CARDIOVASCULAR SURVEYS: MANUAL OF OPERATIONS

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CONTENTS

ABBREVIATIONS

1. INTRODUCTION AND RATIONALE
1.1. Burden of disease
1.2. Cardiovascular Disease Surveys
1.3. Historical background
1.4. Existing Surveys in EUROCISS member countries – a brief overview

2. OBJECTIVES

3. **STRATEGY FOR SURVEILLANCE**
3.1. Surveillance methods and types of registers

4. MINIMUM SET OF QUESTIONS FOR HEALTH INTERVIEW SURVEYS

5. MINIMUM SET OF EXAMINATIONS FOR HEALTH EXAMINATION SURVEYS

6. POPULATION
6.1. Age range
6.2. Gender
6.3. Socio-cultural characteristics
6.4. Ethnic origin and migration level
6.5. Geographic and/or administrative area

7. POPULATION SAMPLING
7.1. Random national samples
7.2. General Practitioner's network
7.3. Opportunistic screenings

8. RESPONSE RATE

9. REPORTING

10. QUALITY CONTROL

11. ETHICAL ISSUES

12. RECOMMENDATIONS

TABLE 1. HES Surveys -- disease: all IHD

TABLE 2. HIS Surveys -- disease: all IHD

TABLE 3. Tools for monitoring CVD

TABLE 4A. Minimum set of recommended questions for CVD/HIS

TABLE 4B. Minimum set of recommended questions for CVD risk factors/HIS
TABLE 5. Step-wise approach for CVD HIS/HES

APPENDIX I

London School of Hygiene Cardiovascular Questionnaire and Diagnostic Criteria

REFERENCES

ABBREVIATIONS

ABI = Ankle/Brachial Index
ACS = Acute Coronary Syndromes
AMI = Acute Myocardial Infarction
AP = Angina Pectoris
ATC = Anatomical Therapeutic Chemical (classification system)
CABG = Coronary Artery Bypass Graft
CHD = Coronary Heart Disease
CVD = CardioVascular Disease
CW = Continuous Wave
2D = 2-Dimensional
DALY = Disability Adjusted Life Year
ECG = Electrocardiogram
ECHIM = European Community Health Indicators Monitoring
EHRM = European Health Risk Monitoring
EU = European Union
EUROCISS = European Cardiovascular Indicators Surveillance Set
EUROSTAT = Statistical Office of the European Communities
GP = General Practitioner
HDR = Hospital Discharge Records
HES = Health Examination Survey
HF = Heart Failure
HIS = Health Interview Survey
IC = Intermittent Claudication
ICD = International Classification of Diseases
IHD = Ischaemic Heart Disease
ISI = International Statistical Institute
LSHTM = London School of Hygiene and Tropical Medicine
MI = Myocardial Infarction
MONICA = MONItoring trends and determinants of CArdiovascular diseases
OECD = Organisation for Economic Cooperation and Development
PAD = Peripheral Arterial Disease
PCI = Percutaneous Coronary Intervention
PIN = Personal Identification Number
PTCA = Percutaneous Transluminal Coronary Angioplasty
PVD = Peripheral Vascular Disease
PW = Pulsed Wave
QoL = Quality of Life
SEP = Socioeconomic Position
WHO = World Health Organization

1. INTRODUCTION AND RATIONALE

1.1 Burden of disease

The most frequent forms of cardiovascular disease (CVD) are those of an atherosclerotic origin, mainly Ischaemic Heart Disease (IHD), stroke, Heart Failure (HF) and Peripheral Vascular Disease (PVD).

CVD clinically manifests itself in middle life and older age, after exposure to risk factors. Even though clinical onset is mainly acute, CVD often evolves gradually and causes substantial loss of quality of life, disability, and life long dependence on health services and medications. The societal costs of CVD are substantial and they are not only those directly related to healthcare and social services, but also include those linked to: a) illness benefits and retirement; b) impact on families and caregivers; and c) loss of years of productive life.

Changes in society's socio-economic conditions and their concomitant influence on lifestyles affect the level and evolution of CVD in populations and individuals, in such a way that small changes in the prevalence of common risk factors like hypertension or smoking might have a large impact on the incidence of CVD [1]. However, the absolute number of patients in need of using health services for CVD conditions does not decrease to the same extent due to an increase in survival and a growth in the proportion of older people.

The magnitude of the problem contrasts with the usual paucity and poor quality of data available on incidence and prevalence of CVD, except for few rigorous but limited studies carried out in certain geographical areas.

Leading causes of CVD morbidity and mortality are IHD and stroke. Just under half of all deaths from CVD are from IHD and nearly a third are from stroke, and this is the case in almost all the European Union (EU) countries.

In 2005, all chronic diseases accounted for 72% of the total global burden of disease in the population ages 30 years and older. CVD alone accounts for 20% of global total Disability Adjusted Life Years (DALYs) in those older than 30 years of age [2].

In terms of health, acute events may mean an increasing number of dependent, chronically ill and disabled people which may cause increasing costs of healthcare

and strain the healthcare system. Despite this, according to the Organisation for Economic Cooperation and Development (OECD), it does not appear inevitable that longer life leads to higher costs. This is one of the reasons why the health system should be largely oriented to work on preventive actions.
Epidemiological studies have shown that CVD is preventable to a large extent. Public actions to lower the prevalence of risk factors in the population require a clear understanding and knowledge of the magnitude and consequences of CVD. Once reliable data are available, different preventive strategies can be implemented to reduce the occurrence and impact of disease.

Health Interview and Health Examination Surveys (HIS/HES) to determine the distributions, frequencies and determinants of CVD and their trends are essential to plan and implement prevention and control programmes.

1.2 Cardiovascular Disease Surveys

The objectives of a population health survey is to evaluate the frequency and the distribution of CVD and its risk factors, to evaluate trends and treatment effectiveness, to estimate distribution and prevalence of high risk conditions and to monitor prevention programmes and their effectiveness.
Focusing on the general population, surveys may provide a comprehensive picture of the disease in the community, highlight problem areas and suggest where treatment facilities and strategies are most in need of improvement. They may provide the information needed to plan healthcare services and to develop and test which methods are most useful as a basis for preventive and treatment action. These population-based surveys provide, as well, valuable additional information that can be linked with the information generated by other sources such as population-based registers.
Clinical and vital statistical studies have contributed notably to the understanding of causes and distribution of CVD, but their conclusions usually require verification by direct measurements on defined populations. Moreover, certain types of questions cannot be answered except through the conduct of specific CVD surveys.

CVD surveys are needed in order to understand the characteristics, the burden and the consequences of the disease in the population through:

- the monitoring of the occurrence of disease, i.e to assess the population differences and trends in disease prevalence over time;
- the understanding of the differences and changes in the natural disease dynamics between genders, age groups, social classes, ethnic groups etc.;
- the identification of vulnerable groups;
- the monitoring of the consequences of disease in the community;
- the monitoring of the utilisation of new diagnostic tools and treatments and their impact.

This is crucial in order to:

- develop health strategies and policies;
- plan health services and health expenditures;
- improve appropriate allocation of resources;
- evaluate the effectiveness of interventions.

Surveys must follow standardised procedures and methods in order to:

- avoid biases from diagnostic fashions;
- ensure data comparability (different populations and trends);
- ensure data comparability with other surveys within the country;
- ensure international comparability.

1.3 Historical Background

The modern era of cardiovascular epidemiology began after the Second World War with the establishment of a number of cohort studies. What follows is a brief description of some of the studies that have contributed to our understanding of CVD epidemiology.

