CARDIOVASCULAR EPIDEMIOLOGY OBSERVATORY
2008-2012
HEALTH EXAMINATION SURVEY
ITALY

MANUAL OF OPERATIONS
(Version 10 – December 2011)

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1. AIMS AND PURPOSE OF THE SURVEY

Background
Cardiovascular diseases (CVD) are the leading causes of death and hospitalization in both genders in nearly all countries of Europe. The magnitude of the problem contrasts with the paucity, weak quality and comparability of data available on incidence and prevalence of CVD.

In Italy, the last 30 years witnessed the implementation of longitudinal studies providing baseline data on numerous risk factors collected from random samples of general population followed up for all-cause mortality, fatal and non fatal cardiovascular diseases, cancer and other chronic diseases. Among these, the CUORE Project was launched in 1998 by the Italian Ministry of Health and coordinated by the National Institute of Health (ISS), Unit of Epidemiology of Cardiovascular Diseases (Head of Unit S. Giampaoli) of the National Centre of Epidemiology Surveillance and Health Promotion (CNESPS) with the following aims:

1. implement a surveillance system of coronary and cerebrovascular events (National Population-based Register of coronary and cerebrovascular events);
2. describe the risk factors in the Italian population (Cardiovascular Epidemiology Observatory/Health Examination Survey - OEC/HES);
3. evaluate cardiovascular risk of the Italian adult population.

In 2005, the project included other objectives:
4. train general practitioners on the use and application of risk assessment tools (risk chart and risk score) to transfer research findings into clinical practice;
5. explain the decline in coronary heart disease mortality;
6. update risk charts.

Detailed information of this project are reported in www.cuore.iss.it.

The OEC/HES, the research lines n.2 of the Italian CUORE Project, resulting from a collaboration between the ISS and the National Association of Hospital Cardiologists (ANMCO), represents the major source of information for CVD risk factors at national level, prevalence of high risk conditions and of CVD and other chronic degenerative diseases thanks to the exam of the adult general population and the adoption of standardized methodologies and procedures in data collection and measurements. The first OEC/HES was conducted
between 1998 and 2002 and examined 4908 men and 4804 women, ages 35-74 years, in 52 centres homogeneously distributed throughout the Italian territory. In 2008, a new survey was launched and is still ongoing.

The aims of the OEC/HES are to describe some individual characteristics recognized as risk factors, lifestyle habits (nutrition, physical activity, smoking habit), the prevalence of risk conditions (hypertension, dyslipidemia, obesity, diabetes) as well as to identify pathology areas and other conditions requiring action in terms of prevention, diagnosis, therapy and assistance and to monitor temporal trends of risk factors and CVD prevalence in random samples representative of general population ages 35-79 years.

The added value of the Progetto CUORE is the horizontal approach of the standardized data collection, enabling the collection of information on health and its determinants: health status, health determinants, personal characteristics, uptake of services, etc. The simultaneous collection of data through different sources of information (population based registries, longitudinal observational studies, risk assessment by the general practitioners, cross-sectional survey) produces a global picture of the health of the population, identifying priority areas for treatment and prevention. In addition, the periodic collection of data within the OEC/HES (1st survey: 1998-2002; 2nd survey: 2008-2012) permits to monitor changes in health and effects of health policies and interventions.

To assure data completeness and reliability, the results are supplemented by information collected periodically by the Italian Institute of Statistics through health interview surveys (HIS), and compared with more objective data coming from cancer registers or routine statistics in order to develop an increased investment in health promotion, prevention, rationalization on health care and expenditure, thus providing a powerful framework for a rational policy decision-making process.

In the National Prevention Plan for 2005-2008 launched by the Ministry of Health, cardiovascular prevention ranked first among the four main objectives of the Plan and included: 1. the assessment of cardiovascular risk in the general adult population using the risk charts of the CUORE Project; 2. the management of diabetes; 3. the prevention of complications of stroke and coronary events; 4. the prevention of obesity. Within this framework, an agreement between the Ministry of Health and the Regions was signed on March 2005 and financial support was allocated to implement risk assessment in clinical practice and to support a national training programme for general practitioners (GP) on the
use and application of cardiovascular risk charts and score. GPs were encouraged to collect
data on risk factors and 10-year-cardiovascular risk score to contribute to the Cardiovascular
Risk Observatory (CRO). The aim of the CRO was to demonstrate feasibility and
effectiveness of the application of the risk score and charts in clinical practice and to evaluate
the 10-year risk assessment as first step to implement preventive lifestyle actions at individual
level. The OEC/HES represents the most effective monitoring system to evaluate the results
of the National Prevention Plan.

An important goal in the recent history of the Italian public health was achieved with the
“Guadagnare salute: rendere facili le scelte salutari” (“Gaining health: make healthy choices
easy choices” http://www.ccm-network.it/en_Gaining_Health) action plan of the Ministry of
Health in agreement with the Independent Regional and Provincial Governments. “Gaining
health: make healthy choices easy choices” is an integral part of the chronic disease
prevention and control strategies for the “Gaining health” promoted by the WHO in autumn
2006 and aims to change unhealthy behaviours in order to reduce incidence of chronic
diseases. The strategy of “Gaining health” is based on the four changeable risk factors and
major determining factors for the most frequent chronic diseases: smoking, unhealthy
nutrition, alcohol abuse and physical inactivity. The action plan “Gaining health” was
underwritten on May 2007 when the agreements were signed between the Minister of Health
and the representatives of trade union, business and association entities. One of the most
important protocols of agreement was signed in 2009 with Bread Makers’ Associations for
the gradual reduction of the salt content in bread. The salt intake of the general population is
assessed through 24-hour urine collection performed within the OEC/HES.

Another programme linked to the European programme “Gaining health” and the National
Plan for Prevention is the “Okkio alla Salute - Promotion of healthy lifestyle and growth in
primary school children-” survey (http://www.epicentro.iss.it/okkioallasalute/) launched in
October 2007 by the Ministry of Health and coordinated by the ISS, Unit of Woman child
and adolescent health (Head of Unit A. Spinelli) of the CNESPS. This project is aimed to
estimate the prevalence of overweight and obesity in children and to collect information on
diet and physical activity.

The OEC/HES, in cooperation with other surveillance systems periodically conducted, such
as the Health Interview Survey and the ‘PASSI’ (www.epicentro.iss.it/passi/) health interview
survey for self-perception of health status, the aforementioned ‘Okkio alla Salute’ survey, the
longitudinal studies of the CUORE Project and the Register of Coronary and Cerebrovascular Events for evaluating temporal trend in the occurrence of cardiovascular disease, provides a complete picture of trend, high risk conditions and risk factors in the Italian general population.

**Definition of the scope and objectives of the survey**

The objectives of the Cardiovascular Epidemiology Observatory/Health Examination Survey (OEC/HES) are to assess the prevalence of more frequent chronic diseases, risk conditions and to assess mean levels of risk factors, treatment indicators in a representative sample of the Italian adult population.

More specifically, in the general population ages 35-79 years, the OEC/HES project aims at:

1. describing the distribution of life-style habits (nutrition - consumption of several nutrients, in particular salt, alcohol, and saturated fats - physical activity and smoking habits);
2. describing the distribution of common risk factors (blood pressure, BMI, total and HDL-cholesterol, vital capacity, forced expiratory volume, waist and hip circumference)
3. assessing the prevalence of risk conditions (hypertension, dyslipidemia, overweight and obesity, diabetes, smoking habit);
4. assessing the prevalence of chronic diseases (ischemic heart disease, myocardial infarction, angina pectoris, left ventricular hypertrophy, atrial fibrillation, stroke, TIA, diabetes, chronic kidney disease, BPCO, cancer);
5. monitoring national healthy lifestyle campaigns, in particular evaluating if salt consumption among the general population decreases over time as a result of the programme ‘Gaining Health’;
6. identifying diseases, risk factors and other conditions in different socio-economic status and in different groups, such as women, older people, migrants, which require actions in terms of prevention, diagnosis, treatment and social assistance;
7. studying time trends of risk factors and chronic diseases;
8. contributing to the update of risk charts and individual risk score for the assessment of cardiovascular risk (coronary and cerebrovascular);
9. contributing to the European HES through collection and measurements of health determinants following standardized methodologies recommended by FEHES Project, giving the Italian contribution to the pilot phase of the EHES to build a surveillance system for monitoring health status at European level.

To achieve OEC/HES objectives, it is necessary to enrol and examine a sample of 9,020 individuals aged 35-79 years, randomly extracted from the general population (220 individuals aged 35-79 per 1.5 million residents). This numerosity is sufficient to evaluate disease time trends and identify possible changes in the distribution of risk factors, risk conditions and some chronic diseases.

The project was approved by the Ethic Committees of the ISS on 11 March 2008 and 11 November 2009 and is part of the ‘Gaining Health Program - make healthy choices easy choices –’ of the Ministry of Health.
2. ORGANIZATION AND MANAGEMENT OF THE ITALIAN HEALTH EXAMINATION SURVEY

The ongoing OEC/HES was recognized in 2009 as part of the Joint Action of the European Health Examination Surveys (EHES – Measuring the Health of Europeans http://www.ehes.info/) Projects funded by DG SANCO within the Health Monitoring Programme.

Therefore the manual of operations was developed according to recommendations provided by EHES Project and provides guidelines to implement a Health Examination Survey (HES) in Italy; it has been developed taking into account the Cardiovascular Epidemiology Observatory (OEC) conducted in Italy between 1998 and 2002, the recommendations from the European Health Risk Monitoring (EHRM www.ktl.fi/fehes/) and the Feasibility of a European Health Examination Survey (FEHES www.ktl.fi/fehes/) Projects (funded by DG SANCO within the Health Monitoring Programme), the indications provided during the workshop on Health Examination Survey held in Luxembourg on 9-11 April 2008, the suggestions collected during the training seminars organized in Rome (11-12 February 2010) and in Helsinki (20-22 September 2010) within the European Health Examination Survey (EHES) Project, the recommendations during the site visit of the coordinators of the EHES project (Brescia 25-26 May 2011) and the ongoing OEC/HES (2008-2012) conducted within the CUORE Project - Epidemiology and Prevention of cardio-cerebrovascular disease - in cooperation with the National Association of Hospital Cardiologists (ANMCO) and partially supported by the Centre for Disease Control of the Ministry of Health. Two specific studies are associated to the OEC/HES: the CARHES study (CArdiovascular risk in Renal patients of the Italian Health Examination Survey), supported by the Nephrology Association and the MINISAL-GIRCSI project (Gruppo di lavoro Intersocietario per la Riduzione del Consumo di Sale in Italia) for the reduction of salt consumption among the Italian population, supported by the Centre of Disease Control of the Ministry of Health.

This manual covers the entire survey process from planning, preparation of budget, sampling and recruitment of participants, ethical, legal and data confidentiality issues, fieldwork staff training, selection and execution of measurements, blood sample handling, transport and storage, laboratory analyses, quality control methods and data management.
Survey management

The objectives, the schedule, the allocation of resources and the scope and methodology of the survey are approved by a Steering Committee composed by several experts. At present there are two project managers: Simona Giampaoli, Head of the Unit of Epidemiology of cerebro and cardiovascular disease of the National Centre of Epidemiology, Surveillance and Health Promotion (CNESPS) of the Istituto Superiore di Sanità and Diego Vanuzzo, Head of the Cardiovascular Prevention Centre at the hospital of Udine and designated by the National Association of Hospital Cardiologists (ANMCO). They are responsible for the organization of the survey, by allocating responsibilities and resources, managing the survey process by making decisions, giving guidance, providing and acquiring assistance, motivating team members and solving possible conflicts, day-to-day monitoring and evaluating of the survey process, schedules and budget and making adjustments to these when needed, reporting to the Steering Committee.

Stefania Salmaso, Director of the CNESPS of the Istituto Superiore di Sanità, Roberto Raschetti, Head of the Unit of Farmacoepidemiology of the CNESPS, Marino Scherillo, President of the ANMCO, Attilio Maseri, President of the Association Per il tuo Cuore-Heart Care Foundation are the members of the Steering Committee, those who approve the survey objectives, provides directions and guidelines to meet the survey aims; they work in strict collaboration with the Prevention Area of the ANMCO.

A core group assists the project managers in different subareas of the survey: the field work coordinator (Cinzia Lo Noce) who prepares the field work logistics, training and day to day data collection activities; two data managers (Chiara Donfrancesco and Luigi Palmieri) who are responsible for the computer system, programs, data management, sampling and data analysis; the laboratory specialists (Licia Iacoviello and Amalia De Curtis) who are responsible of sample collection analysis and storage; the expert in ethics (Virgilia Toccalceli) and communication (Eva Benelli); the responsible for coding ECG Minnesota and disease-ICD (Francesco Dima). All the persons mentioned are part of the ISS staff, except Licia Iacoviello who is the director of the Laboratory of Genetic and Environmental Epidemiology of the Catholic University in Campobasso and Eva Benelli, of the ZADIG, Salute Scienza e Ambiente.

Local authorities of each centre involved in the survey (Director-General, Director of the Health Unit, Regional assessors, Mayor) receive the manual of operations and the protocol of
the study, the approval letter from the Ethics Committee of the ISS, the letter of presentation of the project, and the information notice of the project. The approval of the study by the local Ethic Committee is at discretion of the Region. The survey involves also the director of cardiology unit (as the OEC/HES survey is carried out in cooperation with ANMCO) or the director of prevention unit or the director of general medicine unit and a local scientific responsible. They actively cooperate with ISS staff in order to facilitate the screening procedures.

The OEC/HES survey includes blood pressure and pulse rate measurements, blood collection for determinations of total and HDL-cholesterol, triglycerides, fasting blood glucose and hemochrome, anthropometric measurements (height, weight, waist and hip circumference), examinations (ECG, spirometry, CO measurement, bone densitometry), questionnaire on health status, physical activity, smoking habits, personal and family history for cardiovascular diseases; a self-reported food frequency questionnaire (EPIC questionnaire), ADL-IADL self-reported questionnaire are filled by the participants during the survey; the survey includes also 24-hour urine collection; for those 65 and older the Mini-Mental State examination is administered. Biological samples of serum, plasma, buffy coat, red cells packed and urine are stored and preserved at the CNESPS biobank.

Following the FEHES Project recommendations, a pilot test of the entire set of procedures and methods was performed before starting the screening procedures in order to rehearse the main investigation, test computer programs, measurements, timing and eventually identify problems with methods, equipment, space and personnel.

The pilot phase of the OEC/HES 2008-2012 was conducted in the centres of Udine (Friuli Venezia Giulia Region, responsible: Dr Vanuzzo) and Campobasso (Molise Region, responsible: Dr Iacoviello) in 2008.

In Udine, 459 individuals aged 35-79 years were invited by telephone (not by letter) and 222 participated in the screening (participation rate 48%). The pilot phase of Campobasso was carried out within the MOLISANI Project, which resulted quite complicated. On the contrary, the possibility for the Laboratory of Genetic and Ambiental Epidemiology of the Catholic University of Campobasso to become the central laboratory for the OEC/HES emerged immediately. During the pilot phase in Campobasso, 621 individuals aged 35-79 years were invited by letter and 253 participated in the screening (participation rate 40%).
To calculate the participation rate of the pilot study, the following categories were excluded from the original sample as not able to attend the screening: untraceable persons (never answer the phone or wrong or non-existent number) in Udine and persons not receiving the invitation letter (undelivered letter) in Campobasso; moreover, dead persons, persons moved out of the residence area and persons working outside the residence area (domicile outside the residence area). Bedridden and hospitalized persons, disabled persons (using wheelchair and unable to reach the survey site) and seriously ill persons (tumor in final stage with ongoing chemotherapy; psychosis; mental illness; dementia, but not cognitive disturbances) were also excluded as recommended by the regulations of the Ethic Committee of the ISS. After the pilot study, to follow EHES suggestions, people affected by serious senile dementia or mental disorders are contacted (as we cannot know in advance that they are affected by serious senile dementia or mental disorders); if they can be accompanied to the examination centre by a family member or an authorized proxy who can sign the informed consent form, they undergo examinations and are counted as ‘respondents’. All other categories of seriously ill or disabled persons not participating in the screening are counted as ‘non-respondents’.

Time schedule
The planning and preparation of the survey required one year before the fieldwork starting. The pilot study was conducted between March and June 2008 in two regions: Friuli-Venezia Giulia and Molise. The following table shows the OEC/HES time schedule. Up to now, the fieldwork has been planned or completed in 16 Regions. The remaining regions (Tuscany, Trentino Alto Adige, Aosta Valley, Abruzzo) are planned to be covered before May 2012.
In June 2011 the data analysis for basic reports has been completed for the following regions: Friuli Venezia Giulia, Molise, Sicilia, Emilia Romagna, Lazio, Basilicata, Calabria, Sardegna, Campania, Piemonte, Veneto, Marche, Umbria, Lombardia.
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3. TIMING OF THE SURVEY

Periodicity
The recommendation is to repeat the OEC/HES with the EHES core measurements about every five years, while some additional measurements may be repeated less frequently (e.g. every 10 years). More frequent surveys do usually not reveal interpretable changes for most of the measurements. They can be considered on ad hoc basis if there is a need to closely follow trends related to potential effects of specific health promotion activities.

The Italian OEC/HES represents a system of periodically data collection: the survey lasts three-four years and between one survey and the following there is a five-six years break (1st OEC: 1998-2002; 2nd OEC/HES: 2008-ongoing). Data are used to monitor time trends of different indicators (risk factors, lifestyle) and prevalence of risk conditions and chronic diseases. This system has allowed to build a permanent survey team in the ISS at the Unit of Epidemiology of cerebro and cardiovascular diseases of the CNESPS with great expertise on organizing surveys, training local fieldwork staff and conducting surveys.

Length and timing of fieldwork period
There is no general rule for the optimal duration for the data collection. In our experience a four year exam is the minimum time to examine 10,000 adult people involving local personnel and using two sets of standard instruments with one team travelling across the country for training and assessing the quality control.

The 1998-2002 OEC survey was conducted in 52 centres, one every 1.5 million people, each enrolling and examining 200 persons ages 35-74 years; therefore many regions had more than one centre to involve; a complete set of instruments was bought in each centre (blood pressure device, balance, tape for height, refloton for glucose and cholesterol tests). Local staff was involved and a course for the training of the nurses and the doctors was done in Florence. Before starting the fieldwork each centre received the visit of the central coordinator to organize the work, repeat the training and assess the quality control, organize the shipment of the biological sample to the central laboratory and the data transfer to the ISS. The mean time for the fieldwork was about one month in each centre.

In 2008 planning the next survey it was decided to enrol one centre in each region to improve of the organization, the quality control, to have a better control of the shipment of the
biological samples and not least to reduce the cost of the Health Examination Survey. The survey was planned to assess the health status of the population and more exams were included, therefore two complete sets of instruments were bought (spirometer, EKC, bone densitometry, mercury sphygmomanometers, statimeter, balance beam scale, CO measurement). In this round the duration of the screening in each centre depends on the number of persons to be examined in the region, in fact the sample is proportioned to the numerosness of the population in that region; moreover the sample is greater, including 220 persons ages 35-79.

Ideally 20 persons a day are examined. With a sample of 220 persons, usually the screening lasts 12-15 working days, 6 per week (including Saturday for those persons who cannot participate during the working week), while a sample of 660 persons requires at least three months to be examined.

If the survey lasts more than a month, particular attention needs to be paid to regular quality control, re-testing and re-training of the fieldwork staff. It is also recommended to distribute the days of examination of all population subgroups (defined by age and sex) evenly over the whole survey period. A short survey duration usually needs a relatively large temporary staff, with more problems related to training standardization and quality control.

The following table shows the sample size examined in each region and the length of survey period in each region for the OEC/HES planned until 2012. Some of them have completed the fieldwork and the number of persons examined are reported.

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<td>235</td>
<td>April-June 2010</td>
</tr>
<tr>
<td>Umbria</td>
<td>226</td>
<td>June-September 2010</td>
</tr>
<tr>
<td>Veneto-Motta di Livenza</td>
<td>671</td>
<td>October-December 2010</td>
</tr>
<tr>
<td>Veneto-Noale</td>
<td>200</td>
<td>October-December 2010</td>
</tr>
<tr>
<td>Trentino Alto Adige</td>
<td></td>
<td>January 2011</td>
</tr>
<tr>
<td>Lombardia- Brescia</td>
<td>651</td>
<td>May-December 2011</td>
</tr>
<tr>
<td>Region</td>
<td>Number</td>
<td>Time period</td>
</tr>
<tr>
<td>-------------------------</td>
<td>---------</td>
<td>-----------------------</td>
</tr>
<tr>
<td>Lombardia- Montescano</td>
<td></td>
<td>January 2012</td>
</tr>
<tr>
<td>Toscana</td>
<td></td>
<td>March 2012</td>
</tr>
<tr>
<td>Valle d’Aosta</td>
<td></td>
<td>April 2012</td>
</tr>
<tr>
<td>Campania</td>
<td>880</td>
<td>April-October 2011</td>
</tr>
<tr>
<td>Puglia</td>
<td>ongoing</td>
<td>January-March 2012</td>
</tr>
<tr>
<td>Liguria</td>
<td>221</td>
<td>October 2011</td>
</tr>
<tr>
<td>Abruzzo</td>
<td></td>
<td>April 2012</td>
</tr>
</tbody>
</table>

The fieldwork has been finalized in the first 16 regions. The remaining regions (Trentino Alto Adige, Tuscany, Valle d’Aosta, Abruzzo) are planned to be covered by May 2012.

The sample size numerousness varies among regions on the basis of population density, as described in Chapters 4 Sample size and target population.

**Time of the year**

High seasonal variation has been identified in several health determinants as well as in biological measures. Therefore, it is important for the estimation of trends that repeated surveys are carried out at the same time of the year. For best international comparability, the surveys should cover evenly all seasons, which means that the fieldwork should last at least one year.

In the OEC/HES, the fieldwork is usually spread into several months in order to minimize the effect of seasonal variation to measurement results. Usually, fieldwork activities stop in December, during Christmas holiday, in March or April, during Easter and August (all month). When analyzing results of examinations, impact of seasonality on physical activity patterns, food consumption and quality of life is taken into account.

**Weekdays and time of day**

In the OEC/HES it was important to consider some Saturdays and Sundays during the survey period as regular working days to facilitate people who work and raise willingness to participate. This was feasible from the point of view of cost and availability of the local staff involved in the screening.

Although both morning and evening appointments are scheduled to allow easy participation for working people, participants are usually recommended to show up at the screening centre between 8.00 and 9.00 am as blood tests requires a fasting period of at least 12 hours (specified in the invitation letter). The length of time from the last meal (in hours) should be
reported on the questionnaire. After blood pressure measurements, pulse rate for a minute and blood withdrawal, participants undergo examinations starting from 10.00 until 16.00. In our experience practical training is more efficient than a course out of the place of the screening, so we are used to train the personnel during the first days of the fieldwork; in the first days participation rate is around 50%, so it is important to invite 10 persons in order to examine at least 5; the second day 15 persons are invited, the third 20 and the forth 25. In small centres, participation rate tends to increase thanks to the widespread publicity from examinees. As screening proceeds, the staff reaches a good quality in measurements and a constructive group spirit and 30 persons are invited in order to examine at least 20 persons per day, which is the maximum number of persons to be examined in one working day following standardized procedures for all examinations. Out of 20 persons, 12-14 persons are usually examined in the morning, the others during the afternoon. The average duration of the complete set of examinations (except venipuncture) depends on the age of the participant and ranges from 45 to 75 minutes.

**Order of measurements**

The following requirements need to be taken into account to ensure valid measurements and comparability between surveys.

*Clinical measurements*

The order of measurements should be determined as much as possible by:

1. Importance of the measurement: measurements that require 12h fasting are organized only in the mornings and most important measurements are made early in the session, in case the participant is unable to follow the full examination protocol (time constraints, limitations in functional capacity etc.). The core measurements should be conducted first, before additional measurements.

2. Sensitivity of questions: uncontroversial questionnaires should occur early in the interview to allow participants to become relaxed and comfortable with the procedures.

3. Stressfulness of procedure: blood pressure measurement should precede venipuncture to avoid effect of mental and physical stress induced by blood collection and is measured in a quiet room with a comfortable temperature as too cold or too hot temperature affect blood pressure values. Blood pressure measurement should also precede other potentially (mentally or physically) stressful tests/interviews.
4. Other effects on measurement results: blood pressure and blood samples should be taken before physical fitness tests or tests of physical function.

For similarity of the order of the EHES core measurements the following order was recommended: first blood pressure, then anthropometric measurements, third blood samples, and all additional measurements after these.

In the OEC/HES 2008, to follow the order of the measurements of the previous survey (1998), it was suggested to maintain the former order of measurements: reception of participants, blood pressure and pulse rate measurements, blood collection. The subsequent phases (anthropometric measurements, ECG, spirometry, CO measurement, bone densitometry, questionnaires, food frequency questionnaire, ADL-IADL, Mini-Mental State Examination and 24-hour urine collection) are performed according to local organization.

**Questionnaires and interviews**

The decisions on when the questionnaires or interviews will be administered should be based on the following:

1. Before the examination (mailed with the invitation to examinations, administered at the examination site before the clinical measurements or interviews before the examination): when the self-administered questionnaires/interviews are completed before the examination, the responses are not affected by the examination. Self administered questionnaires should be checked during the examination. The questionnaires have to be short and easy to fill in, not to discourage participating in the examinations.

2. During the examination (between measurements): when self-administered questionnaires/interviews are completed during the examinations, the responses can be affected by the examination (e.g. learning that the participant has e.g. high blood pressure). It is recommended to ask questions on acute symptoms and current medication during the examination as these may affect the clinical measurements.

3. After the examination: when the self-administered questionnaires/interviews are completed after the examinations the non-participation can be higher. It is recommended to collect after the examination information on sensitive questions and questions that are less important from the point of view of the top key aims of the survey, but which potentially raise new issues for research and health policy/health care development. The use of sensitive questions after the
examinations should be explained to the participants during the examination to make sure that their final impression of the survey participation is positive.

In the OEC/HES, the self-administered food frequency questionnaire can be filled out before examinations or at home after the examination, and then returned together with urine container.

The ADL-IADL is self-administered and filled during the waiting time.

The face-to-face interview is completed during the examinations. The interviewer has the responsibility to put the participant at ease in order to gain the correct information and avoid that responses are affected by examinations results (e.g. the participant is aware to have high blood pressure, to be overweight etc…).
4. TARGET POPULATION AND SAMPLE SIZE

Target population and sample size
The EHES is a survey of adults defined as persons of age 18 years and more.
For the European Health Examination Survey the following definition for the target population is suggested:
- the set of all persons aged at least 25 years and at most 64 years and having permanent residence in the country;
- the eligible age group can be extended with a lower bound of 18 years and with no limitation for the upper bound.
The definition of the target population does not specify an exact time reference for population. A HES takes time to complete, in some countries several years. The survey will have to be carried out at different times at different places within a country. During that period new cohorts will enter the core age and become eligible while the oldest cohorts will pass the upper age limit and become ineligible. People will move within the country and there will be emigration and immigration. We just have to assume that the general health status that we want to assess does not change significantly within that period.
The sampling frame consists of two stages: 1st stage, the possible cities (primary sampling units) for carrying out the survey can be selected; 2nd stage, the persons eligible; the first stage could be taken once at the start of the survey, the second stage should be taken from the register of residents as close as possible to the time of the screening.
The EHES suggests a minimum of 4000 persons to be invited in each country, 25-64 years, with eight age gender domains (25-34, 35-44, 45-54, 55-64) with at least 500 representative in the sample. The sample size calculation is based on a participation rate of 70%. This minimum size relates to the requirements for statistical power when testing differences between countries for age-gender domains. For the pilot survey a sample size of at least 200 persons with at least 25 persons in each age-gender domain is recommended.
It is not recommended to leave out population groups difficult to contact or institutionalized persons (hospitals, nursing homes, elderly homes, children homes, military barracks, jails and monasteries) or migrants.
In the OEC/HES 1998-2002, 52 centres were selected to participate in the study; the main task of each centre was to randomly enrol and examine 200 individuals aged 35-74 years per 1.5 million residents, also in demographically smaller regions. 9712 persons were examined and their distribution of age and sex is reported in table 1. That numerousness was estimated sufficient to evaluate distribution of risk factors and prevalence of cardiovascular risk conditions for macro areas in Italy. Participation rate was not calculated in each of the 52 centres. In the total sample examined a mean participation rate of 50% was assessed.

<table>
<thead>
<tr>
<th>Age range</th>
<th>Men</th>
<th>Women</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>35-44</td>
<td>1147</td>
<td>1141</td>
<td>2288</td>
</tr>
<tr>
<td>45-54</td>
<td>1218</td>
<td>1232</td>
<td>2450</td>
</tr>
<tr>
<td>55-64</td>
<td>1276</td>
<td>1235</td>
<td>2511</td>
</tr>
<tr>
<td>65-74</td>
<td>1267</td>
<td>1196</td>
<td>2463</td>
</tr>
<tr>
<td>Total</td>
<td>4908</td>
<td>4804</td>
<td>9712</td>
</tr>
</tbody>
</table>

In the ongoing OEC/HES 2008-2012 survey, the target population includes adult men and women aged 35-79 years having permanent residence in the country (Table 2)

<table>
<thead>
<tr>
<th>Age range</th>
<th>Men</th>
<th>Women</th>
<th>Men</th>
<th>Women</th>
</tr>
</thead>
<tbody>
<tr>
<td>35-44</td>
<td>4.430.050</td>
<td>4.411.271</td>
<td>1.025</td>
<td>1.025</td>
</tr>
<tr>
<td>45-54</td>
<td>3.742.872</td>
<td>3.831.769</td>
<td>1.025</td>
<td>1.025</td>
</tr>
<tr>
<td>55-64</td>
<td>3.305.689</td>
<td>3.545.676</td>
<td>1.025</td>
<td>1.025</td>
</tr>
<tr>
<td>65-74</td>
<td>2.668.585</td>
<td>3.240.213</td>
<td>1.025</td>
<td>1.025</td>
</tr>
<tr>
<td>75-79</td>
<td>919.691</td>
<td>1.377.730</td>
<td>410</td>
<td>410</td>
</tr>
<tr>
<td>Italy all ages</td>
<td>27.841.050</td>
<td>29.577.830</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

To achieve the OEC/HES objectives, it is necessary to examine, before the end of 2012, a sample of 9,020 individuals, aged 35-79 years, 4,510 men and 4,510 women, randomly selected from the list of residents and distributed across the Regions. This numerousness
provides a complete and useful picture of the whole Italian territory and estimates for North, Centre, South and Islands of Italy and is sufficient to evaluate disease time trends and identify possible changes in the distribution of risk factors, risk conditions and chronic diseases.

One centre for each region is selected, for a total of twenty centres: this choice (different from the OEC/HES 1998-2002 survey, in which 52 centres were included in the survey) was done planning the survey to reduce the observer variation, to improve the quality control of collected variables, to reduce the cost of the survey and to facilitate the transfer of biological samples to the centralized laboratory for blood tests and to the ISS for storage of the blood and urine samples. Each centre is required to examine 220 individuals aged 35-79 years per 1.5 million residents, also in demographically smaller regions (e.g. in Lazio, the centre of Rome was selected, 660 persons were examined as the resident population in the Lazio region in the age range 35-79 years was approximately 4,500,000; in Umbria region, where the population is less than 1 million people, a sample of 220 individuals was examined).

The survey is conducted on adult men and women, 35 to 79 years old, stratified by age and sex (25 persons of each sex in each age decade between the ages of 35-74 years plus 10 persons of each sex in the last 5-year age group 75-79 years every 220 units).

The access to the register of residents permits to know name, surname, date of birth, sex and address of each selected person and then to send the invitation letter. Invited persons who show up at the examination centre are asked to sign the informed consent form to undergo examinations, to be followed - up over time and for biological samples storage (see chapter 6).

