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ORIGINAL CONTRIBUTION

Risk assessment of the acute stroke diagnostic process using failure modes, effects, and criticality analysis

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Abstract

Introduction: To date, many emergency department (ED)-based quality improvement studies and interventions for acute stroke patients have focused on expediting time-sensitive treatments, particularly reducing door-to-needle time. However, prior to treatment, a diagnosis of stroke must be reached. The ED-based stroke diagnostic process has been understudied despite its importance in assuring high-quality and safe care.

Methods: We used a learning collaborative to conduct a failure modes, effects, and criticality analysis (FMECA) of the acute stroke diagnostic process at three health systems in Chicago, IL. Our FMECA was designed to prospectively identify, characterize, and rank order failures in the systems and processes of care that offer opportunities for redesign to improve stroke diagnostic accuracy. Multidisciplinary teams involved in stroke care at five different sites participated in moderated sessions to create an acute stroke diagnostic process map as well as identify failures and existing safeguards. For each failure, a risk priority number and criticality score were calculated. Failures were then ranked, with the highest scores representing the most critical failures to be targeted for redesign.

Results: A total of 28 steps were identified in the acute stroke diagnostic process. Iterative steps in the process include information gathering, clinical examination, interpretation of diagnostic test results, and reassessment. We found that failure to use existing screening scales to identify patients with large-vessel occlusions early on in their ED course ranked highest. Failure to obtain an accurate history of the index event, failure to suspect acute stroke in triage, and failure to use established stroke screening tools at ED arrival to identify potential stroke patients were also highly ranked.

Conclusions: Our study results highlight the critical importance of upstream steps in the acute stroke diagnostic process, particularly the use of existing tools to identify stroke patients who may be eligible for time-sensitive treatments.

KEYWORDS
diagnostic error, emergency medicine, patient safety, quality improvement, stroke

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INTRODUCTION

Reducing diagnostic error, defined as the failure to establish an accurate and timely explanation of the patient's health problem, is key to achieving high-quality and safe health care.[1] A substantial amount of diagnostic error related morbidity and mortality occurs in patients with vascular disease, including acute stroke.[2] Failure to diagnose acute stroke in a timely fashion can preclude delivery of time-sensitive stroke treatments resulting in adverse clinical outcomes[3,4] and occurs in nearly 10% of stroke patients.[5] Determining sources of diagnostic error among stroke patients being evaluated in the emergency department (ED), a setting with unique operating characteristics that predispose to human error,[6] is an essential first step toward reducing potential patient harms.[7] Many ED-based quality improvement studies and interventions for acute stroke patients have focused on expediting time-sensitive treatments, particularly reducing door-to-needle time,[8,9] rather than the essential first step of reaching an accurate and timely acute stroke diagnosis.

Neither the reasoning of clinicians nor the ED systems and processes, particularly tasks and communications, during the acute stroke diagnostic process have been well characterized.[1,10] Retrospective chart reviews and malpractice claims data have primarily been used to understand the ED diagnostic processes for acute stroke.[11,12] A failure modes, effects, and criticality analysis (FMECA), an engineering method, used initially in high-risk industries such as aerospace and nuclear power, but increasingly applied to health care, involves engaging stakeholders to describe the steps and workflows of a process and to identify the vulnerabilities or failures of each step and then to characterize their underlying causes, frequency, potential harm to the patient, and any existing safeguard(s) to mitigate or eliminate, using standardized scores.[9,13–15] Unlike other process improvement approaches, FMECAs help to counter most organizations' common temptation to focus on the most evident and visible failures, which may not be the most high-risk ones.[16] In this study, we conducted an FMECA of the acute stroke diagnostic process in the ED at three diverse health systems in Chicago, IL, to identify, characterize, and rank order opportunities for system redesign to improve acute stroke diagnostic accuracy and timeliness.

