Application of a Proactive Risk Analysis to Emergency Department Sickle Cell Care

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Supervising Section Editor: H. Bryant Nguyen, MD, MS
Submission History: Submitted November 18, 2013; Revision Received March 20, 2014; Accepted April 23, 2014
Electronically Published June 6, 2014
Full text available through open access at http://escholarship.org/uc/uciem_westjem
DOI: 10.5811/westjem.2014.4.20489

Introduction: Patients with sickle cell disease (SCD) often seek care in emergency departments (EDs) for severe pain. However, there is evidence that they experience inaccurate assessment, suboptimal care, and inadequate follow-up referrals. The aim of this project was to 1) explore the feasibility of applying a failure modes, effects and criticality analysis (FMECA) in two EDs examining four processes of care (triage, analgesic management, high risk/high users, and referrals made) for patients with SCD, and 2) report the failures of these care processes in each ED.

Methods: A FMECA was conducted of ED SCD patient care at two hospitals. A multidisciplinary group examined each step of four processes. Providers identified failures in each step, and then characterized the frequency, impact, and safeguards, resulting in risk categorization.

Results: Many "high risk" failures existed in both institutions, including a lack of recognition of high-risk or high-user patients and a lack of emphasis on psychosocial referrals. Specific to SCD analgesic management, one setting inconsistently used existing analgesic policies, while the other setting did not have such policies.

Conclusion: FMECA facilitated the identification of failures of ED SCD care and has guided quality improvement activities. Interventions can focus on improvements in these specific areas targeting improvements in the delivery and organization of ED SCD care. Improvements should correspond with the forthcoming National Heart, Lung and Blood-sponsored guidelines for treatment of patients with sickle cell disease. [West J Emerg Med. 2014;15(4):446–458.]

INTRODUCTION

Sickle cell disease (SCD) is a painful, chronic, genetic condition that affects 90,000-100,000 individuals in the U.S.[1] and shortens life expectancy to around 40 years.[2-5] While there is wide variation in the use patterns of healthcare by SCD patients, particularly of emergency department (ED) care, there is also substantial evidence of generally poor quality of care for SCD patients in the ED.[6-8] The Emergency Department Sickle Cell Assessment of Needs and Strengths (ED-SCANS, http://sickleemergency.duke.edu/) was developed as a quality improvement (QI) framework for seven key clinical processes of SCD ED care. Patient and clinician characteristics make providing care to persons with SCD in the overcrowded ED a challenge.[6,9,10] The diminishing of attention to pain and pain management in the ED, partially due to crowding, often results in delays to analgesic medication administration.[11]

A FMECA, a prospective quality improvement and patient

safety approach, was applied and sought to identify and qualify risk contributors, often generic, to failed processes and systems. Through risk binning, that is attributing high to low risk characteristics to each process, as well as characterizing the frequency and existing safeguards of these potential adverse events, systems and processes can be assessed as to the consequences of failure and their likelihood as causative factors. The FMECA approach was developed by engineers and originally employed in high-risk industries, such as aeronautics, aerospace, and nuclear power, to identify potential system and process vulnerabilities.[12] It has been increasingly applied to complex healthcare processes, including intravenous drug administration, blood transfusion, and sterilization of surgical instruments.[13-23] In healthcare, a FMECA is conducted through multidisciplinary meetings with clinicians and staff who are involved with and knowledgeable about the system and processes under investigation with the goal of eliciting and generating a comprehensive description of all steps in a defined, specific clinical care process. Although time and resource intensive, a FMECA can provide a robust assessment of potential risks in the healthcare processes and systems and serve as the platform for significant process improvement and system redesign.[24]

We selected this approach over several other quality improvement approaches including value atream mapping (VSM) and root cause analysis (RCA). VSM seeks to identify those events which lead to "waste" of resources, especially time, i.e., process inefficiencies; our aim was not to evaluate the overall waste of resources.[25] RCA was not selected because it evaluates a system event after its occurrence and evaluates trends and assesses risks of underlying causal factors. Our goal was to evaluate specific processes of care in each ED, not in response to a specific event.

Caring for persons with SCD in the ED is complex from a medical, psychosocial, and health services utilization perspective. Pain associated with vaso-occlusive crises (VOC) remains the most common complaint of SCD patients seeking care in the ED.[26] Additional reasons for ED visits include other medical complications not limited to chronic anemia, iron overload from multiple transfusions, ischemic and hemorrhagic strokes, acute chest syndrome, pulmonary embolism, pneumonia, and renal failure.[3] VOC requires parenteral analgesics and is highly time sensitive due to the mortality risk of ischemic or infectious complications.[27,28] Current guidelines for the management of VOC from NHLBI and the American Pain Society recommend the following: (1) immediate assessment and differentiation of typical pain episodes from other complications of SCD; (2) rapid assessment and determination of pain medication requirements and pain control with opioids within 15-20 minutes of ED arrival; and (3) re-assessment of pain every 15-30 minutes.[29,30] These current guidelines are outdated, especially in this age of ED crowding, with unrealistic expectations of door to first dose of 30 minutes, and repeat doses reduced by one-quarter to one-half the initial dose. In an effort to provide more current, evidence based practice for treating SCD, the National Heart Lung and Blood Institute formed an Expert panel to develop evidence-based guidelines. This report will be published in 2014.

