FINAL REPORT

Evaluation of Risk by Active Surveillance in the Emergency Department (ERASED)

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ABSTRACT

Purpose: To identify and characterize hazardous conditions and high-risk situations in an emergency department (ED) using active surveillance.

Methods: This study was conducted in an urban, academic, tertiary care medical center ED with over 45,000 annual adult visits. Trained research assistants interviewed caregivers at the discharge of a systematically sampled group of patient visits across all shifts and days of the week. Caregivers were asked to describe any part of the patient's care that they considered "not ideal." For selected visits, basic demographic, chief complaint, acuity, discharge destination, and total length of stay data were collected. Reports were reviewed by two ED clinicians, and events were categorized into two taxonomies: (1) the segment of emergency care in which the event occurred and (2) an event category and specific event type (general type and descriptor) based on published patient safety work. The occurrence of harm was also determined.

Results: Research assistants completed 656 hours of surveillance. Overall, 487 visits were systematically selected, representing 15% of the total visits during the study period. In total, 1180 caregiver interviews were completed (29 declines), generating 210 discreet event reports for 153 visits. Thirty-two percent of the visits had at least one nonideal care event. Segments of care with the highest percentage of events were diagnostic testing (29%); disposition (21%); evaluation (18%); and treatment (13%). Ten percent of reported events affected all segments of care. Process-related delays were the most frequently reported events within the categories of medication delivery (53%), laboratory testing (88%), and radiology testing (79%). Fourteen (7%) of the reported events were associated with patient harm.

Conclusions: The active surveillance method was feasible and effective in capturing a significant number of nonideal care events during ED visits. These events resulted in delays and patient harm, and they involved failures in the processes of medication delivery, radiology testing, and laboratory testing.

Key Words: patient safety, emergency medicine, errors, adverse events, harm

PURPOSE

The specific aims of this project were as follows:

Aim 1 – Identify errors and adverse events in the emergency department through active surveillance. Real-time, active surveillance of the people and processes within the ED was used to monitor conditions and to identify hazards.

Aim 2 – Compare errors and adverse events through active surveillance with those identified through the standard reporting mechanism. After collection of the data via active surveillance, results were compared with retrospective data generated from the current hospital incident reporting system.

Aim 3 – Use Healthcare Failure Mode and Effect Analysis (HFMEA) for a medication management process that was identified as highest risk. The data generated from Aims 1 and 2 were used to identify a high-hazard medication-related process for which an HFMEA was conducted.

SCOPE

In order to improve a system in any industry, the adverse events that take place within the system must be understood. Since the Institute of Medicine published their seminal report, *To Err Is Human*, there has been a growing awareness of the necessity to understand errors and adverse events in the context of the healthcare environment. Surprisingly, there remains a paucity of information related to patient safety in ambulatory care settings, particularly from the emergency department (ED). The ED represents the first line of care for over 119 million patients annually. Care in the ED represents a complex system in a high-risk environment, making it a critical area for patient safety research.

Current knowledge about the number and types of errors and adverse events occurring within emergency departments is limited. Only a small number of studies have evaluated the epidemiology of errors and adverse events within the ED, with the majority of studies focusing on missed diagnoses of high-stakes conditions. The method often used to collect information about hazards within the ED is voluntary reporting. Many, if not most, hospitals implement incident reporting systems with a classification scheme for types and causes. These systems can provide valuable information for process improvement and identification of hazard, but the quality of voluntary incident reports is highly variable. Furthermore, incident reports provide the so-called numerator of incidents, with little information regarding prevalence of errors and adverse events (the “denominator”). The reports are prone to bias, as the decision to classify an event as an incident is made by the reporter, and the report does not necessarily reflect important factors that are precursors to errors.

Powerful evaluation methods, such as active surveillance and HFMEA, have been developed in order to gain a more comprehensive understanding of hazards within a system. Based on the infection control model, active surveillance consists of continuous and systematic collection, analysis, and interpretation of information. Active surveillance aids in the detection and description of a wide range of errors as they occur. HFMEA is a systematic, proactive method of process evaluation that identifies where and how failures may occur. By doing so, the steps of the process that are most in need of improvement are identified.

