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Study Protocol: Validation and Adaptation of community-worker-administered stroke symptom questionnaire in a periurban Pakistani community to determine disease burden

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Abstract

Background—Stroke is the second leading cause of mortality and the leading cause of disability in the world today. The disease burden is on the rise in developing nations, but there is scarcity of data from these regions to inform policy decisions. Stroke burden can be determined by clinical diagnosis alone in the public health context and is a far more feasible way to assess disease status in low- to middle-income countries like Pakistan. We aim to translate and adapt a validated stroke symptom questionnaire, train community health workers in its administration, and verify it against assessment by two trained neurologists.

Methods/Design—This is a prospective study, which we aim to carry out in Ibrahim Hyderi, a periurban slum of Karachi. We translated into Urdu the questionnaire for verifying stroke free status (QVSFS), which is an internationally validated tool to assess the same. Two community health workers (CHW) will be identified and will receive training by neurologists, which will include teaching regarding stroke pathophysiology, symptomatology, and detection. They will be familiarized with the QVSFS, and their questionnaire administration will be assessed through roleplay. We intend to recruit 322 subjects from the same community and the CHWs will gather data on them. The same subjects will later be assessed by two trained neurologists, and the findings collaborated to validate those obtained by the CHWs. Sensitivity, specificity, positive and negative predictive values, and Cohen's kappa will be determined for the CHW-administered ques-

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tionnaire tested against assessment by two neurologists together and separately for the two CHWs. Data analysis will be done using SPSS version 19.0.

Discussion—The results of this study will determine if and how well CHW-administered questionnaires are at assessing stroke status in a community. This will facilitate use of the same as a practical alternative for stroke surveillance in the country.

Trial Registration: NCT02073955

Keywords

Burden of Stroke; QVSFS; Validation; stroke symptom questionnaire (SSQ)

Background

Stroke is the second leading cause of mortality in the world today after ischemic heart disease, and the leading cause of disability [1]. In 2005, it caused 5.7 million deaths worldwide [2]. A recent systematic review of population-based studies shows a divergent trend in stroke incidence. It shows a 42% decrease in stroke incidence in high-income countries and a greater than 100% increase in stroke incidence in low- to middle-income countries [3]. As the burden of stroke increases with an increase in ageing population, communities in epidemiological transition, also seem to suffer the brunt of this change [4]. However, the health system resources required to counteract this growing burden remain inadequate in these countries.

Consistent with this finding, South Asia represents a quarter of the emerging world and harbors 20% of the global stroke population [5]. Age-adjusted incident rates of stroke reported in South Asia are higher (145–262 per 100,000) compared with other developing countries, but these estimates are mostly derived from Indian studies, many of which are hospital based [6], [7]. Evidence from developed countries inform us that almost one third of stroke patients are never admitted to the hospital, which adds a huge bias to the estimates relying solely on this kind of data [8]. The projected increase in stroke and coronary heart disease (CHD) incidence is also expected to be much greater in South Asia than in any other region worldwide, mainly related to demographic transition [6], [9].

Unfortunately, it is recognized by researchers across the world that there is a serious lack of sound stroke epidemiology data from South Asia, countries that have the largest share of this chronic condition [9]. As a result, strategies to prevent, detect, and treat stroke are lacking in these countries.

Burden of Stroke in Pakistan

Pakistan has a population of over 170 million, and is the sixth most populous country in the world [10]. There are no large population-based studies from Pakistan to determine burden (incidence and prevalence) of stroke in the community. However, there are data suggesting high prevalence of vascular risk factors, namely, hypertension, diabetes, obesity, and smoking, among Pakistanis and this leads to the assumption that the burden of stroke is likely to be high as well [11], [12]. In a recent community-based study carried out in an urban slum of Pakistan, these risk factors were found to be abundant and a combination of two or more of these common vascular risk factors increased the odds of having a stroke significantly [13]. An earlier study had also identified similar risk factors in a single ethnic community [11].