METHODS

Study design and setting

Between October 2020 and May 2021, we conducted an FMECA of the acute stroke diagnostic process at three health systems in Chicago, IL (Table 1). All systems use a "hub-and-spoke" model and participants from both primary stroke centers (PSCs; $n = 2$) and comprehensive stroke centers (CSCs; $n = 3$) were included. Institutional review board approval was obtained at each health system with study participants providing verbal informed consent prior to participation in the study. We use the Standards for Reporting Qualitative Research to report our findings.[17]

TABLE 1 Characteristics of participating health systems

	CSC	PSC	Estimated annual ED visits	Estimated annual stroke hospitalizations
Northwestern University	1	1	145,012	910
Rush Medical Center	1	1	106,096	1095
University of Chicago	1	0	108,188	830

Abbreviations: CSC, comprehensive stroke center; PSC, primary stroke center.

Participants

A learning collaborative (LC) approach was used to conduct the FMECA. LCs have been used increasingly and effectively in health care by bringing together multidisciplinary stakeholders to collectively understand, design, and implement quality and safety interventions. An LC model typically includes: (1) setting a defined and targeted goal, (2) including multidisciplinary teams, (3) including content or domain experts, and (4) holding frequent sessions with sharing of data and experiential learning.[18]

LC participants were recruited by each site's stroke program coordinators. The LC included stroke program coordinators (four nurses), ED physicians (three attending and two resident), neurology physicians (four attending and two resident), one ED nurse manager, ED technicians (two, one of whom is also an emergency medical technician), one radiology technician, and one radiologist. All 20 participants received a modest remuneration (gift certificate) for participation in each LC session.

LC sessions

A total of two 90-min and four 60-min sessions were held. All sessions were held via videoconference due to the COVID-19 pandemic and audio recorded. Research team members with expertise in qualitative research kept field notes during each session. Sessions were scheduled in advance with a several-week interval to ensure high levels of participation.

Process mapping

The first two LC sessions focused on defining the boundaries of the FMECA and performing a "walk down" of the current process from each LC participant's perspective. The scope of the acute stroke diagnostic process considered in this FMECA begins when an ED clinician becomes aware (e.g., emergency medical services [EMS] prenotification, triage nurse identification of a potential acute stroke) of a suspected acute stroke patient and ends at the point at which a diagnosis is made or, if no definitive diagnosis is made, when

a decision about acute treatment and/or hospital admission is made. Participants were asked to describe, in their own words, their roles, tasks, activities, and communications from the beginning to end of the acute stroke diagnostic process. Participants were also encouraged to describe their cognitive and reasoning steps as well as work system components influencing their clinical decision making, using a "think-aloud" approach. The think-aloud approach is a well-studied method of making clinical reasoning processes more explicit and is often used in graduate medical education to train inexperienced clinicians.[19]

Two investigators (J.L.H. and E.R.) documented each described role, task, activity, or communication and cognitive step on the chat board of the video conferencing platform and, then, iteratively, with feedback from LC participants, reordered them to represent the sequence of steps of the acute stroke diagnostic process from the perspective of all participants. The research team leveraged a previously developed process map, focused on interhospital transfer processes for acute stroke patients[15] and incorporated the information from the LC sessions to create a preliminary acute stroke diagnostic process map (Microsoft Visio 2019). Additional brief videoconference sessions were held with select participants for map clarifications. The preliminary process map was then sent to all LC participants via email, and participants were asked to document any additions, deletions, or corrections and send them back to the research team. The research team further refined the process map based on participant feedback. A final LC session was held for all participants to review, reach consensus, and approve a final process map representing a generalizable acute stroke diagnostic process.