In order to have a true sense of the environment of safety, the use of multiple approaches to the identification of hazards is necessary. This project used a combination of active surveillance, standard reporting methods, and FMEA to identify, characterize, and categorize errors, both active and latent, that occur in the ED.

METHODS

Aim 1 – Active Surveillance

Setting. The study was conducted in an ED of an urban, academic medical center located in Baltimore, Maryland, with approximately 45,000 adult visits annually. Pediatric patients, defined as those patients under the age of 18 years, are treated by pediatric specialists in a separate area of the ED.

Selection of Visits. Visits were systematically sampled through the use of sequentially generated financial numbers. Patient visits were eligible for inclusion if (1) the visit occurred in the adult emergency department (patient over the age of 18 years); (2) the financial number for the visit ended in a 0 or 5; and (3) the visit ended (patient discharged home, transferred, or admitted) during the data collection period.

Definitions. The objective in this project was to identify and quantify, using active surveillance, nonideal care events that occur for patients being treated in the ED. Based on the infection control model, *active surveillance* is the continuous and systematic collection, analysis, and interpretation of information. As opposed to passive surveillance, which relies on the initiative of the staff to report events, active surveillance involves direct solicitation of event reports. A *nonideal care event* was described as any event in the patient's care that the caregiver did not feel was ideal. The term "nonideal care event," rather than "error," was developed in order to reduce reporting bias by the caregivers. This terminology was determined, through pilot testing of the surveillance process, to be less fraught with negative connotations and less blame oriented than the term "error." *Harm* was defined as the temporary or permanent impairment of physical or psychological body functions or structure.

Two types of event categorization schemes were developed to facilitate identification of targeted areas for improvement. First, the research team outlined the basic steps in the process of delivering emergency care. These *segments of care* were as follows: triage, registration, evaluation, diagnostic testing, treatment, and disposition. An additional category, *transitions*, was added to account for periods when an event occurred during the transfer of care from one clinician to another. We recognize that the *segments of care* are not wholly mutually exclusive across time. In other words, in an ED, it is possible that evaluation, diagnostics, and treatment may occur interlaced and simultaneously. A second categorization scheme was developed to describe the *event category* (e.g., medication delivery; laboratory testing) and *specific event type* (e.g., administration – wrong drug; results – delay or failure to report results). This taxonomy was derived from the hospital's online event reporting system and was actively refined through review of reported events as the study progressed.

Caregiver and Research Assistant Education. Staff members were educated to the goals of the study and the definition of nonideal care events during regular staff meetings, memorandums, and emails. Residents, through their regular weekly conference, were educated as part of a quality and safety lecture series. Emphasis was placed on the nonpunitive nature of the study and the concept of systems factors, rather than individuals, as they related to events in the ED. Caregivers were instructed to report any events to the standard hospital event reporting system as they would through their normal course of work. Cards were given to all staff with information on how to access the online reporting system.

Four research assistants (RAs) from a cohort of trained RAs at the medical center participated in the study. For this project, each RA had at least a Bachelor's of Science in Nursing degree or a master's level degree in a healthcare-related field (e.g., Master's in Public Health) and experience collecting data within the ED environment. RAs were further trained about patient safety principals and practiced querying caregivers before initation of data collection.

Data Collection. The University of Maryland Institutional Review Board determined this project to be "exempt." Trained research assistants (RAs) contacted all available caregivers for the selected patient visits within 1 hour of the patient's discharge. The caregivers selected for interviews were those responsible for the patient at the time of discharge. For patient visits spanning more than one shift, only the caregivers who were present at the time of discharge were interviewed. Given that UMMC is a teaching hospital with an EM residency, there are typically three caregivers identified for each patient: an attending physician; a resident physician; and a nurse. Technicians are not always present in the department, and, when they are, they do not identify with any particular patient.

