
PM Dalal*, Madhumita Bhattacharjee**, Jaee Vairale***, Priya Bhat****

Abstract

Background: India will face enormous socioeconomic burden because life expectancy is increasing placing larger numbers of older people at risk of stroke and other chronic diseases. In order to plan prevention strategies, reliable information on stroke epidemiology is required. For uniform data collection (population based), WHO recommends use of STEPS Stroke instrument.

Study: A well-defined community (H-ward) with verifiable census data, and representative of population structure of Mumbai (Bombay), was selected. The manual on WHO STEPwise approach to stroke surveillance (STEPS; http://www.who.int/chp/steps/Manual.pdf) was the operational protocol.

Results: During the two year study period (Jan 2005 to Dec 2006), 521 new stroke (CVD) cases (males- 275 and females- 246) were identified; of which 456 (238 males and 218 females) had “first ever stroke” (FES) indicating an annual incidence of 145 per 100,000 persons (CI 95%: 120-170); age adjusted Segi rate:152 /100,000/year (CI 95% 132-172). Two thirds of the FES cases were admitted to health care facilities (Step I: “in-hospital” cases), the remaining 150 (32.8%) either died outside of hospital or were treated at home or nursing homes (Step II: Fatal events in community and Step III: Non-fatal events in community). CVD Diagnosis was supported by CT (Computed Tomography) in 407 (89%) of 456 FES cases: 366 (80.2%) had Ischaemic CVD, 81 (17.7%) had hemorrhagic CVD and 9(1%) were of unspecified category. The mean age was 66 yrs SD±13.60 and women were older compared with men (mean age 68.9rs SD ± 13.12 versus 63.4yrs SD ± 13.53). Hypertension (BP more than140/90 mm Hg) alone or in various combinations was present in 378 (82.8%) cases. Case fatality at 28 days after the FES stroke was 29.8%. Of 320 surviving patients 38.5% had moderate to severe disability.

Conclusions: WHO STEPs stroke surveillance Instrument is simple to use and, practical for community surveys. The data are useful for planning stroke prevention campaigns on public awareness and education with regard to diet, exercise, blood pressure control and early symptoms of minor strokes. ©

INTRODUCTION

As life expectancy increases, India will face enormous socioeconomic burden to meet the costs of management of chronic diseases such as stroke. For planning prevention strategies, reliable information on pattern of disease, exposure to major risk factors and morbidity/mortality trends for cerebrovascular disease (stroke) in defined populations are necessary. In the literature, there are several reports on stroke epidemiology from developed countries using uniform methodology, but there is scant information on population based data from developing countries. There is also great need to monitor these trends using uniform protocols in simple and reproducible way for regional comparisons. For this purpose, WHO proposes the use of STEPS Stroke instrument. We describe observations made during population based stroke surveillance using this instrument over a two year period in an urban area of Mumbai (H-ward), India.

MATERIAL AND METHODS

WHO defines Stroke as “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.” The manual on WHO STEPwise approach to surveillance (STEPS; http://www.who.int/chp/steps/stroke) was the operational protocol. The manual is comprehensive and describes terminologies and methodologies on case assessment data collection and management for Step 1 (In...
In brief, Step 1 (in-hospital) questionnaire contains patient's demographic data (i.e. name, age, sex, ethnicity, occupation, contact details), information on acute stroke event and hospitalization, degree of neurological deficit (National Institute of Health Stroke Scale—NIHSS), stroke sub-type by diagnostic tests and information on current risk factors, data on medical treatment, discharge status and follow-up at 28 days by Modified Rankin scale. In Step 2 (fatal events in community), apart from above information specific details on date of death and information on fatal event by verification of death certificates or medical autopsy or verbal autopsy are listed. In Step 3 (non-fatal events in community), all information as described in Step 1 are collected by interviewing patients at home or nursing home, and current neurological status by Modified Rankin scale is assessed. NIHSS, Modified Rankin scale are described in Appendix.

The duration of study, was twenty four months (January 2005–December 2006). The selected survey population was a well-defined community (H-ward) which has reliable census data (2004) and is representative of the population structure (by sex and mid-decade age bands) of Mumbai (Bombay). In view of state and local elections, the electoral roll on permanent residents is well maintained and periodically updated. The roster lists full name of the family members by, sex, age in years and precise residential location. Use of multiple overlapping source of information confirmed the validity of entries.

