

INDICATORS OF ADVERSE EVENTS IN THE INTENSIVE CARE UNIT A FRENCH MULTICENTRIC STUDY

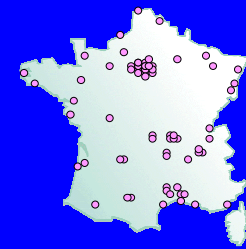
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From the French Outcomerea Study Group <http://www.outcomerea.org>

14 ICU related Adverse events selected by 60 experts with a delphi method.

Adverse events	Definitions
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, dosing intervals.
Error prescribing anticoagulant medication	Failure to comply with recommendations (VIDAL compendium, learned societies, department protocols, local drug committees) regarding the indications, dosage, administration modalities, contraindications, drug interactions, or laboratory monitoring of anticoagulant treatment.
Error administering vasopressors	Vasopressor 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.
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, 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 healthcare worker during care or manipulation of the catheter.
Accidental extubation	Unplanned extubation
Failure to place patient in semi-recumbent position, in the absence of contraindication, during invasive artificial ventilation with enteral nutrition	A patient receiving enteral nutrition is not kept in a 30-45 degree semi-recumbent position during invasive ventilation.
Overinflation of the intubation catheter balloon	Mean pressure in the intubation catheter balloon, measured using a manometer, is equal to or greater than 35 cm H2O.
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 in the internal jugular or subclavian vein, occurring within 48 hours 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 delay between the diagnosis for an acute surgical syndrome and surgical treatment as defined by good practices. We define two kinds of emergencies: extremely urgent requiring immediate surgery and urgent if it requires surgery in no more than six hours following diagnosis.

Selection of centers
An invitation to participate in the study was sent by mail in January 2006 to the directors of 250 ICUs belonging to the French Society of Critical Care Medicine. We selected adult ICUs with more than 6 beds. Among the 250 ICUs, a random sample of 70 ICUs in public and private institutions were taken.

Patient selection
The study period was from the March 27, 2006, 8 AM to April 3, 2006, 8 AM. We included all patients present on the first day at 8 AM. They were followed-up until hospital discharge. Date of hospital discharged was censored on June 30.



ICU Characteristics

Variables	Number (%)
University hospital	35 (50)
Number of hospital beds	642 [-455 - 1000]
Presence of a risk management unit	55 (79.7)
Medical ICU	21 (30)
Mixed ICU	42 (60)
Number of acute beds per unit	13.1±4.9
Physician to patient ratio	3.1 ±1.1
Nurse to patient ratio	2.7 ±0.4
Nurses work 12 hours	32 (45.7)
Written protocol for	
Weaning of MV	37 (52.9)
Sedation	40 (57.1)
Insuline treatment	29 (41.4)
Anticoagulant	48 (68.6)

Patient Characteristics

Variables	Number (%)
Included Patients	1369
Age, yr	61.2±17.8
Male sex, % of men	896 (65.4)
Medical pts	964 (70.4)
SAPS II at admission	45.4±19.8
Co morbid condition	857 (62.6)
Procedure ≥ one day	
Mechanical ventilation	805 (58.8)
Non invasive ventilation	171 (12.4)
Central venous catheter	794 (57.9)
Treatment ≥ on day	
Insuline	801 (58.5)
Vasopressors	428 (31.2)
Anticoagulation	1059 (77.3)
Sedative agents	565 (41.1)
Length of ICU stay	22.3±33.5
ICU mortality	350 (25.5)

FREQUENCY OF THE ADVERSE EVENTS

Adverse event	Nb AE	Nb patients with care	Nb days with care*	NbAE/nb days with care
Suction circuit failure during intubation	2	805	3223	0,6
Laryngoscope dysfunction	0	805	3223	0,0
Accidental removal of a central venous catheter	9	794	3223	2,6
Extubation (TOTAL)	35	805	3223	10,8
<i>Accidental</i>	14	805	3223	4,3
<i>Self Extubation</i>	21	805	3223	6,5
Fall	6	1369	9583	0,6
Overinflation of intubation catheter balloon	261	805	3223	81
Failure to place pt in semi-recumbent position	121	805	3223	37,5
Medication administered to wrong patient	23	1362	9583	2,4
Error administering anticoagulant	23	1033	4362	5,3
Error administering vasopressor	29	428	1371	21,1
Error administering insulin	630	801	3389	185,9
Error prescribing anticoagulant	36	1033	4362	8,3
Pneumothorax related to insertion to a CVC	7	794	3437	2,0
Delay in surgical treatment	10	1362	9583	1,0
TOTAL	1192	1369	9583	209,9

