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Original article

Protocolized emergency department observation care improves quality of ischemic stroke care in Haiti



Shada A. Rouhani^{a,b,c,d,*}, Regan H. Marsh^{a,b,c}, Linda Rimpel^d, Kathryn Anderson^e, Malena Outhay^f, Marie Cassandre Edmond^d, Keegan A. Checkett^{c,d,e}, Aaron L. Berkowitz^{c,g,h}, Gene F. Kwan^{c,i}, Christopher W. Baugh^{a,b}, Jeremiah D. Schuur^j

^a Harvard Medical School, Department of Emergency Medicine, Boston, MA, USA^b Brigham and Women's Hospital, Department of Emergency Medicine, Boston, MA, USA^c Partners In Health, Boston, MA, USA^d Hôpital Universitaire de Mirebalais, Department of Emergency Medicine, Route Chatulée, Mirebalais, Haiti^e University of Chicago, Section of Emergency Medicine, Chicago, IL, USA^f Alameda Health System, Highland Hospital, Department of Emergency Medicine, Oakland, CA, USA^g Brigham and Women's Hospital, Department of Neurology, Boston, MA, USA^h Harvard Medical School, Department of Neurology, Boston, MA, USAⁱ Boston University School of Medicine, Section of Cardiovascular Medicine, Boston, MA, USA^j Brown University, Department of Emergency Medicine, Providence, RI, USA

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ABSTRACT

Introduction: In many low-income countries, Emergency Medicine is underdeveloped and faces many operational challenges including emergency department (ED) overcrowding and prolonged patient length of stays (LOS). In high-resource settings, protocolized ED observation unit (EDOOU) care reduces LOS while preserving care quality. EDOUs are untested in low-income countries. We evaluate the effect protocolized EDOU care for ischemic stroke on the quality and efficiency of care in Haiti.

Methods: We performed a prospective cohort study of protocolized observation care for ischemic stroke at a Haitian academic hospital between January 2014 and September 2015. We compared patients cared for in the EDOU using the ischemic stroke protocol (study group) to eligible patients cared for before protocol implementation (baseline group), as well as to eligible patients treated after protocol introduction but managed without the EDOU protocol (contemporary reference group). We analysed three quality of care measures: aspirin administration, physical therapy consultation, and swallow evaluation. We also analysed ED and hospital LOS as measures of efficiency.

Results: Patients receiving protocolized EDOU care achieved higher care quality compared to the baseline group, with higher rates of aspirin administration (91% v. 17%, $p < 0.001$), physical therapy consultation (50% v. 9.6%, $p < 0.001$), and swallow evaluation (36% v. 3.7%, $p < 0.001$). We observed similar improvements in the study group compared to the contemporary reference group. Most patients (92%) were managed entirely in the ED or EDOU. LOS for non-admitted patients was longer in the study group than the baseline group (28 v. 19 h, $p = 0.023$).

Conclusion: Protocolized EDOU care for patients with ischemic stroke in Haiti improved performance on key quality measures but increased LOS, likely due to more interventions. Future studies should examine the aspects of EDOU care are most effective at promoting higher care quality, and if similar results are achievable in patients with other conditions.

African relevance

- This study was conducted in a low-income country (LIC) with a newly developing emergency care system - similar to African emergency care systems.
- This study investigates diseases which are newly applicable to emergency department observation care, given resource-limited health care systems in low-income countries.

* Corresponding author.

E-mail address: srouhani@bwh.harvard.edu (S.A. Rouhani).<https://doi.org/10.1016/j.afjem.2020.05.007>

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- This study demonstrates improvements in care quality with minimal additional resources.

Introduction

Access to high quality emergency care is essential to improving health outcomes globally, particularly in low-income countries (LICs) [1]. Triage, early disease recognition, and rapid treatment can improve health outcomes for a variety of conditions [2–5]. Well-functioning emergency departments (EDs) can address the causes of 54% of deaths in low- and middle-income countries [6], including cerebrovascular disease. Despite these needs, emergency medicine (EM) remains underdeveloped in most LICs, including Haiti [7].

