FINAL PROGRESS REPORT

Improving ED Quality and Safety by Enhancing Operations and Quality Management

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ABSTRACT

Purpose: The objectives of this project are to further evaluate specific Emergency Department (ED) operational and quality management characteristics and to identify and implement generalizable process improvements to enhance quality and safety in EDs.

Scope: The project will focus on the operational and quality management characteristics impact on one key quality indicator score in the ED: “time-to-percutaneous coronary intervention (PCI)” for patients with acute ST-elevation myocardial infarction (STEMI).

Methods: A quantitative secondary dataset analysis, a proactive risk assessment, and quality improvement methods were used.

Results: Hospitals with the highest and second-highest quartiles of time-to-PCI quality measure had a significantly lower overall acute myocardial infarction mortality rate than did lower-quartile hospitals. The risk assessment, conducted at two hospitals, revealed clear areas of potential delay and vulnerability that can be addressed to decrease door-to-balloon time from 90 to 60 minutes. Fifty-one failure points were identified across four door-to-balloon time phases. Of the 12 high-risk failures, 58% occurred between ECG and catheterization laboratory activation. Total door-to-balloon time during on hours had a median time of 55 minutes (95% confidence interval 46 to 60 minutes) compared with 77 minutes (95% confidence interval 68 to 83 minutes) during off hours.

Key Words: healthcare quality, risk assessment, acute ST elevation myocardial infarction

Purpose:

With this career development award, the applicant sought to gain the necessary formal didactic training and experiential research skills to become an independent investigator, with appropriate expertise to explore the healthcare delivery system characteristics that enable consistent optimal performance. The applicant's interest in this topic emanated from his belief that improved healthcare delivery systems are critical to achieve widespread adherence to evidence-based recommendations. In order to further evaluate the ED operational and quality management characteristics, the applicant articulated the need for advanced skills in mixed-mode (quantitative and qualitative) research design and analytic methods. He assembled a strong mentorship team and identified didactic courses and a research plan to advance his knowledge of (1) quantitative secondary database methods and (2) qualitative methods, such as Failure Modes Effects Analysis, clinician surveys about organizational culture, and quality management and improvement techniques.

The project provided the opportunity for the applicant to apply his formal didactic training and to engage in a research project that further evaluated specific ED operational and quality management characteristics to identify and implement generalizable process improvements to enhance quality and safety in EDs. The applicant was particularly interested in this topic because of the lack of consistent application of evidence-based treatments, despite clear scientific evidence, which remains a persistent challenge across all EDs in the US healthcare system. High-quality care requires more than just excellent medical decision making and physician buy-in to successfully complete evidence-based treatments. It also requires an efficient, coordinated, and effective healthcare delivery system. The question becomes, "Which ED and hospital operational and quality management characteristics contribute to high quality ED care?" and "Exactly how do hospitals and EDs engage in consistent and successful application of knowledge about these operational and quality management characteristics?" For this project, the applicant chose to focus on one key quality indicator score in the ED: "time-to-percutaneous coronary intervention (PCI)" for patients with acute ST-elevation myocardial infarction (STEMI). Although there is an extensive literature about implementation of this process, the time-to-PCI quality indicator is achieved only 40% of the time. There is an excellent reason for evaluating this quality indicator because successful treatment of STEMI, though still a challenge for many EDs, has resulted in reduction of inpatient mortality. Closing the gap in quality of care of patients with STEMI may depend on a complex mix of ED and hospital characteristics. The project focused on the key characteristics, as shown in the following table.

Table 2. ED and Hospital Characteristics that Contribute to Healthcare Quality Outcomes

Operational Measures/Characteristics	Quality Management Characteristics
- Average door-to-physician time	- Hospital directed quality improvement
- Overall ED length of stay of patients	- Internal assessment of clinical standards
- % of patients who left without being seen	- Hospital initiatives to keep waiting times down
- Length of stay of chest pain patients	- STEMI protocols and algorithms

Scope:

Myocardial infarction is a common manifestation of coronary artery disease. Approximately 1.2 million Americans sustain an acute myocardial infarction (AMI) every year.[1] For patients who reach a medical facility, the prognosis has improved over the years.[2] Overall inpatient mortality rates for all myocardial infarctions fell from 11.2% in 1990 to 9.4% in 1999.[3] It is believed that most of the decline is due to decreasing mortality among patients with STEMI.[4] Considering that 25% to 42% of all myocardial infarctions are STEMIs,[3] which extrapolates to 500,000 patients annually in the US, even small improvements in the reducing the mortality rate for STEMI may result in a significant number of total avoided deaths.

Despite excellent evidence and overwhelming recommendations, achievement of the 90-minute time-to-PCI threshold occurs for only 40% of STEMI patients in US hospitals.[5] Bradley et al. has shown that specific resources and actions in high-performing hospitals can reduce the time-to-PCI compared to hospitals that do not have the resources or complete the actions.[6] US hospitals still have not consistently met the goal of 95% of all patients with STEMI to meet the 90-minute threshold of time-to-PCI. Despite the evidence-based science, overwhelming agreement from specialty organizations, awareness of physicians and staff, and known strategies to reduce time-to-PCI, the measure is not being met consistently. New insight into ED and hospital operational measures may be key to understanding and meeting quality measures, such as time-to-PCI and other time-sensitive diseases.