The annual incidence of stroke is reported to be 250/100,000, translating into 350,000 new cases every year, although these estimates are not recent [14]. The more recent community-based study has highlighted the alarmingly high prevalence of stroke/transient ischemic attack (TIA) symptoms in this part of the world [15]. Conducted in a periurban slum of Karachi, this study reported symptoms of stroke or TIA in 21.8% of the people evaluated. In compared with the existing worldwide literature on stroke prevalence, this study shows a lifetime prevalence of stroke that is almost twice the highest reported prevalence in the world to date [15]. A prior study reported a stroke prevalence of 4.8% in a single ethnic group in Pakistan [11].

These observations suggest a population uniquely at risk for stroke [16]. Given the increased mortality in this population from stroke, efforts to inform early detection of stroke using lay workers may have significant policy implications for prevention.

The need for Stroke Surveillance

As the rising risk factors like diabetes and hypertension, demographic transition, and rapid urbanization fuel the

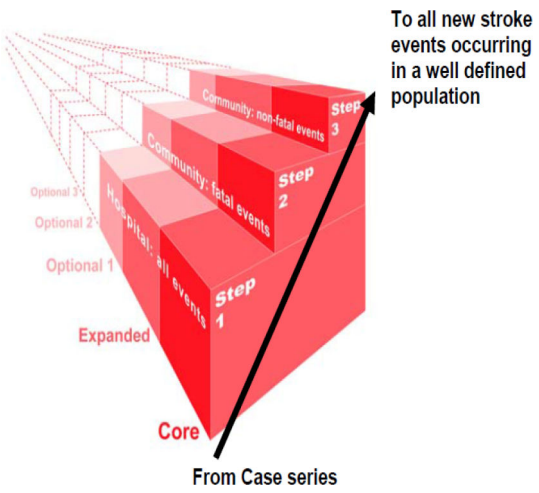

Figure 1. The WHO stepwise approach to stroke surveillance.

stroke burden in Pakistan; there is a need to determine this burden more accurately through surveillance. These kinds of data are needed for stroke to inform better resource allocation in resource poor settings and to plan public health initiatives to reduce the burden of this important condition.

Unlike most chronic diseases that require access to laboratories and medical specialists for diagnosis, stroke is amenable to surveillance primarily because its diagnosis is based on a clinical definition in the public health context [17]. The World Health Organization (WHO) recommends three steps for determination of stroke burden in any community [17], [18] (see Figure 1). Step 1 is hospital-based admission figures. But in countries like Pakistan, where tertiary care hospitals are few, not all people have access to them and health seeking behaviors are inadequate due to low literacy, these figures are not reliable and are often underestimated.

Step 2 is a community-based fatal stroke event register. This helps in identifying cases, in which the patient either did not seek medical care or died before hospitalization. In Pakistan, many deaths go unregistered and the cause of death is also not accurately documented.

Finally, step 3 is a community-based nonfatal stroke event register. These may make up a substantial burden again in a country like Pakistan, where recognition of disease and access to health care leave much to be desired. Hence, this may be the best way of investigating both the incidence and the prevalence of chronic conditions like stroke in countries like Pakistan.

The community-based nonfatal stroke event register may be the most realistic approach to determining the burden that this debilitating condition poses on our health system. However, one of the biggest challenges in implementing this last step and setting up an effective surveillance system is availability of appropriate validated tools for detecting stroke in the community.

Stroke Symptom Questionnaires

SSQs have been in use for several decades to screen individuals for presence of stroke. One such questionnaire was used by investigators of Asymptomatic Carotid Atherosclerosis Study (ACAS), and the Atherosclerosis Risk in Communities (ARIC) study [19], [20].

Another such questionnaire was developed to identify stroke free phenotype for clinical studies on genetics [21], [22]. This QVSFS consisted of eight questions, six of which were related to stroke symptoms, namely, hemiplegia, hemianesthesia, hemianopia, loss of vision in one eye, inability to speak, and inability to understand. The questionnaire was found to be reliable and valid for this kind of screening in subsequent studies [22], [23].

Although designed for ascertaining stroke free status, its six symptoms questions have recently been shown to be an effective tool for screening for stroke or TIA with a high sensitivity and moderate specificity [24]. Hence, these questions have a potential for being used as a public health screening instrument for identifying individuals with symptomatic stroke.

