

Study Protocol: IMPETUS: Implementing a Uniform Stroke Care Pathway in Medical Colleges of India: IMPETUS Stroke

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Abstract

Introduction: In India, a national program for stroke (national programme for the control of cardiovascular diseases, diabetes, cancer, and stroke) and stroke management guidelines exist. Its successful implementation would need an organized system of stroke care in practice. However, many challenges exist including lack of awareness, prehospital notification systems, stroke ready hospitals, infrastructural weaknesses, and rehabilitation. We present here a protocol to investigate the feasibility and fidelity of implementing a uniform stroke care pathway in medical colleges of India. **Methods and Analysis:** This is a multicentric, prospective, multiphase, mixed-method, quasi-experimental implementation study intended to examine the changes in a select set of stroke care-related indicators over time within the sites exposed to the same implementation strategy. We shall conduct process evaluation of the implementation process as well as evaluate the effect of the implementation strategy using the interrupted time series design. During implementation phase, education and training about standard stroke care pathway will be provided to all stakeholders of implementing sites. Patient-level outcomes in the form of modified Rankin Scale score will be collected for all consecutive patients throughout the study. Process evaluation outcomes will be collected and reported in the form of various stroke care indicators. We will report level and trend changes in various indicators during the three study phases. **Discussion:** Acute stroke requires timely detection, management, and secondary prevention. Implementation of the uniform stroke care pathway is a unique opportunity to promote the requirements of homogenous stroke care in medical colleges of India.

Keywords: Implementation, India, stroke, stroke care pathway

INTRODUCTION

Stroke is the second leading cause of death and disability worldwide. Compared with the high-income countries, the low- and middle-income countries carry a higher incidence and prevalence of stroke, and disability adjusted life years.^[1-4] In a recent systematic review, the prevalence rate in India was estimated between 45 and 487/100,000 for urban and 55 and 388.4/100,000 for rural population.^[5] The incidence rates were estimated between 33 and 123/100,000 and 123.57/100,000, respectively.^[5]

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The challenges in stroke care in India include lack of awareness, prehospital notification systems, unavailability of stroke-ready hospitals, infrastructural weaknesses, and unavailability of post-stroke rehabilitation. Although a national program for stroke^[6] and stroke-management guidelines^[7] exist, an organized system of stroke care is still beset with such deficiencies. The Indian health care system exists both as a public and private health model. In a hierarchical model of the public health system, the medical colleges are an important bridge among the rural, district, and tertiary care systems of care. We believe that the situation of the stroke care system at the medical colleges in India stand to gain through a systematic assessment of their stroke care program, adherence to various components of stroke care protocols, challenges faced, level and need of training for various cadres of health care workers in these institutes, and thereafter can be a source of aspiration for district hospitals in stroke care. In the absence of a systematic assessment of its performance, presently, the quality and outcome of stroke care at medical colleges has been largely assumed to be of optimum quality. Our study aims to address this facet.

Acute stroke care pathway has many core components, the effectiveness of which were proved in previous randomized controlled trials and summarized in meta-analyses [Supplementary Table 1]. The overarching aim of this study is to assess the feasibility of real-world implementation of a uniform stroke care pathway (USCP; IMPETUS) in hospitals associated with medical colleges in India. The present study aims at improving stroke care from the time of recognition in the emergency until the discharge of the patient, using an implementation design.

METHODOLOGY

Aims and objectives

This study will be conducted with five objectives which includes:

- To audit the current status of acute stroke care in select medical colleges and identify the barriers and facilitators for the implementation of USCP.
- To provide training and mentoring to the staff at these select medical colleges toward USCP based on the deficiencies observed.
- To assess the feasibility and fidelity of implementing a uniform standard stroke care pathway in select medical colleges.
- To determine the association of implementing uniform standard stroke care pathway with change in outcomes based on mortality, morbidity, and caregiver burden.
- To observe sustainability of practice of the uniform standard stroke care pathways in these medical colleges.

Study design

This is a multicentric, prospective, multiphase, mixed-method, quasi-experimental implementation study intended to examine the changes in a select set of acute stroke care-related

indicators overtime within the sites exposed to the same implementation strategy. We shall conduct process evaluation of implementation of the strategy, as well as evaluate the effect of the implementation strategy using the interrupted time series design. A major strength of this design will be its ability to distinguish the effect of implementation of the intervention strategy from secular change, that is, change that would have happened even in the absence of the intervention. Hence, our study design may be considered as “hybrid-type 3” according to the terminology suggested by Curran and colleagues,^[8] since we are primarily testing the feasibility and fidelity of implementation of the USCP in a setting of medical colleges (to what extent the components of the strategies were implemented, the acceptability of the staff to these strategies, barriers and facilitators of those), while also secondarily collecting data on patient-related clinical outcomes (the 3-months modified Rankin score of the patients).