For those caregivers who agreed to be interviewed, research assistants asked the following questions:

(1) What was your role in the patient's care (e.g., nurse)?
(2) Was this patient's care handed off to you by another staff member?
(3) Was there any part of this patient's care that was not ideal? If yes, please describe how it was not ideal and why you think it might have happened.

In addition to the interviews, the RAs collected basic demographic data for the selected patients and visit characteristics. Given the sensitivity of the questions, no information was collected that could identify an individual patient or caregiver. Caregivers could withdraw from participation at any time during the interview.

Data Analysis. All reports were independently reviewed by two of the investigators (KKH, SS), and the events were categorized into the *segment of care* during which the event occurred and the *event category* and *specific event type*, as derived during the analysis of the data from the active surveillance. Both reviewers referred to alternative methods of categorization, from both within and outside of the literature, in order to constantly and thoroughly test the approach to event categorization. Discrepancies between the two reviewers were resolved through discussion. Throughout the review, continuous reference was made to previously evaluated events in order to ensure consistency throughout the study. The categorization of any event could be questioned at any point in the analysis and review. This would then be resolved through further discussion.

The same investigators (KKH, SS) reviewed all reports to determine whether or not any events had associated harm. It quickly became clear that, in most cases, this could not be determined. When there was enough information, both reviewers had to agree on the occurrence of harm.

Aim 2 – Standard Hospital Incident Reporting System

Data Collection. All reports submitted through the formal hospital incident reporting system with a location of occurrence designated as "Emergency Department – Adult" were extracted for a period of 50 days prior to the start of the active surveillance. Information included the general event category and specific event indicator classifications, the event description as written by the reporter, and whether or not injury was determined to have occurred.

Data Analysis. Reports were independently reviewed by two of the investigators (KKH, SS). Each of the reports was reviewed, and the events were categorized into the *segment of care* during which the event occurred and the *event category* and *specific event type*, as derived during the analysis of the data from the active surveillance. When necessary, event categories were again iteratively reviewed and revised to take into account new information from the incident reporting system.

Aim 3 – Healthcare Failure Mode and Effect Analysis (HFMEA™)

Medication errors are among the most frequent medical errors identified in healthcare and have the potential to cause significant harm. The data generated from Aim 1 was used to identify a high-hazard medication-related process, for which an HFMEA™ was conducted. The HFMEA™ identified process steps in need of improvement, and suggestions for those improvements were made to the ED and pharmacy services administration. The steps involved in the HFMEA™, with a description of the activities, can be found in the *Results* section below.

RESULTS

Aim 1 – Active Surveillance

In total, 656 hours of surveillance were conducted, with 487 visits selected for inclusion, representing approximately 15% of the total visits during the study period. The surveillance represented 82 shifts (26 day, 28 evening, and 28 night shifts) over a 15-week period. Of the 487 visits, there were five visits for which clinician interviews were not obtained. The basic patient demographics and visit characteristics for the 482 visits with associated interviews are described in Table 1.

Table 1. Patient Demographics and Visit Characteristics

Patient Demographics	
Sex	
Male	46 %
Female	54 %
Age Range	
18-29 years	26 %
30-39 years	20 %
40-49 years	27 %
50-59 years	16 %
60-69 years	5 %
70+ years	6 %
Race/Ethnicity	
Black	77 %
White	20 %
Hispanic	1 %
Asian	1 %
Other	1 %
Language	
English	99 %
Spanish	1 %

Visit Characteristics	
Primary Location	
Acute Care	67 %
Urgent Care	32 %
Hallway	1 %
Discharge Destination	
Home	66 %
In-Patient Floor	21 %
ICU	1 %
AMA[1] or Eloped	3 %
RDU[2]	2 %
Other	5 %
Time of Discharge	
Day Shift	32 %
Evening Shift	40 %
Night Shift	28 %
Length of Stay	
Median	341 min.
Range	30-2964 min