Most EDs in Haiti are small and staffed by non-residency trained generalist physicians without specific EM training. An exception is Hôpital Universitaire de Mirebalais (HUM) in central Haiti, where the ED has around-the-clock physician staffing and dedicated resources. Despite HUM's relatively robust infrastructure, it struggles with challenges endemic to EM, including long wait times and prolonged patient length of stay (LOS). As in many places, inadequate inpatient bed availability results in boarding of patients in the ED [8,9]. Inpatient LOS at HUM is further prolonged by factors accentuated in LICs: resource scarcities decrease hospital efficiency, limited primary care systems lead to late-stage disease presentations, and outpatient follow-up options are limited. Thus, ED LOS for patients awaiting admission routinely exceeds 24 h and is often multiple days. In other settings, boarding patients extends ED wait times, compromises care quality, and increases left-without-being-seen rates [10].

In high-resource settings, ED observation units (EDOUs) using condition-specific protocolized care can provide high-quality, cost-effective care in less time than short-stay hospitalizations [11–16]. EDOU patients benefit from extended evaluation and treatment beyond their ED care (mean EDOU LOS in the United States is 15 h) [17], which either enables a safe discharge or uncovers reasons for further hospitalization. Best-practice observation care relies on delivering protocolized care with defined endpoints to patients in dedicated areas [12,16], though in practice EDOU protocol utilization and adherence is variable.

While there is some experience with EDOU use in middle-income countries [18–21], to our knowledge, EDOUs are untested in LICs. If successful, EDOUs could decrease inpatient admissions and reduce the demand for hospital bed-hours, thus alleviating hospital crowding. However, diseases amenable to observation care in high-resource settings may differ from those in limited-resource settings like Haiti.

Ischemic stroke is a candidate for observation care in LICs. Cerebrovascular disease is estimated to be the second leading cause of death in Haiti [22], and one of the top causes of admission to HUM [7]. Despite this, Haiti has few diagnostic or therapeutic interventions for ischemic stroke. Because access to neuroimaging is severely limited in LICs [23], most strokes are diagnosed clinically. Haiti has few functional computed tomography (CT) scanners; HUM has the only public sector CT [24]. There is one magnetic resonance imaging (MRI) device in Port-au-Prince, but it is prohibitively expensive: a brain MRI costs US \$600 while 59% of the population lives below the national poverty line of US\$2.42 per day [25]. There is no angiography in the country. Haiti has one neurologist for a population of 11 million people, so nearly all patients with stroke receive non-specialist care [26]. Stroke severity is not routinely assessed with a standardized system. Few hospitals in LICs, including Haiti, have thrombolytics for stroke [27], and due to barriers accessing care, patients with stroke often have delayed presentations further limiting thrombolytic use. Additionally, in the authors' experience, patients with mild strokes rarely present for care. There are no dedicated stroke units in Haiti, and inpatient physical therapy beds are extremely limited. Given resource limitations, interventions for ischemic stroke currently focus on secondary prevention and risk reduction through blood pressure control, antiplatelet

medications, swallow evaluations, and physical therapy (PT) – which can all be done from an EDOU.

In 2014, HUM created a six-bed EDOU attached to the ED to improve care quality and efficiency. ED leaders developed protocols for nine conditions, including ischemic stroke, and implemented them eleven months later. The objective of this prospective observational cohort study was to evaluate the effectiveness and efficiency of protocol-driven EDOU stroke care at HUM.

Methods

Study setting

One of four academic medical centres in Haiti, HUM opened in 2013 in partnership between the Haitian Ministry of Health and the global non-profit Partners In Health. The HUM ED has around-the-clock dedicated physician staffing with an annual volume of approximately 14,000 visits per year. During the study, the ED was staffed primarily by generalist physicians and three Family Medicine-residency trained physicians; visiting American and Canadian EM faculty provided bedside teaching during daytime hours. Haiti's first EM residency program began at HUM in October 2014; new EM residents were trained by visiting EM faculty and by Haitian emergency care certificate-trained Family Medicine attendings.