The *Framingham Study*, the best-known study, and a model for many others, was launched in the early 1950s. Several thousand men and women of all ages in Framingham, a community near Boston, were examined for certain personal suspected risk factors and followed-up for many years for coronary heart disease (CHD). The most consistent and powerful of these in explaining coronary risk were cigarette smoking, hypertension, plasma lipids and overweight. The control

of these factors has occupied a central role in health promotion and public policy [3].

The *Seven Countries Study* was the first to compare CVD incidence and risk factors using a common protocol and standardised methodology in different international populations (USA, Finland, the Netherlands, Yugoslavia, Italy, Greece, Japan). That study, launched at the end of 1950s and following 12,000 men ages 40-59 years at baseline, found large differences in dietary fat intake, serum cholesterol and heart disease incidence (mortality and morbidity).

The study was unique for its time in standardisation of measurements of diet, risk factors and CVD, training its survey teams and central, blindfold coding, selecting diagnostic criteria for the identification of diseases and analysis of data [4].

The *Whitehall Study*, of almost 20,000 men ages 40-69 years examined in 1960s and followed-up at regular intervals, is still being carried out (and since 1985 women have also been included). This study produced important insight into the determinants of health, highlighting the importance of the social environment in disease causation and cautioning against using stress uncritically as an explanation [5].

The *MONItoring trends and determinants of CArdiovascular diseases* (*MONICA) Study*, from the mid-1980s to mid-1990s, monitored coronary events and classic risk factors for CHD in 38 populations from 21 countries. Population surveys to estimate trends in risk factors were carried out in men and women ages 35-64 years.

Risk factors were measured with standard procedures during two surveys based on independent probability samples of the population at the beginning and the end of the 10-year period, generally with a third survey in the middle [1].

1.4 Existing Surveys in EUROCISS member countries – a brief overview

Table 1 and 2 provide a description of the main surveys on CVD. Almost all these do not specifically focus on CVD but are general health surveys, where CVD is monitored as part of the overall health monitoring of the population (i.e. as part of the national health survey). As shown in Table 1, the HES periodicity varies among countries. Methods of data collection include specific questions and/or the London School of Hygiene and Tropical Medicine (LSHTM) questionnaire for the evaluation of symptoms, medical examination and Electrocardiogram (ECG).

HIS are included in Table 2; they usually report findings from general questions on health conditions elicited through the use of self-administered questionnaires. Therefore, some conditions such as the prevalence of hypertension and diabetes could be underestimated given that only a part of diabetics and hypertensives are aware of their condition [6].

The source of all information reported in these tables is the questionnaire filled in by each EUROCISS Project partner. Data have been last updated in 2006, therefore any change occurred after this time period is not reported.

2. OBJECTIVES

The purpose of the EUROCISS Project is to provide a general guide and updated methods for the surveillance of CVD to those EU countries which lack appropriate surveillance systems and therefore wish to perform a survey in order to produce comparable and reliable indicators.

This manual represents a useful tool to estimate CVD prevalence, a core indicator recommended by the EUROCISS Project research Group for inclusion in the short list of health indicators set up by the European Community Health Indicators Monitoring (ECHIM) Project. This Project was launched in 2005 with the aim of implementing health monitoring in EU [7].

The procedures illustrated in this manual are designed with the main goal of simplicity and ease of implementation. Starting from a minimum data set and following a step-wise procedure, a standardised model for the implementation of surveys is provided.

These Survey procedures are aimed at describing the prevalence of the following CVD conditions: Myocardial Infarction (MI); HF; Angina Pectoris (AP); Peripheral Arterial Disease (PAD); Stroke; and IHD.

More detailed surveys may collect information on risk factors, social and demographic variables of population.

3. STRATEGY FOR SURVEILLANCE

3.1 Surveillance methods and types of registers

Surveillance is the ongoing, systematic collection, analysis, interpretation and dissemination of health information to health professionals and policy makers. Surveillance, defined as a continuous, and not episodic or intermittent activity, differs from monitoring [8,9].

Disease surveillance in a population can be done using many different data sources (Table 3). Most countries have national databases on causes of death and on discharge diagnoses for hospitalised patients.

Mortality statistics have for many years been the main tool for monitoring CVD trends and comparing health, disease pattern and mortality within and between countries. Causes of death are coded according to the International Classification of Diseases (ICD) to make data comparable among countries but the different ICD versions adopted by countries and different methods of ascertainment have led to problems in comparison.

In recent years routine statistics have also included hospital discharge diagnoses which, in some countries, are coded according to the same ICD as the mortality data.

Many countries have also HIS/ HES. These surveys are primarily used for monitoring CVD prevalence, risk factors (health behaviour, social network, environmental risk factors) and disease consequences (disability, reduced physical function, unemployment).

Relationship between Registers and Surveys

HIS and HES were developed to supplement information collected from routine information systems with additional details on socio-demographic characteristics, data on risk factors and physical/biological measurements in order to develop consistent public health policies. Based on the self-reports (HIS) and with the added benefit of physical examinations (e.g. blood pressure) and/or biological measurements (e.g. serum cholesterol) (HES), surveys enable policy makers to set priorities and to monitor trends in the health of the population.

Data for health monitoring, including monitoring of CVD, can be obtained from both registers and surveys; these instruments complement each other, since one has limitations not present in the other.

In general, institutional-based registers such as hospital discharge or General Practitioner's (GP) register can provide an overview on treated morbidity and suggest hypotheses for further investigations. These types of registers are valuable for healthcare services evaluation, but are not sufficient for health monitoring purposes. There are two main reasons for this: firstly, registers are subject to selection bias, as health service users differ from the general population. Secondly, estimates of prevalence are difficult to obtain, as the denominator (i.e. total number of patients seen within a particular time period) remains unclear or must be approximated; in addition, the numerator is sometimes also questionable due to the lack of exhaustivity of the registration process. Population-based register can partly overcome this problem, but coverage remains a major concern.

Population health surveys can overcome much of the selection bias affecting register data, provided that participation rates are high in all population subgroups. The added value of a population-based survey is the horizontal approach of data collection, enabling the collection of a wealth of information on health and its determinants: health status, health determinants, personal characteristics, uptake of services, etc. The simultaneous collection of these elements from the same person makes it possible to produce a global picture of the health of the population, identifying priority areas for treatment and prevention. In addition, when data are periodically gathered over time, changes in health and effects of health policies and interventions can be monitored.

The population health survey brings together the arguments for an increased investment in health promotion and prevention, and rationalisation on healthcare and expenditure. This information thus provides a powerful framework for a rational policy decision-making process.

On the other hand, the results of health surveys have to be interpreted with caution as compared with more objective data coming from registers or routine statistics. Selection bias may result from non-response due to those who refuse to participate or could not be reached. As data are collected in a sample of the

population, statistical methods have to be applied taking into account the sampling design in order to interpret the results adequately. In addition, due to the relatively small sample size, health surveys are usually not suitable for health monitoring in small geographic areas. For these purposes, particular surveys targeted to special populations or applying small-area methodology are more appropriate techniques.

Health Information Surveys and Health Examination Surveys

HIS may be part of a permanent system of data collection at a national or regional level. They can be repeated periodically, in a new sample of the population, or follow up over time all or a subgroup of those recruited at baseline. One of the main characteristics of a survey is that most of the information gathered is provided by the individuals themselves, with all the potential subjectivity involved. Their experience and how they feel in relation to their own health status plays a major role, as well as the level of knowledge they have about it. Medical diagnoses refer to the declaration of a person answering the question: 'Has a doctor ever told you that you have …?' without any objective verification of the diagnosis by medical records; in some instances the self-reported information may not be sufficient to assess CVD morbidity. On the other hand, not only the conditions are considered, but there is also the possibility of investigating their impact on the functional status of the respondent; hence functionality and disability related to the disease are also important issues that can be investigated by a survey.