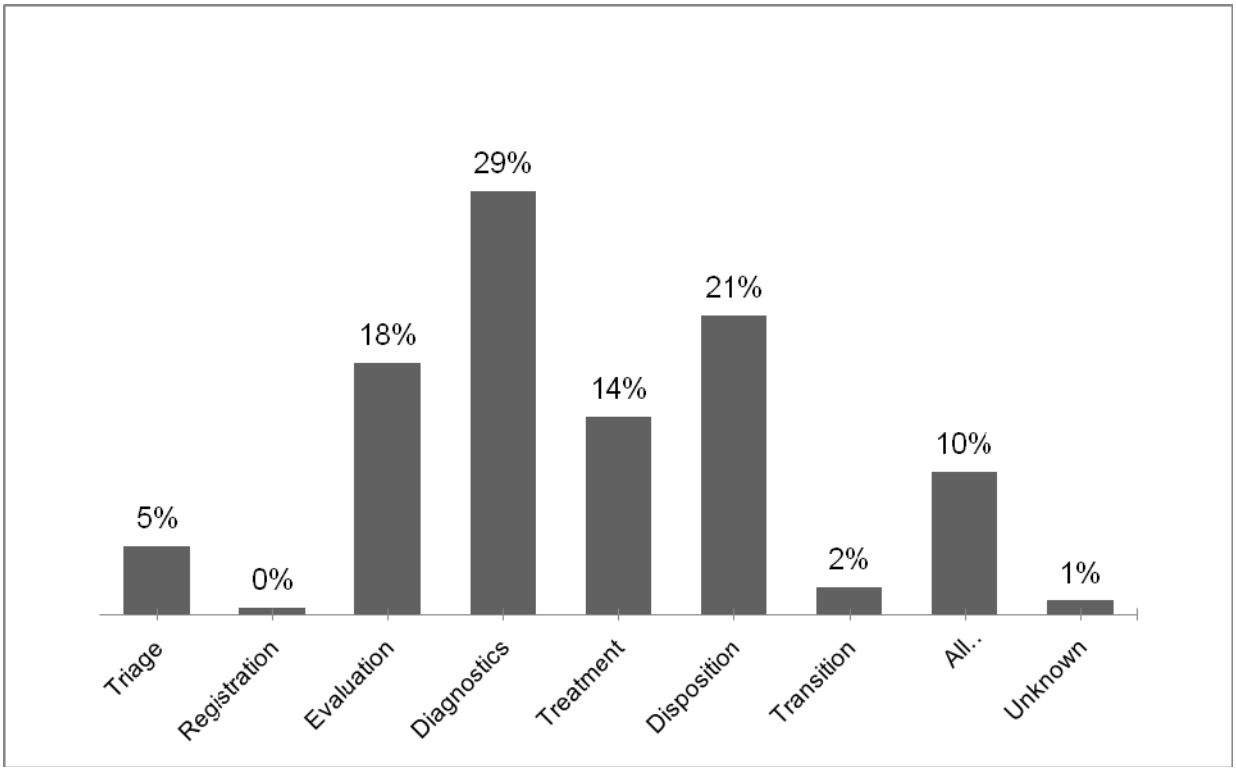
[1] AMA: Against Medical Advice
[2] RDU: Rapid Diagnostic Unit

There were 1180 interviews conducted for the 482 visits, with a median of three interviews conducted for each selected visit. Interviews were conducted with nurses (39% of interviews), resident physicians (32%), attending physicians (28%), and technicians (1%). Of note, the number of technicians working in the ED was significantly reduced prior to the start of the project. There were 27 declined-to-participate responses. Because no individual identifying information was collected for the caregivers, it is not known how many unique individuals are represented by the 27 declines.