Establishment of EDOU care at Hôpital Universitaire de Mirebalais

To determine the effectiveness and efficiency of protocolized EDOU care for ischemic stroke, we studied a planned phased EDOU implementation. In January 2014, the 15-bed ED added six beds in an adjacent room to create an EDOU. Initially, this space was used for informal, non-protocolized observation care. Hemodynamically stable patients needing prolonged ED stays were placed there at the ED provider's discretion. Physicians wrote unstructured general orders without standardized observation protocols. However, there were pre-existing general guidelines for stroke care and all ED physicians had received stroke care training.

From January–November 2014, a department committee developed and refined EDOU protocols via an iterative process based on a literature review of condition-specific protocols used in other settings and adaptation to the local context. In December 2014, we implemented nine evidence-based EDOU protocols, including one for ischemic stroke care. Subsequently, physicians provided standardized, protocol-driven EDOU treatment with checkbox EDOU order sets; additional orders could be added at their discretion. Protocols were introduced at staff meetings and reminders made on handoff rounds; nurses were encouraged to prompt physicians on protocol use. The ischemic stroke protocol (Appendix A) included medication recommendations for gradual blood pressure reduction, aspirin for secondary prevention, and instructions for patient education and a nursing swallow evaluation. It also included guidelines for discharge prescriptions and follow-up care. Protocol endpoints included a blood pressure under 160/90 or 170/90 mmHg (depending on the patient's arrival blood pressure) and the ability to swallow or presence of a nasogastric tube. The same PT evaluations and linkages to services were available to inpatients and EDOU patients.

Patient selection and data collection

We searched the electronic medical record to identify patients using the visit date and ED diagnosis. Trained research assistants screened for eligibility the medical records of all patients with a diagnosis of stroke, ischemic stroke, transient ischemic attack, cerebral vascular accident, or cerebral infarction. The research assistant then extracted data from eligible patient charts into a standardized data collection tool using REDCap [28]. The principal investigators reviewed the initial charts

Table 1
Descriptions of study comparison groups.

	Baseline group	Contemporary reference group	Study group
Description	Patients who would have been eligible for the EDOU stroke protocol, but were cared for prior to protocol implementation	Patients eligible for the EDOU stroke protocol and cared for after protocol implementation, but not managed on the protocol (either due to lack of space, provider choice, or because condition was not recognized as eligible for observation care).	Patients eligible for and cared for on the EDOU stroke protocol
Eligible visit dates ^a	January 1, 2014–November 30, 2014	February 1, 2015–September 30, 2015	February 1, 2015–September 30, 2015
Location of care	ED and/or inpatient service	ED and/or inpatient service	ED/EDOU; unless admitted from EDOU

ED: Emergency department.

EDOU: Emergency department observation unit.

^a To allow a run-in period for protocol implementation, we excluded patients seen in the two months after protocol implementation (December 2014 and January 2015).

entered for accuracy. Data extraction was not blind.

Group inclusion and exclusion criteria

This cohort study compared patients aged 18 years or older with presumed ischemic stroke in three groups (Table 1): a “baseline group,” a “contemporary reference group,” and a “study group.” Patients in all groups met all protocol inclusion criteria without any protocol-specific or general EDOU exclusion criteria (Fig. 1). Given our study utilized chart review, we could not determine why contemporary reference patients were managed without the EDOU protocol.

For all groups, we excluded patients whose total LOS (time from ED arrival to hospital departure) was ≤ 4 h or ≥ 7 days. Though our maximum LOS is well above what is expected in high-resource settings, we chose this because of local barriers to disposition and overall health system performance. We included patients if they met inclusion criteria without exclusions regardless of the location of care, as inpatient bed availability rather than clinical condition frequently determines where patients requiring short stays are treated. We analysed groups for differences in triage acuity, age, comorbidities, initial blood pressure, and days from symptom onset to ensure comparability. Given the limited nature of our electronic medical records, we only considered

comorbidities reported on the paper ED physician note, which has checkboxes for common comorbidities including prior stroke, heart failure, hypertension, renal insufficiency, and human immunodeficiency virus.