Self-reported information on disease can be more reliable if integrated with questions on drug specific consumption.

HES are designed to investigate health issues: data are collected using survey questionnaires; in addition, physical examination and/or biological testing are carried out to obtain objective measurements to complement the subjective reporting of individuals.

A HIS/HES can vary in size and complexity, from an interview with a few measurements and/or blood assay to a comprehensive health examination taking several hours to complete. Some CVD risk factors can only be identified by

clinical measurements such as blood pressure, blood lipids, blood glucose. ECG is also an important tool to assess CVD, in particular to detect an old myocardial infarction, atrioventricular conduction defects, arrythmias and left ventricular hypertrophy. It can be read according to the Minnesota Code, that changes qualitative diagnoses into quantitative results; in fact, Minnesota Code allows researchers to measure waves magnitude and duration and to transform them into numerical measures [10]. More clinical information can be obtained by clinical examinations carried out by nurses and doctors, which enables the actual prevalence of many CVD conditions to be assessed. Hand–held echocardiography is recommended to make a reliable diagnosis of HF [11].

High costs of clinical examination make HES difficult to carry out; only few HIS and HES use properly standardised and sensitive methods to assess CVD morbidity.

Ad hoc CVD surveys provide important information on risk factors and disease prevalence but are seldom representative of the whole country. They are usually conducted on adults and often have some age cut-off (e.g. exclude subjects older than 70 years). Their reliability depends greatly on the participation rate and methodologies adopted. If conducted in representative population samples, *ad hoc* CVD surveys may provide a reliable estimation of CVD prevalence. Standardised procedures and methods are available, such as the questionnaires from the LSHTM used to identify effort AP, old MI and intermittent claudication (IC). These have been used for many years in population studies and are available in different languages. They may evaluate the presence of symptoms, of great importance for the health system when evaluating the burden of disease, because they record not only the acute manifestations of a previous disease (for example old MI), but also the symptoms (for example chest pain) which contribute to the use of health services and to health costs.

4. MINIMUM SET OF QUESTIONS FOR HEALTH INTERVIEW SURVEYS

Detailed guidelines about population health survey design and methods are provided in other publications [12]. A document produced by the Statistical Office of the European Communities (EUROSTAT) Task Force 2 is available on the website europa.eu.int/comm/eurostat [13]. This manual provides further indications specific for HIS on CVD questions.

Self-completed questionnaires, direct interviewer-administered questions and telephone interviews are common methods used to collect information from individuals enrolled. Questionnaire design depends on the method of administration and questionnaires need to be validated.

As a general recommendation, a strategy for surveillance would be to use a national population health survey as the instrument of choice to collect information on CVD risk factors and prevalence. A minimum set of questions should be included (short module), together with a longer and more detailed module to be administered periodically, for example every 5-10 years.

Essential items to be recorded in any survey are: full name, gender, marital status, date of birth, area of residence, identification number, date of interview and identity of the interviewer. In order to respect privacy and confidentiality of respondent, full name, area of residence, identification number and exact day of birth are never disclosed; even if the respondent gives informed consent, the anonymity is preserved (especially in the case of sensitive health data). Recording the Personal Identification Number (PIN), which is used by the national health service, makes it possible to link data collected with hospital discharge records (HDR) or death certificate, eventually for the follow-up. Educational level (expressed as years of education) and occupational classification are important because CVD recognises a Socioeconomic Position (SEP) influence (See also Section 6.3) [14].

The most important outcome measures in surveys are estimates of the prevalence of CVD (old MI, AP, IC, HF, Stroke). These can be obtained by asking directly about each condition, or can be measured indirectly through questions to assess symptoms. When designing a questionnaire to obtain such estimates, it is

important to consider that all current techniques for measuring the prevalence of CVD have some limitations, for example symptom questionnaires have poor specificity for IHD and cannot be relied upon for cross-cultural comparisons of prevalence. The comparison of prevalence estimates based on a history of diagnosed heart disease may be biased by differences in access to medical care and diagnostic facilities. If HIS can be combined with HES, the addition of clinical examinations can improve on the estimates. For example, ECG criteria for prevalence of IHD (standardised through use of Minnesota coding) are more likely to yield unbiased comparisons of prevalence than questionnaire alone.

The minimum set of questions and recommendations for each condition are reported below. Irrespective of presence of symptoms, the presence of the condition diagnosed by a doctor, together with the use of medication to treat the condition, should be considered indicative of the presence of the disease. Moreover, questions like "Have you ever told by a doctor that you had …heart disease?" can be followed by questions about the diagnostic and therapeutic procedures performed (Percutaneous Transluminal Coronary Angioplasty -PTCA-; Coronary Artery Bypass Grafting -CABG-; specific medication).

4.1 Angina Pectoris

AP is the commonest symptom of IHD. To assess angina, a minimum set of standard questions (A. Recommended Questions) or the standard WHO (World Health Organization)/LSHTM questionnaire (B: Recommended Questionnaire) can be used. The standard questionnaire of the LSHTM (see Appendix I for the original version including diagnostic criteria) has been widely used; it was originally validated in men against clinical diagnoses, but it is a questionnaire that records symptoms in a standardised manner (chest pain relieved by rest) rather than the presence of disease. Especially in women, the questionnaire fails to distinguish coronary from non-coronary symptoms [15]. The questionnaire is also not recommended for use in older people [16]. Anyway, presently it represents the standardised tool translated in all languages.

A. Recommended questions

Have you ever been told by a doctor that you had angina pectoris?

If Yes: [How old were you when you had the first attack?]

[Have you had an attack in the past 12 months?]

Are you currently (in the last 2 week) taking any medicines, tablets or pills because of your angina pectoris?

If Yes: [Name the medicines you are taking]

Interventions (CABG, PTCA):

Have you ever undergone any surgery procedure because of your condition?

If Yes: [How long ago was it?]

[What type of surgery did you undergo?]

Angioplasty (balloon treatment for angina pectoris)

CABG

Other_____]

B. Recommended Questionnaire

Chest Pain on Effort - LSHTM questionnaire

Note: please do not proceed to next question if your answer is marked with asterisk (*)

- *Have you ever had any pain or discomfort in your chest?*
  - Yes (ask next question)
  - No *
- *Do you get it when you walk uphill or hurry?*
  - Yes
  - No *
  - Never hurry
- *Do you get it when you walk at an ordinary pace at the level?*
  - Yes
  - No
- *What do you do if you get it while you are walking?*
  - Stop or slow down
  - Carry on *

Record 'Stop or slow down' if subject carries on after taking nitroglycerine

- *If you stand still, what happens to it?*
  - Relieved
  - Not relieved *

If relieved:

- *How soon?*
  - 10 minutes or less
  - More than 10 minutes *
- *Will you show me where it was?*
  - Sternum (upper or middle)
  - Sternum (lower)
  - Left anterior chest
  - Left arm
  - Other
- *Do you feel it anywhere else?*
  - Yes
  - No
- *Did you see a doctor because of this pain (or discomfort)?*
  - Yes
  - No

  If yes, what did he say it was?

4.2 Myocardial Infarction

To assess an old MI standard questions (A. Recommended Questions) or the Rose questionnaire (B: Recommended Questionnaire) can be used as well.

A. Recommended questions

Have you ever been told by a doctor that you had myocardial infarction (heart attack)?

If Yes: [How old were you when you had the first attack?]