Through the 1180 interviews, 263 reports of nonideal care events were generated (53% by nurses, 28% by resident physicians, 19% by attending physicians, 0% by technicians). The 263 reports represented 210 unique (nonduplicative) events for 153 visits. *Thirty-two percent of visits had at least one associated nonideal care event reported, with 13% of the visits having more than one event.*

The nonideal care events were categorized into the segment of care in which they occurred (Figure 1). Twenty-nine percent of the unique events occurred during the diagnostic phase, which included laboratory and radiology testing. Events during the disposition phase (e.g., no inpatient bed availability) accounted for 21% of the discrete events. The results as categorized by event category and specific event type are listed in Table 2. A significant portion of events reported were related to delays or failures, particularly for laboratory and radiology study and result acquisition. Ten percent of the events were related to all segments of the care process. In this category, we chose to include visits when the patient left prior to having evaluation and treatment completed: patients who left against medical advice (AMA) or eloped from the department.

Figure 1. Nonideal Care Events by Segment of Emergency Care



Thirteen visits had a total of 14 events that met criteria for harm, with the majority of these being related to repeated attempts at obtaining intravenous (IV) access (N=7). Other events that led to recognized harm included a case in which there was an incomplete triage evaluation, leading to a significant delay in definitive care for a patient with an acute coronary syndrome; an incomplete initial ED evaluation that led to a missed diagnosis that was discovered by the subsequent shift; an adverse drug event (allergic reaction); and a case in which definitive treatment was delayed because of a reported lack of resident supervision of the consulting service. In a majority of cases, there was no clear report on harm. Given that emergency department care typically represents early care in what may be a prolonged course or hospitalization, it is perhaps not surprising that the vast majority of events fell into an uncertain category. Simply stated, from active surveillance in the ED, it is very difficult to tell whether a nonideal event led to any definitive harm.

Table 2. Events by Category and Type (N=210)

Category	Type	Total Number (No. with known harm)
Care Transfer or Discharge	Inpatient bed availability – delay or failure	31
	Patient left ED before completion of visit (e.g., left against medical advice or eloped)	11
	Delay in transfer of care not related to bed availability	7
	Incomplete discharge	2
	Inadequate follow-up	2
Laboratory Testing	Results – delay or failure to report	20
	Performance – delay or failure to obtain specimen	4
	Ordering – delay or failure to order	3
	Performance – lost or misplaced specimen	2 (1)
	Performance – hemolyzed specimen	2
	Results – delay or failure to act on results	2
Radiology Testing	Performance – delay or failure to perform	13
	Results – delay or failure to report results	5
	Performance – wrong study performed	3 (1)
	Ordering – delay or failure to order	1
	Ordering – wrong study ordered	1
	Results – discrepancy in reading	1
ED Evaluation	Delay or failure to evaluate	10
	Mis-triage (includes over- and under-triage)	5
	Inaccurate or incomplete triage evaluation	4 (1)
	Prolonged time in waiting room	3
	Inaccurate evaluation	1 (1)
	Other	1
ED Consultation	Consultant evaluation – delay or failure	18
	Consultant communication – delay or failure	2
	Inadequate resident or fellow supervision	1 (1)
Medications	Dispensing – delay or wrong time	5
	Medication not available in ED	3
	Ordering – delay or failure	2
	Administration – delay or failure	2
	Adverse drug event	1 (1)
	Medication not available from pharmacy	1
	Ordering – wrong dose	1
	Ordering – wrong time	1
	Dispensing – wrong route	1
Procedures	IV access – unanticipated difficulty obtaining access	7 (7)
	Other procedures – unanticipated difficulty	2
	IV access – IV malfunction	1 (1)
Communication		6
Documentation		6
Patient Factors (e.g., intoxication, behavioral issues)		5
Patient Complaints		4
Other Testing		1
Patient Falls		0
Not Enough Information to Classify		5

Aim 2 – Standard Hospital Incident Reporting System

During the 50-day period preceding the active surveillance in the ED, the hospital's online event reporting system had 63 reports (61 nonduplicative) representing 58 visits. Less than 1% of the total number of visits occurring during the data collection period had a reported event. This differs significantly from the 32% of visits with at least one reported event as determined in Aim 1 through active surveillance.