As per the WHO STEPS protocol, out of total 337,391 permanent residents, 156,861 (46%) were 25 years or older and were eligible if they met the inclusion criteria for stroke. Census information provides information on location by street, building, and colony. Information leaflets on stroke awareness and the purpose of the study were circulated to local residents. In a special meeting of local medical practitioners, the WHO protocol was introduced and discussed. General practitioners, major hospitals, nursing homes, Computerized Tomography (CT) diagnostic centres, and municipal health authorities participated or

### Appendix: National Institute of Health Stroke Scale (NIHSS)

<table>
<thead>
<tr>
<th>No.</th>
<th>Category</th>
<th>Response / Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>1A</td>
<td>Consciousness</td>
<td>Alert -0 / Arousable -1 / Obtunded -2 / Unresponsive -3</td>
</tr>
<tr>
<td>1B</td>
<td>Answers to questions</td>
<td>One – 1 / Neither – 2</td>
</tr>
<tr>
<td>1C</td>
<td>Commands</td>
<td>Both correctly – 0 / One correctly – 1 / Neither – 2</td>
</tr>
<tr>
<td>2</td>
<td>Gaze</td>
<td>Normal -0 / Partial palsy -1 / Total palsy -2</td>
</tr>
<tr>
<td>3</td>
<td>Visual fields</td>
<td>No loss -0 / Partial hemianopsia -1 / Complete -2 / Bilateral -3</td>
</tr>
<tr>
<td>4</td>
<td>Facial palsy</td>
<td>None – 0 / Minor – 1 / Partial – 2 / Complete -3</td>
</tr>
<tr>
<td>5</td>
<td>Motor arm</td>
<td>No drift -0 / Drift &lt;10 sec -1 / Falls&lt;10 sec -2 / a. left, b. right No effort against gravity – 3 / No movement -4</td>
</tr>
<tr>
<td>6</td>
<td>Motor leg</td>
<td>No drift -0 / Drift &lt;10 sec -1 / Falls&lt;10 sec -2 / a. left, b. right No effort against gravity – 3 / No movement -4</td>
</tr>
<tr>
<td>7</td>
<td>Ataxia</td>
<td>None – 0 / One limb – 1 / Two limbs -2</td>
</tr>
<tr>
<td>8</td>
<td>Sensory</td>
<td>Normal -0 / Mild loss -1 / Severe loss -2</td>
</tr>
<tr>
<td>9</td>
<td>Language</td>
<td>Normal -0 / Mild – 1 / Severe -2 / Mute or global aphasia -3</td>
</tr>
<tr>
<td>10</td>
<td>Dysarthria</td>
<td>None – 0 / Mild – 1 / Severe -2</td>
</tr>
<tr>
<td>11</td>
<td>Extinction</td>
<td>None – 0 / Mild – 1 / Severe -2</td>
</tr>
</tbody>
</table>

**Total NIHSS Score:** (00-42)

**Legend:** NIHSS is a scoring technique defines degree of neurological deficit ranging from none (0), mild (1) or severe (2 to 4) for eleven categories of neurologic functions. For practical purpose score of 0 to 5 indicates mild deficit, 6 to 15 denotes moderate deficit and score of more than 15 is suggestive of severe neurologic deficit.

(Source: Goldstein LB, Samsa GP. Reliability of the National Institutes of Health Stroke Scale. Extension to non-neurologists in the context of a clinical trial. Stroke 1997;28:307-10)

### Modified Rankin scale

<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>No symptoms at all</td>
<td>0</td>
</tr>
<tr>
<td>No significant disability despite symptoms</td>
<td>1</td>
</tr>
<tr>
<td>Slight disability</td>
<td>2</td>
</tr>
<tr>
<td>Moderate disability, but able to walk without assistance</td>
<td>3</td>
</tr>
<tr>
<td>Moderate disability, but unable to walk without assistance</td>
<td>4</td>
</tr>
<tr>
<td>Severe disability</td>
<td>5</td>
</tr>
</tbody>
</table>

**Legend:** Modified Rankin Scale measures independence rather than performance of specific tasks. Scale consists of six grades from 0 to 5; 0 denotes no symptoms and 5 indicates severe disability. For clinical purpose, mild disability range is from 0 to 2; moderate disability ranges from 3 to 4 and 5 indicates severe disability.

cooperated in the study. The clinical syndrome of limb weakness accompanied by speech or visual disturbance and/or imbalance posed no major difficulty in identification of CVD case by the patient or caregiver.