Validation of most SSQs has been carried out in hospitals or other clinical setups using trained research assistants [21]–[25]. However, when translated in local language, using relevant terminology, a similar set of questions were shown to have an excellent sensitivity in a community-based validation study in Mexico [26]. The sensitivity was in the range of 70% when administered by CHWs in another recent study from Brazil [27].

In a resource poor country like Pakistan, access to tertiary care settings is limited for a vast majority of people. Therefore, a similar SSQ based on commonly reported stroke symptoms in Pakistani population can help trained community workers identify community dwelling stroke patients. Once shown to have scientific validity, these can be implemented with low cost and can serve as useful instruments for planning local health care systems for stroke detection and surveillance.

Role of CHW

CHW have been variably defined over the past few decades. However, all definitions entail a core set of charac-

teristics. They are individuals who live in the community, serve as connectors between health care providers and the community members and work toward health promotion in their respective communities [28], [29]. They receive a short defined training and are not necessarily attached to any formal institution [30].

The role of CHWs has evolved tremendously over the past couple of decades. In developed countries, they have helped in overcoming barriers to health care for underserved communities, helped in reducing overall health care costs and improved self-care of chronic diseases [29]. In developing countries, there has been little focus on utilizing them for noncommunicable disease surveillance or interventions [31]. Isfahan Healthy Heart Program (IHHP) [32], [33] is perhaps, the best example from this region so far, where community workers have been trained to assess cardiovascular risk factors with a goal for primary prevention and improving health behaviors.

However, other examples like these are hard to find in the field of noncommunicable diseases. Now, with the rising burden of these conditions in our part, there is a strong need to explore the utilization of CHWs in this area as well.

Gold Standard for Validation

For definitive diagnosis of stroke and also to determine its subtype, brain imaging is the best available modality. This includes both computerized tomography (CT) and magnetic resonance imaging (MRI) of the brain. Ideally, these should serve as gold standard for stroke diagnosis. However, there were several reasons why we do not plan to utilize this gold standard, and instead consider the opinion of two neurologists based on history and physical exam as gold standard for our validation study.

First, both CT and MRI carry some risk to the subject, even though very minimal. Therefore, we cannot justify their use in subjects with no indication. Since this is a validation study, there is a need to evaluate both positive and negative cases using the gold standard for diagnosis.

Second, in the public health context, the definition of stroke is clinical and not imaging based. According to WHO, stroke is defined 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” [17], [34]. Therefore, using a clinical diagnosis as gold standard seems appropriate.

Other studies that have validated similar SSQs have all used a similar gold standard [22], [24]–[27]. None has utilized imaging to validate their findings. Judging by this, assessment by neurologist is an accepted gold standard the world over.

Finally, due to logistic and financial constraints, it does not seem possible for us to image more than 300 subjects, most of whom do not have stroke symptoms. (See Figure 2: a framework justifying our selection of gold standard)

Gaps in Knowledge

With the rising burden of stroke in a transitional country like Pakistan, there is a need to come up with effective means of stroke surveillance in order to measure the true burden of this devastating condition.

We do not know how well do stroke symptoms identified through CHW-administered questionnaires correlate with assessment of stroke by a neurologist based on history and physical exam. SSQs have thus far not been validated against objective measures in Pakistan.

If community workers can be shown to effectively screen and identify community dwelling stroke cases, larger community programs can be implemented and interventions can be planned.

We thus initiated this study with the objective to translate, adapt, and validate a SSQ for identification of stroke symptoms by CHW in a periurban Pakistani community and to determine the feasibility of using such a tool to assess the prevalence of stroke symptoms in this community.

Methods/Design

Study Design

In this validation study, criterion validation of a SSQ and its administration by CHWs will be done. The gold standard we are using is the assessment by two neurologists based on history and physical exam. In case of a discrepancy in the assessment of the two neurologists, a third neurologist will evaluate the participant, and this third assessment will be considered final. The inter-CHW agreement will be assessed by having the same subject evaluated by both CHWs.

In addition, based on the community-worker-administered questionnaire, we also aim to determine the prevalence of stroke symptoms in the validation community using a cross-sectional design.

