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Errors in ICU: How Safe is the Patient? A Prospective Observational Study in a Tertiary Care Hospital

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Abstract

Objective: Critically ill patients require high-intensity care and may be at especially high risk of iatrogenic injury because they are severely ill. We sought to study the incidence and nature of adverse events and serious errors in the critical care setting.

Design: We conducted a prospective 12 month observational study. Incidents were collected with use of a multifaceted approach including direct continuous observation. The physicians independently assessed incident type, severity, its preventability as well as systems-related failures.

Measurements and main results: The primary outcomes of interest were the incidence and rates of adverse events and serious errors per 1000 patient-days. A total of 242 patients were studied during 1190 patient-days. We found 60 adverse, including 33 (55%) non preventable and 27 (45%) preventable adverse events as well as 114 serious errors. The rates per 1000 patient-days for all adverse events, preventable adverse events, and serious errors were 80.5, 36.2, and 149.7, respectively. Among adverse events, 13% (8/60) were life-threatening or fatal; and among serious errors, 10% (12/114) were potentially life-threatening. Among all the errors whether adverse or serious errors, medication errors were the commonest (37.93%; 66/174).

Conclusions: Adverse events and serious errors involving critically ill patients were common and often potentially life-threatening. Although many types of errors were identified, failure to carry out intended treatment correctly was the leading category.

Keywords: Errors; Intensive care unit; Adverse events

Introduction

The Institute of Medicine's 1999 ground breaking report "To Err Is Human" estimated that opportunities for medical errors cause 44,000–98,000 deaths each year [1]. Although there is a lot of controversy surrounding the mortality estimates do exist, it is evident that medical errors and accidental injuries do occur quite frequently [2,3]. Critical care medicine is fast-paced, complex, and commonly requires urgent high-risk decision-making, often with incomplete data and by physicians with varying levels of critical care training. These factors may lead to higher medical error rates than elsewhere. Critically ill patients are particularly vulnerable to iatrogenic injury because of the severity and instability of their illness and their frequent need for high-risk interventions and medications [4]. To better understand the incidence and nature of serious medical errors in critical care settings we conducted an epidemiologic study to describe the frequency and types of adverse events and near-misses so as to formulate potential prevention strategies.

Materials and Methods

This study was conducted as part of patient safety initiative from June 2013 to Jun 2014, for a period of one year. Data for the current study were collected during rotation periods on nursing staff and residents equally distributed throughout the 12 months. Residents and nursing officers rotated in the intensive care unit maintained the traditional schedule of working overnight as per the hospital policy. The study occurred in the 13 bedded ICU of an 800-bed tertiary care academic hospital, with hospital-based physicians, surgeons and anesthesiologists assuming primary responsibility for patient care.

Definitions

Term	Definition
Medical Error	Failure of a planned action to be completed as intended or the use of a wrong plan to achieve a plan
Serious medical error	A medical error that causes harm or injury or has the potential to cause harm. It includes both intercepted serious errors (caught before reaching a patient) and non-intercepted (not caught before reaching a patient, but because of good fortune or patient reserve the error did not cause a clinically detectable harm.
Adverse Event	Any injury due to a medical management, rather than an underlying disease. These can be non-preventable or preventable.

Table 1: Study definitions.

The definitions used in this study are provided in Table 1 which are as per the Harvard Medical Practice study; however it did not require adverse event to be a cause for prolongation of hospitalization or disability at discharge. Serious medical errors included preventable adverse events, intercepted serious errors, and non-intercepted serious errors [5,6]. Medication-related adverse events or Adverse Drug Events (ADEs) were injuries due to a drug [7,8].

