8. Caps of the storage tubes are removed in advance at the site of sample preparation. In the background is the pipetting scheme and in the foreground the label sheet in which the spare labels are left.

Note! Place the bar code labels on the tubes in an upright direction, see Figure 6.1.7, and so that the scale marks remain visible.

6.1.1.6.4 Handling blood collection tubes with gel

The temperature during centrifugation should be at least 20°C-22°C. At lower temperature the viscosity of the gel will result in incomplete separation of serum and cells.

Because separation of serum in a gel tube is complete, the serum can be poured directly into a pooling tube in case of several blood tubes. The gel tube should be inspected after centrifugation for the following:

- The surface of the gel should be horizontal
- The serum and cell layers should be separated clearly
- No red cells on top of the gel should be visible
- There should be no fibrin strands in the serum
- The serum should not be clotted, it should appear as a liquid. Blood in a gel tube can be centrifuged only once due to red cell contamination of the serum. If any red cell streaks are seen in the serum, transfer the serum into an empty centrifuge tube and re-centrifuge.

6.1.1.6.5 Hemolysed samples

- If one serum sample is hemolysed, this tube should not be pooled with non-hemolysed serum samples. Hemolysed and non-hemolysed samples are pipetted into aliquots separately. Only the non-hemolysed samples are pooled.
- If more than one serum sample is hemolysed, they may be both pooled.
- The hemolysed aliquots (primary key number) are documented on the laboratory sheet.
- For standardised documentation of the degree of hemolysis, each lab technician should have a color guide available for estimating the hemolysis, eg. 0, +, ++, +++. See Figure 6.1.9 for an example on hemolysis grade of serum/plasma.

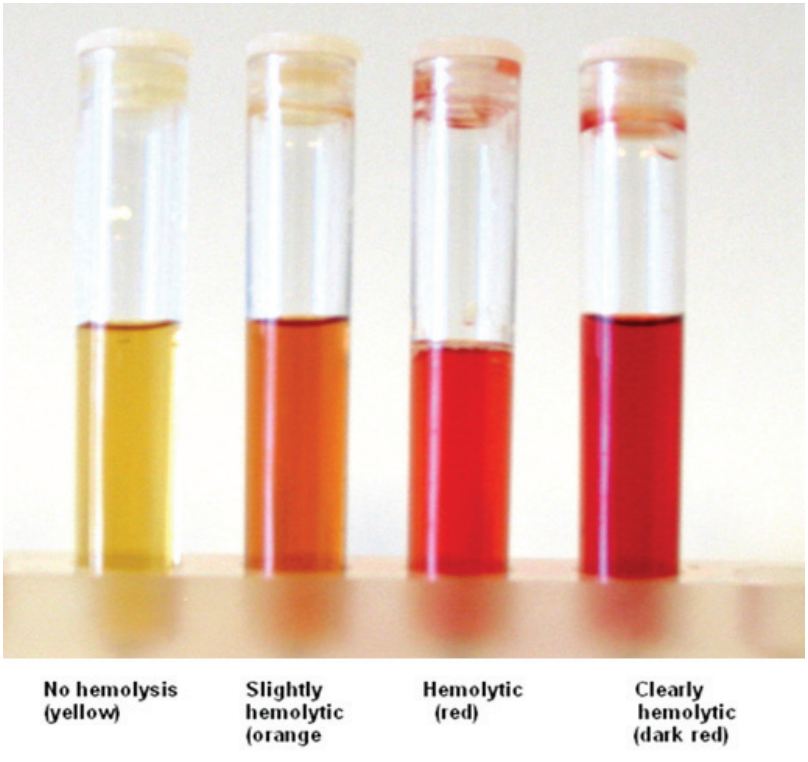


Figure 6.1.9. Example of the hemolysis grade of the samples

6.1.1.6.6 Transfer of tubes into boxes and freezer

To ensure a high quality of the samples, the tubes should be placed without delay into their boxes awaiting them in the freezer. The boxes must be prelabelled before placing them into the freezer. Mark the boxes according to the sample type, see Figure 6.1.10.

To avoid misplacing or misreading in the future, a common filling order of tubes should be used at all laboratory sites, eg. from left to right and down.

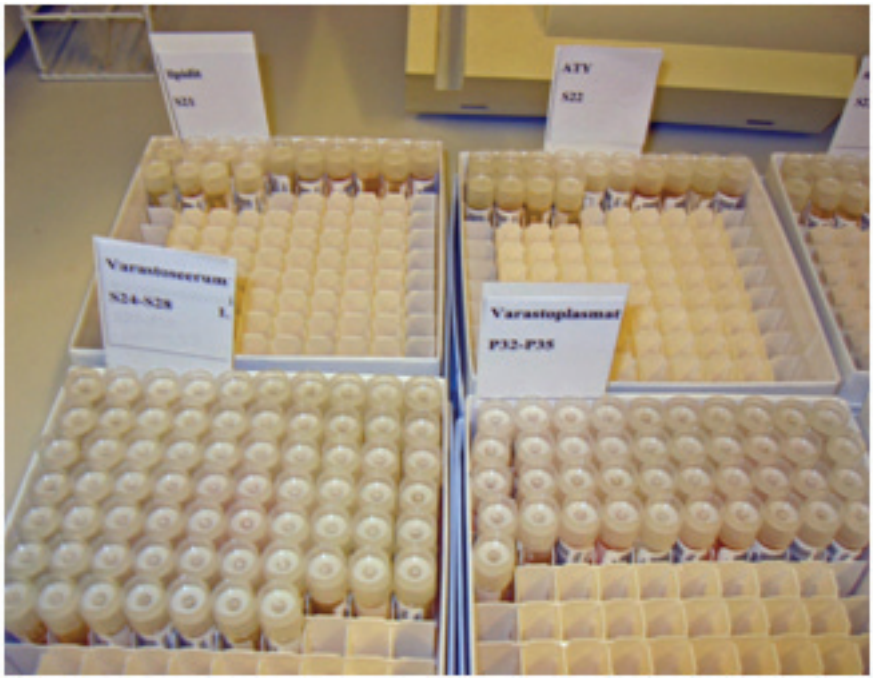


Figure 6.1.10. Aliquots in their storage boxes and at the back of each box a paper slip showing type of sample

6.1.1.6.7 Sample shipment

To the national HES laboratory

The frozen samples in their respective storage boxes should be sent packed in dry ice in one or a few batches at the end of the fieldwork period to the NHES Laboratory. The sample boxes should be packed in leak proof secondary packaging. Enough absorbent material must be placed in the secondary packaging. Adhere to the national regulations concerning transport/mailing of biological samples.

To EHES RL

If the proposed the EHES RL (Helsinki) is in place, a certified transport company/courier able to arrange the shipment of the samples to the EHES RL (Helsinki) should be contacted in advance.

The courier will collect the samples at the NHES Lab and will provide insulated rigid outer packaging and an adequate amount of dry ice. The

company will also help you take care of the paperwork. The shipment has to be packed according to the IATA (International Air Transport Association) regulations. The packing should be done according to Packing Instruction 650 for Diagnostic specimens. The specific regulations should also be followed for dry ice.

Before the courier arrives, please make sure that the amount of storage boxes you will be shipping is known so that the amount of dry ice supplied is sufficient for the samples to stay frozen. To make sure that the samples are kept frozen and are in good condition when arriving at the EHES RL, one tube should be placed upside down in every box.

Before sending the samples to either laboratory, please inform the contact persons by email about the sending details (date, mode of transport and the courier). This ensures that the transport will be documented for future checking.

6.1.1.7 Maintenance of quality at the laboratory site

6.1.1.7.1 Laboratory personnel

- The key factor of quality lies in the training of the personnel. Each person is responsible for his/her work quality.
- The personnel must be trained in advance. Supervisors are responsible for their training according to the National HES Manual.

6.1.1.7.2 Work

- Problems arising during practical work are discussed with the assigned contact persons for laboratory work. Their contact information is found in the field work manual.
- All tasks of the day are to be finalized during that day, no loose ends.

6.1.1.7.3 Actions at the laboratory site and feedback

The field personnel are obliged to document all deviations from the manual in a diary and report these to the NHES laboratory. After completion of the survey the diaries and other documents are to be returned to the NHES laboratory. Feedback to the NHES laboratory in the form of email and SMS are also saved.

6.1.1.7.4 Instructions/manual

All personnel should have the same version of the laboratory instructions including attachments. Each examination site has access to the laboratory manual which contains the following instructions:

- Information on the contact persons
- Instructions on actions to take if a technician gets stuck by a blood contaminated needle (see Part B, Section 6.1.1.8.2)
- List of supplies
- Centrifuge manual
- Safety procedures for handling dry ice (see Part B, Section 6.1.1.8.3)
- Chart on grade of hemolysis (see Figure 6.1.9)
- One copy of a complete laboratory manual should be found at the site including operation procedures and information on contact persons, in order for checking in case the personal instructions are lost.

6.1.1.8 Safety issues

6.1.1.8.1 Laboratory work on the field

Following safety issues should be taken into account when planning the laboratory work on the field and they also need to be addressed during the training of the fieldwork staff:

- **It is prohibited to eat or drink in the laboratory area!**
- Wearing protective clothing is not allowed outside the laboratory area, like in the recreation room or cafeteria.
- Table surfaces are disinfected by wiping with a 70 % ethanol solution at the end of the day. Any surface or object which is contaminated with blood or other human specimen must be desinfected immediately.
- During blood withdrawal protective gloves should be used if the nurse is used to working with gloves. New gloves should be worn for each new subject.
- If the technician does not wear protective gloves, he/she should disinfect the hands with a disinfectant between each new subject.
- Disposable gloves must be used throughout handling of blood samples!
- The sampling needle is removed directly into the needlebox from the adapter/holder without touching the needle.
- If the subject is suspected/has informed of HIV, hepatitis or other contagious disease, the technician should use nitrile rubber gloves. The stasis and adapter are disposed of in **the biological waste container as well as the gloves.**

6.1.1.8.2 Exposure to contaminated blood

An accidental exposure to blood contaminated with HIV, hepatitis or other contagious disease can occure:

- by needle stick
- from handling blood contaminated broken glass or other sharp object
- in case blood splashes in the eye or mouth
- if blood gets on an area of the skin having eczema or an unhealed wound.

In case of accident, immediate actions are needed:

- Make sure that the accident will not be repeated. In case of broker tube, collect the pieces of broken glass by tongs or a pan and brush. Do not pick up pieces with your hands.
- Save the sample tube with its identification codes in order for the source of the possible contamination to be determined if needed.
- Let the blood flow freely from the wound and rinse with copious amounts of water, for about 5 minutes.
- Do not apply pressure on the wound.
- If there is blood on eczemic area of the the skin, an unhealed wound or cut, apply a (> 70%) ethanolic compress on the area for at least 2 minutes.
- Rinse the eye(s) with clear (tap) water or a specific eyewash solution.

Contact immediately your supervisor and a medical centre or hospital. Field supervisors should be equipped with necessary telephone numbers and addresses of the nearest medical professionals in order to act swiftly if accidents occur. For each incidence of exposure to contaminated blood an incidence report should be prepared.

Depending on country, there are local occupational laws and regulations as well as insurance issues to take into consideration. It is recommended that the national manual has information on legislative and occupational matters relating to accidents in the laboratory.

6.1.1.8.3 Handling of dry ice

Safe handling of dry ice requires that following issues are taken into account.

Handling

Solid carbon dioxide=dry ice is extremely cold -78.5°C. Always handle dry ice with care and wear protective cloth or leather gloves whenever touching it. If touched briefly it is harmless, but prolonged contact (>5 sec) with the skin will cause injury similar to a burn.

If handled incorrectly indoors carbon dioxide will replace oxygenated air and will cause suffocation. Signs of a high content of carbon dioxide in the air are headache, nausea and unconciousness. If exposed, move the person into an area with fresh air.

Storage

Store dry ice in an insulated container. Do not store dry ice in a completely airtight container as carbon dioxide gas (CO2) is evolved from dry ice. Take care of proper air ventilation wherever dry ice is stored and handled. Carbon dioxide gas is heavier than air and will sink first to low areas and replace oxygenated air. Do not store dry ice in a freezer because it may cause the freezer to turn off.

