MANUAL ON MONITORING CARDIOVASCULAR DISEASES

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and

Noncommunicable Diseases including Mental Health Focus 
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Introduction

Strengthening the assessment of the noncommunicable disease (NCD) burden and monitoring trends are critical for effective planning, implementation and evaluation of programmes and services, as well as for supporting policy development and marketing.

Over the past years, the availability of NCD data at the country and Regional level has gradually improved. Databases on the status of NCD epidemiology and cancer services at the Regional level have been established, including a Regional Profile on Cardiovascular Diseases, Diabetes, Associated Risk Factors and a Regional Database on Cancer in the Western Pacific Region published in September and December 1999, respectively.

Another important challenge is to develop simplified methods of epidemiological data collection, analysis and monitoring, particularly on risk factors, that can be applied in developing countries with limited resources and technical expertise. In response to the challenge, a WHO regional review group on NCD surveillance met in Melbourne, Australia, in November 1999. The group reviewed different epidemiological instruments, including a proposal on simplified NCD surveillance. It recommended a comprehensive set of simplified indicators and NCD risk factor survey and monitoring methods.
The WHO Collaborating Centre for Cardiovascular Epidemiology at the University of Newcastle, Australia, has collaborated with WHO to prepare a manual on cardiovascular disease (CVD) monitoring. The Manual reviewed by the group has now been finalized for distribution after wide consultation.

The aims of this manual are:

1. To introduce standardized methods for data collection, analysis and quality control in epidemiological assessment and monitoring for CVD.

2. To develop appropriate indicators for measuring the efficiency and impact of programmes on prevention and control of CVD.

This Manual is designed to be usable for monitoring morbidity at the country level where data collection systems may not be very advanced. Risk factor surveys will need to supplement this information; they are the subject of other manuals and standards in development.

The Manual can be a very useful tool to support CVD monitoring. It will assist the simplification and standardization of CVD data collection and analysis in the Region. The Manual can also serve as training material for health workers. Continuous efforts will be needed to introduce these methods more widely into NCD epidemiological practice in the Region.

Noncommunicable Diseases
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1. Monitoring incidence
of cardiovascular disease

1.1 Introduction

The diverse social, economic and cultural structure of countries in the Western Pacific region will affect the specific requirements of a national system for the surveillance of cardiovascular disease. Bennett et al. (1995) outlined the following reasons and benefits of a national monitoring system for the Australian population. Most of these points will hold for any population. A monitoring system is required to:

(i) monitor progress towards national targets;

(ii) measure the human cost of cardiovascular disease in terms of total and premature mortality, hospital and other morbidity, person-years of life lost, and the impact of the disease and its treatment on the quality of life of the patients and their families;
(iii) measure the economic costs of cardiovascular disease in terms of costs of treatment, earnings foregone, etc.;

(iv) ensure that the scope for prevention of these diseases is fully and effectively exploited; and

(v) check that preventive and therapeutic interventions of proven efficacy are being used as widely and effectively as possible, and that resources are gradually being withdrawn from other strategies that have been less rigorously evaluated or have been shown to be of less value.

The benefits of a monitoring system are:

(i) report on national trends and patterns of CVD and related data;

(ii) provide data for the setting and monitoring of goals and targets associated with cardiovascular disease;

(iii) enable the study of differential rates of CVD among population groups (e.g., socioeconomic groups, immigrant groups, men and women, regions);

(iv) provide data for the evaluation of preventive, diagnostic and treatment interventions; and

(v) provide timely data for use in planning and managing CVD health services nationally and locally.

The purpose of this Manual is to recommend methods that can be used to monitor the incidence of cardiovascular disease (as defined by the World Health Organization) within countries in the Western Pacific region. In some countries it will be possible to use routinely
collected data, while in others it may be necessary to establish sentinel centres to monitor the incidence of cardiovascular disease in a representative sample of the population. For some components, such as coronary deaths and definite myocardial infarction, the goal is to measure the incidence of disease and produce valid estimates of time trends within the population. For other components, such as medical therapy, the goal is to monitor trends recognizing that the criteria may vary over time and that documenting of differences in levels of service is important.

