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Establishing Organized Stroke Care in Low- and Middle-Income Countries: From Training of Non-specialist to Implementation

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Abstract

Low- and middle-income countries (LMICs) suffer from a higher stroke burden compared to high-income countries with higher mortality and disability due to stroke. However, the availability of resources, both infrastructural and personnel, is widely discrepant. The lack of specialist neurologists or stroke physicians in LMICs makes it imperative to rely on alternative models of stroke care. Task-sharing models such as the physician-led model or the non-specialist model have been evaluated previously with evidence for feasibility and cost-effectiveness. We propose to implement and assess the effectiveness of a non-specialist model of stroke care across 3 LMICs through a structured capacity building program, augmented by a tailored mobile application to guide the non-specialists in delivering optimal stroke care. This study will provide essential information on the effectiveness of a non-specialist driven delivery of stroke care on a larger scale across different regional contexts.

Keywords

Non-specialist stroke care, physician-led stroke care, alternative stroke care models, telestroke

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Introduction and Rationale

Stroke is the third leading cause of disability worldwide.[1] However, the burden of stroke is greater in low- and middle-income countries (LMICs) than high-income countries (HIC). A recent global burden of disease study stated that 86% of all stroke-related deaths and 89% of stroke-related disability-adjusted life-years (DALY) occurred in lower-income, lower-middle-income, and upper-middle-income countries.[2] Many factors are responsible for this disparity: lack of public awareness, resource-limited health systems, expensive or unaffordable acute stroke treatments, and limited availability of neurologists, physiotherapists, occupational therapists, and trained nurses.[3,4] A survey conducted by Asian Stroke Advisory Panel exploring systems of stroke care in member countries in Asia reported wide discrepancies in the number of neurologists per 1,00,000 population with LMICs like Pakistan and India having 0.30 to 0.96 as compared to HICs like Japan with 67.80 neurologists per 1,00,000 population, respectively.[5] Similarly, the number of neurologists in Africa is estimated to be 0.03 per 1,00,000 people while the World Health Organization advocates at least 1 per 1,00,000 neurologists.[6] Due to this shortage of trained personnel, many stroke patients are managed by non-specialists with insufficient knowledge or training. In many LMICs, there are less than 1 skilled rehabilitation practitioners per 1,00,000 people, and completely unavailable speech and language therapists which interfere with proper rehabilitation after stroke and hence increase the stroke-related DALYs.[7,8]

The lack of adequate neurologists and specialist stroke care professionals in LMICs stresses the importance of relying on alternative models of stroke care like task-sharing with non-specialists (ie, physicians and nurses) for delivery of optimal and uniform stroke care. Non-specialists are trained health-care practitioners such as physicians and nurses

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but not specialized in stroke care and management. The non-specialist model also known as the physician-led model consists of capacity building and skills developments of nurses and physicians about stroke care delivery and best practices, with the focus being primarily on preservation of life and discharge planning.[3] Capacity building has been identified as part of essential stroke services by the World Stroke Organization roadmap for quality stroke care.[9] Key elements of training for basic stroke care include fever, sugar, and swallow (FeSS) protocol, blood pressure and glycemic control, and management of complications.[10] A successful implementation of the non-specialist model was illustrated in Tezpur district, a remote area of Northeast India with improvements in quality measures and reductions in in-hospital complications.[11]

Advances in technology can facilitate both training of non-specialists and stroke care delivery. For example, telestroke offers the opportunity to provide stroke care in locations deprived of specialists physically on-call.[12,13] In poor resource settings, interventions to train and empower physicians to manage people with stroke according to guidelines have shown improved care and better outcomes.[3,14] An ongoing cluster randomized trial (SMART INDIA) is comparing smartphone-based telestroke and stroke physician-led acute stroke management in 22 district hospitals without a neurologist in India.[15] Although the non-specialist model has been established as a cost-effective and culturally acceptable solution to improve stroke care, a large-scale implementation of this model has not been assessed. We propose to develop a non-specialist driven model of stroke care that can be implemented across hospitals which do not have stroke specialized facilities to help provide a uniform and equitable pathway of stroke care in LMICs. We plan to leverage mobile application technology to facilitate training of non-specialists.

This study aims to implement a non-specialist driven model of stroke care in 4 sites across 3 LMIC. We also aim to assess the effectiveness of this model on knowledge, attitude, and practices of non-specialists and the impact on key quality measures of stroke care.