Transport

Dry ice sublimates at 10% or 2-5 kg per 24 hours. It should be transported in a styrofoam box with a lid which allows gas to escape. Do not fix the lid gastight with eg. tape. The thicker the walls of the box, the better, 2 cm to 5 cm. Mark the box: DRY ICE.

When transporting dry ice in a car, be sure to ventilate it constantly. Mailing and courier companies have special instructions for transporting dry ice containers. When sending dry ice by air, be sure to contact the flight company or a courier company for instructions.

Burn treatment

Treat dry ice burns the same as a regular heat burns. See a doctor if the skin blisters or comes off. Otherwise if only red it will heal in time as any other burn. Apply antibiotic ointment to prevent infection and bandage only if the burned skin area needs to be protected.

Disposal

Unwrap and leave dry ice at room temperature in a well-ventilated restricted area. It will sublimate from solid to gas.

6.1.1.8.4 Vaccination of fieldwork staff

The fieldwork staff working with needles and blood samples should be vaccinated for hepatitis B. The person responsible for ensuring that the staff is immunized should be documented to the national manual and checked before start of the fieldwork.

6.1.1.9 Ergonomics

The correct posture and equipment are important issues for maintaining the long term well-being of the staff. Some recommendations to enhance work ergonomics:

- Keep your hand below your elbow level when taking blood samples, pipetting and using the computer
- Adjust the height of the chair to enable a correct posture
- In case the height of the chair is too high for your feet to rest on the floor, use a foot rest

- If the lighting in the room is not sufficient, use a portable spot light
- The nurse's chair should not be equipped with wheels, but should have arm rests.

6.1.1.10 Waste disposal

- Waste of human origin generated during blood withdrawal and blood processing, like blood-containing tubes, disposable gloves, paper wipes, table top protective sheets etc. are disposed of in the **biological waste container.**
- The biological waste is disposed of according to the local facility regulations.
- Full and sealed **needle disposal containers** are disposed of according to the local facility regulations or sent to the NHES laboratory.
- **Biological risk waste** (subject has informed of having HIV, hepatitis or other contagious disease) should be sent to the NHES laboratory according to its guidelines.

6.2 Additional measurements

6.2.1 Collection of urine samples

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6.2.1.1 Rationale

The intake of sodium (consumed as common salt) is associated with elevated blood pressure, one of the major risk factors for cardiovascular disease. Reducing sodium intake is identified as one of the objectives in the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013–2020 (World Health Organization 2013). Monitoring sodium intake is essential in reporting the success in reducing sodium intake. However, measuring sodium intake is challenging. Estimating sodium intake by dietary assessment methods is difficult as the salt content of recipes in food composition databases is often not equivalent to the actual salt content consumed by the subjects, and because salt added during cooking and at the table is difficult to quantify (Brown 2009, McLean 2014). Because of problems concerning other methods, urine samples with 24-hour urine collection remain as the (established) gold standard measure of sodium intake (Bentley 2006, Pan American Health Organization–World Health Organization 2010, Whitton 2016).

The aim of the present chapter is to give recommendations as to collection of urine samples in population surveys. Urine samples are a priori intended for the measurements of sodium (Na), potassium (K), creatinine, albumin and iodine (I). Other analytes such as environmental biomarkers can be analyzed, but may require use of various preservatives and storage conditions.

6.2.1.2 Types of urine samples

Three means of collection can be used:

- Spot samples
- Overnight samples
- 24-hour collection

Each type of collection has its pros and cons. The composition of urine varies highly during the day depending on activity, nutrition and rest. Especially the levels of sodium, potassium and several hormones elicit a diurnal variation. Moreover, even at fixed salt intake, 24-hour urine collection for sodium excretion shows an infradian rhythmicity (fluctuation in periods of more than 24 hours) and a large day to day variability (Lerchl 2015, Rakova 2013, Titze 2014). It has been estimated that seven to ten 24-hour urine collections are needed for a reliable assessment of an individual's usual sodium intake of a given time (Ler-

chl 2015). The composition of sodium and other dietary biomarkers in urine also varies from day to day depending on food consumption. Dietary habits and intake tend to vary between weekdays and weekends (An 2016), and therefore, the urine samples should ideally be collected during both weekdays and weekends.

6.2.1.2.1 Spot samples

Spot samples are the easiest way to collect and handle urine. They can be obtained anytime and thus ensure a high participation rate and are logistically easy to organize. First morning spot sample, on the other hand, is the first void after the night. It is generally more concentrated than spot urine.

Spot urine suffers from large fluctuations due to dilution, which cannot always be normalized or corrected by creatinine. Spot urinary sodium concentration (even when sodium: creatinine ratio is used to account for urinary concentration) is likely to represent an individual's sodium intake over a short time period (only a few hours) (McLean 2014). Age, blood pressure level, drugs, posture and diurnal variation in hormone levels may result in a large hour to hour and daytime to nighttime variation in the excretion of sodium (Cogswell 2015). Thus, a spot urine sample is not a reliable determinant of 24-hour excretion of sodium at the individual level but it may provide estimates adequate for monitoring population sodium intake (McLean 2014). In addition, baseline 24-hour urine assessment has been recommended as the golden standard for monitoring population sodium intake (WHO/PAHO Regional Expert Group for Cardiovascular Disease Prevention through Population-Wide Dietary Salt Reduction 2010).

6.2.1.2.2 Overnight urine sample

For overnight samples, the urine passed before going to bed is discarded, but all urine voided during the night is collected including the first morning void. Overnight urine samples are collected at the participant's home, and need to be brought back to the examination site or picked up from the participant's home. Overnight urine sample has also been used for estimating sodium intake, but like for spot samples, its reliability remains controversial (Cogswell 2015).

6.2.1.2.3 24-hour urine sample

24-hour urine collection is conducted at the participant's normal daily living environments, starting in the morning and ending the following morning. This is the most cumbersome way of obtaining urine as the subjects need special equipment and they should adhere strictly to the protocol. 24-hour urine sample is the most reliable measure of sodium intake as a mean of approximately 90% of ingested sodium is excreted in the urine over the same period (Ji 2012, McLean 2014). Thus, despite the efforts required from the subjects, the collection of 24-hour urine samples in health examination surveys is encouraged.

6.2.1.3 Equipment

There are several different manufacturers of urine collection containers. Some are easy to handle and the participant can use them at home. They may consist of a jar into which urine is voided or transferred and equipped with a needle. A specimen of urine is taken from the jar into an evacuated tube using the needle. Thus only a small urine sample needs to be transported. Some caution is needed in handling due to the needle.

6.2.1.3.1 Equipment for spot samples of urine

- It is recommended to use sample cups that allow closed-system transfer of urine directly from the collection container to an evacuated tube.
- Evacuated tube

6.2.1.3.2 Equipment for overnight samples of urine

- Beaker with lid for voiding, 1000 ml, plastic, for collection and storage.

6.2.1.3.3 Equipment for 24-hours collection of urine

- Sampling beaker with lid for voiding, 1000 ml, plastic
- Collection container with lid, 3 l, for collecting beaker aliquots, plastic with a 0.1 ml scale. Alternatively for volume estimation, a large, 0.5 or 1 l measuring glass (plastic) can be used.

6.2.1.3.4 Equipment for handling and storage

- Plastic storage tube, e.g. 3 ml storage tubes that fulfill the needs of the storage. Cryo vials must be used if stored at -70^{o}C or colder.
- Storage box for plastic tubes. Suitable storage boxes for the cryo vials.
- Pipet
  - either pipet with disposable tip for transferring the sample and disposable tips
  - or disposable Pasteur pipet, plastic
- Stirring rod, plastic
- Freezer, see Part B, Section 6.1.1.2.3

A personal label sheet containing a label for the urinary sample is reserved for each participant at the laboratory/examination site. The laboratory form (Appendix 6.3) is for documenting pre-analytical events and data concerning collection.

6.2.1.4 Collection and storage of urinary specimen

6.2.1.4.1 Spot urine

Spot samples may be collected either at the examination site or the participant may collect the sample at home before or after the health examination. Ideally, spot samples are collected on a normal day with no preceding fasting.

- A spot urine specimen can be collected anytime during the day at the examination site. The bladder is voided into the beaker. The survey personnel transfers 2 ml into a plastic storage tube or several tubes if needed with a Pasteur pipet and caps the tube. The remaining urine is disposed of. Alternatively, a sample cup with integrated transfer device can be used from which the survey personnel (or the participant) transfers the sample to an evacuated tube.
- In case the participant collects the sample at home, a sample cup with integrated transfer device is used from which the participant transfers the sample to an evacuated tube. The evacuated sample tube may be sent to the examination site by mail.
- The specimen can be left at ambient temperature (0-30 ^{o}C) for a few hours, but are best preserved refrigerated (+4 ^{o}C). The urine must not be frozen (under 0 ^{o}C) before processed by survey personnel. At the examination site, nurse/ laboratory assistant will label the tube and store it at -20 ^{o}C or -70 ^{o}C.

6.2.1.4.2 Overnight urine

- The bladder is emptied and the urine discarded before going to bed. The date and exact time are recorded.
- All urine voided during the night is collected into the container. The last void is collected when 8 hours have elapsed from start of collection, just after rising up from the bed. Thus, all urine after going to bed including the first morning void is collected. As the time should encompass 8 hours, the participants should ideally be advised to go to bed at for example 10 pm or 11 pm and rise up at 6 am or 7 am, respectively.
- The exact time when the collection was ended is recorded. The urine specimen is stored at room temperature sheltered from direct sunlight in the container. The urine must not be frozen (under 0 ^{o}C) before processed by survey personnel.
- The container is delivered to the examination site/laboratory on the same day or picked up from the participant’s home.
- At the examination site, the urinary sample is mixed well and the volume measured or read. At least one aliquot (preferably several aliquots) of 2 ml are transferred to a storage

tube for sodium measurement, labelled and stored at -20 ^{O}C or -70 ^{O}C. Preferably several aliquots are made for storage and future use. The remaining urine is disposed of.

6.2.1.4.3 24-hour urine

- The collection begins in the morning by discarding the first void. The date and time are recorded.
- After this all urine is collected by using the beaker for pouring its contents into the container. The last void is collected when 24 (±2) hours have elapsed since the beginning of the collection. End of collection (date and time) are recorded.
- During and after the collection, the container is stored in a cool place, preferably refrigerator (+4 ^{O}C) and sheltered from direct sunlight. The urine must not be frozen (under 0 ^{O}C) before processed by the survey personnel.
- The container is delivered to the examination site on the same day when the collection ends. Alternatively, the survey personnel may pick up the sample from the subject's home.
- Completeness of collection is checked by the survey personnel.
- At the examination site/ laboratory the urinary specimen is mixed well and the volume measured or read from the scale of the container. At least one aliquot (preferably several aliquots) of 2 ml are transferred to a plastic storage tube, labelled and frozen at -20 or -70 ^{O}C. The remaining urine may be disposed of.
- The regular medication and other medication taken on the day of urine collection are recorded.

6.2.1.5 Instructions for subjects

The survey personnel inform the participant of the practical details of collection. The spot samples can be collected at the examination site. However, verbal and written instructions are needed. As the morning sample and the 24-hour sample are collected at the subject's home, thorough written instructions, in addition to verbal instructions, should be given to the subjects, for the collection of these samples.

6.2.1.5.1 Instructions on spot samples

The survey personnel give the equipment and verbal and written instructions to the subject. The subject is instructed to pass first some urine into the toilet at the examination site. Then some urine is passed into the container. The rest of the urine can be passed into the toilet.

Written instructions on spot samples to participants:

1. Clean your hands and, if possible, your genitals.

2. Men, retract your foreskin. Women, hold open the entrance to your vagina.
3. Start to urinate into the toilet, wait for a second or two, and without stopping the stream of urine, collect some urine in the sample cup.
4. You do not need to fill the sample cup to the top.
5. Finish passing the rest of your urine into the toilet.

