Selected Medical Errors in the Intensive Care Unit
Results of the IATROREF Study: Parts I and II

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***Rationale*: Although intensive care units (ICUs) were created for patients with life-threatening illnesses, the ICU environment generates a high risk of iatrogenic events. Identifying medical errors (MEs) that serve as indicators for iatrogenic risk is crucial for purposes of reporting and prevention.**

***Objectives*: We describe the selection of indicator MEs, the incidence of such MEs, and their relationship with mortality.**

***Methods*: We selected indicator MEs using Delphi techniques. An observational prospective multicenter cohort study of these MEs was conducted from March 27 to April 3, 2006, in 70 ICUs; 16 (23%) centers were audited. Harm from MEs was collected using specific scales.**

***Measurements and Main Results*: Fourteen types of MEs were selected as indicators; 1,192 MEs were reported for 1,369 patients, and 367 (26.8%) patients experienced at least 1 ME (2.1/1,000 patient-days). The most common MEs were insulin administration errors (185.9/1,000 d of insulin treatment). Of the 1,192 medical errors, 183 (15.4%) in 128 (9.3%) patients were adverse events that were followed by one or more clinical consequences (n = 163) or that required one or more procedures or treatments (n = 58). By multivariable analysis, having two or more adverse events was an independent risk factor for ICU mortality (odds ratio, 3.09; 95% confidence interval, 1.30–7.36; $P = 0.039$).**

***Conclusions*: The impact of medical errors on mortality indicates an urgent need to develop prevention programs. We have planned a study to assess a program based on our results.**

Keywords: adverse event; IATROREF; intensive care unit; medical error; quality indicator

AT A GLANCE COMMENTARY

Scientific Knowledge on the Subject

In intensive care units (ICUs), the complexity of care and severity of illnesses result in a high risk for iatrogenic events. Medical errors are common and cause morbidity and mortality in critically ill patients.

What This Study Adds to the Field

After careful adjustment for severity of illness, experiencing more than two adverse events was associated with a threefold increase in the risk of ICU death.

Patient safety a key component of hospital performance is a focus of increasing attention at all levels of the health care system most notably when designing health care policies and hospital quality assurance programs. Iatrogenic events are major contributors to mortality morbidity hospital stay prolongation and health care costs. In intensive care units (ICUs) the complexity of care and severity of illnesses result in a high risk of iatrogenic events (1–3). Enhanced error reporting and disclosure are the key detection strategies recommended in Australia in 2000 (4), in the U.S. by The Joint Commission in 2000 (5), in the United Kingdom in 2000 (6), and in France in 2006 (7).

Critically ill patients are highly vulnerable to medical errors, because they usually have both underlying comorbidities and acute organ dysfunctions (8). In addition, the life-sustaining treatments and highly technical routine care used in ICUs provide many opportunities for medical errors. Efforts have been made to develop standardized definitions of medical errors (9, 10). To be good-quality indicators, medical errors must be common, preventable, reproducible, easy to diagnose and to collect, associated with high morbidity and mortality, and easy to report without fear of punishment. In critical care, there is no generally accepted list of medical errors exhibiting these characteristics.

The objectives of this study were to select medical errors suitable for use as quality indicators, using a modified Delphi technique (part I of the IATROREF I Study) and then to evaluate the incidence of these medical errors in French ICUs (part II) and to assess their relationship with mortality. Some of the results of this study have been previously reported in the form of an abstract (11).

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METHODS

Selection of Indicators

See the online supplement for details of the Delphi process used to select the indicators. We defined a medical error as the failure of a planned action to be completed as intended (i.e., error of execution) or the use of a wrong plan to achieve an aim (i.e., error of planning) and an adverse event as an injury caused by a medical intervention that resulted in harm (12).

Selection of Centers

An invitation to participate in the study was sent by mail in January 2006 to the directors of 250 ICUs having more than 6 beds, and who belonged to the French Society for Critical Care Medicine. Seventy closed ICUs in public and private institutions agreed to participate in the study.