Clinicians, however, report significant barriers to following recommended guidelines in the ED and frustration with the care and management of SCD patients. Some perceive SCD patients to be "drug seeking" and many providers report a lack of understanding of opioid requirements for SCD and other chronic pain patients, especially those on chronic daily opioid therapy.[31] Clinicians are reluctant to order and administer appropriate high-dose opioids, resulting in delays and sub-therapeutic treatment of VOC episodes.[6,31] A further frustration of ED clinicians is the frequent use of the ED by a small fraction of patients with SCD, who may make 100 or more visits over several years.[6,32,33] The research team hypothesizes that the population of SCD patients with such intense ED use may well have other significant neurocognitive deficits and unmet psychosocial healthcare needs that lead to such dramatically high ED use. Ultimately, care of the patient with SCD in the ED is multifaceted and complex.

The aim of this project was to 1) explore the feasibility of applying a failure modes, effects and criticality analysis (FMECA) in two EDs examining four processes of care (triage, analgesic management, high risk/high users, and referrals made) for patients with SCD, and 2) report specific failures of these care processes in each ED.

METHODS

Study Design and Sample

We conducted a prospective FMECA at two urban EDs in the Southeastern United States, each affiliated with an academic medical center and with an emergency medicine residency training program. Site 1 had an adult ED patient volume of about 61,000 in 2011, with nearly 600 SCD visits annually. Site 2 had an adult patient volume of 73, 000 in 2011, with nearly 500 annual SCD visits.

We recruited FMECA participants because of their involvement with and knowledge of the care of SCD patients in the ED. Participants at each site included representatives of ED physician and nursing leadership, ED physicians and nurses, an ED pharmacologist, ED and hospital social workers. Select members of the Sickle Cell Clinic team (hematologists, nurses, one physician assistant, nurse practitioner, social worker, and educator) also participated. One patient with SCD who received care at each site was also recruited to contribute. Members received a $75 gift card for participation. Two in-person FMECA sessions were held at each of the two sites. The project was approved by the institutional review boards at both study sites and participants provided written consent.

Procedures

Quality Improvement Framework: Emergency Department

Sickle Cell Assessment of Needs and Strengths (ED-SCANS)

Four of the seven processes recommended by the ED-SCANS were selected for analysis during the FMECA. The ED-SCANS is a decision support tool developed as a quality improvement framework to address the complex healthcare needs of SCD patients in the ED; it is comprised of seven algorithms (http://sickleemergency.duke.edu/).[10] The ED-SCANS can be used to guide the clinical management of individual SCD patients in the ED and develop best practice protocols to support their care in that setting. Four algorithms -- (1) triage; (2) analgesic management; (3) identification of the high risk/user; and (4) need for referrals to a physician or for psycho-social support if discharged home -- were the focus of desired QI activities and this FMECA. Due to the complexity of conducting a FMECA to analyze four processes, we determined that processes relevant to the other three ED-SCANS algorithms (diagnostic evaluation, disposition, and need for an analgesic prescription if discharged home) would not be assessed. Future work would be necessary to analyze these processes. A brief description of each of the four algorithms is outlined below:

1. Triage: Assessment of vital signs and chief complaints suggestive of something other than pain related to a VOC and assignment of a triage priority score.
2. Analgesic management: Individualized pain management, or generic departmental pain management protocols, or weight-based or patient-controlled analgesia (PCA) opioid dosing regimens
3. Assessment of the high ED user/high risk patient: Defined as patients with more than 3 ED visits or hospitalizations/year, SCD patients who do not have a primary care provider (PCP), or have other difficulties obtaining appointments, and SCD patients who are pregnant; and
4. Referrals: Identification and coordination of medical and psycho-social referrals made in the ED for discharged patients.

Session 1: Process Mapping.

In the first FMECA session at each site, the research team explicitly identified the process boundaries of ED SCD care for each of the four processes (triage, analgesic management, identification of the high- risk or high-user patients, and referral). Participants were encouraged to describe their own involvement, tasks, and experiences during the process of caring for an SCD patient and to comment on routinely used "workarounds" or "shortcuts" rather than recite hospital protocols and policies.[13,34-37] After completion of Session 1, the research teams translated the description of each of the four SCD processes into site-specific process maps for each decision (Microsoft Visio 2010; Microsoft Corporation, Redmond, WA). The researchers then used the process maps to create a site-specific FMECA risk assessment chart for each decision, a document that listed all ED SCD care process steps, using Excel software (Microsoft Excel 2010; Microsoft Corporation, Redmond, WA).

Session 2: Risk assessment.

During the second FMECA session at each site, participants were given each of the four site-specific process maps. These maps were used to populate the 'process step" column of the FMECA risk assessment charts developed for each process (triage, analgesic management, high risk/higher user, and referrals) at each site. To complete the risk assessment charts, participants systematically reviewed each process step for each process map, and identified, for each step, weak points or failures and their causes (failure mode causes). Next, FMECA participants, as a group, estimated the frequency of each identified potential failure and the likely consequences for the patient of each identified potential failure.