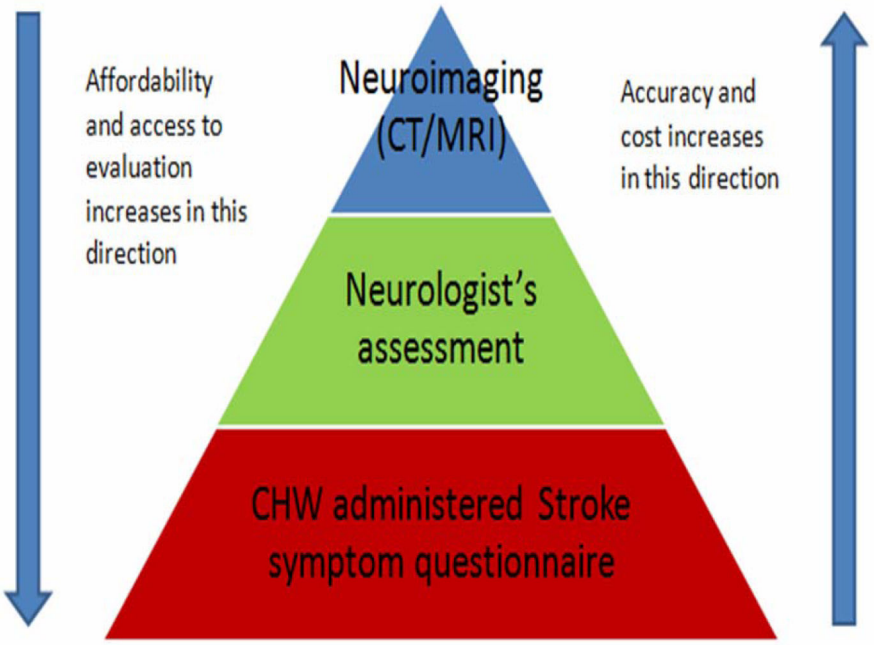

Figure 2. Conceptual framework showing different methods of stroke evaluation.

Study Setting

Karachi, the largest city of Pakistan, has a population of 23.5 million with a population density of 6,000 people per square kilometer. There are five administrative districts that are further divided into 18 towns. Our study setting is the Bin Qasim Town, located in the southeastern part of Karachi along the Arabian Sea and the Indus River delta. This study is being carried out at Ibrahim Hyderi, a periurban settlement of Karachi, which is one of the seven union councils of Bin Qasim Town. Ibrahim Hyderi has a population of 150,000. There are several ethnic groups in Ibrahim Hyderi, although the community is predominantly Sindhi in origin. Over 99% of the population is Muslim. The neighborhood is focused on the fishing industry.

The Aga Khan University has been actively involved in various health projects at Ibrahim Hyderi. In recent past, AMAN foundation has also started a community health project in the area. They have mapped a population of 50,000 people spread over 32 small neighborhoods, called "paras." We have collaborated with the AMAN foundation for this project.

Inclusion and Exclusion Criteria

Participants

All permanent residents of the community are eligible for inclusion if they are above 40 years of age, willing to participate in all components of the study, (that is CHW interview and neurologists' assessment) and can answer for themselves or have a surrogate willing to provide necessary information. Surrogate is defined as one who has lived in the same household as the individual, who was the primary caregiver and had access to the medical record / information of the patient. As this is a validation study, individuals refusing to participate in any of its components will be excluded from the study.

Chw

Two CHWs, one male and one female, will be recruited from this community. Their minimum educational requirement is matriculation, which is equivalent to 10 years of education. They should have no medical background, since we want our training to have a greater generalizability.

Neurologist

Two neurologists will evaluate each subject in the validation part of the study. Both are required to have completed training in the faculty of neurology with a postgraduate degree. A third neurologist may be needed in case of a difference in evaluation of two primary neurologists. Similar qualifications are required for this person as well.

Study Team

The study team consists of a principal investigator (PI) —a neurologist by training, two CHW, one field supervisor, and one other neurologist.

PI will be responsible for recruitment and training of CHW and field supervisor. In addition, she will also conduct neurological assessments for the validation part of the study. CHW will be responsible for door-to-door data collection. Field supervisor will be responsible for overseeing data collection at the field site and will ensure completeness and accuracy of data. Second neurologist will be responsible for neurological assessments for the validation part of the study.