Definitions

HUM does not have MRI imaging to confirm an ischemic stroke diagnosis and has CT imaging only intermittently due to local resource constraints. When CT was available, we diagnosed ischemic stroke in patients with stroke-like symptoms with no mass or haemorrhage on a brain CT. When CT was unavailable, as is typical in most of Haiti, providers presume a diagnosis of ischemic stroke in patients with stroke-like symptoms without signs highly suggestive of haemorrhage, such as vomiting or depressed level of consciousness [29], and/or using decision aids developed for resource-limited settings [30,31]. Given potential benefits from aspirin use even if stroke type is unknown [32,33], providers are taught to give aspirin for presumed ischemic stroke even if haemorrhagic stroke cannot be excluded. For study patients without a CT scan, we defined stroke type by the provider's discharge diagnosis.

Study outcomes

The primary study outcomes were care quality and/or process measures for ischemic stroke care. Predefined quality measures were: 1) aspirin given in the ED [3,34], 2) documented swallow evaluation [34], and 3) PT evaluation or documented not to require PT evaluation. We also analysed rates of electrocardiogram (ECG) and head CT completion. The primary process measure was total LOS (time between ED check-in and hospital departure). If check-in time was not recorded, we substituted the first available time in the visit (e.g., triage time). To analyse linkage to care, we considered the number of patients seen in the hospital clinic for follow-up after discharge.

Data analysis

Data were analysed in SAS version 9.3 using *t*-tests, chi-squared, Fisher exact and ANOVA tests. We considered two-tailed *p*-values ≤ 0.05 significant. Our primary outcome was improvement in quality metrics between the baseline and study groups. As a secondary outcome, we assessed temporal trends by comparing the contemporary reference and baseline groups to evaluate if care quality changed over time when the protocol was not used. Similarly, we compared the study group to the contemporary reference group – the two groups post-protocol implementation – to further elucidate differences attributable to the protocol.

<p><u>Protocol exclusion criteria</u></p> <ul style="list-style-type: none"> • Non-responsive or responsive only to pain • SpO₂ <90% without supplemental oxygen • Blood pressure > 240/120 mmHg after medication • Hemorrhagic stroke^a • Atrial fibrillation <p><u>Protocol inclusion criteria</u></p> <ul style="list-style-type: none"> • Ischemic stroke^a • Blood pressure < 240/120 mmHg <p><u>General EDOU exclusion criteria</u></p> <ul style="list-style-type: none"> • Shock • Respiratory depression or failure • Depressed mental status
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Fig. 1. Inclusion and Exclusion Criteria for the Emergency Department Observation Unit (EDOU) Protocol for Stroke Management. ^aSince local resource constraints meant head CT scan was sometimes unavailable, providers were trained that both confirmed and presumed ischemic strokes could be included, while confirmed or presumed hemorrhagic strokes were excluded.

Table 2
Patient demographics and characteristics at time of presentation.

Characteristic	Baseline group (n = 82)	Contemporary reference group (n = 34) ^a	Study group (n = 22) ^b
Mean age ± SD (years)	64 ± 14	59 ± 15	58 ± 14
Mean initial Systolic BP ± SD (mmHg)	156 ± 37	157 ± 33	175 ± 28
Mean days since onset of stroke symptoms ± SD ^c	4.5 ± 4.9	4.4 ± 4.7	4.9 ± 7.1
Mean number of comorbidities ± SD	0.7 ± 0.6	0.8 ± 0.5	0.7 ± 0.6
Gender			
Male	34 (41%)	18 (53%)	2 (9.1%)
Female	48 (59%)	16 (47%)	20 (91%)
Triage acuity ^d			
Red (highest priority)	7 (9.0%)	2 (5.9%)	0 (0%)
Orange	21 (27%)	7 (21%)	8 (36%)
Yellow	39 (50%)	23 (68%)	13 (59%)
Green (lowest priority)	11 (14%)	2 (5.9%)	1 (4.5%)

p values for comparison between groups all > 0.05 except gender (p = 0.004). EDOU: Emergency department observation unit.

SD: Standard deviation.

mmHg: millimeters mercury.

^a EDOU-eligible (met protocol criteria) patients not cared for in the EDOU, visit date after protocol introduction.

^b EDOU patients cared for under protocol guidelines after protocolized care implementation.

^c Excludes 16 patient in the baseline group, seven in the contemporary control group and five in the study group missing values for days since onset of symptoms.

^d Excludes four patients in the baseline group missing a triage acuity.