When the data were classified into the segments of care in which the events occurred, 49% of the reports had to do with *all segments*. This was an effect of the prominence of online reporting of patients who left against medical advice or eloped from the ED (27 of the 61 nonduplicative reports). There were no events categorized in either *triage* or *disposition*, and only one event each was categorized in *registration, evaluation,* and *transfer* segments.

When evaluating the 61 nonduplicative events by category and type, 44% were in the *care transfer or discharge* category, and all had the type *left before completion of visit*. The next most reported events were *medications* (18% of reported events), *patient factors* (13%), and *procedures* (10%).

Of note, there were no falls reported during the active surveillance. Also of interest, there were no online event reports of delays to inpatient bed transfers, which accounted for 15% of all events reported with the method of active surveillance. Clinicians and ED patients are acutely aware of the issues with "boarders," defined as patients who are residing in the ED for more than 120 minutes after the time of bed request. It is interesting that there is no clear way to report this type of event through the online system, though it is of notable concern to the ED clinicians.

As we hypothesized, there were differences in the quantity and types of information collected through each evaluation method, with active surveillance providing more information about issues at the departmental level, particularly with ED processes (e.g., laboratory studies, radiology studies). The online system provided more information about events that are considered high-risk situations at the hospital level (e.g., patients leaving against medical advice, falls). For both reporting systems, 7% of the reported events were determined to have caused harm.

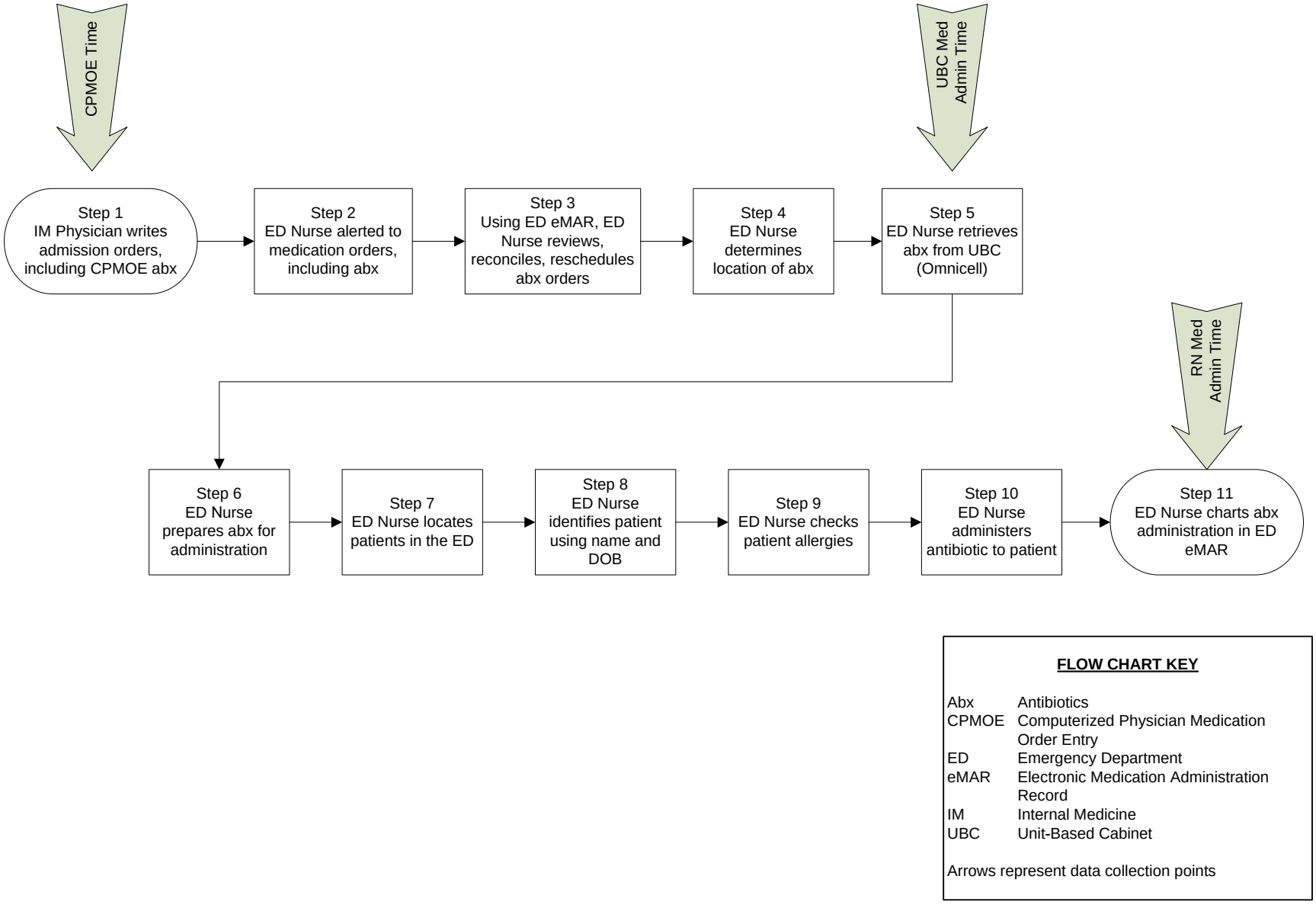
Aim 3 – Healthcare Failure Mode and Effect Analysis (HFMEA™)