Data Collection Tool

Translation and Adaptation of the SSQ

The QVSFS exists in English language. It has six common stroke symptom questions. An additional question regarding sudden onset facial weakness was added to it, and a single question on physician diagnosis of stroke is maintained. The question regarding TIA is being excluded as we do not expect understanding of this condition to exist in our community. Culturally, relevant pictures have been developed to assist understanding of the stroke symptom questions (See Additional file 2).

The questionnaire has been translated into Urdu by the primary investigator, who is also a practicing neurologist, so that the medical terminologies that are pertinent to the local setting can be used. This questionnaire has also been back translated to ensure clarity, by two bilingual individuals, a neurologist and a nonneurologist, who were asked to give written feedback. No major issues with clarity were found in this process.

To ensure similar clarity in the field setting, a group discussion with AMAN's community workers was held at their community health center at Ibrahim Hyderi, where they were given a brief overview of the project. We plan to conduct a field test, where 30 forms will be distributed among those who have volunteered to test this questionnaire for us. They will be asked to collect data and give feedback regarding clarity of questions and any other difficulties encountered in the process of data collection. In a second meeting with these workers, verbal feedback on the questionnaire's performance will be taken and any amendments will be incorporated if and as suggested.

Components of the Tool

1. **Questionnaire for CHW:** consisting of six sections.
   - **Section 1 and 2: Demographic information.** This includes subject identification (ID), household number, name, age and gender of the subject, date and time of interview, ethnicity, language spoken at home, education, nature of work, and few questions related to socioeconomic status.
   - **Section 3: Stroke symptom questionnaire.** This includes eight questions related to stroke symptoms experienced in the past. These are to be explained with the help of pictures provided. Information will also be collected on whether the subject needs more than two clarifications to answer each question.
   - **Section 4: Comorbid conditions.** Information will be collected on self-reported comorbidities like diabetes, hypertension, heart disease, hospitalization for stroke and frequency of physician visits.
   - **Section 5: Stroke knowledge questionnaire.** Sixteen true/false statements concerning knowledge of stroke risk factors, symptoms, and management will be asked from the subjects. Option of 'Do not know' is also given.
   - **Section 6: Feasibility questions.** This section enquires about the number of stroke symptom questions requiring more than two clarifications and the time it took to complete the questionnaire.
2. **Questionnaire for Neurologist:** A structured questionnaire has been developed for the Neurologist's assessment, so as to standardize the history and physical examination carried out by the two study neurologists.

An additional file contains the questionnaires for CHW and Neurologists (See additional file 2)

Recruitment and Training of CHW

Two CHW, one male and one female, will be hired for the purpose of data collection using the eligibility criteria. A manual has been developed to standardize the training of the CHWs. This manual contains information regarding the objectives of the study, the job description of the CHW, pathophysiology, symptomatology and diagnosis of stroke, as well as instructions on how to approach subjects and handle refusals in the community. (See additional file 1 for manual of Instructions)

A two day workshop will be conducted by the PI. In this workshop, the CHW will be introduced to basic information about stroke in a didactic session. Pictures and videos will be used to explain various aspects.

The questionnaire will then be explained in detail and the PI will demonstrate the administration of questions with the help of pictures, which will further be polished through role playing. Any queries shall be addressed.

Pilot Phase

A pilot phase will involve administration of around 10 questionnaires. This will ensure elimination of mistakes prior to formal data collection. After data collection is complete, data will be checked for sensitivities and specificities against each CHW and if required CHWs will be retrained and data will be recollected on a sample of few subjects to allow sensitivity and specificity calculations and to address the specific problems identified for each CHW.

Sampling Technique

For the validation part of the study, systematic sampling will be employed. This will be done because we want to cover most *mohallas* of Ibrahim Hyderi so as to have greater generalizability. We hope to recruit subjects on all days of the week, in order to get male representation, which is expected to be low on working days due to their employment commitments.

For the prevalence part of the study, a random list of households will be drawn from an already available list and subject will then be selected randomly from all members in a given household.