Risk table creation

The final process map was then used by participants to complete a risk table during four additional LC sessions. For each step in the process map, LC participants were asked to systematically identify potential vulnerabilities or failures and their underlying causes. They were then asked to estimate and score for each failure its (1) frequency, (2) harm or impact to a patient, and (3) strength of existing safeguards. A standardized FMECA risk assessment scoring matrix was used to score the frequency, impact, and safeguard characteristics of each failure that was developed prior to the third LC session (Figure 1). Participants were encouraged to review any relevant incident reporting records as well as stroke care quality data, typically collected to maintain PSC or CSC certification, to estimate their scores. To score failures, we used a consensus procedure wherein participants discussed the perceived level of risk of particular work system vulnerabilities based on their review of institutional data as well as their individual clinical experiences.[20] Scores were then used to calculate a risk priority number (RPN; frequency × safeguard × harm) or criticality number (CN; frequency × harm) for each failure. RPNs and CNs were then ranked to prioritize the most critical or high-risk failures for targeted interventions and/or system redesign. After all sessions were completed, the final risk table was presented to the LC for additional comments and feedback, a form of member checking.[21]

RESULTS

A total of 28 steps were identified in the acute stroke diagnostic process (Figure 2). The process begins with multiple ways for patients to arrive in the ED, with or without ED prenotification by EMS from the field. Regardless of ED arrival modality, activating a stroke code in triage triggers a series of parallel diagnostic processes, including a head CT and a neurology consultation either by telestroke at PSCs or by an in-house neurology physician at CSCs. If a stroke code is not activated either before or upon patient ED arrival, obtaining a head CT and neurology consultation occurs after completion of multiple linear steps. Many steps in the diagnostic process are iterative and include obtaining a focused medical history, including comorbidities, risk factors for stroke, and medications, and establishing a last known well (LKW) time, conducting a physical examination, and gathering information about the presenting illness/event from collateral sources. Important cognitive steps, described by LC participants, include determining whether (1) reported signs/symptoms are new, (2) the examination includes a measurable neurological deficit, (3) the neurological findings are consistent with acute stroke, and (4) the neurological findings suggest a large-vessel occlusion (LVO).

The 10 highest risk failures, ranked by RPN and CN, are shown in Table 2. The majority of the failures occur at the early stages of the ED acute stroke diagnostic process. Failure to use a tool to identify the subgroup of patients with possible LVO (e.g., Rapid Arterial oCclusion Evaluation [RACE] scale[22] or Los Angeles Motor Scale [LAMS])[23] early in the acute stroke diagnostic process was the highest ranked risk. Use of an acute stroke screening tool early in the diagnostic process to identify potential stroke among patients with neurological complaints (e.g., Recognition of Stroke in the Emergency Room [ROSIER] scale)[24] was also a high-risk failure. Lack of familiarity and ease of use of these screening tools by clinicians (e.g., ED nurses, physicians) was described as a key underlying cause of the failure. Additionally, unusual and complex clinical presentations that were not obviously suggestive or stroke were a source of failure to use stroke screening tools.

Failure to accurately and rapidly gather history of the present event or illness early in the diagnostic process and to establish a LKW time was also highly ranked. Inability to obtain information directly from the patient, for example, due to aphasia at ED arrival or cognitive impairment at baseline, is frequent (>50% of patients). Inability to obtain key event details from family members or bystanders, if present at the time of symptom onset, as well as failure of EMS providers to obtain and/or share such information with ED clinicians are also high-risk failures. All highly ranked failures lead to missed or delayed stroke diagnosis, except for *false-positive* acute stroke diagnoses wherein delayed or missed diagnosis of other serious conditions (e.g., seizure, sepsis) are potential adverse consequences.

