WHO STEPS Stroke Manual

The WHO STEPwise approach to stroke surveillance

World Health Organization

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Table of Contents

Continued on next page

Table of Contents, Continued

Section 1: Introduction

Overview

Introduction

This section is an introduction to the STEPS Stroke Surveillance Manual.

Purpose

The purpose of the manual is to provide guidelines and supporting material for sites embarking on a STEPS stroke surveillance study, so they are able to:

- Plan and prepare the surveillance study scope and environment
- Recruit and train data collection staff
- Establish and maintain the stroke register
- Report and disseminate the results.

Intended audience

The manual is primarily intended for the stroke surveillance site principal investigator. Parts of the manual are also intended for data collection staff.

Guide to using the manual

The manual has been written in modular parts and is structured to follow the sequence of events required to implement a STEPS Stroke study. It is divided into eight sections. Each section is introduced with a table of contents to help readers find specific topics. The manual includes both general information and specific instructional material that can be extracted and used for:

- Training
- Data Collection
- Data Entry

Page numbers have two components. The first number refers to the section and the second to the page number in that section.
For example: 3-6 indicates Section 3, page 6.

In this section

This section contains the following topics:

Rationale for Stroke Surveillance

Introduction

Well-conducted stroke surveillance (with accurate and complete registers) provides essential data that can be used to improve appropriate allocation of health resources.

Definition of surveillance

Surveillance is the ongoing, systematic:

- collection
- analysis
- interpretation, and
- dissemination of health information.

Purpose of STEPS stroke surveillance

The purpose of the WHO STEPS stroke surveillance study is to provide health workers and policy makers with a standardized tool to:

- Assess the magnitude of stroke.
- Describe populations at risk.
- Identify associated risk factors.
- Monitor trends over time.
- Provide the basis for designing and implementing interventions.
- Monitor and evaluate the effectiveness of interventions.

The evidence

Globally, cerebrovascular disease (stroke) is the second leading cause of death. It is a disease that predominantly occurs in mid-age and older adults.

WHO projects that in 2005, stroke will have accounted for 5.7 million deaths world wide, equivalent to 9.9 % of all deaths. Over 85% of these deaths will have occurred in people living in low and middle income countries and one third will be in people aged less than 70 years.

Rationale for surveillance

While many countries struggle with the consequences and problems of communicable diseases, chronic noncommunicable diseases are on the rise. In addition to being a major cause of death, many surviving stroke patients are disabled and need help in activities of daily living, which must be provided by family members, the health system, or other social institutions.

Lack of data on stroke from many countries hampers efficient coordination of stroke prevention, treatment, and rehabilitation. Due to future demographic changes, strategies to reduce future stroke burden and ensure adequate health resources are urgently needed. WHO STEPS stroke surveillance provides the framework for data collection and comparisons between and within populations.

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Rationale for Stroke Surveillance, Continued

Surveillance key to prevention

Clinical trials and epidemiological studies have shown that stroke to a large extent is preventable. However, public actions to lower the prevalence of exposure to risk factors are unlikely to be taken, if the magnitude and consequences of stroke are not identified.

Prevention strategies

Once reliable data are available, different prevention strategies can be implemented to reduce the occurrence and impact of stroke as described in the table below:

Prevention strategy	Aimed at reducing..	For example, through..
Primary	Occurrence of stroke in the first place.	• Identification of individuals at high overall risk of stroke or CVD (hypertensive people or diabetics) • Population wide initiatives to increase physical activity • Legislation to control tobacco smoking
Secondary	Impact of stroke in people who already suffer from a stroke or TIA.	• Intensified reduction in exposure to major cardiovascular risk factors • Anti platelets and antihypertensive treatment,
Tertiary	Consequences and damages in stroke patients.	• Treatment of infections in the acute stage, • Management of co-morbidities, and • Improved rehabilitation.

About Stroke

Introduction

Stroke is a clinically defined disease making it possible to capture data and follow trends in incidence or hospital admission rates in many different countries irrespective of access to technological equipment.

Stroke is a costly disease because of the:

- large numbers of premature deaths
- ongoing disability in many survivors, and
- impact on families or caregivers.

Standard WHO definition

The recommended standard WHO stroke definition is:

"**A focal (or at times global) neurological impairment of sudden onset, and lasting more than 24 hours (or leading to death), and of presumed vascular origin"** [5].

Notes:

- This definition excludes:
  - Transient ischemic attack (TIA), which is defined as focal neurological symptoms but lasting less than 24 hours.
  - Subdural haemorrhage.
  - Epidural haemorrhage.
  - Poisoning.
  - Symptoms caused by trauma.

- "Global" refers to patients with subarachnoid haemorrhage or deep coma but excludes coma of systemic vascular origin such as:
  - Shock.
  - Stokes-adams syndrome.
  - Hypertensive encephalopathia.

- Stroke is a clinical diagnosis and not based on radiological findings.

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About Stroke, Continued

Types of stroke

There are three major stroke sub groups as follows:

- Ischemic stroke.
- Intracerebral haemorrhage.
- Subarachnoid haemorrhage.

Type	Caused by	Diagnosis based on
Ischemic stroke	Sudden occlusion of arteries supplying the brain. Due either to a thrombus formed: • directly at the site of occlusion (thrombotic ischemic stroke), or • in another part of the circulation, which follows the blood stream until it obstructs arteries in the brain (embolic ischemic stroke).	• Neuro imaging recordings **Note:** it may not be possible to decide clinically or radiological whether it is a thrombotic or embolic ischemic stroke.
Intracerebral haemorrhage	Bleeding from one of the brain's arteries into the brain tissue. **Note:** May be more prevalent in developing countries possibly due to diet, physical activity, insufficient treatment of raised blood pressure, and genetic predisposition.	• Neuro imaging recordings.
Subarachnoid haemorrhage	Arterial bleeding in the space between the two meninges, pia mater and arachnoidea. **Note:** Typical symptoms are sudden onset of very severe headache and usually impaired consciousness.	• Neuro imaging, or • Lumbar puncture.

Note: Each type differs with respect to survival and long-term disability.

General major symptoms

Symptoms should be of a presumed vascular origin and should include one or more of the following definite focal or global disturbances of the cerebral function:

- Unilateral or bilateral motor impairment (including lack of coordination)
- Unilateral or bilateral sensory impairment
- Aphasia/dysphasia (non-fluent speech)
- Hemianopia (half-sided impairment of visual fields)
- Forced gaze (conjugate deviation)
- Apraxia of acute onset
- Ataxia of acute onset
- Perception deficit of acute onset

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Other symptoms

Other symptoms that may be present but are not adequate for stroke diagnosis (often resulting from other diseases or abnormalities such as dehydration, cardiac failure, infections, dementia, and malnutrition) are as follows:

- Dizziness, vertigo
- Localized headache
- Blurred vision of both eyes
- Diplopia
- Dysarthria (slurred speech)
- Impaired cognitive function (including confusion)
- Impaired consciousness
- Seizures
- Dysphagia

Subarachnoid haemorrhage

For Subarachnoid haemorrhage at least one of the following must be present in addition to the general major symptoms:

- Recent subarachnoid hemorrhage, aneurysm or arteriovenous malformation (necropsy/autopsy)
- Blood in the Fissura Sylvii or between the frontal lobes or in the basal cistern or in cerebral ventricles (CT or MRI)
- Blood stained cerebrospinal fluid (>2 000 red blood cells per mm^3), aneurysm or an arteriovenous malformation (angiography)
- Blood stained cerebrospinal fluid (>2 000red blood cells per mm^3) also xanthochromic and intra-cerebral haemorrhage (necropsy or CT).

Stroke like symptoms

A broad range of other diseases may cause similar symptoms, for example:

- HIV/AIDS
- Tuberculosis
- Syphilis
- Intracerebral cancer

These diseases are known to be able to cause focal neurologic disturbances and thereby mimic a stroke. Attention to the development of symptoms is an important factor to consider in order to avoid other diseases being misinterpreted as vascular disease, and leading to ineffective preventive strategies.

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Types of stroke events

There are four types of stroke events:

Type of stroke event	Defined as occurring in a person who has..
First ever	Never had a stroke before. **Note:** Previous TIA is not considered a stroke as symptoms last less than 24 hours.
Recurrent	A history of a previous stroke more than 28 days prior and who is registered with a new stroke event.
Non-fatal	Survived at least 28 days after the onset of the stroke symptoms.
Fatal	Died within 28 days of stroke symptom onset.

New stroke events

For a new episode of symptoms to be counted as a new stroke event, general stroke criteria as defined above must be met and either:

- the previous event in the same arterial distribution must have occurred 29, or more days previously (by subtraction of dates), or
- the new event is unequivocally in a different arterial territory from a earlier one occurring 28 or fewer days previously.

If a patient experiences further acute symptoms suggestive of stroke within 28 days of the onset of a first episode and in the same carotid or vertebral artery territory, this second episode is not counted as a new stroke event.

Major Risk Factors

Introduction

Stroke is a multi factorial disease where a combination of risk factors, which do not all have to be present, will over time influence the subject's likelihood of suffering a stroke.

Major risk factors

The major risk factors can be divided into the following categories:

Category	Risk factors
Modifiable	• Elevated blood pressure • Tobacco use • Physical inactivity • Diet (low fruit and vegetable consumption) • Heavy alcohol consumption • Overweight • Diabetes
Environmental	• Passive smoking • Access to medical treatment.
Non-modifiable	• Age • Sex (eg. high age and male sex are in many populations associated with an increased risk). • Family history; genetics

Other risk factors

In developed countries, diabetes mellitus as well as atrial fibrillation and other cardiac diseases are other important modifiable risk factors for ischemic stroke.

The role of hypercholesteremia as risk factor for stroke is currently part of an ongoing discussion. There is evidence that lower total cholesterol levels might be associated with a decreased risk of ischemic stroke but also might be accompanied by higher rates of hemorrhagic strokes.

In-hospital Management and Facilities

Introduction

In-hospital management refers to stroke patients admitted to a health facility.

Specialist stroke teams

Stroke patients admitted to a hospital department with a specialized stroke team or multi-disciplinary approach have a better outcome than patients admitted to departments without such teams or approach. This is measured in terms of long term reduction of death, and of dependency and institutionalisation.

Early rehabilitation and early mobilization of patients with severe neurological deficits helps lower disability after stroke and avoids complications.

Medication

Different treatments and medications identified in the STEPS Stroke instrument have all been shown to reduce risk of stroke in selected groups of patients in predominantly high-income countries. These are explained in the following table.

Type of medication	Used to
New and old anti-hypertensive drugs	Lower blood pressure and reduce stroke occurrence.
Aspirin (and Dipyridamole)	Prevent a new ischemic stroke.
Anti-coagulant therapy	Prevent cardiac embolism in patients with atrial fibrillation.
Plavix	Prevent new ischemic stroke
Intravenous treatment with tissue plasminogen activator (tPA)	Dissolves the blood clots in patients with acute ischemic stroke.

Overview of STEPS Stroke

Introduction

The WHO STEPwise approach to stroke surveillance provides a flexible system and an opportunity for all countries to get started and contribute and share data on stroke.

Basis of STEPS Stroke

STEPS Stroke is a sequential process. It starts with gathering information on stroke patients admitted to heath facilities (Step 1), then moves to identification of fatal stroke events in the community (Step 2), and on to collection of data on non-fatal stroke events in the community (step 3).

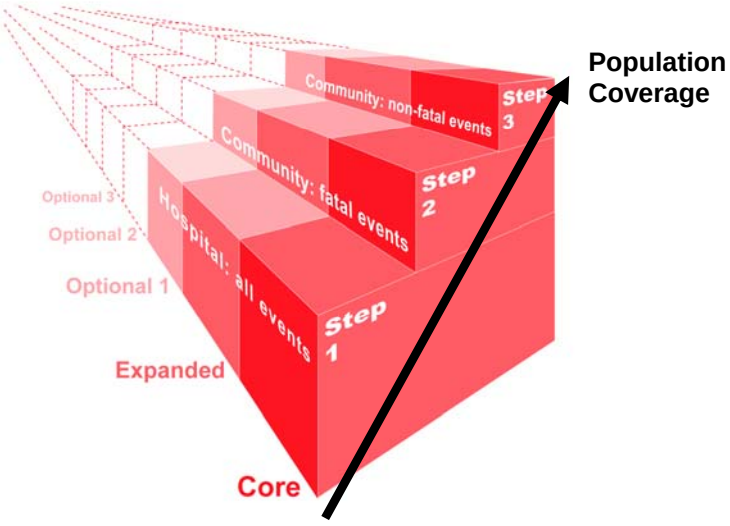
Within each Step (1, 2 and 3) there are a further two possible levels of information that can be collected (Core, and Expanded).

By using the same standardized approach, all countries can monitor trends within countries and between countries.

The STEPS Stroke instrument was developed, in part, by using the protocol from the WHO MONICA Project.

STEPS Stroke diagram

The following diagram illustrates the general concept of the WHO STEPwise approach



Note: All three Steps together with population coverage are necessary to measure stroke incidence.

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Overview of STEPS Stroke, Continued

STEPS stroke tools

A suite of tools have been developed to help methodically and consistently work through the STEPS surveillance process. This suite of tools is called the STEPS Stroke Starter Kit and includes a:

- STEPS Stroke manual
- STEPS Stroke instrument
- Forms and templates
- Data entry tool (to create a stroke register)

STEPS Stroke Instrument

The STEPS stroke instrument is a standardised questionnaire used to collect data stroke patient data to be entered into the register using the data entry tool.