[Have you had an attack in the past 12 months?]

Are you currently (in the last 2 week) taking any medicines, tablets or pills because of your myocardial infarction?

If Yes: [Name the medicines you are taking]

Interventions (CABG, PTCA):

Have you ever undergone any surgery or operation because of your condition?

If Yes: [How long ago was it?]

[What type of surgery did you undergo?]

[Angioplasty (balloon treatment for angina)

CABG

Other]

B. Recommended Questionnaire

Possible Infarction - LSHTM questionnaire

- Have you ever had a severe pain across the front of your chest lasting for half an hour and more?

– Yes

– No

- Did you see a doctor because of this pain?

– Yes

– No

If Yes: [What did he say it was?]

[How many of these attacks have you had?]

1st attack: date_____ duration of pain_____

2nd attack date_____ duration of pain_____

3rd attack date_____ duration of pain _____

4th attack date _____ duration of pain _____

4.3 Stroke

It is difficult to use a questionnaire survey to measure the prevalence of an old cerebrovascular accident: many patients with stroke are unable to participate (they are not able to reach the place of screening or are hospitalised/in a long-term care home or are too impaired). For these reasons, if the institutionalised population is not included in the survey, stroke registers are more likely to yield valid data.

Recommended questions

Have you ever been told by a doctor that you had a stroke?

If Yes: [How old were you when you had your stroke?]

[Have you had a stroke in the past 12 months?]

Are you currently (in the last 2 weeks) taking any medicines, tablets or pills because of your stroke?

If Yes: [Name the medicines you are taking]

4.4 Heart Failure

No validated set of questions to assess symptoms of HF exists, since symptoms are not sufficiently specific for the disease. The European Society of Cardiology provided guidelines for the diagnosis of heart failure for use in clinical practice and epidemiological surveys [17]. According to these guidelines, objective evidence of cardiac dysfunction has to be present to establish the presence of heart failure, in particular: presence of symptoms of HF (at rest or during exercise), objective evidence (preferably by echocardiography) of systolic and/or diastolic cardiac dysfunction (at rest) and, in cases where the diagnosis is in doubt, response to treatment directed towards HF. The presence of shortness of breath or fatigue can be assessed by means of the WHO questionnaire [12], but a clinical examination is required to verify the presence of ankle swelling and pulmonary crepitations or rhonchi.

Recommended questions

Have you ever been told by a doctor that you had heart failure?

If Yes: [How old were you when you suffered from heart failure?]

[Have you suffered from heart failure in the past 12 months?]

Are you currently (in the last 2 weeks) taking any medicines, tablets or pills because of your heart failure?

If Yes: [Name the medicines you are taking]

4.5 Intermittent Claudication

IC is the commonest symptom of PAD. To assess PAD, LSHTM questionnaire is recommended.

Recommended questionnaire

Intermittent Claudication - LSHTM questionnaire

Note: please do not proceed to next question if your answer is marked with asterisk (*)

- Do you get pain in either leg on walking?
– Yes
– No *
- Does this pain ever begin when you are standing still or sitting?
– Yes *
– No
- In what part of your leg do you feel it?

– Pain includes calf/calves

– Pain does not include calf/calves*

If calves not mentioned, ask: Anywhere else?

If calves not mentioned, ask: Anywhere else?

- *Do you get it if you walk uphill or hurry?*

– Yes

– No *

– Never hurries or walks uphill

- *Do you get it if you walk at an ordinary pace on the level?*

– Yes

– No

Does the pain ever disappear while you are walking?

– Yes *

– No

- *What do you do if you get it when you are walking?*

– Stop or slow down

– Carry on*

- *What happens to it if you stand still?*

– Relieved

– Not relieved*

- *How soon?*

– 10 minutes or less

– More than 10 minutes

The set of questions asking about each doctor-diagnosed condition is further summarised in Table 4A.

4.6 Other relevant topics

Measurement of ***Quality of Life (QoL)*** and disability are relevant for health policy and disease burden in the population. Various standard questionnaires are available for measuring quality of life and functional capacity (e.g. SF36/SF12, EUROQOL).

Family history asks whether a first-degree relative (parent, sibling or offspring) was ever diagnosed with a premature (<55 years in men, <65 years in women)

coronary or stroke event. It is also important to specify the number of cases and the number of brothers/sisters and sons.

The minimum information to be collected on ***medical history*** should include diagnoses of hypertension, dislipidemia, diabetes and medications currently used. It is helpful to ask participants to bring medication with them at the screening so that names can be accurately recorded.

Recommended questions suggested by the European Health Risk Monitoring (EHRM) [18] are:

Hypertension

When was your blood pressure last measured by a health professional?

-Within the past 12 months

-1-5 years ago

-Not within the past 5 years

Have you been told by a health professional in the past year (12 months) that you have elevated blood pressure or hypertension?

-Yes

-No

-Uncertain

Are you currently taking medication prescribed by a doctor to lower your blood pressure?

-Yes

-No

-Uncertain

Has a doctor in the past year ordered you to change your way of life, in order to lower your blood pressure?

-Yes

-No

-Uncertain

Cholesterol

When was your blood cholesterol last measured?

-Within the past 12 months

-1-5 years ago

-Not within the past 5 years

Have you been told by a health professional in the past year (12 months) that you have raised (elevated) blood cholesterol?

-Yes

-No

-Uncertain

Are you currently taking medication prescribed by a doctor to lower your blood cholesterol level?

-Yes

-No

-Uncertain

Has a doctor in the past year ordered you to change your lifestyle in order to lower your total blood cholesterol?

-Yes

-No

-Uncertain

Diabetes

Have you ever been told by a doctor that you have diabetes?

-Yes

-No

-Uncertain

Are you currently taking insulin or pills to control diabetes?

-Yes

-No

-Uncertain

Medications taken by participants should be coded according to the pharmacological classification. See Anatomical Therapeutic Chemical (ATC) classification for Cardiovascular System at the following website: http://www.whocc.no.

The set of recommended questions for CVD risk factors are further summarised in Table 4B.

Standard questions on **smoking**, **drinking**, **physical activity**, **diet** exist and can be found in several HIS/HES [19].

Already existing questions should be reviewed and used when possible, before starting to create new questions. Other Health Monitoring Projects, in particular the EHRM Project [18], reviewed the measurement protocols of national health surveys in Europe and provided recommendations for the measurement of major chronic disease risk factors

5. MINIMUM SET OF EXAMINATIONS FOR HEALTH EXAMINATION SURVEYS

A step by step approach is recommended, taking into account time and budgetary restraints. Priorities on a minimum set of questions and examinations to include should be based on public health criteria, starting from a basic set of questions/examinations and building up layers of complexity on the basis of user needs and available resources. A stepwise approach is proposed in Table 5.

Measurements based on physical examination are generally difficult to standardise. For example, a clinical examination is less accurate than an ECG for a diagnosis of arrhythmias. However, special equipment may be difficult and cumbersome to use, specialised personnel may need to be employed and the procedure may be costly, time consuming and demanding for the respondent. Hence, when cheap and quick measurements exist they should be the first choice. Where a method exists, but is expensive, it can be used in a sub-sample to validate estimates obtained from less costly techniques (e.g. waist and hip circumference for visceral fat distribution instead of a tomography).

Each measurement should be standardised and ethically approved, which means easy to perform, not expensive and without risk of harm to the patient.

5.1 Risk factors

The minimum set of measurements should include indicators for risk factors, in particular: arterial blood pressure, anthropometric measurements (height, weight and waist circumference) and a blood sample (for lipid and glucose measurements).