Patient Selection

The study period was from March 27, 2006, at 8 A.M., to April 3, 2006, at 8 A.M. No holidays occurred during this period, making full staffing likely. We included all patients who were in study ICUs on at least 1 day of the study week. Readmitted patients were also included. The study was approved by the Advisory Committee for the Protection of Individuals involved in Biomedical Research, which waived the requirement for written informed consent.

Data Collection

ICU characteristics. The following ICU characteristics were recorded: hospital (university, community, or private hospital; number of beds; and whether the hospital had a risk-management unit), structure of the unit (type, number of acute and intermediate beds, number of senior physicians and fellows, physician-to-patient ratio, and nurse-to-patient ratio), shift for nurses and assistant nurses, whether the unit had a patient-safety program, whether deaths were routinely discussed during specific meetings, ICU mortality, and ICU length of stay. We recorded whether the unit had written procedures for weaning off mechanical ventilation, dialysis, sedation, insulin, and anticoagulant prescription; as well as the extent to which these guidelines were known and followed by the ICU staff.

Patient characteristics. In each center, investigators were free to choose between paper and an electronic file at a data collection website (http://www.iatroref.outcomerea.fr/iatroref/). The same data were collected by both methods. Data written on paper were later entered into the computer, using software that automatically detected inconsistencies. At the end of the study, missing data and inconsistencies were resolved by E-mails sent to each center. Date of hospital discharge was censored on June 30, 2006. The following characteristics were recorded: demographic characteristics (age, sex); underlying diseases, using the Knaus classification (13); admission category (medical, scheduled surgery, or unscheduled surgery), invasive procedures (number of arterial or venous central lines, number of peripheral intravenous devices, number of days of mechanical and noninvasive ventilation), reason for admission (with nine categories defined prospectively before the study, namely, respiratory, cardiac, or renal failure; coma; multiple organ failure, acute exacerbation of chronic pulmonary disease, monitoring, trauma; and scheduled surgery), and number of days with specific medication categories (preventive and curative anticoagulants, sedatives, neuromuscular blockers, insulin, vasoactive drugs, and inotropic drugs). The Simplified Acute Physiology Score (SAPS II) (14) at admission was computed using the worst physical and laboratory data during the first 24 hours in the ICU. Stay duration in the ICU and acute care hospital and vital status at ICU and hospital discharge were recorded.

Safety indicators. The study steering committee wrote a guide for the investigators, explaining how to collect data on patients and medical errors. The guide supplied the definitions (Table 1) and a list of common situations in which each medical error might occur. The ICU physician in charge of the study in each center, assisted by a head nurse, evaluated the consequences of each medical error using preestablished lists and assessed severity on a 6-grade scale (1, no change in management; 2, clinical monitoring; 3, additional laboratory or radiological investigations; 4, additional medical or surgical treatment; 5, initiation of treatment for organ dysfunction; and 6, contribution to death). Contribution to death was assessed as none, improbable, not very probable, somewhat probable, probable, or certain. For 1 week, a 24-hour hotline (M.G.O. or L.S.) was open for answering queries about the study. A daily E-mail was sent to each center to provide support.

Audit. Of the 70 centers, 16 (22.8%) were selected at random for an audit during the study. For practical reasons, two centers were audited on Day 2, one on Day 3, three on Day 4, two on Day 5, and eight on Day 8. The audits were conducted by eight intensivists, each with at least 2 years of ICU experience, who were trained by three study investigators (J.F.T., M.G.O., and L.S.). The auditors were given a guide that contained methods for collecting data on patients and medical errors; definitions of selected medical errors and their consequences; and grades for reporting severity, preventability, and relation with death.

Statistical Analysis

Patient and center variables are reported as numbers (percentage) for qualitative data and medians (Q1–Q3) for quantitative data. Numbers of medical errors on each day were compared by Cochran-Armitage test. Reproducibility of the clinical and laboratory data and of the occurrence of medical errors was tested using κ coefficients or intraclass correlations. Center-based risk factors of medical errors were determined by comparing incidences according to the characteristics of the units, using the Wilcoxon test or Kruskal-Wallis test, as appropriate. We used conditional logistic regression to identify patient-based risk factors for medical errors, taking into account stratification on center and the time spent in the study. Parameters significantly associated with the risk of medical errors were introduced in a hierarchical multivariate logistic mixed model using the GLIMMIX procedure available in SAS 9.13 (SAS Institute, Cary, NC). A backward selection procedure was used to select independent risk factors with $P < 0.05$, and results were routinely adjusted on time spent in the study.