The STEPS stroke instrument covers three different 'Steps' of stroke data collection (Step 1, Step 2 and Step 3). Within each Step, there are three different levels of data collection complexity (Core, Expanded, Optional) as follows:

Step		Core	Expanded	*Provides data on*
1	Hospitalized events (fatal and non-fatal)	Demographic information Time of onset Vital status day 10	Treatment Disability Type of stroke	*Stroke admissions and hospital case fatality*
2	Fatal events in the community	Demographic information Death certificates, or Verbal autopsy	Autopsy/ necropsy reports Type of stroke	*Stroke mortality*
3	Non-fatal events in the community	Demographic information Time of onset Vital status day 10	Treatment Disability Type of stroke	*Stroke incidence and case fatality*

Recommended steps

The optimal stroke surveillance system requires collection of data from all three steps and provision of census data from the source population.

Costs and complexity increase with more detail. The level of complexity will therefore depend on development of health services and resources, and each participating country may collect precisely the amount of data that it finds is feasible.

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Surveillance

While a stroke study can be a one off exercise, surveillance involves commitment to developing the stroke register on an ongoing and /or repeated basis. This may also be in the form of repeat studies (every 5 to 10 years) particularly to look at hospital or population trends.

It is recommended that when a STEPS Stroke Surveillance register is launched for the first time, there should be a plan for future follow-up to measure trends. This can be achieved by either of the following methods:

- continuous surveillance as part of a broader health information system, or
- annual registers repeated at 5 yearly intervals.

It is recommended that the minimum period of observation is one complete year because of possible seasonal variations.

Stroke Surveillance Process Overview

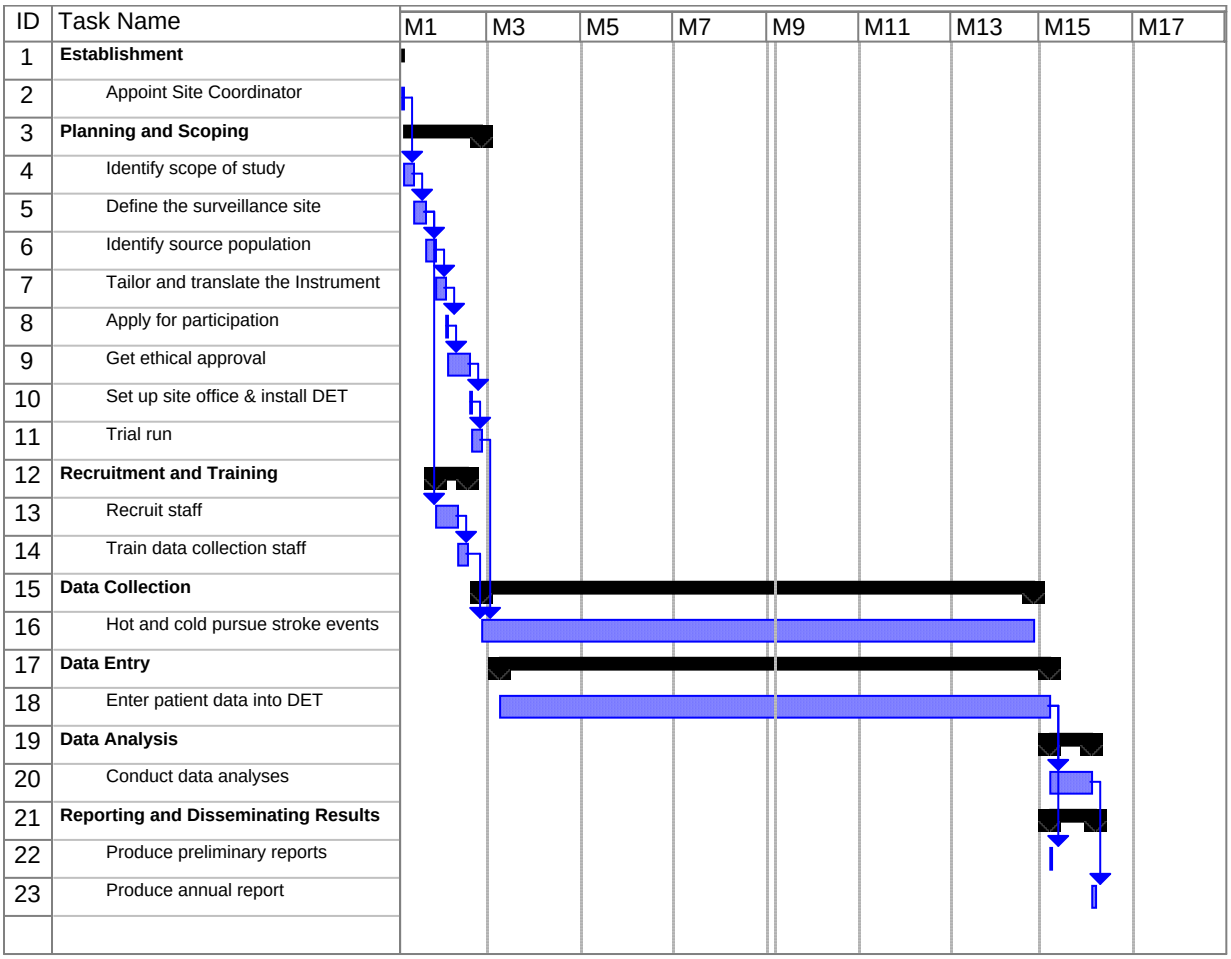
Introduction

For STEPS Stroke Surveillance to be effective, the whole process needs to be properly planned and organized before being implemented. Guidelines are provided below to help you plan your STEPS stroke surveillance study.

Key stages, tasks and timeframes

The minimum recommended total timeframe to collect data for a STEPS stroke study is 12 months.

The chart below shows each of the main stages and tasks in a STEPS Stroke study with indicative timeframes for each phase and task.



Section 2: Roles and Responsibilities

Overview

Introduction

There are a number of entities involved in coordinating and implementing STEPS Stroke surveillance. Representation is covered at the:

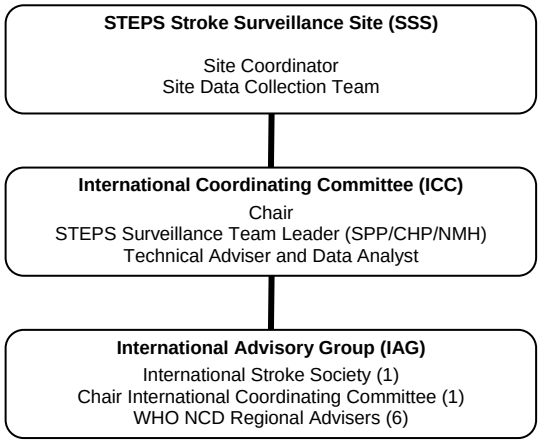
- country (national or sub national)
- regional, and
- global level.

Purpose

The purpose of this section is to provide an overview of the core roles involved in STEPS Stroke surveillance.

STEPS stroke surveillance network

The diagram below shows how the global Stroke surveillance network is organised.



In this section

This section covers the responsibilities for the following roles:

Site Coordinator

Introduction

The STEPS stroke surveillance (SSS) site coordinator is the local principal investigator. This key person is responsible for planning and coordinating the local STEPS Stroke surveillance study.

The site coordinator should be familiar with the entire manual to understand the whole STEPS stroke surveillance process.

Skills and attributes

The site coordinator will need to have the following qualifications and, general skills and attributes:

- Neurological or stroke physician (or study nurse) with proven experience in the field of cerebrovascular disease.
- Good understanding of the general philosophy and objectives of the global STEPS Stroke surveillance process
- Proficient in English
- Good written and oral communication skills
- Ability to recruit and train interviewer staff

Level of authority

The site coordinator should have sufficient authority to:

- Negotiate and obtain resources for the whole stroke study.
- Oversee progress of the national, sub-national, district or local STEPS stroke surveillance implementation.
- Contribute to the disease prevention and health promotion activities that will arise from the data gathered by STEPS Stroke.

Core roles

The core roles of the site coordinator may include all or some of the following:

Role	Description
1	Planning and preparing for a STEPS Stroke study.
2	Applying for participation.
3	Identifying and securing local funding and / or "in kind" support.
4	Handling ethical approval.
5	Recruiting and training interview staff.
6	Supervising data collection and adjudicating difficult diagnoses.
7	Reporting results.
8	Planning and preparing for future studies.
9	Liaising with the International coordinating unit (ICU), local authorities, WHO NCD regional, country and WHO representatives and other stakeholders.
10	Completing test stroke cases provided by ICU for quality control purposes.

Site Data Collection Staff

Introduction

The STEPS Stroke surveillance (SSS) site data collection staff are all those who have been trained to collect the study data and enter it into the stroke register.

Interviewer roles

Data collection roles will depend on the scope of the study. Core roles for a data collection staff member may include all or some of the following. Specific tasks are identified in Section 5.

Role	Description
1	Actively identifying stroke patients admitted to (or occurring within) the hospital on a daily or weekly basis.
2	Retrospectively reviewing records of stroke patients.
3	Resolving difficult cases (where a patient needs to be assessed by an experienced medical practitioner or neurologist).
4	Recording patient details on the Stroke instrument
	Entering instrument data into the register (using the data entry tool)
5	Following up with patients at day 28.
6	Liaising with and reporting any difficulties to the site coordinator.

Skills and attributes

Interviewers should have the following general skills and attributes:

- Good basic knowledge of different clinical symptoms of stroke.
- Good understanding of the different case finding methods (hot and cold pursuit).
- Excellent understanding of the stroke definition and the instrument questions.
- Have a sensitive approach towards people who are in a stressed situation or are recalling a sad moment in life.
- Good oral, written and keyboard skills.
- Good attention to detail.
- Ability to follow instructions consistently but raise concerns when appropriate.
- Work well with others to achieve results.

International Coordinating Committee

Introduction

The International Coordinating Committee (ICC) provides technical support and guidance for STEPS stroke surveillance.

Objectives

The main objective of the ICC is to oversee the practical and logistic issues relating to the overall coordination and implementation of STEPS Stroke surveillance.

Core roles of the unit

The core roles of the ICC are to:

- Register surveillance site participation
- Support the site coordinator
- Provide access and support to STEPS surveillance tools and reference material
- Draft and distribute a regular stroke newsletter
- Oversee the overall implementation of the STEPwise approach to stroke surveillance (STEPS Stroke)
- Analyse hospital registers and help report and share results.
- Ensure quality control.

ICC members

Members of the ICC include:

- Chair
- STEPS Surveillance team leader
- Technical adviser
- Data analyst

Chair

The ICC chair is responsible for advocacy around STEPS Stroke and overseeing the practical and logistic issues relating to the overall implementation of STEPS Stroke. The core roles include:

- Advocate on behalf of ISS and WHO at major international stroke meetings.
- Develop closer links between the major NGOs and WHO around stroke surveillance.
- Help expand the number of Stroke surveillance sites.
- Liaise with site coordinators on a regular basis.
- Report to WHO, ISS and the IAG on a regular basis.

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International Coordinating Committee, Continued

STEPS Surveillance team leader

The STEPS team leader, based in the Department of Chronic Disease and Health Promotion, is responsible for the ensuring linkages with the STEPS risk factor surveillance activities and. Other activities include:

- Support and maintain the linkages on the STEPS web page
- Receive all applications for participation and refer to the ICU technical adviser
- Provide administrative support where required
- Arrange meetings of the International Advisory Group during routine NCD Regional Advisers retreats.
- Update the mapping of STEPS stroke sites in line with the STEPS risk factor surveys.

Technical adviser

The technical adviser is responsible for:

- Supporting participating stroke surveillance sites (SSS) with general information about the manual
- Providing technical support to participating SSS
- Keeping a log of all registered surveillance sites.
- Preparing first drafts of the annual report and collating comments from site coordinators.
- Providing information/data as requested from the ICC chair, ISS, and WHO.
- Ensuring relevant WHO regional and country people are informed
- Updating and maintaining the Stroke STEPS Stroke surveillance manual.

Data analyst

The data analyst is responsible for:

- Developing and maintaining Stroke data entry tool (DET) in collaboration with the technical adviser.
- Modifying the Stroke DET in accordance with experience from the feasibility study of the SSS;
- Collecting and collating data for the annual report.
- Supporting data analyses, data reporting of core indicators and participating in data interpretation.
- Contributing to the annual report and annual update of the stroke manual.

International Advisory Group

Introduction

The international advisory group (IAG) provides global stroke surveillance coordination.

Members

Members of the IAG include:

- President, International Stroke Society
- ICC chair
- WHO STEPS Surveillance team leader
- WHO NCD regional advisers (6)

Core roles

The core roles of the IAG are to:

- Act as an advocacy body for stroke surveillance.
- Assist in translating the data into policy and programmes.
- Ensure the long term sustainability of STEPS Stroke surveillance.
- Oversee overall strategic direction and annual work plans.
- Provide feedback on quarterly progress reports.
- Identify potential participating stroke surveillance sites.
- Assist with fundraising efforts.

Section 3: Planning and Preparing a Stroke Study

Overview

Introduction

This section covers the tasks that need to be conducted to plan and prepare for a STEPS stroke surveillance study.

Intended audience

This section is primarily designed to be used by those fulfilling the following roles:

- Site coordinator
- International coordinating unit

Using existing case registration systems

In some settings, there will be other hospital-based chronic disease case registration systems that cover large populations. Where these systems already exist, consider working with the registration teams and adding stroke surveillance to their work.

In this section

This section covers the following topics:

Process Overview and Eligibility

Introduction

Before applying for stroke surveillance participation, some initial prerequisite actions and criteria must be defined.

Process overview

The table below shows each stage in the planning, scoping and eligibility process.