* Total of days with the selected care during the study period

Severity scale

0. No modification of care
1. Clinical need for monitoring
2. Need for additional laboratory or radiological examination
3. Need for additional medical or surgical treatment
4. Need for startup a treatment for organ dysfunction
5. Involving death

Preventability scale

0. Excluded
1. Far from probable
2. Not very probable
3. Enough probable
4. Probable
5. Certain

SEVERITY OF THE ADVERSE EVENTS

Adverse event	No effet N (%)	At least one effet N (%)	Total
Suction circuit failure during intubation	1 (50.0)	1 (50)	2
Accidental removal of a central venous catheter	4 (44.4)	5 (55.6)	9
Extubation (TOTAL)	12 (34.3)	23 (65.7)	35
<i>Self extubation</i>	6 (28.6)	15 (71.4)	21
<i>Accidental</i>	6 (42.9)	8 (57.1)	14
Fall	4 (66.7)	2 (33.3)	6
Overinflation of intubation catheter balloon	257 (98.5)	4 (1.5)	261
Failure to place pt in semi-recumbent position	103 (85.1)	18 (14.9)	121
Medication administered to wrong patient	22 (95.7)	1 (4.3)	23
Error administering anticoagulant	17 (73.9)	6 (26.1)	23
Error administering vasopressor	20 (69.0)	9 (31)	29
Error administering insulin	587 (93.2)	43 (6.8)	630
Error prescribing anticoagulant	26 (72.2)	10 (27.8)	36
Pneumothorax related to insertion to a CVC	2 (28.6)	5 (71.4)	7
Delay in surgical treatment	0 (0.0)	10 (100)	10
TOTAL	1068	173	1205

PREVENTABILITY THE OF THE ADVERSE EVENTS

Considered Event	Rather UnPreventable N (%)	Rather Preventable N (%)	Total
Suction circuit failure during intubation	1 (50.0)	1 (50)	2
Accidental removal of a central venous catheter	5 (55.6)	4 (44.4)	9
Extubation (TOTAL)	5 (14.3)	30 (85.7)	35
<i>Self extubation</i>	1 (16.7)	5 (83.3)	6
<i>Accidental</i>	29 (11.1)	232 (88.9)	261
Failure to place in semi-recumbent position	32 (26.4)	89 (73.6)	121
Medication administered to wrong patient	1 (4.3)	22 (95.7)	23
Error administering anticoagulant	1 (4.3)	22 (95.7)	23
Error administering vasopressor	1 (3.4)	28 (96.6)	29
Error administering insulin	144 (22.9)	486 (77.1)	630
Error prescribing anticoagulant	26 (72.2)	10 (27.8)	36
Pneumothorax related to insertion to a CVC	6 (85.7)	1 (14.3)	7
Delay in surgical treatment	3 (30.0)	7 (70.0)	10
TOTAL	230	974	1205

Definition of preventable: when scored enough probable, probable or certain

Brief outline of context:

Selection by a panel of experts of the most representative adverse events (AE) in the intensive care unit (ICU) setting followed with a multicentre study to determine their incidence, impact on outcome and preventability.

Brief outline of problem:
In ICUs, as the workload is higher, the risk for AE is thought to be important. The absence of knowledge on the incidence and consensus on which AE should be prevented makes it difficult to conduct homogeneous and comparable clinical trials or initiatives to improve safety in the ICU.

Assessment of problem and analysis of its causes:

A panel of 60 experts used a Delphi technique to select 14 AE with these characteristics: common, source of morbidity, reproducible and easy to collect.

Strategy for change:

One week multicentre cross-sectional study carried out in a sample of 70 ICUs in France.

In each centre a senior physician was in charge of data collection and was provided with paper and electronic files, guidance, and a 24 hour helpdesk. We collected the usual data to describe ICU patients and for each one of the 14 AE events was provided a list of possible clinical and therapeutic consequences. The reporting had to include the severity and preventability for each AE both reported using a 6 grades scale.