The EHES Project recommends to enrol a population sample in the age-range 25-64 years. Therefore, in the regions of Veneto and Piemonte, it has been decided to involve two additional centres to cover the missing age range 25-34 years. Two samples of 200 persons aged 25-64 have been examined in the municipalities of Noale and Torino following standardized procedures. Both the OEC interviewer-administered questionnaire and the EHES self-administered questionnaire, translated into Italian, have been used in Noale and Torino.

**General requirements for centres participating in OEC/HES 2008-2012**

To be eligible for participation in the OEC/HES 2008-2012, each centre should meet the following requirements:
- easy access to local registry office for sample selection;
- availability of local general practitioners to collaborate recommending their patients to participate at the screening;
- availability of local authorities to collaborate supporting the costs of local premises (not necessarily an hospital) and laboratory blood tests;
- availability of local survey personnel, possibly nurses and secretaries, to support fieldwork activities (prepare letters of invitation, arrange telephone calls to invite recruited persons, schedule appointments, welcome participants, perform laboratory measurements and interviews, enter data, communicate results to the examinees);
- availability of local medical personnel for reading exams, for laboratory tests and other responses to be communicated to the examinees;
- availability of well-equipped rooms, in particular: a big room where participants are welcomed and wait for interview/examinations; a relaxed room for questionnaires administration; a quiet room with comfortable temperature for performing blood pressure measurement; a room for performing ECG, anthropometric measurements, bone densitometry, spirometry and CO measurement; a room for blood collection and laboratory tests, with a centrifuge, a -30°C or -80°C freezer for blood samples storage and containers and collections for special waste.

Local authorities of each centre involved in the survey (Director-General, Director of the Health Unit, Regional assessors, Mayor) receive the manual of operations and the protocol of the study, the approval letter from the Ethic Committee of the ISS, the letter of presentation of the project, and the information note of the project explaining that the survey aims at giving a complete picture of the Italian population’s health status and facilitates the planning and evaluation of future preventive programmes. The submission of the study to the local Ethics committee, which has only the function to give an opinion, is at discretion of the Region. The survey involves also the director of cardiology unit (as the OEC/HES survey is carried out in cooperation with ANMCO) or the director of prevention unit or the director of general medicine unit and a local scientific responsible who actively cooperates with ISS staff and facilitate screening procedures.

It is recommended to send the information note and the letter of presentation of the project also to the local general practitioners (GPs) who can encourage patients enrolled to participate in the study. In small centres, it is also recommended to inform the parish priest, local
pharmacies, elderly clubs, as well as local press and TV, although a widespread survey publicity could increase the request for participation from persons not enrolled in the study. Once the approval is obtained, the local register office is contacted to obtain the list of residents of the centre in the age range 35-79 years, possibly in electronic format. The random selection of the sample can be done at local level or by the ISS after receiving the list of residents. The list of residents does not contain information on institutionalized people, prisoners or seriously ill persons, therefore only undeliverable letters (unknown address) and deaths occurred between the request of the list of residents and the invitation letter are excluded to calculate response rate.

Each centre is asked to nominate a local scientific responsible who would actively cooperate and facilitate screening procedures. All fieldwork activities must follow the indications reported in the manual of operations of the OEC/HES and any other extra screening examinations must be performed only after the established set of screening procedures.

Some centres were selected by the ISS as they have a surveillance system of coronary and cerebrovascular events (National Population-based Register of Cardiovascular Events) and the collection on a regular basis of risk factors in these areas is of great importance. The Register exists in the following regions, covering the whole region or only specific areas: Friuli Venezia Giulia, Veneto, Lombardia, Emilia Romagna, Sicilia, Campania and Toscana. Up to now, Friuli Venezia Giulia, Sicilia (Caltanissetta area), Emilia Romagna (Modena area) agreed to participate in the survey.
5. SAMPLING PROCEDURES

The sampling frame consists of two stages: 1\textsuperscript{st} stage, the possible cities (primary sampling units) for carrying out the survey can be selected; 2\textsuperscript{nd} stage, the persons eligible; the first stage could be taken once at the start of the survey, the second stage should be taken from the register of residents as close as possible to the time of the screening.

It was not possible to use a two-stage sample design recommended by the EHES as within each Region the centre is selected only if it meets the general requirements reported in the study protocol and manual of operations and necessary to implement screening procedures. The survey is sustainable if there is the support at local level: personnel, laboratory, screening centres, biological samples transfer to the central laboratory. (see chapter 4). Once the municipality has been selected, the sample is stratified by age and sex and is randomly selected from the list of residents so that every eligible person has the same probability of being sampled. Only in regions where the sample to examine is too large (e.g. Lombardy), the survey was conducted in two centres.

Upon suggestion of Johan Heldal, expert in statistical methods and standards and member of the EHES Reference Centre (RC), our country will provide the RC with the population resident, by age and sex, of all Italian municipalities (8,100) stratified by Region to evaluate the probability for each individual of being sampled using the recommended EHES two-stage sampling design. Table 3 shows the target population (35-79 years) for each municipality and Region and the number of persons to be examined in each centre (last updated June 2011).

<table>
<thead>
<tr>
<th>Region</th>
<th>Selected Municipality</th>
<th>Total population (35-79 years) municipality</th>
<th>Total population (35-79 years) in the Region</th>
<th>Sample size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Valle D’Aosta</td>
<td></td>
<td></td>
<td>74,496</td>
<td>220</td>
</tr>
<tr>
<td>Piemonte</td>
<td>Veruno</td>
<td>1,049</td>
<td>2,640,080</td>
<td>660</td>
</tr>
<tr>
<td></td>
<td>Torino</td>
<td>1,281,158</td>
<td>200</td>
<td></td>
</tr>
<tr>
<td>Liguria</td>
<td>Arenzano</td>
<td>7,234</td>
<td>1,000,527</td>
<td>220</td>
</tr>
<tr>
<td>Lombardia</td>
<td>Brescia</td>
<td>663,051</td>
<td>5,635,571</td>
<td>660</td>
</tr>
<tr>
<td>Lombardia</td>
<td>Montescano</td>
<td>261</td>
<td></td>
<td>220</td>
</tr>
</tbody>
</table>
In each centre, the population sample is extracted from the list of residents. Sample extraction is performed in the selected municipality or by the ISS upon receipt of the list of residents. If the municipality covers a large area (e.g. city of Rome), the sample is extracted in the district of the screening centre. To develop the list of the eligible persons, it is necessary to create a sequence of random numbers according to the number of residents for each age decade, for men and women separately; then list and number the name of residents in alphabetical order and extract the person corresponding to the random number. To ensure that the numerousness required is reached independently of participation rate, the number of persons randomly extracted from the resident list of each centre participating in the screening is three times greater than the one originally established.

Sample extraction procedure includes the following consequential steps:
- age decade is determined by subtracting the year of birth to the current year;
- age decades (35-44; 45-54; 55-64; 65-74) and last quinquennium of age (75-79) are determined by subtracting the year of birth of each individual to the current year;
- the individuals of each single decade/quinquennium are listed by alphabetical order and are numbered progressively;
- a sequence of random numbers corresponding to three times as many persons as required for each decade (25 of each sex) and quinquennium (10 of each sex) is created for every 1.5 million residents;
- the individual corresponding to the first random number is extracted and so on.

To make an example, in a sample of 220 residents, 75 persons of each sex in each age decade (25 x 3) plus 30 of each sex in the last 5-year age group (10 x 3) are randomly extracted.

The first 25 individuals extracted are invited by letter to participate in the study. The invitation letter, usually sent 15 days prior to the beginning of screening procedures, reports the date of appointment, the exact location of the survey site, the contact information for confirming or re-scheduling the appointment or obtaining more information about the screening. If the first contact attempt is non-successful for recruiting the selected person (the person does not show up to the scheduled appointment, the person has not refused invitation, the letter does not come back for unknown person), a second letter is sent. If also this attempt fails, a telephone call is made, although reaching people by home telephone is difficult as majority of people nowadays has only mobile phone, which is not included in telephone books. After three failed attempts (two invitation letters and one telephone call), the first individual in the next group of 25 is invited in order to reach the required numerosity of 220 men and women per 1.5 million residents stratified by age and sex (25 persons of each sex in each age decade between the ages of 35-74 years plus 10 persons of each sex in the last 5-year age group 75-79 years).

A good participation rate is essential to generalize results yielded from the sample to the general population. To calculate the participation rate, reasons behind refusal from persons contacted should be noted. Substitution of a non-contact is allowed if one of the following conditions occurs: the invitation letter comes back as the person is unknown, the person has domicile out of the area of the screening, the person has emigrated or died. Persons are coded as ‘non-participants’ if one of the following conditions occurs: the person refuses to participate (unknown reason; lack of time; personal reasons; health problem; feeling healthy); the person is temporarily away from the survey area (e.g. holiday); the person is affected by serious pathologies or advanced stage of disease (tumor in final stage with ongoing chemotherapy; psychosis; mental illness); serious disability (the person uses wheelchair and is unable to reach the screening location); dementia (but not cognitive disturbances); the person...
is hospitalized; the person was contacted but it was unable to schedule an appointment; the person has language problems; the person refuses to participate for other reasons. As for resident immigrants, it is necessary to work as much as possible to make them participate and understand the best they could the questions included in the questionnaire. In the case they show language understanding difficulties, it is possible to ask other immigrants to help them understand questions.

Regarding approaches to getting people to come to the screening, no monetary incentives are used, but participants receive results of instrumental and laboratory examinations and also detailed lifestyle recommendations (tips for healthy eating and physical activity).
6. LEGAL, ETHICAL AND DATA CONFIDENTIALITY ISSUES

In the HES it is important to obtain informed consent, to respect privacy and confidentiality, to avoid harm and to maintain well-being of participants. Before conducting a HES, it is important to find out if there are any ethical restrictions to be considered. All fieldwork staff members and all persons working at the Central Office need to be well informed why the informed consent is needed and that it is both a legal and ethical obligation. They should also know which topics are covered in the informed consent form and why they are important.

General recommendations on the ethical conduct of a HES
The following international reference documents should be consulted before applying for ethical approval of the survey, considered to be pillars of the ethical standards for biomedical research involving humans and also using human biological samples:

- Declaration of Helsinki, "Ethical Principles for Medical Research Involving Human Subjects", adopted in June 1964 (last rev. 2008);
- Convention for the protection of human rights and dignity of the human being with regard to the application of biology and medicine; The Oviedo Convention, 1997;
- Council of Europe, Committee of Ministers. Recommendation. Rec (1990) 3 concerning medical research on human beings;
- Council of Europe, Committee of Ministers. Recommendation. Rec (1994) 1 of the Committee of Ministers to member states on human tissue banks (adopted by the Committee of Ministers on 14 March 1994 at the 509th meeting of the Ministers’ Deputies);
- Council of Europe, Committee of Ministers. Recommendation Rec (2006) 4 of the Committee of Ministers to member states on research on biological materials of human origin (adopted by the Committee of Ministers on 15 March 2006 at the 958th meeting of the Ministers' Deputies).
• International Declaration on Human Genetic Data, 16 October 2003 (UNESCO).

Moreover, the Italian legal norms and ethical recommendations taken into account for the setting of legal and ethical procedures were:
• Italian Authority for Personal Data Protection: Authorization to Genetic Data Treatment, 22nd February 2007

Ethic Committee of the OEC/HES 2008-2012
The Ethic Committee of the ISS examined the documentation related to the OEC/HES (protocol of the study, informed consent, information notice and curriculum vitae of the responsible of the Project) and approved all aspects of the study on March 2008, including the protocol, the informed consent, the safeguarding of privacy and the use of data and biological materials. The request to participate with the Italian data in the European Health Examination Survey (EHES) Project and then contribute to the development of an European surveillance system was approved at the Ethic Committee meeting on November 2009. The Italian data, held in an anonymous format, are recorded in a central database together with data from the health examination surveys (EHES) conducted in other European countries.

To obtain approval for an HES, the following issues should be presented to the Ethic Committee: 1) establishment and duration of maintenance of the biological bank; 2) criteria for the enrolment of people affected by serious senile dementia or mental disorders incapable to give informed consent; 3) possibility to withdraw from the study and consequent destruction of the biological material; 4) procedure of data protection; 5) procedure of patient’s health status updating given that clinical records cannot be accessed independently;
6) possibility to use data and biological materials for the purposes of future research; 7) possibility to provide patients with examination results and lifestyle counselling to prevent disease occurrences; 8) destruction of identification data from participants who have died during the survey period; 9) responsibilities of the survey researchers in relation to long-term storage and use of biological materials. All points were exhaustively clarified to the Ethic Committee by the responsible of the study before the beginning of the HES pilot phase. More precisely, the Responsible of the study highlighted that: 1) 30 years is the minimum time period for the development of a consistent number of cerebro and cardiovascular events necessary to study the association between risk factors and cardiovascular and other chronic diseases and follow disease trend; 2) physically and mentally disabled people incapable to give informed consent but willing to participate in the study undergo examinations only if accompanied by a family member who signs the informed consent form; 3) at any point during the study the person may withdraw from the study, asking for the destruction of his/her biological materials; 4) all data from persons who accepted to collaborate in the study and to be followed over time are kept strictly confidential. Collected data, stored in a computer database at the ISS and protected by two different passwords, can only be accessed by the researcher who conducts the study; individual records are kept anonymized in a separate file from that which includes names or other information that could be used to identify the participant. Biological samples are introduced into aliquots of small volume, paillettes, that are labelled with an identification number to respect the privacy of study participants and clinical information are linked to biological samples through a secure method. A specific software keeps track of all the stored samples and their location in the containers. If the person is somehow concerned about a possible violation of his/her privacy, he/she can contact the Responsible of the study; 5) the consent to an anagraphical research in the future needs to be obtained from the participant in order to realize the follow-up (vital status, total and cause-specific mortality, collection and validation of acute and chronic events); 6) at the end of the screening, examination results are collected in a folder and given to the participant. The folder contains also explanations of the exams performed on the participant and lifestyle recommendations, which represents an incentive for persons to participate in the study; 7) identification data from participants who have died during the survey period are destroyed to respect their privacy in case of future use of their clinical data, which become “irretrievably anonymized”; 8) biological samples are stored in the biological bank of the CNESPS of the
ISS and only the biobank personnel will be provided with patient’s name and address or any other information that can be used, if necessary, to identify him/her. The results of the study can be published or presented at scientific meetings but the identity of the participant will be protected as the data will be aggregated.

After receiving approval from the Ethic Committee, the next step is to identify the appropriate Ethic Committee in each single Italian Region involved in the survey and its requirement for applying for approval. The procedures for obtaining this approval need to start as early as possible, preferable at the beginning of the planning phase.

**Safeguarding of privacy, data protection and subjects’ rights**

As stated in the Declaration of Helsinki, “Every precaution should be taken to respect the privacy of the subject and the confidentiality of the patient’s information...”, which has become increasingly important, given the progress made in information technology and the consequent ease of access to data. That privacy is safeguarded is ensured through legislation (generally a “Data Protection Act”). Given that performing a HES includes collecting individual data and that these data constitute a particular type of personal data (i.e., sensitive data regarding health) all aspects of data protection should be covered, in particular: access to data, the exchange of data, record linkage, and anonymization procedures. In Europe, the most important document regarding data protection is the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data. The issue of ensuring data protection is also of extreme importance in developing informed consent material.

To understand better the concept of data protection, some commonly used terms are defined below. More detailed definitions are provided in the abovementioned Directive.

- **Personal Data**: information regarding an identifiable person, that is, one who can be directly or indirectly identified, in particular by reference to an identification number or to factors specific to his/her physical, physiological, mental, economic, cultural or social identity.

- **Processing of Personal Data**: any operation (automatic or not) performed on personal data, for example, collection, storage, adaptation or alteration, retrieval, linkage, destruction and dissemination.
- **Controller**: the person or entity that determines the purposes and means of the processing of personal data.

- **Processor**: the person or entity that processes personal data on behalf of the controller.

- **Personal Data Act** (or Data Protection Act): legislation for protecting the privacy of natural persons in the processing of personal data.

- **Sensitive Data**: personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, trade-union membership, criminal convictions, and data concerning health or sex life.

- **Right of Access**: the right of a human subject to consult the data collected on him/her.

- **Duty of Notification**: the obligation of the controller to notify the data protection authorities of the intention to perform data processing, including a description of the processing.

**Informed consent**

Before performing any kind of research involving humans, informed consent must be obtained, which goes beyond merely getting an individual to sign a written form. It is a process of communication between an individual and the health care professional who is conducting the study, with the goal of ensuring that the individual fully understands the scopes of the study, the methods adopted, and how the data will be used. This communication process is both an ethical and a legal obligation. The concept of consent is relevant to both the performance of the study itself and protecting the privacy of the individual. The first step in obtaining informed consent is to provide the study candidate with information, which must be complete and clear, given that the ultimate goal is to ensure that participants are truly informed. The way in which the information is presented could also influence the OEC/HES participation rate.

This information can be contained on either the same document used to obtain the participant’s signature (generically referred to as the “informed consent form”) or on a separate document known as an “information notice”. The information notice can be provided to the study candidate some time before the informed consent form, so that the candidate has sufficient time for reading and understanding the information before agreeing to participate. It can also be provided together with the “invitation letter”, which is used as an introduction to explain in general what the study is about, its importance, and how and when the candidate will be contacted. The invitation should be brief yet “appealing” (for more information on the
invitation letter, see Chapter 7, “Recruitment of participants”). In developing informed consent material, setting up telephone help-lines for answering candidates’ questions and providing clarifications can also be considered, as can the translation of material into other languages. A web-site dedicated to the HES could also be created, with all of the information about the study, including the information notice itself.

Information note

The information note is provided to the study candidate to make him/her truly informed about the objectives of the study before signing the informed consent form. It is important that the participant fully understands the scopes of the study, the methods adopted and how the data are used. For this reason, the information notice should be complete, self-explanatory and easy to understand.

The participant shall be told that the examinations he/she undergoes are performed for his/her own interest and that collected data from all participants are pooled for research purposes.

The person enrolled should feel part of the study and free to decide whether or not to give the consent to the use of his/her data.

The way in which the information is presented could also influence the HES participation rate.

The information note must be signed by the Responsible of the Study. The information note should be provided to the study candidate some time before signing the informed consent, so that the candidate has sufficient time for understanding the information before agreeing to participate.

Below is provided the information note used in OEC/HES 2008-2012 and sent to the recruited participants, local authorities (Director-General, Health Director of the Health Unit and regional assessors) and to the general practitioners to inform them about the initiative.

THE PROGETTO CUORE – Epidemiology and Prevention of Cardiovascular Disease - Information note for participants – Health Examination Survey

Cardiovascular disease (CVD) represents the main cause of death, the most frequent cause of hospitalization and one of the leading causes of disability; CVD is also one of the main causes of disability and cognitive impairment in old age.
A great deal is nowadays known about cardiovascular risk factors, conditions associated with an increased probability of developing CVD. Most recent epidemiological studies have demonstrated the reversibility of risk, that is the possibility to reduce or postpone the occurrence of disease by reducing risk factors. Given the burden of CVD, significant public health efforts are focused on its prevention.

Periodic population surveys and CVD registers are important tools to monitor activities aimed at fighting CVD and to assess prevalence, attack rate, case fatality of most serious forms of ischemic heart disease and stroke, mean levels of cardiovascular risk factors, prevalence of high risk conditions and treatment indicators. For this reason, the aims of the Epidemiologic Cardiovascular Observatory/Health Examination Survey (OEC/HES) 2008-2012 are: 1) to describe, after 10 years from the first survey performed between 1998 and 2002, some individual characteristics recognized as risk factors, lifestyle habits (nutrition, physical activity, smoking habit) as well as the prevalence of risk conditions (hypertension, dyslipidemia, obesity, diabetes); 2) to identify pathology areas and other conditions requiring action in terms of prevention, diagnosis, therapy and assistance; 3) to monitor temporal trends of risk factors and CVD in statistical samples representative of general population aged 35-79 years.

The OEC/HES has represented the Italian reference point for CVD and other chronic degenerative diseases thanks to the adoption of standardized methodologies and procedures for data collection and measurements. Data are published and are available on the website of the CUORE Project for single regions, macro-areas and for the whole country (www.cuore.iss.it).

Recently, the interest has been progressively focused on the need to include other determinants and indicators of chronic degenerative diseases. Also, the implementation of an health examination survey has become a real possibility and a chance to participate with Italian data in the European Health Examination Survey and then contribute to the development of an European surveillance system.

Health Examination Surveys are based on randomly enrolled population samples and are particularly suited for providing information on behaviours and health determinants: anthropometric, physiological, and clinical measures, hematochemical parameters, useful information to assess prevalence of chronic diseases, need for health services and access to them, functional capacity and nutritional status are collected through the direct examination
of population. To achieve OEC/HES 2008-2012 objectives, it is necessary to enrol and examine a sample of 9,020 individuals aged 35-79 years, randomly extracted from the general population (220 individuals aged 35-79 per 1.5 million residents). In random sampling, each individual has the same probability of being chosen, also those physically or mentally incapable to giving consent. In this case, study objectives and rights of participant are illustrated to a family member. This numerosity is sufficient to evaluate disease time trends and identify possible changes in the distribution of risk factors, risk conditions and cardio-cerebrovascular diseases.

One or two centres maximum are selected in each Region. In each centre, a number of individuals sufficient to cover the total sample established for the whole Region is extracted from the list of residents. The screening personnel are properly trained to perform physical examinations.

The following screening procedures are performed: questionnaire (including questions about anagraphical data, habits and lifestyle, in particular dietary habits, past history of disease, current therapies, need of health services, in particular hospitalizations, family history of coronary heart disease, cerebrovascular diseases, diabetes, hypertension and hypercholesterolemia), venipuncture for testing total, HDL and LDL cholesterol, triglycerides and fasting blood glucose, anthropometric measurements (weight, height, hip and waist circumference), blood pressure measurement, electrocardiogram (ECG), 24-hour urine collection (for sodium, potassium, iodine and urinary creatinine measurement), carbon monoxide assessment, bone densitometry, spirometry.

All procedures and methodologies used follow international recommendations and quality controls.

Biological samples are examined at the central Laboratory of Genetic and Ambiental Epidemiology of the Catholic University of Campobasso and at the Department of Clinical and Sperimental Medicine, Faculty of Medicine and Surgery, University Ferderico II of Naples.

Biological samples (serum, plasma, buffy coat and packed red blood cells) are stored at the biological bank of the National Centre of Epidemiology, Surveillance and Health Promotion of the National Institute of Health (ISS) for a minimum period of 30 years, which is the minimum time period for the development of a consistent number of cerebro and
cardiovascular events necessary to study the association between risk factors and cardiovascular and other chronic diseases and follow disease time trends.

At the end of the screening, examination results are collected in a folder and given to the participant. The folder contains also explanations of the exams performed on participant and lifestyle recommendations.

The ISS coordinates training, standardization, quality control and support activities and is responsible for data analysis.

The enrolled population is followed over time for total and cause-specific mortality and for fatal and non-fatal coronary and cerebrovascular events; the surveillance activity includes collection and linkage of mortality data and hospital discharge diagnoses of resident population.

To achieve the objectives of the event registration, the following information are collected: resident population in the study area for men and women and for 5-year age group, cause-specific death certificates for all residents in the study area, hospital discharge records from hospitals and clinics to which residents were admitted. Suspected events can be then identified and classified following the diagnostic categories of major international epidemiologic studies (MONICA Project, WHO).

The CUORE Project received approval from the Ethics Committee of the ISS on 15 March 2006, on 11 March 2008 and on 11 November 2009. The request to participate with the Italian data in the European Health Examination Survey (EHES) Project and then contribute to the development of an European surveillance system was approved at the last meeting in November 2009. The Italian data, held in an anonymous format, are recorded in a central database together with data from the HES conducted in other European countries. The CUORE Project is partially funded by the Centre for Disease Control of the Ministry of Health and is part of the programme ‘GAINING HEALTH’, aiming at:

1. Gaining health making healthy diet the easiest choice (nutrition)
2. Gaining health facilitating movement and physical activity (physical activity)
3. Gaining health encouraging smoking cessation (fighting smoking)
4. Gaining health discouraging excessive alcohol (fighting alcohol abuse)

The ‘GAINING HEALTH’ Programme is subscribed by:
Ministry of Health; Ministry of Agriculture, Nutrition and Forestry Politics – INRAN; Ministry of Family Affairs; Ministry of Public Education; Ministry of Economics and
Data and urine samples collected within the OEC study are used in two specific studies: the CARHES study (CArdiovascular risk in Renal patients of the Italian Health Examination Survey), aiming at assessing the association between chronic kidney disease and cardiovascular risk, and the MINISAL-GIRCSI (Good practice on diet: assessment of sodium, potassium and iodine concentration in the diet of the Italian population) aiming at assessing average daily consumption of sodium, potassium and iodine in adult Italian population.

**PERSONAL DATA PROTECTION LAW**

All data collected by this study will be handled in accordance with the Italian law on the protection of personal data (Legislative decree n.196/2003)

Your personal data will be stored and processed by an electronic system in accordance with privacy regulations and will be used solely for the purposes of this research study.

Clinical records will be kept strictly anonymized; after collection they will be kept in a separate file from that which includes anagraphical data and only the project Responsible and persons in charge of the data processing (researchers and technicians of the ISS) will be entitled to link them.

Personal data shall be communicated to third parties only if necessary for the purpose of the study.

You will be able to exercise all rights according to Article 7 of the Legislative decree nr. 196/2003 that we wholly reproduce for your convenience.

1. The interested party shall have the right to obtain confirmation as to whether or not personal data concerning him/her exist, regardless of their being already recorded, and communication of such data in intelligible form.
2. The interested party shall have the right to be informed:
   a) of the source of the personal data;
   b) of the purposes and methods of the procession;
   c) of the logic applied to the procession, if the latter is carried out with the help of electronic means;
   d) of the identification data concerning data controller, data processors and the representative designated as per Article 5, paragraph 2;
   e) of the entities or categories of entity to whom or which the personal data may be communicated and who or which may get to know said data in their capacity as designated representative(s) in the State’s territory, data processor(s) or person(s) in charge of the processing.
3. A data subject shall have the right to obtain:
   a) updating, rectification or, where interested therein, integration of the data;
   b) erasure, anonymization form or blocking of data that have been processed unlawfully, including data whose retention is unnecessary for the purposes for which they have been collected or subsequently processed;
   c) certification to the effect that the operations as per letters a) and b) have been notified, as also related to their contents, to the entities to whom or which the data were communicated or disseminated, unless this requirement proves impossible or involves a manifestly disproportionate effort compared with the right that is to be protected.
4. A data subject shall have the right to object, in whole or in part:
   a) on legitimate grounds, to the processing of personal data concerning him/her, even though they are relevant to the purpose of the collection;
   b) to the procession of personal data concerning him/her, where it is carried out for the purpose of sending advertising materials or direct selling or else for the performance of market or commercial surveys.
In accordance to the above mentioned law, you will have the right to ask for the destruction of your biological sample (blood and urine) at any point during or after the study by making a written request to the responsible of the study.

**Informed consent form**

Key elements in the informed consent can be defined as information, understanding, competence, voluntariness, and decision making.

- All information the participant has received about the study, including the invitation letter, information leaflets, media campaigns etc. are important for the informed consent and they should be provided in language understandable to the selected persons.
- To ensure understanding, information should be provided both orally and in writing.
- Competence refers to the adequate decision making capacity of the participant.
- Voluntariness refers to the capacity to make a choice freely and in the absence of coercion. The participants should know their right to withdraw from the study at any time.
- For the decision making, the participants need time to read the information in peace and think about it before discussing with the fieldwork staff and signing the informed consent form.

The informed consent should be obtained in an active communication process between the fieldwork staff member and the participant. The fieldwork staff member is recommended to illustrate in simple words the key points of the consent to the participant and check if he/she has well understood the contents of the information note. The participant should be offered the possibility to ask questions or express doubts before signing the consent form and also during the examination visit. The fieldwork staff member should try to maintain a friendly and warm attitude to make participants feel comfortable and free to decide whether or not to give the consent to the use of his/her data.

The ‘partially restricted consent’ model is used in the OEC/HES 2008-2012. The following items are included in the informed consent form: declaration of having read, understood and approved the information provided in the Information Note; assurance of data confidentiality; possibility to withdraw from the study at any time; future uses of data and biological samples;
statement to contact subject for follow-up of morbidity and mortality; statement to consent to store and use biological samples for future research in the field of cerebro and cardiovascular disease; name of the person receiving the consent. The study candidate is asked to sign three copies of the informed consent form: one is given to the participant together with the results of instrumental and laboratory examinations, one is stored at local level and one is stored at the ISS.

The informed consent form used in OEC/HES 2008-2012 is shown below

**Cardiovascular Epidemiology Observatory - Informed consent form**

**Section A. Consent to participate in the Study**

I, the undersigned, Mr/Mrs/Miss: ____________________________
born in (place of birth) ____________________________
on (date of birth) ____________________________

After reading the “Information Notice” and receiving a copy of it,

**DECLARE**

- that I have read and understood the Information Notice;
- that I have received clear and detailed information about objectives and procedures of the study;
- that I accept that biological samples (serum, buffy coat, packed red cells) extracted from my blood will be preserved in a biological sample bank;
- that I accept that the above-mentioned material will be stored for up to 30 years in the biological bank of the National Institute of Health;
- that I have been informed and give permission to use my blood sample in future research within the field of cerebro and cardiovascular disease for the period specified above;
- that I have been informed and accept that results of screening and haematochemical examinations foreseen by the study protocol are stored magnetically, kept strictly confidential and used exclusively for research purposes;
- that I have been informed that the result of the research will be published only in aggregate and anonymous form exclusively for research purposes;
- that I have been informed that the study foresees regular update of vital and anagraphical status, as well as identification of cerebro and cardiovascular events using available sources of information mentioned in the study protocol (clinical records, GPs, registry offices, etc) and hereby I consent to this updating;
- that I have been informed that the study received approval from the Ethics Committee of the National Institute of Health;
• that I have been informed that my data, held in an anonymous format, will be recorded in a central database together with data from the health examination surveys (HESs) conducted in other European countries to contribute to the development of an European surveillance system;
• that I am aware that my participation in this study is voluntary and that I may withdraw from the study at any time and without giving any reasons. I know that refusal to participate or withdrawal from the study will involve no penalty, no discrimination or loss of benefits;
• that I know that for further information I can contact the Scientific Responsible of the study or any designated person.

I declare that I have read and understood the explanation provided to me and I voluntarily agree to participate in this study.  

[YES]  [NO]

I give permission for my blood sample to be stored in the biological bank of the National Institute of Health for up to 30 years and its use in future research in the field of cerebro and cardiovascular disease. I was informed that any future study will be published in the CUORE Project web site. I give also my permission to be re-contacted for any eventual follow-up.

[YES]  [NO]

Section B. Consent to the use personal data

I have read and understood the information on use of personal and sensible data (articles 7,8, 9,13 of the Legislative Decree n. 196/2003) reported in the “Information Notice”.

I give permission to the use my personal data for the purposes of this study and the management of biological samples.

[YES]  [NO]

Date:_____________________

Signature of the Participant       Signature of the local Responsible
7. RECRUITMENT, SCHEDULING APPOINTMENTS AND MOTIVATING PARTICIPANTS

This chapter provides guidelines for recruitment process, recruitment methods, definition of participation rate and non-participant data. The strategy and methods for recruitment have to be determined based on feasibility, survey budget, and regional cultural characteristics.

A high participation rate is extremely important to the reliability and validity of the survey. Participation rate depends directly on the success of recruitment. Proper recruitment is necessary for the HES to be ethically acceptable. Since non-respondents tend to have different health characteristics from the rest of the sample, their omission often results in bias. Unfortunately, the direction and extent of the bias are often unpredictable: some subjects refuse to come for examination because they feel fit and cannot be bothered, others because they feel ill and afraid. The amount of bias introduced depends on the frequency of the condition in the sample as a whole, the proportion of non-respondents, and the extent to which the non-respondents are atypical.

Since the likelihood of bias depends on the cause of non-response, the investigator should report the numbers that fall into various categories – for example, removed since census, on holiday, ill, dead, or refused to take part.