<table>
<tr><th>Stage</th><th>Description</th></tr>
<tr><td>1</td><td>Define the scope of the study (Step 1, 2, 3).</td></tr>
<tr><td>2</td><td>Identify the study site.</td></tr>
<tr><td>3</td><td>Identify the source population from which the cases will be derived

<table><tr><th>If the source population is</th><th>Then</th></tr><tr><td>Available</td><td>Apply for full participation</td></tr><tr><td>Not available</td><td>Apply for limited participation (case series only)</td></tr></table></td></tr>
<tr><td>4</td><td>Prepare the instrument.</td></tr>
<tr><td>5</td><td>Obtain sustainable funding</td></tr>
<tr><td>6</td><td>Apply for participation.</td></tr>
<tr><td>7</td><td>Get ethical approval.</td></tr>
</table>

Note: Each of these stages is explained in more detail below.

Identifying the Scope

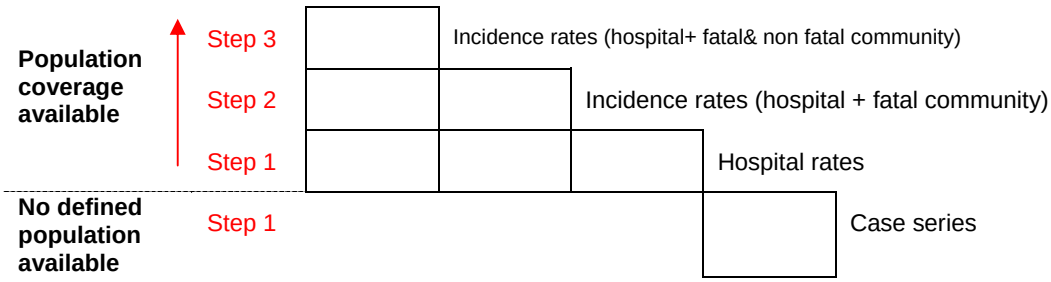
Introduction

The focus of STEPS Stroke surveillance is reflected in the core of the stroke instrument.

All countries should be able to undertake the core items of Step 1, although not all countries will have access to the defined population from which the stroke events arise.

Stroke study grades

The table below provides an overview of the different levels of a STEPS Stroke study. The usefulness of the study is influenced by the quality, completeness and population coverage. A case series poses the greatest challenge in interpretation, but can be the only option in those countries where there are no census data for the catchment area covered by the selected hospitals.



Step 1 data collection

A Step 1 study is based on stroke patients admitted to a health facility (hospital).

The information collected in this Step (with a defined source population only) provides a hospital based stroke register with hospital based data on:

Step 1	Register of
Core	• Stroke admissions • Severity of stroke • Survival rates for this group of patients.
Expanded	Pre-stroke exposure to major risk factors

Step 1: Main outcomes

The main outcomes from this Step include:

- Hospital admission rate estimates
- Health facility resources allocated to stroke patients
- Functional status of stroke patients at discharge.
- Risk factor exposure

Note: Step 1 does not provide estimates of stroke in the population because some patients are cared for and die in the community rather than in hospital.

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Identifying the Scope, Continued

Step 2: Data collection

A Step 2 study builds on the hospital register in Step 1 and adds data on fatal stroke events in the community. This data is derived from death certificates and verbal autopsy reports.

Step 2: Outcome

The main outcome from Step 2 (combined with the hospital register from Step 1) is calculation of specific mortality rates and years of life lost due to stroke in the study population. These can be broken down by:

- Age and sex
- Proportion of fatal events treated out of health facilities
- Years of life lost because of stroke (YLLs).

Step 3: Data collection

A Step 3 study builds on the register in Step 1 and 2 and adds data on non-fatal stroke events in the community (within the same study population).

This step must have a well defined source population for calculating the stroke rates and a way of identifying all cases (or a representative sample) cared for entirely in the community Data collected in this step includes:

- Nursing homes
- Private health facilities
- Local health professionals

Step 3: outcomes

The main outcome from Step 3 (combined with Step 1 and Step 2 results), is the calculation of incidence and case-fatality rates. It provides the opportunity to estimate:

- Stroke incidence, prevalence, and case fatality
- Years of Life lived with Disability (YLDs)
- Estimate of needs for long term care.

Recommended scope

The minimum recommended scope for most countries should be Step 1 with a defined source population and Step 2 if at all possible.

Information on incidence rates and case fatality collected in Step 3 are the most valuable epidemiological measures for public health initiatives for stroke prevention. It is therefore highly recommended that there is a clear intention to advance the study to include all three Steps.

Financial support

Once you have identified the scope of your study, you will need to set out a budget and seek financial support (from local or national sources or in kind) to cover all expenses of the study for the whole study period.

Defining the STEPS Stroke Surveillance Site

Introduction

The next stage in the process of being eligible to participate includes identifying and/ or describing the STEPS stroke surveillance site. This may differ depending on the Steps (1,2 and/ or 3) being covered.

Step 1: hospital based register

For Step 1 - hospital based register, you will need to define the health facilities, or network of health facilities that you plan to include in the study.

These could include:

- All health facilities in the (source population) area
- A small group of interested health facilities
- Interested wards within defined health facilities.

Step 2 and 3 community events

For Step 2 and 3 - fatal and non- fatal community based events, you will need to define the community, have access to all death certificates and/ or verbal autopsy.

Defining health facilities

To define the health facilities, use the hospital information sheet in Section 7 and include:

- Number and type of hospitals included in the study
- Number of wards
- Number of beds
- Whether brain imaging is available.

Once defined, the selected health care facilities will be referred to as the STEPS stroke surveillance site.

Defining the community

To define the community, you must send the ICU a copy of the latest census report.

Patient eligibility

A patient is eligible for inclusion in the Stroke study, if:

- normally resident in the defined stroke surveillance site, or
- admitted to the participating hospital or health facility.

Continued on next page

Defining the STEPS Stroke Surveillance Site, Continued

Estimation of stroke events	To be eligible to participate, you must be able to estimate a minimum of 250 stroke patients per year in the source population from which the cases will be derived, (ie, hospital and / or community). These can be based on previous experience or the results of a pilot study. **Note:** This minimum number is required to ensure meaningful analysis of the data by age and sex.
Data collection timeframe	As a minimum, stroke event registration should be undertaken continuously over a period of 12 months in the defined surveillance site as stroke occurrence varies at different times of the year.

Identifying the Source Population

Introduction

Calculation of epidemiologic rates is based on the number of stroke events occurring in the source population.

One of the first steps in setting up surveillance studies is therefore to specify and describe the population in which the study is going to take place.

Requirement

A defined source population should include population counts broken down by:

- each age group to be included in the stroke surveillance study
- sex, and
- total counts.

Source of information

In many settings, source population counts can be obtained from:

- Population census lists
- Inter census estimates
- Population registers

Where source population data does not exist

In settings where source population data does not exist, you will only be able to do a limited study and be able to produce a case series stroke register. Interpretation of this data over time poses major challenges.

Population coverage

Sites that wish to estimate admission rates for Step 1 and/or do Step 2 and Step 3 must provide an accurate estimate of the source population at the time of application.

To provide a reliable estimate of the impact of stroke occurrence, representative regional population coverage (up to 1 million) is recommended. Including more than 1 million people or entire country populations is usually not possible and would require a sample system to be established and a much larger team than the one recommended in this manual.

Continued on next page

Identifying the Source Population, Continued

Factors to consider

The table below lists some factors to consider for population coverage.

Coverage	Guidelines
Districts	Consider both urban and rural **Note:** Often there are differences between urban and rural districts with respect to exposure to risk factors, treatment of predisposing diseases, for example hypertension, and access to health authorities and facilities.
Hospitals	Include both private and public (state run).
Gender	Include both men and women.
Socio economic status	Allow a representative range of socio economic groups.

Age range

For practical and financial reasons, you should restrict the Core study to age groups where stroke usually occurs, for example from age 45 to 84 years.

If you need to expand the study to assess stroke cases in the very young or very old, you may wish to include other age ranges. See the table below for guidance on expanded and optional age ranges.

STEPS levels	Age range
Core	45-84
Expanded	15 - 44 85 +

Note: It is often difficult to determine actual stroke in the very elderly due to co-morbidity. Including the expanded age range 85+ can therefore skew results.

Sex

Stroke rates are often higher in men than in women, but the differences are not as marked as for other chronic diseases (such as heart disease).

Men and women should therefore be presented separately in all analyses.

Continued on next page

Identifying the Source Population, Continued

Source population form

Once you have identified the stroke surveillance site and if you can identify the source population, you will need to complete the WHO STEPS stroke source population form. A copy of this form is available in Section 7.

Question	Completion guidelines
1	Enter the calendar year (1 January to 31 December) for which information is being provided. Include all 4 digits of the year (for example 2005). If a one-year study period covers two calendar years, please indicate the months in the space before entering the calendar year, and enter the first calendar year only. **Note:** If other calendars are used, these will need to be converted to an international standard to allow cross country comparisons.
2	Enter the official counts for men and women in each age range to be covered in your study

Modifying the Stroke Instrument

Introduction

The stroke instrument is a standard document that allows comparisons and international trends analysis and should not be changed. It uses a standard international calendar and is the basis for the standard data entry tool.

Minor modifications

Despite the need for standardisation, some minor local modifications may be required in some settings (for example, to clarify terminology or provide a more comprehensive assessment of stroke occurrence and treatment). The following table provides guidance on possible situations where the Instrument may be modified to local requirements.

	If..	Then..
Terminology	The terms used in some Core 'standard' questions do not fit the cultural setting (for example, ethnicity).	Alter the term for local relevance, but ensure the original meaning is retained.
Additional information	You require additional data on stroke occurrence and treatment (for example, use of tPA) and you have available resources.	Add selective, but limited questions as Optional items.
Link to previous data	You require specific data to link to previous surveys	Add selective, but limited questions as Optional items
Expanded questions	Particular expanded (only) questions are not covered in study scope.	Omit these questions

Note: Expansion of the basic core questions is suggested only in settings where resources are available and in local needs.

Modification rules

There are some fundamental rules that must be observed when making any modifications to the standard stroke instrument. These include:

- Never delete a question or measure from the Core Instrument.
- Never change the standard coding numbers.
- Place additional questions or measures at the end of the relevant section as an Optional item.
- Do not place additional questions or measures in between other Core or Expanded questions.
- Code added questions or measures coded with the letter 'X' so they stand out
- Remove from the instrument the Expanded sections and Steps (ie 2 and or 3) that are not being covered by your site.
- Send your final draft to the ICU for review before starting the study.

Continued on next page

Modifying the Stroke Instrument, Continued

Translating the Instrument

Follow the guidelines below to select appropriate translators and ensure accurate and appropriate translation of the stroke instrument and all other interviewing materials.

- Initial translation of material should be conducted by at least one translator (ideally by health and survey experts who have a basic understanding of the key concepts).
- The instrument must then be back-translated into the original language by another translator to ensure accurate reproduction of meanings (ideally by linguistic experts who can explain the terms used and suggest alternatives).

Quality standards for translation

The following are recommended guidelines for translation:

- Translate medical terms into expressions understood by all health professionals.
- Translate the original intent of the questions with the most appropriate equivalent term in the local language.
- Develop an inventory of local expressions used as well as comparisons of expressions in other languages.
- Where there are many dialects and/or languages that are not available in written format, carefully plan specific translation protocols.

Applying for Participation

Introduction

Once you have addressed the prerequisite actions and identified the scope of your stroke study, you will need to apply to the ICU for participation in a WHO STEPS Stroke surveillance study.

Purpose

The purpose of the application for full participation is to set out:

- Location and health care facilities to be included in the study
- Details about the site coordinator (including expertise)
- Scope of the study and desired goals
- Source population
- Required resources
- Financial support
- Data management environment.
- Contact details.

Application for participation template

A stroke application for participation template can be found in Section 7. Once completed, you will need to forward this to:

STEPS Stroke Surveillance
Surveillance and Primary Prevention (SPP)
Department of Chronic Diseases and Health Promotion
World Health Organization
20 Avenue Appia
CH 1211 Geneva, Switzerland

Fax: +41 22 791 47 67
Email: **STEPS@who.int**

Participation acceptance

Once your application has been accepted by the ICC, you will be given provisional SSS participation status. Full participation will be granted once you have received ethical approval from your local ethical review committee. You will receive the following from ICC:

Acceptance stage	Received from ICU
Provisional	• Stroke surveillance site code • Interviewer codes • Hard copy of the Stroke Manual
Full	• Password to logon to the STEPS stroke web site and download the data entry tool

Getting Ethical Approval

Introduction

To ensure that each stroke survey is conducted in a technically and ethically sound manner and in appropriate consideration of the local context, every stroke surveillance application should undergo ethical review and approval.

Process

Ideally, ethical approval should be sought by submission of a proposal and application to a hospital ethics review committee or other relevant body.

Where no such established process exists, it is recommended that an application for ethical review be prepared and submitted through an ad hoc local mechanism within the Ministry of Health.

Making a submission

Follow the steps below to make a submission and obtain ethical approval and access to information used as the sampling frame for the survey.

Step	Action
1	Draft a formal submission
2	Identify and contact the relevant committee, seeking guidance on rules, submission processes and procedures and committee sitting times.
3	Adapt submission as necessary and submit to the appropriate committee requesting guidance on expected timeframe for approval. **Note:** Emphasize that all data collected are kept confidential.
4	Follow-up with committee to get clearance.

Note: The STEPS stroke advisory committee can provide further advice on making a submission.

Expected timeframes

Preparing and obtaining approval for submissions to ethics committees can take weeks and even months depending on their rules of operation and how often committees sit.

Possible issues

Some of the issues that can occur while trying to gain ethical approval include:

- Committee does not sit for months
- Committee takes too long to provide consent
- Ethical approval is declined
- The Committee wants modifications to the instrument that threaten its value.

Continued on next page

Getting Ethical Approval, Continued

Informed consent

In addition to getting ethical approval for the study, it is also recommended that there is a process for patients to give verbal and/ or written consent before taking part in the study. In some countries this is mandatory.