Score	EFFECT/IMPACT/CONSEQUENCE OF FAILURE (Severity)		FREQUENCY OF FAILURE (Occurrence)		EXISTING SAFEGUARD (Detection)	
1	None	No reason to expect failure to have any effect on safety, health, environment, or mission.	None	1/10,000	Almost Certain	Current control(s) almost certain to detect failure mode. Reliable controls are known with similar processes.
2	Very Low	Minor disruption to process. Repair of failure can be quickly accomplished through verbal communication/phone call. No process delay. **Example: Blood glucose level not documented by nurse.**	Very Low	1/5,000	Very High	Very high likelihood current control(s) will detect failure mode. • Automatic mean of detection that prevents the process from continuing. **Example: EPIC: automated AS screening scale that if > threshold requires performance of severe stroke/LVO scale.**
3	Low	Minor disruption to process. Minor process delay (~1–4 min). **Example: Radiology tech pager not working; no AS screening scale performed in field.**	Low	1/2,000	High	High likelihood current control(s) will detect failure mode. • Semiautomatic mean of detection **with warning** that does not prevent the process from continuing. **Example: A pop-up window with a reminder of how long the patient has been in the ED.**
4	Low to Moderate	Moderate disruption to process. Minor to moderate process delay (~5–9 min). **Example: No ED prenotification of possible AS by EMS; AS screening scale not performed in triage.**	Low to Moderate	1/1,000	Moderately High	Moderately high likelihood current control(s) will detect failure mode. • Semiautomatic mean of detection that does not prevent the process from continuing. **Example: A pop-up window of differential diagnosis of stroke that does not require any action.**
5	Moderate	Moderate disruption to process. Moderate process delay (~10–19 min). **Example: Stroke symptoms not recognized by "greeter"/nurse; neurology resident/telestroke MD delay in responding.**	Moderate	1/500	Moderate	Moderate likelihood current control(s) will detect failure mode. • *Double human* review with a checklist or standard aid or *triple human* review without checklist or standard aid. **Example: Neurology MD (after EMS, triage nurse and/or ED MD) reviews history and physical examination without checklist or standard aid.**
6	Moderate to High	Moderate disruption to process. Moderate to high process delay (~20–29 min). **Example: Patient unable to report LKW and no family present in ED; no contact information in EMS record to gather "event" history from family.**	Moderate to High	1/200	Low	Low likelihood current control(s) will detect failure mode. • *Single human* review with a checklist or standard aid or *double human* review without checklist or standard aid. **Example: ED MD (after EMS and/or triage nurse) gathers history of event and performs physical examination without a checklist or standard aid.**
7	High	High disruption to process. Significant process delay (≥30 min). **Example: Stroke code not activated at triage; no severe screening stroke/LVO screening scale used and patient needs to return to CT scanner for a CTA.**	High	1/100	Very Low	Very low likelihood current control(s) will detect failure mode. • Formal single human review without aid/checklist; review is routinely part of the process. **Example: Neurology MD gathers history of event.**
8	Very High	Very high disruption to process. Significant process delay. **Example: Walk-in patient, stroke symptoms not recognized by greeter or by triage nurse: patient waits hours before evaluation.**	Very High	1/50	Remote	Remote likelihood current control(s) will detect failure mode. • Informal single human review without aid/checklist (review is not routinely part of the process). **Example: CT technician asks if CTA is needed after CT.**
9	Hazard	Potential safety, health or environmental issue.[1] **Example: tPA treatment delivered to nonstroke patient with hemorrhagic complication; missed opportunity to give tPA/EVT treatment, due to false-negative diagnosis and lapsed treatment window.**	Very High	1/20	Very Remote	Very remote likelihood current control(s) will detect failure mode. • No human review done at the time of the event. **Example: Monthly (after the fact) review of AS cases, including false negative, false positive.**
10	Hazard	Potential safety, health, or environmental issue.[2] **Example: Protocol violation: treatment outside 4.5-hr window or with absolute contraindication to tPA; missed tPA/EVT resulting in death; missed hemorrhagic stroke with herniation**	Very High	1/10+	Almost Impossible	No known control(s) available to detect failure mode. **Example: Stroke symptoms not recognized.**

FIGURE 1 Standardized scores of FMECA to optimize acute stroke diagnostic process. AS, acute stroke; EVT, endovascular thrombectomy; FMECA, failure modes, effects, and criticality analysis; LKW, last known well; LVO, large-vessel occlusion; tPA, tissue plaminogen activator.