Study design and data collection

Patients admitted to the ICU during the observation periods were followed till transfer out, discharge, or death. Not all the patients admitted to the ICU were included in the study. We randomly selected the patients who will be part of the study to avoid bias of selection, since the observers were mostly the treating physicians. All staff and patient-related data were kept confidential. A two pronged approach was used to capture suspected adverse events and serious errors (collectively referred to as incidents). The primary method of data collection was the direct continuous observation method used in prior ICU error studies [9,10]. The on-call resident was responsible for new admissions and for the entire unit overnight and under the supervision of call duty physician/anesthesiologist/surgeon. Observed activities of interest included physical examinations, physician order entry, diagnostic interpretations of test results, and medical procedures, including compliance with sterile techniques. Nursing staff entered routine orders both during and after team rounds. The residents and the nursing staff doing the majority of procedure are all had minimum 3 years of experience in working in a busy intensive care unit. The observer initially entered suspected incidents into a semi structured confidential diary and then into standardized data forms. If the observer detected an ongoing potentially harmful error unknown to the clinical staff, they were trained to promptly alert the staff. Observers were trained to capture potential incidents using consistent and objective techniques [9]. The inter observer percent agreement for the occurrence of a serious medical error was 82%. Voluntary or solicited reports (Forms) were the second method of incident identification Anonymous, confidential incident reporting forms, could be completed by any unit staff member. Duplicate incident reports were deleted. All the incident reports thus collected were put up to the hospital Patient Safety Committee which went through the details of each incident and then classified the incidents after deliberations.

Event Type	Severity Event	Description and Error Classification
Non preventable Adverse event	Fatal	Acute renal failure resulting in death following sepsis secondary to major trauma
	Life-threatening	Transfusion-related acute lung injury following a red blood cell transfusion in a patient with anemia, syncope, and coronary artery disease
	Severe	Tonic-clonic seizures during imipenem treatment for pseudomonal pneumonia. The antibiotic dosing was appropriate and the seizures resolved after conversion to a different antibiotic.
Preventable Adverse event	Fatal	Fatal septic shock resulting from central venous catheter related bacteremia in a patient with acute respiratory failure from an exacerbation of COPD. Rule-based procedure error: failure to take precautions or follow protocol to prevent accidental injury.
	Life-threatening	Unresponsiveness, hypopnea, and oxygen desaturation after IV lorazepam followed by IV midazolam for a procedure in a patient with a GI hemorrhage. Reversal with flumazenil prevented the need for intubation. Knowledge-based medication error, associated with inadequate training or supervision.
	Severe	Worsening severe ileus in a patient admitted with a DM and cellulitis on a fentanyl IV in advertently not discontinued for 2 days following attending physician recommendations to stop the narcotic infusion. Skill-based (slip) medication error: accidental failure to discontinue a medication order.
Non-intercepted serious error	Life-threatening	Patient with an AMI and immediately after coronary artery stenting inadvertently began receiving subcutaneous heparin instead of full-dose IV heparin. Error not recognized for 12 hrs, but no apparent adverse event occurred. Knowledge-based medication error: choosing the wrong route and dose.
	Severe	Order to discontinue IV furosemide drip at 10 mg/hr was inadvertently omitted following recognition of over diuresis and dehydration in a patient with pneumonia. Error discovered 12 hrs later, after the patient diuresed 3.5 L, but without clinical sequelae. Skill-based (slip) medication error: failure to discontinue a medication.
Intercepted serious error	Life-threatening	Order for IV octreotide at 500 g/hr was intercepted by and corrected to 50 g/hr for a patient with an acute upper GI hemorrhage from esophageal varices. Skill-based (slip) medication error: wrong dosage due to an extra zero.
	Severe	Resident read the wrong day's chest radiograph for a patient with postoperative pulmonary edema. Resident was later informed that the correct radiograph demonstrated worsening edema and a new infiltrate, and new therapy was instituted. Skill-based (slip) diagnostic and monitoring error due to selecting the wrong test to interpret.

Table 2: Examples of adverse events and serious errors.