Finally, to qualify the most critical systematic and process failures, the research team applied a method, developed by the US Department of Energy and adapted for healthcare, in which each potential failure is categorized by a "risk bin," depending on its frequency and consequence scores.[36] The process of risk binning permits the prioritization (from highest to lowest by significance and frequency) of failures for selection for targets of QI initiatives and efforts. Following the second session, researchers met with individual participants, as needed, to fill in any perceived gaps in the risk chart.

In Session 2, frequency of a potential failure was measured as remote (F1), uncommon (F2), common (F3), or frequent (F4). Consequences to the patient of each identified potential failure were measured as none (C1), some (C2), serious (C3), or significant or certain (C4). Criticality risk bins were categorized as low, medium or high (Table 1). A failure with a high frequency score (F4) and a high consequence score (C4), for example, was ranked as a "high" criticality failure, whereas a failure that occurred at a high frequency rate (F4) but had little consequence (C1) was scored as a "low" criticality failure.[38] Safeguards for the processes were explored and rated as (S1) if a formal policy or procedure was in place to prevent the failure, (S2) if the process was a standard of practice with no policy in place, and (S3) if there was nothing. For example, a policy existed at Site 1 that allowed the triage nurse to obtain an analgesic order from a physician in the event of delayed placement in a treatment space. This was rated as (S1), to address the risk of delays to analgesic administration, despite the existence of a policy and procedure, in the event of crowding.

Data Analysis

All sessions were digitally recorded and transcribed, and the research team also took detailed field notes. After the first and second sessions, FMECA participants were asked, independently, to review their site-specific process maps and risk charts and to offer revisions or corrections and researchers met with individual participants, as needed, to fill in any gaps. We then examined the final four process maps and FMECA risk assessment charts from each site to identify similar and different risks across both study sites.

Table 1. Risk matrix for frequency and consequence of a failure.

Frequency	Consequence			
	CP1 none	CP2 some	CP3 serious	CP4 significant
F1 remote	Low	Low	Low	Medium
F2 uncommon	Low	Low	Medium	Medium
F3 common	Low	Medium	Medium	High
F4 frequent	Low	Medium	High	High

Table used with permission and adapted from G Coles, B Fuller, K Nordquist, et al. Three Kinds of Proactive Risk Analyses for Health Care. *Joint Commission Journal on Quality and Patient Safety*. 2010; 36:365-375, Appendix A.

Table 2. Participants by site in a risk assessment analysis related to patients with sickle cell disease (SCD).

Provider Type/site	Number of participants	
	Site 1	Site 2
Hematologist	1	1
Emergency Physician	4	2
Emergency department (ED) nurse	6	3
Nurse practitioner	3	0
Physician assistant	0	1
Pharmacist	1	0
ED administrator	2	2
Educator	3	0
Social worker	2	1
SCD Patient	1	1
Total	23	11

RESULTS

The FMECA included a total of 23 participants. Participant characteristics for each site are described in Table 2. Each FMECA session lasted approximately three hours. A process map and risk assessment chart was developed for each of the four processes. Because the process maps were developed to inform the risk assessment chart, only results from the risk assessment charts are presented and discussed. An expert facilitator led the FMECAs, and high-level support from physician and nursing leadership to encourage participation was a key component. Despite the complexities of describing SCD ED care at two different sites, the application of FMECA was feasible and participants reported high satisfaction with having an opportunity to identify failures and vulnerabilities in the high-risk processes that lead to breakdowns in SCD ED care. The FMECA required more time to complete than originally planned. Results specific to each of the four care processes are discussed below.

Triage and Analgesic Management

Both sites identified multiple, similar complex failures in triage and analgesic administration, despite significant differences in their protocols. For example, at both sites triage nurses assessed vital signs and chief complaints and attempted to determine if an open ED bed was available. If a bed was not available patients were placed in the waiting room. This process step was identified as high risk because it occurred frequently due to ED crowding at both sites, and because of erroneous triage assessment, and resulted in a delay in SCD patients receiving analgesics, the potential of undetected serious complications, and an inability to perform recommended re-assessments. However, Site 1 offered the triage nurse an option of requesting and obtaining an order for a first and repeat dose of sub-cutaneous opioid for any SCD patient with an existing treatment plan, when an ED bed was unavailable. However, it was widely acknowledged that triage nurses infrequently used this option. Site 2 did not have a similar option.

While several policies were in place at Site 1 to facilitate analgesic management, widespread lack of implementation and adherence was identified as a key failure. Obtaining timely intravenous access was a high-frequency, high-risk process at both sites, which contributed to significant delays in receiving analgesics. Site 1 used individualized analgesic dosing protocols available in the electronic medical record, and weight-based dosing was used when individual protocols were not available. Site 2 had a generic analgesic protocol available for management of ED SCD patients, but it, reportedly, was often not used. Site 1 also used a patient-controlled analgesia (PCA) protocol that required re-assessments of pain every 10 minutes with orders for re-administration of additional doses through the PCA. However, the protocol was usually not followed because of its complexity. Re-assessment and re-dosing for unrelieved pain were identified as high-risk areas at both sites. Difficult intravenous access was another barrier to providing rapid administration of analgesics at both sites. While resources such as ultrasound were available at both sites, they were frequently not used. Process steps, potential failures, consequences, safeguards, and risk bins for analgesic administration at both sites are presented in Tables 3 and 4, as examples.