Methods

Design

This study is an investigator initiated, prospective, multicenter, before-and-after, effectiveness-implementation hybrid design study being conducted in 4 centers across LMICs, namely India, Armenia, and Malaysia. This study aims to assess the feasibility and impact of a structured capacity building program among non-specialists in low-resource settings on the quality of care and clinical outcomes in patients with stroke.

The study received ethics approval from the Institutional Ethics Committee of the Central Coordinating Centre (St Stephen's Hospital, Delhi, India) as well as from the respective participating stroke centers (Padhar Mission Hospital, Madhya Pradesh, India; Makunda Christian Leprosy and General Hospital, Assam, India; Goris Hospital, Goris, Armenia; HAT Tuanku Mizan, Kuala Lumpur, Malaysia). The study will be conducted in 2 phases: (a) phase I: training and capacity building of non-specialists and (b) phase II: impact of the implementation on quality of stroke care and clinical outcomes.

Baseline Evaluation

Prior to the initiation of the study, the following will be done.

1. **Identification of hospitals and team of core health-care professionals:** Four mid-level, nonstroke-ready hospitals with access to basic neuroimaging services (CT scanner) will be identified from 3 different LMICs (India, Armenia, and Malaysia). The LMIC countries were selected based upon the research team members' native countries and the feasibility of a nonspecialist model in the respective country. In each hospital, a core team of health-care professionals will be identified consisting of 1 lead physician and nurses and rehabilitation professionals who will be directly involved with admitting and managing stroke patients in their respective center. The availability of at least 1 physician on-call 24 × 7 will be mandatory.
2. **Development of stroke care modules and electronic case record form (eCRF):** Fourteen virtual training modules will be developed and recorded prior to training the non-specialists. The virtual training modules will include lecture materials and audio-visual aids on evidence-based stroke care. The modules will comprise topics on core competencies of stroke care including recognition and diagnosis of stroke, standardized neurological assessment, stroke management, stroke unit protocols, management of complications, stroke rehabilitation and early mobilization, and secondary prevention (see Table 1 for all the planned modules). The content of each module will be translated into Armenian to ease the training of non-English proficient medical personnel in rural regions of Armenia.
   In parallel, an eCRF will also be developed for documentation of patient data, time metrics, and key quality indicators from each of the hospitals at various timepoints during the study.
3. **Development and validation of the knowledge, attitude, and practices (KAP) questionnaire**

   Development of questionnaire: From a review of literature and the American Heart Association/American Stroke Association guidelines on management of acute

Table 1. Topics for Training Module Development.

Theme	Module Number	Title	Topics Covered
Stroke overview	1	What is stroke?	Burden and epidemiology, stroke types
Neurological assessment	2	National Institute of Health Stroke Scale (NIHSS): When and How?	Administration of the NIHSS, timing of the assessment, rating of each item
	3	Modified Rankin Scale (mRS)	Administration of the NIHSS, timing of the assessment, score
Pathophysiology of stroke	4	Mechanisms of stroke	Ischemic and hemorrhagic stroke, subtypes, stroke etiology, clinical presentation
	5	Localization of stroke	Neuroanatomy and vascular anatomy, stroke symptoms
Medical management	6	Hyperacute management	Core and penumbra, hyperacute management of stroke based on stroke type, stroke pathway, postthrombolysis care
	7	Surgical management	Acute surgical interventions,
Organization of stroke care	8	Stroke unit care	Overview of stroke unit and how to organize care, types of stroke units
Rehabilitation and prevention of complications	9	General rehabilitation	Overview of rehabilitation care
	10	Early mobilization, spasticity and contractures	Timing to initiate early mobilization, strategies to mobilize, exercises to reduce spasticity and prevent contractures
	11	Swallow screening	Stages of swallowing, aspirations, bedside swallowing screening and assessment
	12	Dysphagia management	Management: food consistency, positioning, alternative route, oral hygiene
	13	Support and manipulation of paretic arm	Prevention of subluxation, manipulation of the paretic arm, support and slings
	14	Positioning	Positioning in bed and on a chair and prevention of pressure sores

ischemic stroke, a set of prototype questions will be formulated by the team of neurologists and rehabilitation professionals in the research team. The questions will be prepared addressing various aspects of knowledge, attitude, and practice of management of people with stroke in their acute- and immediate postacute phase ranging from symptom recognition, grading of stroke severity, management of physiological parameters such as FeSS protocol, prevention of poststroke complications, and rehabilitation including early mobilization and positioning. Each question will be scored on a 5-point Likert scale ranging from strongly agree to strongly disagree with the higher scores indicating better KAP. The questionnaire content will be further reviewed and refined by the team and a final set of questions will be included into the questionnaire. A small proportion of the total questions will be reverse marked with negative answers to minimize convenient answering by respondents.