Incident classification

Incidents were collected for the entire ICU. Incidents not rated as adverse events or serious errors were excluded. For exampl, a pneumothorax in a patient with severe acute respiratory distress syndrome was excluded if it was judged to have occurred as a result of the underlying disease process, rather than as a consequence of therapy (Table 2). On the other hand, a pneumothorax immediately following a central venous catheter insertion was rated as an adverse event. Observers judged severity of an adverse event on a four-point Likert scale (significant, severe, life-threatening, fatal) and preventability on a five-point Likert scale (prevented, definitely preventable, probably preventable, probably not preventable, definitely not preventable). Errors were further classified according to the associated individual and systems factors and the behavioral performance class or type. Performance errors were classified as skill based errors (failure to carry out intended plans of action, including slips or unintended acts and lapses or omitted acts), rule-based mistakes (such as using an incorrect treatment protocol), and knowledge-based mistakes.

Statistical analysis

Categorical variables in the intensive care unit were compared with Fisher's exact test. Comparisons of non-normally distributed continuous variables were made with the Wilcoxon's rank-sum test. Comparisons of means of normally distributed continuous variables were made with Student's *t*-test. Rates of incidents in the ICU were compared by means of the binomial test. Individual incidents could be associated with multiple systems and/or cognitive stage errors, such that total percentages could exceed 100.

Results

During 312 observation days there were 242 observed admissions and 1190 observed patient-days. The patient demography is as per listed in Table 3. In the final analysis only 174 out of 266 reports were considered as adverse event or serious medical error by the Patient Safety Committee (PSC) to be included into the study. Out of the observer detected 198 medical errors 164 were considered to be taken into the study by the PSC, while out of 68 voluntary solicited disclosures only 15 were taken into the study. Many of the reports that were considered to be 'non-critical' were nosocomial infections and pressure sores. These were excluded from the final analysis as there was no single triggering event that could be identified to have caused them.

Adverse events and serious errors

There were a total of 60 adverse events, at a rate of 80.5 adverse events per 1000 patient-days (Tables 4-6). There were 14 life-threatening or fatal adverse events and 46 significant or severe adverse events. The most common adverse events as categorized by organ systems were respiratory (19%), infectious (15%), cardiovascular (12%), and dermatologic and soft tissue (9%). Among all adverse events, % were judged preventable. There were a total of 114 serious errors, at a rate of 158.4 serious errors per 1000 patient-days. Among serious errors, 15.7% (n=18) were judged to be potentially life-threatening.

Incidents were categorised as 1) airway-related, 2) line-related, 3) drug errors, 4) dislodgement of devices other than endotracheal and tracheostomy tubes (accidental extubations and decannulations were included under airway-related incidents). Equipment related incidents were not taken into consideration for error results.

Profile	No
Observed Patients	242
Admission Source	
Emergency Department	82
Transfer from other ward	104
Operating room	56
Principal reason for admission	
Acute coronary syndrome	03
Pulmonary edema/CHF	02
Cardiogenic shock	01
Conduction abnormalities	06
Acute Respiratory failure	48
Acute exacerbation of COPD/Asthma	27
Pneumonia	34
Pulmonary emboli	01
Acute Gasrtrointestinal Hemorrhage	05
Acute Pancreatitis	08
Sepsis syndrome	22
Acute renal failure	09
Acute Neurological disorder/stroke	18
Head Injury	-
Anaemia	12
Other	46

Table 3: Patient Demographics.

Events	No	Prevalence
Adverse Events		
Preventable	33 (36.2)	0.19
Non-Preventable	27 (44.3)	0.55
Total	60 (86.7)	0.13
Non Injurious Serious errors		
Intercepted	68 (89.6)	0.23
Non-Intercepted	46 (60.6)	0.57
Either	114 (158.4)	0.6

Table 4: Incident frequencies.

	Adverse			Non Injurious Serious events		
	Preventable	**Non-preventable**	**All**	**Intercepted**	**Non-Intercepted**	**All**
Significant	13	10	23	31	22	53
Severe	14	9	23	23	20	43
Life Threatening	6	8	14	14	4	18
Fatal	0	0	0	NA	NA	NA
Total	33	27	60	68	46	114

Table 5: Initiation of enteral feeds.