To estimate the relationship between medical errors and ICU death, we built a multivariate model using conditional logistic regression with stratification by center and the time spent in the study. A stepwise process (SLE = 0.2, SLS = 0.05) was used to select a subset of predictive variables from this initial list of variables of clinical interest: age, severity of illness at admission (SAPS II) (14), comorbidity, symptoms and diagnosis at ICU admission, transfer from ward, mechanical ventilation, central venous and arterial catheters, vasoactive drugs, anticoagulants, insulin, sedation, and neuromuscular blockers. The number of medical errors and the number of adverse events were then tested separately in a multivariate hierarchical logistic mixed model. All hierarchical logistic mixed models included random intercept to reflect center variability and were adjusted on time spent in the study. All tests were two-sided, and statistical analyses were performed with SAS 9.13.

RESULTS

ICU Characteristics

The 70 study ICUs included 1,377 patients. After exclusion of the 8 patients who were entered twice, 1,369 patients were left for the study. ICU and patient characteristics are shown in Tables 2 and 3, respectively. Almost half the ICUs had written procedures for respiratory care or insulin or anticoagulant treatment, which were followed in most ICUs.

Safety Indicators

During the study, 1,192 medical errors were reported for 1,369 patients. At least one medical error occurred in 367 (26.8%) patients, for a rate of 2.1/1,000 patient-days. The rate of second occurrences of specific errors was 203/367 (55.3%). The most common medical error was error in insulin administration, with a frequency of 185.9/1,000 days of insulin treatment. Insulin was used in 801 (801/1,369, 58.5%) patients, according to an individually tailored protocol in 30 centers and to a standardized protocol in 40 centers. We examined the characteristics of 36 (90%) of the 40 standardized protocols and found no correla-

TABLE 1. DEFINITIONS OF SELECTED MEDICAL ERRORS

Medical Error	Definition
Suction circuit failure during intubation	The suction system does not work properly: The pressure decrease is not sufficient to ensure removal of pharyngeal, gastric, and/or bronchial secretions during intubation
Laryngoscope dysfunction	The laryngoscope does not work properly: The light is not strong enough or does not turn on during laryngoscopy, assembly of the blades on the handle is difficult or impossible, there is no contact
Medication administered to wrong patient	Medication intended for patient A is given to patient B
Error administering anticoagulant medication	Anticoagulant therapy is not given as prescribed. The divergence may relate to the planning and/or execution of the prescription: drug given, dosage, preparation and administration modalities, dosing times, or dosing intervals
Error prescribing anticoagulant medication	Failure to comply with recommendations (learned societies, department protocols, local drug committees) regarding the indications, dosage, administration modalities, contraindications, drug interactions, or laboratory monitoring of anticoagulant treatment
Error administering vasoactive drugs	Vasoactive therapy is not given as prescribed. The divergence may relate to the planning and/or execution of the prescription: drug given, dosage, or preparation and administration modalities
Error administering insulin	Insulin therapy is not given as prescribed (including as per department protocol). The divergence may relate to the planning and/or execution of the prescription: drug given, dosage, or preparation and administration modalities
Accidental removal of a central venous catheter	Unplanned complete removal of a central venous catheter by the patient or by a health care worker during care or manipulation of the catheter
Accidental extubation	Unplanned extubation
Failure to place patient in semirecumbent position, in the absence of contraindication, during invasive mechanical ventilation with enteral nutrition	A patient receiving enteral nutrition is not kept in a 30–45 degree semirecumbent position during invasive ventilation.For this indicator, patients were excluded if they had a contraindication to the semirecumbent position (hemodynamic instability, spinal surgery, injury to the thoracolumbar spine, or unstable fracture of the pelvis) or if they were in the prone position
Overinflation of the endotracheal balloon	Mean pressure in the endotracheal balloon, measured with a manometer and recorded on the medical chart, is equal to or greater than 35 cm H_2O
Pneumothorax related to insertion of a central venous catheter	Partial or complete pleural detachment by a gaseous effusion on the same side as insertion (or attempted insertion) of a catheter into the internal jugular or subclavian vein, occurring within 48 h of insertion (or attempted insertion), diagnosed radiologically or diagnosed clinically, with a need for drainage of such urgency as to preclude previous radiography
Fall	The patient falls
Delay in surgical treatment	Excessive time between the diagnosis of an acute condition requiring surgery and the surgical procedure according to good clinical practice. Surgery must be performed with no delay at all in patients who have immediately life-threatening lesions (e.g., rupture of large vessels, aortic dissection, or ectopic pregnancy). Surgery must be performed within 6 h of the diagnosis of other lesions (e.g., compound fracture, peritonitis, or acute limb ischemia)