In recognition of the diversity within the region we propose a taxonomy that would allow us to distinguish between the process of data collection and the content of the data (Table 1). Four levels of data collection are considered. The first level involves collecting information that is currently available and accessible. This requires a retrospective audit of data that is available from individual clinics, health centres and hospitals. Data from these sources will give crude estimates of the prevalence of each of the various forms of cardiovascular disease. The second, third and fourth levels will be explained in more detail in the next section but they require a substantial increase in commitment and resources. The second level is establishing a sentinel site and conducting periodic monitoring of the relevant health facilities. If a representative population can be selected, the sentinel site will provide good quality information and enable estimates of the incidence of disease to be calculated. Trends in the incidence of disease can be determined if monitoring is repeated at the sentinel site. The third level is similar to the second level but monitoring at the sentinel site should be continuous. This will allow more accurate estimates to be obtained. The fourth level is only relevant to those countries in which a national monitoring system is established but should be the goal for all countries.
<table>
<thead>
<tr>
<th>Data sources</th>
<th>Methods</th>
<th>Uses</th>
<th>Potential Biases</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Data from patients of individual clinics or health centres.</td>
<td>All patients identified in one clinical setting.</td>
<td>Clinical Audit and hypothesis generation.</td>
<td>Selection bias.</td>
</tr>
<tr>
<td>2. Sentinel data collection from defined geographic population on intermittent basis</td>
<td>Select a defined population of a city or rural area. Define the population for the denominator. Select the hospitals or other medical facilities which cases of cardiovascular disease will attend</td>
<td>Estimates of disease burden and scope for prevention. Trends over time if repeated. Progress towards national goals and targets.</td>
<td>Will need training of observers to avoid measurement bias, including cause of death coding. Repeat surveys to use same method to avoid bias. Selection bias if the sentinel population not representative of the whole country.</td>
</tr>
</tbody>
</table>
3. On-going registration from a defined population.

- Define the population and all new cases which arise.
- Identify routinely collected data sources.
- Interpret quality, usefulness of these.
- Identify linkages between register and routine data.

4. Routine national mortality and morbidity data collection systems.

- Population defined. All deaths certified and notified.
- Hospitals and health facilities have routine classification and notification system.
- Interpret quality, usefulness and appropriateness.
- Identify linkages between components of the system.

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**Table 1. Hierarchy of the process. (continued)**

<table>
<thead>
<tr>
<th>3. On-going registration from a defined population.</th>
<th>4. Routine national mortality and morbidity data collection systems.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Define the population and all new cases which arise. Identify routinely collected data sources. Interpret quality, usefulness of these Identify linkages between register and routine data.</td>
<td>Population defined. All deaths certified and notified. Hospitals and health facilities have routine classification and notification system. Interpret quality, usefulness and appropriateness Identify linkages between components of the system</td>
</tr>
<tr>
<td>May have selection bias unless care is taken to include all those with disease, not just those severe enough to present clinically. Confounding bias (for time comparisons) possible if standardization for age and socio-economic status etc. not performed.</td>
<td>Will need training of observers, careful and standardized coding systems, validation of measures, and completeness of data collection to avoid biases.</td>
</tr>
</tbody>
</table>
1.2 Establishing a sentinel site

See Appendix 1.

1.3 Using routinely collected data

Routinely collected data may be available through death certificates and hospital separation data, but the diagnostic criteria for cause of death or cause of hospital admission may vary between countries. Another potential problem is that some cardiovascular events may be double counted. For example, patients transferred between hospitals during the same clinical ‘episode’ would not usually be identified unless it is possible to link records. Also deaths in hospital would be counted both from death certificates and hospital records. Thus, methods are needed to avoid double counting of cardiovascular events as far as possible.