For further details on informed consent, see Section 5, data collection guidelines.

Section 4: Preparing the Stroke Surveillance Site

Overview

Introduction

Once your application for participation has been accepted, and you have received your Stroke surveillance site code (SSS code), you will be able to recruit or obtain staff through secondment and set up the data entry tool.

Intended audience

This section is designed for use by those fulfilling the role of the Site coordinator.

In this section

This section covers the following topics:

Recruiting Staff

Introduction

The number and type of staff recruited to do data collection will depend on the following:

- Scope and size of the stroke study (including Step 1, 2 and or 3)
- Source of data to be collected (ie active recruitment, or retrospective record review)
- Qualifications and skills of interested applicants

Core roles

The core roles of data collection staff are covered in Section 2.

Where to get people from

In many countries, recruitment is likely to be an informal process where staff are 'seconded' from other duties within a health facility or health authority. For example, junior staff in training. In this situation, arrangements for their release or scheduled participation may need to be negotiated and explicitly agreed upon.

Where there is not sufficient available staff or specific skills are required formal recruitment may be necessary.

Number of staff

For a STEPS Stroke study that intends to register 250 cases per year, you will need to recruit two data collection staff.

It is normal to screen a larger number of patients, and data collection must be ensured during sick leave, annual leave, etc.

More staff may be needed if data collection is spread over a large area. This includes multiple hospital coverage and in places where death certificates are not centralized.

Briefing and Training for Data Collection Staff

Introduction

Training is likely to be informal and will depend on the level of skill and qualifications of data collection staff.

Purpose

The purpose of the briefing and training is to ensure:

- Uniform application of the STEPS stroke surveillance materials.
- Good overall quality of data collected.
- Useful and meaningful results reported.

What to cover

Depending on the qualifications and skills of staff recruited and type of data collection, briefing and/ or training could cover some or all of the following topics:

Topic	What to cover	Reference
STEPS stroke surveillance	• Basis of STEPS stroke and rationale for the study • About stroke • Key vascular risk factors • Medical treatment	Section 1
Roles	Roles and responsibilities of data collection staff	Section 2
Data collection	• Methods for identifying stroke patients (hot and cold pursuit) • Interview skills • Recording patient responses • Using the STEPS stroke instrument • Using the Q by Q Guide • Administration • Test cases	Section 5 Section 7
Updating the stroke register	• Using the data entry tool	Section 6

Setting up the Stroke Surveillance Site

Introduction

To set up the STEPS stroke surveillance site, an office space will need to be identified or established for:

- Coordinating the STEPS Stroke study.
- Entering patient data entry into the data entry tool.
- Maintaining the stroke register and relevant files.

Office equipment and supplies

General office equipment and supplies required for the stroke surveillance site office include:

- Photocopier
- Shelving
- Filing cabinets or boxes
- Telephone
- At least one computer with internet connection
- Office stationery supplies (paper, pens, envelopes, staplers etc).

Software

The following is a list of software that you will need to have setup on your office computers:

- Microsoft Office '98 or higher recommended for reports, correspondence and general word processing
- Virus scanning software (if connected to the internet and/ exchanging files outside the office)
- MS Access ('98 or higher) for data entry.
- Standard Data Entry Tool (DET)

For information on installing the DET see page 4-5 below and for further information on using the DET see Section 6.

Note: The DET is a standard tool that is only available in English.

Other technical requirements

To conduct an "ideal" stroke study, you will need access to brain imaging equipment at the surveillance site. This may not be feasible in all settings.

Installing and Preparing the Data Entry Tool

Introduction

It is important to properly set up and install the Data Entry Tool (DET) prior to starting data collection. The setup process involves:

- Creating a folder for the DET
- Receiving and installing the DET
- Preparing the DET for data entry.

Create DET folders

Follow the steps below to create appropriate STEPS Stroke folders on the computer that will be used to enter data and establish a register.

Step	Action	Recommended folder name
1	In Windows Explorer, create a primary folder (directory) for all your Stroke files, including: • data • code • documents, and • other files.	Use either: • C:\SSS200X(insert appropriate year), or • other appropriate drives if your disk is partitioned you are on a network.
2	Create a sub-folder under the STEPS Stroke primary folder to contain your data files	C:\SSS200X\data

Receiving the DET

Once you have been authorized by the ICU to participate in a STEPS Stroke study, the ICU data analyst will email you the appropriate version of the DET.

Note: Make sure you have ordered the version of the DET which corresponds to the Microsoft Access® version on your computer or local network (e.g. DET for MS Access 97).

Installing the DET

Follow the steps below to install the DET onto your computer.

Step	Action
1	Unzip the DET attachment
2	In Windows Explorer, copy the following files into the C:\SSS200X folder: **WHO_Original.mdb** **WHO_Original_Data.mdb** **Note:** All export files of the Data Entry Tool are automatically stored into this folder.

Continued on next page

Installing and Preparing the Data Entry Tool, Continued

Installing the DET (continued)

Step	Action
3	In Windows Explorer double click the file: **WHO_Original.mdb**
4	Click OK in the Entering SSS code box.
5	Click on the SSS code button in the configuration window.
6	Enter your SSS code and click OK in the SSS code window.
7	Repeat step 9 to confirm your SSS code.
8	Click the Close button in the configuration window.
9	Click the Close button in the start window.

Error messages

You will get one of the following error messages if you incorrectly entered your SSS code and will need to repeat steps 7-10 above to correct:

- Invalid data entry
- Wrong SSS code
- Invalid SSS code.

Test Run

Introduction

Prior to starting the stroke study, it may be useful to complete a test run of the:

- STEPS stroke instrument
- Case finding process
- Access to records
- Case registration process, and
- Data transfer of results

Test patients

Identify and approach a sample of 25 patients to be part of the test run. If possible, the test cases should include:

- Both men and women.
- People with differing levels of education.
- A broad age range (within the target study range).
- More than one ethnic group (if appropriate).

Feedback

At the end of each interview, ask the patient the following questions and record their feedback:

- Did any of the questions make you feel uncomfortable?
- How could we improve the format or layout?
- Were there activities that we missed?
- How else could we improve this survey?

Evaluation and refining the Instrument

On completion of the trial:

- Compile all patients' comments into a single report.
- Where necessary, adapt and refine the Instrument - taking care not to change intended meanings.
- Send the instrument to the ICU for comment and quality assurance.

Note: The ICU will also provide feedback on the overall quality of collected data.

Section 5: Data Collection Guidelines

Overview

Introduction

This section provides generic guidelines for data collection staff.

Intended audience

This section is designed for use by those fulfilling the following roles:

- Interviewers
- Stroke principal investigator

In this section

This section covers the following topics:

Case Finding Methods

Introduction

The main case finding methods used to identify stroke cases are:

- Hot pursuit (active, ongoing recruitment)
- Cold pursuit (retrospective record review)
- Combination of hot and cold pursuit.

Hot pursuit

Hot pursuit refers to ongoing 'active' identification of all stroke events as they occur.

The main purpose is to confirm that the criteria for stroke is met and ensure complete identification of all events including mild stroke events.

Hot pursuit involves regularly checking the following:

- Daily hospital admissions
- Emergency rooms
- Wards
- Death certificates

Cold pursuit

Cold pursuit refers to retrospective identification of stroke events, for example, based on information from hospital discharge records, or death certificates.

This identification method relies on diagnoses made by several doctors of varying neurological experience who are not working to a protocol. It requires a team identifying and validating stroke events when it is convenient, based on information from routine data sources. Direct examination of the patient is often not possible, and the diagnosis is based on data from records.

Combined approach

Many studies use a combined approach with a mix of hot and cold pursuit to ensure the most complete identification of stroke events (so called overlapping identification sources or overlapping sources of information).

Some of the patients must have been identified as soon as possible after symptoms onset with the possibility of direct examination, while the remaining events are based on routine data.

For example, the researchers have done direct examinations after hospital admission but to ensure the completeness of the data, hospital discharge records, death certificates etc. are checked, physicians are asked to report non-hospitalized stroke events

Identifying Stroke Patients in Hospitals (Step 1)

Introduction

Surveillance of stroke managed in hospitals should be limited to patients who:

- Are admitted to any unit, ward, division or department of the hospital with a provisional diagnosis of having experienced the onset of a new stroke.
- In-hospital patients who suffer a stroke due to the treatment of another disease.

Identifying stroke patients

Stroke patients may be identified through the following hospital systems and channels:

- Emergency room daybook (or register)
- Admissions book (or register)
- Outpatient clinics
- Radiology departments
- Specialist physicians or neurologists
- Physiotherapists, speech or occupational therapists
- Discharge records
- Death certificates

Note: It is necessary to devise systems in each hospital to detect patients who suffer from an in-hospital stroke, whether intra-operatively or at some other time, and whether in acute or on long-stay wards.

Difficult cases

While many cases are straightforward, stroke has a long differential diagnosis. Resolving the difficult cases requires that the patient be assessed by an experienced medical practitioner and preferably by an internal physician or a specialist neurologist.

Re-assessment of the patient at least 24 hours after the initial presentation may be vital to differentiate stroke from TIA and other neurological or medical diseases such as hemiplegic migraine and epilepsy.

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Identifying Stroke Patients in Hospitals (Step 1), Continued

Diagnosis

The table below provides an example of some of the diagnoses that should be considered for STEPS stroke registration.

Stroke specific	Focal and global signs that could be caused by stroke
• (acute) stroke *or* (acute) cerebrovascular episode • cerebral *or* cerebellar embolus, thrombosis *or* infarction • occlusion, thrombosis *or* embolus of carotid, (pre) cerebral *or* vertebral artery • lacunar hemorrhage *or* stroke • subarachnoid, (primary) intracerebral, cerebellar *or* pontine hemorrhage *or* stroke • ruptured berry aneurysm • transient (cerebral) ischemic attack	• (acute) hemiplegia *or* (acute) hemiparesis • faint, fit, funny turn, (acute) confusional state *or* loss of consciousness – for investigation • (acute) dysphasia, dysarthria, dyspraxia or homonymous hemianopia – for investigation • amaurosis fugax • acute monocular blindness

Note: Further details on symptoms for the three major stroke types can be found in Section 1, About Stroke.

Identifying Fatal Stroke Patients in the Community (Step 2)

Introduction

The three main methods for identifying and estimating the number of stroke patients that die out of hospital include:

- Verbal autopsy
- Death certificates
- Medical autopsy

Verbal autopsies

Verbal autopsies (VAs) are increasingly being used to monitor the distribution of deaths by cause in places where medical certification of cause of death is uncommon. This technique is based on the assumption that most causes of death have distinct symptom complexes, and that these can be recognized, remembered and reported by health professionals or lay respondents.

Official WHO verbal autopsy for adult deaths is currently being developed.

Sites that wish to undertake VA in their stroke studies should contact researchers who have had previous experience with this epidemiological tool.

If VA is to be used in Step 2 please indicate this on the application for participation form.

Death certificates

Communities that have universal medical certification of cause of death can provide direct data on deaths due to stroke. Be aware that delays in processing death registrations and certificates may occur and also a wide variety of terms may be used to describe fatal stroke. Methods for searching death registrations may include:

- Electronic keyword search
- Manual record search by visual sighting.

Validation of codes and diagnosis

Both the codes used and diagnosis of stroke as the immediate or underlying cause of death should be validated as indicated in the table below.

Validation of	Based on
Codes	• Medical and medico-legal records (within 28 days of death) • Interview with decedent's next-of-kin or other informant.
Diagnosis	• Clinical signs according to the stroke definition • Neuro imaging or autopsies

Continued on next page

Identifying Fatal Stroke Patients in the Community (Step 2), Continued

Medical autopsies

Since medical autopsy rates are declining in many countries autopsies are unlikely to provide a substantial coverage of fatal strokes. However, records of post mortem examinations are an accessible way of getting information for the surveillance system. They provide a valid diagnosis, and contribute to a more complete understanding of the stroke occurrence in the study population.

Estimating Non-Fatal Stroke Events in the Community (Step 3)

Introduction

The two main methods for estimating numbers of non-fatal events in the community include:

- Tracking medical practices (health facilities) by survey, and
- Hemiplegia/ hemiparesis survey.

Primary health care facilities

Where there are general practitioners are widely used at primary health care facilities, these should be included in the surveillance.

In some countries there are only few general practitioners or only a proportion of stroke patients who ever have contact to them. In these sites, local healers may be the primary contact person and it is important to consider the potential for collaboration.

General practitioners

You will need to use different survey techniques depending on the size of the study population as follows.

If the study population is	Then
Small (limited size)	Include all the general practitioners and local health facilities in the study (eg. public health care centres, nursing homes, rehabilitation centres etc).
Large (entire population)	Survey a representative sample of medical practitioners to assess the number of cases that they have managed over a defined, preceding period.

Local healers

Given instructions on stroke symptoms, local informal healers may be able to provide a contact to the patient, which then can be examined for stroke symptoms.

Note: This procedure is likely to underestimate the true rate as mild cases are unlikely to be detected, but the overall effect on the estimates is likely to be minor.

Continued on next page

Estimating Non-Fatal Stroke Events in the Community (Step 3), Continued

Postal study of

In many communities, studies covering a representative sample of the target population can be conducted quickly and easily by post rather than by personal contact. If you do this, you will need to adjust the results (by numerical factors) to allow for:

- Sampling
- Response proportions, and
- Events actually managed in hospitals

For example, suppose that a 5% sample survey of 800 doctors achieved a 75% response and indicated that, between them, over the preceding two years, the 30 doctors who responded had managed 60 non-fatal cases of stroke without admitting the patient to hospital. In addition, if an average of 600 events per annum had been registered through surveillance in hospitals during the same period, then the estimated total number of non-fatal stroke events annually in that population is:

600 + (60/2 x 800/30) = 1,400.