6.2.1.5.2 Instructions on overnight samples

The survey personnel should explain the written instructions on overnight urine collection to the participant. The survey personnel should emphasize the importance of collecting all urine during the night of collection and the first morning void in full. The collection equipment in question as well as written instructions (Section 6.2.1.5.4) and a form (Appendix 6.3) on urine collection are given to the participant.

Written instructions on overnight urine collection to participants:

The overnight collection should encompass 8 hours. Thus, the time from going to bed until rising up should be 8 hours (for example from 10 pm to 6 am or from 11 pm to 7 pm).

1. Empty bladder into the toilet just before going to bed in the evening. This is the start time of your collection.
2. Write the date and the start time on the laboratory form given to you with these instructions.
3. If you need to pass urine during the night, collect the urine in full.
4. Keep the urine container at room temperature and sheltered from direct sunlight. The urine must not be frozen.
5. The last void is collected in the morning just after rising up from bed. This is the end time of your urine collection.
6. If you don't need to urinate during the night, only the first morning urine (in full) is included in the collection.
7. The end time is the time of the last urine collection. Write the date and the end time on the laboratory form.
8. Return your specimen to the examination site on the same day. (Alternatively: The survey personnel will pick your collection from you at a given time.)

The laboratory form given to participants before overnight urine collection should have an identification label on it (Appendix 6.3).

6.2.1.5.3 Instructions on 24-hour urine samples

The survey personnel should explain the written instructions on 24-hour urine collection to the participant. The survey personnel should emphasize the importance of collecting all urine during the given 24-

hour period. The participant is encouraged to follow a normal day with respect to eating and drinking during the collection. Excessive physical activity and drinking of alcohol should be avoided. The collection equipment as well as written instructions (Section 6.2.1.3) and a laboratory form (Appendix 6.3) are given to the participant.

Written instructions on 24-hour urine collection to participants:

1. In the morning of 24-hour urine collection, write your start date and time on the laboratory form given to you with these instructions.
2. Urinate at the start time but do not collect this urine.
3. Use the plastic beaker provided to catch all the urine you pass each time you urinate for the next 24 hours.
4. Pour the urine into the collection container after each time you urinate. Rinse the plastic cup with tap water after each use.
5. If possible, keep the urine in the refrigerator.
6. To end your urine collection 24 (±2) hours after the start time, pass the last urine that belongs to the 24-hour collection and add it to your collection. Write your end date and time on the laboratory form.
7. Return your specimen to the examination site on the same day. (Alternatively: The survey personnel will pick your collection from you at a given time.)

6.2.1.6 Exclusion criteria for all urine samples

Persons

- with any condition that would make urine collection difficult,
- who refuse to provide the sample, and
- with menstruation

are excluded.

If pregnant women are included in the sample, their results must be analyzed separately from those of other adult participants.

The 24-hour urine sample is considered incomplete, if the volume of the sample is ≤500 ml, if the collection time is <22 or >26 hours, or if "more than few drops" of urine were missed during the collection.

Reasons for exclusion or judging a sample as incomplete should be recorded.

6.2.1.7 Use of spot urine to estimate 24-hour excretion of sodium

Several equations have been proposed to convert spot urine sodium into an estimate of 24 h excretion. These include the equations by Ka-

wasaki (Kawasaki 1993), Tanaka (Tanaka 2002), a Danish model (Toft 2014), the WHO Pan American Health Organization (PAHO) (WHO/PAHO Regional Expert Group for Cardiovascular Disease Prevention through Population-Wide Dietary Salt Reduction, 2010) and that developed in the INTERSALT project (Brown 2013). The PAHO and the INTERSALT formulae have usually produced the most accurate estimates of population sodium intake. However, the best equation to be used for the population in question should always be assessed.

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6.3 Recording forms for biological sample collection and sample handling

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On the field there are several different recording forms:

- laboratory recording forms including sample collection and handling forms.

The recording forms can be paper forms or electronic forms. In addition detailed recording of information on participation and all contacts with selected persons is needed either in computerized logistics programmes or paper forms.

6.3.1 Sample collection

Sample collection recording forms include pre-analytic factors before sample collection and actual sample collection. For blood sample collection, issues which should be recorded are listed under Part B, Section 6.1.1 and for urine collection under Part B, Section 6.2.1.

Examples of the sample collection forms are in the Appendix 6.1 and Appendix 6.3.

6.3.2 Sample handling

The sample handling form includes issues relating to the processing of the samples on the field. The specification of the issues that should be recorded for blood sample handling are listed under Part B, Section 6.1.1.

An example of the sample handling recording form is in the Appendix 6.2.

Appendix 6.1 Blood sample collection recording form

Measuring the Health of Europeans

Blood sample collection recording form

Participant id: ☐☐☐☐☐☐

ID of the person drawing the blood sample: ☐☐☐☐☐☐

Time and room temperature of the sample collection

Date of the sample collection (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

Time of the day (hh:mm): ☐☐☐☐

Room temperature (^{o}C): ☐☐

Reason if blood sample not collected at all

- ☐ Vein could not be found/difficult to take a blood sample
- ☐ Refused
- ☐ Other, specify: ☐

Has the person fasted at least 8 hours

- ☐ Yes
- ☐ No

When the participant has eaten his/her lastest meal or drank a sweetened drink (hh:mm)

☐☐☐☐

Posture of the subject during the blood collection

- ☐ Sitting
- ☐ Supine

Reason for supine posture

- ☐ Fainting
- ☐ Bed driven or difficulty to sit still
- ☐ Other, specify: ☐

Arm used for blood collection

- ☐ Left
- ☐ Right

Reason for use of right arm

- ☐ No vein found on left arm
- ☐ No left arm/amputation of left arm
- ☐ Cast on left arm
- ☐ Other, specify: ☐

Number of tubes collected

- ☐ All
- ☐ Only ☐☐ tubes
- ☐ None

Number of haemolysed sample tubes ☐☐

Appendix 6.2 Blood sample handling recording form

Measuring the Health of Europeans

Blood sample handling recording form

Participant id: ☐☐☐☐☐☐

ID of the person handling the blood sample: ☐☐☐☐☐☐

Time of the sample handling on the field

Date of centrifuging samples (dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐

Time of the day when samples were centrifuged (hh:mm): ☐☐☐☐

Date of freezing samples to at least -20 ^{O}C (dd.mm.yyyy) ☐☐ ☐☐ ☐☐☐☐

Time of the day when samples were frozen to at least -20 ^{O}C (hh:mm) ☐☐☐☐

Time of the sample handling in the laboratory

Date of freezing samples to at least -70 ^{O}C (dd.mm.yyyy)

☐☐ ☐☐ ☐☐☐☐

Date of lipid analysis (dd.mm.yyyy)

☐☐ ☐☐ ☐☐☐☐

Date of glucose analysis (dd.mm.yyyy)

☐☐ ☐☐ ☐☐☐☐

Date of Hba_{1c} analysis (dd.mm.yyyy)

☐☐ ☐☐ ☐☐☐☐

Appendix 6.3 Urine sample collection recording form

Urine sample collection recording form

Participant id: ☐☐☐☐☐☐

Overnight sample collection

Start of the sample collection
Date of the sample collection
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time of the day (hh:mm): ☐☐☐☐

End of the sample collection
Date of the sample collection
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time of the day (hh:mm): ☐☐☐☐

If sample collection was incomplete,
Time(s) ☐
Estimated amount(s)
☐
of urine missed during the collection

Storage of urine before transfer
☐ cool (below 15°C)
☐ room temperature

Regular medications
☐

Medication(s) taken during the collection
☐

Following issues are recorded by the survey personnel when receiving the sample

Data when the sample was received
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time when the sample was received (hh:mm):
☐☐☐☐

Measured volume of urine: ☐☐☐☐ml

Urine sample collection recording form

Participant id: ☐☐☐☐☐☐

24 -hour sample collection

Start of the sample collection
Date of the sample collection
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time of the day (hh:mm): ☐☐☐☐

End of the sample collection
Date of the sample collection
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time of the day (hh:mm): ☐☐☐☐

If sample collection was incomplete,
Time(s) ☐
Estimated amount(s)
☐
of urine missed during the collection

Possible exceptions from usual/normal day
- ☐ Excessive sweating
- ☐ Sickness
- ☐ Menstruation

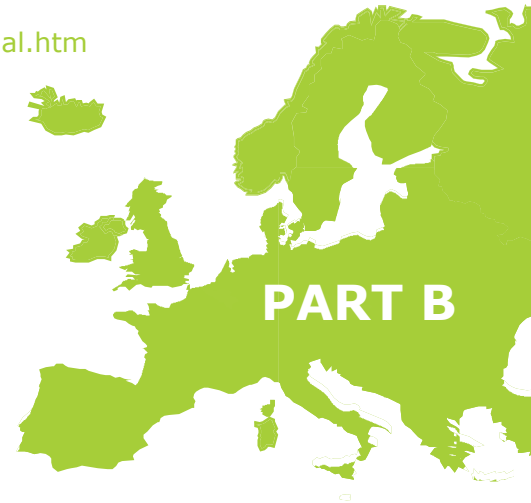
Storage of urine before transfer
- ☐ cool (below 15ºC)
- ☐ room temperature

Regular medications

Medication(s) taken during the collection

Following issues are recorded by the survey personnel when receiving the sample

Data when the sample was received
(dd.mm.yyyy): ☐☐ ☐☐ ☐☐☐☐
Time when the sample was received (hh:mm):
☐☐☐☐
Measured volume of urine: ☐☐☐☐ ml



7. EHES questionnaire

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The initial version of this questionnaire was developed in parallel with Eurostat activities in revising the EHIS questionnaire in 2011-2012, using the draft of January 2012 of the EHIS questionnaire as the reference. After completion of the EHIS wave 2 questionnaire, this EHES questionnaire was updated in 2016. The actual questions were not changed, but there were some clarifications to the instructions. There may be some changes for EHIS wave 3 which need to be checked when EHIS wave 3 questionnaire is available.

This chapter describes the EHES core questionnaire. These questions should be included in every national HES. They supplement the information collected through the physical measurements and biological samples.

There has been an intention to stick to EHIS questions whenever possible in order to improve comparability between these two surveys, and to facilitate the combination of EHES and EHIS if a country wishes to carry out these jointly. The EHES questionnaire also includes questions which are not in EHIS. Some of such questions are modifications of EHIS questions. Many of the non-EHIS questions come from the EHRM recommendations (Tolonen et al 2002). The source is indicated for each question. The reference to EHIS questions EHIS wave 2 (EHIS 2013) More information about the selection of the questions and questionnaire administration can be found in Part A, Chapter 5. More information on the use of questionnaire data in EHES reporting can be found in Part C, Chapter 4.

Most of the questions in the EHES questionnaire are recommended to be administered by interviewers. Some countries may use self-administration for the entire questionnaire or mixed-modes of questionnaire data collection to maximize response. If several data collection modes are used, these should be recorded for each participant. The order of the questions should be the same as in the EHES questionnaire, even if the national questionnaire includes additional questions. In some questions, the interviewer can use a show card with response options for

the respondent. If the respondent has vision problems or finds it difficult to read, the interviewer can read these to the respondent, making a short pause between them.

The questions and their order are given here. The layout of the actual questionnaire will need to be planned separately for each survey. The layout depends on whether the questionnaire is administered as an interview or self-completion and, in both cases, on whether paper forms or direct entry onto a computer is used. If the questionnaire is by interview, we advise including answer alternatives 'refusal' and 'don't know' for use by the interviewer but these should not be read or shown to the respondent. Also some changes in question wording for a few questions may be needed for self-administration, e.g. not using the "introductions" given before the actual question, or specifying the household members.

Under each question there are instructions for translation and cultural adaptation, as well as for the interviewer. For self-administered questionnaires the interviewer's instructions can be used while checking the questionnaires.

This questionnaire differs from the questionnaire used during the EHES Pilot Project in 2010-2011. The current questionnaire is similar and closer to the EHIS wave 2 questionnaire.

7.1 Core questionnaire items

Minimum European Health Module (MEHM)

Introduction:

"I would now like to talk to you about your health."

Q1. How is your health in general? Is it...

|__| very good
|__| good
|__| fair
|__| bad
|__| very bad?