Study setting

The study will be conducted in the selected 22 medical colleges and their associated hospitals spanning a geographical representation from all India [Figure 1]. The medical colleges are the tertiary care centers situated either in district headquarters or the capital city of a state. In each of the medical colleges, the stroke care team, including physicians and nurses, and other ancillary staff will be part of the study.

Uniform stroke care pathway

The USCP is a systematic arrangement of aspects of stroke care and management right from the first contact in the emergency room to inpatient acute stroke care, evaluation, secondary prevention, and follow-up. The various elements are outlined in Figure 2. These are driven from evidence-based research and both national and international guidelines. The core key interventions included in USCP are listed in Supplementary Table 1.

Implementation strategies

Our main implementation strategy will be imparting education and training to stakeholders about the components of the USCP including their efficacy and effectiveness in disability and/or death limitations as well as secondary prevention of stroke. This will potentially increase the trained manpower for optimized stroke care delivery in the medical colleges.

It will include the substrategies like training of the trainer (ToT), continuous training by local implementers, distribution of education materials, and continuous online training by central coordinators. We will also give standard training to implement these interventions while providing care to any acute stroke patients. Education will be through audio/video lectures. Education material will be distributed during educational meetings. Pre-post knowledge assessment of all participating stakeholders will be conducted by research staff during administration of the trainings.

Our supplementary implementation strategy will be feedback of implementation process outcomes to the local stakeholders during



Figure 1: Study collaborating sites

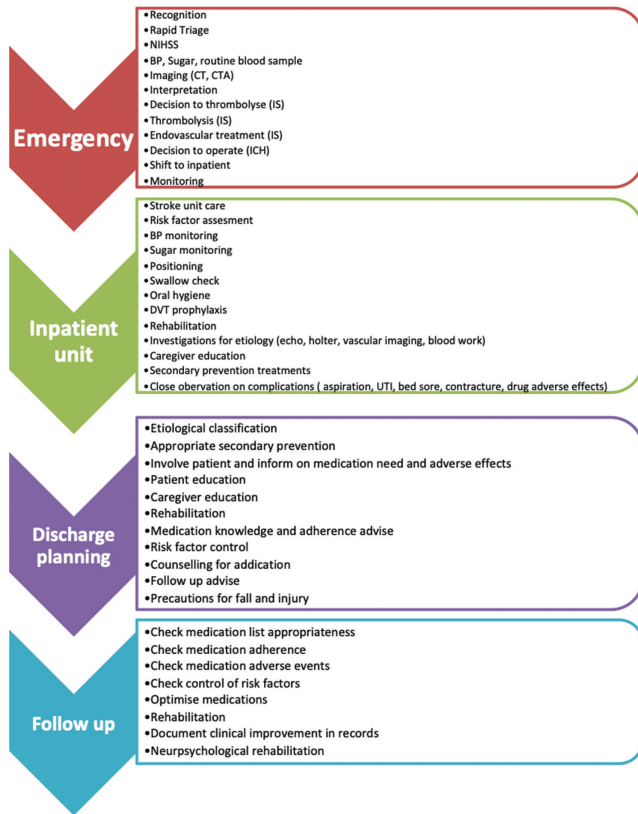


Figure 2: Components of the uniform stroke care pathway

phase 2 of the study. Feedback will be given to every participating site and their local stakeholders every fortnight during continuous online training by the central coordinating team.

Study participants

The study participants will consist of: (a) Patients with acute stroke (both ischemic stroke and intracerebral hemorrhage) admitted in the emergency and inpatients units: All consecutive patients with suspected acute stroke upto 72 h of onset presenting to the emergency of the collaborating institutions during 3 to 18 months of the study period will be recruited after an informed consent. (b) Faculty members working in emergency and inpatients units: Faculty members involved in stroke care and treatment, from neurology, neurosurgery, and medicine specialty will be eligible to participate in the study. (c) Residents working in emergency and inpatient units: Residents posted in emergency services, inpatient services, and outpatient care will be eligible to participate in the study. (d) Nursing staff working in emergency and inpatient units: Nursing staff posted in the emergency services, inpatient services, and outpatient care will be eligible to participate in the study. (e) Ancillary staff working in emergency and inpatient units: Orderlies, ward boys, guards, posted in the emergency services, inpatient services, and outpatient care will be eligible to participate in the study. (f) Caregivers of patients with stroke: Any family member/relative who identifies themselves as a caregiver and spends at least 6 h/day with the patient. Paid professional caregivers shall not be eligible for the study participation.