Note: For further advice on defining a sample of the population and adjusting results, please contact the ICU.

Hemiplegia/ hemiparesis survey

In most communities the causes of adult-onset hemiplegia or hemiparesis are limited to stroke and head injury and can be distinguished from patient history.

If the incidence of residual hemiplegia following stroke and the survival time are constant within a given community, trends in the prevalence of hemiplegia will reflect trends in the incidence of stroke.

This could be useful for stroke surveillance because hemiplegia is recognisable and identifying cases does not require self diagnosis. The prevalence of hemiplegia can therefore be identified by questionnaire based population surveys or interviews with a representative from selected households. The problem, however, is that even prevalence of stroke is relatively rare.

Notes: The linkage between prevalence of hemiplegia/ hemiparesis and incidence of stroke has not been validated in a study so far.

Interview Skills

Introduction

Although much of the data that needs to be collected can be obtained from records, some contact with patients or next of kin may be required.

Participation

The patient (or person being interviewed) needs to feel comfortable about the interview and can refuse to be interviewed as participation is voluntary. The interview should therefore be as natural as possible and conducted politely, like a normal conversation.

Behaviour and tact

The table below provides guidelines on appropriate behaviour during an interview:

Behaviour	Guidelines
Respect confidentiality	Maintain the confidentiality of all information you collect.
Respect patient's time	You are asking patients for their time so be polite and prepared to explain.
Tact	If you feel that a person is not ready to assist you, do not force them but offer to come back later.
Friendly disposition	Act as though you expect to receive friendly co-operation and behave accordingly.
Body language	Maintain good eye contact and adopt appropriate body language.
Pace of interview	Don't rush the interview. Allow the patient enough time to understand and answer a question. If pressured, a patient may answer with anything that crosses their mind.
Patience	Be patient and polite at all times during the interview and ensure you have set aside enough time for patients with aphasic disturbances.
Appreciation	Thank them for their help and cooperation.

Continued on next page

Handling refusals

Be prepared to obtain co-operation from a patient who does not want to be interviewed. In general, be pleasant good-natured and professional and most patients will co-operate.

If..,	Then..,
The patient becomes defensive	• Show patience and understanding • Provide token agreement and understanding of his/her viewpoint, that is, saying something like, 'I can understand that' or 'You certainly have the right to feel that way.' • Convey the importance of the study to the patient and that all stroke patients are being registered.
You may have visited at a bad time.	Try again later.
The patient may have misunderstood the purpose of the visit.	Try to explain the purpose again.
You think you may get a 'no'	Try to leave and suggest coming back later before you get a partial or an absolute 'no'.

Patient consent

Each patient (or family member) should provide verbal and/or written consent in accordance with local standards before taking part in the Study.

A consent form template is available in Section 7.

Recording Responses for Registration

Introduction

All results that are recorded on the STEPS instrument must be written as clearly as possible to avoid ambiguity and confusion when checking and entering the results.

Requirements

Some general requirements for recording survey information are as follows:

- Record the patient identification number on every page of each instrument.
- Do not erase any notes made.
- If a question has been skipped by mistake, correct it.
- If a patient changes his/her mind on one of the options, record the new answer.
- Record only answers that are relevant to the study.
- Record comments or explanations in brackets in the instrument next to the corresponding question.
- Don't get too absorbed recording. Keep the patient's interest by saying the patient's response aloud as you write it down.
- Standard agreement on how to write numbers.

Handling issues

Use the table below to help with some common issues you may encounter.

If..	Then..
You are uncertain about a response	Repeat the question and record the answer exactly. Do not paraphrase a response.
A question doesn't apply or the patient doesn't know and these options are not available on the instrument	• For "don’t know" record: 9, 99 or 999 etc
You have missed a question	Go back and ask the question, making a note that the question was asked out of sequence.
Missing data is not discovered until after the interview	If possible, re-contact the patient and ask the question. Note that the question was asked out of sequence. If not possible, then write “missed’.

Continued on next page

Recording Responses for Registration, Continued

Checking and editing

At the end of each interview check the instrument and make sure that:

- All the questions have been answered.
- The information recorded is clear and legible for others to read.
- Probing comments are indicated.
- Check that all the information has been completed including the ID number on every page.
- Review the instrument to check it is complete and that every question has been answered.

Completing the Stroke Instrument

Introduction

Once the standard stroke instrument has been translated and printed it is ready for use during the study.

One instrument is to be completed for every patient documented in Step 1, Step 2 and Step3. All items on the instrument must be completed for the response to be valid.

Cover page

The bottom part of the first page of the instrument, contains identification information, including the patient names. It is very important that these details are kept confidential at all times and that you tell the patient that they will be kept confidential.

Core and core expanded items

The instrument contains Core (unshaded) and Expanded items (shaded) response options for each Step you will need to complete.

Introductory statements

Where a section of items has an introductory statement, you must read this out to the patient.

Entering the patient's response

For some items on the instrument, there may be one or more possible responses. Each possible response has an associated code. You will need to enter the appropriate response code in the box for each item. For example:

Stroke classification

(S1 6)	What subtype of stroke was diagnosed? *[select one]*	Ischemic stroke	(1)	[ ]
		Intracerebral hemorrhage	(2)	
		Subarachnoid hemorrhage	(3)	
		Unspecified type	(4)	

Unknown responses

The table below shows what to enter as a last resort where the patient does not respond with a standard response.

If a hospital record or patient response is	And number of [ ] is	Then enter
Unknown Don't know	[ ]	9
Unknown Don't know	[ ][ ]	9 9
Unknown Don't know	[ ][ ][ ]	9 9 9

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Completing the Stroke Instrument, Continued

Q by Q Guide For further instructions on completing individual questions and see the sections below and the Question by Question Guide in Section 7.

Guide to Completing All Stroke Events

Introduction

Accurate core participation and patient characteristic information is essential for analysing and reporting on the overall results of the STEPS Stroke surveillance.

This part of the instrument should be completed for every patient documented in Step 1, Step 2 and Step 3. If the age and sex of a patient has been missed out, the instrument cannot be used in the analysis, as most analyses are grouped by these criteria.

Guidelines on how to complete some questions in this section are given below with further guidance given in the Question by Question Guide in Section 7.

Patient identification number

The patient identification number is to be written on each page of the patient specific documents at the time the completed instrument is being entered into the register.

Contact name and address
I 9 - I 13

An acute stroke event often results in dramatic consequences for the patient after discharge from hospital. This may mean the patient goes to live with relatives or a nursing home for long term care. The contact person, phone number and address should therefore be for someone who knows about the actual living situation of the patient. Children or other close relatives could serve as contact persons for the patient. The relationship of the contact person to the patient should also be documented.

Dates of birth and age
I 14 (Core)

In some countries exact dates of birth and/or age are not known. In these situations age has to be estimated. To estimate someone's age, you will need to ask them how old, or at what stage in life they were at the time that a number of widely known major local events occurred.

Information on acute stroke event

If the exact onset of stroke symptoms is unknown (e.g. stroke occurred during sleeping), ask the patient or another person when the first symptoms of stroke were noticed and enter that date.

To differentiate between a first-time event and a recurrent event it is important to obtain information about possible previous strokes. Please note that that the following are not counted as a stroke:

- Previous TIA
- Silent strokes (ie detected by scanning but did not result in a neurological deficit longer than 24 hours).

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Expanded information

Expanded questions are shown in the shaded boxes. Some of these questions may have been adapted so the terms and phrases make sense to patients in your environment. Some of the adaptations may include relevant:

- Ethnic, racial and or cultural groups.
- Highest level of education.
- Categories of work.
- Income level.

Guide to Completing Step 1: Events Admitted to Hospital

Introduction

This section is to be completed for all stroke patients admitted to hospital. Information collected includes:

- Hospital admission
- Stroke classification
- Vascular risk factors
- Medical treatment
- Secondary prevention
- In-hospital management
- Follow up of the patients

Note: Each of these is explained in more detail below.

Hospital admission S1 1 (Core)

Stroke patients admitted to hospital must have survived until hospitalisation, and must have been able to get to the hospital either:

- by themselves
- with the help from relatives/care givers, or
- using any kind of emergency medical service.

Note: Despite differences between countries and changes in admission practices over time, data based on hospitalised events gives valuable information for local health authorities, and constitutes the first step to a better understanding of stroke in the population.

Hospital departments S1 2(Expanded)

There are 7 possible answers for indicating in which departments or units the patient was treated. The available options are explained in the table below.

Department/unit	Refers to patients managed at..
Intensive care	An intensive care unit, including any type of acute medical unit.
Medical	A general medical ward, including a geriatric unit.
Neurological	A general neurological ward.
Neurosurgical	A general neurosurgical ward.
Rehabilitation	A specialized rehabilitation unit, except a rehabilitation stroke unit.
Stroke	Acute and rehabilitation stroke units.
Other	Other units, e.g. outliers or patients on surgical wards.

Continued on next page

Guide to Completing Step 1: Events Admitted to Hospital,
Continued

Living situation S1 3

Living condition options are explained in the table below.

Option	Refers to patients living
Independent at home	Without depending on any assistance from relatives or professionals
Dependent at home	Depending on assistance from relatives or professionals
Community facility	In nursing or residential homes, serviced flat or other long term care facility.

Modified Rankin scale (Expanded) S1 4

If possible, the Modified Rankin scale prior to acute stroke event should be assessed retrospectively based on the information provided by patient and/ or close relatives. The number corresponding to the patient's functional level is to be entered. The scale is divided into 6 levels (from level 0 to level 5) as described in the table below.

Scale		Description
0	No symptoms	No symptoms at all
1	No significant disability	No significant disability despite symptoms, ie. can do all usual activities
2	Slight disability	Unable to do all previous activities, but able to look after own affairs without assistance
3	Moderate disability Able to walk without assistance	Requiring some help but able to walk without assistance
4	Moderate disability Unable to walk without assistance	Unable to walk without assistance, and unable to attend to won bodily needs without assistance
5	Severe disability	Bedridden, incontinent, and requiring constant nursing care and attention.

Note: The modified Rankin Scale measures independence rather than performance of specific tasks. Mental as well as physical adaptations to the neurological deficits are incorporated, and the score gives an impression of whether the patients can look after themselves in daily life.

Continued on next page

Neurological signs
S 1 5

Neurological deficits, for example, disturbances of consciousness, are an important predictor of stroke severity. Neurological deficits present at the first medical examination after hospitalisation should be documented to adjust potential differences in outcome and disability for stroke severity. The different levels of deficit are explained in the table below.

Neurological deficit type	Refers to
Disturbed consciousness	Disturbances of consciousness, including semi consciousness, e.g. not fully aroused, and coma, either response to pain only or no response at all
Weakness/paresis	Motor deficits of the upper or lower limbs.
Speech disturbances	Speech disturbances present on admission, like aphasia or dysarthria.

Stroke classification
S1 6 (Core)

Stroke events can be classified into either

- Ischemic stroke
- Intracerebral haemorrhage
- Subarachnoid haemorrhage, or
- Unspecified.

It is recommended that stroke types are classified as a result of neuro-imaging.

Whether an event is haemorrhagic versus ischemic is also of importance from a clinical perspective in terms of treatment and early secondary prevention, as aspirin should not be given to patients with haemorrhagic stroke and anticoagulation as well as thrombolysis is obviously contraindicated in hemorrhagic strokes.

Where no diagnostic examination was done to verify the subtype of stroke, choose the option *Unspecified.*

Note: For further details on stroke classification, see Section 1, About Stroke.

Continued on next page

Subtype diagnosis S1 7 (Core)

Diagnosis of stroke subtype, refers to patients where the subtype classification was verified from one of two methods as follows:

Diagnosis by	Explanation
Clinical diagnosis alone	Clinical diagnosis alone and was not verified by brain imaging (or in subarachnoid hemorrhage on lumbar puncture) in non-fatal cases or also by medical autopsy in fatal cases; please indicate also clinical diagnosis alone if any scoring system not based on brain imaging or medical autopsy was used
Diagnostic techniques	In non-fatal cases to patients where the subtype of stroke was verified by brain imaging; subtype verification of subarachnoidal hemorrhage might also be based on lumbar puncture alone; in fatal cases verification of stroke subtype might also be based on medical autopsy.

Risk factors S1 10 (Expanded)

The main modifiable risk factors that are present pre-stroke are listed and defined in the table below.

Risk factor	Defined as a patient who pre-stroke..
Atrial fibrillation	Has atrial fibrillation in ECG prior to stroke (records seen) or during hospitalization.
Current tobacco use	• Is a current tobacco user (smoking and other forms of tobacco), or • Was a recent tobacco user but stopped less than 3 months before acute stroke event.
Diabetes mellitus	• Has been diagnosed with or has self reported diabetes mellitus, and • Uses antidiabetic drugs
Hypercholesterolemia	• Has reported elevated plasma total or LDL cholesterol level, or • Uses lipid-lowering medication
Raised blood pressure	• Has diagnosed or self reported raised blood pressure, or • Uses antihypertensive drugs.

Continued on next page

Pharmaceutical treatment S1 11 S1 12 (Core)

Pharmaceutical treatment means continuous medication. The only exception is for thrombolysis, which is only given one time. The table below lists the categories of drug type and drugs used in each category.

Drug type	Including
Anticoagulant	• Warfarin • Heparin
Anti diabetic	• Antidiabetic medications • Insulin injections
Antiplatelet	• Aspirin • Clopidogrel • Dipyramidol
Cholesterol lowering	• Statins
Blood pressure lowering	• Thiazides • ACE inhibitors • Beta-blockers • Calcium channel blockers

In hospital assessment S1 13 and 14 (Expanded)

The in-hospital assessment questions refer to assessments of the listed disorders during hospitalization, irrespective of whether the patient was treated or not after the first visit.