The results from several Australian studies on the accuracy of routinely collected data provide the basis for the recommendations in this Manual. Studies of the validity of hospital data for non-fatal AMI and other acute episodes of CHD have been conducted in Newcastle and Perth as part of the World Health Organization (WHO) MONICA Project (to MONItor trends and determinants of CArdiovascular disease) and in Queensland as part of the Queensland Heart Attack and Morbidity and Mortality Study (QHAMMS). Similar studies on the validity of death certificates for CHD were also conducted as part of the WHO MONICA Project. Data from other health areas are available through the New South Wales (NSW) Acute Cardiac Care study - a study that examined the management of patients with acute cardiac ischaemia in over 30 hospitals in NSW. The validity of hospital data for strokes has been assessed by the Perth Community Stroke Study.
Many countries do not have as many resources necessary for data collection as in countries such as Australia. While using the experience gained through the MONICA and other surveillance systems that have been established, the Australian experience has been modified to take account of resource limitations.

**Age**

It is proposed that data be collected for the population aged 30-79 years. To make comparisons between countries, the use of the SEGI world population as the reference population for age standardized rates is suggested. In general, it is suggested that the compilation of age-specific rates be done in 10-year bands.

**Definition of an event**

The diagnostic categories for all episodes of disease relate to the principal discharge diagnosis only. These data can be collected on a regular or intermittent basis. Both ICD-10 and ICD-9 codes have been provided here.

1.3.1. Suggested optimal data set required to be collected. (Note: these are based on assessing the use of evidence-based interventions as well as the disease burden.)

**Acute myocardial infarction (AMI)**

- Population rates of fatal and non-fatal AMI (needs death certificates, census and hospital separations).
- In-hospital deaths.
- Time between onset of pain and hospital arrival.
• Proportion admitted to hospital given thrombolysis.

• Proportion with appropriate indicators given thrombolysis.

• Proportion discharged on beta blockers.

• Proportion discharged on aspirin.

• Proportion entering rehabilitation programme.

• Proportion admitted to hospital who have angioplasty/CABG in 12 months.

Unstable angina pectoris (UAP)

• Hospital admission rates (although it should be recognized that the diagnosis of UAP is unreliable in most countries and that many people discharged with a diagnosis of UAP will actually have had an episode of prolonged chest pain).

Angioplasty/coronary artery bypass graft surgery

• Rates for the population, age and sex specific.

Stroke

• Population rates of fatal and non-fatal strokes (needs death certificates, census and hospital separations).

• Proportion of those with stroke who are admitted to hospital.

• Time between onset of symptoms and arrival at hospital.
• Proportion of those admitted to hospital who die.

• Proportion of those admitted who are managed in an organized stroke unit. An organized stroke unit is a ward within a hospital that is established for the sole purpose of treating stroke patients.

• Proportion discharged on aspirin.

• Proportion who are physically dependent 6 months after discharge.

**Congestive cardiac failure (CCF)**

• This will be very difficult to identify and hospital discharge data on CCF due to non-valvular heart disease may be useful.

**Diabetes**

• Population rates of deaths from and with diabetes (needs death certificates, census and hospital separations).
1.3.2 Suggested statistics to be derived from the above data

Acute myocardial infarction

For monitoring incidence of AMI it is recommended that:

- The rate of acute coronary events be calculated as the sum of the rate of coronary deaths estimated from death certificates and the rate of non-fatal AMIs estimated from hospital separations.

- For fatal coronary events, deaths with ICD-10 codes I20-I25 (ICD-9 codes 410-414) be used with small adjustment factors to account for underestimation.

- For non-fatal AMI, hospital separations be used where the patient is discharged alive, the primary diagnosis is coded I21, I22 using ICD-10 (410 using ICD-9) and the length of stay is greater than 2 days. Small adjustment factors should be used to account for overestimation due to hospital transfers, readmissions and other effects.

- Validation studies of the coding of death certificates and hospital diagnoses are needed in the context of on-going quality assurance, the changes from ICD-9 to ICD-10, and checking the general applicability of the present recommendations.
Angina pectoris

For monitoring incidence of angina pectoris it is recommended that:

- The rate of angina pectoris be obtained by counting all patients who had an unbooked (emergency) admission to hospital and who were given a primary discharge diagnosis coded I20 or I24 according to ICD-10 (411 or 413 according to ICD-9).