Sample Size Estimation

We hypothesize that the CHW-administered stroke symptom questionnaire has at least moderate agreement with assessment by neurologist

H_0: Ƙ<0.4 and Ha: Ƙ>0.4

For the validation study, using *Power Analysis and Sample Size PASS version 11*, a sample size of 322 has been calculated. For a test of interrater agreement using kappa statistic, this sample size of 322 subjects achieves 80% power to detect a true kappa value of 0.55 in a test of H0: kappa ≤ 0.40 versus Ha: kappa > 0.40 when there were two categories with frequencies equal to 0.21 and 0.79. This power calculation was based on a significance level of 0.05. The value of kappa = 0.4 is taken as it is the lower accepted limit for moderate agreement [35]. A 15% change above this is taken as our alternative hypothesis, which is very close to the value of kappa reported by the only other validation study of this nature [27]. The frequencies of 0.21 are taken based on the prevalence data available from the only community-based study from Karachi [15].

For the secondary objective of the study to determine the prevalence of stroke symptoms in the community *Open Source Epidemiologic Statistics for Public Health (OpenEpi) software version 2.3.1* was used. For prevalence of stroke symptoms in a population of 50,000 individuals, using a 95% confidence level, 21.8% estimated stroke symptom prevalence reported previously (from a similar stroke symptom based community study); and 3% bound of error, a required sample size of 718 participants has been calculated.

Study Procedure

Duration of three months is scheduled for the data collection on 322 subjects for validation part of the study. A CHW will approach the eligible participant and perform required assessment. Within two weeks of being assessed by a CHW, the participant will be reassessed by the second CHW. Within one to three weeks of CHW assessment, the participant will be evaluated by two neurologists on the same day.

Figure 3 demonstrates the flow of the study. The time between any two evaluations will be kept as minimum as possible so that any new event could not affect the validity of the study.

Data Quality Management

Each subject will be assigned a unique three-digit ID, which they shall be required to reproduce at all subsequent evaluations. All data will be kept under lock and key at all times. Once entered, data will be identified only with the unique ID.

Statistical Analysis

Statistical analysis will be performed using the SPSS version 19.0 for Windows (SPSS Inc., Chicago, IL, USA). Descriptive statistics will be calculated for all demographic variables. For categorical variables like gender, income, comorbid conditions etc. frequencies with proportions will be calculated. For continuous variables, like age and time taken to fill questionnaire, data will be reported as mean with standard deviation.

We aim to calculate stroke symptom prevalence as the proportion of people with a positive stroke symptom

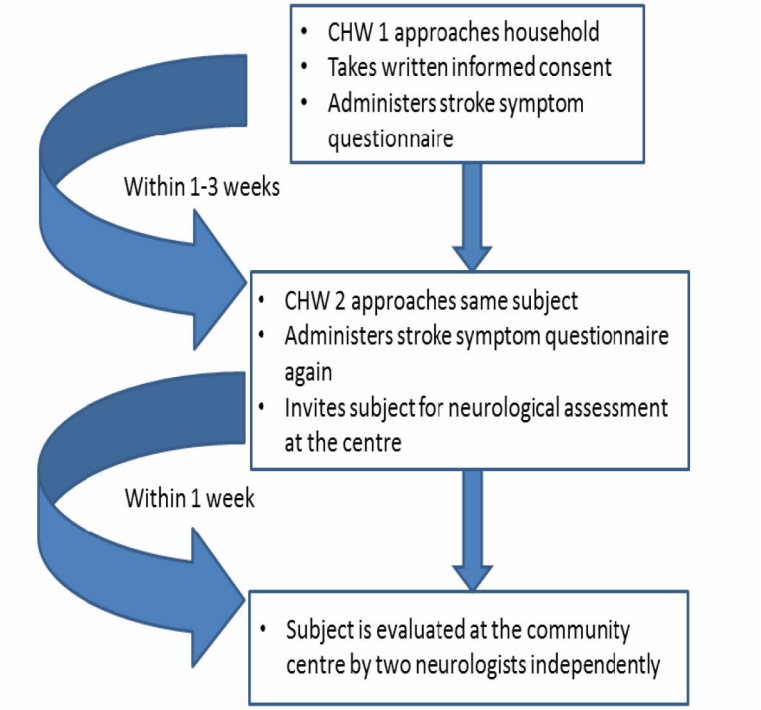

Figure 3. Study procedure and flow.

questionnaire (SSQ will be considered positive even if response to one item out of eight is in the affirmative). The sensitivity, specificity, positive, and negative predictive values with 95% confidence interval will be calculated by comparing the questionnaire responses with the assessment by a neurologist, which was the gold standard in the study.