Step 1: Define the Process and Scope of Project. Eight percent of reported nonideal care events identified through Aim 1 were related to medication processes. Of particular concern was antibiotic delivery for patients "boarding" in the ED. These patients have a high likelihood of incorrect antibiotic dosing, including omitted, delayed, and duplicate dosing. These data led to the identification of the process for which the HFMEA would be conducted: the processes involved in getting antibiotics, as an inpatient boarding in the ED, through the unit-based cabinet (UBC).

Step 2: Assembling the Team. A cross-disciplinary team of varying levels was organized. The following participants were included on the team: an organization development specialist, who has acted as the project advisor; an executive sponsor, who has ensured that all recommended actions receive support across the institution; physicians, from interns to attendings, representing both the Internal Medicine and Emergency Medicine services; inpatient and ED pharmacists; nurses and nurse managers; a human factors engineer; and information technology representatives.

Step 3: Process Flow Diagram Development. The processes involved in getting antibiotics as an inpatient boarding in the ED, through the unit-based cabinet (UBC), was plotted as a flow chart (Figure 2). Significant time was spent distinguishing the true process from workarounds, which occurred between several of the steps.

Figure 2. HFMEA Flow Chart



Step 4: Hazard Analysis. For each of the process steps, failure modes were determined. The failure modes are the ways that each process step can fail to accomplish its intended purpose and are determined through personal experience and the experience of others. Once the failure modes were determined, the hazard analysis was conducted.

The hazard analysis involved determining the severity and probability of occurrence of the failure modes. The severity of the occurrence was placed into one of four categories, and points were assigned: a c*atastrophic e**vent*, such as death or major permanent loss of function (4 points); a *major e**vent*, including permanent lessening of bodily functioning, increased length of stay, or increased level of care for three or more patients (3 points); a *moderate e**vent*, which included increased length of stay or increased level of care for one or two patients (2 points); or a *minor e**vent*, which did not cause injury or increased length of stay or increased level of care (1 point). For this determination, much discussion occurred over the ability of any of the failure modes to cause a number of different patient outcomes, from no event to death. By consensus, it was decided that the most common outcome of the failure mode would be used to determine the severity.

The probability rating was also determined, and points were assigned: f*requent* – may happen several times in one shift or 1 day (4 points); o*ccasional* – may happen several times in 1 week to 1 month (3 points); *uncommon* – may happen sometime in 1 to 6 months (2 points); or *remote* – may happen sometime in greater than 6 months (1 point). Of note, the probability rating scale was amended to represent the time scale of the emergency department.

In order to determine whether the failure mode warranted further action, the following questions were asked:

> Is this a single-point weakness (criticality)? This question measures whether the entire system will fail if this part of the process fails.
>
> Does an effective control measure already exist? An effective control measure eliminates or significantly reduces the likelihood of the failure occurring.
>
> Is the hazard obvious (detectability)? The question measures the likelihood of detecting failure or the effect of the failure before it occurs.