Study phases

This study will be carried out in three phases according to the objectives [Figure 3]. The phase one (pre-implementation phase) will be of 3 to 5 months duration wherein a baseline assessment of the existing components of acute stroke care will be conducted in each participating site. During this study phase,



Figure 3: Outline of the study phases

we will collect quantitative data, using a predefined checklist to assess existing status of functioning for the following components: acute stroke evaluation and treatment, risk factor assessment, in-hospital care, discharge planning and secondary prevention, rehabilitation, and caregiver education. The respondent will be the key informant at the site level out of the personnel engaged in stroke care (Staff, doctors, and nurses). Information from phase-1 will be analyzed descriptively, compared with a similar end line assessment, and can be used as confounder variables in subsequent analyses.

In phase two (Implementation phase), the implementing strategy, that is, education and training, to the stroke care staff will be imparted according to the principles of USCP using a cascade mechanism—initial training will be given as a ToT to the faculty members of the medical colleges, who in turn will further train their stroke care staff. For the staff at the local collaborating center, there will be a total of four sessions of training conducted in Month 1, followed by monthly for the next five months. This will be followed by two more training sessions at Months 9 and 12. Quality assurance of the training will be performed by participation from the members of the central implementing site during the sessions. The implementation of this phase will be assessed by the pre-post test following training sessions and a checklist to monitor routine of training.

The phase two of the study will also be assessing the third objective of the study, that is, whether it is indeed feasible to implement the components of the USCP. This phase will be assessing the constructs of: (a) feasibility—from the perspective of a health care provider by administering questions on key components of the stroke care and assess their responses; (b) fidelity—of extent of implementation of the key components of the stroke care by applying a checklist on the care provision of each patient; and (c) acceptability, practicality of integration of components, and acceptability of care provider by qualitative methods using focus group discussions among health care provider staff and family-level care provider of stroke patient. Descriptive analysis and domain identification will be conducted for these to understand perceived barriers for implementing USCP and extent to which the USCP is compatible with existing practices.

The phase three will cover objectives 4 and 5 of the study. This phase will be from 13 to 21 months where in sustenance, the practice of trained staff in the stroke care pathway will be assessed, along with patient outcome assessment. This phase

will assess sustenance of the training imparted and knowledge gained during the implementation of the study and also if the uniform stroke care pathway and patient assessment is continuing without further training. Patient-related outcomes will also continue to be assessed during this phase. For each of the patients recruited during this phase, a 30-day mortality, and also an outcome at the end of 3 months will be abstracted from medical records or collected by study staff during follow-up visits or through audio/video phone call. This checklist will be administered by the research staff of the local collaborator for a period of three months for all consecutive patients with acute stroke (both Ischemic Stroke (IS) and Intracerebral hemorrhage (ICH)) admitted in the emergency and inpatients units. For each of the patients recruited during this phase, a 30-day mortality and also an outcome at the end of 3 months will be abstracted from medical records.

Study outcomes

In our hybrid type 3 study, we will measure both implementation outcomes as well as patient-based final impact outcomes. To understand and evaluate the complete process of implementing acute stroke care in the form of USCP at an organization, we will measure outcomes both quantitatively as well as qualitatively. During all three phases, we shall collect patient-level data on indicators pertaining to stroke care components at emergency, inpatient unit, discharge planning, and follow-up.

Quantitative outcomes

We will assess feasibility and fidelity of USCP through a set of quantitative indicators tabulated in the Supplementary Table 2. These include the following: (a) assessment of availability of 24 × 7 CT scan facility; (b) proportion of patients in whom recording of stroke onset time, National Institute of Health Stroke Scale at admission, and other stroke metrics done; (c) proportion of eligible patients who get thrombolysis and/or endovascular thrombectomy; (d) proportion of patients who underwent proper vascular imaging after admission to ward or stroke units, (e) proportion of patients in whom Vitals and Glasgow Coma Scale score recorded properly; (f) proportion of patients will undergo swallow assessment, complete risk factor assessment, and deep venous thrombosis (DVT) prophylaxis; (g) proportion of patients in whom stroke-related complications (e.g., pneumonia, bed sore, DVT, urinary tract infection, acute seizure) are noticed by providers; (h) proportion of patients in whom ischemic stroke subtype classification completed; (i) proportion of patients get appropriate secondary prevention and comprehensive

follow-up advice at discharge (e.g., life-style modifications, compliance, and physical rehabilitation); and (j) proportion of patients' caregiver who get stroke-related education.