Sensitivity, specificity, and predictive values will be calculated for the questionnaire overall and for each item singly. Cohen's kappa coefficient will be used to assess the level of agreement between the questionnaire and neurological assessment and between the two CHWS. 95% confidence interval and p value will be reported for kappa.

Sensitivity analysis will also be done to assess how the questionnaire behaves across the categories of age, gender, education, and socioeconomic strata.

Ethical Considerations

The study protocol has been approved by the Ethical Review Committee (2331-CHS-ERC-12). No financial incentives will be provided to any study participant. Written informed consent and verbal assent will be given by all participants or their surrogate prior to the interview. Those individuals identified as having stroke on neurological evaluation will be given appropriate medical advice by the study neurologists and referred to a tertiary care center if necessary.

Discussion

To the best of our knowledge, this is one of the first comprehensive community-based validation studies on stroke symptom questionnaire from South Asia, a region that harbors 20% of the world's stroke population. Training local people in their language will allow recognition and early seeking of health care. Once validated, such CHW-administered questionnaires can serve as effective tools for screening large populations for this devastating condition.

List of Abbreviations Used

NCD	Non Communicable Disease
CHD	Coronary Heart Disease
TIA	Transient Ischemic Attack
WHO	World Health Organization
ACAS	Asymptomatic Carotid Atherosclerosis Study

ARIC	Atherosclerosis Risk In Communities study
QVSFS	Questionnaire for Verifying Stroke Free Status
CHW	Community Health Worker
IHPP	Isfahan Healthy Heart Program
CT	Computerized Tomography
MRI	Magnetic Resonance Imaging
ID	Identification

Competing Interests:

The authors declare that they have no competing interests.

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Author's Contributions:

MK, AK, OP, and MI designed the study protocol. MK and AA jointly produced the first draft and revisions, MK and AA will be performing neurological assessments for the validation part of the study. MK developed questionnaire for neurologist and some sections for the questionnaire for CHWs. IA, MI-assisted statistically and provide feedback and support. MJ and Anita Andani will be responsible for data management. JR, AN, and AV will provide logistics support in the community and all field operations, space, data flow, and sharing data for home listings. AK is responsible for overall coordination and supervision of the study: All authors reviewed the manuscript for important intellectual details.

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References

1. Di Carlo A. Human and economic burden of stroke. *Age and ageing* 2009;38(1):4–5.
2. Strong K, Mathers C, Bonita R. Preventing stroke: saving lives around the world. *The Lancet Neurology* 2007;6(2):182–187.
3. Feigin VL, et al. Worldwide stroke incidence and early case fatality reported in 56 population-based studies: a systematic review. *The Lancet Neurology* 2009;8(4):355–369.
4. Mukherjee D, Patil CG. Epidemiology and the global burden of stroke. *World Neurosurg* 2011;76(6 Suppl):S85–90.
5. Strong K, Mathers C, Bonita R. Preventing stroke: saving lives around the world. *Lancet Neurol* 2007;6(2):182–7.
6. Gupta R, et al. Epidemiology and causation of coronary heart disease and stroke in India. *Heart* 2008;94(1):16–26.
7. Das SK, et al. A prospective community-based study of stroke in Kolkata, India. *Stroke* 2007;38(3):906–10.
8. Giroud M, et al. A hospital-based and a population-based stroke registry yield different results: the experience in Dijon, France. *Neuroepidemiology* 1997;16(1):15–21.
9. Kulshreshtha A, et al. Stroke in South Asia: a Systematic Review of Epidemiologic Literature from 1980 to 2010. *Neuroepidemiology* 2012;38(3):123–129.
10. World Population Data Sheet - Population Reference Bureau. 2011
11. Jafar TH. Blood pressure, diabetes, and increased dietary salt associated with stroke--results from a community-based study in Pakistan. *J Hum Hypertens* 2006;20(1):83–5.
12. Jafar TH, Chaturvedi N, Pappas G. Prevalence of overweight and obesity and their association with hypertension and diabetes mellitus in an Indo-Asian population. *Canadian Medical Association Journal* 2006;175(9):1071–1077.
13. Itrat A, et al. Risk factor profiles of South Asians with cerebrovascular disease. *International Journal of Stroke* 2011;6(4):346–348.
14. Khealani BA, Hameed B, Mapari UU. Stroke in Pakistan. *JPMA. The journal of the Pakistan Medical Association* 2008;58(7)
15. Kamal A, et al. The burden of stroke and transient ischemic attack in Pakistan: a community-based prevalence study. *BMC neurology* 2009;9(1):58.
16. Qureshi AI, et al. Paradoxical Increase in stroke mortality among Asian Indians in the United States. *Journal of Vascular and Interventional Neurology* 2014
17. World Health, O. *WHO STEPS Stroke Manual: The WHO STEPwise approach to stroke surveillance* GenevaWorld Health Organization2006