- Primary discharge codes of I20 or I24 according to ICD-10 (411 or 413 according to ICD-9) be considered together for validation studies of angina pectoris. There is insufficient information in medical records to distinguish between cases of unstable angina pectoris and stable angina pectoris.

Investigations and procedures

For monitoring the number of coronary investigations and procedures, booked admissions coded to I20 to I25 according to ICD-10 (413 to 414 according to ICD-9) should be subdivided into: (i) admissions with percutaneous transluminal coronary angioplasty (PTCA) and coronary artery bypass grafts (CABG): and (ii) admissions without PTCA or CABG. The admission rates for each of these categories (separately) should be monitored, without any adjustments.
**Stroke**

Not all patients with strokes are treated in hospital and the experience in certain countries, such as Australia, is that hospital separation data cannot be used to measure past trends in attack rates for acute strokes because of the rapidly changing proportions of nonfatal cases admitted to hospital. If the proportion of cases admitted to hospital in other countries can be confirmed to be constant through validation studies, it is possible to use hospital separation data to monitor trends in strokes in those countries.

Estimates of the rate of admission to hospital for an acute stroke can be made using the following selection algorithms: Total acute stroke is the sum of nonfatal stroke and fatal stroke.

(i) where non-fatal stroke is defined as: non-fatal hospital separations coded as acute stroke (ICD-10 codes I60, I61, I63, I64, I66 while ICD-9 codes 430, 431, 434 or 436), OR acute stroke is coded in another diagnostic field for an admission of at least three days’ duration that is unbooked, and

(ii) fatal stroke is defined as: deaths with ICD-10 codes I60, I61, I63, I64, I66 (ICD-9 codes 430, 431, 434, 436).

Further studies should be undertaken in different countries to test the algorithms described above and to determine the proportion of nonfatal cases admitted to hospital. Similar methods should be used to determine ‘first’ events, defined in terms of no previous admission because of acute stroke within a defined period (for example, five years).
Congestive cardiac failure

Definitive diagnostic tests for (CCF) are not conducted in most countries on a routine basis. However, the clinical characteristics of CCF are sufficiently distinctive for it to be recognized. Even so, monitoring of CCF using hospital separation data will give poor estimates of the true extent of the disease because a large proportion of patients with CCF are discharged from hospital without any mention of CCF in their primary or secondary discharge diagnoses codes. Furthermore, validation of discharge diagnoses of CCF is not feasible due to the lack of consistency in documentation of signs and symptoms of CCF in medical records.

There was an increase in the number of patients given a primary discharge diagnosis of congestive cardiac failure (ICD-10 code I50 while ICD-9 code 428) between 1987 and 1989 in Australia. This was at least partly due to a transfer of patients between discharge codes. The increase levelled out after 1989 and, apart from this aberration, the age standardized rate of CCF as a primary discharge diagnosis remained relatively constant between 1990 and 1996. It is likely that half of the increase between 1987 and 1989 occurred because, for certain types of events, CCF codes were substituted for codes for hypertensive disease (ICD-10: 110-115; ICD-9: 401-404). Therefore, the analysis of longitudinal data that cross this period may need to combine the categories for hypertension and CCF.

A substantial increase in CCF as a secondary discharge diagnosis was observed in Australia after 1987. This is likely to be due to the change to case-mix funding based on diagnosis related groups.
Diabetes

Hospital separation data for principal or any mention of diabetes (ICD-10: E10-E14; ICD-9: 250).
2.

Indicators

These will span the range from mortality, hospital separations and case fatality to prevalence of population risk factor levels. The actual goals will not be specified, as these will have to be set by each country to reflect current patterns and realistic goals.

These indicators should be assessed every 5 years to allow the trends to be assessed.

After the first assessment of the indicators, local and national goals should be established that will allow trends over time to be measured in an attempt to see how much movement there is towards these goals.

2.1 Risk factor indicator

• Proportion of adults who smoke regularly, aged 18 and above.

• Proportion of secondary school students who smoke.
• Proportion of adults not engaged in regular physical activity, aged 18 and above.

• Proportion of adults who are overweight or obese, aged 18 and above.