High ED Use and High Risk Patients

Quality care processes to identify ED patients with high ED use or those at high risk did not exist at either site. For example, while participants at both sites acknowledged significant frustration with a small number of patients who were high ED users, neither site had any formal process in place to identify this subset of ED SCD patients in "real time," nor any formal process for reviewing these cases and identifying solutions.

Referrals

The ED-SCANS recommends a brief psychosocial assessment to identify unmet needs of patients who might benefit from follow-up services after discharge to the community (http://sickleemergency.duke.edu/sites/default/files/ED-Scans_Adult-Algorithms.pdf). Neither site had any process in place for conducting a psychosocial assessment, even for patients with frequent ED visits or those at high risk of severe disease. Although Site 1 had both a SCD program social worker and ED social workers who could assist with psychosocial assessments and referrals, there were no process guidelines in place to use these resources. Site 2 had no identified ED staff to assist in performing psychosocial assessments or making referrals.

DISCUSSION

This study involved the performance of a complex FMECA of all steps involved in four processes of ED care for patients with SCD, based on a SCD QI framework, the ED-SCANS. We found multiple processes were reflective of high-risk areas. We carefully followed the process of assigning frequency and criticality. The large number of high-risk areas is reflective of how complicated and in need of improvement the care processes are. Caring for persons with SCD in the ED is not just about pain.

In general, key findings at Site 1 were the following: (1) poor adherence to current analgesic protocols, and (2) failure to maximize the use of existing resources. In general at Site 2, the FMECA identified (1) a lack of structured SCD ED care processes and protocols, and (2) lack of resources to provide optimal SCD ED care. Patient input at each session was invaluable. As existing policies and processes were discussed, patients often validated the lengthy delays to analgesic administration and that these processes were not used. For example, at Site 1 triage nurses are allowed to administer an analgesic in the waiting room if a delay is unavailable. Patients verified that they were unaware of this option, and not offered analgesics at triage.

Reports from both sites indicate that findings from the FMECA are being used to guide ongoing QI efforts. Members of the FMECA teams at both sites continue to meet monthly. Collaborative efforts between the two sites are continuing through monthly teleconference calls during which progress on the identified high-risk areas are discussed.

Typically, a FMECA is paired with other QI methods. For example, a rapid cycle, process improvement method, the plan-do-study-act (PDSA), is being used by both sites to review the FMECA findings, enact the redesign and process improvement, study the results, and implement additional process improvements to successfully implement process changes.[39,40] Individual members of the teams at both sites have used the results of the FMECA to focus their work on the two identified high-risk areas: (1) revision of analgesic management policies and related clinician education. and (2) implementation of processes to obtain psychosocial assessments and referrals. At Site 1, the PCA protocol was revised to facilitate a more achievable time interval between administration of repeat analgesic doses. When no changes in real-time processes were noted, the team reviewed the risk binning results again and determined that the route of administration was a barrier. The protocol was modified and the route of administration for initial doses was changed from PCA to intravenous bolus doses. Initial results following this change have been favorable. Re-education of staff on the subcutaneous protocol has also been implemented. At Site 2, the emphasis has been on the development of individualized opioid pain management protocols and development of a SCD-specific protocol. Review of randomly selected medical records at each site has shown decreases in times from arrival to placement and from arrival to first dose of opioid analgesia.

Education was identified as a barrier to process re-designs implementation. A one-day workshop on SCD was offered in 2012, and a two-day workshop was offered in 2013, to members at both study sites; FMECA team members from both sites attended. A SCD Champion Program was also created at both sites, modelled after the pain resource nurse (PRN) program established to provide education to nurses about SCD and pain management.[41] PRNs participate in unit-based QI activities, provide unit-based education to their peers, and attend ongoing multi-disciplinary SCD Champion quarterly education and operational meetings. SCD Champion nurses at both study sites participate in these activities and are identified as resource nurses to physicians and nurses in their respective departments, and a means of sustaining the progress being made.

The second focus for each QI team was the identification of unmet psychosocial needs and follow-up care for patients with SCD, especially for persons at high risk or with high ED use. At Site 1, the QI team implemented a process that automatically "pages" an ED social worker, upon arrival of every adult with SCD. The social worker conducts a brief, targeted, psychosocial screening interview to identify unmet psychosocial needs. Prior to the last quarter of the project, no patients received referrals to psychological or behavioral services. Now, all patients are evaluated by the social worker during the hours a social worker is available, which includes 24/7 on weekends and approximately 14 hours/day during the week. At Site 2, the team is devising means to engage a consistent process that will allow for psychosocial referrals. At both sites, high-risk patients and high ED users are being better identified.