Personal contact (by nurse, physician or key local figure or the senior investigator) and convenient appointments, arrangements for time off from work, transportation, screening centre easily reachable, etc. may help elicit cooperation and overcome resistance to response.

Recruitment process

The purpose of the recruitment process is to ensure as high participation rate as possible. The recruitment process includes all stages, where selected participants are contacted to provide information and to make appointment to examination visits.

First contact attempt

To obtain a high participation rate the first contact attempt is crucial; the success of the first contact saves costs. In the OEC/HES 2008-2012 the first contact attempt is made by a personal invitation letter, accompanied by the information notice. The invitation letter should be easy to understand, even by participants with slight linguistic or cognitive impairment; it
should state that the examinations are free and refusals to participate do not compromise any future health assistance.

The following information and instructions for the participants should be included in the letter of invitation:

- objectives of the survey;
- importance of the survey for improving public health;
- importance of participation and benefits for participant;
- brief description of the measurements;
- details of the appointment: date and hour of appointment; exact location of the survey centre;
- contact information: name of the person to contact, telephone number and time to call.

Contact information important to re-schedule, confirm, cancel the appointment, or ask further information on the survey. Participants are asked to confirm their appointment. The opportunity to re-schedule the appointment on weekends and to obtain a certificate of absence from work should be mentioned;

- indication for fasting: the minimum recommended fasting time is 12 hours (blood drawing is performed in the morning). The participant can drink some water and take his/her regular medicines before the visit;
- identification: participants are recommended to bring sanitary card (including address and fiscal code), or any other valid identification card;
- medication: boxes of medicines/prescriptions should be taken along to the examination visit;
- participants are recommended to bring eye glasses to fill in self-administered questionnaire
- name and signature of the leader of the survey: sometimes it may be necessary that the letter is signed by both the local responsible and the national coordinator to give more emphasis to the event. Website address for more information on the survey.

The invitation letter should be sent to the participant 15 days prior to the beginning of screening procedures: if recruited persons get the invitation too early they may forget the date of the appointment; on the contrary, if they get it too late, they may be unable to change their previous engagements.
The invitation letter sent to the participants in the OEC/HES 2008-2012 is reported at the end of this chapter.

The invitation letter should be accompanied by the information note including the objectives of the survey, the importance of the survey for improving public health, the required numerosity, information on sample selection, a brief description of instrumental and laboratory examinations, information on delivery of examination results, storage of biological samples, personal data treatment, ethical approval, and on future follow up with collection of morbidity and mortality data. Also the information note should report the name and signature of survey leader. The information note is reported in chapter 6.

The following information are provided to the participant before starting the visit:

- smoking: the participant should abstain from smoking one hour before the examination (affects blood pressure measurements).
- vigorous physical exercise: the participant should abstain from vigorous physical exercise one hour before the examination (affects blood pressure measurements and blood samples).
- presence of family members, proxy: their presence can be allowed if needed e.g. in case of problems with understanding the language, speaking, hearing or cognitive capacity.

Re-contact attempt

In the OEC/HES 2008-2012 if the first contact attempt is non successful for recruiting the selected person (the person does not show up to the scheduled appointment, the person has not refused invitation, the letter does not come back for unknown person), a second letter is sent, checking accuracy, correctness and recentness of the contact information. If also the second attempt fails, a telephone call is made, although reaching people by home telephone is difficult as majority of people nowadays has only mobile phone, which is not included in telephone directories. Telephone directories often contain alphabetical lists of householders names, therefore it is not easy obtain the number of married women. A personal approach by a phone call may be more effective because allows to explain the objectives of the study, to stress the importance of participation and to schedule the appointment taking into account the requests or needs of the participant. It is important to state that all the participants are equally important to the survey regardless of their health condition. If a second letter of invitation is sent, it is usually important to modify it with respect to the first letter of invitation in order to
explain the importance of participation and the willingness to meet participant’s needs, e.g. the hours in which the measurements are taken can be more flexible (evenings, week-ends). After three failed attempts (two invitation letters and one telephone call), recruitment attempts end. The figure 1 shows different responses to contact attempts. The next in the list of sampled persons is invited in order to reach the required numerosity of 220 men and women per 1.5 million residents (25 per each decade of age and sex between 35-74 years plus 10 for the last quinquennium of age 75-79 and sex). Substitution of a non-contact with a neighbour or a person with similar characteristics is not acceptable. The number of persons invited to participate should be recorded as they represent the denominator of participation rate. To calculate participation rate, the following categories should be excluded: persons who died between recruitment and invitation, persons who moved out of the sampling area; persons whose invitation letter has returned to sender for unknown address are considered unresolved if they are in the list of the residents. A short non participant questionnaire may be offered to those who refuse; this questionnaire may be answered by a proxy if the selected person cannot be reached or is otherwise incapable to answer it. That was not possible in the OEC/HES 2008-2012; the enrolled population will be followed over time for total and cause-specific mortality; to achieve the objectives of mortality registration, the following information will be collected and stored also for non-respondents: name, surname, date of birth and residence. This will allow linkage with total and cause-specific deaths and comparison between respondents and non-respondents.
**Participation rate**

A good participation rate is essential to generalize results yielded from the sample to the general population.

It is recommended to include almost one centre for each Region (see Chapter 5 Sampling procedures).

It is recommended to perform all screening phases at one single centre, therefore people accepting to participate in the study normally go through all screening phases, except when they are unable to undergo examinations despite consensus given (e.g. difficulty in withdrawing blood, persons on dialysis, difficulty to have weight/height measured for persons on wheelchair). Consequently, usually there is no difference between participation rates and response rates at each stage of data collection. Participation rates vary significantly across places: usually, they are higher in small towns and suburban areas than in metropolitan areas.

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**Figure 1. Responses to contact attempts**

![Diagram showing responses to contact attempts]

- First contact attempt (letter)
  - Not reached
  - Unable to arrange an appointment
  - Appointment made-no show
  - Other reason

- Outside age range
  - Moved abroad
  - Died
  - Unknown addressee

- Refusal

- Second contact attempt (letter)

- Third contact attempt (phone call)

- Participates

- Recruitment ends
Definition
A person should be classified as eligible or not eligible. Eligibility criteria are used to define the target population (Figure 2).

Figure 2. Eligibility criteria

Here below the classification of the original survey sample is reported. The definitions are:
- **Eligible**: A person is coded as eligible, if she/he belongs to the target population (see Chapter 04. Target population and sample size).
- **Participant**: an eligible person is coded as participant if she/he has at least one valid examination measurement, such as height and weight, in addition to some questionnaire results.
- **Non-participant**: persons are coded as ‘non-participants’ if one of the following conditions occurs: the person refuses to participate (unknown reason; lack of time; personal reasons; health problem; feeling healthy); the person is temporarily away from the survey area (e.g. holiday); the person is affected by serious pathologies or advanced stage of disease (tumor in final stage with ongoing chemotherapy; psychosis; mental illness), serious disability (the
person uses wheelchair and is unable to reach the screening location; cognitive disturbances); the person is hospitalized; the person was contacted but it was unable to schedule an appointment; the person has language problems; the person refuses to participate for other reasons.

- Not eligible: A person selected to the sample is coded as not eligible if she/he does not belong to the target population. This includes over-coverage of the sampling frame (i.e. possible persons who are in the sampling frame although they do not belong to the target population, e.g. not within the age limits) and persons whose invitation letter comes back as he/she is unknown, persons with domicile out of the area of the screening, persons who died or moved out of the sampling unit after sample selection. Substitution of a non-eligible person from the list of samples persons is allowed if one of the above circumstances occurs. The reason for being not eligible should be recorded. Persons who were temporarily absent during the survey period because of work, studies, tourism, hospitalization, or for other reasons are part of the target population and therefore eligible.

- Unresolved: There may be persons whose eligibility status cannot be resolved. In a typical case, the invitation letter was returned to the survey administration indicating that there is no such person in the address, although he/she was in the list of residents; other contacts were not possible or not successful; no information was available to assess the eligibility status.

Although it may be likely that the person does not belong to the target population, there is no certainty about this. The number of unresolved persons is usually small, but may be substantial in some countries, where good sampling frames are not available or when the register of residents is not updated.

To calculate the participation rate, the following categories are excluded from the original sample as not able to attend the screening: persons not receiving the invitation letter (undelivered letter), dead persons, persons moved out of the residence area after the sample selection. They can be substituted with persons from the sample list. The formula to calculate participation rate and its fractions, co-operation rate and contact rate, are shown in the next table:
Calculating participation rates

<table>
<thead>
<tr>
<th>Equation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PR = (number of participants) / (number of eligible or unresolved)</td>
<td>Calculating participation rate</td>
</tr>
<tr>
<td>Co-operation = (number of participants) / (number of eligible)</td>
<td>Co-operation rate</td>
</tr>
<tr>
<td>Contact rate = (number of eligible) / (number of eligible or unresolved)</td>
<td>Contact rate</td>
</tr>
<tr>
<td>Note that PR = contact rate x co-operation rate</td>
<td></td>
</tr>
</tbody>
</table>

Target participation rate

Recruitment efforts should be geared towards obtaining the highest possible participation rate so that the sample will represent the target population. The target participation rate should be at least 70% but preferably higher; only a few surveys have reached participation rate of 70% or higher during the last few years, this is why special attention should be given to increase participation rate.

It is known that non-participant are more often young men from lower socio-economic class; they have also worse health profile, more psychological disorders, are more often smokers and have higher total and cause-specific mortality than participants.

Ways to increase participation

Selection and training of personnel

Competence and motivated survey personnel play an important role during the recruitment process. They should be trained to make enrolled persons feel valued and appreciated, part of the study and aware that their contribution to future research on chronic disease prevention is important. They should be professional, friendly, respectful, showing caring manner towards participants and fluent in national language. Proper training to manage telephone calls is important: what are the correct answers to frequently asked questions, how to persuade uncertain participants in an acceptable manner, what options can be offered in case of difficulties in scheduling a visit (week-ends, evening hours), whether to ask reasons for non-participation, etc.

Factors affecting participation rate

During the recruitment process there are several important issues that influence the motivation to participate, such as multiple contact attempts; communication plan involving local press, local General Practitioners’ and other health operators; possibility to schedule appointments
on weekend; possibility to re-schedule an appointment and to withdraw from the study at any time for any reason; prolonged opening hours; providing participants with examinations’ results; offering certification of absence from work; etc.

In addition, the letter of invitation should be structured to favour participation in the study. It should state the survey relevance for public health and that data and samples collected are pooled only for research purposes and will be kept anonymous. Signature of the invitation letter by a respected person may increase the feeling of being valued.

To facilitate participation of resident migrants showing language difficulties, they should be assured that one member of the family (usually a younger component) or other migrants may help them understand questions if necessary.

No monetary incentives should be used to encourage attendance but examinations results and tailored detailed lifestyle recommendations (tips for healthy eating, physical activity and smoking cessation) may act as incentives.

In addition to the recruitment process, motivation of the personnel is also important during the fieldwork. Issues that increase motivation at the examination site are:

- friendly atmosphere, so that participants feel welcome and appreciated;
- examination site near participants’ home;
- comfortable facilities, e.g. room privacy is important;
- fluent change between measurements (no waiting times or minimal waiting);
- possibility to interrupt visit and re-schedule it in a later time;
- possibility to be accompanied by a family member or a proxy, if needed.

Also the importance of keeping promises and adjusting to different situations (e.g. special needs) are important issues for the motivation, since a disappointment or frustration may cumulate unwanted attitudes towards the survey. Rushed attention may create negative feelings.

**Partnership for enhancing participation**

Partnership and collaboration with local organizations, professionals and communities help to raise awareness of the importance of the survey, and to arrange easy access to the examinations.
Pre-notification prior to survey to local government and health authorities of each centre involved in the survey is an effective way to favour participation; they should be notified to ensure the community’s understanding and support; they should receive the manual of operations and the protocol of the study, the approval letter from the Central Ethic Committee, the letter of presentation of the project, and the information note of the project explaining that the survey aims at giving a complete picture of the Italian population’s health status; an overview of the health status facilitates the planning and evaluation of future preventive programmes. Local health authorities, in particular GPs, should be notified to encourage patients enrolled to participate in the study. In small centres, parish priest, local pharmacies, elderly clubs, departments of prevention, as well as local press and TV, should receive information about the study, although a widespread survey publicity may lead to request for participation from persons not enrolled in the study. The way to publicize the screening depends on local organization: some use local meetings, others press conferences or local press; surveys sponsored by academics or governmental organization have, in general, higher participation rates compared to surveys sponsored by commercial organizations. Cooperation with regional or local hospitals, research centres and universities may increase the interest in participation.
THE PROGETTO CUORE – Epidemiology and Prevention of Cardiovascular Disease

Letter of invitation

Dear Mr/Mrs/Ms,

you have been enrolled to participate in the Progetto CUORE - Epidemiology and Prevention of Cardiovascular Disease. This project aims at assessing the distribution of cardiovascular risk factors in the Italian population, the number of persons at high risk of cardio-cerebrovascular diseases and of those who have already experienced an event, in order to prevent the occurrence of these diseases, which represent the main cause of mortality, morbidity and disability in our country.

The scientific protocol of the study, of which you find enclosed the information notice, foresees:
- an accurate collection of your clinical data and of those of your relatives in a questionnaire administrated by an health operator; information on lifestyles, nutrition and physical activity will be collected;
- a medical examination with weight, height, waist, hip measurements; pulse rate and blood pressure measurements;
- the execution of electrocardiogram, bone densitometry and spirometry;
- a venipuncture for assessment of fasting blood glucose, total and HDL cholesterol, haemocrome;
- 24-h urine collection.

At the end of the screening, you will receive results of the examinations performed on you so that you can inform your physician. Biological samples will be stored at the biobank of the National Centre for Epidemiology, Surveillance and Promotion of Health of the National Institute of Health.
Your participation is free and will involve no cost to you. You can withdraw from the study at any time and without giving any reasons. Withdrawal from the study will have no consequences on your clinical controls.
Any information about you collected in this study will be used exclusively for scientific purposes.

The examination will be performed on ............................................................

at .............................................................................................................

Fasting from at least 12 hours is required. It is also recommended to bring eyeglasses and the boxes of medicine you regularly take, in order to take note of prescriptions made by your physician.

We hope you can accept to contribute to the collection of relevant epidemiological data on prevention of cardio-cerebrovascular diseases

Thank you for cooperation

Date ...................................................... Dr .........................................................
8. QUALITY ASSURANCE

Training programme

The training programme should be considered when planning and preparing surveys. It is essential to outline the training at early stages of the planning process, as this will affect both budgeting (training costs) and timing of the data collection. Training is a key element of standardization and quality assurance.

All members of the national survey team, both those working at the central office and all fieldwork staff members should participate in the training programme. It is essential for the quality of the survey that everyone, including secretaries and assistants working at the central survey office, those who contact the selected persons, send the invitations and schedule the visits, data managers, statisticians and all field work staff members know and understand the aims of the survey and the whole data collection process.

All survey staff members are recommended to read the manual before training sessions and eventually update it at the end of the screening on the basis of suggestions arisen during fieldwork procedures.

The National Institute of Health (ISS) is responsible for training fieldwork staff members. The training sessions takes place during the first week of the screening in each selected centre although its duration may vary depending on the previous survey experience of the selected staff members and distribution of tasks between the fieldwork members. To allow substitution of other fieldwork members when needed and rotating tasks, each team member is trained to handle several measurements. If screening lasts more than planned, refresh training sessions are foreseen.

Outline for training seminar

The training should include both general issues for all staff members, general fieldwork skills and practices for the fieldwork staff, and specific training for each selected measurement. If the staff members have experience from previous surveys some parts of the general training may be only short refresher lectures. Practical measurement sessions are needed also for the experienced staff members to ensure that the standards are followed correctly.

The training for all survey members should include the following topics:
- purpose and aims of the survey: it is important that all staff members understand the importance of the survey and are able to describe the aims and purpose of the survey to the participants in a standard way;

- ethical issues and confidentiality: what is data confidentiality and how it is assured by all staff members, why an informed consent is needed, what is meant by the informed consent, and how the informed consent should be obtained;

-random samples and the importance of high participation rates: how people are selected, and why all selected persons are equally important regardless of their health status or other characteristics, how participation can be encouraged and motivated;

- the importance of standardization and quality assurance: understanding the aims of audit visits and quality assurance, the role of the survey manuals, the importance of consulting supervisors when needed;

- survey organization: roles and responsibilities of each staff member at the central office and in the fieldwork teams;

- communication skills, including similarities and differences in professional conduct during survey data collection and clinical practice in normal health care settings;

- working with the local health care professionals e.g. to build and maintain good collaboration, so that they encourage their patients to participate in the survey, and referring participants with abnormal measurement results to their GPs or other local health care professionals;

- how the survey results will be reported and published, publicity rules and working with local media during fieldwork;

- data management system and IT skills for data entry, handling and reporting.

Fieldwork staff members who administrate the questionnaire on health status are also trained to make participants feel at ease, establish a friendly atmosphere, and ask all questions and record answers correctly, especially in case of open ended questions.
The training for the members of the field work teams who are carrying out the measurements should include the following topics:

- specific procedures for each interview module or instrument;
- specific measurements: rationale why they are measured, measurement techniques, including practical training and certification if needed;
- giving feedback to participants concerning measurement results;
- consulting survey physicians and local health care professionals when needed;
- safety of the fieldwork team members (e.g. actions needed in case of needle stick injuries, violently acting and aggressive participants).

For example, the personnel responsible for collecting blood samples should be familiarized with the part of the protocol that pertains to blood collection. The safety instructions for protecting the participant and the nurse or technician during the blood sample collection should be reviewed. Similarly those who will carry out the blood pressure measurements need specific information on why standardized blood pressure measurements are needed, what are the key steps in the measurement protocol, how the results are recorded and how the results are explained to the participants. The practical training will include e.g. carrying out adequate number of measurements observed by supervisors and feedback sessions.

**Selection of trainers**

The trainers should meet the following criteria established by the EHES Reference Centre (RC):

- have participated in training seminars organized by EHES RC
- are well informed both on the aims and purposes of the national survey as well as on EHES standards;
- have specific expertise in the subject area (e.g. survey ethics, blood pressure measurements)

The supervisors and persons with experiences from previous surveys can act as training assistants to train the other team members.

**Use of training materials and different training methods**

The trainers should be encouraged to read the survey manuals before the training sessions, during and/or after the training. The survey manuals form the basis for all training.
Open discussions between all field work members and other survey staff members should be encouraged during the training sessions. During the fieldwork, meetings with the supervisors, audit visits and feedback sessions will support learning and point out the importance of standardization.

**Duration and timing of the training**

In the OEC 1998-2002 the training section was centralized in Florence at the ANMCO offices with a two days course; all the nurses involved in the fieldwork and the local cardiology responsible of the survey participated to the meeting. During the screening a site visit was organized in order to check how the measurements were done and how the date were collected; that visit was also important for quality control. After that experience we realize that the course was not helpful for those centres which were not able to start immediately. Planning the OEC/HES 2008-2012 we agreed than the best time for training could be the first week of screening: in this way, trainees have the possibility to observe trainers and progressively substitute to them in performing measurements as they gain expertise. To allow substitution of other fieldwork team members when needed and rotating tasks it is recommended that each team member will be trained to handle several measurements, even if the measurements are carried out by teams where the staff members have different tasks. Retraining during fieldwork should be organized if the fieldwork lasts for more than two or three months to ensure that the standards are kept. Retraining is essential also if observer effects or non-adherence to survey standards are observed during audit visits or by other forms of quality control during the fieldwork.

**Pilot survey**

The pilot phase of the OEC/HES 2008-2012 was conducted in the centres of Udine (Friuli Venezia Giulia region, responsible: Dr Vanuzzo) and Campobasso (Molise region, responsible: Dr Iacoviello) in 2008 with the aim of evaluating the entire survey process and obtaining additional information for the planning of the full-size survey. In Udine, 459 individuals aged 35-79 years were invited by telephone (and not by letter) and 222 participated in the screening (participation rate 48%). It became soon evident that recruiting participants by phone was not successful. It is difficult to reach women and migrants, whose telephone numbers are not included in phone books. Therefore, in
Campobasso we decided to invite recruited persons by letter. The pilot phase of Campobasso was carried out within the MOLISANI Project. Conducting the two studies contemporarily was quite complicated but this gave the possibility to the Laboratory of Genetic and Ambiental Epidemiology of the Catholic University of Campobasso to become the central laboratory for the OEC/HES 2008-2012. During the pilot phase in Campobasso, 621 individuals aged 35-79 years were invited by letter and 253 participated in the screening (participation rate 40%).

The pilot surveys have helped the fieldwork staff familiarize with potential practical problems. Use of equipment, computer programs, data management, and blood sample processing, storage and transfer were tested. Willingness of invitees to participate was also tested in order to develop strategies to increase participation rate in the full-size survey. Average duration of interviews and examinations were calculated in order to plan personnel resources.

**Quality control**

Standardisation of measurements, training of personnel and quality control are essential to assure reliable and comparable data. It is recommended to use survey instruments whose sensitivity and specificity have already been assessed. It is also important to periodically check that instruments are perfectly functioning and that the same instruments are used for the whole duration of the screening. Personnel assigned to screening should be properly trained and quality control should be assured for the whole collection period. To perform a survey, many health operators may be needed and their activities should be under regular quality control for the whole collection period in order to ensure validity and comparability of data.

To reduce measure variability it is important to take into account:

- season of year (continuous survey takes care of this);
- time of day (morning/afternoon);
- setting;
- time of last meal or last cigarette (counting at least 12 hours from the end of the last meal if laboratory analysis includes lipids);
- time from the venipuncture and the centrifugation of blood samples; that is important for the fasting blood glucose test; it is known that glucose value reduces of 5% each hour.
A pilot study to test the entire set of procedures and methods is needed before starting screening procedures to:

- rehearse the main investigation;
- identify problems with methods practicality, reliability and validity;
- familiarize staff with practical problems;
- result in refinement of techniques;
- to make observations on respondents reactions;
- record time to do interview and study procedures;
- test appropriateness of arrangement of the questionnaire- and "flow" of procedures;
- allow better estimates of space, personnel, supply and equipment needs.

**Survey management**

For quality assurance, it is important that there is a well defined survey organization and professional coordination. In both surveys, the OEC 1998-2002 and the OEC/HES 2008-2012, the National Institute of Health (ISS) has coordinated the training of survey personnel, standardization of measurements, quality control and is responsible for data analysis. The survey project leader avails herself of the support of a group of experts in order to assure an effective survey organization.

**Agreement on survey procedures**

The OEC/HES 2008-2012 manual describes in a very detailed manner the procedures to be used in the HES. All recommendations provided by the EHES Manual of Operations are followed and all deviations from them were discussed with the EHES Reference Centre (RC). The OEC/HES 2008-2012 manual is developed in English to facilitate communication with the EHES RC and other partner countries. However, a national language version of the manual is also available.

**Organizing quality control for the survey procedures**

**Internal quality control**

The procedure for examinations are planned carefully and a routine retraining of all personnel doing examinations is performed.
To comply with EHES recommendations, some changes have been introduced with respect to the previous survey OEC 1998-2002. For example, two consecutive measurements of blood pressure were performed in the OEC 1998-2002 survey, three are performed in the OEC/HES 2008-2012 survey although position of participant and methodology are the same; weight is measured with a standard electronic scale in the OEC 1998-2002 survey, with a balanced beam scale in the OEC/HES 2008-2012. To study temporal trends, the mean value of 1st and 2nd measurements is still considered (as in previous surveys), while the mean value of 2nd and 3rd measurements is considered to make comparison with EHES partner countries.

During the OEC/HES 2008-2012 survey, blood pressure, weight and height measurements are particularly subjected to quality control measures.

For blood pressure:
- number of measurements of both systolic and diastolic blood pressure;
- proportion of identical blood pressure values in the two measurements performed;
- frequency with which the last digit occurs: 0,2,4,6,8 should have the same chance of occurring (20% each).

It is recommended to report the name of the measurer; it is useful to check mean values and standard deviations of single parameters measured; if standard deviation is too much different from the team average, the procedure for blood pressure measurement should be checked and, if necessary, explained again.

**External quality assessment (EQA)**

Data obtained from the OEC/HES 2008-2012 are assessed by the EHES Reference Centre (RC). The EHES RC is responsible for reviewing the version of the OEC/HES 2008-2012 national manual and assessing survey and quality control procedures through the site visit. External laboratory quality performance is also assessed by the RC.

**Evaluation of the achieved quality**

The evaluation of the OEC/HES 2008-2012 procedures used, data generated in the surveys and data and information generated through external controls are evaluated by the RC, with the help of the national survey coordinator and organizers. The report of the site visit held from the EHES –RC at Brescia on May 24-25 2011, is available.
9. DATA MANAGEMENT

Planning of the data management should be part of the general planning of the survey from the beginning. Well-planned data management facilitates good quality and availability of the data for analysis. Data management ensures that the data recorded during the fieldwork are available for analyses, and that the available data are complete (no data collected from the participants are lost), correct and verifiable (the relationship between the original data collected and data in the final data storage can be described). In this way the data analyses will be done using the correct data, the analyses will be done without errors and documented properly, so the whole analysis can be repeated later. Data management includes also the security of the data storage.

A detailed plan for the data management including all phases of the survey (sample selection and recruitment; appointment scheduling; survey data collection; recording the laboratory and exams; error checking, corrections, and documentation of the data; data transfer and storage) has been created at the beginning of the OEC/HES 2008-2012.

A central database has been developed to store separately personal data and data on measurements; they are maintained in the National Institute of Health (ISS).

Subject identification

In the OEC/HES 2008-2012, every participant in the survey is identified using the serial number which includes the code identifying the region, the code identifying the centre and the code identifying the subject. It does not include sensitive information which make possible to identify the person (sex, date of birth, or fiscal code). The code identifies the region goes from 01 to 20 (in Italy there are 20 regions); the code identifies the centre goes from 101 to 122 and is consecutive to the time of the survey (in two regions two samples are enrolled one in Noale - Veneto – and the other in Torino – Piemonte); the codes identifies the subject is consecutive with the presentation of the person at the screening centre and varies from 1 to 220 or more depending on the number of participants in each centre. Identification of the eligible persons is not available for OEC/HES 2008-2012, but documentation on non-respondents, not resolved or not eligible are available at the ISS. Information on not respondent are recorded by the local staff, when the eligible persons call the screening centre (usually a nurse involved in the fieldwork has this task) to confirm or change or refuse the appointment. These
information are coded by the central staff using the classification suggested by the EHES and input in the file of *Anagrafe*; this file correspond to the eligible list of participants extracted following the procedures described in chapter 5; due to the sensitive data (it includes name, surname, data of birth, sex, address) this file is available only in one computer and accessible only to one person with a password. A copy of that file is available at the storage backup device; in that file is recorded the participation status (respondent or non respondent) and eventually the reason for non participation. The number and type of contact attempts (1\textsuperscript{st} letter, 2\textsuperscript{nd} letter, phone call) is a useful information to record, but not includel in the OEC/HES 2008-2012 survey.

**Sample selection, recruitment and appointment scheduling**

A file with the appointment schedule is send to the centres at the beginning of the screening: for each day of the screening the list of the participants (name, surname, place and data of birth, address) with the day and time of the appointment for the examination. In the invitation letter indicates the day and the time of the appointment for the examination; moreover the name, the phone and time to call the nurse is indicated to confirm the appointment. This is important to take the note of the number of appointments per day; for example if the subject is unable to participate at the screening in the day scheduled he/she can changes to a more convenient date and time during the screening period. Regarding the future surveys it might be important to keep a record of change appointment times.

**Survey data**

Recording the survey measurements and getting data from different examination sites to the common database are essential part of the data management.

When the person is welcome to the screening centre and before signing the informed consent the following information are recorded:

- serial number assigned to every participant: this is unique and will be included in all the paper documents, laboratory tests and other exams of the participants (EKG, nutrition questionnaire, ADL-IADL questionnaire, spirometry, bone densitometry);
- anagraphical data (surname, name, married surname), checking that the anagraphical data reported in the appointment list are correct;
- fiscal code;
- sex;
- date and place of birth;
- country of birth (used as a proxy to evaluate immigration)
- address and home or mobile phone number (work, relative’s phone number, etc.)
- self-reported weight and height, flu vaccination.

Recording the survey measurements and getting data from different examination sites includes:

- self-administered questionnaires: ADL-IADL in the OEC/HES 2008-2012 are self-administered and input in the software of database later, usually in the afternoon after the screening;
- interview: the OEC/HES 2008-2012 interview is a computer assisted data collection; this way reduces the number of manual data transfer and facilitates data checking at early stage;
- recording the values of physical measurements: in the OEC/HES 2008-2012 values of vital capacity and forced expiratory volume in one second from spirometry; stiffness, t-score and z-score from bone densitometry are input in the database by the result sheet, usually in the afternoon after the screening;
- recording the laboratory results: in the OEC/HES 2008-2012, total and HDL- cholesterol, fasting blood glucose and hemocrome are assayed at local level; these laboratory tests are input in the software of the database usually in the afternoon after the screening;
- recording the number of the paillettes of serum, plasma, buffy coat prepared in the laboratory and the identification number of the biological sample; this number is different from the serial number of the subject, it correspond with the serial number of the biological specimen bank;
- recording the quantity of 24hour urine collection; when the participant come back to the screening centre to give the container with 24hour urine, the nurse control the quantity of the urine and input the data in the software of the database and stores 4 tubes in the freezer.

The inclusion in the database software of the physical measurements and of the laboratory tests allows to prepare the result-sheet for the participant. All the important results (blood pressure, height, weight, hip, waist, body mass index, spirometry, bone densitometry, cardiovascular risk) are printed and give to the participant when he/she comes back to the screening centre with the 24-hour urine collection.
Usually at the end of the screening the centralized laboratory send to the ISS the laboratory results, the identification number correspond to the serial number of the biological specimen bank.

The self-reported diet questionnaire is centralized coded and by optical read getting in electronic format.

Errors and incompleteness of the records are prevented by routine checking of the forms and the data by the staff. For relevant data not obtained by the subject a specific code is used. To prevent loss of records, the subject identification code is recorded at all stages and also laboratory samples are labelled with bar codes with a reference to the subject identification code.

In the OEC/HES, a computer-assisted data collection is used. Each collaborating centre is provided with the ‘CuoreOEC’ software to collect data from face-to-face questionnaire on health status. The software is segmented into several independent sections, one for each questionnaire topic, and allows users to insert all information about blood pressure, anthropometric measurements, bone densitometry, spirometry and laboratory analyses on a daily basis. At the end of each section, the software alerts user of missing or incomplete data before saving information, therefore data incompleteness is avoided. The first page of the software is completed during welcome of participants and includes name of the region and of the municipality, date of examination, anagraphical data, identification code, address, telephone, fiscal code and self-reported weight and height values. Anagraphical data, identification code and date of examination appear on each page of the software.

After the end of each regional screening, information collected through the computerized questionnaire are also stored on an external hard drive.

Some information (personal data, weight and height measurement, waist and hip measurement, self reported height and weight, blood pressure measurement, room temperature, hours of fasting, level of total, HDL cholesterol, glycaemia) are also collected in a paper form.

**Error checking, correction and documentation of the data**

Mean, standard deviation, minimum and maximum and frequency distribution of every continuous variable are calculated and compared with standard values. Frequency distribution
of every categorical variable is calculated and compared with standard values as well.
The paper form is checked if a value is found to be out of standard interval or internal to the
standard interval but close to the lower bound or upper bound. If the variable is not included
in the paper form the plausibility of the value is checked evaluating linked variables, e.g.,
weight is checked evaluating height, waist and hip circumference. When evaluation regards
laboratory determinations the centralized laboratory is also contacted.
When the value is recognized as not acceptable is recorded as missing value.
The SAS Software through a syntax saved in a file is used to document data management
quality controls and all modification of the database.