Qualitative outcomes

Through focused group discussion during various study phases, we will measure a few qualitative outcomes. We can assess providers' acceptability of USCP through measuring their satisfaction with USCP. We know practicality/integration of USCP by assessing providers' perspective about extent to which the USCP is compatible with existing practices. We will identify various organizational culture and climate-related barriers and facilitators during the pre-implementation phase while assessing the feasibility and appropriateness of USCP during the last two phases by qualitative outcomes.

Patient-based outcomes

We will observe change in 30 days mortality during each time point of various study phases. We will also observe change in three months patient disability outcome assessed on modified Rankin score dichotomized at 2 or below as a good outcome.

Analysis plan

Analysis of the key indicators and main outcome variable

During these phases, a series of weekly measurements (for example the percentage of stroke patients attending the emergency departments of study sites, who received specific components of the USCP (Supplementary Table 2)) will be used to measure the impact of the strategy intervention using a segmented regression analysis of interrupted time series model.

In our study, the different participating study-sites shall be contributing data across the indicators. We shall be aggregating the data from all the sites and developing a single time series of data aggregated across all sites; however, an analysis of aggregated data is likely to have less power than a multilevel regression analysis of the time series from the individual sites. Hence, we shall also conduct separate segmented regression analyses at each site, and then estimate the overall effect by pooling the estimates of intervention effect across sites using inverse variance weights in a meta-analytical model. We shall also explore a multilevel analysis approach by fitting a single model to the data from all sites and then account for heterogeneity across sites by incorporating random effects of intercepts and slopes for the sites. Since we consider that the effects of the strategy are unlikely to be immediate, hence, in the analysis of interrupted time series, we shall be more concerned about the changes in slope between pre-implementation and post-implementation phases, instead of testing the immediate changes in level of the outcome after the interruption (*the intercept*).

Data management

Data management will follow the principles of Good Clinical Practice. An electronic Case Report Form (CRF) (eCRF) developed by the authors (RB, PH, and IP) will capture all relevant data variables. Access to the eCRF will be restricted,

via a study-specific web portal, with only authorized personnel, including authorized personnel from the participating medical colleges, who are able to make entries. All principal investigators of the participating institutes or their designee will be responsible for eCRF entries at local sites, trained by the research team of RB, and will also confirm that data are accurate, complete, and verifiable. In exigent situations, if data are entered by the participant into a paper CRF, completed anonymous questionnaires will be returned by post to the office of RB at AIIMS New Delhi for data entry. Where practical, data will be validated at the point of entry into the eCRF. Any additional data discrepancies will be flagged to RB and also any changes recorded to maintain a complete audit trail (reason, date, and who made the change). Data will be stored in the server database.

DISCUSSION

Although acute stroke care is likely to be heterogeneous as per strata of health care, resources, and prioritization,^[9] till date, no systematic audit has assessed the quantum and reasons of such heterogeneity in India. Ours will be first study focusing on mentoring of medical colleges as a critical health care setting to impart best available care to patients of acute stroke. This study, while auditing the quality of care, will also do a systematic enquiry of barriers and facilitators to the implementation of homogenous standard USCP structured by various evidence-based interventions. We will also assess feasibility and fidelity of this stroke care pathway at participating sites by implementing it in real settings through education and training of stakeholders.

Since neurologists are limited, and medicine specialists play a vital role in stroke care, this study is the first systematic effort to also train non-neurology medical specialists in medical colleges toward evidence-based acute stroke care.

Approaches to implementation of science are varied.^[10] This study follows one of the sophisticated techniques to assess the feasibility, fidelity, and outcome of implementing a complex set of activities in a systems approach for ensuring adherence to a set of uniform stroke care pathway and also assess the barriers. While the individual components of the stroke care pathway are not new, and are well utilized in practice upto varied degrees in these settings, our study will assess this variation of present practice, and also the extent such care pathway for stroke patients could be implemented. An ongoing study on patients with transient ischemic attacks also aims to identify barriers in therapy and post-implementation change on patients' outcomes.^[11]

Many difficulties are perceived in establishing an acute stroke pathway.^[12,13] In a recent survey, infrastructural weakness and lack of appropriate use of structured pathways was observed as key barriers in stroke care.^[13] This study emphasized the critical need of developing stroke units for optimizing care. A study from Ghana has also focused on many important barriers that are potentially different from the High Income Countries