Face and Content validation: An expert panel of senior neurologists will be designated, each of whom independently will rate the questionnaire for content, applicability, relevance, and validity. The content validity index will be calculated and based on the suggestions from the panel. If any, revisions will be made to the questionnaire and recirculated for approval. Once finalized, the questionnaire will be administered to 200 nonneurologist volunteers (physicians, nurses, and rehabilitation professionals) from the 3 LMICs for validation and content validity will be calculated. The volunteers will be identified from hospitals other than the 4 selected hospitals for the implementation study. This finalized KAP questionnaire will then be used for assessing the knowledge, attitudes, and practices of the core health-care professionals' team at each of the identified hospitals at different timepoints during the study.

Table 2. Key performance indicators.[17]

Performance indicator		Benchmark[11]	Data source	Timeline
Primary	Change in KAP of healthcare professionals	Significant changes from pre-post	KAP Questionnaire	Pre-post training
	Swallow screening performed within 24h of admission	Increase of 20% of initial swallow screening (or a target of 20% of patients admitted receiving a swallowing assessment)	ENIGMA app	Within 24h post admission
	Hospital length of stay	Significant reduction in hospital length of stay	ENIGMA app	After discharge
Secondary	Administration of antiplatelet drugs within 48 hours of admission	Increase of 10% of antiplatelet drug prescription (or a target of 10% of patients admitted receiving antiplatelets)	ENIGMA app	Within 48h of admission
	Occurrence of early mobilisation in the hospital	Increase of 20% of patients mobilized within 24-48h of admission	ENIGMA app	After discharge
	Occurrence of medical complications	Reduction of 20% of medical complications	ENIGMA app	After discharge
	Prescription of secondary stroke prevention medications	Increase of 10% of patients receiving secondary stroke prevention medications	ENIGMA app	After discharge
	modified Rankin Scale scores of 0-2 at 3 months follow-up	Significant increase in the proportion of patients having a good outcome on the modified Rankin Scale	ENIGMA app	At 3-month follow-up

Abbreviation: ENIGMA app: ENhancing Stroke Care Interventions for Global Medical Assistance app, KAP: Knowledge, attitudes, and practices.

4. **Collection of baseline data:** Prior to the initiation of phase I, baseline data will be collected. The developed KAP questionnaire will be administered to the identified core team of health-care professionals at each of the 4 hospitals from India, Armenia, and Malaysia to assess and document baseline levels of knowledge, attitudes, and practices in stroke care. Similarly, the eCRF will be used to document baseline patient demographics and data prior to the capacity building phase after written, informed consent.

Phase I

1. **Training and capacity building of non-specialists:** Phase I will consist of training and capacity building of the core team of non-specialists identified at each of the hospitals over a 3-months period. The pre-recorded training modules will be delivered fortnightly to the nonspecialist teams in the 4 hospitals via WhatsApp Messenger (Meta Platforms) and/or email. Non-specialists will be given 2 weeks to go through the recorded modules and additional virtual meetings (Zoom communications) will be organized between the local site investigator and hospital teams to answer questions pertaining to the delivered module.
2. **Development of the mobile application:** Simultaneously, an easy-to-use mobile application (app) with separate tailored sections for physicians and nurses will be developed to guide the non-specialists in delivering evidence-based stroke care. This app called the ENIGMA (ENhancing Stroke Care Interventions for Global Medical Assistance) app will include a step-by-step algorithm for stroke management, with protocols for standard of care, links to the recorded training modules, and summaries for quick reference for management of common poststroke complications. In addition, a section for data collection will be included for documenting patient demographics and outcome parameters.

   A post-training KAP, both immediate and delayed (after 3 months), will be studied to assess the effectiveness of the virtual capacity building.