Sample size

Assuming 50% of patients would achieve appropriate care quality metrics, with 80% power to detect a 20% difference between study and control groups and a two-tailed significance level of 0.05, the desired sample size was 93 in each group.

Ethical approval

This study was approved by institutional review boards at Partners Healthcare (Boston, USA) and Zanmi Lasante (Port-au-Prince, Haiti).

Results

138 patients met inclusion criteria: 82 whose visits occurred prior to EDOU protocol implementation (baseline group), 22 managed on the EDOU stroke protocol (study group), and 34 treated after protocol implementation but managed without the protocol (contemporary reference group). Study participants ranged in age from 18 to 90 years (mean 62 ± 14 years, Table 2). Patients presented an average of 4.5 days after symptom onset. Although the gender distribution differed between groups (p = 0.004), the groups' characteristics were otherwise similar.

Though the desired sample size was not met, patients managed on the EDOU protocol (study group) still met care quality measures at higher rates than both the baseline and contemporary reference groups (Fig. 2). Overall, 20/22 patients (91%) in the study group received aspirin, compared to 14/82 (17%, p < 0.001) and 8/34 (24%, p < 0.001) in the baseline and contemporary reference groups, respectively. Similarly, 11/22 patients (50%) in the study group had a PT consult, compared to 8/82 (9.8%, p < 0.001) and 6/34 (18%, p = 0.010) in the baseline and contemporary reference groups, respectively. Patients in the study group were also more likely to have a swallow evaluation (p < 0.001) (Fig. 2). The baseline and

contemporary reference groups did not differ significantly on the above measures (all p > 0.05).

Fewer contemporary reference patients had a head CT compared to the study (p = 0.003) or baseline groups (p = 0.002). Head CT rates were similar between the study and baseline groups (p = 0.35). More study group patients had an ECG done or followed up in clinic compared to the baseline group (p = 0.007 and 0.031 respectively, Fig. 2).

Almost all patients (92%) were managed entirely within the ED or EDOU; admission rates did not vary significantly between groups (Fig. 2). Among non-admitted patients, management on EDOU stroke protocol was associated with increased LOS (28 h, Table 3) compared to the baseline (19 h, p = 0.023) and contemporary reference groups (15 h, p = 0.006).

Discussion

Our study suggests that protocolized EDOU care can markedly improve care quality measures for patients with ischemic stroke. Patients cared with the EDOU stroke protocol were more likely to receive aspirin for secondary prevention and to receive PT and swallow evaluations. However, study group patients had longer LOS, likely because they received more treatments. To our knowledge, our study is the first to examine both EDOU care in an LIC setting and an EDOU stroke protocol in any setting.

Findings from this study support previous literature demonstrating that protocolized care improves care quality [12,35]. In our study, the percentage of patients receiving aspirin increased five-fold with the EDOU protocol: a simple measure with potential to improve long term outcomes [3]. Similarly, swallow evaluations and PT consultations can improve quality of life. Patients on the EDOU protocol had ECGs done at nearly twice the rate of the control groups. Since atrial fibrillation was an exclusion-criteria for our protocol, this may have reminded physicians to check an ECG, which may have identified some patients in need of anticoagulation to prevent future strokes, though we cannot verify this. Notably, these quality gains were achieved with low programmatic cost as the protocol featured inexpensive treatments, required minimal staff education, and had negligible administrative costs.

Though this study was observational, the difference in the study group compared with the contemporary reference group suggests the improvements were not due to temporal trends or changes in unmeasured confounders over time. The contemporary reference and baseline groups experienced similar care on most quality measures, while the study group received significantly higher care quality than both comparison groups. This implies neither time, increased training nor the presence of the EDOU protocol itself improved care quality without specific use of the protocol for patient management.

This study was not designed to determine if the observed care quality improvements require an EDOU, or if a similar protocol implemented without an EDOU resource could achieve comparable outcomes. However, the baseline care quality metrics were poor despite an existing stroke care protocol and previous provider trainings. Future studies should analyse the most effective components of the EDOU protocol: for example, checkbox order sets, defined outcomes for discharge, or protocols that empower nurses to prompt physicians for missing orders. In particular, the efficacy of checklists is well-documented and warrants future study [36,37]. Future studies should also examine how protocol compliance changes over time.