tion with insulin administration errors in a hierarchical negative binomial regression model (data not shown). Table 4 reports the frequency of medical errors, according to the number of days in the study and to the procedure or treatment related to the medical error. We found no relation between the hour of reporting (occurrence or discovery of the medical error) and the occurrence of each medical error (data not shown). Table E2 (*see* the online supplement) displays the results of the univariate analysis of risk factors for medical errors involving selected ICU and patient characteristics. Only patient-related factors were significant and were entered into the multivariable model. In the multivariable model, factors independently associated with having at least one medical error (odds ratio [OR], 95% confidence interval [95% CI]; *P* value) included scheduled surgery (0.54, 0.31–0.96; $P = 0.035$), insulin prescription during the study week (1.60, 1.10–2.35; $P = 0.015$), central venous catheter during the study week (1.80, 1.22–2.64; $P = 0.003$), mechanical ventilation during the study week (2.41, 1.64–3.55, $P \leqslant 0.0001$), and number of days in the study (1.46, 1.35–1.58; $P < 0.0001$). The intercenter covariance parameter estimate was 1.72 (SD, 0.40), indicating highly significant residual variability across centers that was not explained by the model. The independent risk factors for experiencing at least one medical error could be used to identify groups of patients that differ regarding their levels of risk. Table E3 (*see* the online supplement) displays the observed risk of medical errors according to the number of criteria met (patients admitted for emergency surgery, use of mechanical ventilation, central venous catheter, or insulin prescription during follow up). For example, patients meeting at least three of these four criteria (i.e., 55.3% of the overall population) contributed 65.9% of all medical errors.

Severity of Medical Errors

Of the 1,192 medical errors, 183 (15.4%) in 128 (9.3%) patients were classified as adverse events and were followed by one or more clinical consequences (n = 163) or required one or more procedures or treatments (n = 58). Clinical monitoring was required for 74/1,192 (6.2%) events, laboratory or radiological investigations for 28/1,192 (2.3%) events, medical or surgical treatment for 30/1,192 (2.5%) events, and treatment for organ dysfunction for 2/1,190 events. Four deaths were attributable to adverse events (one after self-extubation and three after delayed surgical treatment). One cardiac arrest occurred after accidental extubation; there were no neurological sequelae and the patient died 2 months later from multiple organ failure induced by nosocomial infection. Severity was greater than level 3 (need for monitoring or radiological investigation) for the following numbers of events: accidental extubation (n = 4), overinflation of the intubation catheter balloon (n = 2), failure