The context, settings, and participants differ by aim.

- Aim 1 was accomplished by an analysis of secondary datasets: (1) Medicare Provider Analysis and Review (MedPAR), Medicare outpatient, and Medicare Denominator files; (2) CMS Hospital Compare website to gather the time-to-PCI quality indicator scores; (3) University HealthSystem Consortium (UHC) ED Cycle Time Benchmarking Project; and (4) American Hospital Association Survey that included hospitals and de-identified patients from all over the US.
- Aim 2 was performed at two different ED sites. The first, the Northwestern Memorial Hospital's ED, is located in the most affluent neighborhood of Chicago, IL. This academic, urban ED has over 85,000 patient visits per year, including 50 patients with STEMI who were reported to CMS' Health Compare in 2008. For the STEMI quality indicator of interest, time-to-PCI quality indicator, Northwestern Memorial Hospital scored 94%. The second ED site, Vista Health System is located in Waukegan, IL, about 40 miles north of Chicago. This private, nonacademic, urban ED has over 35,000 patient visits per year. Vista Health System is located in a largely Hispanic neighborhood and has been deemed as serving medically underserved population by the Department of Health and Human Services, based on the index of medical underservice due to patient incomes below the poverty line.

Methods

Specific Aim 1: Analyze secondary data to determine which ED and hospital **operational characteristics** contribute to superior performance of the time-to-PCI quality indicator and contribute to reduction in AMI mortality.

Aim 1 consisted of a retrospective, cross-sectional study design using secondary databases. A national database of hospital discharge data that had been stratified by operational characteristics was used to measure adjusted all-cause mortality and time-to-PCI quality indicator score for each hospital in order to compare outcomes across operational characteristic stratifications.

Each operational characteristic from the 2008 University HealthSystem Consortium (UHC) Time Cycle database was evaluated. Data from the 2008 CMS Medicare files were used for outcomes for inpatient and 30-day mortality rates of patients with AMI. Time-to-PCI quality indicator scores were obtained from the CMS website, Hospital Compare. Hospital characteristics were obtained from the 2008 American Hospital Association (AHA) Annual Survey. Each hospital's identification number was used to link the three datasets, and then a cross-sectional analysis of inpatient mortality, 30-day mortality, and time-to-PCI quality indicator scores for AMIs admitted to each hospital between January 1 and December 31, 2008, was performed.

Adjusted inpatient mortality rates for AMI, as well as scores on time-to-PCI quality indicator, for hospitals with high- and low-performing operational measures were compared. The primary outcome of interest was inpatient and 30-day mortality for patients admitted through the ED with the primary discharge diagnosis of AMI (obtained from the MedPar files and Medicare inpatient, outpatient, and enrollment files). The time-to-PCI quality indicator scores, found on the CMS Hospital Compare website, were a secondary outcome measure.

Each hospital was assigned a single operational characteristic composite score based on equal weights of their operational characteristics from the UHC Time Cycle Benchmarking Project. The hospitals were then ranked and divided into quartiles. The hospital quartiles were used to evaluate any significant differences in the outcomes of interest.

Because a number of factors at the individual level contribute to mortality after AMI, basic demographic characteristics, such as age, gender, and race (which have been demonstrated to portend differential outcomes after AMI) and comorbidities that complicate patients with STEMI care and worsen survival, were included. As pre-STEMI health is an important contributor to outcome following hospitalization, the population was adjusted for case mix. A severity of illness score, as defined by Krumholz et al,[7] was used to identify co-morbid ICD-9 codes incorporating ICD-9 disease comorbidities from 1 year prior to hospital admission.

AMI inpatient mortality, AMI 30-day mortality, and time-to-PCI quality indicator scores at hospitals with varying levels of performance on their operational characteristics were compared using chi-squared tests of goodness of fit. All analyses were also performed using tests for trends and test of heterogeneity to detect effect modification and were compared to summary Mantel-Hanszel test odds ratios. Logistic regression analyses using death as the dependent variable were performed to determine whether differences in adjusted mortality exist for patients with AMI treated at hospitals with varying levels of performance of operational characteristics (by quartile). Finally, because patients with STEMI/AMI were likely to be clustered at the level of the hospital, a mixed-effects logistic regression was constructed in which the outcomes were a function of fixed and observed covariates at the patient, hospital, and operational measure levels as well as unobserved random variation at the hospital level.

Specific Aim 2*:* Assess **quality management characteristics** by conducting a Failure Mode Effects and Criticality Analysis (FMECA) of ED treatment of STEMI at two hospitals (a high-operating-margin hospital and a low-operating-margin hospital).

Failure Mode and Effects Analysis (FMEA) and Failure Modes, Effects, and Criticality Analysis (FMECA) are methods designed to identify potential failure modes of a process. An FMECA elicits information about any failures for each step in a process including the underlying cause of any failure, the frequency, consequence, and existence of any safeguards against each failure. An FMECA also permitted ranking of failures from high to low risk. The scope of the FMECA was the process of ED management of patients with STEMI. Six steps of the FMECA process were completed.