Indicator

EHES/ECHI indicator: Self-perceived health

Instructions for translation and cultural adaptation

The reference is to health in general rather than the present state of health, as the question is not intended to measure temporary health problems. It is expected to include the different dimensions of health, i.e. physical, social and emotional functioning, and biomedical signs and symptoms.

Answer category *"fair"*: this intermediate category should be translated into an appropriately neutral term ("not good, not bad"), as far as possible keeping in mind cultural interpretations.

Instructions for the interviewer

This question refers to the participant's own assessment and should not be interpreted or assessed by anyone else, whether an interviewer, health care professional or relative. Self-perceived health is influenced by impressions or opinions from others, but these impressions should be processed by the individual in relation to his/her own beliefs and attitudes. Thus the question should not be presented to a proxy. Respondents should not be asked to compare their health with others of the same age or with their own previous or future health state.

Source

EHIS wave 2, question HS1 (EHIS 2013)

Q2. Do you have any longstanding illness or longstanding health problem? (By longstanding I mean illnesses or health problems which have lasted, or are expected to last, for 6 months or more.)

|__| Yes
|__| No

Indicator

EHES indicator: Prevalence of people with longstanding illness

ECHI indicator: Self-reported chronic morbidity

Instructions for translation and cultural adaptation

The wording should be chosen based on language and culture, choosing terms 'chronic' and/or 'longstanding' according to what is best understood. It is intended to ask if people 'have' a chronic condition, not if they really suffer from it. However, it seems that in some countries/languages it would be strange to use the word 'have' and that the verb 'suffer' means the same as 'have'. 'Health problem' may not to be understood in some countries/languages and therefore 'illness or condition' is the alternative.The main characteristics of a longstanding illness or health problem are that it is permanent and may be expected to require a long period of supervision, observation or care.

"Longstanding or chronic": illnesses or health problems should have lasted or are expected to last for 6 months or more; therefore, temporary problems are not of interest.

"Illness or health problem": conditions, not only diseases, include e.g. pain.

The words *"disability, handicap or impairment"* should not be included in the question.

Instructions for the interviewer

For consequences of injuries/accidents and of congenital conditions, birth defects, etc. the answer is 'yes'.

If needed, the interviewer can explain that the question refers to all longstanding health problems and illnesses, not only those diagnosed by a doctor.

In case the respondent has had a longstanding disease that doesn't/ didn't bother him/her or it is kept under control with medication, the interviewer should record answer 'Yes'. For instance, for a person with a high blood pressure or diabetes without current symptoms, the answer is 'Yes'. Problems that are intermittent are included, even when they are symptomatic for less than six months at a time, e.g. allergy.

Source

EHIS wave 2 question HS2 (EHIS 2013)

Q3. For at least the past 6 months, to what extent have you been limited because of a health problem in activities people usually do? Would you say you have been …

|__| severely limited
|__| limited but not severely or
|__| not limited at all?

Indicator

EHES indicator: Prevalence of people with longstanding restrictions in daily activities

ECHI indicator: Long-term activity limitations

Instructions for translation and cultural adaptation

The purpose of the question is to measure the presence of chronic or longstanding limitations.

"Activity limitations": difficulties the individual experiences in performing an activity, task or action

"In activities people usually do": The question should clearly show that the reference is to the activities people usually do and not to the activities the respondent actually does. Neither a list with examples of activities nor a reference to the age group of the subject is included in the question. This question gives no restrictions by culture, age, gender or the subjects own ambition.

"Severely limited": an extremely difficult situation to perform or accomplish activities that people usually do.

Specification of health concepts (e.g. physical and mental health) should be avoided.

Instructions for the interviewer

The question refers to person's own assessment of whether he/she is hampered in at least one daily activity, because of any current physical or mental health problem, illness or disability. This can also be reported by a proxy who is well aware of the subject's limitations in daily activities. People with longstanding limitations due to health problems have adapted, and may have reduced their activities. The activity limitations are assessed against a generally accepted population standard, relative to cultural and social expectations by referring to activities people usually do.

The question aims to measure longstanding limitations. The time period refers to the duration of the activity limitation and not of the health problem. The limitations must have started at least six months ago and still exist at the moment of the interview.

New limitations which have not yet lasted 6 months are not considered, even if they are expected to continue for more than 6 months. E.g. if the subject has recently been diagnosed having, e.g., diabetes, he/she knows that it is not curable, so it is long-standing and it may be controlled or not, and it might have consequences or not, but this is not known yet. The question refers to the individual's experience, whether his or her diabetes has had longstanding disabling consequences. The answer should be based on this past experience, being 'yes' (1 or 2) if the person is currently limited and has been limited in activities for at least the last 6 months.

Only the limitations directly caused by one or more health problems of whatever type are considered. Limitations due to financial, cultural or other none health-related causes should not be taken into account. Limitations due to injuries, accidents, congenital conditions and birth defects etc., shall be considered.

Source

EHIS wave 2 question HS3 (EHIS 2013)

7.2 Diseases and chronic conditions

Introduction

"Here is a list of chronic diseases or conditions".

Q4. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?

Myocardial infarction (heart attack)	|__| Yes	|__| No
Coronary heart disease or angina pectoris	|__| Yes	|__| No
High blood pressure (hypertension)	|__| Yes	|__| No
Elevated blood cholesterol	|__| Yes	|__| No
Stroke (cerebral haemorrhage, cerebral thrombosis)	|__| Yes	|__| No
Diabetes	|__| Yes	|__| No

Indicators

EHES indicators: Prevalence of self-reported myocardial infarction, Prevalence of self-reported coronary heart disease, Prevalence of self-reported high blood pressure, Prevalence of self -reported elevated blood cholesterol, Prevalence of self-reported diabetes. Furthermore, information on these diseases and conditions are needed for CVD risk estimates.

ECHI indicator: Diabetes, self-reported prevalence.

Instructions for translation and cultural adaptation

The list can be expanded by other diseases and conditions from the EHIS questionnaire or additional diseases and conditions of national interest. A show card of the list of diseases and conditions can be used.

"Medical doctor": any physician who conducts medical examination and makes diagnosis, prescribes medication and gives treatment for diagnosed illnesses, disorders or injuries, gives specialized medical or surgical treatment for particular types of illnesses, disorders or injuries, and or gives advice and applies other methods for preventive medicine.

Instructions for the interviewer

This question refers to diagnosed diseases or conditions, i.e. a medical doctor has told that the subject has the disease or condition. Diseases or conditions that the subject assumes to have, but which have not been confirmed by a medical doctor are not considered.

"Coronary heart disease or angina pectoris": heart related chest pain. All ischaemic heart diseases should be included.

"Diabetes": excluding gestational diabetes, i.e. high blood sugar values during pregnancy.

Source

Modified from EHIS wave 2 question CD1 (EHIS 2013): The EHIS question refers to "during the past 12 months" and does not specify that the disease or condition should have been "diagnosed by a medical doctor". The EHES measurements make it possible to estimate future health

risks, and these modiciations provide an essential improvement to the risk estimation. In the EHIS question there are 10 other diseases/conditions, but not "Elevated blood cholesterol".

7.3 European Health Care Module

Medicine Use

Introduction

"I'd now like to ask about your use of medicines in the past two weeks."

Q5. During the past two weeks, have you used any medicines that were prescribed for you by a doctor?

|__| Yes
|__| No

Indicators

Introduction to more specific questions (see Q6).

Instructions for translation and cultural adaptation

The question refers to any medicines prescribed by a medical doctor or a dentist. Medicines recommended by a pharmacist, nurse etc. are not included.

Instructions for the interviewer

For women, also add: 'Exclude contraceptive pills or hormones used solely for contraception'.

"Medicine": any product including tablets, liquids, creams etc, that is used to alleviate symptoms, to prevent illness, or to improve poor health, and which is ordinarily purchased from a pharmacy.

"Doctor": refers to any medical doctor (physician) or dentist.

"During the past two weeks": the preceding period of 14 days.

"Prescribed": medicines which were written on a prescription by a doctor. Here are also included the medicines which were originally prescribed by a doctor even though the respondent has not recently visited the doctor to renew the prescription. Medicines that have been prescribed but have not been used during the past two weeks are not recorded.

Source

EHIS wave 2 question MD1 (EHIS 2013)

Q6. Were the medicines for ... ? (Asked if Q5 = "Yes")

High blood pressure	|__| Yes	|__| No
Lowering the blood cholesterol level	|__| Yes	|__| No
Diabetes	|__| Yes	|__| No

Indicator

EHES indicators: Prevalence of anti/hypertensive drug treatment in the population, Prevalence of lipid lowering drug treatment in the population, Prevalence of diabetes drug treatment in the population. Also used for Effectiveness of anti-hypertensive dug treatment, Effectiveness of cholesterol treatment and Effectiveness of diabetes treatment, as well as for Prevalence of actual or potential hypertension, Prevalence of actual or potential elevated non-HDL cholesterol, Prevalence of actual or potential diabetes in the population.

Instructions for translation and cultural adaptation

Use of medicines for specific health conditions related to EHES measurements are included in the core question. The list can be expanded by other medication for diseases and conditions. A show card of the list of medicines can be used.

In addition to this question, it is recommended to collect the names of all currently used prescribed medicines or bar codes in the packages, if feasible. These provide additional information on medication and diseases and conditions.

Instructions for the interviewer

Ask the respondent to specify if he/she took the medicine(s) for the listed health conditions. Show card may be used.

Source

Extracted from EHIS wave 1 question MD2. The question was not included in EHIS wave 2.

Preventive services

Introduction:

"Now I would like to ask about your blood pressure, blood cholesterol and blood sugar."

Q7. When was the last time that your blood pressure was measured by a health professional?

|__| Within the past 12 months
|__| 1-5 years ago
|__| Not within the past 5 years

Indicator

EHES indicators: Proportion of the population with blood pressure measurement within the past 12 months, Proportion of the population with blood pressure measurement within the past 5 years.

Instructions for translation and cultural adaptation

"Measured by a health professional" is included in the question wording because measurements by lay persons or self-monitoring should not be considered.

Instructions for the interviewer

"Health professional": a medical doctor, nurse, health visitor, midwife or other trained health professionals. Measurements by lay persons or measurements carried out by the person him-/herself are not included here.

Source

Modified from EHIS wave 2 question PA2 (EHIS 2013): The EHIS question has five response alternatives: "Within the past 12 months", "1 to less than 3 years", "3 to less than 5 years", "5 years or more", "Never". The EHIS question was considered unnecessarily difficult, especially concerning the difference between "5 years or more" and "Never".

Q8. When was the last time that your blood cholesterol was measured by a health professional?

|__| Within the past 12 months
|__| 1-5 years ago
|__| Not within the past 5 years

Indicator

EHES indicators: Proportion of the population with cholesterol measurement within the past 12 months, Proportion of the population with cholesterol measurement within the past 5 years.

Instructions for translation and cultural adaptation

"Measured by a health professional": Referral and analysis by a health professional is expected and this is included in the question wording, because tests by lay persons or self-monitoring should not be considered.

Instructions for the interviewer

"Measured by a health professional": referral or analysis by a medical doctor, nurse or other trained health professionals. The samples may be taken in a laboratory (fasting or non-fasting) or by using test strips. Tests by lay persons or self-monitoring are not included here.

Source

Modified from EHIS wave 2 question PA3 (EHIS 2013): The EHIS question has five response alternatives: "Within the past 12 months", "1 to less than 3 years", "3 to less than 5 years", "5 years or more", "Never". The EHIS question was considered unnecessarily difficult, especially concerning the difference between "5 years or more" and "Never".

Q9. When was the last time that your blood sugar was measured by a health professional?

|__| Within the past 12 months
|__| 1-5 years ago
|__| Not within the past 5 years

Indicator

EHES indicators: Proportion of the population with blood glucose measurement within the past 12 months, Proportion of the population with blood glucose measurement within the past 5 years.

Instructions for translation and cultural adaptation

"Measured by a health professional": Referral and analysis by a health professional is expected and this is included in the question wording, because tests by lay persons or self-monitoring should not be considered.

Instructions for the interviewer

"Measured by a health professional": Referral and analysis by a health professional, a medical doctor, nurse or other trained health professionals. The samples may be taken in a laboratory (fasting or non-fasting) or by using test strips. Tests by lay persons or self-monitoring are not included here.