Protocols and operational guidelines for these measurements have been published as part of the EHRM Project [18]. A brief summary of methods to measure major risk factors follows below:

Arterial blood pressure – Blood pressure should be measured by a qualified nurse or physician, before drawing blood, applying the appropriate cuff (normal of for obese persons) on the right arm, with a mercury sphygmomanometer, or a validated automated device, with the participant sitting, after 4 minutes rest. Three

consecutive measurements should be performed and their mean (or the mean of the second and third) used in the analysis.

Anthropometric measurements – These should be measured with subjects wearing light clothing. ***Height and weight.*** A wall height ruler and a standard electronic scale should be used for height and weight respectively. Data should be computed in the body mass index (BMI = weight in kg divided by the square of the height in metres). ***Waist circumference*** – should be measured in cm by means of an insertion tape passed around the waist, defined as the mid point between the iliac crest and the costal margin. The subject should be in the standing position.

Laboratory tests – Total cholesterol and HDL-Cholesterol levels should be assayed on non-fasting blood samples into a laboratory certified for lipid tests by the Cholesterol Reference Method Laboratory Network. Glycemia should be assessed taking a blood sample after eight hours fasting.

Recommended procedures for more specialised CVD-specific tests are detailed below. The selection of these measurements will depend on the specific questions the survey is designed to answer, the overall burden on the respondent, cost and time considerations. The minimum required is to perform an ECG.

5.2 Electrocardiogram

The ECG is a graphic time-based record of voltage change produced on the body surface by electrical events in the heart muscle. It is employed in CVD survey for the following reasons: provide information on rate, rhythm, conduction and state of myocardium; it is useful in diagnosing manifestations of IHD (myocardial infarction, hypertrophy, angina pectoris); the information contained in the ECG is additional to and independent of that obtained by medical history and physical examination; it is of value in establishing categories of risk for future cardiac events and mortality and is an objective quantitative record of a bioelectrical signal characteristic of the individual. The participant should lie supine and the arms rest comfortably along the trunk. The position of the chest electrodes should be: V_1 fourth intercostals space, right sternal edge; V_2 fourth intercostals space, left sternal edge; V_3 midway between V_2 and V_4; V_4 fifth intercostals space where it is crossed by the midclavicular line; V_5 left anterior axillary line with the

horizontal position of position 4; V_6 same horizontal level but at the left midaxillary line.

The recording of at least five technically good complex per lead is suggested to facilitate the reading by Minnesota code.

Recommended procedures for Minnesota code

The recommended procedure for recording a resting ECG and the technical requirements for a suitable electrocardiograph are described in detail in the reference manual for the Minnesota code [10]. Minnesota code is a score to classify Q waves (item 1), ST junction (item 4) and segment depression and T waves (item 5), A-V conduction defect (item 6), ventricular conduction defect (item 7) and arrythmias (item 8). This does not need to be performed by a cardiologists; it is possible to train any observer who has a good basic technical education.

Minnesota coded major Q waves (codes 1.1 or 1.2) are recommended as the standard criterion for IHD in prevalence surveys. Use of more specific criteria including stand T-Wave changes as a measure of prevalence in epidemiological surveys is to be discouraged. In women especially, these ECG signs have poor specificity for IHD [12].

5.3 Ankle-Brachial Index (ABI) [12]

The ankle- brachial index, a ratio of ankle systolic blood pressure to arm blood pressure, is used in clinical practice to assess the patency of the lower extremity arterial system and to screen for the presence of occlusive PAD. Because of its good reliability and validity, non-invasive nature, and ease of use, the ABI has been used in epidemiologic studies to estimate the prevalence of PAD. Reports indicate that low ABI values (e.g. ≤ 0.9) are strongly associated with CVD risk factors, preclinical and clinical CVD, and CVD mortality, thus can be considered a marker for generalised atherosclerotic disease.

However, there is uncertainty regarding the lower normal limit of the ABI, with published abnormal cut-off points ranging from 0.80 to 0.98. Varying the value defining an abnormal ABI can markedly affect estimates of PAD prevalence, yet adequate studies have not been conducted in healthy population to determine the

normal ranges and lower abnormal cut-off point values of the ABI. A resting ankle-brachial blood pressure ration of less than 0.9 or a fall in ankle blood pressure of 30 mmHg or more in one or both legs is taken as evidence of PAD.

To measure the ABI, the participant should assume a supine position and rest comfortably for at least 5 minutes before the pressure is measured. This ensures that any changes in pressure that might have occurred due to previous walking have a chance to stabilise. Right and left arms and both legs should be measured. Blood pressures will be obtained in the following order: right arm, right ankle, then left arm, left ankle or simultaneously bilateral brachial artery and ankle.

5.4 Echocardiography *[20, 21, 22] (to be performed only in a subgroup)*

Echocardiography is a powerful diagnostic tool that provides immediate access for the evaluation of cardiac and vascular structures and assessment of heart function. However, echocardiography is best used after a careful history, physical examination, appropriate ECG, and chest radiograph have been obtained so that the appropriate questions can be asked. Indiscriminate use of echocardiography or its use for "screening" is not indicated.

Two-dimensional imaging can accurately quantify cardiac chamber sizes, wall thickness, ventricular function, valvular anatomy, and great vessel size.

Furthermore, echocardiography should be performed by laboratories with adequately trained physicians. Echocardiography is useful for assessing the presence of HF.

5.5 Ultrasound of peripheral arteries (carotides and femoral arteries) *[23]*

The Doppler principle states that the frequency of reflected ultrasound is altered by a moving target, such as red blood cells. The magnitude of this Doppler shift relates to the velocity of the blood cells.

Doppler ultrasonography shows the direction and velocity of blood flow and thus can detect turbulent flow due to narrowing or blockage of blood vessels. Color Doppler ultrasonography shows the different rates of blood flow in different colours. Doppler ultrasonography and color Doppler ultrasonography are

commonly used to help diagnose disorders affecting heart, arteries and veins in the neck, trunk, legs, and arms.

Currently, Doppler echocardiography consists of three modalities: Pulsed Wave (PW) Doppler, Continuous Wave (CW) Doppler, and color Doppler imaging.

PW Doppler measures flow velocity within a specific site (or sample volume) and is used in combination with the 2-dimensional (2D) image to record flow velocities within discrete regions of the heart and great vessels.

CW Doppler, on the other hand, can record very high blood flow velocities but cannot localise the site of origin of these velocities along the pathway of the sound beam.

Colour flow Doppler uses PW Doppler technology but with the addition of multiple gates or regions of interest within the path of the sound beam. In each of these regions, a flow velocity estimate is superimposed on the 2D image with a colour scale based on flow direction, mean velocity, and sometimes velocity variance.

6. POPULATION

Before planning a survey, a detailed description of the characteristics of the target population under surveillance is necessary, in particular: age range, gender distribution, socio-cultural characteristics, including ethnic origin and migration level; whether institutionalised people should be included or not; moreover geographic and/or administrative area and differences between urban and rural areas need to be identified.

When selecting the target population, a number of decisions need to be made. For example, whether or not to boost populations of interest (such as minority ethnic groups) or age groups of interest (such as older age groups for specific conditions).

6.1. Age range

For CVD surveys the age range is one of the most important criteria for selection of the respondents.

The EUROCISS Project suggests a wide age-range, that is 35+ years. The choice of the upper limit will depend on the condition of interest.

In the case of some pathologies (i.e. HF), surveys conducted among very old individuals are limited in their ability to detect different concomitant pathologies. It is therefore advisable to establish the upper age limit to 75-80 years. Young people (younger than 50 years), might be excluded from a survey of HF since they rarely have such disease, except in relation to congenital heart disease.