The frequency of an event was defined by the ratio between the number of indicators collected for 1000 days of exposure (after stratification on the centre, the number of days spent in the week of study and exposure to the specific risk).

Measurement of improvement:

We included 1369 patients (age 61.2 ± 17.8; male sex: 65.5%; 70.4% medical admissions; SAPS II 45.4 ± 19.8) totalling 9583 days of risk exposure. The characteristics for the reported AE are detailed in the table below.

After adjustment on severity and duration of exposure to the risk (logistic generalized model), the occurrence of more than 5 iatrogenic events significantly increased the risk of death (OR: 3.66 [1.25-10.7]).

Effects of changes:

We were able to determine the incidence, severity and preventability for the most descriptive events of actual safety problems in French ICUs. This knowledge provides the basis to design quality improvement programs.

Lessons learnt: Adverse events are common in the ICU setting (cumulative incidence of 210 events for 1000 days of risk exposure) and source of morbidity and mortality. There are wide variations in the frequency, severity and preventability between the AE.

We selected the errors in insulin delivery, in anticoagulant prescription and delivery and accidental extubation or catheter removal as having the best combination of frequency, severity and preventability. The last phase of our study, performed in 2007 is designed as a multifaceted program to increase the safety in the ICU by reducing the incidence and morbidity related to these 5 AE.

Message for others: The design of an action to enhance safety in the ICU needs to select AE with those characteristics: frequency doesn't need to be high but shouldn't be too rare, and most importantly reproducibility, severity and preventability need to be important.

Impact of the Adverse events on mortality

Adverse event	Alive	Dead	Adjusted OR 95% CI	P-value
Number of AES				0.23
0	772	230	1	
1	117	47	0.95 (0.57-1.58)	
2	37	20	1.03 (0.45-2.36)	
3	28	16	1.78 (0.65-4.88)	
4	32	12	1.08 (0.41-2.85)	
≥ 5	33	25	3.66 (1.25-1.76)	
Number of AEs followed by clinical or therapeutic consequences				0.013
0	940	301	1	
1	63	30	1.17 (0.62-2.22)	
≥ 2	16	19	5.20 (1.73-15.63)	
Number of AEs without consequences				0.52
0	806	247	1	
1	98	42	0.93 (0.53-1.63)	
2	38	17	1.08 (0.47-2.47)	
3	25	14	1.66 (0.66-4.16)	
≥ 4	52	30	2.03 (0.84-4.92)	

The multivariable model using a conditional logistic regression found 11 variables independently associated with death: sex, length of ICU stay, age, SAPS II (>30, >50), co-morbidities (leukaemia, cancer), transfer, central venous catheter, mechanical ventilation, vasopressors.

After adjustment for these prognostic variables to assess the impact of adverse events on ICU mortality. We found that more than five adverse events was an independent risk factor for ICU mortality (Odds ratio, OR: 3.66, 95% Confidence, 95%CI: 1.25-1.76, p=0.023). When adverse events were followed by consequences, more than 2 had a substantial impact on mortality (OR: 5.20, 95% CI: 1.73-15.63).

The Next Study: IATROREF III

a Multifaceted Program for Improving Quality of Care in ICU

ClinicalTrials.gov: NCT00461461

--> Just finished including patients.

5 Adverse events in 3 groups :

- 1: Error in insulin delivery,
- 2: Error in anticoagulant prescription and delivery
- 3: Unplanned catheter removal, Unplanned extubation

3 ICUs participated in a multicenter cluster randomized design to assess the effectiveness of the multifaceted intervention.

We randomized each unit to compliance with ICU guidelines as usual or implementation of the multifaceted intervention to prevent one of the AEs. Randomization occurred at the ICU level.

Units that did not use the intervention program serving as controls.

The randomization procedure was repeated every 2 1/2 months for a total of four 21/2-month periods in 2007-2008.

For each one of the adverse events we designed a multifaceted program to reduce it's incidence, including meetings and lectures to discuss the concerned care, and the pathophysiology of the adverse event. Pocket cards with the nature of the care and recommendations for avoiding the AE. Feedback Meetings with the staff to discuss recent adverse events, causes, preventability and to design procedures to avoid the concerned AE.

OUTCOMEREA