

Impact of Standardised Order Sets on Functional Outcome of Acute Ischaemic Stroke Patients: A Research Protocol

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ABSTRACT

Introduction: Standard order sets, which are pre-decided measures that guide clinical decisions and treatment, are shown to benefit quality of care in various medical conditions, including stroke. The use of such order sets for stroke management has shown positive outcomes in various studies. The American Stroke Association advises the use of standard order sets to raise the efficiency of acute stroke care.

Need of the study: In rural tertiary care hospitals of India, the challenge is due to factors such as late patient presentation, poor infrastructure, and lack of trained staff. These result in reduced stroke care and poorer outcomes. Therefore, introducing standard order sets in such settings could reduce the lacunae in stroke management quality and improve patient care.

Aim: To study the impact of implementing standardised order sets on overall outcome of patients of acute onset ischaemic stroke.

Materials and Methods: The study will be prospective observational study. This study is designed to know the effect

of using standard order sets for study of outcomes of with acute onset ischaemic stroke. The study will be conducted in Acharya Vinoba Bhave Rural Hospital (AVBRH), a tertiary care hospital situated in the rural area of Wardha district. Study will be carried out over the period of two years. The data collection process for this study will be divided into three phases: the pre-implementation phase, the implementation phase, and the post-implementation phase. A total of 600 patients will be included in the study. Qualitative data will be coded into quantitative variables as needed, and new variables will be created based on the collected data to facilitate analysis. For example, age groups may be categorised, and time intervals calculated. These preparatory steps are essential for ensuring that the data is ready for robust analysis, ultimately enabling a thorough evaluation of the impact of standardised order sets on the outcomes of acute ischaemic stroke in a tertiary care rural hospital in India.

Keywords: Acute stroke management, Post-implementation phase, Pre-implementation phase, Rural India

INTRODUCTION

Acute onset ischaemic stroke is a main cause of morbidity and mortality. In India, stroke incidence is rising due to limited access to specialised stroke care facilities [1]. Timely and effective management is necessary in reducing the associated disability and death [2]. Standard order sets, which are pre-defined measures that guide clinical decision-making and treatment protocols [3]. These can help the management process, ensuring that interventions such as thrombolysis are administered promptly [4]. The implementation of order sets for stroke management has given positive outcomes in several studies. The American Stroke Association advises the use of standardised order sets to raise the efficiency and effectiveness of acute stroke management [5]. However, there is less data on the impact of such interventions in resource-limited areas, particularly in rural India [6].

In rural tertiary care hospitals in India, the challenge is due to factors such as delayed patient presentation, poor infrastructure and lack of trained staff [7]. These challenges often result in poor stroke care and poorer outcomes. Therefore, introducing standard order sets in such settings could potentially reduce the gap in stroke management.

This study aims to know the impact of using standard order sets on the outcome of patients with acute onset ischaemic stroke. By noting key measures such as functional outcomes, time of critical therapy, duration of hospital stay and in-hospital mortality, this research seeks to provide evidence for the use of order sets in improving stroke care in a resource-limited set up.

AIM

To study the effect of using standard order sets on the outcome of patients of acute onset ischaemic stroke.

Primary objective: To study the effect of standard order sets on the functional outcome of patients with acute ischaemic stroke, as guided by the modified Rankin Scale (mRS) and the National Institutes of Health Stroke Scale (NIHSS) score, at the time of admission, at the time of discharge and one month after discharge.

Secondary objectives:

1. To study effect of order sets on the time to critical therapy, the door to needle time for thrombolysis.
2. To find the effect of order sets on the duration of hospital stay for patients of acute ischaemic stroke.
3. To assess the effect of order sets on in-hospital mortality rates among patients with acute ischaemic stroke.
4. To compare the overall adherence to stroke management guidelines before and after use of standard order sets.

REVIEW OF LITERATURE

Elder KG et al., conducted a study to know the effect of use of a standard order set on for acute stroke treatment. By retrospectively studying medical records of patients treated, they found that the use of the order set improved mandatory care standards [8].

Akwe J and Wallace JM noted the benefits of creating electronic health record order sets for improving adherence to The Joint Commission National Quality Measures for ischaemic stroke. Their study showed that the implementation of these order sets led to better adherence with stroke management guidelines [9].

Maus V et al., studied order of treatments in endovascular therapy for ischaemic stroke. Their retrospective analysis of data revealed that performing mechanical thrombectomy before carotid artery stenting shown higher rates of successful reperfusion and better

clinical outcomes after 90 days, rather than reverse order. This study shows the importance of treatment sequence in improving patient care in acute onset ischaemic stroke [10].

MATERIALS AND METHODS

Ethical committee approval: The study will be conducted only after a clearance is obtained from the local ethical committee of Datta Meghe Institute of Medical Sciences, Wardha by submitting a synopsis giving all the proposed study details and protocols. The Institutional Ethics Committee (IEC) reference number is DMIMS(DU)/IEC/2024/267.