Though not a study endpoint, the significant delay between onset of stroke symptoms and presentation has important public health implications. Based on our experience, we suspect this represents a combination of barriers to accessing services and a need for community education about stroke. To reduce morbidity, health systems must improve time to presentation, encourage presentations for transient ischemic attacks and minor strokes, and strengthen secondary prevention. Future research should document the reasons for delays in accessing care.

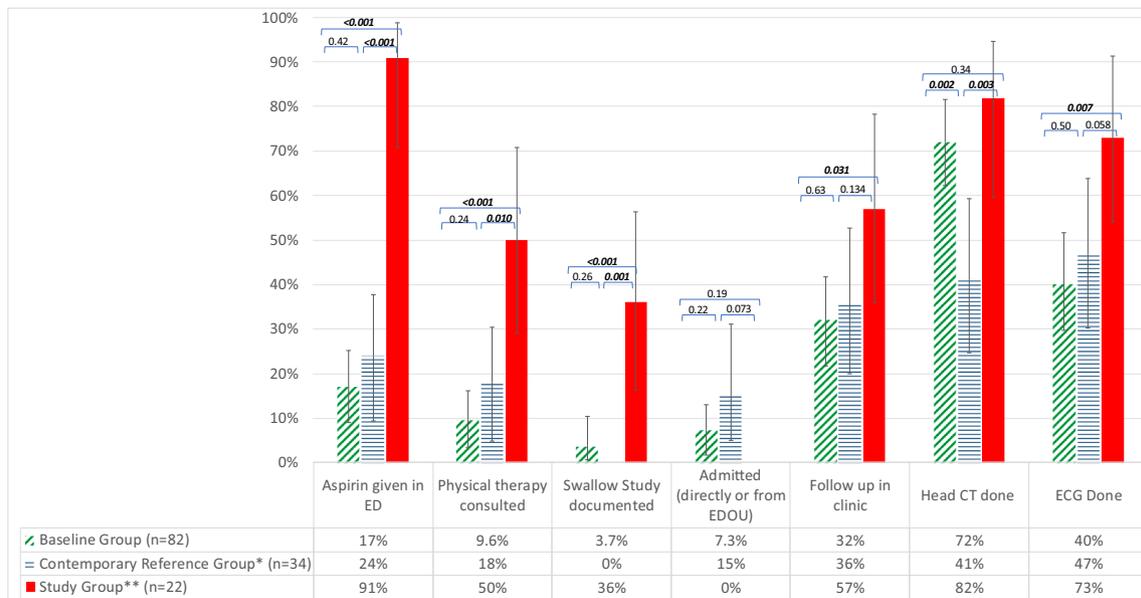


Fig. 2. Rates of achievement of stroke care quality measures between different study groups. Error bars reflect 95% confidence interval for each measure. p-Values for comparisons between groups shown above line connecting different study groups. p-Values in bold and italics met the 0.05 threshold for significance.

EDOU: Emergency department observation unit

*EDOU-eligible (met protocol criteria) patients not cared for in the EDOU, visit date after protocol introduction

**EDOU patients cared for under protocol guidelines after protocolized care implementation

Table 3

Effect of protocolized EDOU care on total length of stay.

	Baseline group	Contemporary reference group ^a	Study group ^b	Difference, study group to baseline group	Sensitivity analysis: difference contemporary reference to baseline (95% CI)
Mean total LOS, all patients (hours)	25 (n = 82)	23 (n = 34)	28 (n = 22)	3.0 (-10 to 16) p = 0.65	-2.4 (-14 to 8.9) p = 0.68
Mean total LOS, admitted patients (hours)	105 (n = 6)	67 (n = 5)	N/A (n = 0)	N/A	-38 (-101 to 24) p = 0.20
Mean total LOS, patients managed only in ED or EDOU (hours)	19 (n = 76)	15 (n = 29)	28 (n = 22)	9.3 (1.3 to 17) p = 0.023	-3.7 (-9.5 to 2.2) p = 0.22

ED: Emergency department.

EDOU: Emergency department observation unit.