**Transfer and storage of the data**

Computerized data are stored on an external hard drive from which data are further
transferred into the central OEC/HES 2008-2012 database. Collected data, protected by two
different passwords, can only be accessed by the researcher responsible of the database in
order to prevent disclosure of information to unauthorized individuals. The access to
information is done only through proper identification and authentication of the user. The
database does not include personal data but only the personal identification number.
Individual records are kept anonymized in a protected file, separate from that which includes
names or other information that could be used to identify the participant. The information
connecting survey data to personal identification of the subject is available only to persons
authorized to have access to such data.
Detailed information on data transfer and confidentiality can be found at Chapter 4 of this
manual ‘Legal, ethical and data confidentiality issues’.

The ‘CuoreOEC’ software offers also data backup, which is usually performed on a daily
basis to prevent accidental loss of data.
10. SELECTED MEASUREMENTS

HES collect data through physical and clinical measurements, questionnaires and analysis of biological samples. This chapter outlines these measurements, the importance and rationale of them. Measurements have been divided into core and additional measurements. Core measurements are a minimum set of measurements which should be included. When more funding are available and information are needed, additional measurements can be added.

Criteria for selecting the measurements

The selected measurements should be based on objectives of the survey and research questions as well as analysis plan. It is important to review each measurement carefully to make sure that they are really needed and that they provide required valid information for selected indicators. One measurement may contribute to several indicators. As a guideline for selecting the measurement the criteria in the next table should be used. The EHES core measurements meet these criteria, but also the additional measurements have been evaluated against them.

Criteria for selecting the measurements for HES

<table>
<thead>
<tr>
<th>The criteria for selecting the measurements</th>
<th>Rationale and importance of the criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of international standards</td>
<td>Internationally standardized measurement protocols are recommended to be used when ever possible; this ensures comparability of the results between countries and in time.</td>
</tr>
<tr>
<td>Clear interpretation of the results</td>
<td>The measurements need to reliable.</td>
</tr>
<tr>
<td>Practicality, easy to administrate</td>
<td>The measurements need to be feasible at population level.</td>
</tr>
<tr>
<td>Interesting for participants</td>
<td>It is recommended to have at last one measurement that motivates people to take part. This may increase the participation rate. Personal results can also be interpreted and used to estimate needs for care and preventive activities for the individual.</td>
</tr>
<tr>
<td>Acceptability to the participant</td>
<td>The selected measurements should not be too time consuming, causing extra burden, pain or discomfort for the participants.</td>
</tr>
<tr>
<td>Ethical acceptability</td>
<td>Measurements have to be ethically approved and safe for the participants, as well as accepted by health care professionals. If</td>
</tr>
</tbody>
</table>
deviations from normal values are identified, access to care and preventive activities needs to be assured.

<table>
<thead>
<tr>
<th>Costs</th>
<th>Costs of measurements and available funds need to be in balance. Selecting one expensive measurement may drop out several cheaper ones.</th>
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</thead>
<tbody>
<tr>
<td>Public health importance</td>
<td>Selected measurements should address key public health problems.</td>
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</table>

**The core measurements**

The core EHES physical and clinical measurements, analyses of blood samples and questionnaire items, collect data mainly on major chronic diseases (e.g. cardiovascular diseases and diabetes), and their risk factors (e.g. obesity, high blood pressure and high serum cholesterol) which are preventable at both individual and community level.

Physical measurements are needed because self-reported data is not sufficiently reliable to follow population level trends or to make comparisons between populations. These selected measurements are also the ones that have been measured in previous national HESs conducted in Europe.

The core physical measurements are: height, weight, waist circumference, blood pressure.

Body Mass Index (BMI) is a widely used indicator of obesity. It is defined as body weight divided by the square of height. The increase of obesity and overweight among the population is one of the most important public health issues in developed countries. Overweight and obesity represent a high risk factor for diseases of the circulatory system, diabetes and other chronic diseases.

Waist circumference is used as an indicator of abdominal obesity. Since increasing evidence has shown that waist circumference reflects the accumulation of visceral fat better than waist-to-hip ratio, the waist circumference is the preferred measure in population studies.

Measuring blood pressure gives a prevalence of actual and potential hypertension. Single-occasion blood pressure measurement has been shown to be a strong indicator of coronary and cerebrovascular risk. However, the diagnosis of hypertension requires follow-up and observed high blood pressure on several occasions.
The EHES surveys include the collection and analysis of biological samples. The core blood samples are: non-fasting blood for total and HDL cholesterol and fasting blood sample (8-14 hours) for glucose.

High serum total and HDL cholesterol are major risk factors of cardiovascular diseases. Increased glucose level in blood may indicate insulin deficiency or insulin resistance which indicates risk for diabetes. Because of potential difficulties in requiring fasting from all participants, the glucose may cover only a sub-sample of the survey. It should be noticed that the fasting should not last more than 14 hours.

The EHES core questions are mostly questions that are necessary for the reporting and interpretation of the data from the physical measurements and biological samples. Whenever possible, the EHIS (European Health Interview Survey) questions should be used.

The EHES core questionnaire includes questions on household size, sex, age, marital status, socioeconomic status, height and weight, general health, chronic diseases, use of medication, smoking.

Age and sex enable reporting of the HES results by sex and age group and the age-adjustment of the results for comparison between populations. Education, occupation and household income are needed for the estimation of socioeconomic differences in the population.

Asking height and weight also enables to estimate the differences of measured and self-reported height and weight between the countries, and by sex, age and socio-economic status.

The three questions on general health form the Minimum European Health Module (MEHM), which is expected to be included in all European social and health surveys, in order to link results among surveys according to these standard health characteristics of the population. The structural indicator Healthy Life Years is calculated on the basis of questions of MEHM. More generally the three questions are used for the calculation of the prevalence of perceived health, self-reported longstanding illnesses or health problems and long-term activity limitations.

The questions on chronic diseases measure the main public health concerns, which are also a major reason for using the health care services. Measuring chronic morbidity is useful for
overall evaluation of health and health status. It is also useful for the study of health care systems in terms of evaluation, policy formulation and assessment of need for health care. The answers to the questions on specific diseases are needed from the same person as the physical measurements are taken. For example, the question on use of medication on hypertension is commonly combined with the results of blood pressure measurement to see how well hypertension is treated and controlled in the population. Also, the cholesterol and glucose levels in blood are often combined with the related questions.

Smoking is an important factor for lung diseases and cancer, other cancers and diseases of the circulatory system. Lung, trachea and larynx cancer is the type of cancer with the higher standardized death rate among men in EU. In addition, important policy activities are developed in order to limit tobacco consumption.

**Additional measurements**

In addition to the core measurements other physical measurements and questions may be included. When choosing the additional measurements, the criteria shown in the table should be kept in mind. Additional measurements can be added to the survey as modules that are relevant for example to specific subgroups of the population, such as certain age groups, ethnic groups or other sub-populations of regional/local interest.

When selecting additional measurements, their implications to the survey administration, the time taken for training, by administrating the questionnaire and carrying out the physical measurements, the costs and the periodicity of the survey should be considered. If the survey will be repeated frequently, different additional modules can be considered for each round of data collection. When the survey will be carried out less frequently, it may be feasible to build a more comprehensive survey covering several health topics. There is a commonly used target that the physical/clinical measurements should be limited to take one hour. Some evidence suggests that longer surveys are less acceptable to respondents. But there are also experiences where a more comprehensive survey with long examinations has been attractive to the participants as it gives more information on their own health.

Although the following measurements have been performed in the majority of centres participating in the OEC/HES 2008-2012, we include the following among additional
measurements as not considered as core measurements in the EHES: hip circumference, lung function test, carbon monoxide assessment, ECG, bone densitometry, 24-hour urine collection, diet and physical activity questionnaire, family history for cardiovascular diseases; they have been added with the following rationale:

- assessment of trend of some diseases. On the basis of the rich tradition of epidemiological studies of cardiovascular diseases and the experience in ECG reading through Minnesota code we have decided to include an ECG at rest to assess the prevalence of some conditions, such as left ventricular hypertrophy, atrial fibrillation and ischemic cardiopathy;
- assessment of some indicators of respiratory function, such as the Forced Vital Capacity and Forced Expiratory Volume in 1 Second;
- assessment of carbon monoxide exposure (cigarette smoke, chimneys, etc…);
- assessment of calcium in bones through bone densitometry;
- diet in order to evaluate food consumption, daily intake of food items, food groups and nutrients.

The EPIC food frequency self-administered questionnaire is used; the same questionnaire is administered to the participants enrolled in the cancer epidemiological studies.

The introduction of these additional measurements aims also at increasing participation rate. After the launch of salt reduction campaign and the agreement with bread makers, the 24-hour urine collection has been introduced to monitor the consumption of sodium and potassium in the general population.

All procedures and methodologies used follow international recommendations and quality controls.

Biological samples (serum, plasma, buffy coat and packed, blood cells, urine) are stored at the biological bank of the CNESPS of the ISS for a minimum period of 30 years, which is the minimum time period for the development of a consistent number of cerebro and cardiovascular events necessary to study the association between risk factors and cardiovascular disease and follow disease trend.
11. NON-PARTICIPANT INFORMATION

In order to assess the non-participation bias, it is important to collect information on non-participants to evaluate potential biases in estimates. This is important even when the participation rate is high, it is important to collect information on non-participants to evaluate potential biases in estimates. This may be done through a questionnaire to be sent to non-participants to collect information on reasons behind refusal and health condition. If it is not possible to send the questionnaire, at least follow-up of mortality is recommended. Some key information such as age, sex, and some aspects of social status can be obtained from the sampling frame.

Data to be recorded

For each person invited to participate in the OEC/HES, number and type of contact attempts is recorded. If contacted, it is recorded if the person participated, refused or dropped out after having agreed to participate. Information on completed and not completed examinations is recorded. Reasons behind refusal should be recorded.

Reasons for non-participation should be recorded as follows:

- *Refused*: no reason given
- *Refused*: lack of time
- *Refused*: personal principle
- *Refused*: health problem (e.g. disability restricting access to the examination site or is hospitalised)
- *Refused*: feeling healthy (therefore thinks that there is no reason to participate)
- *Contacted*: not able to schedule an appointment (e.g. participant could only attend during evening hours or week ends)
- *Contacted*: no show (does not come to the scheduled visit, and the visit cannot be re-scheduled)
- *Not contacted*: not reached (no address/phone number available, outdated information)
- *Not eligible*: moved abroad (not known at the address; the letter was back to the sender)
- *Not eligible*: age out of survey range
- *Temporarily unavailable*: e.g. holiday
- *Language problems*
- *Not eligible*: died

- *Impossible to examine* for other reason (this reason should be specified, if feasible)
12. SELECTING THE EXAMINATION SITE

The selection of the survey site has to be based on general requirements, national practices and cultural factors. It is one of the key steps in implementing a survey, as it may positively affect the quality of data collected and participation rate.

Requirements for examination site
Potential examination site are:
- Participant’s home;
- Temporary examination site outside health care organizations, for example school premises;
- Examination site within existing health care premises, such as a health centre or GP office (with the regular staff allowed to use the premises);
- Mobile examination site, for instance a bus equipped for examination.

All examination sites have their advantages and disadvantages

<table>
<thead>
<tr>
<th></th>
<th>Participant’s home</th>
<th>Temporary examination site</th>
<th>Examination site within existing health care premises</th>
<th>Mobile examination site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Access by participants</td>
<td>Easy access</td>
<td>Requires effort</td>
<td>Requires effort</td>
<td>May be easy if mobile examination site can be taken close to the participants</td>
</tr>
<tr>
<td>Cost for participants</td>
<td>None</td>
<td>Travel costs</td>
<td>Travel costs</td>
<td>Some travel costs</td>
</tr>
<tr>
<td>Environment</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atmosphere</td>
<td>Relaxed</td>
<td>Some tension</td>
<td>Some or a lot of tension</td>
<td>Some tension</td>
</tr>
<tr>
<td>Privacy</td>
<td>Limited privacy if other family members at home</td>
<td>Can be controlled</td>
<td>Can be controlled</td>
<td>Can be controlled</td>
</tr>
<tr>
<td>Temperature</td>
<td>Cannot be controlled by the survey team</td>
<td>Can usually be controlled</td>
<td>Can usually be controlled</td>
<td>Can be controlled</td>
</tr>
<tr>
<td>Quietness</td>
<td>Cannot be controlled by the survey team</td>
<td>Can usually be controlled</td>
<td>Can usually be controlled</td>
<td>Can be controlled</td>
</tr>
<tr>
<td>Safety of the field work staff</td>
<td>Limited and cannot be controlled</td>
<td>Can be controlled</td>
<td>Can be controlled</td>
<td>Can be controlled</td>
</tr>
<tr>
<td>Travel cost of field work staff</td>
<td>Expensive</td>
<td>Some</td>
<td>Some</td>
<td>Some</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------</td>
<td>------</td>
<td>------</td>
<td>------</td>
</tr>
<tr>
<td>Traveling for field work staff</td>
<td>Lot of traveling</td>
<td>Some</td>
<td>Some</td>
<td>Some</td>
</tr>
<tr>
<td>Restriction to measurements</td>
<td>Only measurements for which devices can be transported easily and which do not have specific environmental requirements</td>
<td>Generally none</td>
<td>Generally none</td>
<td>Generally none, sometimes a lack of facilities for specific measurements may come up (e.g. limited space)</td>
</tr>
<tr>
<td>Calibration/standardization of the measurements</td>
<td>Difficult</td>
<td>Can be done</td>
<td>Can be done (but if used equipment of health care centre, standardization and calibration may be difficult)</td>
<td>Can be done</td>
</tr>
<tr>
<td>Acceptability</td>
<td>Some people are not willing to let the survey team into their home</td>
<td>Generally accepted</td>
<td>In some countries may not be highly valued among some people</td>
<td>Generally accepted</td>
</tr>
<tr>
<td>Time and cost for setting up an examination site</td>
<td>Minimal</td>
<td>Time consuming</td>
<td>Takes some time (depends on used equipment, if equipment from the health centre are used, careful calibration before fieldwork is needed, otherwise like temporary examination site)</td>
<td>Time consuming and costly</td>
</tr>
<tr>
<td>Cost of the maintenance of the examination site</td>
<td>None</td>
<td>Some costs</td>
<td>Some costs (depends on agreements with the local health care administration)</td>
<td>Costly</td>
</tr>
</tbody>
</table>

In the ongoing OEC/HES, one centre (municipality) for each region is selected, for a total of twenty centres, also in demographically smaller regions with less than 1.5 million residents. Within each region the centre is selected within existing health care premises only if it meets the general requirements reported in the study protocol and manual of operations and necessary to implement the screening procedures.
Once the centre has been selected, the sample is stratified by age and sex and is randomly selected from the list of residents. Only in regions where the sample to examine is too large (e.g. Lombardy), the survey is conducted in two centres.

To be eligible to participate in the OEC/HES, each centre should meet the following requirements:

- easy access to local registry office for sample selection;
- availability of local premises (not necessarily an hospital) and local survey personnel, possibly nurses and secretaries, to support fieldwork activities (prepare letters of invitation, arrange telephone calls to invite recruited persons, schedule appointments, welcome participants, perform laboratory measurements and interviews, enter data, communicate results to the examinees);
- availability of local medical personnel for reading electrocardiogram (ECG) and for preparing laboratory and other responses to be communicated to the examinees;
- availability of well-equipped rooms, in particular: a big room where participants are welcomed and wait for interview/examinations; a relaxed room for questionnaires administration; a quiet room with comfortable temperature for performing blood pressure measurement; a room for performing ECG, anthropometric measurements, bone densitometry, spirometry and CO measurement; a room for blood collection and laboratory tests, with sufficient energy for freezers and centrifuge.
- availability of a centrifuge, a vortex and a big container for special waste collection;
- availability of a -30°C freezer for blood samples storage;
- materials for blood collection: vacutainers for serum, plasma and buffy coat with EDTA, needles and a small container for special waste collection.

The ISS provides the instruments necessary to perform measurements. In particular: mercury sphygmomanometer with stethoscope; balanced beam scale, statimeter or wall height rule and measuring tape; containers for 24-hour urine collection and urine storage tubes; paillettes filling machine, paillettes, visotube, glasses; bone densitometer; spirometer; electrocardiographer; carbon monoxide (CO) measuring instrument; chronometer; thermometer to measure ambient temperature.

In the OEC/HES, a mobile examination site does not exist, therefore the examination site is selected within existing local health care premises.
In selecting the examination site, also the following issues should be considered:
- participants should have easy access to the examination site, which therefore should be near the participants’ workplace or residence. Especially in urban areas, transportation is not easy and people are not necessarily willing to travel to another side of the city, but in rural areas longer distances can be considered acceptable. In addition, the OEC/HES does not foresee reimbursement of travel costs afforded by participants. In the city of Rome, to obviate to transportation problems, the sample was extracted in the district of the screening centre (S. Giovanni hospital);
- the availability of public or in another way organized transportation to the examination site needs to be assured;
- access of participants with limited functional ability (e.g. those using a wheelchair);
- the examination site should be near a hospital or a laboratory to allow for blood sample storage and analyses.

The only way to be sure that the examination site is suitable for carrying out physical measurements is to visit the place before selecting it. This requires adequate time and personnel resources during survey preparation.
13. QUESTIONNAIRE AND ITS ADMINISTRATION AND VALIDATION

This chapter considers issues that need to be taken into account when preparing the questionnaire and planning the questionnaire administration.

The questionnaire design has impact on participation rate and validity of the obtained data. Language, wording of the questions, selection of the response alternatives, formulation of sensitive questions, recall bias, order of questions, jump rules and the length of the questionnaire are the main elements of questionnaire design.

The proper wording of the questions is essential; the questions should be simple and straightforward. This ensures that respondent understands the questions correctly. When formulating the questions the effort must be devoted to avoiding ambiguity in the wording. Professional or highly technical terms, slang, abbreviations or words which may be considered as insulting should be avoided. In each question only one thing should be asked. All the questions should be available in the native language of respondent. This permits to have the same version of the questionnaire available in different languages. When formulating the questions it is good to remember that people tend to forget events and it is usually easier to remember things that happened recently.

The order of the questions in the questionnaire is also important: a poorly organized questionnaire may confuse respondent, bias the responses, has an effect on response rate, as well as willingness to answer sensitive questions; all the questions should be grouped by the topic, this makes answering easier. The length of the questionnaire affects response rate as well as reliability of the data. A short questionnaire increases the response rate but may lack important questions for the indicators; the ideal length for a self-administered questionnaire is 15 minutes and for the face-to-face interview 30 minutes.

Survey questionnaires can be filled in either by the respondent or by an interviewer, both have advantages and disadvantages; the questionnaire administration mode may affect participation rate and the accuracy and reliability of the responses. Self-administration of the questionnaire is cost effective but assumes that participants are not visually impaired and have a good literacy level; in paper forms it requires separate data entry. Interviews are time consuming and carry additional personnel costs, but they eliminate the issues of literacy level and visual impairment and they provide an opportunity for clarifying the questions if needed.
In the HES data collection, proxy use during the interviews is only allowed when the selected person him/herself is unable to respond due to major limitations in communication skills and/or cognitive ability. The reason for proxy use and type of proxy should always be recorded.

**OEC/HES Questionnaire (adopted in Italy in 1998-2002 and 2008-2012)**

This questionnaire include face-to-face ‘core’ questions and data on physical measurements and biological samples.

The core questionnaire includes the majority of EHES ‘core questions’. Only some questions (educational level; job; monthly income; diseases diagnosed by a physician; prescribed medications; passive smoking) differ slightly from the EHES ones. During the Italian HES, a screening conducted in Noale (Veneto) and Torino (Piemonte) demonstrated that there are no great differences in answers when administrating both questionnaires.

Questions are closed-ended, except those investigating current or past (for persons in retirement) job, preferred brand of cigarette, medications for hypertension, hypercholesterol, diabetes and other conditions.

The questionnaire is available in electronic version and includes different independent sections. A specific software to collect data from questionnaire is available. The software is segmented into several independent sections, one for each questionnaire topic, and allows
users to insert all information about blood pressure, anthropometric measures, bone densitometry, spirometry and laboratory analyses on a daily basis. The software is designed to check data quality, therefore data inconsistencies are not allowed. At the end of each section, the software alerts user of missing or incomplete data before saving information. Anagraphical data, identification code and date of examination appear on each page of the software. After the inclusion of all data and examinations results, the software permits to print the cardiovascular risk score (“Print the risk score”) or, alternatively, the CUORE Project risk chart (“Print the CUORE chart”), depending on the availability of the HDL-cholesterol value. The risk score can be printed only for participants aged 35-69 years free from cardiovascular events. All participants are provided with a printed copy of results of all instrumental and laboratory examinations (“Print patient data”). The software offers also data backup, which should be performed on a daily basis.

Here below the questionnaire is reported; in italic the rational behind the question

**ANAGRAPHICAL DATA**

Anagraphical data, address, home phone number, country of birth (which can be used as a proxy to evaluate migration) and fiscal code (corresponding to the National Sanitary Service identification code) are recorded.

Region

Examination centre

Examination date

Identification number

Surname .............................................................. ................................................... ..............

Name ..................................................................................................................

Married surname (if married or widow) .............................................................

Fiscal code .............................................................. ................................................... ..............

Sex M F

Date of birth day month year
Place of birth: nation of birth and city of birth.

Address
Telephone
Self-reported height
Self-reported weight

Even though height and weight will be also measured in HES they should also be asked. Asking height and weight also enables the comparisons of the measured and self-reported height and weight at the European HIS. These data are also used by the National Institute of Statistics (ISTAT) to validate anthropometric data collected through their Health Interview Survey.

Do you usually undergo annual flu vaccination? ...................... YES | YES NO |
Have you undergone it in the year 2010/2011? ....................... YES | YES NO |

Participants are also asked if they usually undergo flu vaccination and if they have been vaccinated against the last flu (2010-2011); this information was added recently to evaluate the association with the cardiovascular diseases as recently demonstrated

WHAT IS YOUR MARITAL STATUS?
1. single
2. married/cohabitant
3. separated/divorced |
4. widowed
5. other
6. other
9. insufficient data

HOW MANY PERSONS OLDER THAN 18 YEARS LIVE IN THE HOUSEHOLD (INCLUDING YOURSELF)?
| PERSONS
This information is used, together with education level and type of job, to define socio-economic position. Usually, in low-income families, children tend to stay at home as they can’t find a job.

WHAT IS YOUR HIGHEST EDUCATION DEGREE YOU HAVE OBTAINED?
1. university degree
2. upper secondary education
3. lower secondary education
4. primary education
9. insufficient data

Highest level of education completed means level successfully completed and must be associated with obtaining a certificate or diploma. Persons who have not completed their studies should be coded according to the highest level they have completed (e.g., if upper secondary school diploma was not obtained, the lower secondary school licence should be reported). The category ‘university degree’ includes the traditional four-year university course but also the other university courses lasting less than 4 years and the diploma obtained after specialized upper secondary schools (e.g. dietician, social assistant, sanitary assistant). The primary certificate includes also the years of primary schools (e.g. third year) even if the licence is not obtained.

HOW MANY YEARS HAVE YOU SPENT AT SCHOOL OR IN FULL-TIME STUDY?
[ ] years

WHAT IS YOUR CURRENT JOB? ........................................................................................................
ILO CODE [ ]
If codes 1 = student, 7 = housewife, 9 = unemployed, 10 = retired, 23 = disabled person, 24 = temporary lay-off or in the mobility list
Occupation is coded following the ILO coding system of 1968, reviewed and updated, which is the most commonly used in Italian longitudinal studies and can be converted into that used in MONICA and MORGAM studies.

For housewives or women in retirement:
DO YOU USUALLY FULFILL DOMESTIC TASKS?
1. No
2. Yes, but only light domestic tasks
3. Yes, all tasks, including the heavy one (e.g., doing the laundry, scrubbing the floors, washing windows etc.)

If in retirement
WHAT WAS YOUR JOB?
describe the job
ILO code NO.

BLOOD PRESSURE AND ANTHROPOMETRIC MEASUREMENTS

1st MEASUREMENT OF THE ARTERIAL BLOOD PRESSURE AND PULSE RATE
SYSTOLIC, mm Hg
DIASTOLIC, V phase di Korotkoff, mm Hg
PULSE RATE, 1 min
Time of blood pressure measurement

2nd MEASUREMENT OF THE ARTERIAL BLOOD PRESSURE
SYSTOLIC, mm Hg
DIASTOLIC, V phase, mm Hg

3rd MEASUREMENT OF THE ARTERIAL BLOOD PRESSURE
SYSTOLIC, mm Hg
DIASTOLIC, V phase, mm Hg

RIGHT ARM CIRCUMFERENCE, cm
(in cm, rounding down decimals to nearest 0 or 5)

Type of cuff used 1 = adult normal 2 = obese
Room temperature

Hours of fasting before blood drawing

HEIGHT, in cm, rounding to the nearest value
WEIGHT, in kg and hectograms, rounding to 200 grams

WAIST CIRCUMFERENCE, in cm,
(rounding decimals to the nearest 0 or 5)

HIP CIRCUMFERENCE, in cm,
(rounding decimals to the nearest 0 or 5)

CARBON MONOXIDE, p/mil

PHYSICAL ACTIVITY
This section includes a set of questions on physical activity at work and during leisure time.
The section on physical activity includes three questions investigating on:
1. current job or past job for those who do no longer work (in retirement, on income support, unemployed, disabled);
2. stress at work (for those in retirement, data are referred to the past job period);
3. physical activity during leisure time (for all interviewed data are referred to the current period).
The questions foresee four different answers regarding type, duration and intensity of physical activity. The interviewed person can choose the answer which explains better his/her physical activity at work and during leisure time and his/her condition of stress.
For housewives, fulfilling domestic tasks is considered physical activity at work; for women who have a job, fulfilling domestic tasks is considered physical activity during leisure time.

A. If currently employed
WHAT IS THE PHYSICAL ACTIVITY DERIVING FROM YOUR JOB? choose an answer by referring to the main job or activity
1. work done mainly sitting at a desk and generally without the need to walk
2. work that implies standing and walking for a long time, but does not oblige to carry or move heavy weights (this answer also includes normal housework, except hard work)
3. work that implies a lot of walking and handling heavy weights (this answer also includes regular hard housework, such as doing the laundry, scrubbing the floors manually)
4. hard manual work, with great efforts and lifting and handling heavy weights.
HOW LONG HAVE YOU BEEN DOING THIS JOB?   [ ] [ ] [ ]

B. If retired or unemployed or disabled person or temporary lay-off
WHAT WAS THE PHYSICAL ACTIVITY DERIVING FROM YOUR JOB IN THE PAST?
1. work done mainly sitting at a desk and generally without the need to walk
2. work that implies standing and walking for a long time, but does not oblige to carry or move heavy weights (this answer also includes normal housework, except hard work)
3. work that implies a lot of walking and handling heavy weights (this answer also includes regular hard housework, such as doing the laundry, scrubbing the floors manually)
4. hard manual work, with great efforts and lifting and handling heavy weights.

HOW LONG HAD YOU BEEN DOING THIS JOB?   [ ] [ ] [ ]

ARE YOU UNDER STRESS WHILE WORKING?
Reply is needed also for the categories without income — housewives, students — retired persons should refer to the previous activities; reply is not required only if you have never worked

1. work with little responsibility and without stress, lack of tension
2. an easy job, but with a state of stress and highly emotional
3. work implying responsibility and continuous deadlines with work stress
4. no job satisfaction and/or a sense of being unable to face problems, family worries

WHAT IS YOUR PHYSICAL ACTIVITY DURING YOUR LEISURE TIME? Choose an answer that describes a situation that has persisted for 6 months
1. usually you read, watch television, go to the movies or spend your leisure time in other sedentary activities
2. you walk, ride a bicycle or do some kind of physical activity for at least 4 hours a week. Indicate if you don’t do anything more tiring than going to work on foot or by bicycle, or gardening, if you go hunting or fishing, if you play ping-pong
3. you do sports as a hobby, such as running, swimming, tennis, gymnastics, or you do hard work in the garden or at home or other similar efforts (this is valid if this activity is carried
out at least 3 times a week)

4. you train regularly or you play sport professionally such as athletics, skiing, swimming, football, basketball, tennis, several times a week

**SMOKING HABIT**

This is a detailed section. Cigarette smoking history and habit are recorded for both smokers and past smokers; passive smoking among non-smokers is also investigated. Current smokers are subdivided into occasional smokers smoking less than 28 cigarettes/month, occasional smokers smoking more than 28 cigarettes/month, and regular smokers.

**DO YOU SMOKE?**

YES, REGULARLY fill in section A

NO fill in section B

OCCASIONALLY less than a cigarette per day, fill in section C

INSUFFICIENT DATA use this answer only in special cases (e.g. the subject leaves before completing the questionnaire) because this prevents filling in the remaining parts of the questionnaire on smoking and it is necessary to go to next section

**IF YOU SMOKE ONLY PIPE OR SIGARS GO TO SECTION D**

**SECTION A : for those who smoke regularly**

HOW MANY CIGARETTES DO YOU SMOKE ON AVERAGE EVERY DAY?

|  ||  |

DO YOU INHALE SMOKE?

|  | YES  |  | NO

DO YOU SMOKE FILTER CIGARETTES?

|  | YES  |  | NO

WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE? _________________

WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?

0.5 cm

1 cm

|  cm

2 cm

3 cm
WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

\[\text{\_\_\_\_\_\_}\]

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?

\[\text{\_\_\_\_\_\_}\]

HOW LONG HAVE YOU BEEN SMOKING AS YOU DO NOW? \[\text{\_\_\_\_\_\_} \text{\_\_\_\_\_\_}\] years

WOULD YOU LIKE TO STOP SMOKING?

\[\text{YES} \quad \text{NO}\]

HAVE YOU EVER TRIED TO STOP SMOKING?

\[\text{YES} \quad \text{NO}\]

If yes how long have you been without smoking?

\[\text{\_\_\_\_\_\_} \text{\_\_\_\_\_\_] years} \quad \text{\_\_\_\_\_\_] months \text{\_\_\_\_\_\_}\]

OVERALL, HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? \text{sum up the partial periods}

\[\text{\_\_\_\_\_\_} \text{\_\_\_\_\_\_} \text{\_\_\_\_\_\_] years}\]

Go to section D

SECTION B: for those who do not currently smoke

HAVE YOU EVER SMOKED CIGARETTES REGULARLY IN THE PAST?

\[\text{YES} \quad \text{fill in all this section} \quad \text{NO} \quad \text{Go to section D}\]

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

\[\text{\_\_\_\_\_\_}\]

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?

\[\text{\_\_\_\_\_\_}\]

WHEN DID YOU STOP SMOKING REGULARLY?

\[\text{\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_}\]
if in the last year, specify:
1 = less than one month
2 = between one and six months
3 = between six and twelve months
8 = for more than a year
BEFORE STOPPING REGULARLY, HAVE YOU GONE WITHOUT SMOKING FOR SOME TIME?
YES    NO
How long have you gone without smoking? *sum up the partial periods?* [ ] [ ]

*Go to section D*

**SECTION C: for those who smoke occasionally**

HOW MANY DAYS A WEEK DO YOU SMOKE CIGARETTES?
*from 1 to 6 or less than 1 day a week, code 1*

*NOTE: if a smoker smokes even only one cigarette a day, he is a regular smoker and needs to fill in section A*

[ ]

HOW MANY CIGARETTES DO YOU SMOKE ON AVERAGE EACH DAY YOU SMOKE?

*Calculate the number of cigarettes smoked in a week by multiplying the numbers of cigarettes smoked per day for the number of days: if its greater than 28, go to section CI*

[ ] [ ] [ ]

HAVE YOU EVER SMOKED CIGARETTES REGULARLY IN THE PAST?

YES    fill in all the questions of this section
NO    go to section C2

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

[ ] [ ] [ ]

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?
WHEN DID YOU STOP SMOKING REGULARLY?

if in the last year, specify:
1 = less than one month
2 = between one and six months
3 = between six and twelve months
8 = for more than a year

BEFORE STOPPING REGULARLY, HAVE YOU GONE WITHOUT SMOKING FOR SOME TIME?
YES [ ] NO [ ]

HOW LONG HAVE YOU GONE WITHOUT SMOKING? *sum up the partial periods*

go to section D

SECTION C1 : for those who smoke occasionally more than 28 cigarettes a week

DO YOU INHALE SMOKE? YES NO
DO YOU SMOKE FILTER CIGARETTES? YES NO
WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE? ...........................................
WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?
0,5 cm
1 cm
2 cm
3 cm
WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR? [ ]
HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTE REGULARLY? [ ]
HOW LONG HAVE YOU BEEN SMOKING?
<table>
<thead>
<tr>
<th>years</th>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>WOULD YOU LIKE TO STOP SMOKING?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>HAVE YOU EVER TRIED TO STOP SMOKING?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes HOW LONG HAVE YOU GONE WITHOUT SMOKING?