LIMITATIONS

Since this study was conducted in only two institutions, the key failures in the process of ED SCD assessment, treatment, and referral, as well as the causes, frequencies, and consequences, may differ from other institutions. Rather than being designed to identify all failures in the systems

Table 3. Site 1 analgesic risk analysis.

Step ID	Process Step	Failure Mode	Failure Mode Causes	Frequency Score	Consequences	Consequence Score	Safeguard	Safeguard Score	Risk/Bin
1	Obtain analgesic order								
	Medical doctor (MD) available to initiate protocol	MD not readily available	Providers may also order oral or intra-muscular; some patients may not want sub-cutaneous (SC)	F4	Delay in initiating pain protocol; pain worsens	C3	Policy states which MD to approach for initial order.	S1	High
2	Obtain supplies to administer dose								
	Intravenous (IV) access	Delay in getting access	Anatomy; system issues (patient load acuity); patient preference	F4	Delay in initiating pain protocol; pain worsens; delay in getting; lack of continuing to give SC or bolus doses	C3	Intake nurse; ultrasound capable nurses; residents to place external jugular; other nurses with skills in IV	S2	High
	Ultrasound (US) nurse available	US RN not available	Ultrasound trained nurse not always on duty; ultrasound trained nurse busy with another patient; ultrasound machine may not be available; other patient may be waiting for ultrasound IV.	F4	Same as above	C3	Residents/attending can put in an external jugular (EJ) catheter and ultrasound guided IV's, can continue to give SC doses	S2	High
	Patient continuous analgesia (PCA) pump available	Not available	Pumps stored back of pediatric ED, during high volume PCAs are more difficult to find; not enough stock; key not available	F4	Same as above	C3	During day time, someone will go down and get a pump; but bio engineering does not always have a pump available	S3	High

RN, registered nurse

Table 3. Continued.

Step ID	Process Step	Failure Mode	Failure Mode Causes	Frequency Score	Consequences	Consequence Score	Safeguard	Safeguard Score	Risk/Bin
	If applicable: resident nurse (RN) trained to access port	Not all RN's trained to access port	Difficulty, unable to draw blood or can draw but not infuse	F2	Same as above	C3	Peripheral IV; flush with heparin; reposition pt.	S1	Medium
3	PCA analgesic administration								
	Obtain MD PCA loading dose and order	Not ordered, or not ordered per protocol	MD trainees typically taught IV bolus methods only, not familiar with use of PCA in SCD; residents not initiating PCA order; lack of knowledge that loading dose can be given as many as 4 bolus doses every 10 minutes; non-emergency medicine residents unfamiliar with ED SCD PCA order form; wrong PCA form completed; wrong dose ordered; attending MD does not review PCA order before nurse implementation	F2	Delays in care	C3	Electronic medical record of clinic notes and ED notes with prescribed doses are readily available	S1	Medium
	PCA doses re-administered q 10 minutes x4	Not followed	Nurse availability for frequent re-dosing; opioid administration requires a 2-RN check; delay because must locate & obtain PCA key & another RN may have it; boluses not being given consistently per PCA order	F4: being given but not every 10 minutes as per protocol	Poor pain control; decreased pt. satisfaction, quality of care; staff frustration; poor pt. - clinician interactions	C3	May be receiving PCA demand and continuous dosing	S1	High
	Re-assess pain each hour; PCA protocol: reassess medication use every 2 hours	Not followed	Nurse availability for frequent re-evaluation; increased acuity or patient load prevents	F3	No change in analgesic management based on pain score and RASS (sedation) score prompt; increasing pain; longer length of stay	C3	Electronic flag with PCA usage	S1	Medium
	If inadequate pain relief, administer rescue doses x2 and adjust continuous and PCA doses	Not followed	Not routine practice	F4	Inadequate pain management	C3	Order set is clear and stipulates rescue dosing & adjusted PCA doses	S1	High

PCA, patient continuous analgesia; *MD*, medical doctor; *IV*, intravenous; *ED*, emergency department; *RASS,* Richmond Agitation Sedation Scale; *SCD*, Sickle Cell Disease

Table 4. Site 2 analgesic risk analysis.

Step ID	Process Step	Failure Mode	Failure Mode Causes	Freq Score	Consequences	Consequence Score	Safeguard	Safeguard Score	Risk/bin
1	Treatment bay, IV and O2 established								
2	Obtain analgesic order								
	MD available for analgesic order	MD not readily available	Busy caring for other patients; may be in an ED room; if MD is not caring for the patient or has not examined the patient; hesitancy to write analgesic order	F3	Delay in initiating pain medication;	C3	Nurse "hunts" to find an MD; nurse advocates for MD to write an order	S3	Medium
	Acute pain protocol ordered?	Not readily used by ED MDs	Lack of familiarity with acute pain protocol by "off service" trainees; MDs have fear of using protocol because of high dose of hydromorphone and frequency (also can give ondansetron + diphenhydramine);	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Smaller than recommended or split doses are ordered; MD asks nurse to recheck pt for pain; patient is encouraged to notify if pain not resolved; inadequate pain medication dose administered	S1	High
	Patient reassessed every 15 minutes if on acute pain protocol	Never achieved	Re-dosing every 15 minutes is practically impossible; nurse tied up with other patients; Can only prepare one dose at a time. Need to go to (1) pyxis, (2) pull medication, (3) draw up medication, (4) administer medication, (5) document administration and (6) monitor patient. This takes more than 15 minutes with each dose.	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Part of a protocol	S1	High

MD, medical doctor; *IV*, intravenous; *ED*, emergency department; *SCD*, Sickle Cell Disease

Table 4. Continued.