Similarly, if the survey is conducted to assess the prevalence of individuals who have experienced stroke, it is necessary to increase the age limit up to 84 years and to exclude young people, thus restricting the age range to 55-84 years.

As for surveys conducted among individuals with IHD or previous MI, the suggested age range is 35-80 years, thus excluding the age range 80-84 years, whose individuals are at higher risk of stroke rather than MI, and including IHD in young people.

Therefore, for the most exhaustive CVD survey the recommended age range to cover all the above-mentioned conditions is 35-84 years.

6.2. Gender

Population has to involve both genders. If an estimation of prevalence of some CVD is required, larger samples of women have to be selected because of the lower prevalence of the disease in this group.

6.3. Socio-cultural characteristics

Social classification is important because rates of ill-health display marked social gradients in most societies. Understanding the causes of these gradients is a key area of research into the epidemiology and control of CVD.

Occupational status, rate of school attendance and revenue could be used to classify socioeconomic status.

Education could be assessed asking about the highest level attained (compulsory education, higher education, university), and the number of studying years. Because differences are evident among countries with respect to school systems, it could be useful to obtain both data.

In some countries a national classification of occupational status exists. For instance, the system traditionally used by the Registrar-General for England and Wales assigned occupations to one of six classes: professional (I), managerial (Il), skilled non-manual (III-N), skilled manual (III-M), semi-skilled manual (IV), and unskilled manual (V). If no official classification exists, it should at least be possible to classify occupations as manual ("blue-collar") or non-manual ("white-collar"), or as manual work, clerical work, free profession.

Most countries use the international classification CISCO 88, in which the first digit defines the ten main occupational classes.

Income could be useful to define the socio-economic status. While this information may be obtained without difficulties in some countries (e.g. UK where these data are routinely collected) in others countries people may be unwilling to declare their earned income.

6.4. Ethnic origin and migration level

Data on ethnic groups, defined by parentage, religious and cultural characteristics are important but very sensitive.

Assessing ethnic origin is important given that CVD prevalence usually differs between ethnic groups. Considering the large number of migrants coming into Europe, the migration level is now crucial to evaluate CVD morbidity. For instance, the prevalence of some CVD, i.e. those CVD derived from rheumatic diseases, differs largely between European and extra European countries.

6.5. Geographic and/or administrative area

Geographical or administrative borders of the surveillance area must be clearly defined.

Administrative borders do not necessarily identify an homogeneous ethnic group. As a consequence, in some areas the CVD prevalence cannot be representative of the whole country. To evaluate the environmental impact on CVD prevalence, it is necessary to specify if the area is urban or rural.

7. POPULATION SAMPLING

Samples of population with the aforementioned characteristics could be chosen from the general population, or from the GP patients' list or else through opportunistic screenings.

The results yielded from the sample may be generalised to the general population from which it has been selected with a degree of precision, but only on the grounds that:

1. the sample must be representative of the parent population;
2. the sample must be sufficiently large;
3. there must be adequate participation.

In determining sample size it is often useful to seek the assistance of a statistician. The kind of information needed to determine sample size includes:

l. the objectives of the study including the plan for statistical analysis;
2. the accuracy of the measurements to be made;
3. the degree of precision required by the investigator when generalisations from a sample to the population are made;
4. if the groups are to be compared, the magnitude of the differences which the investigator regards as meaningful;
5. the investigator's resources.

The larger the sampling size, the less the sampling variation: roughly the usefulness of a sample is proportional to the square root of its size. The recommended method of sampling is probability sampling, where each individual unit in the total population has the same probability or likelihood of being selected.

The first requirement is a nominal roll or sampling frame identifying each individual member or unit of the population from which the sample is to be drawn (e.g. population census lists, voter lists, tax lists, household registers, lists of employees).

7.1. Random national samples

Random national samples could be used in questionnaire study both interviewer-conducted and self-distributed. Physical examination of a random national sample

is expensive to undertake and some cluster samples may be much easier to identify and examine. International comparisons are easily based on studies of restricted samples within each country. It is important to have representative samples from different geographical areas (North, Centre, South).

Random national samples have the advantage to be representative of the population, but their limitations lie in the fact that they may be spread across different areas too far from each other and their examination is usually expensive.

7.2. General Practitioner's network

From a GP's network samples could be selected from randomly recruited patients and from volunteer recruited patients. It is recommended that patients be randomly selected from GP's lists. This kind of selected sample, being very heterogeneous, is more representative of the general population. Samples from GP's network are also relatively easy to enrol.

7.3. Opportunistic screenings

Medical examinations not directly related to CVD, such as business checkups, voluntary blood donation, prevention initiatives (including free health visits), occasional checkups for pathologies are different from CVD surveys which provide data on population samples. These samples are not representative of the whole population.

8. RESPONSE RATE

A high response rate is extremely important, since non-respondents tend to have different health characteristics from the rest of the sample, and their omission therefore 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.

With a high-prevalence condition a poor response rate is less likely to be serious, provided that non-respondents are not different from those who respond (e.g. younger, of lower socio-economic status etc).

Unfortunately most cardiovascular conditions have low prevalence rates. In a study of the ECG changes of infarction in a population with a true prevalence of 2%, failure to examine 20% of the sample among whom the prevalence was 5% would lead to a prevalence estimate among respondents of 1.25%, a proportionately serious error.

The primary aim must therefore be to obtain a response rate such that serious bias will not occur even if the non-respondents are unrepresentative. In practice this cannot always be achieved, and one must then try to assess the bias resulting from the omission of non-respondents on the basis of such information as is available for the whole sample – e.g., age, gender, and residence.

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. Direct assessment of bias may sometimes be possible by making a special effort to interview or examine a sub-sample of the non-respondents.

A protocol should specify the sequence of efforts to follow up non-responders and a record keeping system to document and monitor this.

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

response.

Populations with the following characteristics may have a low response rate, which may vary among countries:

- ethnic minorities;
- elderly;
- low education and occupational status;
- poorer classes;
- illness - U-shaped curve - lower response in the most sick and the most well;
- mental illness;
- institutionalised people often not included unless specifically sampled for;
- feeble memory.

9. REPORTING

The purpose of a HIS/HES is to present a picture of disease in a population at a particular point in time. The survey provides estimates of the disease prevalence, that is the number of patients who have experienced AP, HF, MI, stroke, IC and with high risk conditions (hypertension, hyperlipidaemia, diabetes). The prevalence is one of the indicators included in the ECHIM short list [7], together with attack rate and incidence which can be obtained through population-based registers.

The prevalence should be presented for the age ranges 35 to 44 years, 45 to 54 years, 55 to 64 years, 65 to 74 years, 75 to 84 years, 85 years and over (if included), according to EUROCISS recommendations, and provided for men and women separately. Indicators should be directly standardised by age (35 to 74 years) and gender using the European population as a reference [24].

10. QUALITY CONTROL

Standardisation of measurements, training of personnel and quality control are essential to assure reliable data. Manuals of operations containing detailed procedures and methods on standardisation, training and quality controls are already available [13]. It is recommended to use survey instruments whose sensitivity and specificity have already been assessed. Such questionnaires, laboratory techniques, diagnostic criteria and procedures for measurements are already available in literature. For example, the EHRM Project produced recommendations, protocols and manual of operations for chronic disease risk factors surveys, including CVD risk factors [19].

Personnel assigned to screening should be properly trained and quality control should be assured for the whole collection period. To perform a survey many medical personnel 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:

- 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).

A pilot test of 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;
- familiarise staff with practical problems;
- result in refinement of techniques before going into the field;
- 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.