Study design: This is a prospective observational study, performed to evaluate the effect of implementing standardised order sets on the outcome of acute ischaemic stroke. The study will be conducted in Acharya Vinoba Bhave Rural Hospital (AVBRH), a tertiary care hospital situated in the rural area of Wardha District. Study will be carried out over the period of two years.

Study duration: This study will be carried out from August 2024 to July 2026.

Study Population:

Inclusion criteria:

- 1) Patients aged 18 years and above;
- 2) Diagnosed with acute ischaemic stroke confirmed by Neuro-imaging (CT or MRI);
- 3) Patients admitted under Neurology department of the hospital.

Exclusion criteria:

- 1) Patients with haemorrhagic stroke;
- 2) Patients with Transient Ischaemic Attack (TIA);
- 3) Patients or families who decline participation in the study.

Sample size: The sample size will be calculated on the basis of the following formula:

Sample size for frequency in a population:

Population size (for finite population correction factor or fpc) (N):	900	
Hypothesised % frequency of outcome factor in the population (p):	50% \pm 5	
Confidence limits as % of 100 (absolute \pm %) (d):	5%	
Design effect (for cluster surveys-DEFF):	1	
Sample size (n) for various confidence levels:		
Confidence	Level (%)	Sample size
95%		270
80%		140
90%		209
97%		310
99%		383
99.9%		492
99.99%		565
Equation		
Sample size $n = \frac{DEFF \cdot Np(1-p)}{(d^2/Z^2_{1-\alpha/2} \cdot (N-1) + p^2(1-p))}$		

Results from OpenEpi, Version 3, open source calculator--SSPropor

270+27 (10%)=297 rounded off to 300;

300 in each group.

A total of 600 patients will be enrolled in the study, with 300 patients in the pre-implementation group and 300 patients in the post-implementation group.

Study Procedure

Data collection process: The data collection process for this study will be divided into three phases: pre-implementation, implementation of order sets, and post-implementation.

Pre-implementation phase: Data will be collected from medical records of patients diagnosed with acute ischaemic stroke before the

implementation of standardised order sets. This involves identifying relevant patient records and extracting necessary information, including demographic details, clinical characteristics, time metrics, treatment details and outcomes.

Implementation of order sets: This involves the development and introduction of order sets for acute onset ischaemic stroke management. These will include protocols for initial patient assessment, imaging procedures, thrombolysis administration, and supportive care. This phase is crucial for ensuring that staff is well-prepared to incorporate the order sets into routine practice.

Post-Implementation Phase

In the post-implementation phase, data will be collected prospectively from patients at the time of admission and at the time of discharge and one month after discharge, after the order sets have been implemented. This data collection will include demographic information, clinical characteristics, time metrics, treatment details, and duration of hospital stay and in hospital mortality. This phase aims to collect data that reflects the effect of the order sets on patient outcomes.

Data Entry and Management

To maintain data integrity, all collected data will be entered into a secure, computerised database. Regular checks will be conducted.

Primary Outcome

The NIHSS score, a measure of stroke severity, is expected to show a significant improvement at discharge and one month post-discharge, indicating better recovery due to more timely interventions and standardised care protocols. The mRS, which gauges a patient's level of disability or dependence, is expected to show a lower score (indicating better functional independence) at discharge and at the one-month follow-up.

Secondary Outcomes

The introduction of order sets is expected to reduce the door-to-needle time for thrombolysis in patients with acute ischaemic stroke. This could lead to quicker administration of critical therapies and more timely interventions, potentially improving patient outcomes. It will lead to more efficient treatment workflows, reducing unnecessary delays in patient management and facilitating faster clinical decisions. It would shorten the duration of hospital stays, lowering the risk of in-hospital mortality and improve survival rates. This can help to increase adherence to stroke management guidelines. This will lead to more consistent application of evidence-based practices in the treatment of acute ischaemic stroke.

STATISTICAL ANALYSIS

Firstly, data cleaning will be done to identify and correct any missing values. Necessary changes will be made to ensure a complete dataset. Qualitative data will be coded into quantitative variables and new variables will be created based on the collected data to help analysis. For example, age groups may be categorised and time intervals calculated. The Analysis of Variance (ANOVA) test, which is a statistical significance test, will be used. SPSS Statistics 23 is a statistical software to be used.

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AUTHOR DECLARATION:

- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

PLAGIARISM CHECKING METHODS: [Jain H et al.](#)

- Plagiarism X-checker: Dec 04, 2024
- Manual Googling: Jan 31, 2025
- iThenticate Software: Feb 10, 2025 (13%)

ETYMOLOGY: Author Origin

EMENDATIONS: 6

Date of Submission: **Dec 04, 2024**

Date of Peer Review: **Jan 04, 2025**

Date of Acceptance: **Feb 12, 2025**

Date of Publishing: **Jul 01, 2025**