• Proportion of adults with high blood pressure, aged 30 and above.
  - Proportion of those with high blood pressure or on treatment for high blood pressure who are on treatment for high blood pressure.
  - Proportion of those on treatment for high blood pressure whose blood pressure is below 160mmHg systolic.

• Proportion of adults with high blood cholesterol, aged 30 and above.
  - Proportion of those with high blood cholesterol or on treatment for high cholesterol who are on treatment for high cholesterol.

• Contribution of saturated fat as a proportion of total energy intake, aged 18 and above.

• Proportion of adults who are diabetic, aged 18 and above.
  - Proportion of adult diabetics whose HbA1c is less than 7.
2.2 Indicators for disease patterns

Coronary heart disease

- Incidence rate for AMI, ages 30-79. This comprises mortality from CHD and hospital separations for AMI. It is an indicator of the effectiveness of prevention of CHD.

- Proportion of patients who die before leaving hospital after acute myocardial infarction. An indicator of both selection of those who arrive at hospital and effectiveness of interventions in hospital.

- Median delay between onset of chest pain and presentation for emergency care at hospital, all ages. An indicator of pre-hospital response time to a cardiac emergency and uptake by the public of education messages.

- Time from presentation at emergency department to receipt of thrombolysis or angioplasty, all ages. An indicator of in-hospital response time to a cardiac emergency.

- Hospital separation rates for principal diagnosis of unstable angina, all ages. An indicator of the use of hospital resources for unstable angina.

- Hospital separation rates for principal diagnosis of congestive heart failure, all ages. An indicator of the use of hospital resources for congestive heart failure.

- Proportion of cardiac patients who enter and complete a rehabilitation programme, all ages. An indicator of the net effect of promoting rehabilitation programmes and their availability.
• Proportion of patients admitted to hospital with AMI who have angioplasty or revascularization within 12 months. An indicator of the use of high technology resources for the treatment of and prevention of mortality from coronary heart disease.

**Stroke**

• Incidence rate for stroke, all ages. This comprises mortality from stroke and hospital separations for stroke. An indicator of the effectiveness of prevention of stroke.

• Median delay between onset of stroke symptoms and presentation for emergency care, all ages. An indicator of pre-hospital response time to a stroke emergency and of the uptake by the public of education messages.

• Proportion of patients admitted to hospital with acute stroke who are managed in organized stroke units (dedicated multidisciplinary teams), all ages. An indicator of the availability of organized stroke units.

• Proportion of stroke patients who are physically dependent 6 months after diagnosis of acute stroke event. An indicator of the effect of acute care and rehabilitation following a stroke event.

• Proportion of stroke patients admitted to hospital who die during hospitalisation (case fatality). An indicator of selection for hospital care and effectiveness of in-hospital management.

• Death rate for stroke, all ages. An indicator of the effect of prevention and treatment and management of a stroke.
Diabetes

Death rate for diabetes, ages 30-79. An indicator of coding practices as well as the effect of prevention and treatment of diabetes.
Appendix 1:

Establishing a sentinel site

A balance has to be struck between the ideal and the practical. If only one centre is to be established in a country it is hoped that the centre will be typical (in its morbidity and mortality levels and trends) of the country as a whole. Where a country has greatly contrasting regions the possibility of setting up several centres should be considered.

The study population

For practical reasons of monitoring CVD, the study population should have well defined geographical boundaries and, ideally, should be an administrative unit for both the local governing body and the provider of medical services. This will ensure that the population which utilises the medical services is the same population for which information on the size and age distribution of the population can be obtained.
Study populations should be investigated to find methods of identifying people who have an acute CVD event while travelling or working outside the study area. This problem arises particularly if the study population is a sub-population of a city; it is less important if a total community is involved.

The number of people in the study population should be determined by the expected number of morbid or fatal events in the age group concerned. The number of events will determine the precision of the estimated rate of events and this will become particularly important if the data are to be used for estimating trends in event rates. Event rates for CVD should be estimated separately for men and women and sample size calculations should be done separately for men and women. In the calculation below, the rate of coronary deaths and the 95% confidence interval are estimated for a hypothetical population of 40,000 people in which 100 coronary deaths were observed in a 1-year period. The estimated rate of coronary death is 250 per 100,000 population and we are 95% confident that the true rate is between 201 and 299 per 100,000 population. A table for various populations sizes and rates of events is shown in Appendix 2.