Using the answers to the above questions and the HFMEA decision tree, we then determined the most important steps on which to focus improvement efforts (Table 3).

Step 5: Actions and Outcome Measures. For those failure mode causes in which the action is to proceed as determined by the decision tree, we developed a description of the action, identified the outcome measures, and identified the persons responsible for completing or ensuring completion of each action.

There are three measures currently being collected. The measures will be used to judge the overall success of our process improvements and include:

1. Time of computer physician medication order entry (CPMOE) to ED antibiotic administration time
2. Time of CPMOE to medication dispensing time
3. Antibiotic dispensing time to ED antibiotic administration time

Implications and Value

The most important implication of improving the delivery of antibiotics for ED patients is the improvement in healthcare outcomes. In addition, secondary gains from this aim of the project include (1) improving the process of delivery for all medications; (2) improving the system for ordering laboratory studies and radiology testing; and (3) improving procedures for computer downtimes, which goes beyond the emergency department to affect the entire hospital.

Table 3. HFMEA Summary

STEP	FAILURE MODE	ACTIONS
Step 1: Inpatient physician writes admission orders, including antibiotics, through computerized physician order entry	Computer system down, affecting all patients *(Hazard Score 9 – severity of effect is major, probability of occurring is occasional)*	Real-time, parallel computer system
		Improve computer downtime procedure: (1) Develop a procedure so that ED administration has ability to stop a scheduled downtime
		Improve computer downtime procedure: (2) Develop pharmacy order sheets that can be scanned – to be used for orders during scheduled or unscheduled downtimes
		Improve computer downtime procedure: (3) Develop a flow chart describing downtime medication order entry procedures for each staff type
	Order entered incorrectly *(Hazard Score 4 – severity of effect is minor, probability of occurring is frequent)*	Medication reconciliation for boarded patients: create a “boarded patient” status, designate a pharmacy, develop plan for transition from ED to floor pharmacy once bed available
Step 2: ED Nurse is alerted to medication orders, including antibiotics, by inpatient physicians	Nurse not alerted to antibiotic orders *(Hazard Score 4 – severity of effect is minor, probability of occurring is frequent)*	Develop improved tracking systems
Step 3: Using the ED electronic medication administration record, ED Nurse reviews, reconciles, reschedules antibiotic orders to correspond to patient medication activities in the ED	Incorrect ED RN review, or reconciliation, or rescheduling of antibiotics *(Hazard Score 4 – severity of effect is minor, probability of occurring is frequent)*	Have last antibiotic dose information easily accessible in the ED electronic medication administration record

CONCLUSIONS

This project is the first to deploy active surveillance of hazards and risks in the emergency department. As expected, active surveillance was found to be a feasible method to gather information at the department level and allowed for the systematic sampling of patient encounters to arrive at an estimate for the number of nonideal events taking place in the ED. When compared with the formal hospital incident reporting system, the active surveillance methodology captured a large number of nonideal events. Nearly one third of the sampled visits contained at least one nonideal event, representing a huge potential for systems changes in a large number of areas.

Active surveillance was found to be particularly effective in describing events related to care delivery processes in the ED. This method captured hazardous conditions, such as delayed or missed diagnostic studies (e.g., radiology and laboratory studies) and time-sensitive therapeutic actions, that were not captured with the formal hospital incident reporting system. The surveillance data reflected the amount of effort that ED team members have to spend in tracking and prodding the delayed processes, particularly those that require the coordination of multiple clinicians across multiple departments. Compared with other care settings, teams in the emergency department are confronted by a heterogeneous patient population, a rapid pace of diagnostic activities, and coordination of care with a multitude of services within the hospital. Initiating and tracking multiple threads of diagnostic and treatment activities creates a high cognitive workload for the ED teams. The results support efforts to develop ED team cognitive aids for tracking processes and the early identification of process issues.