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 role of the Site coordinator and associated advisory group.

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.

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Process Overview and Eligibility

Introduction

Before registering an interest in applying for participation in STEPS Stroke (see section 7b), 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>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
</table>
| 1     | Define the type and scope of the study (Step 1, 2, 3). The three options are as follows:  
- a hospital register case series (Step 1 with no population base)  
- a hospital register linked to a defined population base (Step1)  
- an incidence study linked to a defined population base (Steps 1-3)  |
| 2     | Identify the study site. |
| 3     | Identify the defined study population from which the cases will be derived (see Section 1-12)  
| **If the source population is** | **Then..** |
| Available | Apply for full participation |
| Not available | Apply for limited participation (case series only) |
| 4     | Prepare the instrument. |
| 5     | Obtain sustainable funding. |
| 6     | Apply for participation. |
| 7     | Get ethical approval. |

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 design
The table below provides an overview of the different designs 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 may be the only option in those countries where there are no census data for the catchment area covered by the selected hospitals. (see Section p1-12, 1-13).

<table>
<thead>
<tr>
<th>Step 1: Main outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>The main outcomes from this Step include:</td>
</tr>
<tr>
<td>• Health facility resources allocated to stroke patients</td>
</tr>
<tr>
<td>• Functional status of stroke patients at discharge.</td>
</tr>
<tr>
<td>• Risk factor exposure.</td>
</tr>
<tr>
<td>• Hospital admission rates when combined with population estimates from which the stroke patients are derived.</td>
</tr>
<tr>
<td><strong>Note:</strong> Step 1 alone does not provide estimates of stroke incidence in the population because some patients die before hospital admission can be arranged and others are cared for in the community rather than in hospital.</td>
</tr>
</tbody>
</table>

**Continued on next page**
### Step 2: Data collection
Step 2 builds on the hospital register in Step 1 by validating death certificates from routine sources to include fatal stroke events that have occurred in the same community but out of hospital. These data are derived from death certificates need to be validated by verbal autopsy (see section 5-5, 5-6).

### Step 2: outcomes
The main outcome from Step 2 (combined with the data from 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 occurring outside of health facilities
- Years of life lost because of stroke (YLLs).

### Step 3: Data collection
The surveillance of stroke is complicated by the fact that a high number of cases are not admitted to hospital. Step 3 is therefore the most challenging subset of eligible patients to identify. Their identification is vital for the accurate determination of stroke incidence. These strokes are a combination of milder and more severe strokes than those that come to hospital, and consequently their inclusion influences case fatality.

### 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. It also allows estimates of:

- 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 - preferably with a well defined source population from which eligible patients are derived.

Some countries will be able to achieve a population based register (involving all 3 steps). This provides the most valuable epidemiological measures for public health initiatives for stroke prevention. It is therefore recommended that there is an intention to advance the study to include all three Steps or subgroups of patients, if resources allow and access to central death certificates is available.

### 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 type of register being planned: case series or one which produces hospital rates.

### Step 1: hospital based register
When developing a hospital based register is to be linked to a population, all health facilities, or network of health facilities, that are found within the defined population need to be identified and involved in the study. These could include:

- All health facilities in the (source population) area
- A small group of health facilities that admit most stroke events
- Wards within defined health facilities that admit most stroke events.

**Note:** To define the health facilities, complete the hospital information form in section 7d. Once defined, the (group of) selected health care facilities, together with the source population, will be referred to as the **STEPS stroke surveillance site (SSS)**.

### Step 2: strokes dying outside hospital
Key case finding sources include access to routine death certificates and an ability to verify all deaths possibly due to a stroke event (including "old age") by use of verification using verbal autopsy techniques.

### Step 3 events cared for only in the community
Key case finding sources for stroke cases cared for entirely at home, involves the collaboration and cooperation of, among others, to ensure ongoing support and referral of eligible cases to the study and may involve the following:

- General practitioners and other health care providers in the community who need to notify the study team of all such events
- Community health nurses and village elders/church leaders or
- Alternative medicine practitioners, faith healers etc

### Defining the population
Once you have defined the source population or community (preferably from the most recent census) from which the stroke cases will be identified, send the ICU a copy with the application (see section 7d).