The medical research officers received intensive training on definitions/terminologies in respect to questionnaire and responses, including independent assessment of neurological deficit at onset and disability status at 28 days by Modified Rankin scale (MRS). They identified “first ever stroke” (FES) as defined in the WHO manual. Where information was not possible to obtain the item was coded as “incomplete data”. Stroke diagnosis was cross-checked by medical practitioner/consultant and was supported in the majority of cases by diagnostic tests (e.g. CT scan). All suspected stroke cases were traced by “hot pursuit” (prospective case registration) or “cold pursuit” (retrospective case registration) or a combination of both. The stroke team made periodic (daily/weekly) visits to health care facilities to ascertain completeness of case assessment and to minimize “under-reporting” of events especially those cared for out of H Ward hospitals.

Ethics Committee recommended that names of the subjects in the study and their contacts were not divulged without permission. After completing the defined responses to questionnaire by itemized codes, the data on each new stroke case were transferred to a Central registry.

Statistics

Statistical analysis was carried out using “True Epistat (version:5.3)” on following variables: age, sex, previous stroke, stroke sub type, delay from onset to admission, NIH score on admission, timing of CT scanning, vital status at day 28 (alive/dead status), MRS score at day 28 and associated risk factors. Gender differences on above variables were also assessed by chi-square test and log likelihood ratio test. To calculate age standardized incidence rates by direct method with Segi 1996 world population,9 True Epistat package (version 5.3, Epistat services, USA) was used and this enabled us to compare similar age standardized incidence rates as reported for different studies.

RESULTS

During the study period 521 cases with new stroke events were identified: 456 patients had “first ever stroke” (males- 238 and females- 218) and 65 had a history of previous stroke. The overall crude annual incidence rate for “first ever stroke” (FES) is 145 per 100,000 persons, (CI 95%: 120-170); this rate for men and women is 149 and 141.5 per 100,000 persons respectively. Age standardized rate of total FES by direct method with Segi 1996 world population is: 152/100,000 persons/year (CI 95% 132-172); similar age standardized rates for men is 162/100,000 persons /year (95% CI: 133-192) and for women is 141 /100,000 persons /year (95% CI- 114-167).

The overall mean age was 66 yrs, SD± 13.60; women were older (68.9 yrs) as compared to men (63.4 yrs). Table 1 and Fig. 2 show percentage distribution of population by age and sex and incidence of “first ever stroke” cases per 100,000 per year.

Two-thirds (67.2%) of FES cases were seen at health care (“in-hospital”) facilities (Step I) and the remaining 150(32.8%) of 456 FES were treated at home or nursing homes (Step II and Step III). Clinical diagnosis on new stroke event (FES) was supported by CT (Computed Tomography) data in 407(89.2%) of 456 cases. Diagnostic tests indicated that, 366(80.2%) had ischaemic stroke, 81(17.7%) had hemorrhagic stroke and 9(1.9%) were of unspecified type. There was no significant gender difference with regard to neurological deficit on admission, timing of first scan, stroke subtype, alive or dead status at day 28. For risk factor analysis reliable data for hypertension (by history, by value-BP more than 140/90 mm Hg, supported by anti-hypertensive drug therapy or physician’s prescription) was available in 378 (82.8%) cases; however, verifiable data for other risk factors like diabetes mellitus, ischaemic heart disease, tobacco use, lipid levels were not available for analysis in every case.

Disability status (by MRS) and Case fatality rate: At day 28, 

<table>
<thead>
<tr>
<th>Age Groups</th>
<th>25-34</th>
<th>35-44</th>
<th>45-54</th>
<th>55-64</th>
<th>65-74</th>
<th>75-84</th>
<th>85-94+</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Population</td>
<td>47,298</td>
<td>38,245</td>
<td>29,806</td>
<td>20,232</td>
<td>14,401</td>
<td>5,593</td>
<td>1,286</td>
<td>1,56,861</td>
</tr>
<tr>
<td>FES cases</td>
<td>6</td>
<td>26</td>
<td>55</td>
<td>96</td>
<td>140</td>
<td>92</td>
<td>41</td>
<td>456</td>
</tr>
<tr>
<td>Cases/100,000/yr</td>
<td>6.3</td>
<td>33.9</td>
<td>92.2</td>
<td>237.2</td>
<td>486</td>
<td>822.4</td>
<td>1594</td>
<td>145</td>
</tr>
</tbody>
</table>
| 95% CI | 2-13 | 23-47 | 72-110 | 210-270 | 440-530 | 770-880 | 1520-1670 | 152 / 100,000 persons/year (95% Cl: 132-172). for males it is 162/ 100,000
320 (70%) of 456 FES cases were alive and here 176 (38.5%) had moderate to severe disability pointing to burden of stroke; whereas 29.3% (134 cases) had minimal disability; and in 2.1% (10 cases) information was missing. By 28 days, 136 (29.8%) of 456 FES died. Here, 82 (17.9%) were stroke related deaths, and 54 (11.8%) deaths appeared related to co-morbid conditions (e.g., cardiopulmonary illness etc.).