Source

Modified from EHIS wave 2 question PA4 (EHIS 2013): The EHIS question has five response alternatives: "Within the past 12 months", "1 to less than 3 years", "3 to less than 5 years", "5 years or more", "Never". The EHIS question was considered unnecessarily difficult, especially concerning the difference between "5 years or more" and "Never".

7.4 European Health Determinant module

Height and weight

Height and weight are needed to calculate BMI. Even though height and weight will be measured in the HES, they should also be asked. For some persons the questionnaire will be the only data source. This enables for example the analysis of non-participants' BMI in the case

that the subject has only filled in the questionnaire but does not want to take part in the physical examinations. Asking height and weight prior to the measurement also enables comparison of measured and self-reported height and weight (reporting bias).

Introduction:

"Now I'm going to ask you about your height and weight."

Q10. How tall are you without shoes? (in cm)

|__|__| cm

Indicators

EHES indicators: Self-reported height, Self-reported BMI

Instructions for translation and cultural adaptation

Specification "without shoes" is needed in the question.

Instructions for the interviewer

"Height without shoes": measured when the person has bare feet or light socks. An estimate can be asked when the respondent indicates that she/he doesn't know the exact answer.

Source

EHIS wave 2 question BM1 (EHIS 2013)

Q11. How much do you weight without clothes and shoes? (in kg)

|__||__||__| kg

Indicators

EHES indicators: Self-reported weight, Self-reported BMI

Instructions for translation and cultural adaptation

If this is asked in a self-administered questionnaire, an instruction for pregnant women to record weight before pregnancy should be added. As an alternative, a specific question on pregnancy status may be included and both current weight and weight before pregnancy recorded.

Instructions for the interviewer

"Weight without clothes and shoes": body weight measured when the person is undressed or in underwear. For pregnant women weight before pregnancy should be recorded. An estimate can be asked when the respondent indicates that she/he doesn't know the exact answer.

Source

EHIS wave 2 question BM2 (EHIS 2013)

Smoking

Questions on smoking are recommended to be included in a self-completion questionnaire.

Instruction

"The following questions are about your smoking habits and exposure to tobacco smoke"

Q12. Do you smoke?

|__| Yes, daily
|__| Yes, occasionally
|__| Not at all

Indicator

EHES indicator: Prevalence of daily smokers, Prevalence of occasional smokers, Prevalence of ex-daily smokers

ECHI indicator: Regular smokers

Instructions for translation and cultural adaptation

"Do you smoke": whether the respondent currently smokes, regardless of the amount or kind of tobacco product.

"To smoke": breathing in and out of the smoke of tobacco products (manufactured cigarettes, hand rolled cigarettes, cigars, pipes, etc.). Electronic cigarettes and smokeless tobacco products (e.g. snuff) are not included.

"Daily" includes almost daily

Instructions for the interviewer

"Smoking": all kinds of tobacco products (manufactured cigarettes, hand rolled cigarettes, cigars, pipes, etc.) are included. Electronic cigarettes and smokeless tobacco products (e.g. snuff) are not included.

Record *"Yes, daily"* also if the person smokes almost daily.

Source

EHIS wave 2 question SK1 (EHIS 2013)

Q13. On average, how many times do you smoke per day (= number of cigarettes, cigars, pipefulls of tobacco etc.)? (asked if Q12 = "Yes daily" or "yes occasionally")

|__|__| times

Indicator

EHES indicators: Number of times smoked per day among daily smokers, Number of times smoked per day in population

Instructions for translation and cultural adaptation

Use the term *"average"*, not generally or usually. The question is asked also from occasional smokers because some persons do not consider themselves as daily smokers even though they smoke a couple of times on most days. In the analysis only daily smokers are included for the first indicator.

Instructions for the interviewer

"Per day": For occasional smokers it is the average over all days, i.e. not only over the days when they smoke. If the average is less than 0,5, code "0".

"Pipefull": the full content of the pipe, even when smoked with intervals.

Source

EHRM (Tolonen 2002). EHIS wave 2 question SK3 "On average, how many cigarettes do you smoke each day?" (EHIS 2013)

Q14. Which of the products do you frequently smoke? (Asked if Q12 = "Yes, daily")

Manufactured cigarettes	|__| Yes	|__| No
Self-rolled cigarettes	|__| Yes	|__| No
Pipe	|__| Yes	|__| No
Cigars	|__| Yes	|__| No

Indicator

EHES indicators: Prevalence of manufactured cigarette smoking among daily smokers, Prevalence of self-rolled cigarette smoking among daily smokers, Prevalence of pipe smoking among daily smokers, Prevalence of cigar smoking among daily smokers

Instructions for translation and cultural adaptation

"Frequently": regularly.

If other kinds of tobacco products are commonly smoked in the country, they (or "other") should be added to the list of alternatives.

Instructions for the interviewer

"Frequently": regular use, not including occasional, rare use, e.g. one occasional cigar on a specific day

Source

EHRM (Tolonen 2002) EHIS wave 2 question SK2 "What kind of tobacco product do you mostly consume", has response categories "Cigarettes (manufactured and/or hand-rolled", "Cigars", "Pipe tobacco" and "Other" (EHIS 2013). The change to current EHIS question was not considered important, and it could compromise the assessment of trends from the past.

Q15. Have you ever smoked cigarettes, cigars or pipes daily or almost every day for at least one year?

|__| Yes
|__| No

Indicator

Prevalence of ex-daily smokers

Instructions for translation and cultural adaptation

"Ever": past lifetime

Asked to identify past smoking that is clearly more than just trying a couple of times as an experiment. This question should be made also to those who reported in Q12 that they now smoke daily.

Instructions for the interviewer

"Ever smoked daily, or almost daily, for at least one year": refers to a period of at least about a year while smoking daily or almost daily, regardless of the daily amount.

Source

EHRM (Tolonen 2002)

Q16. For how many years have you smoked daily? Count all separate periods of smoking daily. If you don't remember the exact number of years, please give an estimate.

|__|__| years

Indicator

EHES indicators: Number of years smoked among daily smokers, Prevalence of years smoked daily in population.

Instructions for translation and cultural adaptation

"Daily": includes almost daily

Instructions for the interviewer

If a person has smoked daily for 10 years, then he/she stopped smoking for 2 years after which he/she started to smoke occasionally for another 5 years followed by 2 years of daily smoking then the number of years of daily smoking is 12.

If a person started smoking daily less than a year ago record '0' as the number of years.

Source

EHIS wave 1 (EHIS 2011). Not in EHIS wave 2.

Q17. When did you stop smoking daily? (If you have quit smoking several times, give the time when you last stopped smoking daily?) (Asked if Q12="YES, OCCASIONALLY" or "NOT AT ALL" and Q15 = "YES")

|__| Within the past week
|__| 1 week - less than 1 month ago
|__| 1 month - less than 1 year ago
|__| 1 - 5 years ago
|__| More than 5 years ago

Indicator

To be used in additional analyses to (a) characterize the difference between daily and past smoking and (b) to provide information on the non-smoking period since daily smoking.

Instructions for translation and cultural adaptation

Needed for CVD risk estimates. Those who have stopped smoking daily less than a year ago can be included in current smokers.

Instructions for the interviewer

Refers to the latest time when stopped smoking or started smoking less than daily.

Source

EHRM (Tolonen 2002).

7.5 Background Module / Core Social Variables

Q18. Sex of respondent

|__| Male
|__| Female

Instructions for translation and cultural adaptation

The biological sex of the respondent. Information may be obtained from the sampling frame, and may not need to be asked.

Instructions for the interviewer

In order not to embarrass the respondent, the interviewer can record the sex of the respondent without asking her/him.

Source

EHIS wave 2 question SEX (EHIS 2013)

Q19. What is your date of birth?

|__|__| |__|__| |__|__|__|__| DD MM YYYY

Indicator

Only the year of birth and age in full years at the time of the examination would be transferred to EHES RC.

Instructions for translation and cultural adaptation

The information may be obtained from the sampling frame, but this may need to be verified with the respondent. In case the exact date of birth (as above) cannot be collected (due to national data protection rules), year of birth and month of birth should be considered.

If none of the above is possible, then age at last birthday should be asked in the questionnaire.

Instructions for the interviewer

Date of birth as recorded in the ID card of the respondent, preferably checked from the ID card.

If age is asked, *"Age at last birthday"* means age in completed years, i.e. age expressed as the number of birthday anniversaries passed on the date of reference.

Q20. Are you living with someone as a couple?

|__| Yes
|__| No

Indicator

Living as a couple

Instructions for translation and cultural adaptation

De facto arrangement indicating social support.

Instructions for the interviewer

Including those who are legally married, living in consensual union or registered partnership.

Source

FEHES (Tolonen 2008)

Q21. How many years have you spent at school or in full-time study?

|__|__| years

Indicator

One of the indicators of socioeconomic status.

Instructions for translation and cultural adaptation

This will be used to classify the respondents to thirds of years of education among the respondents, which is an indicator of socioeconomic status.

Instructions for the interviewer

Includes basic education as well as occupational and academic training in full years. The instructions for the interviewer may include examples of average length of studies for different levels of education, to be used when needed to assist in calculating the full years.

Source

EHRM (Tolonen 2002)

Q22. What is the highest level of education or training successfully completed (Based on ISCED-2011 classification)

|__| ISCED0 – early childhood development, pre-primary education
|__| ISCED1 - primary education
|__| ISCED 2 - lower secondary education
|__| ISCED 3 - upper secondary education
|__| ISCED 4 - post-secondary but non-tertiary education
|__| ISCED 5 - tertiary education; short-cycle
|__| ISCED 6 - tertiary education; bachelor level or equivalent
|__| ISCED 7 - tertiary education; master level or equivalent
|__| ISCED 8 - tertiary education; doctoral level or equivalent

Instructions for translation and cultural adaptation

Each country should prepare its own response categories according to the educational system of the country. The response categories should be compatible with the ISCED classification. (http://www.uis.unesco.org/UISQuestionnaires/Pages/Education.aspx)

Instructions for the interviewer

"Highest level of education completed": level successfully completed and associated with obtaining a certificate or a diploma. When determining the highest level, both general and vocational education should be taken into consideration. Persons should be coded according to the highest level they have completed. Persons still in education have to indicate their last level of education successfully finished.

Include any work-based training. Any qualification which has been achieved in connection with work should be taken into account regardless of the type of qualification, regardless of who paid for the education or whether the education took place in the premises of the company or not.

Source

EHIS wave 2 question HATLEVEL (EHIS 2013)

Q23. How would you define your current labour status?

|__| Carrying out a job or profession, including unpaid work for a family business or holding, including an apprenticeship or paid traineeship, etc.
|__| Unemployed
|__| Pupil, student, further training, unpaid work experience
|__| In retirement or early retirement or has given up business
|__| Permanently disabled
|__| In compulsory military or community service
|__| Fulfilling domestic tasks
|__| Other inactive person

Instructions for translation and cultural adaptation

"Current labour status": people's own perception of their main status differs from the strict definitions used in the ILO definitions. For instance, many people who would regard themselves as full-time students or homemakers may be classified as ILO-employed if they have a part-time job. Similarly, some people who consider themselves 'unemployed' may not meet the strict ILO criteria of taking active steps to find work and being immediately available.

"In compulsory military or community service": this code might not be relevant in some countries

Instructions for the interviewer

"Current": The situation at the time of the interview should be recorded. For instance, if a person has recently lost a job or has retired recently, or the activity status has changed otherwise in a definitive manner, the person's own perception of his/her main activity at present is recorded. No other specific reference period should be considered.

If the participant is e.g. a student who is also working, the labour status is determined on the basis of the most time spent.

Source

EHIS wave 2 question MAINSTAT (EHIS 2013)

Q24. How many persons live in the household, including yourself?

|__|__| persons

Q25. How many of them are aged less than 14 years? (Asked if more than 1 person lives in the household)

|__|__| persons

Indicator

The total number household members and the number persons aged under 14 is needed to calculate the equivalised household's total net monthly income. In case more detailed information on household members is needed for the sampling frame, more questions may be added.