18. Truelsen T, et al. Standard method for developing stroke registers in low-income and middle-income countries: experiences from a feasibility study of a stepwise approach to stroke surveillance (STEPS Stroke). *Lancet Neurol* 2007;6(2):134–9.
19. Lefkowitz DS, et al. A pilot study of the end point verification system in the Asymptomatic Carotid Atherosclerosis Study. *Journal of Stroke and Cerebrovascular Diseases* 1992;2(2):92–99.
20. Toole JF, et al. Self-reported transient ischemic attack and stroke symptoms: Methods and baseline prevalence: the Aric Study, 1987–1989. *American journal of epidemiology* 1996;144(9):849–856.
21. Meschia JF, et al. Verifying the stroke-free phenotype by structured telephone interview. *Stroke* 2000;31(5):1076–1080.
22. Jones WJ, Williams LS, Meschia JF. Validating the Questionnaire for Verifying Stroke-Free Status (QVSFS) by neurological history and examination. *Stroke* 2001;32(10):2232–2236.
23. Meschia JF, Lojacono MA, Miller MJ. Reliability of the questionnaire for verifying stroke-free status. *Cerebrovascular Diseases* 2004:17.
24. Sung VW, et al. Sensitivity and specificity of stroke symptom questions to detect stroke or transient ischemic attack. *Neuroepidemiology* 2011;36(2):100–4.
25. Karanjia PN, et al. Validation of the ACAS TIA/stroke algorithm. *Neurology* 1997;48(2):346–351.
26. Del Brutto OH, et al. [Validation of a screening questionnaire for stroke detection in Spanish-speaking communities]. *Rev Neurol* 2004;39(4):301–4.
27. Abe IM, et al. Validation of a stroke symptom questionnaire for epidemiological surveys. *Sao Paulo Med J* 2010;128(4):225–31.
28. Rhodes SD, et al. Lay health advisor interventions among Hispanics/Latinos: a qualitative systematic review. *American journal of preventive medicine* 2007;33(5):418–427.
29. Noor HH. Role and Effectiveness of Community Health Workers Among Underserved US Populations. 2012
30. Ayala GX, et al. Outcome effectiveness of the lay health advisor model among Latinos in the United States: an examination by role. *Health education research* 2010;25(5):815–840.
31. Hafeez A, et al. Lady health workers programme in Pakistan: challenges, achievements and the way forward. JPMA-Journal of the Pakistan Medical Association2011;61(3):210.
32. Sarraf-Zadegan N, et al. Isfahan Healthy Heart Program: a comprehensive integrated community-based program for cardiovascular disease prevention and control. *Acta cardiol* 2003;58(4):309–20.
33. Sarrafzadegan N, et al. Outcomes of a Comprehensive Healthy Lifestyle Program on Car-diometabolic Risk Factors in a Developing Country: the Isfahan Healthy Heart Program. *Arch Iran Med* 2013;16(1):4–11.
34. Hatano S. Experience from a multicentre stroke register: a preliminary report. *Bull World Health Organ* 1976;:54.(5) 541–53.
35. Landis JR, Koch GG. The measurement of observer agreement for categorical data. *Biometrics* 1977;33(1):159–74.

Additional Files:

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Additional file 1: Information manual for the community health worker for assessing stroke in the community

Additional file 2: Stroke assessment forms for CHW and Neurologist