<table>
<thead>
<tr>
<th>years</th>
<th>months</th>
</tr>
</thead>
<tbody>
<tr>
<td>HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? sum up the partial periods</td>
<td></td>
</tr>
<tr>
<td>years</td>
<td></td>
</tr>
</tbody>
</table>

Go to section D

SECTION C2: for those who have always smoked occasionally

<table>
<thead>
<tr>
<th>YES</th>
<th>NO</th>
</tr>
</thead>
<tbody>
<tr>
<td>DO YOU INHALE SMOKE?</td>
<td></td>
</tr>
<tr>
<td>DO YOU SMOKE FILTER CIGARETTES?</td>
<td></td>
</tr>
<tr>
<td>WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE?</td>
<td></td>
</tr>
<tr>
<td>WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?</td>
<td></td>
</tr>
<tr>
<td>0,5 cm</td>
<td></td>
</tr>
<tr>
<td>1 cm</td>
<td></td>
</tr>
<tr>
<td>2 cm</td>
<td></td>
</tr>
<tr>
<td>3 cm</td>
<td></td>
</tr>
<tr>
<td>HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTE REGULARLY?</td>
<td></td>
</tr>
<tr>
<td>HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? sum up the partial periods</td>
<td></td>
</tr>
<tr>
<td>years</td>
<td></td>
</tr>
</tbody>
</table>

Go to section D

SECTION D: questions on cigars and cigarillos

| YES, currently on a regular basis |
| NO, never go to section E |
OCCASIONALLY, less than one per day
YES, only in the past go to section E
INSUFFICIENT DATA go to section E

HOW MANY CIGARS OR CIGARILLOS DO YOU SMOKE PER WEEK?  

In case of two values, insert the average value

SECTION E: questions on pipe

HAVE YOU EVER SMOKED A PIPE?

YES, currently on a regular basis
NO, never go to section F

OCCASIONALLY, less than one pipe bowl per day YES, only in the past go to section F
INSUFFICIENT DATA go to section F

HOW MANY GRAMS OF TOBACCO DO YOU SMOKE PER WEEK?  

a folding packet contains 50 g of tobacco

SECTION F: passive smoking

This section must be filled in only by those who do not currently smoke or smoke occasionally

HOW MANY HOURS ON AVERAGE A DAY ARE YOU EXPOSED TO PASSIVE SMOKING WITHIN CLOSE RANGE?

hours of exposition to passive smoking

9 insufficient data

ALCOHOL AND SALT CONSUMPTION

Daily or week consumption of wine, aperitifs or liquorous wine, strong drinks and the daily number of coffee (including cappuccino) are recorded.

DO YOU CURRENTLY DRINK WINE?

(000) no
(020) only 1 or two glasses per day
(050) about ½ litre per day
(100) about 1 litre
(150) about 1 ½ litre
(200) about 2 litres
(250) about 2 ½ litres
(300) about 3 litres
more than 3 litres (specify) ………………

HOW MANY APERITIFS AND/OR SPIRITS DO YOU DRINK PER DAY ON AVERAGE?
(00) none
(03) 1 or 3 per week
(07) from 3 to 5 per week
(11) from 6 to 7 per week
(24) from 1 to 3 per day
(48) more than 3 per day

HOW MUCH BEER DO YOU DRINK PER DAY ON AVERAGE?

(00) none
(15) about ½ litre
(30) about 1 litre
(60) more than 1 litre

HOW OFTEN DO YOU ADD SALT AT TABLE?
never or rarely
quite often
always or very often

HOW MUCH BREAD DO YOU EAT PER DAY?
Less than 3 slices or 3 small bread rolls
4-5 slices or 4-5 small bread rolls
More than 5 slices or 5 small bread rolls
I always eat no salt or low salt bread
HOW MANY TIMES A WEEK DO YOU EAT CHEESE, SAUSAGES OR SALAMI?
0-2 times
3-4 times
5 or more times

DO YOU USUALLY GET VERY THIRSTY, ESPECIALLY AFTER A MEAL?
never or rarely
quite often
always or very often

WHEN YOU EAT OUT, FOOD IS USUALLY PERCIEVED AS
insipid
normal
salty

ARTERIAL BLOOD PRESSURE AND HYPERTENSION
HAS ANY DOCTOR OR OTHER HEALTH WORKER TOLD YOU THAT YOUR
ARTERIAL BLOOD PRESSURE IS HIGH?
YES
NO go to section G
INSUFFICIENT DATA go to section G

OVER THE LAST TWO WEEKS, HAVE YOU TAKEN ANY MEDICINES
PRESCRIBED BY A DOCTOR TO LOWER YOUR BLOOD PRESSURE?
YES
NO go to section G
UNCERTAIN go to section G

HOW MANY TYPES OF MEDICINES DO YOU TAKE? 

MEDICINE 1
Name of the medicine .................................................................
Do you take it on a daily basis? YES NO
Number of pills a day | Number of pills a week |
MEDICINE 2
Name of the medicine .................................................................
Do you take it on a daily basis? YES | NO |
Number of pills a day | | Number of pills a week |

MEDICINE 3
Name of the medicine .................................................................
do you take it on a daily basis? YES | NO |
Number of pills a day | | Number of pills a week |

SECTION G------------------------------------------
WHEN WAS THE LAST TIME YOUR BLOOD PRESSURE WAS MEASUERED?
During the last 12 months
At least 1 year but less than 5 years ago |
5 years ago or more

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR BLOOD PRESSURE?
YES | NO | UNCERTAIN |

CHOLESTEROLAEMIA
HAVE YOU EVER BEEN TOLD BY A DOCTOR OR OTHER HEALTH WORKER THAT YOUR CHOLESTEROL LEVEL IS HIGH?
YES |
NO | go to section H
INSUFFICIENT DATA | go to section H

OVER THE LAST TWO WEEKS, HAVE YOU TAKEN ANY MEDICINES PRESCRIBED BY A DOCTOR TO LOWER YOUR CHOLESTEROL LEVEL?
YES |
NO | go to section H
UNCERTAIN | go to section H

HOW MANY TYPES OF MEDICINES DID YOU TAKE? |

MEDICINE 1
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ][ ]

MEDICINE 2
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ][ ]

MEDICINE 3
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ][ ]

WHEN WAS THE LAST TIME YOUR CHOLESTEROL WAS MEASURED?
During the last 12 months [ ]
At least 1 year but less than 5 years ago [ ]
5 years ago or more [ ]

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR CHOLESTEROL?
YES [ ] NO [ ] UNCERTAIN [ ]

DIABETES
HAVE YOU EVER BEEN TOLD BY A DOCTOR OR OTHER HEALTH WORKER THAT YOU HAVE DIABETES?
YES [ ]
NO [ ] go to page 16
INSUFFICIENT DATA [ ] go to page 16

OVER THE LAST TWO WEEKS HAVE YOU TAKE ANY MEDICINES, INCLUDING INSULIN, TO CONTROL YOUR DIABETES?
YES [ ]
NO [ ] go to page 16
HOW MANY TYPES OF MEDICINES DID YOU TAKE?  

MEDICINE 1
Name of the medicine .................................................................
do you take it on a daily basis?     YES     NO
Number of pills a day |  Number of pills a week |

MEDICINE 2
Name of the medicine .................................................................
do you take it on a daily basis?     YES     NO
Number of pills a day |  Number of pills a week |

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR GLYCAEMIA LEVEL?
YES |  NO |  UNCERTAIN |

ASPIRIN
OVER THE LAST TWO WEEKS HAVE YOU TAKEN ASPIRIN TO PREVENT OR CURE HEART DISEASES?
YES |  NO |
NO |
NO, but I took aspirin for other reasons (NOT HEART DISEASES) |
INSUFFICIENT DATA |

WHAT IS THE NAME OF THE MEDICINE CONTAINING ASPIRIN DO YOU TAKE?
do you take it on a daily basis?     YES     NO
Number of pills a day |  Number of pills a week |

DO YOU FOLLOW CONTINUING ORAL OR INTRAVENAL CORTISON THERAPY?
YES |  NO |  UNCERTAIN |
SPECIFY ________________________________
DO YOU FOLLOW CONTINUING TIROXINE (EUTIROX) THERAPY?
YES, [ ] SPECIFY ______________________________
NO [ ]
UNCERTAIN [ ]

MEDICINE USE
This section aims at measuring actual use of all medicines based on a doctor’s initiative or recommendation. Here are also included the medicines which were prescribed in the past by a doctor and recently, the respondent has not visited the doctor to renew the prescription.
Medicines taken following the recommendation of a pharmacist should not be considered as medicines recommended by a doctor.
Medicines should be coded later using the first level ATC (Anatomical Therapeutic Chemical) classification system.

DO YOU TAKE OTHER MEDICINES ON A REGULAR BASIS?
YES [ ] NO [ ] go to next section

HOW MANY TYPES OF MEDICINES DO YOU TAKE? [ ]
Insert the number of medicines taken

MEDICINE 1
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ]

MEDICINE 2
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ]

MEDICINE 3
Name of the medicine .................................................................
do you take it on a daily basis? YES [ ] NO [ ]
Number of pills a day [ ] Number of pills a week [ ]

MEDICINE 4
ANGINA PECTORIS

The section includes the questionnaires of the London School of Hygiene and Tropical Medicine -LSHTM with questions on presence and duration of pain during exercise (walking briskly uphill) and relief; also information on surgical procedures (PTCA and CABG) are collected. The questionnaire has been validated and, although many years have passed since its introduction and it is not so appropriate for women and elderly people, it is still the most used questionnaire.

The questionnaire must be interrupted if the answer falls in a field marked with an asterisk (*) and the interviewed must go to the section on myocardial infarction

HAVE YOU EVER FELT PAIN, DISCOMFORT, OPPRESSION OR WEIGHT IN THE CHEST?
YES | NO |*

DOES THIS PAIN OCCUR WHEN YOU WALK QUICKLY OR UPHILL?
YES | NO |*

DOES THIS PAIN OCCUR WHEN YOU WALK AT A USUAL PACE ON THE FLAT?
YES | NO |*

WHAT DO YOU DO WHEN THIS PAIN OCCURS WHILE YOU ARE WALKING?
Indicate the first answer if you go on walking after taking a pill of trinitroglycerin
you stop or slow down   |   |  
go on walking at the same pace   |*  |

WHAT HAPPENS WHEN YOU STOP?
the pain disappears    |   |
the pain does not disappear   |*  |

HOW LONG AFTER DOES THE PAIN DISAPPEAR IF YOU STOP OR SLOW DOWN?
10 minutes or less | |
more than 10 minutes | |*
WHERE IS PAIN LOCATED?

HAVE YOU UNDERGONE CORONARY BYPASS SURGERY?  YES | | NO | |*
HAVE YOU UNDERGONE ANGIOPLASTY SURGERY?  YES | | NO | |*

**MYOCARDIAL INFARCTION**

This section investigates the occurrence of old myocardial infarction and, eventually, hospitalization. Hospitalization date, hospital name, name of the cardiologist or general practitioner are recorded.

HAVE YOU EVER FELT A VERY STRONG PAIN IN THE LOWER PART OF YOUR CHEST FOR AT LEAST HALF AN HOUR?
YES | | NO | |
AFTER THIS PAIN, WERE YOU DIAGNOSED WITH ACUTE MYOCARDIAL INFARCTION, HEART ATTACK, CORONARY ATTACK, MYOCARDIAL ISCHAEMIA?
YES | | NO | |
HOW WAS THIS DIAGNOSIS MADE?
1. during hospitalisation
2. with an ECG made at home or at the clinic
3. without an ECG
HOW MANY ATTACKS OF THIS KIND HAVE YOU EXPERIENCED?
1st ATTACK  
month | || | year | || |
duration of the pain  
hours | || |
LAST ATTACK  
month | || | year | || |
the duration of the pain ______ hours ____________

if the answer to this section of the questionnaire is YES, indicate the name and address of the doctor, the hospital or clinic

CEREBROVASCULAR ACCIDENTS

Cerebrovascular accidents include acute neurological episodes provoked by ischaemia or cerebral haemorrhagia and characterized by loss of consciousness and/or paralysis affecting any body part, and/or vertigo with dizziness, and/or blurred vision, and/or slurred speech. The time when the first and last events occurred is recorded. In the blank space at the end of the section the name of the general practitioner, his/her address, the hospital or clinic where the person was hospitalized are recorded.

HAVE YOU EVER EXPERIENCED EPISODES CHARACTERISED BY THE MORE OR LESS SUDDEN LOSS OF THE USE OF THE MUSCULAR FORCE OF A LEG AND/OR OF AN ARM AND/OR OF ONE PART OF THE FACE?

YES |__| NO |__|

IF YOU HAVE EXPERIENCED SIMILAR EPISODES MORE THAN ONCE, INDICATE HOW LONG AGO THIS OCCURRED:

1. Less than two weeks ago
2. Less than a month ago
3. Less than three months ago ______
4. Less than six months ago ______
5. More than six months ago
6. You do not remember

DID YOU LOOSE CONSCIOUSNESS?

YES |__| NO |__|

DID YOU LOOSE THE USE OF SPEECH?

YES |__| NO |__|

HOW LONG HAVE YOU REMAINED DISABLED?

1. Less than 24 hours
2. From 1 to 7 days ______
3. From 8 to 28 days
4. More than 28 days
ON THIS OCCASION, WERE YOU DIAGNOSED WITH BRAIN HAEMORRHAGE, CEREBRAL THROMBOSIS, CEREBRAL ISCHAEMIA, PARALYSIS?

YES |__| NO |__|

HOW WAS THIS DIAGNOSIS MADE?
1. during hospitalisation
2. at home
3. without any particular examinations

**TIA**

*The term TIA indicates a transient ischaemic attack of brief duration characterized by loss of consciousness and/or paralysis affecting any body part.*

HAVE YOU EVER SUFFERED TEMPORARY LOSS OF SPEECH?

YES |__| NO |__|

HAVE YOU EVER NOTICED A SUDDEN DECREASE OF THE MUSCULAR FORCE OF AN ARM OR OF A LEG THAT RAPIDLY GOT WORSE?

YES |__| NO |__|

HAVE YOU EVER EXPERIENCED DIZZINESS WITH SPEECH PROBLEMS OR A SENSE OF MENTAL CONFUSION?

YES |__| NO |__|

HAVE YOU EVER NOTICED A SUDDEN SHORT EPISODE CHARACTERISED BY A DECREASE IN EYESIGHT?

YES |__| NO |__|

DESCRIBE ANY OTHER NEUROLOGICAL PROBLEMS

........................................................................................................................................

........................................................................................................................................

ON THIS OCCASION, WERE YOU DIAGNOSED WITH TIA (TRANSIENT ISCHAEMIC ATTACK)?

NO |__|

YES, during hospitalisation |__|

YES, at home |__|

YES, without any particular examinations |__|
CLAUDICATIO INTERMITTENS

Claudicatio intermittens is a syndrome caused by inadequate blood flow to the lower extremities and is characterized by the impossibility, due to pain, to take more than a certain number of paces, that is constant and specific for each person. This section includes the London School of Hygiene and Tropical Medicine -LSHTM- questionnaire.

The questionnaire must be interrupted if the answer falls in a field marked with an asterisk (*).

DO YOU SUFFER FROM PAIN IN THE LEGS WHEN YOU WALK?

YES |_|    NO _|

DO YOU EVER FEEL THIS PAIN WHEN YOU ARE STANDING STILL OR SITTING?

YES |_|    NO _|

IN WHAT PART OF THE LEG DO YOU FEEL THIS PAIN?

1. The pain includes both calves or only one  ___
2. The pain does not include the calves * ___

DO YOU FEEL PAIN WHEN YOU WALK QUICKLY OR UPHILL?

YES |_|    NO _|

DO YOU FEEL THIS PAIN WHEN YOU WALK AT A USUAL PACE ON THE FLAT?

YES |_|    NO _|

DOES THE PAIN EVER DISAPPEAR WHILE YOU ARE STILL WALKING AT THE SAME PACE?

YES |_|    NO _|

WHAT DO YOU DO WHEN THIS PAIN OCCURS WHILE YOU ARE WALKING?

you stop or slow down

you go on walking at the same pace *

WHAT HAPPENS WHEN YOU STOP?

the pain disappears

the pain does not disappear *

HOW LONG AFTER DOES THE PAIN DISAPPEAR IF YOU STOP OR SLOW DOWN?
10 minutes or less
more than 10 minutes *

HAVE YOU UNDERGONE ANY SURGERY TO IMPROVE THE CIRCULATION OF THE LOWER LIMBS (EXCLUDING VEIN OPERATIONS)?
YES |_|    NO |_

DISEASES AND SELF-PERCEIVED HEALTH
The section on diseases includes a list of diseases such as bronchial asthma, COPD, hepatic cirrhosis, renal diseases, endocrinal diseases, malabsorption, autoimmune diseases, fractures, depression, and cancer. At the bottom of diseases section it is possible to describe other diseases and hospital admissions including dates, hospital names, and discharge diagnoses.

DO YOU HAVE OR HAVE YOU EVER HAD ANY OF THE FOLLOWING DISEASES OR CONDITIONS?

- Bronchial Asthma
  - no |_| yes, with doc | yes, no doc
- Chronic obstructive pulmonary disease
  - no |_| yes, with doc | yes, no doc
- Cirrhosis of the liver
  - no |_| yes, with doc | yes, no doc
- Kidney disease
  - no |_| yes, with doc | yes, no doc
- Chronic renal insufficiency
  - no |_| yes, with doc | yes, no doc
- Urinary calcolosis
  - no |_| yes, with doc | yes, no doc
- Glomerular nephritis
  - no |_| yes, with doc | yes, no doc
- Interstitial nephropaty/ Pyelonephritis
  - no |_| yes, with doc | yes, no doc
- Polycystic kidney
  - no |_| yes, with doc | yes, no doc
- Endocrinal disesease
  - no |_| yes, with doc | yes, no doc
- Malabsorption (celiac disease)
  - no |_| yes, with doc | yes, no doc
- Autoimmune diseases
  - no |_| yes, with doc | yes, no doc
- Previous fractures
  - no |_| yes, with doc | yes, no doc
- Depression
  - no |_| yes, with doc | yes, no doc
- Cancer (malignant tumour/place and description)
  - no |_| yes, with doc | yes, no doc

Other, specify __________________________________________________________
SELF-PERCEIVED HEALTH

It is assessed on a 0-10 point self-perceived health status scale (0: worst; 10: best); the participant is asked to rate his health status. The concept is restricted to an assessment coming from the individual and not from anyone outside that individual, whether an interviewer, health care worker or relative. Self-perceived health is influenced by impressions or opinions from others, but is the result after these impressions have been processed by the individual relative to their own beliefs and attitudes. 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 function and biomedical signs and symptoms. It omits any reference to an age as respondents are not specifically asked to compare their health with others of the same age or with their own or future health state. It is not time limited.

HOW DO YOU CONSIDER YOUR ACTUAL HEALTH STATUS?
(To help you answer correctly, please refer to the scale below, where 10 represents the best health status and 1 the worst)

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
</table>

FAMILY HISTORY

The interviewed person is asked if his/her father, brothers, sons and his/her mother, sisters, daughters suffered from angina pectoris, myocardial infarction, cerebrovascular event or stroke and/or underwent by-pass, angioplasty at different age ranges (<55 years old, 55-64, 65-74, >75). The number of persons experiencing the above diseases/surgical procedures is recorded. If parents, brothers, sisters, sons, daughters have hypercholesterolemia, hypertension and diabetes, this should be recorded. The total number of brothers, sisters, sons, daughters is recorded.

HAVE YOUR FATHER, YOUR BROTHERS, YOUR SONS SUFFERED FROM ANY OF THE FOLLOWING CORONARY DISEASES: ANGINA PECTORIS OR MYOCARDIAL
INFARCTION, AORTA-CORONARY BYPASS SURGERY OR ANGIOPLASTY? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>&lt;55yy</th>
<th>55-64yy</th>
<th>65-74yy</th>
<th>&gt; 75yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNCERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HAVE YOUR FATHER, YOUR BROTHERS, YOUR SONS SUFFERED FROM ANY CEREBROVASCULAR DISEASES OR STROKE? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>&lt;55yy</th>
<th>55-64yy</th>
<th>65-74yy</th>
<th>≥ 75yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNCERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HAVE YOUR MOTHER, YOUR SISTERS, YOUR DAUGHTERS SUFFERED FROM ANY OF THE FOLLOWING CORONARY DISEASES: ANGINA PECTORIS OR MYOCARDIAL INFARCTION, AORTA-CORONARY BYPASS SURGERY OR ANGIOPLASTY? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>&lt;55yy</th>
<th>55-64yy</th>
<th>65-74yy</th>
<th>≥ 75yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNCERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

HAVE YOUR MOTHER, YOUR SISTERS, YOUR DAUGHTERS SUFFERED FROM ANY CEREBROVASCULAR DISEASES OR STROKE? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<table>
<thead>
<tr>
<th>Age Range</th>
<th>&lt;55yy</th>
<th>55-64yy</th>
<th>65-74yy</th>
<th>≥ 75yy</th>
</tr>
</thead>
<tbody>
<tr>
<td>YES</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NO</td>
<td></td>
<td>_</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UNCERTAIN</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE A HIGH LEVEL OF CHOLESTEROL OR TRIGLYCERIDES IN THEIR BLOOD?

YES
NO
UNCERTAIN

DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE HIGH PRESSURE?

YES
NO
UNCERTAIN

DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE DIABETES?

YES
NO
UNCERTAIN
INSTRUMENTAL ACTIVITIES OF DAILY LIVING AND THE ACTIVITIES OF DAILY LIVING (IADL-ADL)

Self-reported questionnaire Minimum European Health Module (MEHM) provided by the National Institute of Statistics (ISTAT). The basic ADL refers to the items: moving between rooms, use the lavatory, washing and bathing, dressing and undressing, getting in and out of bed, and feeding oneself. Mobility refers to: moving outdoors, using stairs, walking at least 400 metres, carrying heavy objects for 100 m. IADL refers to the items: preparing own meals, doing light housework, doing heavy housework.

Here below the questionnaire is reported:

How is your health in general?
[ ] Very good
[ ] Good
[ ]
[ ] Bad
[ ] Very bad

Do you have any longstanding chronic diseases or health problem? (Longstanding means illnesses or health problems which have lasted, or are expected to last, for 6 months or more)
[ ] Yes
[ ] No

For at least the past 6 months, to what extent have you been limited because of a health problem in activities you usually do?
[ ] Severely limited
[ ] Limited but not severely
[ ] Not limited at all

<table>
<thead>
<tr>
<th>You are able to:</th>
<th>Yes, without difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Not able</th>
</tr>
</thead>
<tbody>
<tr>
<td>See newspaper print (considering your normal use of eyeglasses or contact lenses)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
### You are able to:

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, without difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Not able</th>
</tr>
</thead>
<tbody>
<tr>
<td>See the face of someone 4 metres away (across a road)? (considering your normal use of eyeglasses or contact lenses)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Hear what is said in a conversation with several people (considering your normal use of hearing aids)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Walk 500 metres on a flat terrain without a stick or other walking aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Walk up and down a flight of stairs without a stick, other walking aid, assistance or using the banister</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bend and kneel down without any aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using your arms, can you carry a shopping bag weighing 5 kilos for at least 10 metres without any aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Use your fingers to grasp or handle a small object like a pen without any aids</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bite and chew on hard foods such as a firm apple without any aid (without the help of a denture)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

### Do you usually have difficulty doing any of these activities by yourself?

<table>
<thead>
<tr>
<th>Activity</th>
<th>Yes, without difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Not able</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feeding yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Getting in and out of a bed or chair</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Dressing and undressing alone</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using the toilet</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bathing or showering</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Preparing meals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using the telephone</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Shopping</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Managing medication</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Light housework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Occasionally heavy housework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Taking care of finances and everyday administrative tasks</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>
MINI MENTAL STATE EXAMINATION (M.F. FOLSTEIN)

The Mini Mental State Examination (M.F. Folstein) is used in persons aged 65+ to assess the global cognitive function. The test includes questions on orientation to time and place registration, attention and calculation recall, language and visual construction. The maximum score is 30 points. The test was originally created for a clinical setting but is extensively used in epidemiological studies.


Assess the level of sensorium along a continuum:
alert = 1, somnolent = 2, stupor = 3, coma = 4

Give 1 point for each correct answer and sum all points at the end of the test
10 seconds for each answer

[ ] What year are we in now (season)?
[ ] What season are we in now?
[ ] What month is it?
[ ] What is the date today?
[ ] What is the day today?

[ ] What State do we live in?
[ ] What Region do we live in?
[ ] With town do we live in?
[ ] Where are we now?
[ ] Which floor are we on?

‘I will say the names of 3 unrelated objects, pay attention as I will ask you to repeat them in a few minutes’

Say the names clearly and slowly, about one second for each.

[ ] sock [ ] blue [ ] charity

Could you repeat them?
20 second for repetition, keep saying them until he can repeat all 3, up to 5 trials.
‘Could you slowly count backwards by 7 beginning with 100?’

Give 1 point for each correct subtraction even if it is made beginning with a wrong number

‘Could you recall the 3 words I previously asked you to remember?’

Give 1 point for each correct answer

‘Please name the objects I will show you’

What is this? (show a pencil)   ___
What is this? (show a watch)   ___

‘Please, repeat the following

‘TIGRE CONTRO TIGRE’*   ___

Only one trial is allowed

Give 1 point for correct answer

Ask the subject if he/she is right-handed or left-handed. If right-handed ask:

‘Take a paper in your left hand, fold it in half, and give it back to me’ (if left-handed, ask to take the paper in the right hand)

Score 1 point for each part correctly executed.

___ Take the paper with the correct hand
___ Fold it in half
___ Give it back to the interviewer

‘Read the sentence written on this piece of paper and do what it says (show to the subject a piece of paper with the sentence CLOSE YOUR EYES) (1 point)

Give 1 point if the subject closes his/her eyes
Give the subject a blank piece of paper and ask him/her: ‘Write the first sentence that comes to your mind’. Do not dictate a sentence, it is to be written spontaneously. It must contain a subject and verb and be sensible. Correct grammar and punctuation are not necessary.
Give 1 point if the sentence is correct.

On a clean piece of paper, draw intersecting pentagons, each side 3 cm., and ask the subject: ‘Copy this drawing exactly as it is’
The answer is correct if there are 10 angles, two of them intersecting; do not consider hand waving due to tremor.
Give 1 point if the drawing is correct.
* this represents a difficult expression to repeat

SECTION RESERVED TO WOMEN
Cardiovascular disease is a different disease for women than it is for men for several aspects: diffusion, age range of interest and seriousness. These differences depend on types and amount of sexual hormones. This section investigates the use of hormone replacement therapy in menopausal women and the use of contraceptive pill in fertile women.

DO YOU STILL HAVE YOUR MENSTRUAL PERIODS?
YES, regularly
YES, but not on a regular basis or with cycles interrupted less than 6 months ago
NO
Pregnancy

AT WHAT AGE DID YOU GO COMPLETELY IN MENOPAUSE?
Insert the age in years after six months without cycles
99= insufficient data

HAVE YOU TAKEN HORMONES FOR MENOPAUSE OVER THE LAST MONTH?
YES, pills, injections or plasters
NO
INSUFFICIENT DATA

MEDICINE 1
Name of the medicine .................................................................
do you take it on a daily basis? YES | NO |
Number of pills a day | Number of pills a week |

MEDICINE 2
Name of the medicine ..............................................................
do you take it on a daily basis? YES | NO |
Number of pills a day | Number of pills a week |

MEDICINE 3
Name of the medicine ..............................................................
do you take it on a daily basis? YES | NO |
Number of pills a day | Number of pills a week |

HAVE YOU TAKE CONTRACEPTIVE PILLS OR INJECTIONS OVER THE LAST MONTHS?
YES | NO |

INSUFFICIENT DATA |

THE EPIC FOOD FREQUENCY QUESTIONNAIRE

It is used to collect information about dietary habits. The questionnaire is self-administered and includes images to define food portions; it is usually filled out at home and then returned together with 24-hour urine sample or while waiting for examinations or administered questionnaire. The EPIC questionnaire investigates general dietary habits (preferred food items, type of dressing, cooking modalities, etc.), frequency of meals consumed away from home and how frequently (weekly, monthly, yearly) each specific food is generally consumed. The participant is asked to specify the size of the portion usually consumed. The questionnaire contains printed pictures for showing portions in questions on alcohol intake and food consumption/diet.

The EPIC questionnaire is automatically read by an optical scanner, therefore the participant should be instructed to fill in fully the circle even if the answer to the question on the consumption of a particular food item is ‘never’. The software designed specifically for EPIC transforms information about food consumption into daily intake of food items, food groups and nutrients.
Checking questionnaires and interviewing

Interviewing

The questionnaire should be administered by properly trained personnel. Fieldwork staff are trained how to read questions (tone of voice, time necessary to read questions and to wait for answers). The interviewer should be familiar with the background and meaning of the questions. He/she should know how his/her interaction with the participant and different interviewing techniques will affect reliability of the survey and data quality. These should be described during the training. The interviewer should try his/her best to make the participant feels at ease and create a friendly contact.

The interviewer is recommended to read the questions and all possible answers as they are written trying not to influence the answer through intonation of the voice or facial expression (translation into regional or local language must be avoided). The wording of the question must not be modified. If the participant does not seem to understand the question, the question must be repeated three times. If, after three attempts, the participant is still unable to answer, the order of the words or the words themselves can be changed provided that the meaning of the question is not altered and the answer is not suggested. The order of the questionnaire should be followed: when the participant tries to start talking from topics which come later in the questionnaire they should be kindly instructed to listen to the next question. The answers should be recorded so that the participant does not focus on observing what the interviewer is writing.

If for any reason the interview is interrupted (i.e. the participant feels uncomfortable and does not wish to continue or the participant is suddenly taken ill), the participant is given the possibility to finalize the interview at a later time.

It is recommended to give positive feedback at the end of the interview so that the participant feels that his/her responses and time spent with the interview are valued.

At the end of interview all problems encountered (problems in communication skills, cognitive ability, hearing or reading, proxy use, other disturbing factors, etc.) should be recorded.

The questionnaire on general health status can be administered to participants by the same interviewer after blood drawing and blood pressure measurements.
Checking the self administered questionnaires

Self-administered questionnaire includes: ADL, IADL and food frequency. The food frequency questionnaire, used to collect information about dietary habits, is self-administered and it is usually filled out at home and then returned together with 24-hour urine sample. At the end of examination visit, the fieldworker checks if the respondent has filled all items in the right way.

Checking the self-administered questionnaires should include the following steps:
- trying to fill in missing items: if the respondent has not filled in all questions because he/she has had problems in understanding the question or in choosing the answer, the fieldworker should give some further explanations.
- correcting items where the respondent has selected several options in questions where only one option is allowed: the fieldworker should ask the subject to choose the one that reflects his/her situation best.
- correcting if jump rules have not been followed: the fieldworker should help the respondent to clarify the situation.
14. MEASUREMENT PROCEDURES IN THE EXAMINATIONS

Blood pressure

Rationale
Blood pressure is the pressure exerted by circulating blood upon the walls of blood vessels. The blood pressure varied during day for each individual. To describe blood pressure, 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 relaxed between beats.

Elevated blood pressure means values equal to or higher than 140 and/or 90 mmHg.
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.

In the last survey OEC, conducted between 1998 and 2002 the prevalence of hypertension in the general population (35-74 years, all regions covered) was 33% in men and 31% in women; at that time the prevalence was computed including systolic blood pressure as mean of two consecutive measurements equal or greater than 160 mmHg or diastolic blood pressure as mean of two consecutive measurements equal or greater than 95 mm Hg or under specific treatment.