Incident type	Preventable	Serious Error (Intercepted and non-intercepted)
Airway	13	14
Accidental Extubation/Decannulation	03	0
Blocked tube	02	0
Esophageal intubation	01	02
Bleeding from tracheostomy	01	02
Aspiration during intubation	0	03
Pilot balloon tubing of cuff accidently cut	01	03
Tooth dislodged	01	00
False passage during tracheostomy	01	00
Ventilator put on standby for suctioning, not switched on afterwards	00	04
Attempted tracheostomy in ICU, failed due to retro-sternal goitre	01	00
Expiratory port of T tube blocked	01	00
Unnoticed Ventilator disconnection	00	00
Non-Airway related	7	22
Line related incidents		
Ischaemia from arterial lines	1	00
Pneumothorax	1	00
Haemothorax	1	00
Failed to insert central line after multiple attempts	2	06
Arterial hits	3	14
Abnormal bleeding	3	02
Drug-related errors		
Missed dose	2	22
Wrong dose	8	26
Wrong route	1	04
Not labelled, wrongly labeled	0	02

Wrong dilution	01	01
Delayed administration	00	01
Other medication error due to ordering or execution of treatment(LASA)	0	0
Dislodgements	1	24
Central venous catheters	1	07
Chest drains	0	08
Jejunal feeding tubings	0	03
Epidural Catheters	0	02
Abdominal drains	0	04

Table 6: Type and frequency of incidents.

Airway-related incidents

Airway-related incidents constituted 20% (n=12) of all adverse events and 12.2% (n=14) of all non-injurious serious errors reported. This comprised of 9.3 incidents per 1000 ventilator days. Three endotracheal tubes were dislodged by accident and these together formed the majority of adverse airway incidents. All of the patients were re-intubated. Blocked endotracheal or tracheostomy tubes occurred on 2 occasions. 73% (n=19) were classified as miscellaneous which included oesophageal intubation, bleeding from tracheostomy, etc. as mentioned in Table 6. Non-airway-related incidents constituted 85.02% of all incidents.

Line-related incidents

These constituted 16.6% (n=29) (7 adverse and 22 non injurious serious errors) of all incidents. There was one instance of signs of digital ischaemia from arterial lines manifest as bluish discoloration. These changes completely reversed after removing of the lines. A total of 186 central venous catheters were inserted during this period--complicated by one pneumothoraxes and no haemothorax. Arteries were hit on 17 occasions during central venous catheter insertion. Abnormally high bleeding or haematomas happened on three occasions.

Drug errors

These constituted the maximum observed errors. There were 37.93% (n=66) (12 adverse and 54 Non injurious serious errors) incidents related to drug administration which included omitted doses, wrong dose, wrong route, unlabelled or wrongly labelled syringe, wrong patient, failure to discontinue medication. In one instance, streptokinase that was intended to be given intrapleurally was administered accidentally by the intravenous route.

Dislodgements

Twenty five dislodgements were reported (apart from accidental extubations and decannulations which were included under airway complications). These included central venous catheters (8), chest drains (8), and jejunal Feeding tubes (3), epidural catheters (2) and an abdominal drain (4).

Discussion

We found that serious medical errors with potential for or actually causing harm were common in critical care settings. Our findings translate into a daily rate of 0.6 adverse events and 1.2 serious errors per 100 days for a 13 bed critical care unit, less or consistent with other ICU study findings, suggesting that the problem of accidental injuries in critical care is substantial [11-14]. Many previous studies have suggested significant under-reporting [15,16]; we believe our study may have been no exception. In fact, such studies do not reliably reveal absolute incidences as there is no strong denominator. We found that most of the errors were failures to carry out intended plans of action. In general, medicine has focused more on determining what to do than on ensuring that plans are effectively executed. In addition to adverse events, identifying the incidence and epidemiology of serious errors is important for improving safety. These errors did not cause harm either because the patient had sufficient reserve to buffer an error (nonintercepted serious error) or because the error was caught before reaching the patient or before harm developed. Under other conditions, serious errors could cause preventable adverse events and therefore are useful to measure as they provide “free lessons” and can provide insight as to how to improve safety. We found direct observation to be especially valuable in detecting near-misses, as they are far less frequently reported or documented in patient charts than adverse events [9]. Our findings also suggest that direct observation could be a valuable data collection tool for an institution’s quality improvement program. Preventable adverse events and near misses were often associated with deficiencies in systems-related factors, which contribute to repeated errors, usually by different clinicians, and are amenable to correction by providing unit-wide or hospital-wide solutions. These findings are consistent with prior inpatient safety work not restricted to critical care settings.