11. ETHICAL ISSUES

The Helsinki declaration requires that biomedical research with human subjects must conform to generally accepted scientific principles.

The "Recommendation n. R (97)5 of the committee of ministers to EU member states on the protection of medical data" [25] gives guidelines to how medical data can be registered, stored and used in a way that ensure the rights and the fundamental freedoms of the individual and in particular the right to privacy. *(Adopted by the Committee of Ministers on 13 February 1997at the 584th meeting of the Ministers' Deputies).*

In the following the most important recommendations are presented:

"*Medical data should be collected and processed only by health-care professionals, or by individuals or bodies working on behalf of health-care professionals. Individuals or bodies working on behalf of health-care professionals who collect and process medical data should be subject to the same rules of confidentiality incumbent on health-care professionals, or to comparable rules of confidentiality.*"

"*Medical data shall be collected and processed fairly and lawfully and only for specified purposes."*

"Medical data may be collected and processed:

a. if provided for by law for:
   - *i. public health reasons; or*
   - *ii. subject to Principle 4.8[*], the prevention of a real danger or the suppression of a specific criminal offence; or*
   - *iii. another important public interest; or*

b. if permitted by law:

[*] Processing of genetic data for the purpose of a judicial procedure or a criminal investigation should be the subject of a specific law offering appropriate safeguards.

i. *for preventive medical purposes or for diagnostic or for therapeutic purposes with regard to the data subject or a relative in the genetic line; or*

ii. *to safeguard the vital interests of the data subject or of a third person; or*

iii. *for the fulfilment of specific contractual obligations; or*

iv. *to establish, exercise or defend a legal claim; or*

c. *if the data subject or his/her legal representative or an authority or any person or body provided for by law has given his/her consent for one or more purposes, and in so far as domestic law does not provide otherwise."*

'Whenever possible, medical data used for scientific research purposes should be anonymous. Professional and scientific organisations as well as public authorities should promote the development of techniques and procedures securing anonymity.

However, if such anonymisation would make a scientific research project impossible, and the project is to be carried out for legitimate purposes, it could be carried out with personal data on condition that:

a. *the data subject has given his/her informed consent for one or more research purposes; or*

b. *when the data subject is a legally incapacitated person incapable of free decision, and domestic law does not permit the data subject to act on his/her own behalf, his/her legal representative or an authority, or any person or body provided for by law, has given his/her consent in the framework of a research project related to the medical condition or illness of the data subject; or*

c. *disclosure of data for the purpose of a defined scientific research project concerning an important public interest has been authorised by the body or bodies designated by domestic law, but only if:*

i. the data subject has not expressly opposed disclosure; and

ii. despite reasonable efforts, it would be impracticable to contact the data subject to seek his consent; and

iii. the interests of the research project justify the authorisation; or

d. the scientific research is provided for by law and constitutes a necessary measure for public health reasons.'

In 1985 the International Statistical Institute (ISI) formed a Declaration on Professional Ethics, which most national statistical agencies have agreed on. The declaration can be found at http://isi.cbs.nl/ethics.htm. In short, the declaration covers obligations to society (considering conflicting interests), obligations to founders and employers (clarifying obligations and roles, guarding privileged information), obligations to colleagues (maintaining confidence in statistics, communicating ethical principles) and obligations to subjects (refers to human subjects, including individuals, households and corporate entities: in particular, avoiding undue intrusion, obtaining informed consent, modifications to informed consent, protecting the interest of persons, maintaining confidentiality of records, inhibiting disclosure of identities).

In CVD surveys it is important to obtain informed consent, to respect privacy and confidentiality, to avoid harm and to maintain well-being of the respondent.

Before conducting a CVD survey, it is important to find out if there are any national ethical restrictions to be considered.

A specific ethical issue to be considered relative to HIS/HES is related to how to deal with suspected, previously undiagnosed, pathological findings (e.g. hypertension) because of the implications e.g. with insurance policies.

12. RECOMMENDATIONS

The following ‘steps’ are recommended when planning and implementing CVD Surveys.

They are in some ways arbitrary and not purely sequential. Many “steps” take place simultaneously and recurrently throughout the conduct of a survey.

1. Definition of objectives

The aims should be specified in precise as well as general terms.

The definition of specific aims should be based on the current state of knowledge in the country and on a thorough review of the literature.

2. Choice of study population

The choice of a study population depends on a subtle balance of a number of issues:

- suitability - adequate numbers of persons at risk;
- feasibility - logistic and cost considerations;
- availability - accessibility, likelihood of cooperation.

3. Selection of variables to be measured

The characteristics to be measured are referred to as variables whether measured numerically (age, blood pressure, height, weight, cholesterol) or categorically (gender, education level, presence of CVD).

During the planning of a study it is necessary to select and define variables which will be measured (refer to Table 5).

4. Selection of measurement instruments

Methods of collecting information should be selected and applied for the following:

1. questionnaires - interview or self-administered;
2. physical examination - clinical examination by a physician (e.g. pulse rate)
3. special investigations - ECG, blood tests, weight, height etc.

5. Definition of diseases

It is also important to have clear operational definitions of CVD. Clinician establishes diagnosis by clinical judgement – avoiding rigid rules.

In a survey, unless standard working definitions are used, the findings will not be reproducible. This means that only a person who answers positively to all questions of LSHTM questionnaire for effort angina will be classified as having angina symptoms.

6. Planning the records

The types of records to be prepared include: the lists of persons to be examined; the appointment books and the letters of introduction and invitation; informed consent according to local legislation.

7. Planning the analysis and coding

Decisions on Statistical Techniques to be used in analysis, if statistician consulted, should be outlined in the planning stage.

8. Planning for time, personnel, space, supplies and equipment

To implement a survey, it is necessary to prepare budget and obtain funds; to set the time line of stages and activities; to provide a list of the numbers and types of personnel needed and for what periods (clerks, technicians, editors-and data staff, physicians, nurses, interviewers, field coordinator, etc.); to establish the amounts and types of space needed and for-what periods; to arrange personnel recruitment and training.

In addition, forms should be printed, maps and census materials should be available, sampling frames should be prepared and types of equipment and supplies needed at each stage should be provided.

Population surveys do not require highly trained clinicians or highly-skilled personnel, usually trained nurses can conduct the study.

9. Incorporation of plans in a written protocol

It is necessary to specify in writing the detailed plans as they relate to aims,

methods of procedure and plans for data analysis.

10. Recruitment of the population

Successful recruitment of a study population requires careful preparation through personal contacts and an educational campaign. In this way individuals will be motivated to join the study and community leaders will be supportive and have pride in their association with the project.

The contacts and campaigns must be made with the interests of the different groups in mind. The population or community should be understood in terms of organisations, political and cultural make up and interests in planning these contacts.

Institutional human studies or ethics committees may need to approve.

11. Recruitment and training of staff

It is recommended that interviewers and others in contact with the community are carefully selected, capable, personable and interested.

Criteria procedures for selection should take into account special needs and characteristics of the study population and the procedures to be employed.

Regular meetings for feedback and reinforcement, ongoing surveillance of techniques and results, periodic re-standardisation and quality control are required.

12. Field organisation

If a survey includes a number of procedures each done by a different worker, it is necessary to design a “line of flow” where participants pass from one station to another. A precise knowledge of staffing needs on basis of pre-tests and pilots, of the numbers of interviewers, clerks, technicians, physicians, nurses, administrative staff, of routine work done in regular working hours and of regular meeting for in-service education and problem solving is required. Persons undergoing examinations must be notified with results.

