

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.
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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.

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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 estimated that in 2005, stroke 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

Other expected outcomes

Other expected outcomes of setting up surveillance sites include:

- Building expertise and high quality systems for long-term community surveillance of chronic noncommunicable diseases, especially stroke
- Establish a research network
- Increase awareness of noncommunicable disease in the community.
- Establish country-specific priorities for the prevention and management of stroke in the context of national integrated plans for chronic disease prevention and control (see http://www.who.int/chp/chronic_disease_report)

Surveillance: key to prevention

Above all, clinical trials and epidemiological studies have shown that stroke to a large extent is preventable. Public actions to lower the prevalence of exposure to risk factors, however, are unlikely to be taken, if the magnitude and consequences of stroke and other major chronic diseases 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.	<ul style="list-style-type: none"> • 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 use.
Secondary	Impact of stroke in people who already suffer from a stroke or TIA.	<ul style="list-style-type: none"> • Intensified reduction in exposure to major cardiovascular risk factors • Anti platelets and antihypertensive treatment.
Tertiary	Consequences and damages in stroke patients.	<ul style="list-style-type: none"> • Treatment of infections in the acute stage • Management of co-morbidities • 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.

A costly disease Stroke is a costly disease because of the:

- Large numbers of premature deaths,
 - Ongoing disability in many survivors,
 - Impact on families or caregivers and
 - Impact on health services.
-

Standard WHO definition The recommended standard WHO stroke definition is as follows:

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.

This clinical definition has four components:

- A neurological impairment or deficit of
 - Sudden onset, and
 - Lasting more than 24 hours (or leading to death), and
 - Of presumed vascular origin.
-

Notes on the standard definition The WHO standard 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 encephalopathy.

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: <ul style="list-style-type: none"> • 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). 	<ul style="list-style-type: none"> • Neuro imaging recordings <p>Note: it may not be possible to decide clinically or radiological whether it is a thrombotic or embolic ischemic stroke.</p>
Intracerebral haemorrhage	Bleeding from one of the brain's arteries into the brain tissue. <p>Note: May be more prevalent in developing countries possibly due to diet, physical activity, insufficient treatment of raised blood pressure, and genetic predisposition.</p>	<ul style="list-style-type: none"> • Neuro imaging recordings
Subarachnoid haemorrhage	Arterial bleeding in the space between the two meninges, pia mater and arachnoidea. <p>Note: Typical symptoms are sudden onset of very severe headache and usually impaired consciousness.</p>	<ul style="list-style-type: none"> • 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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About Stroke, Continued

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 ($>2\,000$ red 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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About Stroke, Continued

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	First ever (also called "first in a lifetime") refers to people who have never had a stroke before. Note: Previous TIA is not considered a stroke as symptoms last less than 24 hours.
Recurrent	There are two types of recurrent strokes: <ul style="list-style-type: none">• A history of a previous stroke event at some time in the past which meets the WHO definition, and• A history of a new stroke event occurring more than 28 days after onset of a stroke event already registered.
Non-fatal	A stroke case who survived at least 28 days after the onset of the stroke symptoms.
Fatal	Died within 28 days of stroke symptom onset.

First ever stroke events A first ever stroke event is the same as first in a lifetime event. (see Key definitions and epidemiological concepts Section 1-12)

Recurrent stroke events For a new episode of symptoms to be counted as a new or recurrent 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.

Equally, if a patient experiences further acute symptoms suggestive of stroke after 28 days of the onset of a first episode, this second episode **is** counted as a new stroke event.

Note: Each **event** is registered separately. This means that 2 (or more) forms will be completed for the same individual who experiences multiple new acute stroke events that meet the criteria.

Major Risk Factors

Introduction

Stroke is a multi factorial disease where a combination of risk factors, all of 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	<ul style="list-style-type: none">• Elevated blood pressure• Tobacco use• Physical inactivity• Diet (low fruit and vegetable consumption)• Heavy alcohol consumption• Overweight• Diabetes
Environmental	<ul style="list-style-type: none">• Passive smoking• Access to medical treatment.
Non-modifiable	<ul style="list-style-type: none">• 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.

Key sources on information on country level risk factors

WHO has developed two major tools for collecting, displaying and analysing data on the major 8 major risk factors which are common to CVD.

- The STEP wise framework for surveillance of Risk Factors for chronic diseases; see website: <http://www.who.int/chp/steps>
- The Global NCD InfoBase provides biennial updates on available country-level risk factor data including comparable mortality estimates for stroke.

See website: http://www.who.int/ncd_surveillance/infobase

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 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 identifies three different groups of stroke patients who make up the burden of stroke in any given community or population. They are listed in the order of complexity of identifying them:

- Information on stroke patients admitted to health facilities (Step 1);
- Identification of fatal stroke events in the same community (Step 2);
- Estimates of non-fatal stroke events in the same community (Step 3).