TABLE 2. CHARACTERISTICS OF THE 70 STUDY INTENSIVE CARE UNITS

Variable	Data
Hospital	
University hospital, n (%)	35 (50)
Number of hospital beds, median (25th percentile, 75th percentile)	642 (455–1,000)
Presence of a risk management unit, n (%)	55 (78.5)
ICU	
Medical, n (%)	21 (30)
Surgical, n, (%)	7 (10)
Mixed, n (%)	42 (52.9)
Number of acute beds per unit, mean ± SD	13.1 ± 4.8
Number of intermediate beds per unit, mean ± SD	2.7 ± 4.2
Number of units without intermediate beds, n (%)	42 (60)
Number of units with a safety-reporting program, n (%)	37 (52.8)
Meetings on ICU deaths, n (%)	23 (32.8)
Number of attending physicians, mean ± SD	5.46 ± 1.91
Number of junior physicians, mean ± SD	2.75 ± 2.06
Day off after duty for physicians, n (%)	61 (87.1)
Training of junior physicians on duty, n (%)	40 (57.1)
Patient-to-physician ratio	
Mean ± SD	3.05 ± 1.12
Median (25th percentile, 75th percentile)	2.78 (2.23–3.72)
Patient-to-nurse ratio, day (night)	
Mean ± SD	2.72 ± 0.45 (3.14 ± 0.68)
Median (25th percentile, 75th percentile)	2.6 (2.5–3)
Patient-to-nursing assistant ratio, day (night), mean ± SD	4.26 ± 1.54 (5.35 ± 3.09)
12-h shifts for nurses	36 (51.4)
Years of ICU experience for nurses, mean ± SD	4.09 ± 2.05
Written procedures*	
Weaning off mechanical ventilation, n (%)	
None	37 (52.8)
Known and almost always or always followed	21 (30)
Unknown or not followed	12 (17.1)
Sedation, n (%)	
None	40 (57.1)
Known and almost always or always followed	21 (30)
Unknown or not followed	9 (12.8)
Insulin treatment, n (%)	
None	29 (41.4)
Known and almost always or always followed	34 (48.5)
Unknown or not followed	7 (10)
Anticoagulant, n (%)	
None	48 (68.5)
Known and almost always or always followed	12 (17.1)
Unknown or not followed	10 (7)

Definition of abbreviation: ICU = intensive care unit.

* Information about written procedures was obtained from the head physician and head nurse of each study ICU.

to place the patient in the semirecumbent position in the absence of contraindications (n = 2), error administering vasoactive drugs (n = 5), error administering insulin (n = 15), error prescribing anticoagulation medication (n = 2), pneumothorax related to insertion of a central venous catheter (n = 2), delay in surgical treatment (n = 7), and error administering anticoagulation medication (n = 1). For 44/1,192 (3.7%) medical errors, no data were obtained about possible consequences. No consequences were recorded for suction circuit failure during intubation, falls, or medications given to the wrong patient. Table E4 (*see* the online supplement) displays the consequences, including additional treatments, of the other medical errors.

Relationship between Medical Errors, Adverse Events, and Mortality

The multivariable conditional logistic regression model identified 11 variables independently associated with death (*see* Table E5 in the online supplement). After adjustment for these variables in the hierarchical model, we found no significant association between the number of medical errors or the occurrence of the most frequent medical error and ICU death (Table 5). However, having more than two adverse events increased the risk of death (OR, 3.09; 95% CI, 1.30–7.36). As shown in Table E6 (*see* the online supplement), this association persisted when the analysis was restricted to mechanically ventilated patients (OR, 3.08; 95% CI, 1.29–7.36). Clustering of events had no effect on the prognostic model.

Audit

Audits were performed in 16 of 70 (22.8%) ICUs, for a total of 193 patients and 576 ICU days. Agreement was perfect for accidental removal of central venous catheter, falls, and extubation (Kappa, 95% CI, K = 1). Agreement was substantial for failure to place in the semirecumbent position with mechanical ventilation and enteral nutrition (K = 0.74; 95% CI, 0.4–1), pneumothorax (K = 0.66; 95% CI, 0.05–1.0), overinflation of the intubation catheter balloon (K = 0.78; 95% CI, 0.64–0.92), insulin administration errors (K = 0.74; 95% CI, 0.64–0.84), anticoagulant administration errors (K = 0.72; 95% CI, 0.42–1), and anticoagulant prescription errors (K = 0.70; 95% CI, 0.43–0.98). Agreement was almost perfect for medication given to the wrong patient (K = 0.89; 95% CI, 0.75–1). For errors in