In Italy, blood pressure has been, and still is, measured with the mercury sphygmomanometer. Recently, due to toxicity of mercury, the European Union has banned the use of mercury devices and the use of automated devices has increased. Therefore, for the future, it is recommended to maintain the same instrument or at least perform a validation study to see how comparable readings with the mercury sphygmomanometer and the automated devices are.

The standardization of the blood pressure measurement procedures is important to obtain as valid readings as possible. Blood pressure levels are affected by the following issues:
### Activity

<table>
<thead>
<tr>
<th>Activity</th>
<th>Systolic blood pressure (mmHg)</th>
<th>Diastolic blood pressure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full bladder</td>
<td>Increases 10 to 15 mmHg</td>
<td></td>
</tr>
<tr>
<td>Not resting 3 to 5 minutes before measurement</td>
<td>Increases 10 to 20 mmHg</td>
<td>Increases 14 mmHg</td>
</tr>
<tr>
<td>Back/feet unsupported</td>
<td>Increases 5 to 15 mmHg</td>
<td>Increases 6 mmHg</td>
</tr>
<tr>
<td>Supine posture instead of sitting posture</td>
<td>Increases 3 to 10 mmHg</td>
<td>Decreases 1 to 5 mmHg</td>
</tr>
<tr>
<td>Full bladder</td>
<td>Increases 10 to 15 mmHg</td>
<td></td>
</tr>
<tr>
<td>Not resting 3 to 5 minutes before measurement</td>
<td>Increases 10 to 20 mmHg</td>
<td>Increases 14 mmHg</td>
</tr>
<tr>
<td>Back/feet unsupported</td>
<td>Increases 5 to 15 mmHg</td>
<td>Increases 6 mmHg</td>
</tr>
<tr>
<td>Supine posture instead of sitting posture</td>
<td>Increases 3 to 10 mmHg</td>
<td>Decreases 1 to 5 mmHg</td>
</tr>
<tr>
<td>Legs crossed</td>
<td>Increases 5 to 8 mmHg</td>
<td>Increases 3 to 5 mmHg</td>
</tr>
<tr>
<td>Participant talking during the measurement</td>
<td>Increases 10 to 15 mmHg</td>
<td>Increases 6 to 10 (refs.)</td>
</tr>
<tr>
<td>Arm below heart level</td>
<td>Increases up to 10 mmHg</td>
<td>Increases up to 11 mmHg</td>
</tr>
<tr>
<td>Arm above heart level</td>
<td>Decreases</td>
<td>Decreases</td>
</tr>
<tr>
<td>Physical exercise</td>
<td>Increases up to 22 mmHg</td>
<td>Increases 7 to 8 mmHg</td>
</tr>
<tr>
<td>Left arm instead of right arm</td>
<td>Decreases 1 to 3 mmHg</td>
<td>Decreases 1 mmHg</td>
</tr>
<tr>
<td>Diaphragm of the stethoscope instead of bell</td>
<td>Decreases 2 mmHg</td>
<td>Decreases 0 to 2 mmHg</td>
</tr>
<tr>
<td>Cuff too small</td>
<td>Increases 10 to 40 mmHg</td>
<td>Increases 5 to 12 mmHg</td>
</tr>
<tr>
<td>Cuff too large</td>
<td>Decreases 10 to 30 mmHg</td>
<td></td>
</tr>
</tbody>
</table>

### Equipment

**Measurement by the mercury sphygmomanometer**

- Mercury sphygmomanometer
- Stethoscope
- 2 cuffs of different size (medium and large):

<table>
<thead>
<tr>
<th>Cuff</th>
<th>Arm circumference</th>
<th>Bladder size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medium (13cm)</td>
<td>≤ 34 cm</td>
<td>11.5 cm x 27 cm</td>
</tr>
<tr>
<td>Large (14.5cm)</td>
<td>&gt; 34 cm</td>
<td>12 cm x 35 cm</td>
</tr>
</tbody>
</table>

- non-elastic measurement tape, for measuring arm circumference
- thermometer, for recording room temperature
- stop watch (or a watch with a second hand), for recording the time of measurement

Blood pressure is taken before blood drawing, on the right arm, with the subject in a sitting position after 5 minutes rest, using the double-cuff (normal adult and obese adult) Riva-Rocci mercury sphygmomanometer and the bell of the stethoscope.
Exclusion criteria

Blood pressure should be measured from all participants except if a person has malformations and/or amputations of both arms; cast, open sores, rashes, and recently lymph node removed which prevents proper placement of the cuff.

Measurement procedures

Setting up the measurement site

Blood pressure should be measured in a quiet room with a comfortable temperature. Any disturbance should be avoided. The room temperature should be recorded for each participant. The measurer should be in a sitting position in front of the subject. The sphygmomanometer should be placed on a platform 10-15 cm high so that the measurer has his/her eyes at the level of the mercury column. Before measurement, the measurer should make sure that the mercury column is at 0 level. If this is not so, the sphygmomanometer should be slightly bent toward the side of the mercury column bulb. The measurer should make sure also that the tube is clean when the top of the mercury column is at 0 level.

The chair of the participant should be adjusted to the proper height and should have a backrest so that he/she can feel relaxed and comfortable.

As for future surveys, if it won’t be possible to use mercury sphygmomanometer, it is recommended to use the automated blood pressure monitoring device with at least two cuffs, medium and large. The equipment is almost the same necessary for blood pressure measurement with mercury sphygmomanometer.
Preparation for the measurement

Instructions to the participants

Before coming to the examination, participants should be instructed to abstain from doing heavy physical activity, eating, smoking and avoid exposure to cold temperature for one hour before measurement. The participant should be also instructed to empty his/her bladder before the measurement and to remain relaxed and avoid talking during measurement.

The participant should remove outer garments and all other tight clothing. The sleeve of shirt, blouses, etc. should be rolled up without being constrictive so that the upper right arm is bare for the cuff; the remaining garments should not be constrictive and the cuff should not be placed over any garment.

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 and legs should be uncrossed. Any other different position should be recorded.

Position of the arm

The measurement should be made on the right arm. If not possible, e.g. the arm is deformed, amputated, or has rashes, adhesive dressing, casts, open sores, hematomas, wounds, arterovenous shunt or any other intravenous access device, the left arm should be used. The use of left arm and reason for this should be recorded on the questionnaire.

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 the palm is facing up. The arm forms a 45 degrees angle with the trunk.

Selection of the cuff

A set of 2 cuffs of different sizes are usually available and special attention should be paid to using the proper cuff width in relation to arm size, measured using a non-elastic measurement tape (medium if arm circumference is ≤33 cm, large if arm circumference is ≥34 cm) placed at the mid-point between the acromion process of the scapula and the olecranon. The measurement should be read to the nearest centimetre and recorded.
The length of the bladder of the cuff should be at least 80% of arm circumference and be placed so that its lower edge is about 2 cm above the antecubital fossa; the tubes from the cuff should not be under the arm or the arm should not rest on the tubes.

The subject should sit with the cuff around the arm for at least 5 minutes before the measurement can be taken. During this time, data on blood pressure measurement (time of measurement, room temperature, arm circumference and type of cuff) are recorded on the questionnaire.

**Number of measurements**

Three consecutive blood pressure measurements are recommended, a few minutes apart (the time usually necessary for blood pressure values registration). One-minute pulse rate should be measured at the wrist between the first and the second measurements.

**Measurement protocol**

1. Participant is asked not to talk and not to look at the mercury column during the measurements
2. Measure the arm circumference and select the correct cuff size.
3. Place the cuff 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.
4. Palpate the radial pulse with left hand fingers.
5. Inflate slowly the cuff closing the valve of the inflation bulb and watch the mercury column: the level of the top of the meniscus of the mercury column is noted at the point when the radial pulse disappears; deflate the cuff quickly and disconnect the cuff tube from the sphygmomanometer.
6. Record the value and add 30 mmHg to this value to obtain the peak inflation level.
7. Wait for 30 seconds or raise the arm for 5-6 seconds and connect again the cuff tube to the sphygmomanometer. Locate the brachial pulse and place the bell of the stethoscope at this point (it is advisable to use the bell as it eliminates background noises). Earpieces of the stethoscope should be place into the external auditory meatus (from back to front facing outward). If it is not possible to feel the brachial
pulse, the bell of the stethoscope should be placed inside the bicep muscle tendon and never below the cuff.

8. Inflate rapidly the cuff to the peak inflation level and then deflate the cuff at a rate of 2mmHg per second. Read the value corresponding to the top of the meniscus of the mercury column. Blood pressure measurements should be recorded to the nearest millimetre. If the top of the meniscus falls halfway between two markings, choose the marking immediately below. Record systolic and diastolic blood pressure: the systolic level corresponds to the first appearance of a clear sound followed by an equal one (Korotkoff Phase I); the diastolic level (Korotkoff Phase V) corresponds to the last sound heard. Slowly deflate the cuff until at least 10 mmHg after the complete disappearance of heart rate. Then rapidly deflate the cuff by fully opening the valve of the inflation bulb. Disconnect the cuff tube from the sphygmomanometer.

9. After the first blood pressure measurement, heart rate should be measured for one minute

For the second and third measurements, repeat steps 7 and 8.

**Pulse rate**

Pulse rate should be measured once at the end of the first measurement of blood pressure.

It should be measured at the right wrist by placing the middle fingers of the left hand on it to locate the radial artery; when a pulse is found, the number of beats felt within a one minute period should be counted using a stop watch (or a watch with a second hand).

**Feedback to participants**

The participant should be informed about his/her blood pressure levels. The mean of the three measurements is communicated to the participant and reported of the results’ form.

**Automated 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. Participant is asked to sit still for 5 minutes before starting the measurement
2. Participant is asked not to talk during the measurements
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 use that the batteries are inserted or that the adapter is on.
6. Press the “ON” button: all the symbols on the display will light up for approximately two seconds in order to check the display
7. All the symbols then disappear and the air release symbol begins to flash
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 tied up.
9. Push the “START” button: the device automatically determines the correct level of inflation pressure
10. When the target inflation values are reached, the air is automatically released. The value in the display counts downwards
11. As soon as the monitor detects the pulse, the symbol begins to flash
12. When the monitor no longer detects the pulse while the cuff pressure is dropping, the systolic and diastolic pressure are displayed
13. 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
14. After one minute, the second measurement is made by repeating steps 9-13. The participant should not change position during this wait
15. After another minute, the third measurement is made by repeating steps

**Quality assurance**

Quality assurance of the blood pressure measurement includes 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 fieldwork

**Training of the measurers**

Training of the blood pressure measurers should include:
- Theory about why it is important to measure blood pressure in the general population; why blood pressure measurement has to be standardized and the implications of the changes in the procedure.
- Practical training ideally with people with different blood pressure levels [Training manual, R. Prineas]

In our experience, we have observed that training of local staff during the first week is very useful: it allows to check the positions, better blood pressure hearing, choose the right time necessary for measurement. The main aim of the HES is to describe the characteristics of the general population, usually healthy; therefore it is important to perform measurements and examinations according to standardized procedures and respecting the required time. Performing measurements in the right way may be useful also in clinical practice.

The use of the double stethoscope allows to check the level of attention of the measurer, the velocity the cuff is deflated and the reliability of measurement. After measurement, the trainer and the measurer should record blood pressure values; comparison is made after at least 10 measurements. The measurement made by the measurer should not be more than 2 mmHg different from that made by the trainer. Double stethoscope should be used until differences between measurements reduces.

**Checking the equipment and regular calibration of the devices**

All equipment should be checked regularly. If any problems are observed during the checks, the device in question should be replaced and this is recorded.
Checks or when new examination place is set up

When the examination site is set up in new centre, the following issues from the equipment should be 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 rises 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.

Moreover, 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.

From an automated device

Make sure that the arm-circumference-adapter cord of the device unit is securely plugged in or in case 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.

From the 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 the stethoscopes

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 automated device

Calibration protocol; connect the mercury manometer, adult cuff, and the automated device air tube with the T-tube; tightly wrap the adult cuff over the calibration cylinder; release the valve of the inflation bulb to remove the air inside the cuff.
completely; push the ON/OFF button to turn on the monitor; set the MODE selector to
CHECK: close the valve of the inflation bulb and inflate the cuff to 300, 250, 200,
150, 100, 60 and 0 mmHg; compare the pressure values displayed on the monitor to
the one on the mercury manometer and record the automated device readings at each
level.

Quality control by coordinating office during the field work
The coordinating office organizes audit visits to the field to monitor the measurements. At
regular intervals, the following indicators should be checked from the data:
- distribution of terminal digits for systolic and diastolic measurements: frequency of the last
digit 0,2,4,6,8 should have the same chance of occurring (20% each);
- 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 average;
- the proportion of identical measurements for the same participants to determine if the
measurers are really doing all 3 measurements for each subject.

Anthropometric measurements
Height
Rationale
The measurement of height and weight are important as they allow for the calculation of Body
Mass Index (BMI: weight in kg/height in m²). Height and weight are also used to calculate
reference values for respiratory indicators (vital capacity and forced expiratory volume). Self-
reported height and weight values during Health Interview Surveys are often more likely to
underestimate the real values, therefore measuring height and weight with standardized
methodologies allow to compare self-reported values with measured ones and to estimate the
difference.
BMI is a widely used way to measure overweight (BMI > 25 kg/m² < 30) and obesity (BMI ≥ 30 kg/m²). obesity is a known risk factor for many chronic diseases. There is a clear
association between obesity and type 2 diabetes, hypertension and dyslipidaemia.
By calculating the BMI from participants it is possible to estimate the prevalence of the
obesity in the population and to follow the time-trends.
Waist circumference is used as an indicator of abdominal obesity. By measuring the waist circumferences from all the participants, it is possible to estimate the prevalence of abdominal obesity in the population and to follow the time-trends.

To obtain valid and reliable values, it is important to perform anthropometric measurements following standardized methodologies. Following the recommendations provided by this manual takes a few minutes. It is recommended to perform the anthropometric measurements in one room with the participant undressed, with only underwear on: this facilitates measurement and reduces variability due to weight of different outer garments. In some cultures, undressing may not be acceptable. This should be respected; in that case, the waist circumference can then be measured over a thin shirt.

### Measurement protocol

#### Equipment

- Height rule (stadiometer)
- Steps
- Carpenter’s level

#### Setting up the measurement site

The height rule is attached vertically to the hard flat wall surface with the base at floor level. A carpenter’s level is used to check the vertical and horizontal (triangle) placement of the rule.
The height rule does not have a fixed rod, it is recommended to mark with a tape the straight line for the rule down to the floor. The floor surface must be hard and not covered by elastic or soft material (moquette).

**Exclusion criteria**
Height should be measured to all participants except if a person is immobile or in a wheelchair; if has difficulties in standing straight; if the participant’s hairstyle (e.g. turban) prevents the proper use of the equipment.

**Measuring height**
The participant is asked to remove his/her shoes, heavy outer garments and is asked to stand with his/her back to the wall, feet together and back of the head, shoulder blades, buttocks and heels touching the wall. The participant is asked to look straight ahead so that the top of the external auditory meatus (ear canal) is level with the inferior margin of the bony orbit (cheek bone). Obese persons with difficulties keeping feet together may be allowed to stand with toes looking slightly outward but heels close to each other.
If the participant is taller than the measurer, the measurer should stand on steps so that he/she can properly read the height rule.
Once the participant has reached a correct position, the triangle placed on the height rule should be slided down to the head until the hair is pressed flat. If the last significant digit is followed by 5, round down if last significant digit is even, round up if odd (e.g. 187.5 becomes 188; 186.5 becomes 186).

**Recording**
Height is recorded on the questionnaire after the participant has moved away.

**Feedback to the participant**
The participant is informed about his/her height. The height is reported in the results’ form. Also BMI is calculated.
Quality assurance
Quality assurance of height measurement includes following components: training of the personnel; checking the equipment and calibration of the devices when a new examination place is set up; audit visits and evaluation of the measurement data during the fieldwork.

Training of the measurers
Training of local staff is performed during the first week of screening. If survey prolongs, a refresher session about the measurement should be organized at three months interval.

Calibration and checking the equipment
When setting up examination site the instructions of the device need to be followed carefully. The horizontal and vertical placement of the height rule must be checked by using the Carpenter’s level.

Quality control on the field
Regular monitoring of the performance of the measurers.

Quality control by coordinating office
Surprise audit visits to the examination sites to observe the measurers. Regular monitoring of the measurement results by measurer (digit preference, mean and standard deviation).

Weight
Measurement protocol
Equipment
- Balanced beam scale
- Calibrated weights (e.g. 10 kg up to 100kg)
- A carpenter’s level

Setting up the measurement site
Weight is measured with a balanced beam scale. The scale must be placed on a hard floor surface.
The floor should not be carpeted or otherwise covered with soft material. A carpenter’s level (portable or in scale) should be used to verify that the scale is in horizontal position.

**Exclusion criteria**

Weight should be measured in all participants, except immobile or wheelchair bound individuals, or persons who have difficulty standing steady.

**Measuring weight**

The participant is asked to undress to his/hers underwear. If participant refuses to undress, he/she should be asked to take off the shoes, remove heavy outer garments, and at least he/she should empty his/her pockets (mobile phone, keys, wallet, belt) before getting on the scale. If the participant is currently wearing a prosthesis, this needs to be recorded. The interviewer should stand in front of the participant and never behind.

**Balanced beam scale**

The participant is asked to stand in the centre of the platform about 10 cm gap between the heels. The weight should be distributed on both legs and the participant is asked to stand still. The weights are moved until the beam balances, meaning the arrows are aligned.

**Recording**

Weight is expressed in kilograms and hectograms and recorded to the nearest 200 gr on the questionnaire. If the value in hectograms is odd, it must be rounded down.

**Feedback to the participant**

The participant is informed about his/her weight. The weight is reported in the results’ form. Also BMI is calculated.

**Quality assurance**

Quality assurance of the weight measurement includes following components: training of the personnel; checking the equipment and calibration of the devices when a new examination centre is set up; audit visits and evaluation of the measurement data during the fieldwork.
Training of the measurers
Training of local staff is performed during the first week of screening. If survey prolongs, a refresher session about the measurement should be organized at three months interval.

Calibration and checking the equipment
All the calibrations and checking the equipment, and possible actions, should be recorded.

When setting up new examination site
Standardized weights should be used to check the scale when setting up and breaking down the examination site. 10 kilos weights are placed one by one on the scale up to 100 kilos and checked that the scale works properly. If the error is greater than 0.2 kg it should be corrected.

During the fieldwork
Balancing of beam balance scale to zero level should be done at the beginning and end of each examination day. The balanced beam scale is balanced with both sliding weights at zero and the balance bar aligned.

Quality control on the field
Regular monitoring the performance of the measurers.

Quality control by coordinating office
Surprise audit visits to the examination sites to observe the measurers.
Regular monitoring of the measurement results by measurer (digit preference, mean and standard deviation).

Waist circumference
Measurement protocol
Equipment
- non-elastic measuring tape
- full body length mirror with 10 cm x 10 cm grid lines (if mirror is used, Carpenter’s level is needed)
**Setting up the measurement site**

Waist is measured with a non-elastic measuring tape, making sure that the finger of the measurer is not between the tape and the participant’s body. This measuring tape is graduated on one side only.

If mirror is used it is placed against the wall or if the mirror stands its own feet next too the measurement place. By carpenter’s level it should be verified that the grid lines on the mirror are horizontal.

**Exclusion criteria**

Waist circumference should be measured in all participants, except if the person is immobile or in a wheelchair; has difficulty standing straight; is pregnant (over 20 pregnancy weeks); has a umbilical hernia.

**Measuring waist circumference [FOTO]**

The participant is asked to reveal the waist, by loosing the belt, lowering the pants/skirt and lifting the shirt. The participant is also asked to stand still, with feet fairly close together (10 cm) and weight equally distributed on both legs. The hands are hanging loosely beside the body. Waist circumference is measured at a level midway between the lower rib margin and the iliac crest, with the measurer sitting on a chair in front of the participant; The measurer, in sitting position, checks that the measuring tape is in horizontal position by asking the participant to turn over or checking from the mirror. The measuring tape is held firmly, ensuring the horizontal position. The tape should not be too tight or too loose. The participant is asked to breath normally; the reading is taken at the end of light exhale.

**Recording**

Waist circumference is recorded on the questionnaire.

**Feedback to the participant**

The participant is informed about his/her waist circumference. The waist is reported on the results’ form.
**Quality assurance**
Quality assurance of waist circumference includes 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 fieldwork

**Training of the measurers**
Training of local staff is performed during the first week of screening. If survey prolongs, a refresher session about the measurement should be organized at three months interval.

**Calibration and checking the equipment**
The length of the measurement tape is measured by using calibrated length rods at least one a month.
If the measurement tape is stretched it should be replaced.

**Quality control on the field**
Regular monitoring the performance of the measurers.

**Quality control by coordinating office**
Surprise audit visits to the examination sites to observe the measurers.
Regular monitoring of the measurement results by measurer (digit preference, mean and standard deviation).

**Additional measurements**
During the pilot phase, it has been decided to add a number of additional measurements and examinations for the following reasons:
- assessment of trend of some diseases. On the basis of the rich tradition of epidemiological studies of cardiovascular diseases and the experience in ECG reading through Minnesota code we have decided to include an ECG at rest to assess the prevalence of some conditions, such as left ventricular hypertrophy, atrial fibrillation and ischemic cardiopathy;
- assessment of some indicators of respiratory function, such as the Forced Vital Capacity and Forced Expiratory Volume in 1 Second;
- assessment of carbon monoxide exposure (cigarette smoke, chimneys, etc…);
- assessment of calcium in bones through bone densitometry;

The introduction of these additional measurements aims also at increasing participation rate.

After the launch of salt reduction campaign and the agreement with bread makers, the 24-hour urine collection has been introduced to monitor the consumption of sodium and potassium in the general population.

Suggested additional measurements performed in the OEC/HES 2008-2012 are listed in the following Table:

<table>
<thead>
<tr>
<th><strong>Carbon monoxide assessment</strong></th>
<th>assessed using the Micro Smokerlyzer and measured in parts per million (ppmCO); two measurements are performed and the higher value is recorded</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bone densitometry</strong></td>
<td>Portable real-time ultrasonic bone densitometer is used; measurable parameters at the right heel are: STIFFNESS, T score (% of variation compared to healthy young adults) and Z score (% of variation compared to a population of the same age)</td>
</tr>
<tr>
<td><strong>Electrocardiogram</strong></td>
<td>6-lead ECG at rest is performed and is coded by a certified reader according to the Minnesota code (9 items)</td>
</tr>
<tr>
<td><strong>Spirometry</strong></td>
<td>portable spirometer, SpiroPro, is used. Forced Vital Capacity (FVC) and Forced Expiratory Volume in 1 Second (FEV1) are assessed; two measurements are performed and the best of the two is recorded</td>
</tr>
<tr>
<td><strong>24-hour urine collection</strong></td>
<td>for determination of urinary sodium, potassium, creatinine, microalbumin, and iodine concentrations</td>
</tr>
</tbody>
</table>

**Feedback to participants**

The feedback to the participants is an important part of the fieldwork procedures. For many participants, this is one of the main reasons to participate to the HES. The feedback on anthropometric measurements and blood pressure could be provided to the participant right after the measurements. Results of the blood analysis, usually need more time and cannot be provided during the same visit when blood samples are collected.
Examination results should be collected in a folder and given to the participant at the end of examination visit (or are mailed to the participant later on). The folder should also contain explanations of the examinations and lifestyle recommendations, including healthy diet and physical activity suggestions. For those participants who have both total cholesterol and HDL assessments, the individual risk score for persons aged 35-69 years free from previous cardiovascular event can be printed; for those participants who have total cholesterol only, risk chart for persons aged 40-69 years can be printed. For all participants it is possible to print results of measurements, examinations and blood tests. The folder should also contain laboratory blood results, ECG, spirometry and bone densitometry printouts, and a copy of the signed informed consent. In the OEC/HES 2008-2012 the results are provided when the participant come back to the centre to give the 24-hour urine collection.
15. ANALITIC LABORATORY, BLOOD SAMPLE COLLECTION AND STORAGE OF THE SAMPLE

The purpose of a health examination survey is to collect data and biological samples from a random population.

Generally one nurse/laboratory technician/phlebotomist is needed per centre. The key factor of quality lies in the training of the personnel, which must be trained in advance according to the National HES Manual.

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.

**Selection of analytic laboratory**

Analyses are performed both at a local and at a selected central reference laboratory. Those performed at a local laboratory include total cholesterol, HDL-cholesterol, glycaemia, and complete haemochrome and immediate determinations are given to the examined persons as result. Criteria for the selection of the local laboratory include: availability of room and materials necessary for blood collection, proximity to the screening centre, reasonable cost of determinations, availability of a freezer for biological samples storage. As for quality control, usually local laboratories follow regional standards.

Successively all analyses pertaining to the core measurements (total cholesterol, HDL-cholesterol, glycaemia, triglycerides, creatinine, albuminuria) and the specific analyses (urinary creatinine, urinary albumin, calcium, phosphorus and parathormone) for the CARHES study (CArdiovascular risk in Renal patients of the Italian Health Examination Survey) and the MINISAL-GIRCSI project (Gruppo di lavoro Intersocietario per la Riduzione del Consumo di Sale in Italia) are performed at the central Laboratory of Genetic and Ambiental Epidemiology of the Catholic University of Campobasso. The selection of this laboratory as the central laboratory was based on the following important criteria: it is involved in important population studies (the Moli-sani Project www.moli-sani.org); good performance in internal and external quality assessment programmes; it is under the quality control of the Centre for Disease Control of Atlanta for the following determinations: total cholesterol (TC), tryglycerides (TG) and High Density Lipoprotein-C (HDL-C).
Blood sample collection

During the entire survey, the blood withdrawal, processing, storage and transport are to be maintained as uniform as possible by adhering to the manual of operations.

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/适应器 are compatible with each other.

Blood collection is performed for determination of total and HDL-cholesterol, triglycerides and fasting glycaemia concentration. More blood samples than needed for the core measurements are collected and stored in the CNESPS biological bank of the ISS for additional measurements on the samples in the future.

Participants are invited to show up at the screening centre between 8 and 9 am as blood extraction requires a fasting period of at least 12 hours (specified in the invitation letter). The length of time from the last meal in full hours should be reported on the questionnaire. After blood extraction, blood pressure and heart rate measurements, participants undergo screening examinations starting from 10.00 am.

All blood samples are drawn with the subject in a sitting position. If required by the participant, blood drawing can be performed with the subject in supine position. The subject should also abstain from intense physical activity and from smoking for at least 30 minutes before blood collection. Blood should be collected from the vein in the antecubital fossa or from any other vein of the arm and blood stasis should least no more than one minute.

The following safety rules should be followed:
- 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 % etanol solution at the end of the day; any surface or object which is contaminated with blood or other human specimen must be disinfected immediately;
- during blood withdrawal protective gloves should be used; new gloves should be worn for each new subject;
- disposable gloves must be used throughout during handling of blood samples;
- the sampling needle is removed directly into the needlebox from the adapter/holder without touching the needle;
- 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.

The blood collection kit includes:
- 2 blood collection tubes of 4.5 cc with EDTA;
- 1 blood collection tube of 10 cc without preserving;
- 1 thermal bag;
- tourniquet, skin cleaner, pipettes, skin tape, etc.

Tubes are labelled and have different cap colours (usually, tubes with EDTA have violet caps, those without EDTA have yellow or light blue caps).

Other equipment includes:
- special boxes for tube transfer and storage;
- a centrifuge, a vortex and a big container for special waste collection;
- 30°C freezer for blood samples storage;
- set of labels with identification code or name, surname, birth date of the subject to mark the tubes.

Most of the above equipment is provided at local level.

Sample logistics
The biological material (serum, plasma, buffy coat, packaged red blood cells, urine) is collected, stored and sent according to standard methods used in several international studies. Biological samples are processed using materials resistant to low temperature and simple, highly standardised methods allowing for multiple potential uses of the material.

The procedure foresees that 20 cc more blood than that necessary is drawn for immediate determinations by the local laboratory, to be distributed in 3 tubes: 2 with EDTA and 1 without preserving.

After venipuncture, blood collection tubes are filled with blood and those with EDTA are immediately shaken in a delicate manner to avoid coagulation.
The tubes are successively placed in a thermal bag for 2 hours to avoid light exposure and are transferred to the laboratory.

The following equipment is used:

- disposable latex gloves
- 4 plastic tubes of 5 cc
- 4 graduated pipettes
- centrifuge
- shaker Vortex-type
- physiological solution
- 1 insulin microsyringe
The tubes (2 with EDTA and 1 without EDTA for each person) are placed into the centrifuge, making sure they are properly balanced, and spin at 3,200 rpm for 10 minutes.

**Tubes without conservants**
After centrifugation 4ml of serum is aspirated and poured in a clean plastic tube

**Tubes with EDTA**
After centrifugation 4ml of plasma is aspirated and poured in a clean plastic tube; 1ml of buffy coat (1mm above and 1 mm below the grey level between the clotted blood cells and the liquid portion of blood are aspirated) is aspirated and poured into a plastic tube containing 0.25 ml of physiological solution; 1ml of red blood cells is aspirated and poured into a plastic tube containing 0.25 ml of physiological solution.

At this stage, 4 tubes are available, each containing:
- 4ml of serum
- 4ml of plasma
- 1ml of buffy coat + physiological solution
- 1ml of red blood cells + physiological solution

To avoid any waste of biological material after unfreezing, the different samples are introduced into thin plastic cylinders, paillettes, which can be used for different laboratory analyses or at different times. Paillettes, each with a bar code label and a cap (or cotton stopper) of different colour depending on the biological sample contained, are filled and sealed through a machine.
A machine with suction and injection pipes is used to introduce the biological material into each paillette and to heat seal both ends of the paillette, thus assuring minimum outside contamination.
Each tube is inserted into the plexiglas goblet which is fixed to the machine through a vertical slot (tubes work as a tank for the injection tube). The injection tube (one for each person) is placed and fixed using the lock lever without touching the final part of 18 millimetres (with white plastic ring).
The injection tube is extremely delicate, therefore it should not have any contact with paillettes walls. The aspiration tube should be changed if biological material enters into the injection tube connected to the trap.

**Machine functioning**
1. The machine must be turned on 30 minutes before blood samples processing so that welding points reach the temperature of 156°C (the machine works only after this temperature is reached).

2. The gauge of the machine cycles must be chosen so that it is always greater than zero (the machine will automatically stop when the number 000 is reached).

3. The aspiration tube must be clean and in the correct position, the power of the machine, measured in millimetres of mercury (mmHg) must be checked (a graduated knob allows you to choose the aspiration power).

The indicative values required for paillettes filling are the following: for serum and plasma: 20mmHg, for blood red cells and buffy coat: 50mmHg

To verify if the selected power is correct, the aspirated material should soak the first part of the cap until the polyvinyl gel.

4. The green switch must be pushed to make the machine start

The following set of paillettes is used in the filling process:

- 4 paillettes with yellow sheath or cotton stopper (for serum storage) + 2 with white cotton stopper (to be sent to Campobasso)
- 6 paillettes with red sheath or cotton stopper (for plasma storage)
- 2 paillettes with green sheath or cotton stopper (for red blood cells storage)
- 2 paillettes with blue sheath or cotton stopper (for buffy coat storage)

The yellow paillettes need to be PLACED in the storage bunker making sure that extremities with cotton stopper and gel are placed on the aspiration site, that is toward left.
Paillettes will be then filled rapidly with serum contained in tube number 1. The aspiration power should be around 20 mmHg (position 2 of the knob).