Instructions for translation and cultural adaptation

It is sufficient to count those in the household who share expenses with the respondent. However, if household sampling is used, it may be necessary to count all who live in the same address.Whichever definition is used, Q26 should use the same definition.

Instructions for the interviewer

The following persons, if they share household expenses with the respondent shall be regarded as household members (Note: the preceding sentence and the following list should be adapted to the actual definition used for a household in the survey):

- persons usually resident and related to other household members;
- persons usually resident, not related to other household members;
- resident boarders, lodgers, tenants, etc., with no private address elsewhere, actual/intended stay one year or more;
- visitors, with no private address elsewhere, actual/intended stay one year or more;
- live-in domestic servants, au-pairs, etc. , with no private address elsewhere, actual/intended stay one year or more;
- persons usually resident but temporarily absent (for reasons of holiday travel, work, education or similar), with no private address elsewhere and actual/intended absence less than one year;
- children of household members being educated away from home, with no private address elsewhere, continuing to retain close ties with the household;
- persons absent for long periods but having household ties (eg. persons working away from home), child or partner of other household member, with no private address elsewhere, continuing to retain close ties with the household;
- persons temporarily absent but having household ties (eg. persons in hospital, nursing homes or other institutions), with clear financial ties to the household, actual/prospective absence less than one year;

A person shall be considered 'usually resident' if he/she spends most of his/her daily rest there evaluated over the past one year. Persons forming new households or joining existing households shall normally be considered as members at their new location if there is an intention to

stay for more than one year. Similarly, those leaving to live elsewhere shall no longer be considered as members of their original household.

A child who alternates between two households (for instance after his or her parents have divorced) should be considered in the household where he or she spends the majority of the time. Where an equal amount of time is spent with both parents the place of usual residence should be the place where the child is at the time of the survey.

Source

EHIS wave 2 question HHNBPERS (EHIS 2013)

Q26. Which group represents your household's total net monthly income from all the sources (income from work, unemployment benefits, old-age or survivor's benefits, sickness or disability benefits, family/children related allowances, housing allowances, education-related allowance, other regular benefits) after deductions for income tax, national insurance, etc.

|__| Below 1st decile
|__| Between 1st decile and 2nd decile
|__| Between 2nd decile and 3rd decile
|__| Between 3rd decile and 4th decile
|__| Between 4th decile and 5th decile
|__| Between 5th decile and 6th decile
|__| Between 6th decile and 7th decile
|__| Between 7th decile and 8th decile
|__| Between 8th decile and 9th decile
|__| Aboved 9th decile

Instructions for translation and cultural adaptation

The net monthly income of the household. The term *"household"* should refer to the same definition as used in Q24.

The deciles for each country could be taken from a national survey on income, such as EU-SILC survey, with suitable rounding. The number of categories does not need to be exactly 10. This question, together with Questions 24 and 25 can be used to calculate the so called *"Equalized household's total net monthly income"* (modified OECD scale, which is used in EUROSTAT).

Instructions for the interviewer

If the respondent doesn't know the exact or approximate amount for their household, he/she should be requested to indicate the income range corresponding to the total household net income per month.

Source

Questionnaire item to provide data for EHIS wave 2 question HHINCOME (EHIS 2013)

References

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Appendix 7.1 EHES questionnaire

EHES questionnaire

Participant id: ☐☐☐☐☐☐

Health Status Module

Q1. How is your health in general? Is it…

- ☐ very good
- ☐ good
- ☐ fair
- ☐ bad
- ☐ very bad?

Q2. Do you have any longstanding illness or longstanding) health problem? (Longstanding means illnesses or health problems which have lasted, or are expected to last, for 6 months or more)

- ☐ Yes
- ☐ No

Q3. For at least the past 6 months, to what extent have you been limited because of a health problem in activities people usually do? Would you say you have been …

- ☐ severely limited
- ☐ limited but not severely or
- ☐ not limited at all?

Q4. Do you have or have you ever had any of the following diseases or conditions, diagnosed by a medical doctor?

Myocardial infarction (heart attache)	☐ Yes	☐ No
Coronary heart disease or angina pectoris	☐ Yes	☐ No
High blood pressure (hypertension)	☐ Yes	☐ No
Elevated blood cholesterol	☐ Yes	☐ No
Stroke (cerebral haemorrhage, cerebral thrombosis)	☐ Yes	☐ No
Diabetes	☐ Yes	☐ No

Health Care Module

Q5. During the past two weeks, have you used any medicines that were prescribed for you by a doctor (for women, exclude contraceptive pills or other hormones used solely for contraception)?

- ☐ Yes
- ☐ No ⇨ Go to Q7

Q6. Were they medicines for … ?

high blood pressure	☐ Yes	☐ No
lowering the blood cholesterol level	☐ Yes	☐ No
diabetes	☐ Yes	☐ No

Q7. When was the last time that your blood pressure was measured by a health professional?

- ☐ Within the past 12 months
- ☐ 1-5 years ago
- ☐ Not within the past 5 years

Q8. When was the last time that your blood cholesterol was measured (by a health professional)

- ☐ Within the past 12 months
- ☐ 1-5 years ago
- ☐ Not within the past 5 years

Q9. When was the last time that your blood sugar (glucose) was measured by a health professional?

- ☐ Within the past 12 months
- ☐ 1-5 years ago
- ☐ Not within the past 5 years

Health Determinants

Q10. How tall are you without shoes? (in cm)

☐☐☐ cm

Q11. How much do you weight without clothes and shoes? (in kg)

☐☐☐ kg

Q12. Do you smoke?

- ☐ Yes, daily
- ☐ Yes, occasionally
- ☐ Not at all ⇨ Go to Q15

Q13. On average, how many times do you smoke per day (= number of cigarettes, cigars, pipefuls of tobacco etc.)?

☐☐ times

Q14. Which of the products do you frequently smoke?

Manufactured cigarettes	☐ Yes	☐ No
Self-rolled cigarettes	☐ Yes	☐ No
Pipe	☐ Yes	☐ No
Cigars	☐ Yes	☐ No

Q15. Have you ever smoked daily (= almost every day for at least one year)?

- ☐ Yes
- ☐ No

Q16. For how many years have you smoked daily? Count all separate periods of smoking daily. If you don't remember the exact number of years, please give an estimate.

☐☐ years

Q17. When did you stop smoking daily? (If you have quit smoking several times, give the time when you last stopped smoking daily?)

- ☐ Within the past week
- ☐ 1 week - less than 1 month ago
- ☐ 1 month - less than 1 year ago
- ☐ 1 - 5 years ago
- ☐ More than 5 years ago

Social Variables

Q18. Sex of respondent

- ☐ Male
- ☐ Female

Q19. What is your date of birth? (dd mm yyyy)

☐☐ ☐☐ ☐☐☐☐

Q20. Are you living with someone as a couple?

- ☐ Yes
- ☐ No

Q21. How many years have you spent at school or in full-time study?

☐☐ years

Q22. What is the highest level of education or training successfully completed

- ☐ early childhood development, pre-primary education
- ☐ primary education
- ☐ lower secondary education
- ☐ upper secondary education
- ☐ post-secondary but non-tertiary education
- ☐ tertiary education; short-cycle
- ☐ tertiary education; bachelor level or equivalent
- ☐ tertiary education; master level or equivalent
- ☐ tertiary education; doctoral level or equivalent

Q23. How would you define your current labour status?

- ☐ Carry out a job or profession, including unpaid work for a family business or holding, including an apprenticeship or paid traineeship, etc.
- ☐ Unemployed
- ☐ Pupil, student, further training, unpaid work experience
- ☐ In retirement or early retirement or has given up business
- ☐ Permanently disabled
- ☐ In compulsory military or community service
- ☐ Fulfilling domestic tasks
- ☐ Other inactive person

Q24. How many persons live in the household, including yourself?

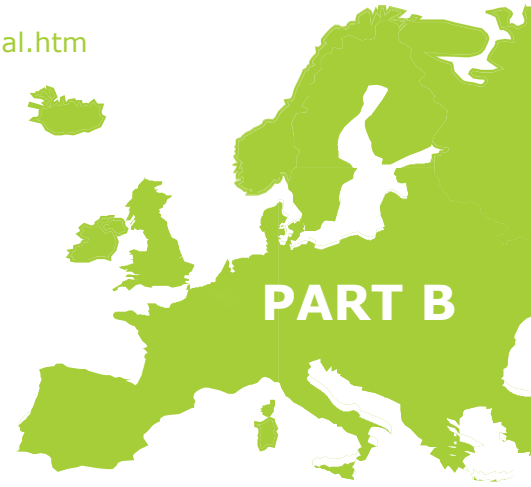
☐☐ persons

Q25. How many of them are aged less than 14 years?

☐☐ persons

Q26. Which group represents your household's total net monthly income from all the sources (income from work, unemployment benefits, old-age or survivor's benefits, sickness or disability benefits, family/children related allowances, housing allowances, education-related allowance, other regular benefits) after deductions for income tax, national insurance, etc.

- ☐ Below 1st decile
- ☐ Between 1st decile and 2nd decile
- ☐ Between 2nd decile and 3rd decile
- ☐ Between 3rd decile and 4th decile
- ☐ Between 4th decile and 5th decile
- ☐ Between 5th decile and 6th decile
- ☐ Between 6th decile and 7th decile
- ☐ Between 7th decile and 8th decile
- ☐ Between 8th decile and 9th decile
- ☐ Aboved 9th decile



8 FEEDBACK TO THE PARTICIPANTS

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Feedback is an important factor in motivating participants. For many participants, getting new information on one's own health is an important reason to participate. Guidelines for giving feedback need to be included in the training of the fieldwork staff and in the national manual. The contents of the feedback and modes for giving it have to be based on the following issues, depending on national circumstances:

- acceptable for the participants and their own health care providers (e.g. GPs),
- the survey setting and competence of the fieldwork staff, and
- national regulations and medical and/or nursing practice guidelines.

8.1 Modes for providing feedback

The feedback on anthropometric measurements and blood pressure can be provided to all participants right after the measurements. Results of the blood analysis are usually mailed or given later. There are several modes for providing feedback. Here are a few options:

1. Results are given and explained after the measurements are completed and before the participant leaves the survey site or, in the case of a home visit, before the nurse leaves.
    - Results are written on a form which is then given to the participant. The form does not include interpretation of the results. Results are explained verbally to the participant and they have an opportunity to ask questions.
    - Results are written on a form which also has a short, basic interpretation of them (e.g. reference values). This form is then given to the participant and results are also explained to them verbally.

2. No results are given in written form to the participant during the visit (they may be only explained verbally) but they are mailed to the participant later, e.g. when all laboratory values are available. The letter including the results also includes short, basic interpretations of the results.
3. Results are not provided directly to the participant, but they are mailed to the general practitioner (GP) of the participant. It is expected that the GP explains the results to the participant. The name and address of the GP is asked from the participant.
4. In cases where the laboratory analyses indicate acute need for medical attention, personal contact (such as a phone call by the survey physician) should be considered instead of only a mailed letter.

When results are explained verbally to the participants, the fieldwork staff should be provided with a few model sentences which can be used. It has to be emphasized always that the survey measurements or samples, taken at one time, can not be used for diagnostic purposes. In case of any abnormal results, these have to be confirmed by repeated measurements, possibly with other additional tests and interpreted by a physician. The measurement results will also depend on adherence to instructions before the measurement (e.g. smoking or fasting), and these need to be taken into account. During the examination visit, important information on the participant's health status may be lacking, which is why all interpretations and comments should be made with caution.

Regardless of the way in which the actual measurement results are given to the participant, additional health promotion material may be available. This material may include leaflets or instructions to consult reliable websites (e.g. NHS 2011 or other national professional websites) about smoking, obesity, hypertension, etc.

8.2 Example of feedback

When explaining the measurement results to the participant, the following phrases are examples of comments that can be used both in written or verbal communication. They need to be adapted to the criteria, thresholds and reference values used in national guidelines.

8.2.1 Blood pressure

"Systolic blood pressure should be below 130 mmHg and diastolic blood pressure below 85 mmHg. Your blood pressure was __ mmHg / __ mmHg. This means that your blood pressure is..."