Patient discharge S1 15 - 18 (Core)

If the patient is alive at discharge (S1 18), there are three possible destinations. These are explained in the table below.

Option		Refers to patients discharged to
1	Home	Private address (either the same or a new address)
2	Other hospital	• Another hospital • Rehabilitation unit • Rehabilitation hospital • Long-stay hospital
3	Community facility	Facilities with access to service and staff eg: • Nursing or residential homes • Long term care facilities for psychiatric disorders • Serviced flat, or • Assisted living

Continued on next page

Modified Rankin scale (Expanded) S1 19

If the patient is alive at discharge, the Modified Rankin scale should be assessed just before discharge from hospital. The number corresponding to the patient's functional level is to be entered. The scale is described on page 5-18 above.

Follow up at day 28 F1 - F7 (Optional)

Follow up on day 28 (from onset of stroke) provides valuable information about the long-term burden of stroke. These optional questions may be difficult to obtain for all registered patients. If a patient or contact person could not be contacted on day 28, try to get all necessary information as soon as possible, and within the next few days.

Some possible ways to follow up with patients after discharge from hospital include:

- Direct examination, e.g. during a home visit, outpatient department or in hospital
- Medical record review, if the patient is still in the hospital at day 28,
- Telephone interview with the patient or close relative, or
- Questionnaire posted to the patient.

Note: Confidentiality, ethical issues and other legal aspects in terms of performing a follow should be clarified before starting data collection.

Verbal autopsies (Optional)

The purpose of Verbal autopsies (VA) is to describe cause of mortality at a community or population level where no better alternative resources exist.

Verbal Autopsies are based on interviews with friends and relatives of a deceased person. After an interview has been conducted, the following takes place:

- A panel of physicians reviews the forms and assigns a probable cause of death
- Medical records coders trained in ICD rules select and code the underlying cause of death, according to a code score
- Mortality results are tabulated using a standard list capable of generating comparable mortality statistics.

Unfortunately, the tools and methods employed are often imperfect and require:

- rigorous validation
- continuous quality assurance

Q by Q guide

Further guidance on how to complete each question in Step 1 is provided in the Question by Question Guide in Part 7.

Guide to Completing Step 2: Fatal Community Events

Introduction

Step 2 covers identifying and registering every fatal stroke event treated in community and not admitted to hospital.

How information is collected
S2 3 (Core)

There are three main methods for collecting information about fatal stroke events in the community. These include:

- Verbal autopsy
- Death certificates
- Medical autopsy

For further information on each of these methods see page 5-5

International classification of diseases (ICD)
S2 4 - 5 (Core)

The International Classification of Diseases (ICD) system is commonly used to record the cause of death on death certificates. There are three versions of the ICD codes and a range of eight or nine coded diseases that may relate to stroke as the cause of death. Some of these disease will not meet the definition of stroke, but should be included in all broad searches for stroke events.

The ICD versions and codes are as follows:

Version	Codes	Disease
ICD 8 ICD 9	430	Subarachnoid haemorrhage
	431	Intracerebral haemorrhage
	432	Other and unspecified intracranial haemorrhage
	433	Occlusion and stenosis of precerebral arteries
	434	Occlusion of cerebral arteries
	435	Transient cerebral ischemia
	436	Acute but ill-defined cerebrovascular disease
	437	Other Ill-defined cerebrovascular disease
	438	Late effects of cerebrovascular disease
ICD 10	I60	Subarachnoid haemorrhage
	I61	Intracerebral haemorrhage
	I62	Other non-traumatic intracranial haemorrhage
	I63	Cerebral infarction
	I64	Stroke, not specified as haemorrhage or infarction
	I65	Occlusion and stenosis of precerebral arteries, not resulting from cerebral infarction
	I65	Occlusion and stenosis of cerebral arteries, not resulting from cerebral infarction
	I67	Other cerebrovascular diseases
	I68	Cerebrovascular disorders in diseases classified elsewhere
	I69	Sequelae of cerebrovascular disease

Continued on next page

Guide to Completing Step 2: Fatal Community Events,
Continued

Q by Q guide	Further guidance on how to complete each question in Step 2 is provided in the Question by Question Guide in Part 7.

Guide to Completing Step 3: Non-Fatal Community Events

Introduction

Step 3 covers identifying and estimating non-fatal stroke event treated in community and not admitted to hospital.

How information is collected S3

There are two main methods for estimating non-fatal stroke events in the community. These include:

- Tracking medical practices (health facilities) by survey, and
- Hemiplegia/ hemiparesis survey.

For further information on each of these methods see page 5-7

Q by Q guide

Further guidance on how to complete each question in Step 3 is provided in the Question by Question Guide in Part 7.

Section 6: Data Entry and Data Management

Overview

Introduction

This section covers all the tasks that need to be conducted to enter and manage the STEPS Stroke study data in the Data Entry Tool (DET) to gradually build up a register that can produce study results.

Intended audience

This section is designed for use by those fulfilling the following roles:

- Data collection staff
- Principal investigator

In this section

This section covers the following topics:

Data Entry

Introduction

STEPS Stroke study data from completed STEPS stroke instruments is to be entered into the data entry tool by trained data collection staff.

Data entry process

Data entry is a systematic process that covers the following main stages:

Stage	Description
1	Entering new patient data
2	Entering the Identification number on patient instruments
3	Validation and error correction
3	Backing up
4	Storing and filing the instruments.

Opening the DET

Follow the steps below to open the DET start window.

Step	Action
1	Open the DET program by clicking the WHO_Original.mdb file in Windows Explorer.
2	The start window will appear. The function of each button is explained in the table below.

Click the button	To
New Patient	Enter new patient records
Search	Search for entered data
Reports	Generate reports of entered data
Data Export	Export entered data
Delete Patient	Delete entered data
Close	Close the data entry tool (DET)

Enter all stroke events data

Follow the steps below to enter new patient data from the All Stroke Events section of the completed STEPS stroke instrument.

Step	Action
1	Click the New Patient button in the start window
2	A unique identification number for each patient will be generated by the Data Entry Tool This consists of the joint SSS code (5 digits) and the patient ID code (6 digits).

Continued on next page

Enter all stroke events data (continued)

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>3</td><td>Write the whole number in the Identification Number boxes at the top of each page of the patient's completed STEPS Stroke Instrument as follows:

SSS Code | Patient ID
Identification Number [1] [1] [2] [2] [0] [0] [0] [0] [0] [0] [0] [1]</td></tr>
<tr><td>4</td><td>Write the first 5 digits (the SSS code) of this number on page 1, I 1 of the paper copy of each patient's completed STEPS Stroke Instrument as follows:

Patient Identification and Patient Characteristics
(I 1) Stroke Surveillance Code [1] [1] [2] [2] [0]</td></tr>
<tr><td>5</td><td>When you have recorded the number, Click Ok</td></tr>
<tr><td>6</td><td>Enter data into the All Stroke Events window exactly as it is written on the paper Instrument.</td></tr>
<tr><td>7</td><td><table><tr><th>If</th><th>Then</th></tr><tr><td>Expanded items (grey boxes on the instrument) have been completed on the instrument</td><td>click the long grey buttons at the bottom of each window to enter expanded data.</td></tr></table></td></tr>
<tr><td>8</td><td>Click the Next button to move to the next window, or Back to edit a previous window.</td></tr>
<tr><td>9</td><td>Log in a spreadsheet or notebook all discrepancies, questions and problems (irregularities) that you cannot resolve. Include:
• Patient ID number
• Instrument Code number (eg. I 14)
• Comment</td></tr>
<tr><td>10</td><td>Click close when you have completed entering the All Stroke Events data.</td></tr>
</table>

Continued on next page

Entering Step 1, Step 2 and Step 3 data

After entering the All Stroke Events data, you will come to the Selection window.

Step	Description
1	Click the appropriate button to enter each Step covered by the study as follows. **Step** / **Description** 1 – Events admitted to hospital 2 – Fatal events in the community 3 – Non-fatal events in the community
2	When data entry is complete, click the Finish button

Validation and error correction

Before moving to the next patient instrument, check and resolve any inconsistencies and/or errors noted in the log book or spreadsheet.

Backing up data

The computer used for data entry should be backed up at the end of each week.

Filing the instruments

All completed instruments that have been entered into the DET should be marked 'entered' on the front page and filed in a secure location.

Data Management

Introduction

To manage the STEPS Stroke data entered using the DET, you may need to perform the following functions:

- Search for a patient record
- Edit data, and
- Delete a patient record

Search for a patient record

Follow the steps below to search for a patient record.

Step	Action
1	Launch the Data Entry Tool from Windows Explorer
2	Click the Search button from the Start window
3	To find a patient record, either enter the patient: • ID number (last 6 digits or the Identification number), or • Family name and /or • First name
A successful search by ID opens the Selection window.	
A successful search by patient's name opens the Register window where all matches for the entered name are listed.	
4	If you searched by patient name, highlight the ID of the correct patient name and click Go to Patient.

Find and edit data

Follow the steps below to find and edit specific patient data.

Step	Action
1	Select the appropriate button corresponding to the section of the instrument you want to search in the selection window, eg. • All stroke events • Step 1 • Step 2 • Step 3
2	Choose the next and back buttons to find the specific data.
3	Edit data and close.

Continued on next page

Deleting a patient record

Follow the steps below to delete a patient record.

Step	Action
1	Launch the Data Entry Tool from Windows Explorer
2	Click the Delete Patient button from the Start window
3	Enter a patient ID and click the Search button.
4	Click Yes to delete the patient record.

Creating Reports

Introduction

You can create and print the following reports from patient data entered into the register using the data entry tool:

- Sex and age distribution
- Stroke subtype distribution

To create a report

Follow the steps below to create a report.

Step	Action
1	Ensure your printer is connected and on.
2	Launch the Data Entry Tool from Windows Explorer
3	Click the Reports button from the Start window
4	Click the type of report you from the Reports window.
5	The selected report will be automatically printed to your printer.

Note: Age distribution (stratified by stroke subtype) can only be calculated after you have created an export file. See Exporting data on page 6-8 below.

Exporting Data

Introduction

To calculate age distribution (stratified by stroke subtype) or to export the data to other software for statistical analysis, you will have to create an export file.

Procedure

Follow the steps below to create an export file:

<table>
<tr><th>Step</th><th>Action</th></tr>
<tr><td>1</td><td>Launch the Data Entry Tool from Windows Explorer</td></tr>
<tr><td>2</td><td>Click the Data Export button from the Start window</td></tr>
<tr><td>3</td><td>
<table>
<tr><th>Click the button</th><th>To automatically</th></tr>
<tr><td>Complete</td><td>Create the following text and Excel files of the complete data:
• CompleteTab.txt
• CompleteTab.xls</td></tr>
<tr><td>Anonymous</td><td>Make the data anonymous by removing identification details data and create the following text or Excel files for data transfer:
• AnonymTab.txt
• AnonymTab.xls</td></tr>
</table>
</td></tr>
<tr><td>4</td><td>Click close to return to the Start window.</td></tr>
</table>

STEPS Stroke Instrument

Including Question by Question Guide (Core and Expanded)

The WHO STEPwise approach to Stroke Surveillance (STEPS)

Noncommunicable Diseases and Mental Health
World Health Organization
20 Avenue Appia, 1211 Geneva 27, Switzerland

For further information: www.who.int/chp/steps

STEPS Instrument
Question by Question Guide

Overview

Introduction

This is the generic STEPS Stroke Instrument template which countries use to develop their own Instrument. It contains the:

- CORE items (unshaded boxes)
- EXPANDED items (shaded boxes), and
- Response options for Step 1, Step 2 and Step 3.
- Step by Step Instruction Guide to each section and question.

Purpose

The purpose of the question by question instruction guide is to provide explanatory and background information to data collection staff as to what is intended by each question.

Other guides

This Question by Question guide is designed to be used in conjunction with other guides available in the STEPS Stroke Manual. Some useful sections are as follows.