Recurrent Strokes: During the two year study period, a total of 521 new stroke events were registered, of which 456 were “first ever strokes” and 65 had had a previous stroke which brought them into the study. Among the recurrent strokes there was no significant gender difference with regard to age groups, stroke subtypes (57 had ICVD, 7 had ICH and 1 was unspecified category), or alive/dead status at 28 days (55 alive and 10 dead). For the purposes of this paper, these patients have been excluded from the analyses.

**Discussion**

To plan effective intervention and stroke preventive strategies, one must know the annual incidence rates; its clinical profile based on supportive diagnostic tests, as well as mortality and morbidity trends. Only epidemiological surveys in defined communities can determine the overall burden on health services, communities and family members. The purpose of WHO STEPS Stroke surveillance (6 modules in 3 steps) is to (i) assess the magnitude of stroke, (ii) describe population at risk, (iii) identify associated risk factors, (iv) monitor trends over time, (v) implement intervention strategies and (vi) evaluate the outcome of intervention. WHO STEPS encourages the collection of standardised core data; options are available for more extended data collection to suit local circumstances or needs. The three “steps” represent different, but overlapping case finding sources with each step representing increasing difficulty in achieving comprehensive coverage.

**Step-1: Hospitalized cases:** The main aim of Step 1 is to collect core data (demography, information on acute event, evaluation and management, identifying stroke subtype, associated risk factors and outcome status by Modified Rankin scale on admission and at 28 days or at discharge) on patients who come to health care facilities enumerated within the defined population. We found the WHO Stroke Surveillance protocol using STEPS questionnaire (Version 2) is simple and practical to administer. Earlier, (2003-2004) we had tested STEPS questionnaire (Version 1.1) in hospitalized cases and had practical experience in administering the basic protocol. Data collection posed no major difficulty; but complete information in some cases was not possible due to short stay or discharge against medical advice or unwillingness for costly tests (e.g., CT scan). The information once coded was easily transferred by “Data Entry Tool” (DET) to a central registry. Stroke awareness leaflets, media reports, meeting with community doctors, to explain stroke as “burden of disease” and guide on comprehensive care played a significant role in successful implementation. It was also shown to be useful to take everyone (patients and family, referring physicians, community and resident doctors, nursing and paramedical staff, administrative and municipal health authorities) in confidence at periodic intervals.

**Step-2: Fatal events in community** In Mumbai, it is mandatory to have “medical certification of cause of death” before disposal of a dead body. This certificate (FORM NO. 4 and 4A) is attested by a registered medical practitioner. It contains information on “Name of deceased” age, sex, residential location, cause of death – immediate cause as well as antecedent and the manner of death (natural, accidental or otherwise). Regular perusal of death registry records for residents of the H Ward, together with follow up and verification of the diagnosis, suggested that these data were by and large properly recorded. For cross-verification of medical illness, attempts were made for a “verbal autopsy” but this was not always successful. The reasons for non-cooperation included the following: (a) family bereavement; (b) resistance to part with copies of documents which sometimes had been filed for insurance / medical claims; and (c) privacy related to illness. The natural calamity (monsoon deluge and post-monsoon havoc) with loss of life and property was also a contributing factor. It is also possible that “sudden deaths” due to stroke may not be correctly classified. However, review of death certificates with the certifying doctor together with “verbal autopsy” proved helpful in reclassifying 36 cases of “encephalopathy” as recent strokes.