- if within normal range: "... normal, but it is recommended that you check your blood pressure (e.g. once a year)";
- if systolic blood pressure is 130-139 mmHg and/or diastolic blood pressure 85-89 mmHg: "... mildly raised and you should consider paying attention to your lifestyles which

may affect the blood pressure. Heavy use of salt and alcohol, as well as overweight and sedentary lifestyle are known to increase blood pressure. Additional information on these can be found from... You should also check your blood pressure regularly, at least once a year"

- if systolic blood pressure is 140-159 mmHg and/or diastolic blood pressure is 90-99 mmHg: "... raised and you should see your doctor/a nurse for follow-up of your blood pressure. It is also recommended to consider adapting your lifestyle to help to decrease your blood pressure";
- if systolic blood pressure is over 160 mmHg and/or diastolic blood pressure is over 100 mmHg: "...considerably raised and you should contact your doctor so that the need for treatment can be assessed and regular follow-up of your blood pressure can be started".

8.2.2 Anthropometric measurements

The phrases need to be considered carefully, not to burden the participants if they have problems with their weight, e.g. the term obese may be considered insulting. For some people, e.g. active sportsmen, the BMI can be raised without any indication of obesity. For height and weight measurements, the following phrases can be used:

- "Body mass index (BMI) can be used to check if you have health risks. BMI is calculated by dividing the weight (in kilos) by the squared height (in metres). The BMI is a measure of whether your weight is within recommended values related to your height. The recommended BMI should be below 25. Your BMI was ___ kg/m2. This means that your values can be classified as ..."
  - if BMI is 18.5-24.9: "... normal weight";
  - if BMI is 25-27: "... overweight. Have you considered or tried to lose some weight? You could consult your healthcare provider to receive advice and support. Weight loss can help to prevent many diseases like diabetes or help to keep your diabetes under control";
  - if BMI is 28 or over: "... obese. Have you considered or tried to lose some weight? You could consult your healthcare provider to receive advice and support. Weight loss can help to prevent many diseases like diabetes or help to keep your diabetes under control ".

For waist circumference measurement, the following phrases can be used:

- "The waist circumference tells us about abdominal fat. Your waist circumference was ___ cm. This is ..."
  - if women have waist circumference below 90 cm or men have waist circumference below 100 cm: "... considered normal.";

- if women have waist circumference above 90 cm or men have waist circumference above 100 cm: "... considered to be above recommended. This is known to be related to the increased risk several chronic diseases, like diabetes."

8.2.3 Hand grip test

For hand grip test, the following phrases can be used:

- "Hand grip strength tests the muscular strength of the hand. This usually reflects also the general muscular strength. The results are related to your sex and age. Your results was ….. kg. This means that your hand grip strength is …"
  - results are based on device and population specific reference values and can be classified to following categories:
    - "Clearly worse than average among men/women of your age"
    - "Slightly worse than average among men/women of your age"
    - "On average among men/women of your age"
    - "Slightly better than average among men/women of your age"
    - Clearly better than average among men/women of your age".

8.2.4 Chair stand test

For chair stand test, the following phrases can be used:

- "Chair stand is a functional test which uses the strength of lower extremities and body muscles. We measured the time you used to stand up 10 times from the chair. The results are related to your sex and age. Your results was …. seconds. This means that your functional capacity is…"
  - results are based on population specific reference values and can be classified to following categories:
    - "Clearly worse than average among men/women of your age"
    - "Slightly worse than average among men/women of your age"
    - "On average among men/women of your age"
    - "Slightly better than average among men/women of your age"
    - Clearly better than average among men/women of your age".

8.2.5 Cholesterol

For total cholesterol, the following phrases can be used:

- "Total cholesterol is a known risk factor for cardiovascular diseases. Total cholesterol should be below 5.0 mmol/l. Your total cholesterol was ___ mmol/l. This means that your total cholesterol is ..."
  - if total cholesterol is below 5.0 mmol/l: "... normal.";
  - if total cholesterol is 5.0-6.5 mmol/l: "... elevated and it is recommended you consider adapting your diet so that you decrease the use of butter, pastries, fatty meat and meat products, etc. If you are overweight, loosing some weight could help to lower your total cholesterol level";
  - if total cholesterol is 6.5 - 8.0 mmol/l: "... elevated and should be controlled by your doctor within three months. If you have other diseases like elevated blood pressure, diabetes, overweight or you smoke, it is recommended to consult your doctor to check if you need additional measurements";
  - if total cholesterol is over 8.0 mmol/l: "... raised and if you are not under treatment for elevated cholesterol, you should contact your doctor without delay so that the result is confirmed and your doctor can assess the need for further treatment.".
- "HDL-cholesterol is so-called 'good cholesterol'. The HDL-cholesterol should be over 1.0 mmol/l. Your HDL-cholesterol was ___ mmol/l. This means that your HDL-cholesterol is ..."
  - if HDL-cholesterol is below 1.0 mmol/l: "... low. You can try to increase your HDL-cholesterol by increasing physical activity and if you are overweight, by losing some weight. Also stopping smoking can increase HDL-cholesterol";
  - if HDL-cholesterol is over 1.0 mmol/l: "... in a good range.".

8.2.6 Glucose

For fasting glucose, the following phrases can be used:

- Fasting glucose is raised in diabetes or if the sample is taken within 1-3 hours of latest meal. If the sample was taken after fasting at least 4 hours, and
  - if fasting glucose is below 6.0 mmol/l: "... normal.";
  - if fasting glucose is more than 6.0 mmol/l but less than 7.8 mmol/l: "... impaired and should be controlled by your doctor, especially if you haven't been diagnosed by

a medical doctor to have diabetes and if you are not under control."

- if fasting glucose is 7.8 mmol/l or higher: "... elevated and should be controlled by your doctor soon, especially if you haven't been diagnosed by a medical doctor to have diabetes and if you are not under control."

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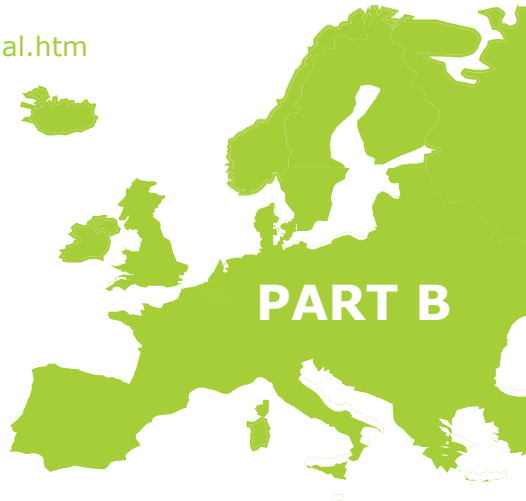

9. Data management

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As described in Part B, Chapter 1, the fieldwork organization usually consists of a Central Office and one or several fieldwork teams. Regarding data management the aspects that need to be defined in the national HES manual are:

- Dividing the tasks between the Central Office and the fieldwork teams;
- Preparations at the fieldwork sites;
- Scheduling of appointments for participants and follow-up of the recruitment process (see Part A, Section 12.3.1.3 and Part B, Section 1.4);
- Collecting the survey data (see Part A, Section 12.3.2) on
  - questionnaires and interviews,
  - physical measurements,
  - laboratory tests and samples;
- Error checking, correction and documentation of the data (see Part A, Section 12.4);
- Transfer and storage of the data (see Part A, Section 12.5).

9.1 Central office

The Central Office should take care of the overall data management preparation as well as coordination during the fieldwork, such as:

- Recruiting necessary staff for data management;
- Choosing, developing and testing software. Arranging computer equipment and network(s) for the fieldwork teams (if computerized data collection is used);
- Arranging the responsibilities, training and support of the fieldwork teams;

- Coordinating the fieldwork data management;
- Processing the survey data received from the fieldwork teams.

9.1.1 Arranging computer equipment and network(s)

In arranging computer equipment and network at least the following things need to be considered:

- Planning the structure of the compurer network and equipment needed;
- Establishing and customizing the network connections;
- Installing the software needed for the survey;
- Planning of software updates during the fieldwork (if needed);
- Establishing communication practices between each fieldwork team and the Central office, including
  - email practices (email accounts needed, policies for reliability and encryption of confidential email),
  - possible remote/VPN connections and
  - mobile connections;

Testing the software and equipment as well as data transfer and storage systems should be done extensively prior to the training of the fieldwork personnel. Time is also needed for analysing the test experiences.

9.1.2 Training, responsibilities and support of the fieldwork teams

From the data management's point of view the training, sharing responsibilities and support of the fieldworkers should include the following issues:

- Providing fieldworkers with necessary skills to use his/hers data recording equipment and software. A special attention should to be paid to the correctness of information and data confidentiality and security;
- Issuing responsibilities to team members. If local (temporary) computer networks will be established for the teams, each fieldwork team should have a named person responsible for data management issues, and his/hers deputy. They can be in charge of putting up/removing the equipment and network connections needed on the field and assist and give advice in basic data management issues;
- Providing an instruction manual regarding the survey software and computer equipment needed in the fieldwork;

- All fieldwork teams need support and supervision from the Central Office. There should be a helpdesk available to serve the teams during the fieldwork.

9.1.3 Coordinating the fieldwork data management

During the fieldwork phase database(s) maintained in the Central Office can be used to monitor and control the fieldwork logistics in the areas of:

- Scheduling of appointments;
- Creating invitations, lists of appointment schedules, calendars, etc. for each fieldwork group;
- Storing fieldwork inventory data regarding contacting invitees, participation, self-administered or interview questionnaires (e.g. the numbers of mailed, returened and completed survey forms), health examination data (e.g. number of examinations) and laboratory samples;
- Generating feedback letters for the participants and forms to be mailed to the invitees and/or filled in during the examination.

9.2 Fieldwork team

The structure and division of tasks in the fieldwork teams are discussed in Part B, Section 1.1.2. The additional things that need to be considered from the data management's point of view are:

- The skills needed when setting up the equipment and network connections if these are needed at the fieldwork site and removing these after the fieldwork phase;
- Basic technical knowledge in using the equipment and software that are used in data collection;
- The responsibilities and practices in backing up and transferring the data to the Central Office can be given to named person(s) or to all members of the team.

Regarding technical details the issues that need to be considered and specified in the national manual are questions *"who does"*, *"when"*, and *"how"*.

9.3 Data management in the field

9.3.1 Recording of the data

The primary sources of the data are questionnaires and interviews, physical measurements, and laboratory tests and samples. There are

different approaches for recording the survey data on the field, depending on the data system which is established for the fieldwork (see Part A, Section 12.3.2):

- The data are recorded on paper forms;
- The data are recorded on computers, from which data files are regularly copied to a server located in the local (fieldwork team's) network or to the Central Office;
- The data are recorded directly to the local (fieldwork team's) network's data storage;
- The data are recorded directly to the central database in the Central Office.