Phase II

1. **Impact of implementation phase:** After the completion of the capacity building and training, phase II will be conducted over 6 months. This phase will include the actual implementation of the nonspecialist model in which trained physicians and nurses will execute evidence-based stroke management protocols using standard operating procedures.
2. **Patient population**: All adult patients with stroke presenting to the respective centers and admitted in medicine or neurology wards will be screened for eligibility, based on the following inclusion and exclusion criteria. Participants will be included if they are aged 18 years and older, have an ischemic stroke or intracerebral hemorrhage with less than

3 months of symptom onset, computed tomography/magnetic resonance imaging shows recent stroke (infarct and/or hemorrhage), and are able to provide signed informed consent (patient or caregiver). Participants will be excluded if they have symptoms mimicking stroke, have cerebral venous sinus thrombosis, aneurysmal subarachnoid hemorrhage, isolated central nervous system or systemic vasculitis, active malignancies, terminal illness, heart failure, or psychiatric illness.

Quality measures like regular monitoring and management of blood pressure, blood sugar, fever, and dysphagia screening as per protocol (FeSS),[16] prophylaxis for deep vein thrombosis, management of other medical complications, initiation of early rehabilitation, and initiation of secondary prevention drugs before discharge will be followed by the trained team of non-specialists. The ENIGMA app will be used by the non-specialists to receive guidance in stroke best-practices and to systematically document demographic details, stroke characteristics, risk factors for stroke, stroke time metrics, stroke severity, brain imaging details, medical complications, medications, length of hospital stay, and discharge plan.

3. **Follow-up:** All patients enrolled in the study will be followed up at 1- and 3 months to assess functional status defined by the modified Rankin Scale (mRS) either in person or over the phone.
4. **Primary and secondary outcomes:** Primary key performance indicators will be (a) percentage change in KAP of the health-care professionals, pre- and posttraining, (b) reduction in the length of hospital stay, and (c) proportion of patients who receive swallow screening test within 24 h (see Table 2 for details on key performance indicators). Other secondary key performance indicators will include (d) proportion of patients who receive antiplatelet drugs within 48 h, (e) proportion of patients who receive early mobilization in the hospital, (f) proportion of patients who develop medical complications, (g) proportion of patients receiving secondary stroke prevention medications, (h) proportion of stroke patients with good outcome (mRS 0-2) at 3 months follow-up. Data on the key performance indicators will be collected at baseline for 3 months (prior to the implementation phase) and compared with data collected for 3 months during the implementation phase.
5. **Sample size estimation:** We will target a sample of 40 non-specialists and 180 people with stroke. Our a priori sample size calculations were based on the results from John et al,[11] based on reduction in length of hospital stay with a difference of mean (standard deviation [SD]) of 1 (2-3) day and an increase in the proportion of swallowing assessment by 36% post-implementation of stroke unit, 80% power, and type 1 error of 5%. Considering a 10% drop out rate, the estimated sample size is 180 people with stroke, 90 in each group (preimplementation and postimplementation) across 4 sites. By taking the following, sample size was calculated. Knowledge, attitudes, and practices will be assessed in a sample of 8 to 10 non-specialists per hospital, for a total sample of 40 using a convenience-based sampling.

Statistical Analysis

Descriptive statistics analysis will be expressed as mean ± SD or median (interquartile range) for continuous variables, whereas categorical variables will be depicted as count (percentage). Data normality will be verified using Kolmogorov Smirnov tests. Chi-square will be used to compare the categorical variables and Student *t* test or Mann Whitney *U* test will be used to compare continuous variables between the groups. It is assumed that the values will be missing at random. Therefore, loss to follow-up will be imputed using multiple imputation using Markov Chain Monto Carlo method.[18] Missing values will be assessed to evaluate if missing at random, prior to consideration of imputation methods. Sensitivity analysis will be performed if variables are not missing at random. Adjusted odds ratio will be calculated using regression analysis after adjusting for baseline variables. The significance level will be set at *P* value <.05. All analysis will be performed using SPSS version 26.0.

Conclusion/Summary

The challenge to optimal stroke care in LMICs is to identify what components of the stroke continuum of care can be cost-effectively implemented to produce the largest gain. Task-sharing with non-specialists is a viable and cost-effective strategy which has been studied in LMICs successfully. This study will provide essential information on the effectiveness of a nonspecialist-driven delivery of stroke care on a larger scale across different regional contexts. Mobile application along with the audio/video audio modules are potential resources which can be utilized for capacity building in other LMICs and can be expanded for a wider dissemination of knowledge to health-care professionals, especially in regions where access to specialist care is lacking. Demonstrating the effectiveness of this non-specialist model will help establish this prototype as an alternative model of stroke-care delivery for use especially in resource-poor countries.

Declaration of Conflicting Interests

The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical Approval

Ethical approval from Institutional Ethics Committee was obtained.

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