Step ID	Process Step	Failure Mode	Failure Mode Causes	Freq Score	Consequences	Consequence Score	Safeguard	Safeguard Score	Risk/bin
	Patient reassessed every 15 minutes if patient NOT on acute pain protocol	Not part of the protocol; not hospital policy	Nursing caring for multiple patients; no opportunity for another dose in 15 minutes (see above).	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Patient asks for more pain medication.	S2	High
	IF no acute pain protocol, find individualized pain medication dose in modified release (MR)	No single location in MR to look up most recent dose; individualized dose may be in clinic note or inpatient note; not clearly identified in MR	Lack of time to search through MR for the last dose in the most recent ED visit. Even if ED visit located, dose may not be the most appropriate dose	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Ask the patient	S2	High
3	Administer analgesic								
	IV access available	Unable to quickly establish IV access	Patient has difficult underlying vascular morphology/physiology Safeguards available, often not used	F2	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Lots of providers with a lot of skill; ultrasound guided; alternative delivery modes; IJ line	S2	Medium
	Definition of IV “push”	No standardized definition of IV “push”; variation in methods used. NOTE: IV “push” = administration over 1-2 minutes; NO piggy-backing of medication.	Reluctance of staff to give IV “push”; patients want the medications to be given “push”. Lack of knowledge and experience of staff; concerns about side effects of IV “push” (e.g., respiratory depression or hypotension).	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Patient has to keep asking for more pain medication.	S3	High

IV, intravenous; *ED*, emergency department; *IJ*, internal jugular

Table 4. Continued.

Step ID	Process Step	Failure Mode	Failure Mode Causes	Freq Score	Consequences	Consequence Score	Safeguard	Safeguard Score	Risk/bin
	Pain medication dosing	Inadequate, non-customized dosing	Lack of knowledge and experience of pain medication doses in SCD patients; clinicians reluctant to give high doses of opioids; MDs order "split" doses or just smaller dose; MDs fear of substance- seeking pts; fear of side effects of high dose pain medications	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Patient asks for more pain medication.	S2	High
	No immediate IV access	Cannot achieve rapid IV access	Protocol is to try 2-3 times to get peripheral, then, seek additional help. Do not use sub-cutaneous route.	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed.	C3	Lots of providers with a lot of skill; ultrasound guided; alternative delivery modes; IJ line	S2	High
4	Order for analgesic given and dose administered								
	Re-assessment of pain	Patient not reassessed in a timely manner	Nursing staff caring for other patients; no automatic alert or reminder available to nursing	F4	Patient has inadequately treated pain, untimely treatment; not adequately re-dosed	C3	Patient asks for more pain medication	S3	High

IV, intravenous; *MD*, medical doctor; *IJ*, internal jugular; *SCD*, Sickle Cell Disease

and processes of ED SCD care, the aim of this study was to demonstrate the application, by healthcare clinicians and staff, of a proactive, risk assessment methodology – FMECA – to the acute, time-sensitive ED SCD process of care, endorsed by the ED-SCANS in order to identify potential failures in SCD processes of care. The FMECA permitted a ranking of the identified failures by greatest risk which, in turn, facilitated the selection of ED-specific targets for development and implementation of interventions.

The FMECA approach has some inherent limitations. It does not include all staff or clinicians involved in ED SCD care and therefore relies on convenience sampling. In this study, more clinicians and staff participated at Site 1 than at Site 2. Having additional participants may have added different perspectives and identified additional steps, failures, and causes. Also, it is possible that participants may not have identified all of the failures or may have inaccurately gauged the frequency or consequence of those identified. To address these issues, FMECA moderators asked probing questions during the sessions to increase discussion, but it is likely that the group did not entirely capture all problems.[42]

An additional limitation relates to the FMECA assessment of the failure's consequence score. Evidence has shown that participants can be, on the one hand, overly optimistic, in that they underestimate potential consequences of a process failure due to the hazard being perceived as considerably frequent, although no severe consequences have actually occurred. On the other hand, they may be overly pessimistic: although they have never experienced or heard about a failure occurring, they cannot exclude that the failure will ever occur. As detailed in a 2008 critique of risk matrices,[43] the quantitative value of risk analysis is limited by the mathematical assumptions of the embedded judgments of frequency and severity rating, in this context, the frequency and severity of barriers to optimal care for patients with SCD. In healthcare, risk contributors are not necessarily "randomly selected pairs of hazards" and in fact represent a number of possible outcomes, based on observed clinical occurrences (consequences). However, our intent at adapting risk analysis to improve the care of SCD patients is qualitative at this point in time, not quantitative, and represents a qualitative assessment of multiple risks that cause a healthcare process to fail.[44] This is a dynamic process, and allowed for the input of multiple providers who can better suggest as a whole the barriers that may be in place. Furthermore, this methodology includes the use of a safeguard or safety intervention, which could be reasonably expected to impact the frequency and severity of risk contributors. The quantitative impact of the barriers and the success of the safeguards can only be determined by analysis of data which is currently underway.