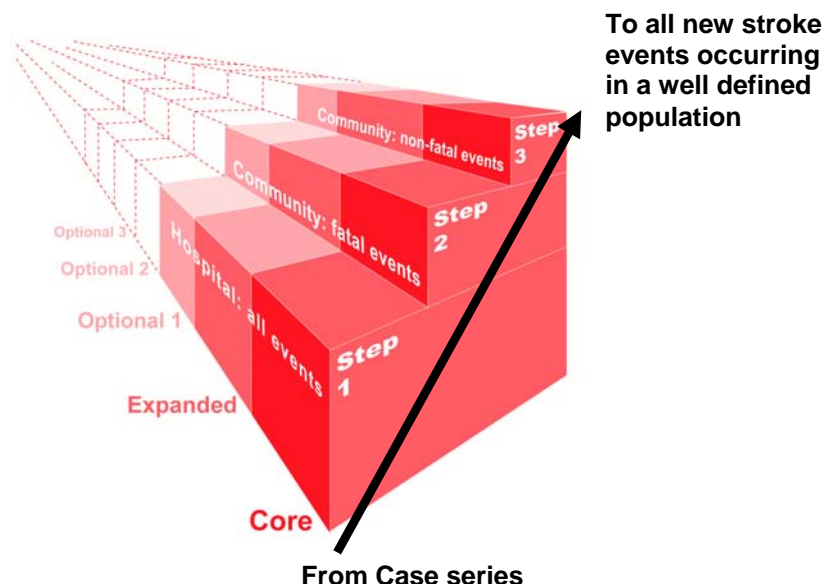
Within each Step (1, 2 and 3) there are a further two possible levels of information that can be collected (Core, and Expanded).

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: An "ideal" stroke incidence study requires that all eligible stroke occurring are identified in residents of the defined source population,

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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 standardized questionnaire used to collect stroke patient data to be entered into the register using the data entry tool.

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

Step		Core	Expanded	<i>Provides data on</i>
1	Hospitalized events (fatal and non-fatal)	<ul style="list-style-type: none"> • Demographic information • Time of onset • Vital status day 10 	<ul style="list-style-type: none"> • Treatment • Disability • Type of stroke 	<i>Stroke admissions and hospital case fatality</i>
2	Fatal events in the community	<ul style="list-style-type: none"> • Demographic information • Death certificates, or • Verbal autopsy 	<ul style="list-style-type: none"> • Autopsy/necropsy reports • Type of stroke 	<i>Stroke deaths</i>
3	Non-fatal events in the community	<ul style="list-style-type: none"> • Demographic information • Time of onset • Vital status day 10 	<ul style="list-style-type: none"> • Treatment • Disability • Type of stroke 	<i>Stroke incidence and case fatality</i>

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 identifying subgroups of patients at each step. The level of complexity will therefore depend on development of health services and resources, and each participating country may collect the amount of data that it finds is feasible. Not all sites will be able to undertake an "ideal" incidence study.

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Some Key Definitions And Epidemiological Concepts

Prevalence and Incidence Prevalence and incidence are fundamentally different ways of measuring the occurrence of a disease although both involve the counting of cases in defined populations at risk.

- The prevalence of stroke is the number of cases in a defined population at a specified point in time - gives a "snapshot" of survivors at any one time
- The incidence is the number of new cases of stroke arising in a given period in a defined population - gives an indication of the risk of stroke.

Date on both prevalence and incidence become much more useful if converted into rates. A rate is calculated by dividing the number of cases by the corresponding number of people in the defined population at risk.

Calculating the Incidence rate Incidence rate (*I*) is calculated as follows:

$$I = \frac{\text{Number of people who get a stroke in a specified time}}{\text{Number of people in the population at risk over the length of time during which each person in the population is at risk}} \times (10)^5$$

Case series A case series refers to stroke cases identified in specified hospital facilities (numerator) but without reference to a defined population from which they came (denominator). Without a denominator, rates can not be calculated. Even so case series present important clinical information about stroke, perhaps for the first time. Case series are often the beginning of the process which helps establish more robust measures subsequently.

Surveillance: ongoing 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 to 10 yearly intervals.

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

Setting Objectives

Long term monitoring of stroke

Establishing a surveillance system for long term monitoring of stroke can help to:

- Understand the clinical profile of stroke patients
 - Develop complete, population-based systems of case ascertainment for stroke
 - Verify the accuracy of routine data systems for monitoring stroke
 - Develop local expertise in epidemiological research methods through education and training.
-

Size and impact of the problem

Undertaking stroke surveillance also helps to determine the size of the problem and help to determine the following:

- Incidence, case fatality and outcome of stroke
 - Impact on health care systems of stroke
 - Use of acute hospital beds, rehabilitation facilities, and requirements for community care including impact on families of stroke
 - Use of effective interventions in the acute phase (stroke unit, use of drugs etc).
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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 a 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.