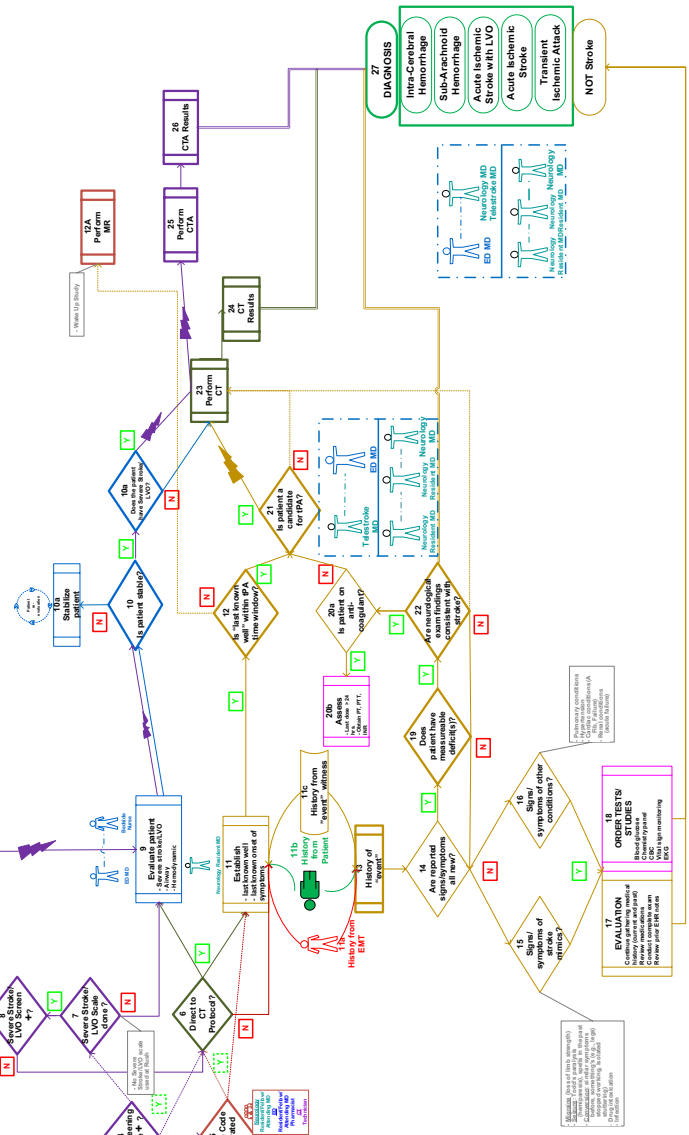

FIGURE 2 Final process map. AS, acute stroke; LVO, large-vessel occlusion; tPA, tissue plaminogen activator.