Topic/section	Reference
Interview skills	3-2-4
Using the STEPS Instrument	3-2-9
Question by Question Guide	3-3-3
Guide to Core Demographic Information (Step 1)	3-3-4
Guide to Behavioural Measurements (Step 1)	3-3-5
Show Cards	3-3-9
Giving Feedback to Participants	3-3-10
Guide to Physical Measurements (Step 2)	3-4-1
Guide to Biochemical Measurements (Step 3)	3-5-1

WHO STEPS STROKE INSTRUMENT

<INSERT COUNTRY/SITE NAME>

All Stroke Events

For further guidance on All Stroke Events, see Section 5, page 5-15

Patient Identification and Patient Characteristics

(I 1)	Stroke Surveillance site Code *Insert 1st 5 digits of automatically generated code from DET*	[ ][ ][ ][ ][ ]
(I 2)	Interviewer Code *Insert code provided by the ICU*	[ ][ ][ ]
(I 3)	Date of completion of the instrument	[ ][ ]/[ ][ ]/[ ][ ][ ][ ] d d m m y y y y

Patient individual records

(I 4)	Patient's family name *Use CAPITALS, include all names*	[_____]
(I 5)	Patient's first name *Use CAPITALS, include all names*	[_____]
(I 6)	Contact phone number *Include area codes (optional)*	[_____]
(I 7)	Contact address *For follow-up questionnaires (optional)*	[_____] [_____]
(I 8)	Unique identification number where available *number, PID etc (optional)*	[_____]

Contact person of patient

Include contact person who can confirm the living situation of the patient

(I 9)	Contact person's family name	[_____]
(I 10)	Contact person's first name	[_____]
(I 11)	Contact person's phone number	[_____]
(I 12)	Contact person's address	[_____] [_____]
(I 13)	Relationship of contact person to the patient	[_____]

Demographic characteristics

(I 14)	Date of birth *If date of birth is unknown, enter approximate year only*	[ ][ ]/[ ][ ]/[ ][ ][ ][ ] d d m m y y y y	
(I 15)	Sex *[select one]* *Include as observed*	Male Female	(1) [ ] (2)
(I 16)	What is your *[insert relevant ethnic/racial groups defined according to local demographic needs]*	XX XX XX Other	(1) [ ] (2) (3) (4)
(I 17)	If other ethnicity, please state	[_____]	

Socioeconomic status

(I 18)	What is the highest level of education the person has completed? *[select one]* *If a person attended a few months of the first year of secondary school but did not complete the year, record "primary school completed".* *If a person only attended a few years of primary school or never went to school, record "less than primary school"*	No formal schooling Less than primary school Primary school completed Secondary school completed High school completed College/ University completed Post graduate degree Unknown	(1) [ ] (2) (3) (4) (5) (6) (7) (9)
(I 19)	Which of the following best describes the <u>main</u> work status of the person over the last 12 months? *[select one]* *The purpose of this question is to help answer other questions such as Whether treatment, survival and rehabilitation may differ according to Employment status*	Government employee Non-government employee Self-employee Non-paid Student Homemaker Retired Unemployed Unknown	(1) [ ] (2) (3) (4) (5) (6) (7) (8) (9)

Information on acute stroke event

(I 20)	Date of stroke *Enter date of stroke symptoms onset, or first noticed*	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(I 21)	Definite stroke *[select one]*	Yes No Insufficient data	(1) [ ] (2) (3)
(I 22)	If the patient has a definite stroke, has the patient had a previous stroke? *[select one]* *Ensure accurate stroke diagnosis for previous stroke events*	Yes, records seen Yes, records not seen No, records seen No, records not seen Insufficient data	(1) [ ] (2) (3) (4) (5)

Step 1: Events Admitted To Hospital

For further guidance on Step 1, Events Admitted to Hospital; see Section 5, page 5-17

Hospital admission

(S1 1) Date of admission to hospital
If in-hospital stroke, insert day of hospitalization from primary disease
[ ][ ] / [ ][ ] / [ ][ ][ ][ ]
d d m m y y y y

(S1 2) Which department(s)/ unit(s) was the patient treated in?
*[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*
If the patient was treated in several units, list all. If Unknown, enter 9

Intensive care unit	[ ]
Medical unit	[ ]
Neurological unit	[ ]
Neurosurgical unit	[ ]
Rehabilitation unit	[ ]
Stroke unit	[ ]
Other	[ ]

(S1 3) What was the living situation of the patient pre stroke?
[select one]
If in-hospital stroke patient, insert living situation prior to hospitalisation

Independent at home	(1)	[ ]
Dependent at home	(2)	
Community facility	(3)	

(S1 4) Modified Rankin scale prior to stroke
[select one]
See Section 5, page 21 of the Stroke manual for further details on the Modified Rankin Scale.

No symptoms at all	(0)	[ ]
No significant disability despite symptoms	(1)	
Slight disability	(2)	
Moderate disability, but able to walk without assistance	(3)	
Moderate disability, but unable to walk without assistance	(4)	
Severe disability	(5)	
Unknown	(9)	

(S1 5) Which of following neurological signs were present at first medical examination after hospitalization?
*[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*
Insert 1 if neurological sign was present at first medical examination 0 if sign was not present and 9 if Unknown.

Disturbed consciousness	[ ]
Weakness/ paresis	[ ]
Speech disturbances	[ ]

Stroke classification

(S1 6) What subtype of stroke was diagnosed?
[select one]
See Section 1, page 6 for explanation of different types of stroke.

Ischemic stroke	(1)	[ ]
Intracerebral hemorrhage	(2)	
Subarachnoid hemorrhage	(3)	
Unspecified type	(4)	

Stroke classification contd.

(S1 7)	How was the diagnosis of stroke subtype verified? *[select one]*	Clinical diagnosis alone By diagnostic techniques	(1) [ ] (2)
(S1 8)	Which of the following diagnostic examinations were performed? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Angiography Carotid Ultrasound CT scanning Electrocardiogram Lumbar puncture Medical autopsy MRI scanning Other	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
(S1 9)	If scanning was performed, what was the timing of the first scan after onset of stroke symptoms? *[select one]* *Timing of the first scan after stroke onset is critical. Delays beyond 2 weeks may lead to a re-absorption of small haemorrhagic stroke causing the event to be misclassified as ischemic stroke.*	Within 24 hours Between 24 h and 7 days Between 8 to 14 days More than 14 days Does not apply Unknown	(1) [ ] (2) (3) (4) (5) (9)

Vascular risk factors

(S1 10)	Which of the following vascular risk factors were noted for the patient? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]* *See Section 5, page 20 for further details on risk factors.*	Atrial fibrillation Current tobacco use Diabetes mellitus Hypercholesterolemia Hypertension	[ ] [ ] [ ] [ ] [ ]

Medical treatment/ secondary prevention

(S1 11)	Did the patient receive one or more of the following medications **while in hospital**? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]* *See Section 5, page 21 for further details on medical treatment.*	Anticoagulant drugs Antiplatelet drugs Thrombolysis Others	[ ] [ ] [ ] [ ]
(S1 12)	Did the patient receive one or more of the following medications **at discharge from hospital**? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]* *See Section 5, page 21 for further details on medical treatment.*	Anticoagulant drugs Antidiabetic drugs Antiplatelet drugs Cholesterol lowering drugs Tablets for high blood pressure Others	[ ] [ ] [ ] [ ] [ ] [ ]

In-hospital assessment

(S1 13) Which of the following assessments were done during the patients stay in hospital? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*

Refers to assessments during hospitalization irrespective of whether the Patient was treated or not after the first visit.

Seen by occupational therapist	[ ]
Seen by physiotherapist	[ ]
Seen by speech therapist	[ ]
Swallowing assessment	[ ]

Complications during hospitalization

(S1 14) Which of the following complications occurred during the patients stay in hospital? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*

Deep venous thrombosis	[ ]
Other CV complication	[ ]
Pneumonia	[ ]

Discharge from hospital

(S1 15) What was the vital status at discharge? *[select one]*

Patient alive	(1) [ ]
Patient dead	(2)

(S1 16) If patient died in hospital, indicate day of death

This date is required to calculate early survival rates.

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]
d d m m y y y y

(S1 17) If patient alive at discharge, indicate date of discharge

This date is required to calculate survival rates and length of hospital stay.

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]
d d m m y y y y

(S1 18) If patient alive at discharge, what was the discharge destination of the patient? *[select one]*

See Section 5, page 21 for further details

Home	(1) [ ]
Other hospital/ other ward	(2)
Community facility	(3)
Unknown	(9)

(S1 19) If patient alive at discharge, Modified Rankin scale at discharge *[select one]*

See Section 5, page 22 for further details.

No symptoms at all	(0) [ ]
No significant disability despite symptoms	(1)
Slight disability	(2)
Moderate disability, but able to walk without assistance	(3)
Moderate disability, but unable to walk without assistance	(4)
Severe disability	(5)
Unknown	(9)

Follow up at 28 day after stroke onset (Optional)

(F 1)	Was it possible to follow up the patient at day 28? *[select one]* *See Section 5, page 22 for further details*	Yes No, no contact No, patient refused	(1) [ ] (2) (3)
(F 2)	If patient was followed up, indicate date of follow up	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(F 3)	How was the 28d follow up of the patient performed? *[select one]* *See Section 5, page 22 for further details* *Use "does not apply" for patients that died within the first 28 days, refused participation or could not be contacted.*	Medical records only Physical examination Telephone interview Postal follow up Other Does not apply	(1) [ ] (2) (3) (4) (5) (6)
(F 4)	What is the vital status at day 28? *[select one]* *Use "unknown" if no follow-up was performed*	Patient alive Patient dead Unknown	(1) [ ] (2) (9)
(F 5)	If patient dead at day 28 indicate day of death	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(F 6)	If the patient alive at day 28, what is the living situation of the patient at day 28? *[select one]*	Home Community facility Still in hospital	(1) [ ] (2) (3)
(F 7)	If patient alive at day 28, Modified Rankin scale at day 28 *[select one]*	*No symptoms at all* *No significant disability* despite symptoms *Slight disability* *Moderate disability*, but able to walk without assistance *Moderate disability*, but unable to walk without assistance *Severe disability* *Unknown*	(0) [ ] (1) (2) (3) (4) (5) (9)

Step 2: Fatal Events in the Community

For further guidance on Step 2, Fatal Events in the Community; see Section 5, page 5-23

(S2 1) Indicate date of death

[ ][ ] / [ ][ ] / [ ][ ][ ][ ]
d d m m y y y y

(S2 2) How was the patient managed in community from stroke onset until death?
[select one]

In nursing home	(1) [ ]
At home by doctor	(2)
Other medical consultation	(3)
Medically unattended	(4)
Insufficient data	(5)

(S2 3) How was the information about fatal stroke events in the community collected?
[select one]
See Section 5, page 5 or further details these methods

Verbal autopsy	(1) [ ]
Death certificate	(2)
Medical autopsy	(3)

(S2 4) If information was derived from **death certificate** which International Disease Classification (ICD) System was used?
[select one]
See Section 5, page 23 for further details on the ICD system

ICD 8 System	(1) [ ]
ICD 9 System	(2)
ICD 10 System	(3)
No ICD System	(4)

(S2 5) If ICD System was used, indicate ICD code
See Section 5, page 23 for further details on ICD codes

[_____]

(S2 6) If a **medical autopsy** was performed, what subtype of stroke was diagnosed?
[select one]

Ischemic stroke	(1) [ ]
Intracerebral hemorrhage	(2)
Subarachnoid hemorrhage	(3)
Unspecified type	(4)

Step 3: Non-Fatal Events in the Community

For further guidance on Step 3, Non-Fatal Events in the Community; see Section 5, page 5-24

(S3 1) How was the patient managed in community? [ ]
[select one]

- In nursing home (1)
- Medically unattended (2)
- At home by doctor (3)
- Other medical consultation (4)
- Insufficient data (5)

(S3 2) How was the information about the non-fatal stroke event in the community collected? [ ]
[select one]

- Survey of health facilities (1)
- Survey of hemiplegia (2)

(S3 3) What subtype of stroke was diagnosed? [ ]
[select one]
See Section 1, page 6 for further information on stroke subtypes

- Ischemic stroke (1)
- Intracerebral hemorrhage (2)
- Subarachnoid hemorrhage (3)
- Unspecified type (4)

(S3 4) How was the diagnosis of stroke subtype verified? [ ]
[select one]

- Clinical diagnosis alone (1)
- By diagnostic techniques (2)

IDENTIFICATION NUMBER [ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ][ ]

WHO STEPS
STROKE INSTRUMENT
<INSERT COUNTRY/SITE NAME>

All Stroke Events

Patient Identification and Patient Characteristics

(I 1)	Stroke Surveillance site Code	[ ][ ][ ][ ][ ]
(I 2)	Interviewer Code	[ ][ ][ ]
(I 3)	Date of completion of instrument	[ ][ ]/[ ][ ]/[ ][ ][ ][ ] d d m m y y y y

Patient individual records

(I 4)	Patient's family name	[_____]
(I 5)	Patient's first name	[_____]
(I 6)	Contact phone number	[_____]
(I 7)	Contact address	[_____]
		[_____]
(I 8)	Unique identification number where available	[_____]

Contact person of patient

(I 9)	Contact person's family name	[_____]
(I 10)	Contact person's first name	[_____]
(I 11)	Contact person's phone number	[_____]
(I 12)	Contact person's address	[_____]
		[_____]
(I 13)	Relationship of contact person to the patient	[_____]

Demographic characteristics

(I 14)	Date of birth	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(I 15)	Sex *[select one]*	Male Female	(1) [ ] (2)
(I 16)	What is your *[insert relevant ethnic/racial groups defined according to local demographic needs]*	XX XX XX Other	(1) [ ] (2) (3) (4)
(I 17)	If other ethnicity, please state	[_____]	

Socioeconomic status

(I 18)	What is the highest level of education the person has completed? *[select one]*	No formal schooling Less than primary school Primary school completed Secondary school completed High school completed College/ University completed Post graduate degree Unknown	(1) [ ] (2) (3) (4) (5) (6) (7) (9)
(I 19)	Which of the following best describes the <u>main</u> work status of the person over the last 12 months? *[select one]* *[INSERT COUNTRY SPECIFIC CATEGORIES]*	Government employee Non-government employee Self-employee Non-paid Student Homemaker Retired Unemployed Unknown	(1) [ ] (2) (3) (4) (5) (6) (7) (8) (9)

Information on acute stroke event

(I 20)	Date of stroke	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(I 21)	Definite stroke *[select one]*	Yes No Insufficient data	(1) [ ] (2) (3)
(I 22)	If the patient has a definite stroke, has the patient had a previous stroke? *[select one]*	Yes, records seen Yes, records not seen No, records seen No, records not seen Insufficient data	(1) [ ] (2) (3) (4) (5)

Step 1: Events Admitted To Hospital

Hospital admission

(S1 1)	Date of admission to hospital	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(S1 2)	Which department(s)/ unit(s) was the patient treated in? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Intensive care unit Medical unit Neurological unit Neurosurgical unit Rehabilitation unit Stroke unit Other	[ ] [ ] [ ] [ ] [ ] [ ] [ ]
(S1 3)	What was the living situation of the patient pre stroke? *[select one]*	Independent at home Dependent at home Community facility	(1) [ ] (2) (3)
(S1 4)	Modified Rankin scale prior to stroke *[select one]*	*No symptoms at all* *No significant disability* despite symptoms *Slight disability* *Moderate disability*, but able to walk without assistance *Moderate disability*, but unable to walk without assistance *Severe disability* *Unknown*	(0) [ ] (1) (2) (3) (4) (5) (9)
(S1 5)	Which of following neurological signs were present at first medical examination after hospitalization? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Disturbed consciousness Weakness/ paresis Speech disturbances	[ ] [ ] [ ]

Stroke classification

(S1 6)	What subtype of stroke was diagnosed? *[select one]*	Ischemic stroke Intracerebral hemorrhage Subarachnoid hemorrhage Unspecified type	(1) [ ] (2) (3) (4)

Stroke classification contd.