TABLE 3. CHARACTERISTICS OF PATIENTS*

Variable	Data
Age, years, mean ± SD	61.2 ± 17.8
Male sex, n (%)	896 (65.4)
SAPS II at admission, mean ± SD	45.4 ± 19.8
Admission type, n (%)	
Medical	964 (70.4)
Scheduled surgery	136 (9.9)
Unscheduled surgery	254 (18.5)
Reason for admission, n (%)	
Respiratory failure	382 (27.9)
Cardiovascular failure	330 (24.1)
Renal failure	58 (4.3)
Coma	212 (15.4)
Multiorgan failure	50 (3.6)
Acute exacerbation of COPD	39 (2.8)
Trauma	52 (3.7)
Monitoring	151 (11.0)
Scheduled surgery	64 (4.6)
Comorbid conditions, n (%)	857 (62.6)
Procedures ⩾1 day, n (%)	
Mechanical ventilation	805 (58.8)
Noninvasive ventilation	171 (12.4)
Central venous catheter	794 (57.9)
Treatments ⩾1 day, n (%)	
Insulin	801 (58.5)
Vasoactive drugs	428 (31.2)
Prophylactic anticoagulation	812 (59.3)
Curative anticoagulation	247 (18.0)
Sedatives	565 (41.1)
Length of ICU stay, days	
Mean ± SD	22.3 ± 33.5
Median (25th percentile, 75th percentile)	10 (4–26)
Mortality, n (%)	
ICU	285 (20.8)
Hospital	350 (25.5)

Definition of abbreviations: COPD = chronic obstructive pulmonary disease; SAPS = Simplified Acute Physiologic Score.
* n = 1,369.

administering vasoactive drugs, agreement was moderate (K = 0.43. 95% CI, 0.17–0.69).

DISCUSSION

We studied the incidence in 70 French ICUs of medical errors selected using Delphi techniques by a large group of professionals belonging to different specialties involved in critical care. The medical error rate was 2.1/1,000 patient-days. The most common medical errors were insulin administration errors. Of all medical errors, we found 15.4% adverse events. Adverse events (i.e., medical errors with either therapeutic or clinical consequences) had considerable prognostic significance, with a threefold increase in mortality among patients who experienced more than two such events.

Among our patients, 26.8% experienced at least 1 of the 14 selected medical errors. In earlier studies, the incidence of all medical errors or adverse events in ICU patients ranged from 6.9 to 56.2% (15–17). Our results are consistent with data reported by De Lassence and colleagues (18) regarding self-extubation (6.4/1,000 vs. 6.5/1,000 in our study) and accidental extubation (3.0/1,000 vs. 4.3/1,000 in our study). The incidence of accidental removal of central venous catheters (2.6/1,000) was in line with data by Lorente and colleagues (2.02/1,000) (19). The 0.88% rate of pneumothorax related to central venous catheters in our patients was lower than usually reported (20, 21). Underreporting is a major obstacle to studies of medical errors. Reasons that may lead to underreporting by staff members include lack of clear definitions of errors (22), fear of punishment, insufficient emphasis on patient safety in the unit leading to inadequate motivation of the staff (23–25), and absence of feedback about the effects of medical errors (22, 26). We sought to avoid these limitations. Thus, we used medical errors that met criteria for good-quality indicators, supplied a detailed definition of each error, and prepared an investigator's guide on data collection. Nevertheless, differences occurred across centers, suggesting underreporting, although we used the reporting method recommended for epidemiological studies (27). The reproducibility of medical error event reporting was good, except for vasoactive drug administration errors. The physicians who performed the audits believed that chart review was usually inadequate for detecting medical errors. Data collection by an external team of ICU staff members (28–30) was strongly recommended by the steering committee but proved infeasible. Collecting all medical errors all the time would be an overwhelming task. The results of this study have helped the French Society of Critical Care Medicine to select medical errors for the purpose of mandatory reporting in French ICUs.