The software which is used to record the survey data should be able to function even if the local network is out of action. If no network connection is available, the survey data exists only in (portable) workstation computers, in which case a frequent routine backup procedure to an extarnal device is necessary. Alternatively, paper forms can be used. (Figure 9.1)

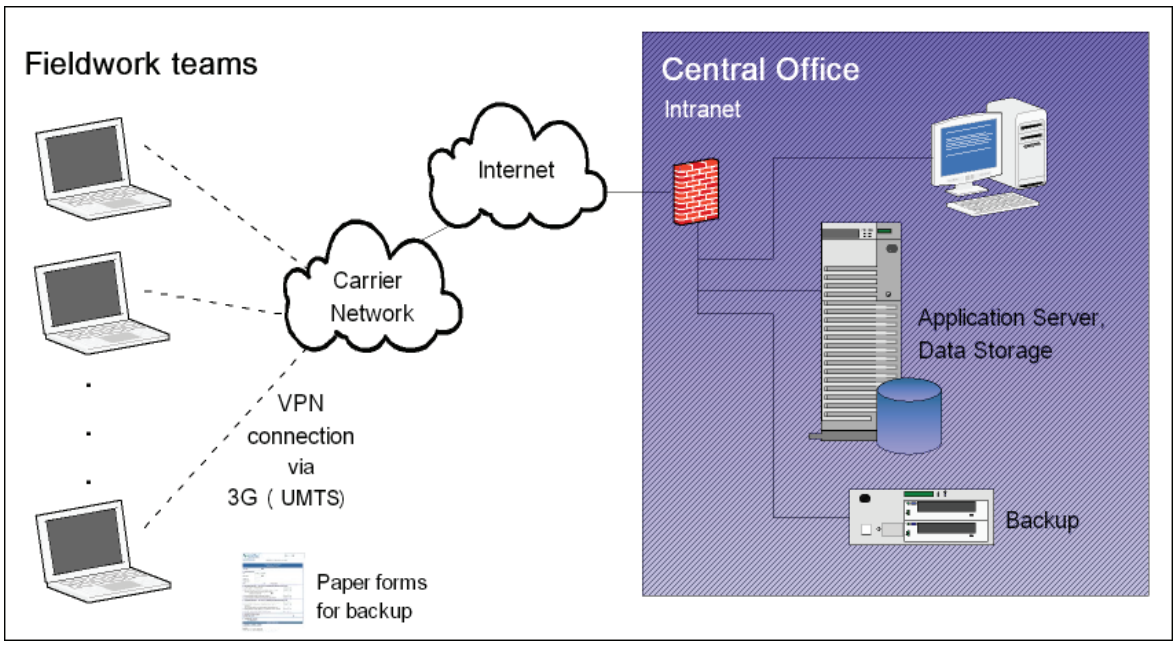


Figure 9.1 Example of a HES data management

If the data are recorded on paper forms these may need to be transformed to electronic format before further processing. If this is done by the fieldwork team by typing the data manually to computer the process will be thenceforth in accordance with the last three cases. If this procedure is done in the Central office (or by an outsourced company), also optical character recognition could be used.

9.3.2 Identification - the follow-up of participants through the survey

To prevent loss or mix-up of the data records, it will be important that each subject is identified correctly at all stages. The purpose of the follow-up of participants is

- to make sure that correct data corresponds to each participant, and
- to monitor in which phase of the survey each participant is.

The primary means both for identifying the survey participants and for monitoring the progress of the survey are:

- Unique subject ID code;
- The subject records in EHES are identified by using four-level codes specified in Part A, Chapter 12.2. The Serial number is assigned by the national survey organizer and is given to all who are selected to the sample. This can be used to identify the subject throughout the survey.
- Barcode;
  - Barcodes with a reference to the subject identification code can be used to facilitate the identification of the participants throughout physical examinations. (When printed on survey forms these can be checked in the beginning of each examination.)
  - Laboratory samples (i.e. blood and storage tubes and storage boxes) should be labelled with bar codes with a reference to the subject identification code.
- Data logs of examinations with a reference to the subject identification code;
- The integrity of the data can be ensured by using control files (including e.g. serial number, birthdate or age, date of examination, etc.) and by comparing information from different data sources.

Logistic database(s) maintained in the Central office can be used to gather data from the field and to monitor and co-ordinate the progress of examinations on the field.

9.3.3 Data error checking

In order to reach the aims of data management during the fieldwork, i.e.

- complete data records;
- no errors;
- no lost or mixed-up records;

routine data checking procedures should exist for the examination forms and the data. These routine procedures include:

- visual checking of key items at the examination site;
- automatic software checks in computer-assisted data collection at the examination site;
- extensive checking for all computerized data in the Central Office.

Optimally the detection of errors should be done when the subject is still at the interview or examination site.

A formal check should be done to verify that there are only allowed data values (e.g. withing specified ranges), and that the structure of the data is logical. The checking criteria should pick out two kinds of situations:

- Data values that are illegal. These may be undefined values of single data items or contradictions between the values of several data items. Such situations always require a correction.
- Unusual data values. These are data values which are possible but uncommon, and should be checked for correctness.

For computerized data, data checks and transformations can be run automatically. Here an online data connection from the fieldwork site to the Central Office may prove itself useful. An extensive data check with proper feedback could be run immediately on the grounds of data checking routines of the central database.

9.3.4 Correcting and documenting the data

To ensure a uniform approach to all changes, changing the data should be done according to pre-defined documented *rules for data verification and correction*. These rules need to be specified in the national manual.

The documentation ensures t*ransparency, consistency, repeatability* and *correctability* of data corrections. Using specific codes for the missing data makes it easier to separate accidental incomplete values within the data (blanks) from reported missing data.

The persons making changes and corrections to the data should receive proper training for the task.

All changes to the original data should be logged. Whenever the original survey data is changed or corrected, the old data should be backed up and there will be a new version of the data. Accordingly, the following information need to be documented:

- The version of the data

- What was changed
- Reason for the change
- Time of the change

By these means no data will be lost and the history of the data can be traced. In this process the original raw data should be backed up and kept separate, unchanged.

9.3.5 Data confidentiality and security

9.3.5.1 Paper forms

To ensure confidentiality and security of the data the responsibilities in collecting and storing the data need to be clarified. This means that person(s) appointed to the task should ensure that all survey documents - i.e. questionnaires, consents, measurement sheets, etc. will be collected and stored safely. Sealed containers can be used here, also during data shipments.

The paper forms should not be left for unauthorized persons to see or get lost. The confidentiality of the data can be further enforced by anonymity; It is recommended not to include any personal identification in the documents and in the sample when this can be avoided, and to use subject ID code or barcode (see Section 9.3.2) instead.

9.3.5.2 Data in electronic format

When not used, the computers and servers should to be locked so that only authorized persons can access them. This involves using encrypted hard disks, especially in all portable computers to ensure that the survey data is secure even if a computer is missing or stolen. It is also necessary to have a safe place where survey laptops are kept between the working period.

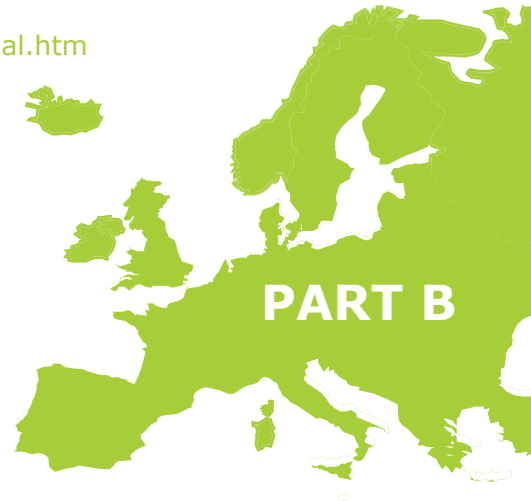
No survey data should be kept or archived in personal user directories or preserved long periods at local computer's hard drive. It is equally important that the personal identification data of survey subjects is encrypted and available only for those who have authorized access to such data. Encrypted transfer for computerized data is equivalent to the sealed containers for the paper forms.

9.3.6 Backing up the data

The data need to be backed up regularly on an external storage device in order to minimize losses of data in case of equipment malfunction, software errors or theft. This can be external hard drive, another computer, optical disk, etc. Also direct transfer of encrypted data to the Central Office is one way to organize the backup of the data.

The backups should be stored separately from the original data source (such as laptops). Full backup on external device should be taken at the end of each working phase.

After completion of the fieldwork phase all workstations need to undergo a routine inspection, in which the survey data is backed up and the data directories are emptied.



10. Quality control

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Quality assurance refers to the measures taken to ensure good quality of the survey. Quality assurance in general is considered in Part A, Chapter 11.

Quality control is a part of quality assurance. It includes monitoring of the correctness and completeness of the measurements and the data, and the actions taken to correct the observed shortcomings. The objective is to detect all quality problems as early as possible, and to fix them before they will bias the results of the survey. Quality control is particularly relevant for the fieldwork phase of the survey.

Here we focus specifically on the quality control and other quality assurance during the fieldwork. Proper training and setting up the examination site are prerequisites for good quality of the fieldwork. These need to be complemented by quality control, which should address the entire process of data collection including self-administered the questionnaires, interviews, physical measurements and biological samples, as well as transfer of materials from one location to the other. In addition to the actual data collection, quality control during the fieldwork should also address issues related to contacting selected persons and participation rates. Regular checking of participation rates in different survey sites and by all fieldwork staff members who contact selected persons may reveal differences in practices. These should be evaluated to assure that best practices are used by all staff members and at each survey site. In addition to participation rates, it's useful to monitor different reasons for non-participation: non-contact, refusals and reasons for refusals, if feasible.

10.1 Calibration of measurement devices and data checking

For each measurement, the calibration of the measurement devices needs to be checked routinely. Depending on the device, this should

be done before each measurement, daily, or weekly. For the EHES core measurements, these measurement-specific quality control procedures are described in Part B of the EHES Manual:

- blood pressure: Part B, Section 5.1.1
- height measurement: Part B, Section 5.1.2
- weight measurement: Part B, Section 5.1.3
- waist circumference measurement: Part B, Section 5.1.4
- collection and handling of blood samples: Part B, Section 6.1.1

Collected data can reveal many quality problems. Therefore, the questionnaire data and the measurement data should be reviewed regularly for

- item non-response,
- frequencies or means and standard deviation of the variables,
- outliers, and
- any technical notes, and other comments attached to the data.

For many measurements, consistency checking and other specific data checking can also be performed. For example, it should be checked that persons who report not having diabetes (Q4 in EHES core questionnaire) have not reported use of medicines for diabetes (Q6). Another example of a specific check concerns the last digit preference of blood pressure measurements.

For each EHES core measurement, the issues which should be checked regularly from the data are described under each measurement protocol in Part B of the EHES Manual.

The detected errors should be corrected whenever the correct data values can be recovered. When this is not possible, the uncertain data should be coded as *"missing data"* They should not be replaced by a guess or 'likely' but uncertain information. If computer-assisted data collection is used, consistency checking can be built into the programs, allowing immediate checking of correct answers and values during the data collection. Also outliers can be detected and prevented by pre-set maximum and minimum values in computer-assisted data collection.

10.2 Data and material transfer

When data and materials, such as paper questionnaires or blood samples, are transferred from one place to another, such as from the examination site to the national data centre or laboratory, it should be ensured that everything that was collected on the field is received at the other end. Log books can be used to record relevant details of the

shipments, and to provide a prompt inventory and acknowledgement by those at the receiving end (see Part B, Section 5.3.3.7).

10.3 Audit visits

The measurement procedures in the field should be monitored routinely by the fieldwork team coordinators. In addition, *audit visits* to the fieldwork site by a person outside the fieldwork team who knows the standard procedures are recommended. Internal (by a member of the national survey organizatin) and/or external (outside the survey organization) audit visits can be organized.

Issues to be checked during the audit visit depend on the examination setting (clinic or home measurement), organization of the fieldwork, and the measurements included. In general, the following issues should be checked during the audit visit:

- How the examination rooms are set up? In case of home visits, how the staff member selects the place in the house/ apartment where the measurements are conducted.
- How the equipment is set up for the measurements?
- The tidiness of the examination site (not relevant for home visits).
- Privacy during the measurements.
- Daily checking and calibration of the equipment.
- Are the equipment calibrated correctly?
- How staff members interact and collaborate with each other?
- How staff members interact with participants?
- How informed consents are obtained?
- Are standardized interviewing techniques followed (if interviews are part of the examination)?
- Are standardized measurement protocols followed when conducting the measurements?
- What happens between the measurements, especially if the participant has to change examination room between measurements (e.g. instructions to participants, waiting times)?
- How the information obtained is stored in the field (e.g. is data protection assured)?
- How materials are prepared for transfer?
- How the materials are transferred?

It is important that the findings of the audit visit are processed with the team. Positive feedback is important: do not address only those issues where something needs to be improved or corrected.

10.4 Re-training and duplicate measurements

If the fieldwork lasts several months or years, the fieldwork staff gets used to doing the measurements routinely. This is good, but to avoid possible wrong routines, which may unintentionally develop over time, re-training of the measurers and re-fresher sessions are needed. During these re-training and/or re-fresher sessions, the standardized measurement protocols are reviewed and measurements should be done on real subjects under supervision. There should also be the opportunity to discuss problems encountered during the field work.

Duplicate measurements by so called *"gold standard"* measurers or devices can be carried out as an additional quality control procedure, when feasible.

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