TABLE 2 Highest ranked failures in the AS diagnostic process

Step number	Description of step	Potential failures	Examples of failure causes	Effect/consequence	RPN (F×I×S)	Criticality number
7	LVO/severe stroke scale performed	• Not done routinely by triage or bedside nurse • Screening tools have an inane error rate	• Provider lacks experience with scale or skill in assessing the scale • Failure to suspect a LVO	• Delay in getting CTA • Delay in initiating transfer to CSC for LVO treatment	432 (6×9×8)	72
11a	Obtaining history from ET)	• No or limited history of current event from on scene providers • No information about LKW time or onset of symptoms	• EMT called away • ED team too busy to get EMT report • EMT definitions of LKW time differ from that of Neurology team or cognitively limited	• Delay in determination of whether signs and symptoms are suggestive of an acute stroke	432 (6×9×8)	48
11b	Obtaining history from patient	• Patient unable to provide necessary information (e.g., LKW, signs and symptoms) • Patient does not know if taking anticoagulant	• Patient transferred from nursing home with little information and patient does not talk or cognitively impaired at baseline • Patient unable to speak because of current event • Symptoms present upon awakening from sleep makes it difficult to establish LKW time	• Delay in determination of whether signs and symptoms are suggestive of an acute stroke • Not knowing LKW can lead to delay in treatment or treatment not offered	432 (9×6×8)	48
2	Triage assessment of suspected acute stroke	• Signs of stroke not recognized in a "walk-in" patient • Stroke symptoms not reported or elicited	• Patient does not provide history suggestive of acute stroke • Unusual/inconsistent reported symptoms • Unusual/inconsistent physical findings	• Delay in suspected stroke diagnosis • Delay in stroke code activation	384 (6×8×8)	48
3	Acute stroke screening scale performed	• Stroke screening scale not used	• Patient unstable • Patient with signs/symptoms suggestive of other acute diagnosis • Signs or symptoms or acute stroke not recognized	• Delay in suspected stroke diagnosis • Delay in stroke code activation	384 (6×8×8)	48
11	Establish LKW time and symptom onset	• Inability to get information about LKW or symptom onset	• Patient unable to provide information about stroke event • No family member/witness available to provide information • EMS did not gather information at the scene	• Delay in determination of whether signs and symptoms are suggestive or an acute stroke	384 (8×6×8)	48
11c	Obtain history from "event" witness	• No witness of event • No contact information for a witness	• Witness not able to come to the ED • EMS did not gather contact information from the witness • Poor documentation of contact information in existing electronic health record	• Delay in determination of whether signs and symptoms are suggestive of "acute" stroke	378 (9×6×7)	42
13	Obtain history of "event"	• No family member/witness available to provide information • EMT did not attempt to gather information • Inconsistent or unclear history from patient/family	• Patient cannot distinguish dizziness versus lightheadedness • Patient/family does not recognize and report gaze deviation • Patient does not know if currently taking an anticoagulant	• Delay in determination of whether signs and symptoms are suggestive of "acute" stroke	336 (8×6×7)	42
1	ED pre-notification of a potential acute stroke	• False positive stroke called in	• Complex patient assessment (e.g., patients with altered neurological baseline) • EMT experience and facility with stroke scale • Multiple different acute stroke scales used at different centers	• Delayed diagnosis of serious conditions other than stroke (e.g., seizure, sepsis) • Treatment delay of other serious conditions (e.g., fluid resuscitation, anticonvulsant administration)	324 (9×6×0)	54
2a	Initial ED assessment of suspected acute ischemic stroke	• Acute stroke screening scale not used	• First ED contact does not suspect stroke - Signs of stroke are not reported or detected	• Delay in diagnosis • Delay in being sent to triage • Delay in stroke code activation	288 (6×8×6)	48

Abbreviations: EMT, emergency medical technician; RPN = F×I×S; LKW, last known well; LVO, large-vessel occlusion; RPN, risk priority number.

DISCUSSION

In a multicenter FMECA, using a LC approach, we created a comprehensive, generalizable process map of the acute stroke diagnostic process in the ED, focusing on an essential process prior to initiation of any acute stroke treatment. The multiple iterative steps identified in the acute stroke diagnostic process include information gathering, clinical examination, interpretation of diagnostic test results, and reassessment. Failure to use, early in the process, existing stroke screening scales, determine LKW, and obtain an accurate history of the event were the highest ranked failures in terms of criticality and risk.

Our FMECA results highlight the critical importance of early consideration and identification of acute stroke in ED patients. Indeed, no high-risk or critical process failures in diagnosis occurred after Step 13. Therefore, facilitating consistent and broad use of existing stroke screening tools as well as risk stratification tools once stroke is suspected is warranted. Additionally, developing clinical decision support to facilitate early consideration of stroke by clinicians who triage and/or initially assess ED patients may also help improve stroke diagnostic accuracy and avoid anchoring.[25] Interventions, including early involvement of stroke specialists, focused on stroke detection among patients presenting with atypical symptoms (e.g., altered mental status, coma, generalized weakness) who we found to be sources of potential failures in Steps 1–3 and whom other researchers similarly have noted are at increased risk of ED misdiagnosis,[3,5] may be particularly helpful. At our study sites, following the multimodal needs assessments of which this FMECA was one component, we engaged the LC in ideation of potential solutions, rank ordering of proposed solutions, and finally a series of design sessions of the highest ranked solutions. Three solutions have been designed: redesign of the stroke code team to formalize roles and responsibilities and distribute tasks across all team members, use of a real-time communication tool by stroke code team members to share information, and creation of an automated best practice alert to reduce false-negative strokes in the ED. Participating sites are now implementing these solutions and will evaluate their effectiveness in improving acute stroke diagnosis.[26]