The patients with the most severe illness were more often the subject of medical errors. Only patient variables were selected by the multivariable model, in line with several earlier studies (17, 20, 31, 32). Prevention programs should target the most severely ill patients, defined by our multivariable model as patients receiving mechanical ventilation, central venous catheterization, or insulin or not undergoing scheduled surgery. The considerable center-to-center variability in medical error rates might be partly ascribable to the short study period but also suggests a potential for improvement. Many system factors that might explain the variability (33) were not investigated and deserve further studies. More specifically, workload, burnout (34), and teamwork climate or job satisfaction (33) may affect medical error rates (35). This multiplicity of factors considerably complicates the development of a safety culture in the ICU, and studies of sources of variability across centers will likely be helpful in the future. Furthermore, our data were obtained in ICUs whose patient-to-nurse ratios were those usually encountered in France. We found no clustering of adverse events at specific times during the 24-hour cycle or on weekends (36, 37). The relation between the complex ICU environment, complexity of the patients, and occurrence of medical errors suggests that guidelines, education, and communication skills training (38) might foster a culture of safety in the ICU, thereby decreasing medical error rates.

The five most common adverse events were errors administering medications (vasoactive drugs and insulin) and events related to mechanical ventilation (unplanned extubation, overinflation of intubation catheter balloon, and failure to place the patient in the semirecumbent position). These results are consistent with those of the Sentinel Events Evaluation (SEE) Study (39). Insulin administration errors deserve further comment. This adverse event was selected by the experts after the first randomized study of tight glucose control (40). Our definition, which included incidents without harm, contributes to explain the high frequency of this event. Given the premature discontinuation of two studies on tight glucose control (41) because of increased rates of hypoglycemia, the results of a meta-analysis (42), and the potential harm associated with hypoglycemia (43), the risk-to-benefit ratio of tight glucose control is still controversial in ICUs. Although insulin administration errors did not consistently cause harm in our study, the potential for harm existed. Therefore, prevention programs must focus on this medical error, as done in part III of this research project, whose results have not yet been published. Had the high rate of insulin administration errors been known at the time, the risk-to-benefit ratio of studies of tight glucose control would

TABLE 4. RATES OF OCCURRENCE OF THE 14 SELECTED MEDICAL ERRORS

Medical Error	Number of Medical Errors	Domain of Care with Opportunity for Medical Errors*	Patients with Domain of Care	Days with Domain of Care†	ME/1,000 Days with Domain of Care; Median (IQR)
Suction circuit failure during intubation	2	IMV	805	3,223	0.6; 0 (0)
Laryngoscope dysfunction	0	IMV	805	3,223	0; 0 (0)
Medication administered to wrong patient	23	All	1,362	5,678	4.1; 0 (0)
Error administering anticoagulant medication	23	AC	1,033	4,362	5.3; 0 (9)
Error prescribing anticoagulant medication	36	AC	1,033	4,362	8.3; 0 (9)
Error administering vasoactive drugs	29	VAD	428	1,379	21.0; 0 (0)
Error administering insulin‡	630	Insulin	801	3,389	185.9; 0 (34)
Accidental removal of a central venous catheter	9	CVC	794	3,437	2.6; 0 (0)
Accidental extubation					
Accidental extubation	14	IMV	805	3,223	4.3; 0 (0)
Self-extubation	21	IMV	805	3,223	6.5; 0 (0)
Failure to place patient in semirecumbent position, in the absence of contraindication, during invasive artificial ventilation with enteral nutrition	121	IMV	805	3,223	37.5; 0 (48)
Overinflation of intubation catheter balloon	261	IMV	805	3,223	81.0; 0 (73)
Pneumothorax related to insertion of central venous catheter	7	CVC	794	3,437	2.0; 0 (0)
Fall	6	All	1,369	5,678	1.1; 0 (0)
Delay in surgical treatment	10	All	1,369	5,678	1.8; 0 (0)

Definition of abbreviations: AC = anticoagulant; CVC = central venous catheter; IMV = invasive mechanical ventilation; IQR = interquartile range; ME = medical error; VAD = vasoactive drug.

* Domain of care associated with opportunities for each selected medical error.

† Total number of days with the relevant domain of care during the study period.

‡ Including 101 insulin errors with at least one clinical consequence: hypoglycemia defined as blood glucose ⩽54 mg/dl (n = 24) or hyperglycemia defined as blood glucose ⩾200 mg/dl (n = 77).

perhaps have been better assessed before the conduct of large randomized studies that exposed patients to harm.