CONCLUSION

This study demonstrates the feasibility of conducting a complex FMECA of each aspect of four clinical processes of SCD ED care at two hospitals. Results from the FMECA identified specific process failures and have been instrumental in determining the focus of QI activities at each site. While a FMECA is an excellent tool for identifying potential weaknesses or failures in complex processes, implementation of process and quality improvement techniques to address the identified failures and vulnerabilities in the ED SCD process of care is also critical. Units and facilities that undertake FMECAs can use the results to guide QI activities to redesign, test, and improve specific processes of care to the benefit of both patients and those who care for them.

ACKNOWLEDGEMENTS

This project was supported by a grant from the Agency for Healthcare Research and Quality, 1 R18 HS 19646.

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Conflicts of Interest: By the *West*JEM article submission agreement, all authors are required to disclose all affiliations, funding sources and financial or management relationships that could be perceived as potential sources of bias. Paula Tanabe was a member of the Expert Report Panel on the Management of Sickle Cell Disease, sponsored by the NHLBI.

REFERENCES

1. Centers for Disease Control and Prevention National Center for Health Statistics. Sickle cell disease, Data and Statistics. 2012. http://www.cdc.gov/ncbddd/sicklecell/data.html. Accessed May 2, 2013.
2. Lanzkron S, Carroll CP, Haywood C, Jr. Mortality rates and age at death from sickle cell disease: U.S., 1979-2005. *Public Health Rep.* 2013;128:110-116.
3. Platt OS, Brambilla DJ, Rosse WF, et al. Mortality in sickle cell disease. Life expectancy and risk factors for early death. *N Engl J Med.* 1994;330:1639-1644.
4. Powars DR, Chan LS, Hiti A, et al. Outcome of sickle cell anemia: a 4-decade observational study of 1056 patients. *Medicine (Baltimore).* 2005;84:363-376.
5. Hamideh D. Trends in Mortality Among Patients with SCD in the United States. Is there any change in the past 10 years? *6th Annual Sickle Cell Disease Research and Educational Symposium & Annual National SCD Scientific Meeting*. Hollywood, FL 2012.
6. Tanabe P, Artz N, Mark Courtney D, et al. Adult emergency department patients with sickle cell pain crisis: a learning collaborative model to improve analgesic management. *Acad Emerg Med.* 2010;17:399-407.
7. Tanabe P, Myers R, Zosel A, et al. Emergency department management of acute pain episodes in sickle cell disease. *Acad*