**Step-3: Non-fatal events in the community.** The most difficult cases to identify are those occurring in the community and potentially represent “missed cases” will result in under-reporting of incidence rates. For example, subjects with uncontrolled hypertension and/or diabetes mellitus often attribute their neurological deficit to underlying co-morbid condition. Denial of minor stroke like symptoms by patients or not reporting to family physician or health care facility is another possibility. Furthermore these subjects with early neurological deficit may be taking local herbal or non-allopathic treatment and might not seek or attend allopathic health care facility. In addition, patients having prolonged TIA where deficit lasts around 24 hours may be misclassified can also result in “under reporting”.

The current trend to advocate thrombolytic therapy within 6 hours of an acute event could result in more rapid reference of “minor stroke” cases (NIH score 5 or less) for diagnostic tests. Unless the subject is hospitalized, medical insurance does not reimburse the cost of CT scanning. This situation may result in hospitalization of acute stroke cases with mild deficit who would have been otherwise treated at home. We believe that our contact with practicing physician’s and community leaders helped us to identify all eligible acute stroke events that occurred in the community of H Ward. Unless there is intensive tracking (mixed pursuit) of community on weekly basis, by health visitors, there is possibility of “under-reporting” of events and thereby...
resulting in lower incidence rates. For developing countries, this situation needs to be taken into consideration.

The Mumbai stroke registry based on reliable census population describes epidemiology of stroke (incidence rates, stroke subtypes, and alive /dead status at 28 days). Experience suggests that the WHO STEPS protocol is feasible and gives useful information to plan intervention strategies. Another approach for studying stroke epidemiology on smaller populations (30,000 or more) has been suggested.10

For Mumbai registry, the age standardized annual incidence rate by direct method with Segi 1996 world population for FES has been 152/100,000; (95% CI 132-172) and this is not significantly different from that reported from China (Jiang),11 Auckland (New Zealand),3 Martinique (ERMANCIA study)12 and Chile (PISCIS study).13 On the other hand, the WHO Rohtak (India) study (1971-74)14,15 quoted an annual incidence of 33/100,000 population for all ages and 356/100,000 for those above the age of 70 years. However, precise details on numerator (for cases) and denominator (for population) are not available for interpretation.

In analysis of proportional frequency of stroke types in selected population (ten studies) around the world, Feigin et al10 reported, that ischaemic strokes were present in about 67.3-80.5%, whereas primary intracerebral haemorrhage was responsible for 6.5-19.6% of cases, subarachnoid haemorrhage accounted for 0.8%-7.0% and 2.0-14.5% were undefined type. In the Mumbai Stroke Registry (2005-06), 80.2% had ischaemic strokes, 14.6% had intracerebral haemorrhage, 3% had subarachnoid haemorrhage and 1.9% were unspecified type. These findings are not significantly different from those reported from above studies.3

The 28 day case-fatality rate in thirteen selected studies has ranged from 17% to 33%, average being 22.9%,3 In the Mumbai Stroke Registry (2005-06), the overall case-fatality rate for FES was 29.8% (136 cases) but the stroke related case-fatality rate was 17.9% (82 cases) and deaths unrelated to stroke were 11.8% (54 cases). The latter were related to concurrent co-morbid conditions like congestive cardiac failure, respiratory infections, sepsis etc.

It is emphasized that there are difficulties in this type of comparative analysis because of regional variations, differing ethnic groups etc but it does give general information with regard to incidence rates, stroke subtypes and case fatality. In absence of time trend studies, future projections to define stroke burden and interventions are not possible.

**SUMMARY**

The World Health Organization (WHO) STEPwise approach to stroke surveillance (WHO STEPS) designed to collect in a standardized manner basic epidemiological data on incidence, major risk factors, morbidity and mortality trends, intervention strategies in recent (acute) stroke. The present report describes the testing of WHO Steps Stroke Instrument (Question guide-Version: 2.0)7 on data collection and management in a defined segment of community (H-ward) in Mumbai. The data collection, case finding methods and reporting templates should be uniform for inter-regional comparisons. The WHO Stepwise approach to Stroke Surveillance is a practical instrument to administer to “in-hospital” cases as well as those occurring in community set up trained health workers will have to follow “mixed pursuit” methods in identifying “minor strokes”. It is proposed that similar surveys should be initiated on representative samples of regional population for comparative evaluation, to plan effective intervention and prevention strategies. Building on the populations enumerated for cancer surveillance purposes, might provide an excellent opportunity in meeting the challenge of understanding the population impact of this increasingly important chronic disease.

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**REFERENCES**

7. World Health Organization. STEPwise approach to stroke surveillance.


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