After turning the machine off (white switch), the following operations should be performed:

1. The 6 paillettes are *REMOVED* from the exit tray and placed horizontally in a container; paillettes need to become cold to be separated (lock levers tend to stick after welding);
2. Tube number 1 (containing serum) is *REPLACED* by tube number 2 (containing plasma);
3. the injection tube is *INSERTED* in the paillette;
4. the second set of paillettes, the red ones, are *PLACED* in the storage bunker;
5. the machine is *RESTARTED* and sequence 1-2 is repeated;
6. the aspiration power is *INCREASED* to around 50 mmHg (position 5 of the knob);
7. Tube number 2 (containing serum plasma) is *REPLACED* by tube number 3 (containing red blood cells) after it has been shaken into the vortex;

8. The third set of paillettes, the green ones, are *PLACED* in the storage bunker and repeat sequence 1-2 is repeated;
9. Tube number 3 (containing red blood cells) is *REPLACED* by tube number 4 (containing buffy coat) after it has been shaken into the vortex;
10. The fourth set of paillettes, the blue ones, is *PLACED* in the storage bunker and sequence 1-2 is repeated;
11. The aspiration power is *DECREASED* to the previous value.

The machine should never be stopped (white STOP switch) during the filling procedure, neither in case of ‘accident’, as the paillette blocked between the welding electrodes could melt and yield material to the slabs; in this case it is preferable to take the plexiglas lid off the rack and manually remove paillettes after stopping the machine.
If a paillette is sealed when is not filled yet, it is necessary to wait until the end of the cycle, cut one extremity of the paillette, remove the numbered cap from the empty paillette, put it on another paillette and place the paillette in the storage bunker.

For each person, 16 paillettes are obtained which will be then stored into the visotubes.

Goblets, plastic-coloured cylinders containing 12 visotubes of different colour (11 triangle-shaped and 1 cylindrical in the middle of each goblet) are used for paillettes storage.

The sequence of colours of visotubes should remain always the same (see the figure). Each visotube corresponds to one person. Goblets are placed horizontally in the freezer at -30°C and are transferred to the ISS under dry ice. Successively they are placed for one or more days into the freezer at -80°C and then transferred into liquid nitrogen tanks at -196°C.

A specific software which keeps track of all the stored samples and their location allows to match the biological bank information with the data bank information.

The cryogenic freezers need to be filled up at regular intervals, depending on the liquid nitrogen containers capacity and the amount of material stored.

Each set of paillettes contains some labels with the same number reported on the cap of the paillette.

At the end of the above procedures, it is necessary to fill in list A-biological bank. More specifically:

- the Centre code, the patient code (4 numbers), surname, name and date of birth are reported;
- bar code identification label with is stucked;
- the number of paillettes filled is reported in the appropriate spaces;
- the number of visotubes and goblets is reported.

Fill in list B – blood collections to be sent together with paillettes with white cotton stopper to the laboratory of Campobasso. In particular:

- date of blood collections;
- bar code identification label is stucked in the appropriate spaces;
- surname, name and identification code of the patient are reported.
Blood collection for laboratory

20 cc of blood

2 tubes with EDTA (shake gently) 1 neutral tube

thermal bag (+4°C)

turn on the machine and wait until it reaches the right temperature centrifuge (after 2 hours)

ASPIRATE:
4 ml of plasma
1 ml of buffy coat (+0.25 ml of physiological solution)
1 ml red blood cells (+0.25 ml of physiological solution)

verify machine’s aspiration power
(20mmHg for serum and plasma; 50mmHg for red blood cells and buffy coat)

PROCEED TO PAILLETES FILLING

6 RED capillars (plasma) 6 YELLOW capillars (serum)
2 GREEN capillars (red blood cells) (2 to be sent to Campobasso)
2 LIGHT BLU capillars (buffy coat)

PROCEED TO PAILLETES STORAGE
(set aside 2 YELLOW paillettes to be sent to Campobasso)

fill in the list A - Biological Bank
fill in the list B - blood collection
Long term storage of the samples

The biological samples are packaged on dry ice for transfer to the biobank of the National Centre for Epidemiology, Surveillance and Health Promotion (CNESPS). For long term storage reserved for additional measurements and future use, the samples are frozen at -80°C or in liquid nitrogen at -196°C.

Subsequently, serum samples are transported to the Laboratory of Genetic and Ambiental Epidemiology of Catholic University of Campobasso, urine samples to the Department of Experimental and Clinic Medicine of the Medical School of the University of Naples Federico II and paillettes containing serum, plasma, buffy coat and packed red cells to the ISS for storage in the CNESPS biobank. Other biological samples collected within several longitudinal studies of the Progetto Cuore are stored in the CNESPS biobank.

The CNESPS biobank aims at storing at low temperature different types of biological material for future research, usually not planned at the beginning of the study, in the fields of biochemistry, molecular biochemistry and genetics.

The stored biological samples are used exclusively for research purposes upon consent of the donor. The biological bank is managed in accordance with international recommendations and ethical guidelines as well as national laws.

Creatinine and albumin are measured and quantified through assessment of urine volume and urine concentration to evaluate renal insufficiency. Calcium, phosphorus and parathormone are measured only in those samples tested positive for albumin and creatinine due to the presence of a chronic renal disease. Sodium, potassium and urinary creatinine are measured in the laboratory of Naples; a tube containing urine is sent to the University of Pisa for iodine determination.

After performing required determinations, each centre is then required to send data, in electronic format, to Simona Giampaoli of the ISS, responsible of the project.

Assay methods for the blood and urine examinations performed at the central Laboratory of Genetic and Ambiental Epidemiology of the Catholic University of Campobasso

- **Evaluation of serum for:**
  - Total cholesterol using the enzymatic colorimetric method;
  - HDL-cholesterol using the direct immuno-enzymatic colorimetric method;
  - Glycaemia using the Trinder-enzymatic colorimetric method;
  - Triglycerides using the enzymatic colorimetric method.
- Creatinine (in all individuals) to estimate glomerular filtration rate (GFR). The enzymatic method calibrated against the reference method (isotope dilution mass spectrometry - IDMS) is used to measure creatinine.
- Calcium, Phosphorus and Parathormone (only in the subgroup affected by chronic renal disease).

**Measurement on 24-hour urine collection:**
- Urinary creatinine and urinary albumin (in all individuals) quantified through assessment of urine volume and urine concentration. Urinary creatinine concentration is measured by using the methodology followed for creatinine assessment; urinary albumin concentration is measured using the immunoturbidimetric method.

**Guidelines on laboratory performance**

Concerning the core measurements, the golden standards are values determined by the Centre for Disease Control (CDC, Atlanta).

The CDC provides an accuracy-based standard for measuring total cholesterol (TC), tryglicerides (TG) and High Density Lipoprotein-C (HDL-C) in national and international laboratories through the three-phase Lipid Standardization Program (LSP) established since 1961. Laboratories have thus the opportunity to standardize the analysis of TC, TG and HDL-C providing traceability to the CDC accuracy base as established for these analytes. The LSP provides high quality labelled reference materials with which the accuracy of a method can be assessed by comparison to CDC reference method values. The CDC reference samples are provided as unknowns with coded identification to eliminate the possibility of analyst bias. These lipid standardization services are offered at no cost to qualified laboratories. The participating laboratory bears only the cost of shipping the CDC frozen reference materials packed on dry ice. The laboratory must be competent in the performance of the procedure and in the use of instrumentation and analytical materials before beginning standardization program. Before analyzing CDC Program samples, the laboratory is required to perform a number of analyses on internal control samples to determine whether analyses are sufficiently precise to meet the specifications of the Program. The standardization program foresees three parts: part I is the familiarization and preliminary evaluation phase: the analyst becomes familiar with the method, reagents, and conditions necessary for performing standardization analyses. Part II is the principal standardization phase and confirms the ability for the laboratory to achieve and maintain acceptable performance. Part III monitors the ability of the laboratory to continue acceptable performance for three months or longer. The results of each part are reported to CDC upon completion. After determining that the laboratory’s performance is acceptable on each part, CDC will notify the laboratory and will schedule shipment of materials for the next part. CDC will provide a report giving
the CDC reference values (RV) and the difference or bias of the result from the RV for each pool. If the
results meet the criteria for standardization a shipment of part II samples will be scheduled. If criteria
are not met, CDC will advise as how to proceed. At this point, the participant may transfer CDC values
to the laboratory’s bench control pools.
16. FIELDWORK STAFF

The National Health Examination Survey is coordinated by the team of the Unit of Epidemiology of Cardiovascular Disease of the CNESPS ISS; the national survey coordinator organises and coordinates the overall fieldwork of the survey:

- coordinating and supervising all fieldwork activities;
- training the local personnel, monitoring quality control and fieldwork;
- extracting the population sample;
- sending survey invitations;
- selecting and agreeing on examination centres (municipality) in the region;
- receiving and processing survey data from the fieldwork teams;
- receiving, storing and analyzing blood and other samples from the fieldwork Teams;
- keeping in contact with relevant regional/local administration and health services of the fieldwork sites;
- disseminating results of the survey at population level.

Each local team should have a named fieldwork team supervisor. The supervisor needs to work in close collaboration with the national fieldwork coordinator. The tasks of the field team supervisor 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 leaves and other absences;
- keeping a regular contact with the ISS;
- checking daily appointment schedules, checking questionnaires (if needed and not built in computer programmes used in data collection);
- organizing and taking care of transfer of data and instruments.

The fieldwork team supervisors should meet or otherwise keep in contact regularly with the ISS to share up to date information from the centre, brings also information from the ISS back to their teams, e.g. feedback from quality control. They are responsible for monitoring that team members carry out their tasks well in daily basis. If there are problems, that cannot be solved within the team, the supervisors should contact the ISS and unclear issues should be sorted out as soon as possible. It is important that the fieldwork team supervisor receives support from the ISS and does not have to deal problems alone.
The satisfaction of the staff is an important issue for the work quality. The national survey coordinator and fieldwork team supervisor have an important role in creating a positive work environment which effects to the staff satisfaction. A good leader should be visible, consult with staff and provide praise and recognition.

Criteria procedures for the selection of fieldwork staff should take into account special needs and characteristics of the study population.

The OEC/HES represents a system of continuous data collection and its objective is to build a permanent survey staff with great expertise able to carry out fieldwork activities, train local fieldwork staff and continue the collection of epidemiological data in the future.

A close cooperation between local and ISS personnel is absolutely necessary for the success of the survey. When selecting local staff, usually the preference goes to young people, who are more interested in training and can, in turn, train other people to carry out fieldwork activities in order to increase knowledge and expertise in the field of epidemiological data collection. However, this is not always possible as local young staff has already a work contract and cannot receive extra funds, therefore retired personnel can also be engaged. The personnel of the Unit of Epidemiology of cerebro and cardiovascular disease of the ISS is composed of the survey project leader (SG) who is also actively involved in fieldwork organization and supports local staff and a technician with expertise in measurements, data collection, IT systems analysis, sample storage and fieldwork procedures (CLN); usually they are supported in the training by one other technician of the ISS (FD). They are responsible for training local survey personnel during the first week of the screening, verifying that all procedures are performed according to the international quality standard and that equipment is properly functioning. If the survey lasts longer than foreseen, an additional visit at the screening centre is usually necessary, also to collect biological samples.

Interviewers and others in contact with the community should be capable, personable, interested, show good manners and friendliness towards participants and be fluent in national language. An additional prerequisite for the ISS personnel is the willingness to travel around the country.

The professional group needed for most measurements consists of physicians, nurses and other health care professionals. More specifically, with the local supervisor the minimum personnel required in the OEC/HES survey in each centre (municipality) are:
- a person to perform secretarial procedures, welcome participants, update the participant list on the basis of refusals and eventually select substitute participants; this person should also assure that all screening phases are well developed and completed, including delivery of urine box for 24-hour collection and results printing, and check if self-administered food questionnaires have been filled out
and data from instrumental and laboratory examinations entered and printed the results for the participant;
- a professional nurse for blood pressure measurement, blood collection and questionnaire administration;
- a professional nurse for performing anthropometric measurements, electrocardiogram (ECG) at rest, bone densitometry, spirometry and CO measurement;
- a laboratory technician for separation and storage of blood samples and for preparation of urine samples.
The above personnel, except for the laboratory technician, are required to work full time over the duration of the screening procedures.

When evaluating the number of survey personnel needed for fieldwork procedures, potential sick leaves and other absences should be taken into account and therefore a few extra persons (one or two) for substitutes should be trained, although rotation between staff members may compromise the accuracy of measurements. To obviate to such a problem, we use to train the whole personnel to perform all screening procedures in order to ensure possibility to rotate duties between staff members in case of absences.
Fieldwork staff may be recruited specifically for the survey. An alternative is to use personnel from the local health care organizations (e.g. primary care units or health centers or hospitals) in the selected survey sites. It is usually easier to ensure standardization of measurements, if fieldwork staff is recruited specifically for the survey. When permanent personnel of the local health services are trained to carry out the survey fieldwork they may be tempted to follow their regular practices instead of the survey protocols. This may happen especially if they also have their regular tasks during the survey, and are only part time carrying out the survey fieldwork. In any case the use of the local personnel in each survey site increases substantially the time and efforts needed for training. The use of regular health service personnel may also affect survey results by the differences in willingness of the survey participants to disclose their personal issues to the practitioners they are familiar with. This familiarity may both enhance and restrict open communication
The personnel should be motivated to strictly follow the survey protocols to ensure reliability and accuracy of the survey results.
All recommendations provided regarding fieldwork staff are only indicative and may vary on the basis of local organization.
17. DISSEMINATION, PUBLICITY AND REPORTING

Words dissemination, communication and publicity are closely linked to each other and often used in overlapping meeting. Here we define these terms as follows:

Dissemination is a transmission of the information to the public without direct feedback from the audience. Dissemination can be for example a seminar presentation, newsletter or newspaper article.

Communication is activity of conveying meaningful information in the way that there is specified sender of the information, message and also intended receiver for the message. Difference between dissemination and communication is blurred.

Publicity is the deliberate attempt to manage the public's perception of the issues. Promotion of the survey can also be considered as one form of publicity.

Dissemination, communication and publicity are all needed and important aspects of health examination survey (HES). With these, survey organizers keep all stakeholders informed about the survey plans, progress and outcomes.

Role of the communication

Before starting recruitment of study population, personal contacts and an educational campaign are implemented to make individuals motivated to join the study and community leaders supportive and have pride in their association with the OEC/HES project.

Local authorities of each centre involved in the survey (Director-General, Director of the Health Unit, Regional authorities, Mayor) receive the letter of presentation of the project, and the information note of the project explaining that the survey aims at giving a complete picture of the Italian population’s health status and facilitates the planning and evaluation of future preventive programmes. The information note and the letter of presentation of the project are also sent to the local general practitioners (GPs) who can encourage patients enrolled to participate in the study. In small centres, the parish priest, local pharmacies, elderly clubs, as well as local press and TV are also informed.

The invitation letter, usually sent to the recruited persons 15 days prior to the beginning of screening procedures, includes the objectives of the survey, the description of instrumental and laboratory examinations and the importance of the survey for improving public health. The invitation letter also states that the examinations are free, privacy is protected and refusals to participate or withdrawal from the study do not compromise future assistance.
A section on the OEC/HES project is available in both English and Italian language on the website of the CUORE Project (www.cuore.iss.it) and gives basic information on the study. Information are kept up to date with the project progress and data about risk factors and health conditions of the population are published as soon as available. This mean of communication serves as an easy solution to communicate to different target audiences. A communication expert helps survey staff in ensuring simplicity but efficacy of web pages.

The OEC/HES survey is also promoted by several local newspapers that highlight the importance of the national HES in providing information on behaviours and health determinants of the general population through direct examination. Local press conference and releases are also usually organized prior to the start of the screening to raise the awareness of local population about the importance of identifying future health threats and health care challenges and thus convince stakeholders and population about the importance of national HES.

The key messages may for instance be:

Health surveys are vital for understanding the health situation and the behaviours of the population, and they provide an evidence-base for health policies.
Identifying health differences between population groups is a prerequisite in the work to narrow down health inequalities
To support healthy aging we need to know the current state of health of adults and children.
The national HES is conducted by a reliable public health authority, the methods are secure and science based, and the results do not serve any other interests but the public benefit.
Participating in the survey will give participants a free-of-charge opportunity to receive up-to-date information on their own health.
Information about people's health is vital to building an efficient health care system geared to our health needs and that of our families. Each individual's contribution is important in making the study representative.
The physical health examination survey will verify and complement data collected through other health questionnaires and registries.
18. BUDGET AND FUNDING

The Italian OEC/HES represents a system of periodically data collection: the survey lasts three-four years and between one survey and the following there is a five-six years break (1st OEC: 1998-2002; 2nd OEC/HES: 2008-ongoing). This system has allowed to build a permanent survey team in the ISS at the Unit of Epidemiology of cerebro and cardiovascular diseases of the National Centre of Epidemiology, Surveillance and Health Promotion with great expertise on organizing surveys, training local fieldwork staff, conducting surveys and data analyses.

There is no general rule for the optimal duration for the data collection. In our experience a four year exam is the minimum time to examine 10,000 adult people involving local personnel and using two sets of standard instruments with one team travelling across the country for training and assessing the quality control.

In 2008 planning the OEC/HES survey it was decided to enrol one centre in each region to improve the organization, the quality control, to have a better control of the shipment of the biological samples. The survey was planned to assess the health status of the population and more exams were included (spirometry, EKC, bone densitometry mercury sfigmomanometers, statimeter, balances, CO measurement). In this round the duration of the screening in each centre depends on the number of persons to be examined in the region, in fact the sample is proportioned to the numerosness of the population in that region: a sample of 220 persons ages 35-79 years each 1.5 million people.

Ideally 20 persons a day are examined. With a sample of 220 persons, usually the screening lasts 12-15 working days, 6 per week (including Saturday for those persons who cannot participate during the working days). If the survey lasts more than a month, particular attention needs to be paid to regular quality control, re-testing and re-training of the fieldwork staff.

Two complete sets of equipment are available in order to conduct the survey in two different regions contemporary. Here the cost of one complete set:

<table>
<thead>
<tr>
<th>Equipment</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>EKG (I do not know exactly!)</td>
<td>2,000 Euro</td>
</tr>
<tr>
<td>Spirometry</td>
<td>3,000</td>
</tr>
<tr>
<td>Bone densitometry</td>
<td>8,000</td>
</tr>
<tr>
<td>Carbone monoxide exposure</td>
<td>400</td>
</tr>
<tr>
<td>2 mercury sphygmanometers and 2 stethoscopes</td>
<td>460</td>
</tr>
<tr>
<td>Height rute (stadiometer) and two measuring tape</td>
<td>120</td>
</tr>
<tr>
<td>Balance beam scale</td>
<td>650</td>
</tr>
<tr>
<td>Machine for paillettes (biological specimen bank*)</td>
<td>30,000</td>
</tr>
</tbody>
</table>
Portable computer and printer  1.000

*Pailletes (for storage of biological specimen, they are very expensive, they have a printed number for the identification of the person)

For the **centralized laboratory** the cost is for **each test** is:

<table>
<thead>
<tr>
<th>Test</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total cholesterol</td>
<td>0.55 Euro</td>
</tr>
<tr>
<td>HDL</td>
<td>3</td>
</tr>
<tr>
<td>Creatinine</td>
<td>0.95</td>
</tr>
<tr>
<td>Fasting blood glucose</td>
<td>0.44</td>
</tr>
<tr>
<td>Triglycerides</td>
<td>0.78</td>
</tr>
<tr>
<td>Insulinemia</td>
<td>4.5</td>
</tr>
<tr>
<td>Glicate haemoglobin</td>
<td>10.0</td>
</tr>
</tbody>
</table>

The cost of the Laboratory Technician is 63.000 Euro per year

**Two-three persons** of the ISS go to each region **for one week (5 days)** for the training of regional personnel (one research director, plus two technicians) correspond:

<table>
<thead>
<tr>
<th>Role</th>
<th>Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research director</td>
<td>400.00 Euro per day</td>
</tr>
<tr>
<td>Technicians</td>
<td>210.00 Euro each per day</td>
</tr>
</tbody>
</table>
REFERENCES


www.cuore.iss.it

www.ehes.info
Examination date

Subject identification number
Surname
Name
Married surname (if married or widow)
Fiscal code
Sex
Date of birth

Place of birth: nation of birth and city of birth.
Address
Telephone
Self-reported height
Self-reported weight

Even though height and weight will be also measured in HES they should also be asked. Asking height and weight also enables the comparisons of the measured and self-reported height and weight at the European HIS. These data are also used by the National Institute of Statistics (ISTAT) to validate anthropometric data collected through their Health Interview Survey.

Do you usually undergo annual flu vaccination? ............................................ YES [ ] NO [ ]
Have you undergone it in the year 2010/2011? ............................................ YES [ ] NO [ ]

Participants are also asked if they usually undergo flu vaccination and if they have been vaccinated against the last flu (2010-2011); this information was added recently to evaluate the association with the cardiovascular diseases as recently demonstrated

WHAT IS YOUR MARITAL STATUS?
1. single
2. married/cohabitant
3. separated/divorced
4. widowed
5. other
9. insufficient data
How many persons older than 18 years live in the household (including yourself)?

[ ] [ ] persons

This information is used, together with education level and type of job, to define socio-economic position. Usually, in low-income families, children tend to stay at home as they can't find a job.

What is your highest education degree you have obtained?

1. university degree
2. upper secondary education
3. lower secondary education
4. primary education
5. insufficient data

Highest level of education completed means level successfully completed and must be associated with obtaining a certificate or diploma. Persons who have not completed their studies should be coded according to the highest level they have completed (e.g., if upper secondary school diploma was not obtained, the lower secondary school licence should be reported). The category 'university degree' includes the traditional four-year university course but also the other university courses lasting less than 4 years and the diploma obtained after specialized upper secondary schools (e.g. dietician, social assistant, sanitary assistant). The primary certificate includes also the years of primary schools (e.g. third year) even if the licence is not obtained.

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

[ ] [ ] years

What is your current job? .......................................................... .......................................................... ..........................................................

ILO code: [ ]

If codes 1 = student, 7 = housewife, 9 = unemployed, 10 = retired, 23 = disabled person, 24 = temporary lay-off or in the mobility list

Occupation is coded following the ILO coding system of 1968, reviewed and updated, which is the most commonly used in Italian longitudinal studies and can be converted into that used in MONICA and MORGAM studies.

For housewives or women in retirement:

Do you usually fulfill domestic tasks?

1. No
2. Yes, but only light domestic tasks
3. Yes, all tasks, including the heavy one (e.g., doing the laundry, scrubbing the floors, washing windows etc.)

If in retirement

What was your job?

describe the job

ILO code NO. [ ] [ ] [ ]
2. BLOOD PRESSURE AND ANTHROPOMETRIC MEASUREMENTS

<table>
<thead>
<tr>
<th>Measurement</th>
<th>SYSTOLIC</th>
<th>DIASTOLIC</th>
<th>Pulse Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st Measurement of the Arterial Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYSTOLIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIASTOLIC, V phase of Korotkoff</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pulse Rate, 1 min</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of blood pressure measurement</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2nd Measurement of the Arterial Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYSTOLIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIASTOLIC, V phase</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3rd Measurement of the Arterial Blood Pressure</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SYSTOLIC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIASTOLIC, V phase</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Measurement</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Right Arm Circumference, cm</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(in cm, rounding down decimals to nearest 0 or 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Type of cuff used</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1 = adult normal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2 = obese</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Room temperature</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>°C</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hours of fasting before blood drawing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>hour</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Height, in cm, rounding to the nearest value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>WEIGHT, in kg and hectograms, rounding to 200 grams</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waist Circumference, in cm,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(rounding decimals to the nearest 0 or 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>HIP Circumference, in cm,</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(rounding decimals to the nearest 0 or 5)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carbon Monoxide, p/mil</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3. PHYSICAL ACTIVITY

This section includes a set of questions on physical activity at work and during leisure time.

The section on physical activity includes three questions investigating on:
1. current job or past job for those who do no longer work (in retirement, on income support, unemployed, disabled);
2. stress at work (for those in retirement, data are referred to the past job period);
3. physical activity during leisure time (for all interviewed data are referred to the current period).

The questions foresee four different answers regarding type, duration and intensity of physical activity. The interviewed person can choose the answer which explains better his/her physical activity at work and during leisure time and his/her condition of stress.

For housewives, fulfilling domestic tasks is considered physical activity at work; for women who have a job, fulfilling domestic tasks is considered physical activity during leisure time.

A. If currently employed

WHAT IS THE PHYSICAL ACTIVITY DERIVING FROM YOUR JOB? choose an answer by referring to the main job or activity

1. work done mainly sitting at a desk and generally without the need to walk
2. work that implies standing and walking for a long time, but does not oblige to carry or move heavy weights (this answer also includes normal housework, except hard work)
3. work that implies a lot of walking and handling heavy weights (this answer also includes regular hard housework, such as doing the laundry, scrubbing the floors manually)
4. hard manual work, with great efforts and lifting and handling heavy weights.

HOW LONG HAVE YOU BEEN DOING THIS JOB? [___] [___]

B. If retired or unemployed or disabled person or temporary lay-off

WHAT WAS THE PHYSICAL ACTIVITY DERIVING FROM YOUR JOB IN THE PAST?

1. work done mainly sitting at a desk and generally without the need to walk
2. work that implies standing and walking for a long time, but does not oblige to carry or move heavy weights (this answer also includes normal housework, except hard work)
3. work that implies a lot of walking and handling heavy weights (this answer also includes regular hard housework, such as doing the laundry, scrubbing the floors manually)
4. hard manual work, with great efforts and lifting and handling heavy weights.

HOW LONG HAD YOU BEEN DOING THIS JOB? [___] [___]

ARE YOU UNDER STRESS WHILE WORKING?

Reply is needed also for the categories without income — housewives, students — retired persons should refer to the previous activities; reply is not required only if you have never worked

1. work with little responsibility and without stress, lack of tension
2. an easy job, but with a state of stress and highly emotional
3. work implying responsibility and continuous deadlines with work stress
4. no job satisfaction and/or a sense of being unable to face problems, family worries
WHAT IS YOUR PHYSICAL ACTIVITY DURING YOUR LEISURE TIME? Choose an answer that describes a situation that has persisted for 6 months

1. usually you read, watch television, go to the movies or spend your leisure time in other sedentary activities
2. you walk, ride a bicycle or do some kind of physical activity for at least 4 hours a week. Indicate if you don’t do anything more tiring than going to work on foot or by bicycle, or gardening, if you go hunting or fishing, if you play ping-pong
3. you do sports as a hobby, such as running, swimming, tennis, gymnastics, or you do hard work in the garden or at home or other similar efforts (this is valid if this activity is carried out at least 3 times a week)
4. you train regularly or you play sport professionally such as athletics, skiing, swimming, football, basketball, tennis, several times a week

4. SMOKING HABIT
This is a detailed section. Cigarette smoking history and habit are recorded for both smokers and past smokers; passive smoking among non-smokers is also investigated. Current smokers are subdivided into occasional smokers smoking less than 28 cigarettes/month, occasional smokers smoking more than 28 cigarettes/month, and regular smokers.

DO YOU SMOKE?
YES, REGULARLY fill in section A
NO fill in section B
OCCASIONALLY less than a cigarette per day, fill in section C
INSUFFICIENT DATA use this answer only in special cases (e.g. the subject leaves before completing the questionnaire) because this prevents filling in the remaining parts of the questionnaire on smoking and it is necessary to go to next section

IF YOU SMOKE ONLY PIPE OR SIGARS GO TO SECTION D

SECTION A : for those who smoke regularly
HOW MANY CIGARETTES DO YOU SMOKE ON AVERAGE EVERY DAY?

DO YOU INHALE SMOKE? YES .......... NO
DO YOU SMOKE FILTER CIGARETTES? YES .......... NO
WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE? ..................................................
WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?
0.5 cm
1 cm
2 cm
3 cm

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?
HOW LONG HAVE YOU BEEN SMOKING AS YOU DO NOW? __ years

WOULD YOU LIKE TO STOP SMOKING? YES NO

HAVE YOU EVER TRIED TO STOP SMOKING? YES NO

If yes how long have you been without smoking?
years __ months __

OVERALL, HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? sum up the partial periods
__ years

Go to section D

SECTION B: for those who do not currently smoke

HAVE YOU EVER SMOKED CIGARETTES REGULARLY IN THE PAST? YES fill in all this section
NO Go to section D

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR? __

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY? __

WHEN DID YOU STOP SMOKING REGULARLY? __

if in the last year, specify:
1 = less than one month
2 = between one and six months
3 = between six and twelve months
8 = for more than a year

BEFORE STOPPING REGULARLY, HAVE YOU GONE WITHOUT SMOKING FOR SOME TIME?
YES NO

How long have you gone without smoking? sum up the partial periods? __

Go to section D

SECTION C: for those who smoke occasionally

HOW MANY DAYS A WEEK DO YOU SMOKE CIGARETTES?
from 1 to 6 or less than 1 day a week, code 1

NOTE: if a smoker smokes even only one cigarette a day, he is a regular smoker and needs to fill in section A
__

HOW MANY CIGARETTES DO YOU SMOKE ON AVERAGE EACH DAY YOU SMOKE?

Calculate the number of cigarettes smoked in a week by multiplying the numbers of cigarettes smoked per day for the
number of days : if its greater than 28, go to section CI

HAVE YOU EVER SMOKED CIGARETTES REGULARLY IN THE PAST?
YES   fill in all the questions of this section
NO   go to section C2

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?

WHEN DID YOU STOP SMOKING REGULARLY?

if in the last year, specify:
1 = less than one month
2 = between one and six months
3 =between six and twelve months
8 = for more than a year

BEFORE STOPPING REGULARLY, HAVE YOU GONE WITHOUT SMOKING FOR SOME TIME?
YES  NO

HOW LONG HAVE YOU GONE WITHOUT SMOKING? sum up the partial periods

go to section D

SECTION C1 : for those who smoke occasionally more than 28 cigarettes a week

DO YOU INHALE SMOKE? YES  NO
DO YOU SMOKE FILTER CIGARETTES? YES  NO
WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE? ...................................................

WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?
0,5 cm
1 cm
2 cm
3 cm

WHAT WAS THE MAXIMUM NUMBER OF CIGARETTES SMOKED EVERY DAY FOR AT LEAST ONE YEAR?

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?

HOW LONG HAVE YOU BEEN SMOKING?

WOULD YOU LIKE TO STOP SMOKING? YES  NO

HAVE YOU EVER TRIED TO STOP SMOKING? YES  NO
If yes, HOW LONG HAVE YOU GONE WITHOUT SMOKING?

years |__| |__| months |__|

HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? *sum up the partial periods*

|__| |__| years

Go to section D

SECTION C2: *for those who have always smoked occasionally*

DO YOU INHALE SMOKE? YES NO

DO YOU SMOKE FILTER CIGARETTES? YES NO

WHAT CIGARETTE BRAND DO YOU USUALLY SMOKE?

WHEN DO YOU THROW AWAY OR PUT OUT A CIGARETTE (actual length of the cigarette end or lit end, for cigarettes without filter)?

0,5 cm
1 cm
2 cm
3 cm

HOW OLD WERE YOU WHEN YOU STARTED SMOKING CIGARETTES REGULARLY?

HOW LONG HAVE YOU GONE WITHOUT SMOKING AFTER HAVING STARTED? *sum up the partial periods*

|__| |__| years

Go to section D

SECTION D: *questions on cigars and cigarillos*

HAVE YOU EVER SMOKED CIGARS OR CIGARILLOS?

YES, currently on a regular basis

NO, never go to section E

OCCASIONALLY, less than one per day

YES, only in the past go to section E

INSUFFICIENT DATA go to section E

HOW MANY CIGARS OR CIGARILLOS DO YOU SMOKE PER WEEK? |__| |__| |__|

In case of two values, insert the average value

SECTION E: *questions on pipe*

HAVE YOU EVER SMOKED A PIPE?

YES, currently on a regular basis

NO, never go to section F

OCCASIONALLY, less than one pipe bowl per day YES, only in the past go to section F INSUFFICIENT DATA go to section F

HOW MANY GRAMS OF TOBACCO DO YOU SMOKE PER WEEK? |__| |__| |__|

In a folding packet contains 50 g of tobacco

SECTION F: *passive smoking*

This section must be filled in only by those who do not currently smoke or smoke occasionally
HOW MANY HOURS ON AVERAGE A DAY ARE YOU EXPOSED TO PASSIVE SMOKING WITHIN CLOSE RANGE?