Emerg Med. 2007;14:419-425.
8. Lazio MP, Costello HH, Courtney DM, et al. A comparison of analgesic management for emergency department patients with sickle cell disease and renal colic. *Clin J Pain.* 2010;26:199-205.
9. Tanabe P, Hasnain-Wynia R. Promoting equity: developing quality measures for sickle cell disease. *Am J Med Qual.* 2012;27:80-82.
10. Tanabe P, Reddin C, Thornton VL, et al. Emergency Department Sickle Cell Assessment of Needs and Strengths (ED-SCANS), a focus group and decision support tool development project. *Acad Emerg Med.* 2010;17:848-858.
11. Hwang U, Richardson L, Livote E, et al. Emergency department crowding and decreased quality of pain care. *Acad Emerg Med.* 2008;15:1248-1255.
12. DeRosier J, Stalhandske E, Bagian JP, et al. Using health care Failure Mode and Effect Analysis: the VA National Center for Patient Safety's prospective risk analysis system. *Jt Comm J Qual Improv.* 2002;28:248-267,209.
13. Burgmeier J. Failure mode and effect analysis: an application in reducing risk in blood transfusion. *Jt Comm J Qual Improv.* 2002;28:331-339.
14. Robinson DL, Heigham M, Clark J. Using Failure Mode and Effects Analysis for safe administration of chemotherapy to hospitalized children with cancer. *Jt Comm J Qual Patient Saf.* 2006;32:161-166.
15. Nickerson T, Jenkins M, Greenall J. Using ISMP Canada's framework for failure mode and effects analysis: a tale of two FMEAs. *Healthc Q.* 2008;11:40-46.
16. Apkon M, Leonard J, Probst L, et al. Design of a safer approach to intravenous drug infusions: failure mode effects analysis. *Qual Saf Health Care.* 2004;13:265-271.
17. Kunac DL, Reith DM. Identification of priorities for medication safety in neonatal intensive care. *Drug Saf.* 2005;28:251-261.
18. van Tilburg CM, Leistikow IP, Rademaker CM, et al. Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. *Qual Saf Health Care.* 2006;15:58-63.
19. Kimehi-Woods J, Shultz JP. Using HFMEA to assess potential for patient harm from tubing misconnections. *Jt Comm J Qual Patient Saf.* 2006;32:373-381.
20. Saxena S, Kempf R, Wilcox S, et al. Critical laboratory value notification: a failure mode effects and criticality analysis. *Jt Comm J Qual Patient Saf.* 2005;31:495-506.
21. Linkin DR, Sausman C, Santos L, et al. Applicability of Healthcare Failure Mode and Effects Analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments. *Clin Infect Dis.* 2005;41:1014-1019.
22. Kozakiewicz JM, Benis LJ, Fisher SM, et al. Safe chemotherapy administration: using failure mode and effects analysis in computerized prescriber order entry. *Am J Health Syst Pharm.* 2005;62:1813-1816.
23. Steinberger DM, Douglas SV, Kirschbaum MS. Use of failure mode and effects analysis for proactive identification of communication and handoff failures from organ procurement to transplantation. *Prog. Transplant.* 2009;19:208-214;quiz 215.
24. Habraken MM, Van der Schaaf TW, Leistikow IP, et al. Prospective risk analysis of health care processes: a systematic evaluation of the use of HFMEA in Dutch health care. *Ergonomics.* 2009;52:809-819.
25. Varkey P, Reller MK, Resar RK. Basics of quality improvement in health care. *Mayo Clin Proc.* 2007;82:735-739.
26. Benjamin LJ, Dampier CD, Jacox A, et al. *Guideline for the Management of Acute and Chronic Pain in Sickle-Cell Disease.* Glenview, IL: American Pain Society;1999.
27. Platt OS, Thorington BD, Brambilla DJ, et al. Pain in sickle cell disease. Rates and risk factors. *N Engl J Med.* 1991;325:11-16.
28. Ballas SK, Lusardi M. Hospital readmission for adult acute sickle cell painful episodes: frequency, etiology, and prognostic significance. *Am J Hematol.* 2005;79:17-25.
29. National Institutes of Health NH, Lung, and Blood Diseases and Resources,. The Management of Sickle Cell Disease. 4th ed: NIH; 2002.
30. Benjamin LJ, Dampier CD, Jacox A, et al. *Guideline for the Management of Acute Pain in Sickle-Cell Disease / Quick Reference Guide for Emergency Department Clinicians.* Glenview, IL: American Pain Society;2001.
31. Pack-Mabien A, Labbe E, Herbert D, et al. Nurses' attitudes and practices in sickle cell pain management. *Appl Nurs Res.* 2001;14:187-192.
32. Carroll CP, Haywood C, Jr., Fagan P, et al. The course and correlates of high hospital utilization in sickle cell disease: Evidence from a large, urban Medicaid managed care organization. *Am J Hematol.* 2009;84:666-670.
33. Carroll CP, Haywood C, Jr., Lanzkron S. Prediction of onset and course of high hospital utilization in sickle cell disease. *J Hosp Med.* 2011;6:248-255.
34. Esmail R, Cummings C, Dersch D, et al. Using Healthcare Failure Mode and Effect Analysis tool to review the process of ordering and administrating potassium chloride and potassium phosphate. *Healthc Q.* 2005;8 Spec No:73-80.
35. Chiozza ML, Ponzetti C. FMEA: a model for reducing medical errors. *Clin Chim Acta.* 2009;404:75-78.
36. Coles G, Fuller B, Nordquist K, et al. Using failure mode effects and criticality analysis for high-risk processes at three community hospitals. *Jt Comm J Qual Patient Saf.* 2005;31:132-140.
37. Day S, Dalto J, Fox J, et al. Failure mode and effects analysis as a performance improvement tool in trauma. *J Trauma Nurs.* 2006;13:111-117.
38. Coles G, Fuller B, Nordquist K, et al. Three kinds of proactive risk analysis for health care. *Jt Comm J Qual Patient Saf.* 2010;36:365-375.
39. Speroff T, O'Connor GT. Study designs for PDSA quality improvement research. *Qual Manag Health Care.* 2004;13:17-32.
40. Langley GJN, K. M. , Nolan TW, Norman CL, Provost LP. *The Improvement Guide: A Practical Approach to Enhancing Organizational Performance*. 1st ed. ed. San Francisco: Jossey-Bass Publishers; 1996.
41. Paice JA, Barnard C, Creamer J, et al. Creating organizational change through the Pain Resource Nurse program. *Jt Comm J Qual Patient*

Saf. 2006;32:24-31.

42. Swain AD. Human reliability analysis: Need, status, trends and limitations. *Reliability Engineering and System Safety.* 1990;29:301-313.
43. Cox L. What's wrong with risk matrices? *Risk Anal.* 2008;28:497-512.
44. Woods DM, Holl JL, Young J, et al. *Leveraging Existing Assessments of Risk Now (LEARN) Safety Analysis: A Method for Extending Patient Safety Learning Advances in Patient Safety: New Directions and Alternative Approaches (Vol. 1: Assessment)*. Rockville MD2008.