Some prior critical care safety studies have identified fewer medical errors than this one. This difference may have occurred because we used a more comprehensive data collection methodology than several of these studies [14-16]. In addition, our adverse event definition was more inclusive than that used in the Harvard Medical Practice Study, which was designed to detect injuries associated with negligence [7]. Because of their importance for quality improvement, we included injuries that did not necessarily result in prolongation of hospitalization or disability on discharge.

In a frequently cited ICU study employing direct observation [16,17], medical errors were defined as deviations from standard conduct with or without the potential for harm, excluding medical decision errors. They found a mean of 1.7 errors per patient-day, with nearly half committed by the physician staff. In a surgical ICU study, life-threatening adverse events resulting from physician care occurred at a rate of 23 adverse events per 1000 patient-days. While many of these studies included patients with cardiac diseases, little prior patient safety research has focused on cardiac critical care. Airway incidents were more or less comparable to other studies. There were no fatal events secondary to airway compromise. Our relatively low incidence of pneumothoraxes compared to other reports was probably because the operators involved had all performed more than 50 central venous catheters previously. We also encountered a relatively high incidence of bleeding-related complications during line insertions, probably because our unit has a high caseload of severe sepsis and conditions like malaria, leptospirosis and dengue fever, characterized by low platelet counts and coagulopathy.

Drug-related incidents were generally associated with no adverse outcomes, except for one instance in which streptokinase that was meant to be given intra-pleurally was given intravenously and resulted in significant bleeding that required blood transfusion.

Twenty five central venous catheters and eight chest tubes were dislodged accidentally during the study period, a major physiological change occurred on two occasions as a result of these. A recent study concluded that patients are harmed by preventable incidents related to lines [18], tubes and drains and that these occurred during periods of low level staffing as well as in the sicker group of patients and children. Hospital-acquired infections in critically ill patients deserve special mention. Catheter-related bloodstream infections are especially hazardous. Although it is often impossible to identify a specific error responsible for an infection, deviations from safe practice standards are associated with higher infection rates. Proven interventions to reduce ICU infection rates include hand-hygiene compliance, full sterile barrier precaution during catheter insertions, and empowering nurses to stop catheter insertion procedures if guideline or sterility violations are observed. Many of the skill-based errors (slips and lapses) found in this study are potentially preventable with information and communication technologies that inform, alert, or remind clinicians of tasks (e.g., ordering medications) and test results needing completion, correction, or confirmation.

Future research in critical care patient safety will need to address the particular challenges of the ICU setting, its patients, and especially its staff. Discrepant attitudes exist between ICU nurses and physicians about teamwork experiences, and ICU staffs have difficulty in discussing errors [19]. It is imperative therefore to create a culture to encourage enhanced communication, such as discussing patient safety issues during ICU rounds and increased incident reporting. This study has several limitations. Our finding may not be applicable to critical care units with a substantially different mean severity of illness or units with markedly different patient types (e.g. surgical) or different staffing models or non-teaching ICU's. Our medication error rates may be higher than found in ICU's with computerized physician order entry or onsite pharmacists; both were absent in our units. Finally, incident reporting is highly dependent on institutional and unit cultures. Higher rates of reported intercepted serious errors in an ICU may be due to increased safety awareness and successful redundancies or built-in checks more frequently catch errors and /or culture supportive of more frequently reporting these errors.

Conclusions

Critical care settings provide lifesaving care for the sickest patients but are also associated with significant risks for adverse events and serious errors. It will be especially important to "engineer out" slips and lapses, to improve the likelihood that treatment in the ICUs is implemented as indented.

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