In this FMECA we found that the most critical step in the ED diagnostic process was screening suspected stroke patients for LVO. Accurate and timely diagnosis of LVO in the subgroup of acute stroke patients potentially eligible for acute endovascular therapy or thrombolysis was of greater importance than detecting stroke among patients ineligible for these treatments or avoiding acute stroke overdiagnosis. This finding likely also reflects the fact that our method of ranking various process failures heavily weighs failures that impact patients' clinical outcomes; delayed thrombolysis or thrombectomy are associated with poorer functional outcomes.[27,28] Interestingly, the imperfect sensitivity and specificity of existing stroke and LVO screening scales was not noted as a critical source of diagnostic failure in our FMECA.[29] Stroke location (e.g., anterior versus posterior circulation) was also not mentioned by LC participants as a source of diagnostic failure, although unusual/inconsistent stroke symptoms and signs were reported.

In our process map, obtaining magnetic resonance imaging (MRI) of the brain was a much further downstream step from initial patient evaluation for the majority of suspected acute stroke patients and failure to obtain MRI of the brain was not highly ranked by study participants. Though it is well established that MRI of the brain is the criterion standard test for cerebral infarction,[30] it is neither practical nor feasible to image all suspected acute stroke patients in the emergency setting.[31] Prior research has shown that symptom characteristics (e.g., duration, rate of onset),[32] initial examination findings (e.g., motor deficits),[33–38] and the use of risk stratification tools can be diagnostically useful and, in some cases, may be superior to a MRI for patients experiencing cerebrovascular ischemia.[39] Improving access to MRI of the brain in the ED, based on our findings, does not appear to be a high-yield strategy to improve acute stroke diagnostic accuracy.

LIMITATIONS

Our study has several limitations. First, neither patients nor caregivers participated in the LC, since the focus was to elucidate the steps and failures in the acute stroke diagnostic process, which is primarily executed by clinicians. However, patients and caregivers are also stakeholders.[40] Second, scoring of potential failures was necessarily based on participants' informal review of their individual hospital system incident reports, stroke-related operational data, and their own clinical experiences making it possible that participants may have over- or underestimated the frequency, severity, or strength of a safeguard of a failure. However, using consensus scoring methods rather than an exclusively mathematical approach as well as the use of real-world data enhances the content validity of our approach.[20,41] Third, while we encouraged LC participants to use the think-aloud approach to detail their clinical reasoning processes steps, we did not engage in detailed discussions of actual or potential cognitive errors that may play an important role in diagnostic inaccuracy.[25] Finally, the generalizability of our findings may be limited beyond urban and suburban centers since, although clinicians from three diverse health systems were part of the LC, all participating sites are in Chicago and neighboring suburbs.

CONCLUSIONS

This study has resulted in the first process map of the acute stroke diagnosis process in the ED and, thus, illustrates the novel use of an failure modes, effects, and criticality analysis to evaluate an important medical diagnostic process. Our findings suggest that future ED-based quality improvement work to reduce stroke misdiagnosis should focus on essential upstream steps, such as early consideration of stroke as a potential diagnosis as well as the consistent use of existing stroke and large-vessel occlusion screening tools to improve stroke detection.

CONFLICT OF INTEREST

The authors declare no potential conflict of interest.

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