Having more than two adverse events was an independent risk factor for ICU mortality. This result agrees with findings from other studies that used different methodologies (20, 43, 44). The mortality attributable to adverse events is difficult to assess for many reasons including case mix, confounding factors for mortality, and occurrence of multiple adverse events in the same

TABLE 5. IMPACT ON MORTALITY OF SUM OF MEDICAL ERRORS IN A GIVEN PATIENT

	Survived	Died	Adjusted OR* (95% CI)	*P* Value
Number of medical errors				0.65
0	772	230	1	
1	117	47	0.88 (0.56–1.40)	
2	37	20	1.04 (0.52–2.11)	
3	28	16	1.73 (0.79–3.78)	
4	32	12	0.81 (0.37–1.77)	
⩾5	33	25	1.29 (0.67–2.49)	
Number of medical errors followed by clinical or therapeutic consequences = adverse events				0.039
0	940	301	1	
1	63	30	1.09 (0.64–1.88)	
⩾2	16	19	3.09 (1.30–7.36)	
Number of medical errors without consequences				0.57
0	806	247	1	
1	98	42	0.81 (0.50–1.32)	
2	38	17	0.89 (0.44–1.81)	
3	25	14	1.72 (0.78–3.79)	
⩾4	52	30	0.95 (0.53–1.69)	
At least one "accidental extubation"†	22	9	0.98 (0.39–2.46)	0.93
At least one "overinflation of the intubation catheter balloon"†	71	42	1.01 (0.61–1.67)	0.98
At least one "failure to place patient in semirecumbent position"†	58	27	0.96 (0.52–1.77)	0.89
At least one "error administering insulin"‡	95	52	1.27 (0.80–2.02)	0.31
At least one "error prescribing anticoagulant medication"§	19	8	0.73 (0.26–2.03)	0.55

Definition of abbreviations: 95% CI = 95% confidence interval; OR = odds ratio.

Note: For the relationship between specific medical errors and mortality, some medical errors were not included in the analysis given their low rates of occurrence, namely, suction circuit failure during intubation (n = 2), medication administered to wrong patient (n = 23), error administering anticoagulant (n = 23), accidental removal of a central venous catheter (n = 9), error administering vasoactive drugs (n = 29), pneumothorax related to insertion of a central venous catheter (n = 7), fall (n = 6), and delay in surgical treatment (n = 10). There were no instances of laryngoscope dysfunction.

* Adjusted for duration of risk exposure and for factors significantly associated with mortality.

† Among patients receiving invasive mechanical ventilation.

‡ Among patients receiving insulin.

§ Among patients receiving anticoagulant.

patient (45, 46) with interactions between adverse events. When these factors were taken into account using appropriate statistical methods, we found that having multiple adverse events correlated with death, in keeping with an earlier study (8).

Strengths of this study include the selection of medical errors by a panel of experts, clear definitions of errors, the audit of the study, and the careful assessment of effects on mortality. These results and the preventability analysis (data not shown) permitted us to design a multifaceted prevention program, which will be evaluated in part III of our IATROREF research project. This study has several limitations. First, the 1-week study period may be too short to allow generalization of our results. Second, considerable reporting differences occurred across centers. Some medical errors were perhaps not reported, despite the brief study duration and daily supportive E-mail to each ICU team. Although we supplied detailed definitions of the medical errors, there may have been some measure of personal interpretation. Differences in motivation and in the emphasis on patient safety, together with the lack of in-person training about the study protocol, probably contributed to the differences in reporting and in the interpretation of clinical consequences, despite the existence of a collection guide. Third, few explanations to the medical errors were suggested. More specifically, the impact of the lack of guidelines in about half the centers and of failure to follow guidelines in a few centers cannot be determined without a root cause analysis of the medical errors.

In conclusion, our study provides new insights into the epidemiology of selected medical errors in the ICU. We established a list of medical errors that can serve as quality indicators in ICUs and we estimated their incidence. The impact of adverse events on mortality indicates an urgent need for prevention programs in ICUs. We have planned a study to evaluate such a program.

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