(S1 7)	How was the diagnosis of stroke subtype verified? *[select one]*	Clinical diagnosis alone By diagnostic techniques	(1) [ ] (2)
(S1 8)	Which of the following diagnostic examinations were performed? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Angiography Carotid Ultrasound CT scanning Electrocardiogram Lumbar puncture Medical autopsy MRI scanning Other	[ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]
(S1 9)	If scanning was performed, what was the timing of the first scan after onset of stroke symptoms? *[select one]*	Within 24 hours Between 24 h and 7 days Between 8 to 14 days More than 14 days Does not apply Unknown	(1) [ ] (2) (3) (4) (5) (9)

Vascular risk factors

(S1 10)	Which of the following vascular risk factors were noted for the patient? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Atrial fibrillation Current tobacco use Diabetes mellitus Hypercholesterolemia Hypertension	[ ] [ ] [ ] [ ] [ ]

Medical treatment/ secondary prevention

(S1 11)	Did the patient receive one or more of the following medications **while in hospital**? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Anticoagulant drugs Antiplatelet drugs Thrombolysis Others	[ ] [ ] [ ] [ ]
(S1 12)	Did the patient receive one or more of the following medications **at discharge from hospital**? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Anticoagulant drugs Antidiabetic drugs Antiplatelet drugs Cholesterol lowering drugs Tablets for high blood pressure Others	[ ] [ ] [ ] [ ] [ ] [ ]

In-hospital assessment

(S1 13)	Which of the following assessments were done during the patients stay in hospital? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Seen by occupational therapist	[ ]
		Seen by physiotherapist	[ ]
		Seen by speech therapist	[ ]
		Swallowing assessment	[ ]

Complications during hospitalization

(S1 14)	Which of the following complications occurred during the patients stay in hospital? *[insert **1** for YES, **0** for NO, or **9** for UNKNOWN]*	Deep venous thrombosis	[ ]
		Other CV complication	[ ]
		Pneumonia	[ ]

Discharge from hospital

(S1 15)	What was the vital status at discharge? *[select one]*	Patient alive	(1) [ ]
		Patient dead	(2)
(S1 16)	If patient died in hospital, indicate day of death	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(S1 17)	If patient alive at discharge, indicate date of discharge	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(S1 18)	If patient alive at discharge, what was the discharge destination of the patient? *[select one]*	Home	(1) [ ]
		Other hospital/ other ward	(2)
		Community facility	(3)
		Unknown	(9)
(S1 19)	If patient alive at discharge, Modified Rankin scale at discharge *[select one]*	*No symptoms at all*	(0) [ ]
		No significant disability despite symptoms	(1)
		Slight disability	(2)
		Moderate disability, but able to walk without assistance	(3)
		Moderate disability, but unable to walk without assistance	(4)
		Severe disability	(5)
		Unknown	(9)

Follow up at 28 day after stroke onset (Optional)

(F 1)	Was it possible to follow up the patient at day 28? *[select one]*	Yes No, no contact No, patient refused	(1) [ ] (2) (3)
(F 2)	If patient was followed up, indicate date of follow up	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(F 3)	How was the 28d follow up of the patient performed? *[select one]*	Medical records only Physical examination Telephone interview Postal follow up Other Does not apply	(1) [ ] (2) (3) (4) (5) (6)
(F 4)	What is the vital status at day 28? *[select one]*	Patient alive Patient dead Unknown	(1) [ ] (2) (9)
(F 5)	If patient dead at day 28 indicate day of death	[ ][ ] / [ ][ ] / [ ][ ][ ][ ] d d m m y y y y	
(F 6)	If the patient alive at day 28, what is the living situation of the patient at day 28? *[select one]*	Home Community facility Still in hospital	(1) [ ] (2) (3)
(F 7)	If patient alive at day 28, Modified Rankin scale at day 28 *[select one]*	*No symptoms at all* *No significant disability* despite symptoms *Slight disability* *Moderate disability*, but able to walk without assistance *Moderate disability*, but unable to walk without assistance *Severe disability* *Unknown*	(0) [ ] (1) (2) (3) (4) (5) (9)

Step 2: Fatal Events in the Community

(S2 1)	Indicate date of death	[ ][ ]/[ ][ ]/[ ][ ][ ][ ] d d m m y y y y	
(S2 2)	How was the patient managed in community from stroke onset until death? *[select one]*	In nursing home At home by doctor Other medical consultation Medically unattended Insufficient data	(1) [ ] (2) (3) (4) (5)
(S2 3)	How was the information about fatal stroke events in the community collected? *[select one]*	Verbal autopsy Death certificate Medical autopsy	(1) [ ] (2) (3)
(S2 4)	If information was derived from **death certificate** which International Disease Classification (ICD) System was used? *[select one]*	ICD 8 System ICD 9 System ICD 10 System No ICD System	(1) [ ] (2) (3) (4)
(S2 5)	If ICD System was used, indicate ICD code	[_____]	
(S2 6)	If a **medical autopsy** was performed, what subtype of stroke was diagnosed? *[select one]*	Ischemic stroke Intracerebral hemorrhage Subarachnoid hemorrhage Unspecified type	(1) [ ] (2) (3) (4)

Step 3: Non-Fatal Events in the Community

(S3 1)	How was the patient managed in community? [ ] *[select one]*	In nursing home	(1)
		Medically unattended	(2)
		At home by doctor	(3)
		Other medical consultation	(4)
		Insufficient data	(5)
(S3 2)	How was the information about the non-fatal stroke [ ] event in the community collected? *[select one]*	Survey of health facilities	(1)
		Survey of hemiplegia	(2)
(S3 3)	What subtype of stroke was diagnosed? *[select one]*	Ischemic stroke	(1) [ ]
		Intracerebral hemorrhage	(2)
		Subarachnoid hemorrhage	(3)
		Unspecified type	(4)
(S3 4)	How was the diagnosis of stroke subtype verified? *[select one]*	Clinical diagnosis alone	(1) [ ]
		By diagnostic techniques	(2)

STEPS Stroke
Application for Participation

Email or fax To: **STEPS Stroke ICC** **STEPS@who.int**
+41 22 791 47 67

From:

Proposed Study Site
Identify the region and/ or site for the planned hospital-based register: [_____]

Site Coordinator
Name: [_____]

Contact address: [_____]

[_____]

[_____]

Phone number: [_____]

Fax number: [_____]

Email: [_____]

STEPS coverage and study grade

Steps 1,2,3 - Grade (I) [ ]
Step 1, 2 - Grade (II)
Step 1 - Grade (III)
Grade 1 - Grade (IV)

STEPS Stroke Study Details

1. Number of stroke events per year
Indicate the estimated number of stroke patients per year (min 250) admitted to the hospital register you plan:
[_____]

2. Health Care Services
Does more than one hospital or health facility provide health care services for the study site? Yes [ ] No [ ]

Briefly describe the number and type of hospitals and health care facilities to be included in your register:

_____

3. Site Coordinator

Does the site coordinator have proven experience in cerebrovascular disease? Yes [ ] No [ ]

Please state kind of experience:

_____

4. Data collection

Does the site coordinator have a good knowledge of English? Yes [ ] No [ ]

Does the site coordinator take responsibility for all aspects of data collection? Yes [ ] No [ ]

5. Duration of the study

Is it possible to collect data continuously for at a minimum, 12 months? Yes [ ] No [ ]

6. Ethics and legal issues

Does the site coordinator take responsibility for all ethical and legal issues related to the study (including approval from local ethics committee, insurance for staff members, providing informed consent, data security etc)? Yes [ ] No [ ]

7. Data management

Are computers available for data entry and management? Yes [ ] No [ ]

Do you have a software licence for Microsoft Access? Yes [ ] No [ ]

Which version? [_____]

Can you ensure secured storage of original and electronic data? Yes [ ] No [ ]

8. Source population

Is data on the source population in the study area of your hospital register available (must be obtained for Grade I-III study)? Yes [ ] No [ ]

If yes, please complete the **Source Population form**

9. Financial support

Have you secured financial support to cover all expenses for the study? Yes [ ] No [ ]

Please state the kind of financial support (in kind, Grant etc): _____

_____

Date Signed (Site Coordinator)

SSS Code [ ][ ][ ][ ][ ][ ]

STEPS Stroke
Source Population Form

Email or fax To: **STEPS Stroke ICC** **STEPS@who.int**
Fax +41 22 791 47 67

From:

Study Site
Calendar year for proposed study: [ ][ ][ ][ ]

Source Population

Source of population information from:

Direct Census count (1) [ ]
Intercensal estimate (2)
Population register (3)
Other (explain) (4)

[_____]

Age group (years)	Instrument Coverage	Number of		Total
		Males	Females	
0 - 14	Optional			
15 - 24	Expanded			
25 – 34	Expanded			
35 – 44	Expanded			
45 – 54	Core			
55 – 64	Core			
65 - 74	Core			
75 - 84	Core			
85 – 94	Expanded			
95 or more	Optional			
Total number of inhabitants in the population including all ages and both sexes.				

Comments

Signed

Name: Signature: Date:

STEPS Stroke Surveillance Site
Hospital Information Form

Email or fax To: **STEPS Stroke ICU** **STEPS@who.int**
+41 22 791 47 67

From:

Surveillance Study Details

Site Coordinator: [_____]

Estimated number of stroke events per year: [_____]

STEPS coverage and study grade:

Steps 1,2,3 - Grade (I) [ ]
Step 1, 2 - Grade (II)
Step 1 - Grade (III)
Grade 1 - Grade (IV)

Optional data collected:

Health Facilities in the Surveillance Site

Hospital Name	Type	No. Wards	No. Beds	Brain imaging available?

Case Finding Methods

Source of population information from:	Hot Pursuit	[ ]
	Cold Pursuit	[ ]
	Mixed Pursuit	[ ]
	Medical autopsy	[ ]
	Verbal autopsy	[ ]

Study Duration

Start of study (date of first enrolled patient)	[_____]	
Anticipated duration	at least 12 months	[ ]
	Ongoing	[ ]

Signed

Name: Signature: Date:

STEPS Stroke
Patient Consent

Dear patient

Introduction

This study is being conducted by the World Health Organization in collaboration with the Ministry of Health, the International Stroke Society and the WHO Regional Office. It is being carried out by professionals from (name of institution). The study is currently taking place in several countries around the world.

Confidentiality

The information you provide is totally confidential and will not be disclosed to anyone. It will only be used for research purposes. Your name, address, and other personal information will be removed from all records and only a code will be used to connect your response to the study. You may be contacted by the study team again to complete information for the study.

Voluntary participation

Your participation is voluntary. If you have any questions about this study you may ask me or contact (name of institution and contact details) or (the site coordinator).

Consent to participate

Signing this consent indicates that you understand what will be expected of you and are willing to participate in this study.

Read by Participant		Interviewer	
Agreed		Refused	

Signatures

I hereby provide INFORMED CONSENT to take part in the STEPS Stroke surveillance study.

Name: _____ Sign: _____

Next of kin: _____ Sign: _____

Witness: _____ Sign: _____

Section 8: Glossary and Reference Material

Introduction

This section provides an alphabetical list of all the terms used in a STEPS surveillance with definitions that are appropriate for STEPS and a list of all the source and reference material used to compile this manual.

In this section

This section covers the following topics.

Glossary of Terms used in STEPS Stroke

Term	Definition
Amaurosis fugax	Periodical blindness of an eye due to embolic occlusion of the artery supplying the retina.
Apraxia	The inability to execute a planned motor act in the absence of paralysis of the muscles normally used in the performance of the act.
Ataxia	Co-ordination disturbances.
Bilateral	Includes both sides of the body.
Case-fatality	The proportion of events which are fatal within a given period of time.
Contra-lateral	Refers to the opposite side of the body.
Demography	The composition of the population.
Diplopia	Double vision.
Dysarthria	A defect in the articulation of the speech.
Dysphagia	Impaired ability to swallow.
Dysphasia	Difficulty with comprehension or production of the language despite intact articulation and phonation.
Hemiplegia	Weakness of the arm and leg on one side of the body.
Homonymous hemianopia	Loss of vision in one half of the visual field. Lesions of the optic nerve behind the chiasm produce contra-lateral visual field deficits.
Incidence	A rate of how many events that occurs per person years.
Intracerebral hemorrhage	Bleeding from intracerebral arteries and may cause stroke symptoms.
Ischemic stroke	Stroke symptoms known to originate from an occlusion of cerebral arteries.
Modified Rankin Scale	A scale that indicates the level of handicap in a person.
Morbidity	A rate of how many people get sick per person years.
Mortality	A rate of how many people die per person years.
Stroke	A clinical diagnosis based on recognisable clinical symptoms indicating a vascular cause of sudden onset of neurological deficits. For definition please see page 1-4.
Subarachnoid hemorrhage	A bleeding from intra cranial arteries leading to blood between two membranes that surround the brain.
Surveillance	Ongoing, continuous collection of epidemiologic data in a population.
Transient Ischemic Attack (TIA)	Sudden neurologic deficits that lasts less than 24 hours, and with full recovery.
Unilateral	Restricted to one side of the body.
Vertigo	A false sense of rotary movement of self or surrounding objects. May be associated with nausea and vomiting.

Source Publications and References

Introduction

This section provides an alphabetical list of :

- References used in this publication
- Resources available from the STEPS team

References and sources used

This section provides an alphabetical list of references and sources used.

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