(HMIC's).^[14] These barriers were identified at all levels of health care and authors recommended need for solutions to facilitate them in low-income health settings. Another survey aimed to study comparison of resources between low and middle-income countries and HMIC's that could be potentially responsible for the relatively limited implementation of international guidelines into stroke practice. Limited access to prehospital care pathway, helpline emergency number, limited neurology, and radiology services were the key components observed.^[15]

Initiatives to improve stroke care have been published previously. At the emergency level, educational practices have been associated with an increase in the number of stroke patients being treated as well as an improvement in the rates of thrombolysis.^[16] The Stroke Ready project^[17] is an initiative at the level of emergency services and community to improve stroke care using an educational initiative. The study aimed to increase rates of acute stroke treatment with intravenous thrombolysis and endovascular stroke treatment.

Strengths and limitations

This study follows the recommended hybrid strategies to assess feasibility of implementing complex interventions as well as allows for their limited evaluation. The study employs mixed methods integrating both quantitative and qualitative approaches for understanding and evaluating the implementation process. The job aids and training manual being employed for the teaching material of this study will serve as a ready reckoner for not only the medical colleges in India but also anyone who wishes to use it for their own centers. Thus, it will help strengthen skilled and trained manpower in medical colleges to impart best available stroke care to patients.

Our study is expected to facilitate a genuine interest among participating individuals to focus on the systems approach of a clinical management protocol, which has the potential to inculcate a team building strategy, and also focus on other clinical areas. This study, however, is not performing an economic evaluation of implementation of uniform stroke care pathway. We, however, expect that we may be able to recognize some potential areas for weak implementation of stroke care pathway and find solutions to improvise them.

We foresee some disruptions in the rollout of the study as a departure from what was originally planned, due to the ongoing COVID-19 pandemic, and its subsequent waves which are unknown in their effects that they will harp upon the study. Hence, in an exigent situation, we might have to do some adaptation in the study to the restrictions imposed by future waves of COVID-19 pandemic, especially since the regular manpower is diverted extensively toward COVID-19 duties.

Ethics and dissemination

The study has been given ethical approval by the Institute Ethics Committee of the All India Institute of Medical Sciences, New Delhi, India. Written informed consent will be obtained from all participants. The research team will ensure that the

study is conducted in accordance with Good Clinical Practices. Findings will be reported to the funder (Indian Council of Medical Research), as well as shared with participating sites, to facilitate local feedback and planning for future improvement and sustenance of the gains. We shall further make attempts to publish the findings in peer-reviewed scientific journals, present at stakeholder meetings, and national and international conferences for effective dissemination.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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Supplementary Table 1: The core components of stroke care

Core components	Level of evidence
Intravenous Thrombolysis	IA
Endovascular Thrombectomy	IA
Stroke Unit care	IA
Deep Venous Thrombosis Prophylaxis	IA
Fever, Sugar, Swallowing (FeSS) Protocol	IA
Stroke Rehabilitation	IA
Secondary prevention (Aspirin, oral anticoagulation, Statin, dual antiplatelet therapy in specific situations, antihypertensives, antidiabetic) and risk factor control.	IA

Supplementary Table 2: Key outcome indicators of the study

Indicator	Implementation outcome construct
Quantitative implementation outcomes	
Assessment of availability of 24 × 7 CT scan Facility	Feasibility
Recording Stroke onset time, NIHSS, Stroke metrics	Fidelity
Provision of Thrombolysis and/or endovascular thrombectomy to eligible patients	Feasibility
Performing Vascular imaging	Fidelity
In Patient Admission	Feasibility, Fidelity
Vitals, Glasgow Coma Scale (GCS) recording	Fidelity
Swallow assessment	Fidelity
DVT prophylaxis	Fidelity
Providing Caregiver Education	Fidelity
Physical rehabilitation	Fidelity
Notification of complications (e.g., Pneumonia, bed sore, DVT, UTI, and Acute seizure)	Fidelity
Appropriate ischemic stroke subtype classification (TOAST)	Fidelity
Risk Factor Assessment and Appropriate secondary prevention	Fidelity
Comprehensive Follow up advice (life-style modification and compliance)	Fidelity
Satisfaction with the USCP	Acceptability, Practicality/integration
Perceived Barriers for implementing USCP	
Extent to which the USCP is compatible with existing practice	Acceptability, Practicality/integration
USCP: Uniform stroke care pathway; DVT: deep vein thrombosis; UTI: urinary tract infection; NIHSS: National Institute of Health Stroke Scale; TOAST: Trial of Org 10172 in Acute Stroke Treatment	