CI: confidence interval.

LOS: Length of Stay.

Total LOS is time from ED check-in until departure from the hospital, either from the ED, EDOU or inpatient ward.

^a EDOU-eligible (met protocol criteria) patients not cared for in the EDOU, visit date after protocol introduction.

^b EDOU patients cared for under protocol guidelines after protocolized care implementation.

Fewer patients in the contemporary reference group had head CTs performed compared with the study and baseline groups. Like most LIC hospitals, HUM faces service constraints, and its CT scanner is sometimes out of service with no available alternative. Haemorrhagic stroke was an exclusion criterion, and though this was intended to mean presumed or proven haemorrhagic stroke, providers may have believed they could not use the protocol if the CT scanner was unavailable. However, differences in head CT rates between groups should not change our study's implications, as our objective was to evaluate care for presumed ischemic stroke. While some clinicians will have concerns about diagnosing ischemic stroke without cross-sectional imaging, the vast majority of patients in LICs cannot access neuroimaging [23]. Providers therefore use their best clinical judgement to determine stroke type and treat accordingly.

Interestingly, total LOS for all patients was similar between groups, but LOS for non-admitted patients (92% of all study patients) was significantly longer for the study group than either reference group. This

differs from high-resource settings, where EDOUs decrease hospital admissions, LOS, and costs [12,38]. In high-resource settings protocolized EDOU care is more efficient because a set of defined interventions occur by routine, rather than relying on independent practitioners' decision-making. The longer LOS in Haiti is likely because patients received few care interventions at baseline. Future studies are needed to determine the impact of longer LOS on ED operations and patient care, and to evaluate if LIC EDOU care is more time-efficient for other conditions. It may be that protocolized EDOU care in LICs primarily improves quality rather than efficiency of care.

Finally, to our knowledge, this is the first study of ischemic stroke care in an EDOU in any setting. While patients with transient ischemic attacks are routinely cared for in EDOUs in high-resource settings [39,40], to our knowledge, stroke patients are usually admitted. While the available treatments differ between regions, future studies should examine if a subset of stroke patients could be cared for in high-resource setting EDOUs.

This study was an observational study at a single rural referral centre in Haiti. Though generalizability to other settings is unknown, our hospital's disease burden is likely similar to hospitals in Haiti and other LICs. Though our sample size was below our target, our results were significant given a large effect size. Still, larger future studies should be considered. Like all chart review studies, our study cannot determine causality, is at risk of bias during data extraction, and is limited by the quality of documentation [41]. However, we used a standardized data collection tool to reduce bias and, reassuringly, our rates of missing data were low. Without an MRI, there was no way to confirm an ischemic stroke diagnosis and patients may have been misdiagnosed. However, since this study examined quality metrics based on presumed diagnosis, misdiagnosis should have limited effect on the results. Finally, baseline care quality was relatively weak; quality improvements may not be as significant in settings where care quality is higher.

Conclusion

Our results demonstrate that protocolized EDOU care for ischemic stroke in an LIC is feasible and improves care quality. This illustrates the value of protocolized EDOU care as a strategy to improve emergency care quality in settings where training and resources are limited. Further studies are needed to evaluate the impact of protocol-driven EDOU care on other amenable conditions.

Dissemination of results

Results from this study were shared with staff at the Hôpital Universitaire de Mirebalais emergency department through a presentation by Dr. Linda Rimpel during a staff meeting. Preliminary findings were presented as abstracts at the American College of Emergency Physicians Meetings in 2015 and 2016.

Authors' contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: SAR contributed 25%; RHM contributed 20%; LR contributed 15%; KA and MO contributed 7% each; MCE and KAC contributed 5% each; and ALB, GFK, CWB and JDS contributed 4% each. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

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Declaration of competing interest

CWB reports no conflicts of interest relevant to this work. CWB has received funding personally from Salix and Janssen Pharmaceuticals, Roche Diagnostics and Nabriva Therapeutics for advisory board work. CWB has received funding personally from Roche Diagnostics for speaking engagements. CWB has received funding personally from the US Department of Justice for expert testimony. The authors declare no further conflicts of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.afjem.2020.05.007>.

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