Example:

In a given population of 40,000 people you expect there will be 100 coronary deaths during the 1-year period of monitoring.

Rate of death is equal to 100 per 40,000 population.

Rate of deaths per 100,000 population equals \(\frac{100}{40,000} \times 100,000 = 250\).

Variance of the rate of deaths per 100,000 equals \(\frac{100,000}{40,000}^2 \times 100 = 625\).
Standard error of the rate of deaths per 100,000 is equal to the square root of the variance $\sqrt{25^2} = 25$.

Therefore the 95% confidence interval will equal $250 \pm (1.96 \times 25)$.

So our estimated rate per 100,000 (with 95% CI) will equal $250 (201, 299)$.

Method of surveillance: In many countries it will not be possible to obtain reliable estimates of morbidity so it is important to obtain reliable data on mortality to obtain a useful measure of the burden of CVD in that population. The logistics of a surveillance system in a particular community will depend on local custom and the health system of the population being studied. However, based on the experience of the WHO MONICA Project, the following guidelines should be followed to establish a sentinel site.

An important requirement of a surveillance system is that event registration procedures are similar throughout the period or the estimates of trends will be invalid. The surveillance system should concentrate on recording information for cardiovascular events consisting of non-fatal coronary events, coronary deaths, non-fatal strokes and fatal strokes. The maximum duration of an event should be well defined. For example, in the MONICA Project an event could last for a period of 28 days. This allows events to be categorized as the first of recurrent events, fatal or non-fatal events, and establishes a denominator for the estimation of case-fatality.

All suspected events should be collected from death certificates, from hospital medical records and from community health services. These events can then be examined for eligibility into the coronary and stroke register based on a predefined definition of an event. There are two possible methods of event finding:
(i) prospective, identifying and following up suspect cases during the hospitalization or medical attention; and

(ii) retrospective, abstracting information from medical records, death certificates and other possible sources without seeing patients at all.

The recommendations in this report are based on prospective registration, although some fatal events among residents of the population are likely to occur outside the study area and notification of these deaths may take several weeks or longer.

In any sentinel site an information gathering system will need to be established to gain information on likely events and to obtain all available diagnostic and other information. The sources will depend on the structure of the local medical and medico-legal services. The following sources may be used to identify cases:

- Death certificates
- Hospital admissions or discharge records
- Community health centres
- Necropsy and medico-legal records
- General practitioners
- Local newspapers
- ECG records
- Laboratory records
- Social insurance records
- Emergency services, for example ambulance

- Interviews with patients and relatives

Once sources of cardiovascular events and criteria for defining cardiovascular events have been determined it is important that methods are not changed over time without measuring the consequence, as a change of sources may cause a spurious change in event rates.

Identification of fatal cases

All death certificates in which codes for cardiovascular disease are mentioned as immediate, main and antecedent or underlying causes of death should be investigated further. The following causes of death should be considered a minimum set for defining events to be followed up for further information:

<table>
<thead>
<tr>
<th>Cause of death</th>
<th>ICD-10 code</th>
<th>ICD-9 code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes</td>
<td>E10-E14</td>
<td>250</td>
</tr>
<tr>
<td>Hyperlipidaemia</td>
<td>E78</td>
<td>272</td>
</tr>
<tr>
<td>Obesity</td>
<td>E66</td>
<td>278</td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertensive</td>
<td>I10-I15</td>
<td>401-405</td>
</tr>
<tr>
<td>Ischaemic</td>
<td>I20-I25</td>
<td>410-414</td>
</tr>
<tr>
<td>Other</td>
<td>I30-I52</td>
<td>420-429</td>
</tr>
<tr>
<td>Stroke</td>
<td>I60-I69</td>
<td>430-439</td>
</tr>
<tr>
<td>Arteries</td>
<td>I70-I79</td>
<td>440-447</td>
</tr>
<tr>
<td>Symptoms</td>
<td>R96, R97,</td>
<td>797-799</td>
</tr>
<tr>
<td></td>
<td>R98, R54</td>
<td></td>
</tr>
</tbody>
</table>

It is possible to exclude those deaths that are due to trauma, chronic obstructive pulmonary disease, cancer, cirrhosis of the liver, or rheumatic heart disease without mention of atherosclerotic heart
or vascular disease. However, if an atherosclerotic condition is mentioned in the sequence of events or if the cause of death is attributed to one of the conditions listed above, the cause of death should be validated.