Participants at two institutions, Northwestern Memorial Hospital, Chicago, IL, and Vista Hospital in Waukegan, IL, were recruited. The FMECA teams included ED physicians, cardiology interventionalist physicians, emergency triage and emergency department nurses, technicians, hospital quality administrators, and hospital executive leaders at each site (approximately eight staff and clinicians at each site).

Three 2-hour sessions were held at each institution. Participants were asked to “walk down” the process by gathering all information about the steps and problems in accomplishing steps the healthcare team goes through when caring for a patient who presents to the ED with signs and symptoms of STEMI. For example, the team was asked to identify the first step as “attaining the ECG.” The team then identified potential failures in accomplishing this step (e.g., lack of a private area to perform the ECG). The team was asked to estimate the frequency of each identified failure and its consequence on achieving the optimal time-to-PCI time. The team was also asked to identify any existing safeguards to mitigate a failure (e.g., protocols, guidelines and policies).

The research team then created a single process map of all of the identified the steps in the processes of caring for a patient who presents to the ED with signs and symptoms of STEMI.

Following creation of the process map, a risk table indicating each identified failure, the underlying causes of each failure, its frequency, its impact on time-to-PCI, and safeguards was created. In a second session, the FMECA team then scored the frequency, impact, and safeguards using standard tables. Finally, a risk priority number (RPN) (frequency X impact X safeguard) was calculated, and the failures were ranked from highest to lowest number.

The failures were then "binned" into high-, medium-, and low-risk bins.

Specific Aim 3: Develop and implement an ED-specific quality improvement methodology for the processes involved in ED treatment of STEMI, based on results in Aims 1 and 2 to enhance the care for STEMI and other time-sensitive ED diseases.

Each risk bin was be further divided into the three phases of the time-to-PCI process (door-to-ECG, ECG-to-activation of catheterization team, and activation-to-PCI).

Each hospital's Safety and Quality Team reviewed the "highest-binned" safety risks in each phase of the time-to-PCI process and selected one identified high-risk safety failure from each phase of the time-to-PCI process for improvement.

To the degree possible, both hospitals tried to work on similar failures. However, because the goal was to design a process for time-to-PCI that accommodated each individual institution's organizational and operational infrastructure, the interventions did not overlap.

A Plan-Do-Study-Act (PDSA) methodology was used for the process improvement.

Results:

For Aim 1, CMS, University HealthSystem (UHC) Consortium, and American Hospital Association data were merged into a single database about patients experiencing acute myocardial infarction (AMI). The analyses for Aim 1 were fully completed and resulted in a peer-reviewed publication.[1]

For Aim 2, as proposed, a Failure Modes Effect Analysis about the systems and processes of care during "door-to-balloon" treatment for patients with ST-elevation myocardial infarction (STEMI) was conducted at two, diverse healthcare organizations: (1) Northwestern Memorial Hospital, Chicago, IL, a major, urban, academic medical center and Vista Hospital, Waukegan, IL, a community hospital, in a under-resourced community. The analyses revealed rich information about causes of delay, medical errors, and near misses in the systems and processes of door-to-balloon time care and the results were published in the *Annals of Emergency Medicine*.[2] This was the first publication about a proactive risk analysis of the systems and processes of care for STEMI that we are aware of and it has been widely disseminated with a press release and several media interviews.

For Aim 3, we worked with the Safety and Quality Improvement teams of each of the two healthcare organizations to develop and pilot test ED-specific, quality improvements for the processes and systems of care in the treatment of STEMI, specifically related to the door-to-balloon time, based on our results, primarily from Aim 2.

List of significant results (positive or negative):
At Northwestern Memorial Hospital, the Quality Improvement team addressed several key failures, including delays in interpreting the EKG, by instituting a systematic process for identifying an Emergency Department (ED) physician responsible for reviewing EKGs at all times. Another identified failure was hesitation to initiate a STEMI code, because it results in the deployment of the entire cardiac catheterization team. A new mechanism was put in place to review all STEMI codes by the Emergency Department and to provide feedback to frontline clinicians about appropriateness of code initiation. Additional process improvements included developing a standard process for changing intravenous lines in the ED prior to transfer to the catheterization laboratory, accelerating the transfer time between the ED and the cardiac catheterization laboratory, and developing a standardized process for communication with the catheterization laboratory. Northwestern Memorial Hospital has decreased their door-to-balloon times substantially. Challenges remain for cases that occur during 'non-work" hours due to limitations in deploying all members of the team.

At Vista Hospital, fewer failures were identified, in part, we believe, because there are fewer "layers" of clinicians providing care. However, the process improvements were less successful, because the hospital had very limited resources. For example, the hospital had limited quality improvement staff to develop and implement any of the recommended improvements and were unable to provide consistent data about the impact of the improvements.

List of Publications and Outputs from the Study:

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03.01.16

[PI Signature] Jane L. Holl, MD MPH [date]

for Dr. Khare who has left Northwestern University.

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