TABLE 1. HES SURVEYS -- DISEASE: ALL IHD

Country	Time period covered by surveys	Periodicity	Age range	Population recruited x 1000	Methods of data collection (last survey)			
					LSHTM	Other quest	Exam	ECG
Denmark Copenhagen City Heart Study	1976-2003	Performed in: 1976-78; 81-83; 91-93, 2001-03	20+	19,7	√	-	√	√
Denmark 2 Surveys at the Research Centre for Prevention and Health in Copenhagen	1964-2005	7 cohorts out of 11 examined 2 or more times	35-85+	41	√	√	√	√
Finland FINRISK/Health 2000	1972-2002	every 5 yrs (FINRISK); every 15 yrs (Health 2000)	30+ (Health 2000)	8 (Health 2000) 10 (FINRISK 2002)	-	√	√	√**
France (ENNS)	2006-2007	every 5 yrs	3-74	6	-	-	b)	-
France (MONICA)	1986-2006	every 10 yrs	35-64 35-74 (2006/2007)	4.800	-	√	b)	√ only in Toulouse
Germany	1997-1999	every 5-6 yrs	18-79	7,1	-	√	√	-
Greece	1994-2006	every 3-4yrs	Adult population	29	-	√	√	-
Hungary	2001	Only once	55-64	8,4	-	√	√	-
Iceland	1967-2005	continuously	All together	30	-	√	√	√
Italy	1998-2002	Performed once Next in 2007	35-74	10	√	√	√	√
The Netherlands	1998-2001	continuously	12+	5	-	√	√	-
Norway 1	1974-2003	discontinuously	30,40,45,60,75	35	√	√	b)	-
Norway 2	1984-86 - 1995-97	Next in 2006-8	20+	80	-	√	b)	-
Poland	2004-2005	Performed once	20-74	19,2	√	√	√	-
Spain (MONICA)	1986-96	every 4 yrs	25-64	1.100	√	-	-	√
Northern Sweden	1985-2004	every 5 yrs	25-64	2,5				
UK	1994-2006	every year	16+	14	-	√	√	-

** only for Health 2000 b) risk factor

TABLE 2. HIS SURVEYS -- DISEASE: ALL IHDCOUNTRY

Country	Time period covered by surveys	Periodicity	Age range	Population interviewed x 1000	Questions included (last year)
Belgium	1997-2004	every 4 yrs	35-85+/all t.	12	AMI, Percutaneous Coronary Intervention (PCI)
Czech Republic	1993-2002	every 3 yrs	15+, 5yrs ranges	25	Stroke, IHD, hypertension
Denmark	1987-2005	Performed in 1987, 91, 94, 97, 2000, 2005	15+	22	AP and all heart diseases
Finland	1978-2004	every year	15-64 (in 2003)	5	AMI, AP, HF
France (ESPS)	1988-2006	every 2 yrs	all	22	Hypertension, AMI, AP, HF, Stroke, Arteritis
Germany	1997-1999	5-6 yrs	18-79	7	AMI, AP, HF, IC, Stroke
Hungary	2000-2003	every 3 yrs	18+	7	AMI, stroke
Italy	1999-2000	every 5 years	20-79	14	AMI, Stroke
The Netherlands	1997-ongoing	continuously	0+	10	AMI, ACS, AP, Stroke
Norway	1968-2005	every 3 year	16+	3	all CVD (ICD-X Q20-28)
Poland	1996 and 2004	Performed twice	All ages	26	IHD
Portugal	1987-1998/99	every 5 yrs	35-75+/all together	49	AMI, Stroke
Spain	1987-2003	Performed in 1987, 95, 97, 2003	0-4, 5-74 (10-year grp), 75+	40	IHD, Hypertension
UK	1994-2004	every year	16+	14	AMI, ACS, HF, AP, Stroke

TABLE 3. TOOLS FOR MONITORING CVD

Data sources	Type of registers/health surveys	Data collection	Main indicators
Routine databases	Mortality Hospital registers Drug dispensing registers	National routine databases	Mortality Hospital Discharges Length of stay (Prescribed medication)
Surveys	HIS/HES	Survey based on random samples of the population Surveys representing cohorts	Prevalence
CVD registers (AMI/ACS and Stroke)	Population based	Record linkage between routine databases including cases occurring outside hospital (mortality + HDR)	Attack rate Incidence Prevalence Case fatality Treatment
		Disease-specific collection of data including cases outside hospital	Attack rate Incidence Prevalence Case fatality Treatment Years of life lived with disability (YLDS) Estimate of long-term care needs

TABLE 4A. MINIMUM SET OF RECOMMENDED QUESTIONS FOR CVD/HIS

ANSWERS: 1= YES 2= NO 8= DO NOT KNOW 9 =REFUSAL; IF "YES" GOTO NEXT QUESTION ELSE GO TO NEXT DISEASE

Question	CVD			
	Angina Pectoris	**Myocardial Infarction**	**Heart Failure**	**Stroke**
FILTR ON AGE:	35-84	35-84	50-84	50-84
1. Have you ever been told by doctor that you had …? **If yes:** 1a. How old were you when you had the first "attack"? 1b. Have you had this condition (health problem) in the past 12 months?				
2. Are you currently (in the last 2 weeks) taking any medicine (pills, drops, inj.) for this condition?				
(If "Yes" name of medicine)*				

3. Have you ever undergone any intervention (CABG, PTCA) because of your problems with your heart?

YES	1
NO	2
Do not know	8
Refusal	9

4. How old were you when you had the last intervention?

…… years old

5. What type of procedure did you undergo?

Angioplasty (balloon treatment for angina)	1
Coronary Artery Bypass Graft (CABG)	2
Other	3
Do not know	8
Refuse	9

TABLE 4 B. MINIMUM SET OF RECOMMENDED QUESTIONS FOR CVD RISK FACTORS/HIS

ANSWERS: 1= YES 2= NO 8= DO NOT KNOW 9 =REFUSAL; IF "YES" GOTO NEXT QUESTION ELSE GO TO NEXT DISEASE

Question	Risk factors	
	Blood pressure	**Cholesterol**
FILTR ON AGE:	ALL	ALL
1. When was your ….last measured by a health professional? **a. within the past 12 months** **b. 1-5 years ago** **c. NOT within the past 5 years**		
2. Have you been told by a health professional in the past year that you have elevated …?		
3. Are you currently (in the last 2 weeks) taking medications prescribed by a doctor to lower….?		
4. Has a doctor in the past year ordered you to change your lifestyle to lower your….?		
(If "Yes" name of medicine)*		

*The list of medicine should be showed by interviewed patients during questionnaire.

TABLE 5. STEP-WISE APPROACH FOR CVD HIS/HES

Level of recommendation	Health Examination Survey (HES)	Health Interview Survey (HIS)
Minimum data collection	• Height • Weight • Blood pressure • Waist circumference • Non-fasting blood sample (Total cholesterol, HDL cholesterol, glucose)	• Age • Gender • Ethnicity • Social class indicator (income, education, occupation) • Smoking • Angina questions • Previous MI questions • Previous stroke questions • Diabetes • Medication use
Minimum + 1	The above plus • Fasting blood sample (e.g. for glucose) • ECG • Ankle/ brachial index • Clinical examination for HF	The above plus • Physical activity • Diet • Alcohol • Heart Failure questions • Rose questionnaire
Minimum + 2	The above plus • Echocardiography	The above plus • Family history • Quality of life • Use of health services
Minimum + 3	The above plus • Ultrasound of peripheral arteries • Other items pertaining to research question	The above plus • PAD questions • Parity • Other items pertaining to research questions

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