Validation should be based on any available medical and medico-legal records and, if necessary (depending on local custom), interviews of the decedent’s next of kin or another informant. Medical records for the period within a minimum of 28 days of death should also be examined for information that may elucidate the circumstances leading to the death. The interview should establish the circumstances surrounding the decedent’s death.

Deaths should be validated based on applying some predefined diagnostic criteria. The criteria should include information on the symptom history, ECGs, cardiac enzymes, necropsy and death certificate data.

**Identification of non-fatal cases**

*Coronary events*

To identify people treated in hospital, all acute medical admission wards as well as hospital laboratory data on cardiac enzymes and ECGs should be monitored on a daily basis to ensure all cases are detected. For people who are treated out-of-hospital, daily monitoring of pathology laboratory records for cardiac enzymes and ECG laboratory records may be a source of case ascertainment.

*Stroke events*

To identify people treated in hospital, all acute medical admission wards as well as hospital laboratory data on cardiac enzymes and ECGs should be monitored on a daily basis to ensure
all cases are detected. In most countries, many stroke patients are treated at home. In this situation, contact must be made with physicians and a protocol established to identify and collect data on stroke patients. The protocol could take a number of forms and might include reviewing charts on a regular basis or providing each office with a log book and a poster reminding them to log all cases of suspected new strokes, or asking the office nurse or assistant to notify the monitoring centre when a new episode of stroke is identified.

**Core data collected**

A guide to the minimum data that should be collected is shown below for coronary heart disease. For other forms of CVD, additional data may be required.

- Patients name and address
- Date of onset
- Survival status at time of discharge from hospital and/or after 28 days
- Gender
- Age
- Discharge diagnosis (if hospitalized)
- ECG readings
- Other diagnostic tests performed (in particular, cardiac enzyme levels if available)
- Symptoms
· Treatments administered

· History of cardiovascular disease

· Number of years of schooling

This is considered the minimum amount of information required for data collection.

Countries with adequate resources may be able to add data as follows:

• Data to help assess the use of evidence based interventions in the clinical care and secondary prevention of the disease. For example the use of aspirin after most CVD categories, the use of thrombolysis and beta blockers after acute myocardial infarction, entry to organized stroke units and rehabilitation programmes and the use of angioplasty and coronary artery bypass surgery.

• Data to assess more accurately the economic and social burden of disease. For example, the level of disability after a stroke, quality of life and return to work after the event.
Appendix 2:

Sample size calculations

Table of sample size calculations.

<table>
<thead>
<tr>
<th>No. of events (annually)</th>
<th>Size of population</th>
<th>Rate of events (per 100,000)</th>
<th>95% confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
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<tr>
<td></td>
<td>40 000</td>
<td>125</td>
<td>90-160</td>
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<td>60-106</td>
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<td>100</td>
<td>86-114</td>
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</tbody>
</table>
The numbers in the above table are based on the following formula:

\[
\text{Rate} = \frac{\text{number of events}}{\text{size of population}}
\]

\[
\text{Rate per 100 000} = \frac{\text{number of events}}{\text{size of population}} \times 100 \,000
\]

\[
\text{Variance (Rate per 100 000)} = \left( \frac{100 \,000}{\text{size of population}} \right)^2 \times \text{number of events}
\]

assuming that the size of the population is constant and that the number of events is a Poisson random variable.

\[
\text{Standard error (Rate per 100 000)} = \sqrt{\text{Variance (Rate per 100 000)}}
\]

Note: Very similar answers will be obtained if you assume that the number of events divided by the size of the population is a binomial random variable.