<table>
<thead>
<tr>
<th></th>
<th>hours of exposition to passive smoking</th>
</tr>
</thead>
<tbody>
<tr>
<td>9</td>
<td>insufficient data</td>
</tr>
</tbody>
</table>

5 ALCOHOL AND SALT CONSUMPTION

Daily or week consumption of wine, aperitifs or liquorous wine, strong drinks and the daily number of coffee (including cappuccino) are recorded.

DO YOU CURRENTLY DRINK WINE?

(000) no
(020) only 1 or two glasses per day
(050) about ½ litre per day
(100) about 1 litre
(150) about 1 ½ litre
(200) about 2 litres
(250) about 2 ½ litres
(300) about 3 litres
more than 3 litres (specify) ………………

HOW MANY APERITIFS AND/OR SPIRITS DO YOU DRING PER DAY ON AVERAGE?

(00) none
(03) 1 or 3 per week
(07) from 3 to 5 per week
(11) from 6 to 7 per week
(24) from 1 to 3 per day
(48) more than 3 per day

HOW MUCH BEER DO YOU DRINK PER DAY ON AVERAGE?

(00) none
(15) about ½ litre
(30) about 1 litre
(60) more than 1 litre

HOW OFTEN DO YOU ADD SALT AT TABLE?

never or rarely
quite often
always or very often

HOW MUCH BREAD DO YOU EAT PER DAY?

Less than 3 slices or 3 small bread rolls
4-5 slices or 4-5 small bread rolls
More than 5 slices or 5 small bread rolls
I always eat no salt or low salt bread

HOW MANY TIMES A WEEK DO YOU EAT CHEESE, SAUSAGES OR SALAMI
0-2 times
3-4 times
5 or more times

DO YOU USUALLY GET VERY THIRSTY, ESPECIALLY AFTER A MEAL?
ever or rarely
quite often
always or very often

WHEN YOU EAT OUT, FOOD IS USUALLY PERCEIVED AS
insipid
normal
salty

6. ARTERIAL BLOOD PRESSURE AND HYPERTENSION
HAS ANY DOCTOR OR OTHER HEALTH WORKER TOLD YOU THAT YOUR ARTERIAL BLOOD PRESSURE IS HIGH?
YES
NO
INSUFFICIENT DATA

OVER THE LAST TWO WEEKS, HAVE YOU TAKEN ANY MEDICINES PRESCRIBED BY A DOCTOR TO LOWER YOUR BLOOD PRESSURE?
YES
NO
UNCERTAIN

HOW MANY TYPES OF MEDICINES DO YOU TAKE?
MEDICINE 1
Name of the medicine .................................................................
Do you take it on a daily basis?  YES  NO
Number of pills a day  Number of pills a week
MEDICINE 2
Name of the medicine .................................................................
Do you take it on a daily basis?  YES  NO
Number of pills a day  Number of pills a week
MEDICINE 3
Name of the medicine .................................................................
do you take it on a daily basis?  YES  NO
Number of pills a day  Number of pills a week
SECTION G

WHEN WAS THE LAST TIME YOUR BLOOD PRESSURE WAS MEASURED?
During the last 12 months
At least 1 year but less than 5 years ago
5 years ago or more

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR BLOOD PRESSURE?
YES [] NO [] UNCERTAIN []

7. CHOLESTEROLAEMIA

HAVE YOU EVER BEEN TOLD BY A DOCTOR OR OTHER HEALTH WORKER THAT YOUR CHOLESTEROL LEVEL IS HIGH?
YES []
NO [] go to section H
INSUFFICIENT DATA [] go to section H

OVER THE LAST TWO WEEKS, HAVE YOU TAKEN ANY MEDICINES PRESCRIBED BY A DOCTOR TO LOWER YOUR CHOLESTEROL LEVEL?
YES []
NO [] go to section H
UNCERTAIN [] go to section H

HOW MANY TYPES OF MEDICINES DID YOU TAKE? []

MEDICINE 1
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES [] NO []
Number of pills a day [_] Number of pills a week []

MEDICINE 2
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES [] NO []
Number of pills a day [_] Number of pills a week []

MEDICINE 3
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES [] NO []
Number of pills a day [_] Number of pills a week []

WHEN WAS THE LAST TIME YOUR CHOLESTEROL WAS MEASURED?
During the last 12 months
At least 1 year but less than 5 years ago
5 years ago or more

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR CHOLESTEROL?
YES [] NO [] UNCERTAIN []
8. DIABETES

HAVE YOU EVER BEEN TOLD BY A DOCTOR OR OTHER HEALTH WORKER THAT YOU HAVE DIABETES?

YES ||

NO || go to page 16

INSUFFICIENT DATA || go to page 16

OVER THE LAST TWO WEEKS HAVE YOU TAKE ANY MEDICINES, INCLUDING INSULIN, TO CONTROL YOUR DIABETES?

YES ||

NO || go to page 16

INSUFFICIENT DATA || go to page 16

HOW MANY TYPES OF MEDICINES DID YOU TAKE? ||

MEDICINE 1

Name of the medicine ..............................................................................................................
do you take it on a daily basis? YES NO
Number of pills a day || Number of pills a week ||

MEDICINE 2

Name of the medicine ..............................................................................................................
do you take it on a daily basis? YES NO
Number of pills a day || Number of pills a week ||

OVER THE LAST 12 MONTHS, WERE YOU RECOMMENDED BY YOUR PHYSICIAN TO CHANGE LIFESTYLE TO LOWER YOUR GLYCAEMIA LEVEL?

YES || NO || UNCERTAIN ||

9. ASPIRIN

OVER THE LAST TWO WEEKS HAVE YOU TAKEN ASPIRIN TO PREVENT OR CURE HEART DISEASES?

YES ||

NO ||

NO, but I took aspirin for other reasons (NOT HEART DISEASES) ||

INSUFFICIENT DATA ||

WHAT IS THE NAME OF THE MEDICINE CONTAINING ASPIRIN DO YOU TAKE?
do you take it on a daily basis? YES NO
Number of pills a day || Number of pills a week ||

DO YOU FOLLOW CONTINUING ORAL OR INTRAVENAL CORTISON THERAPY?

YES || SPECIFY ______________________________

NO ||

UNCERTAIN ||
DO YOU FOLLOW CONTINUING TIROXINE (EUTIROX) THERAPY?
YES, ___ | SPECIFY ______________________________
NO ___
UNCERTAIN ___

10. MEDICINE USE
This section aims at measuring actual use of all medicines based on a doctor’s initiative or recommendation. Here are also included the medicines which were prescribed in the past by a doctor and recently, the respondent has not visited the doctor to renew the prescription.
Medicines taken following the recommendation of a pharmacist should not be considered as medicines recommended by a doctor.
Medicines should be coded later using the first level ATC (Anatomical Therapeutic Chemical) classification system.

DO YOU TAKE OTHER MEDICINES ON A REGULAR BASIS?
YES || NO | go to next section

HOW MANY TYPES OF MEDICINES DO YOU TAKE? ___
Insert the number of medicines taken

MEDICINE 1
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES || NO 
Number of pills a day ___ Number of pills a week ___

MEDICINE 2
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES || NO 
Number of pills a day ___ Number of pills a week ___

MEDICINE 3
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES || NO 
Number of pills a day ___ Number of pills a week ___

MEDICINE 4
Name of the medicine ........................................................................................................
do you take it on a daily basis? YES || NO 
Number of pills a day ___ Number of pills a week ___

MEDICINE 5
Name of the medicine YES || NO 
Number of pills a day ___ Number of pills a week ___

11. ANGINA PECTORIS
The section includes the questionnaires of the London School of Hygiene and Tropical Medicine - LSHTM with questions on presence and duration of pain during exercise (walking briskly uphill) and relief; also information on surgical procedures (PTCA and CABG) are collected. The questionnaire has been validated and, although many years have passed since its introduction and it is not so appropriate for women and elderly people, it is still the most used questionnaire.
The questionnaire must be interrupted if the answer falls in a field marked with an asterisk (*) and the interviewed must go to the section on myocardial infarction.

**HAVE YOU EVER FELT PAIN, DISCOMFORT, OPPRESSION OR WEIGHT IN THE CHEST?**

YES | NO | *
---|---|---

**DOES THIS PAIN OCCUR WHEN YOU WALK QUICKLY OR UPHILL?**

YES | NO | *
---|---|---

**DOES THIS PAIN OCCUR WHEN YOU WALK AT A USUAL PACE ON THE FLAT?**

YES | NO | *
---|---|---

**WHAT DO YOU DO WHEN THIS PAIN OCCURS WHILE YOU ARE WALKING?** *Indicate the first answer if you go on walking after taking a pill of trinitroglycerin*

- You stop or slow down
- Go on walking at the same pace

**WHAT HAPPENS WHEN YOU STOP?**

- The pain disappears
- The pain does not disappear

**HOW LONG AFTER DOES THE PAIN DISAPPEAR IF YOU STOP OR SLOW DOWN?**

- 10 minutes or less
- More than 10 minutes

**WHERE IS PAIN LOCATED?**

![Heart Diagram]

**HAVE YOU UNDERGONE CORONARY BYPASS SURGERY?**

YES | NO | *
---|---|---

**HAVE YOU UNDERGONE ANGIOPLASTY SURGERY?**

YES | NO | *
---|---|---
12. MYOCARDIAL INFARCTION

This section investigates the occurrence of old myocardial infarction and, eventually, hospitalization. Hospitalization date, hospital name, name of the cardiologist or general practitioner are recorded.

HAVE YOU EVER FELT A VERY STRONG PAIN IN THE LOWER PART OF YOUR CHEST FOR AT LEAST HALF AN HOUR?
YES [ ] NO [ ]

AFTER THIS PAIN, WERE YOU DIAGNOSED WITH ACUTE MYOCARDIAL INFARCTION, HEART ATTACK, CORONARY ATTACK, MYOCARDIAL ISCHAEMIA?
YES [ ] NO [ ]

HOW WAS THIS DIAGNOSIS MADE?
1. during hospitalisation
2. with an ECG made at home or at the clinic
3. without an ECG

HOW MANY ATTACKS OF THIS KIND HAVE YOU EXPERIENCED?
1st ATTACK month [ ] year [ ]
duration of the pain hours [ ]

LAST ATTACK month [ ] year [ ]
the duration of the pain hours [ ]

If the answer to this section of the questionnaire is YES, indicate the name and address of the doctor, the hospital or clinic.
13. CEREBROVASCULAR ACCIDENTS

Cerebrovascular accidents include acute neurological episodes provoked by ischaemia or cerebral haemorrhagia and characterized by loss of consciousness and/or paralysis affecting any body part, and/or vertigo with dizziness, and/or blurred vision, and/or slurred speech. The time when the first and last events occurred is recorded. In the blank space at the end of the section the name of the general practitioner, his/her address, the hospital or clinic where the person was hospitalized are recorded.

HAVE YOU EVER EXPERIENCED EPISODES CHARACTERISED BY THE MORE OR LESS SUDDEN LOSS OF THE USE OF THE MUSCULAR FORCE OF A LEG AND/OR OF AN ARM AND/OR OF ONE PART OF THE FACE?
YES [□]  NO [□]

IF YOU HAVE EXPERIENCED SIMILAR EPISODES MORE THAN ONCE, INDICATE HOW LONG AGO THIS OCCURRED:
1. Less than two weeks ago
2. Less than a month ago
3. Less than three months ago first time [□]
4. Less than six months ago last time [□]
5. More than six months ago
6. You do not remember

DID YOU LOOSE CONSCIOUSNESS?
YES [□]  NO [□]

DID YOU LOOSE THE USE OF SPEECH?
YES [□]  NO [□]

HOW LONG HAVE YOU REMAINED DISABLED?
1. Less than 24 hours
2. From 1 to 7 days [□]
3. From 8 to 28 days
4. More than 28 days

ON THIS OCCASION, WERE YOU DIAGNOSED WITH BRAIN HAEOMORRHAGE, CEREBRAL THROMBOSIS, CEREBRAL ISCHAEMIA, PARALYSIS?
YES [□]  NO [□]

HOW WAS THIS DIAGNOSIS MADE?
1. during hospitalisation
2. at home [□]
3. without any particular examinations

TIA

The term TIA indicates a transient ischaemic attack of brief duration characterized by loss of consciousness and/or paralysis affecting any body part.

HAVE YOU EVER SUFFERED TEMPORARY LOSS OF SPEECH?
YES [□]  NO [□]

HAVE YOU EVER NOTICED A SUDDEN DECREASE OF THE MUSCULAR FORCE OF AN ARM OR OF A LEG THAT RAPIDLY GOT WORSE?
YES [□]  NO [□]

HAVE YOU EVER EXPERIENCED DIZZINESS WITH SPEECH PROBLEMS OR A SENSE OF MENTAL
<table>
<thead>
<tr>
<th>Confusion?</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Have you ever noticed a sudden short episode characterised by a decrease in eyesight?</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Describe any other neurological problems</td>
<td>………………………………………………………………..</td>
<td></td>
</tr>
<tr>
<td>…………………………………………………………………..</td>
<td></td>
<td></td>
</tr>
<tr>
<td>On this occasion, were you diagnosed with TIA (Transient Ischaemic Attack)?</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Yes, during hospitalisation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, at home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes, without any particular examinations</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. Claudicatio Intermittens

Claudicatio intermittens is a syndrome caused by inadequate blood flow to the lower extremities and is characterized by the impossibility, due to pain, to take more than a certain number of paces, that is constant and specific for each person.

This section includes the London School of Hygiene and Tropical Medicine -LSHTM- questionnaire

The questionnaire must be interrupted if the answer falls in a field marked with an asterisk (*)

Do you suffer from pain in the legs when you walk? | Yes | No |
|---------------------------------|-----|----|
Do you ever feel this pain when you are standing still or sitting? | Yes | No |
| In what part of the leg do you feel this pain? |…………………………………………………………………..|
|…………………………………………………………………..|
| 1. The pain includes both calves or only one | |
| 2. The pain does not include the calves | |
Do you feel pain when you walk quickly or uphill? | Yes | No |
| Do you feel this pain when you walk at a usual pace on the flat? | Yes | No |
| Does the pain ever disappear while you are still walking at the same pace? | Yes | No |
| What do you do when this pain occurs while you are walking? |…………………………………………………………………..|
|…………………………………………………………………..|
| you stop or slow down | |
| go on walking at the same pace | |
| What happens when you stop? |…………………………………………………………………..|
|…………………………………………………………………..|
| the pain disappears | |
| the pain does not disappear | |

How long after does the pain disappear if you stop or slow down?
10 minutes or less
more than 10 minutes *

HAVE YOU UNDERGONE ANY SURGERY TO IMPROVE THE CIRCULATION OF THE LOWER LIMBS
(EXCLUDING VEIN OPERATIONS)?
YES || NO ||

16. DISEASES AND SELF-PERCEIVED HEALTH
The section on diseases includes a list of diseases such as bronchial asthma, COPD, hepatic cirrhosis, renal diseases, endocrinal diseases, malabsorption, autoimmune diseases, fractures, depression, and cancer. At the bottom of diseases section it is possible to describe other diseases and hospital admissions including dates, hospital names, and discharge diagnoses.

DO YOU HAVE OR HAVE YOU EVER HAD ANY OF THE FOLLOWING DISEASES OR CONDITIONS?

Bronchial Asthma | no | yes, documented | yes, no doc
Chronic obstructive pulmonary disease | no | yes, documented | yes, no doc
Cirrhosis of the liver | no | yes, documented | yes, no doc
Kidney disease | no | yes, documented | yes, no doc
Chronic renal insufficiency | no | yes, documented | yes, no doc
Urinary calcolosis | no | yes, documented | yes, no doc
Glomerular nephritis | no | yes, documented | yes, no doc
Interstitial nephropaty/Pyelonephritis | no | yes, documented | yes, no doc
Polycystic kidney | no | yes, documented | yes, no doc
Endocrinal disease | no | yes, documented | yes, no doc
Malabsorption (celiac disease) | no | yes, documented | yes, no doc
Autoimmune diseases | no | yes, documented | yes, no doc
Previous fractures | no | yes, documented | yes, no doc
Depression | no | yes, documented | yes, no doc
Cancer (malignant tumour/place and anatomo-pathologist description) | no | yes, documented | yes, no doc

Other, specify

___________________________________________________ ________________________
___________________________________________________ ________________________

SELF-PERCEIVED HEALTH
It is assessed on a 0-10 point self-perceived health status scale (0: worst; 10: best); the participant is asked to rate his health status
The concept is restricted to an assessment coming from the individual and not from anyone outside that individual, whether an interviewer, health care worker or relative. Self-perceived health is influenced by impressions or opinions from others, but is the result after these impressions have been processed by the individual relative to their own beliefs and attitudes. 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 function and biomedical signs and symptoms. It omits any reference to an age as respondents are not specifically asked to compare their health with others of the same age or with their own or future health state. It is not time limited.
HOW DO YOU CONSIDER YOUR ACTUAL HEALTH STATUS?
(To help you answer correctly, please refer to the scale below, where 10 represents the best health status and 1 the worst)

1 2 3 4 5 6 7 8 9 10

17. FAMILY HISTORY
The interviewed person is asked if his/her father, brothers, sons and his/her mother, sisters, daughters suffered from angina pectoris, myocardial infarction, cerebrovascular event or stroke and/or underwent by-pass, angioplasty at different age ranges (<55 years old, 55-64, 65-74, >75). The number of persons experiencing the above diseases/surgical procedures is recorded. If parents, brothers, sisters, sons, daughters have hypercholesterolemia, hypertension and diabetes, this should be recorded. The total number of brothers, sisters, sons, daughters is recorded.

HAVE YOUR FATHER, YOUR BROTHERS, YOUR SONS SUFFERED FROM ANY OF THE FOLLOWING CORONARY DISEASES: ANGINA PECTORIS OR MYOCARDIAL INFARCTION, AORTA-CORONARY BYPASS SURGERY OR ANGIOPLASTY? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<55yy 55-64yy 65-74yy > 75yy
YES (n. of events) [ ] [ ] [ ] [ ]
NO [ ]
UNCERTAIN [ ]

HAVE YOUR FATHER, YOUR BROTHERS, YOUR SONS SUFFERED FROM ANY CEREBROVASCULAR DISEASES OR STROKE? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<55yy 55-64yy 65-74yy > 75yy
YES (n. of events) [ ] [ ] [ ] [ ]
NO [ ]
UNCERTAIN [ ]

HAVE YOUR MOTHER, YOUR SISTERS, YOUR DAUGHTERS SUFFERED FROM ANY OF THE FOLLOWING CORONARY DISEASES: ANGINA PECTORIS OR MYOCARDIAL INFARCTION, AORTA-CORONARY BYPASS SURGERY OR ANGIOPLASTY? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<55yy 55-64yy 65-74yy > 75yy
YES (n. of events) [ ] [ ] [ ] [ ]
NO [ ]
UNCERTAIN [ ]

HAVE YOUR MOTHER, YOUR SISTERS, YOUR DAUGHTERS SUFFERED FROM ANY CEREBROVASCULAR DISEASES OR STROKE? (IF YES; SPECIFY THE TOTAL NUMBER OF EVENTS AND THE AGE RANGE)

<55yy 55-64yy 65-74yy > 75yy
YES (n. of events) [ ] [ ] [ ] [ ]
NO [ ]
UNCERTAIN [ ]
NO  |  
UNCERTAIN  |  

DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE A HIGH LEVEL OF CHOLESTEROL OR TRIGLYCERIDES IN THEIR BLOOD?

YES  |  
NO  |  
UNCERTAIN  |  

DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE HIGH PRESSURE?

YES  |  
NO  |  
UNCERTAIN  |  

DID OR DO YOUR PARENTS, YOUR BROTHERS AND SISTERS, YOUR SONS AND DAUGHTERS HAVE DIABETES?

YES  |  
NO  |  
UNCERTAIN  |  

How many brothers do you have?  ||  and sisters?  ||

How many sons do you have?  ||  and daughters?  ||
18. INSTRUMENTAL ACTIVITIES OF DAILY LIVING AND THE ACTIVITIES OF DAILY LIVING (IADL-ADL)

Self-reported questionnaire provided by the National Institute of Statistics (ISTAT). The basic ADL refers to the items: moving between rooms, use the lavatory, washing and bathing, dressing and undressing, getting in and out of bed, and feeding oneself. Mobility refers to: moving outdoors, using stairs, walking at least 400 metres, carrying heavy objects for 100 m. IADL refers to the items: preparing own meals, doing light housework, doing heavy housework.

How is your health in general?

[ ] Very good
[ ] Good
[ ]
[ ] Bad
[ ] Very bad

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

[ ] Yes
[ ] No

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

[ ] Severely limited
[ ] Limited but not severely
[ ] Not limited at all

<table>
<thead>
<tr>
<th>You are able to:</th>
<th>Yes, without difficulty</th>
<th>With some difficulty</th>
<th>With much difficulty</th>
<th>Not able</th>
</tr>
</thead>
<tbody>
<tr>
<td>See newspaper print (considering your normal use of eyeglasses or contact lenses)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>See the face of someone 4 metres away (across a road)? (considering your normal use of eyeglasses or contact lenses)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Hear what is said in a conversation with several people (considering your normal use of hearing aids)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Walk 500 metres on a flat terrain without a stick or other walking aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Walk up and down a flight of stairs without a stick, other walking aid, assistance or using the banister</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bend and kneel down without any aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using your arms, can you carry a shopping bag weighing 5 kilos for at least 10 metres without any aid or assistance</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Use your fingers to grasp or handle a small object like a pen without any aids</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bite and chew on hard foods such as a firm apple without any aid (without the help of a denture)</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Do you usually have difficulty doing any of these activities by yourself?</td>
<td>Yes, without difficulty</td>
<td>With some difficulty</td>
<td>With much difficulty</td>
<td>Not able</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>Feeding yourself</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Getting in and out of a bed or chair</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Dressing and undressing alone</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using the toilet</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Bathing or showering</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Preparing meals</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Using the telephone</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Managing medication</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Light housework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Occasionally heavy housework</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>Taking care of finances and everyday administrative tasks</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

**19. MINI MENTAL STATE EXAMINATION (M.F. FOLSTEIN)**

The Mini Mental State Examination (M.F. Folstein) is used in persons aged 65+ to assess the global cognitive function. The test includes questions on orientation to time and place registration, attention and calculation recall, language and visual construction. The maximum score is 30 points. The test was originally created for a clinical setting but is extensively used in epidemiological studies.


Assess the level of sensorium along a continuum:

- alert = 1, somnolent = 2, stupor = 3, coma = 4

*Give 1 point for each correct answer and sum all points at the end of the test*

*10 seconds for each answer*

- What year are we in now (season)?
- What season are we in now?
- What month is it?
- What is the date today?
- What is the day today?
- What State do we live in?
- What Region do we live in?
- With town do we live in?
- Where are we now?
- Which floor are we on?

‘I will say the names of 3 unrelated objects, pay attention as I will ask you to repeat them in a few minutes’

*Say the names clearly and slowly, about one second for each.*

- sock
- blue
- charity

Could you repeat them?
20 second for repetition, keep saying them until he can repeat all 3, up to 5 trials.

‘Could you slowly count backwards by 7 beginning with 100?’

Give 1 point for each correct subtraction even if it is made beginning with a wrong number

‘Could you recall the 3 words I previously asked you to remember?’

Give 1 point for each correct answer

‘Please name the objects I will show you’

What is this? (show a pencil) —

What is this? (show a watch) —

‘Please, repeat the following

‘TIGRE CONTRO TIGRE’* —

Only one trial is allowed

Give 1 point for correct answer

Ask the subject if he/she is right-handed or left-handed. If right-handed ask:

‘Take a paper in your left hand, fold it in half, and give it back to me” (if left-handed, ask to take the paper in the right hand)

Score 1 point for each part correctly executed.

— Take the paper with the correct hand
— Fold it in half
— Give it back to the interviewer

‘Read the sentence written on this piece of paper and do what it says (show to the subject a piece of paper with the sentence CLOSE YOUR EYES) (1 point)

Give 1 point if the subject closes his/her eyes

Give the subject a blank piece of paper and ask him/her: ‘Write the first sentence that comes to your mind’. Do not dictate a sentence, it is to be written spontaneously. It must contain a subject and verb and be sensible.

Correct grammar and punctuation are not necessary.

Give 1 point if the sentence is correct.

On a clean piece of paper, draw intersecting pentagons, each side 3 cm., and ask the subject:

‘Copy this drawing exactly as it is’

The answer is correct if there are 10 angles, two of them intersecting; do not consider hand waving due to
tremor.

Give 1 point if the drawing is correct.

* this represents a difficult expression to repeat

20. SECTION RESERVED TO WOMEN

Cardiovascular disease is a different disease for women than it is for men for several aspects: diffusion, age range of interest and seriousness. These differences depend on types and amount of sexual hormones. This section investigates the use of hormone replacement therapy in menopausal women and the use of contraceptive pill in fertile women.

DO YOU STILL HAVE YOUR MENSTRUAL PERIODS?

YES, regularly

YES, but not on a regular basis or with cycles interrupted less than 6 months ago

NO

Pregnancy

AT WHAT AGE DID YOU GO COMPLETELY IN MENOPAUSE?

Insert the age in years after six months without cycles

99= insufficient data

HAVE YOU TAKEN HORMONES FOR MENOPAUSE OVER THE LAST MONTH?

YES, pills, injections or plasters

NO

INSUFFICIENT DATA

MEDICINE 1

Name of the medicine ..........................................................

do you take it on a daily basis? YES | NO

Number of pills a day [ ] Number of pills a week [ ]

MEDICINE 2

Name of the medicine ..........................................................

do you take it on a daily basis? YES | NO

Number of pills a day [ ] Number of pills a week [ ]

MEDICINE 3

Name of the medicine ..........................................................
do you take it on a daily basis?  
| YES | NO |

Number of pills a day | Number of pills a week

HAVE YOU TAKE CONTRACEPTIVE PILLS OR INJECTIONS OVER THE LAST MONTHS?

| YES |
| NO |
| INSUFFICIENT DATA |
EHES Core questionnaire
(This questionnaire was self-administered only in the EHES pilot areas, Noale and Torino)

Personal characteristics

Q1. How many persons live in the household (including yourself)? |__|__| persons

Q4. What is your legal marital status? (EHIS HH5.)
- |___| Single, that is, never married
- |___| Married (including registered partnership)
- |___| Widowed and not remarried
- |___| Divorced and not remarried (including legally separated and dissolved registered partnership)
Are you living with a spouse or partner?
- |___| Yes
- |___| No

Q5. What is the highest education leaving certificate, diploma or education degree you have obtained?
(Please, include any vocational training) (EHIS HH7.)
- |___| No formal education or below ISCED 1
- |___| Primary education (ISCED 1)
- |___| Lower secondary education (ISCED 2)
- |___| Upper secondary education (ISCED 3)
- |___| Post-secondary but not-tertiary education (ISCED 4)
- |___| First stage of tertiary education (ISCED 5)
- |___| Second stage of tertiary education (ISCED 6)
Note: the response categories should be named according to the educational system of the country
How many years have you spent at school or in full-time study? |__|__| years

Q6. How would you define your current labour status? (Modified from EHIS HH.8, * modified parts)
- |___| Working for pay or profit -> Go to question Q8.
- |___| Unemployed
- |___| Pupil, student, further training, unpaid work experience
- |___| In retirement or early retirement or has given up business
- |___| Permanently disabled
- |___| Long term sick leave (at least 6 month)*
- |___| In compulsory military or community service
- |___| Fulfilling domestic tasks
- |___| Maternity or paternity or parents’ leave*
- |___| Other, please specify: __________________________

Q7. Have you ever worked for pay or profit (HH.9)
- |___| Yes
- |___| No -> Go to question Q13.

Q8. Are (Were) you an employee, self-employed or working without payment as a family worker? (HH.10)
Q9. What type of work contract do (did) you have? (HH.11) (UNDER CONSIDERATION)
☐ Permanent job/work contract of unlimited duration
☐ Temporary job/work contract of limited duration

Q10. In your (main) job do (did) your work full-time or part-time? (HH.12) (UNDER CONSIDERATION)
☐ Full-time
☐ Part-time

Q11. What is (was) your occupation in this job? (HH.13) (UNDER CONSIDERATION)
Job title: ________________________________
Describe what do (did) you mainly do in your job: __________________________

Q12. What does (did) the business/organization mainly produce or do at the place where you work ( worked) (e.g. chemical, fishing, hotel/restaurant, health and social work, etc.) (HH.14) (UNDER CONSIDERATION)
__________________________________________________________
Q17. Have you had any of the following diseases or conditions, diagnosed by a medical doctor, in the past 12 months? (Modified from EHIS HS.6, modification marked with *) (LIST OF RELEVANT DISEASES UNDER CONSIDERATION)

- [ ] Asthma (allergic asthma included)
- [ ] Chronic bronchitis, chronic obstructive pulmonary disease, emphysema
- [ ] Myocardial infarction
- [ ] Coronary heart disease (angina pectoris)
- [ ] High blood pressure (hypertension)
- [ ] High blood cholesterol *
- [ ] Stroke (cerebral haemorrhage, cerebral thrombosis)
- [ ] Rheumatoid arthritis (inflammation of the joint)
- [ ] Osteoarthritis (arthrosis, joint degeneration)
- [ ] Low back disorder or other chronic back defect
- [ ] Neck disorder or other chronic neck defect
- [ ] Diabetes
- [ ] Allergy, such as rhinitis, eye inflammation, dermatitis, food allergy or other (allergic asthma excluded)
- [ ] Stomach ulcer (gastric or duodenal ulcer)
- [ ] Cirrhosis of the liver, liver dysfunction
- [ ] Cancer (malignant tumour, also including leukaemia and lymphoma)
- [ ] Severe headache such as migraine
- [ ] Urinary incontinence, problems in controlling the bladder
- [ ] Chronic anxiety
- [ ] Chronic depression
- [ ] Other mental health problems
- [ ] Permanent injury or defect caused by an accident

European Health Care Module

Q18. During the past two weeks, have you used any medicines (including dietary supplements such as herbal medicines or vitamins) that were prescribed or recommended for you by a doctor (for women, include also contraceptive pills or other hormones)? (MD.1)

- [ ] Yes
- [ ] No -> Go to question Q21

Q19. Were they medicines for … ? (MD.2) (LIST OF RELEVANT DISEASES UNDER CONSIDERATION)

- [ ] Asthma
- [ ] Chronic bronchitis, chronic obstructive pulmonary disease, emphysema
- [ ] High blood pressure
- [ ] Lowering the blood cholesterol level
- [ ] Other cardiovascular disease, such as stroke and heart attack
- [ ] Pain in the joints (arthrosis, arthritis)
- [ ] Pain in the neck or back
Headache or migraine
Other pain
Diabetes
Allergic symptoms (eczema, rhinitis, hay fever)
Stomach troubles
Cancer (chemotherapy)
Depression
Tension or anxiety

Q20. Have you used other types of medicines that were prescribed to you, such as? (MD.2)
Sleeping tables
Antibiotics such as penicillin (or any other national relevant example)
Contraceptive pills
Hormones for menopause
Some other medicines prescribed by a doctor. If yes: what type of medicines:

European Health Determinants Module

Q23. Do you smoke at all nowadays? (SK.1)
Yes, daily
Yes, occasionally -> Go to question 26
Not at all -> Go to question 26

Q28. How often are you exposed to tobacco smoke indoors at home? (SK.6) (UNDER CONSIDERATION)
Never or almost never
Less than 1 hour per day
1-5 hours a day
More than 5 hours a day

European Background Variables Module

Regarding the last 12 months and all your family needs, how could you consider your family income?
Very good
Adequate
Scarce
Insufficient

Q31. 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. (IN.4)
Less than 1,000,00 euro
| | Between 1.000,00 and 2.000,00 euro |
| | Between 2.000,00 and 3.000,00 euro |
| | Between 3.000,00 and 4.000,00 euro |
| | Between 4.000,00 and 5.000,00 euro |
| | More than 5.000,00 euro |