### Patient eligibility
A patient is eligible for inclusion in the stroke study, if:

- A resident in the defined population of the stroke surveillance site,
- Meets the age selected (see Section page 3-8)
- Has a stroke event within the defined period of time

*Continued on next page*
<table>
<thead>
<tr>
<th>Estimation of expected stroke events</th>
<th>To be eligible to participate, a minimum of 250 stroke patients per year in the source population from which the cases will be derived, (i.e. hospital and / or community) is necessary in order to</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Ensure meaningful analysis of the data by age and sex</td>
<td></td>
</tr>
<tr>
<td>• Have sufficient numbers to detect trends over time.</td>
<td></td>
</tr>
<tr>
<td>These can be based on previous experience or the results of a pilot study.</td>
<td></td>
</tr>
</tbody>
</table>

| Data collection timeframe | As a minimum, stroke event registration should be undertaken continuously over a period of 12 months in the defined surveillance site because it has been shown that stroke occurrence varies at different times of the year (see Section 1-12). |
Identifying the Study Population

Introduction

Calculation of epidemiologic rates is based on the number of stroke events occurring in the defined population at risk. The ideal population comes from a well defined geographic area.

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. This is particularly important if an incidence study is being planned (all 3 steps used in case finding).

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 data for a well defined geographic population does not exist, you will only be able to produce a case series stroke register.

Interpretation of this data over time poses major challenges because of changing hospital practices and because of lack of information about the nature of the population from which the cases come.

Balancing population coverage and number of stroke cases

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 defined study population at the time of application.

To provide a reliable estimate of the impact of stroke occurrence, representative regional population coverage (from around 250,000 total population up to 1 million) is recommended.

Including more than 1 million people 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 Study Population, Continued

Factors to consider

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

<table>
<thead>
<tr>
<th>Coverage</th>
<th>Guidelines</th>
</tr>
</thead>
<tbody>
<tr>
<td>Districts</td>
<td>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.</td>
</tr>
<tr>
<td>Hospitals</td>
<td>Include both private and public (state run).</td>
</tr>
<tr>
<td>Gender</td>
<td>Include both men and women.</td>
</tr>
<tr>
<td>Socio economic status</td>
<td>Allow a representative range of socio economic groups.</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>STEPS levels</th>
<th>Age range (years)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Core</td>
<td>45-84</td>
</tr>
<tr>
<td>Expanded</td>
<td>15 - 44</td>
</tr>
<tr>
<td></td>
<td>85 +</td>
</tr>
</tbody>
</table>

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, although the differences are not as marked as for other chronic diseases (such as heart disease). Men and women should be presented separately in all analyses.

Describing the study population

For a stroke surveillance site intending to undertake complete coverage of possible stroke events occurring in residents in the defined population, details are requested as part of the process of applying for participation in STEPS Stroke Surveillance (see section 3-12). This form is available in section 7b.
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 standardization, 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.

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

Note: Expansion beyond the basic Core and Expanded questions is suggested only in settings where resources are available and local needs require expansion.

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 (unshaded) 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 (shaded) questions.
- Code added questions or measures coded with the letter 'X' so they stand out.
- Finally, remove from the Instrument any Expanded sections and Steps (i.e. 2 and or 3) that are not being covered by your site.
- Send your final draft to the ICC for review before starting the study.
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 register an interest by applying to the ICC for participation in a WHO STEPS Stroke surveillance study (steps@who.int).

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
- Details of planned overlapping case finding methods which will be used
- Defined study population
- Required resources
- Financial support
- Data management environment.
- Contact details.

Application for participation template
A stroke Application for Participation form 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:

<table>
<thead>
<tr>
<th>Acceptance stage</th>
<th>Received from ICC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Provisional</td>
<td>• Stroke surveillance site code&lt;br&gt;• Interviewer codes&lt;br&gt;• Hard copy of the Stroke Manual</td>
</tr>
<tr>
<td>Full</td>
<td>• Password to logon to the STEPS stroke web site and download the data entry tool</td>
</tr>
</tbody>
</table>
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.

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

**Note:** The STEPS stroke coordinating 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.

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### 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.

### Approaching participants

Important issues to raise in obtaining consent for potential participants or their family members include the following:

- Introducing the institution carrying out the study
- Stressing confidentiality
- Indicating voluntary nature
- Reaching agreement on consent to participate.

### Consent letter

A model of a consent letter for patients to give verbal and/or written consent before taking part in the study is given below. See also section 5, data collection guidelines.
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: