Variable compliance with clinical practice guidelines identified in a 1-day audit at 66 French adult intensive care units*

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Objective: **Clinical guidelines should provide a framework for managing patients hospitalized in intensive care units. Little is known about guideline compliance in real-life practice. To evaluate compliance rates for a large bundle of intensive care unit practice guidelines and determine factors associated with noncompliance to these guidelines.**

Design, Setting, and Patients: **A bundle of 13 clinical guidelines was elaborated by a group of senior physicians. Four external consultants validated the process. Then, a 1-day audit was performed at 66 participating adult intensive care units in 39 institutions by a group of 64 junior investigators supervised by senior intensivists. At the bedside, investigators collected data from 625 patients hospitalized in those units.**

Interventions and Measurements: **The eligibility and compliance rates were determined for each clinical recommendation. The rate of full compliance to each eligible clinical guideline was calculated. Mortality data were requested 28 days after the completion of the audit.**

Main Results: **The eligibility rate ranged from 11% (sepsis bundle) to 80% (identified closest relative). The median compliance rate was 75% (60–100), ranging from 24% (sedation monitoring) to 96% (identified closest relative and bacteriological sampling before initiating antibiotics). Our results showed that only 24% (20–27) of patients in our cohort received fully compliant care. The 28-day survival probability was .77 (.73–.80).**

Conclusions: **At the bedside, clinical guidelines are fully applied in 24% of patients. Our study underlines the need to both improve the process of implementation and become cognizant of excessive proliferation of clinical guidelines. (Crit Care Med 2012; 40:3189–3195)**

Key Words: audit; compliance; critical care; evidence-based medicine; guidelines; recommendation

Clinical guidelines aim to improve standards of care for patients and offer the opportunity to apply evidence-based medicine and expert recommendations in routine practice without excessive delay. As evidence shows that care processes are associated with improved outcomes, one of the driving forces behind the use of clinical guidelines is to reduce the large variability observed in clinical practice (1, 2). However, physician compliance to clinical guidelines may be hindered by several hurdles. As described elsewhere, a lack of awareness and familiarity affect physician application of guidelines (3, 4)

The last several decades have born witness to a steady increase in the percent of hospital beds dedicated to the care of critically ill patients as well as resources required to provide this care (5). Despite this rising investment, the outcomes of critically ill patients may be compromised by inappropriate care and deficient application of accepted clinical guidelines. These established "best practices" guidelines include care for patients with severe sepsis and acute respiratory distress syndrome as well as means to optimize use of sedatives and analgesics and decrease risks of ventilator-associated pneumonia, among others (6–10).

Physician compliance with global clinical guidelines in a general intensive care unit (ICU) population remains poorly understood; furthermore, compliance with individual guidelines remains variable at best (11). Our goals were to evaluate the rate of compliance with a bundle of 13 ICU guidelines and to determine factors associated with noncompliance to each of the 13 guidelines used in the care of critically ill patients.

METHODS

Within the parameters of French law, informed consent was waived due to the

***See also p. 3317.**

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Drs. Allaouchiche, Constantin, Lefrant, Leone, and Jaber conceived and designed the study. Drs. Lefrant, Leone, and Ragonnet performed the investigation. Mr. Alonso and Drs. Lefrant, Leone, Fabbro-Peray, and Ragonnet contributed analysis tool. Drs. Allaouchiche, Constantin, Lefrant, Leone, Martin, Fabbro-Peray, and Jaber analyzed the data. Drs. Lefrant, Leone, Martin, Fabbro-Peray, and Ragonnet wrote the article. Dr. Fabbro-Peray has full access to original data.

Members of the AzuRéa Group are listed in Appendix 2.

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observational nature of the study, but all patients and their relatives were informed about the study by ICU physicians and had the opportunity to refuse to participate. The study was approved by the local Ethics Committee of the Nimes University Hospital (IRB09/04/03).

Study Design. As described in a previous study (12), the AzuRéa group is a network that includes 66 ICUs in 39 institutions (35 cities), representing 710 beds. Among these 66 ICUs, 33 units are located in academic hospitals and 33 in nonacademic hospitals. The participants were invited to participate without financial incentive. From January to May 2009, a 1-day audit was conducted after obtaining permission from the ICU directors. However, the medical staff of each unit was kept unaware as to the exact day of the audit. The ICU directors were only informed about the audit 1 day beforehand.

The audit was conducted by a group of 64 resident physicians (Appendix 1). These residents had completed at least 3 yrs in a 5-yr formal critical care program. They should have already worked at least 6 months as a critical care resident in the audited unit. In practice, they managed critically ill patients under the supervision of a senior attending physician (with activities that included physical examination, specialized procedures like central line insertion, prescription of drugs, and involvement in the daily care decision making). Briefly, they were selected for their skills to perform a quality assessment. No resident participating in the study, however, was involved in patient care. Each resident was expected to audit around ten patients. In each academic center, a senior physician was trained before the audit visit. A dedicated hotline was available on the audit day in order to provide a rapid means of communication between residents and senior investigators (J.-Y.L., M.L., and J.-M.C.).

The residents had to fill a case-report form (20 sheets) with the following patient admission variables: age, sex, height, weight, past medical history, admission diagnosis, MacCabe score, Simplified Acute Physiology Score II (13), and admission vital signs. For each ICU stay, residents collected data on the number of organ dysfunctions and infections using the organ system dysfunction and risk prediction score (14) and medical diagnostic codes leading to ICU reimbursement (entitled thereafter billing procedures). On the audit day, residents collected the following variables: Sequential Organ Failure Assessment (15), medical or surgical status, and all data related to ventilatory support, analgesic and sedative administration, hemodynamic variables, nutrition support, anticoagulation use, method of blood glucose control, renal function, infectious processes, and ethical considerations (plan of care, contact with relatives). In addition, data regarding the type of hospital (academic or nonacademic), the number of ICU beds, the ratio of nurses to patients, and the number of billing procedures per patient were collected. The mortality rate was measured 28 days after the audit day by contacting the director of each ICU.

The case report form was elaborated by a group of senior physicians. Thirteen guidelines, according to recent (<5 yrs) French and international consensus conferences, were proposed by senior investigators (B.A., J.-M.C., S.J., J.-Y.L., M.L.) to determine the most consensual attitude for each item. Then, these guidelines were validated by four external physician consultants (the steering committee), who were members of the referential committee of the French Society of Anesthesia and Intensive Care. An initial data analysis was performed to check the ability of studied variables to assess the implementation of each recommendation. The clinical guidelines are shown in Table 1 (7–10, 16–26). The eligibility and compliance criteria of each recommendation are shown in Supplemental Digital Content 1 (http://links.lww.com/CCM/A545).

On the audit day, 625 patients hospitalized in 66 ICUs were included in the study (Table 2). This population was described in a prior study (12). Within the ICU stays, vasopressors, mechanical ventilation, noninvasive ventilation, and renal replacement therapy were used in 417 (67%), 418 (67%), 120 (19%), and 100 (16%) patients, respectively. The eligible population consisted of the number of patients in whom at least one guideline should have been applied. For each guideline, the eligibility rate was defined as the ratio between the number of eligible patients and the total number of patients. For each guideline, compliance was determined as the number of patients in whom the guideline was actually applied among the eligible population for this guideline. In addition, the number of eligible guidelines per patient and the compliance rate per patient were assessed. The patients in whom all the eligible guidelines were fully applied was defined as a full compliance patient and given a score of 100%.

Sample Size Calculation. The expected rate of full compliance per patient was 20% to 50% (11). The number of subjects needed to estimate a rate of full compliance per patient for a bundle of eligible guidelines equal to 50% with a 95% confidence interval (CI) half-width equal to 8% is around 600 patients. This same sample size is also appropriate for estimating a rate of full compliance per patient equal to 20% with a 95% CI half-width equal to 6%. Sufficient patient availability was assessed for the 66 ICUs on the day of the audit.

Statistics. Quantitative variables were expressed as means (SD or medians [first quartile {Q1}, third quartile {Q3}]) according to variable distribution. Qualitative variables were expressed as frequencies (percentages). The 28-day survival probability and 95% CI were estimated using the Kaplan–Meier survival curve method. Survival time was assessed as the time elapsed between ICU admission and death. The patients "lost to follow-up" before 28 days were considered as censored.

The prevalence of full compliance per patient was estimated with its 95% CI. The factors associated with noncompliance were investigated separately for each guideline. A univariate analysis was first performed using chi-square tests or Fisher's exact tests as necessary for qualitative factors and using analysis of variance or Mann–Whitney tests as necessary for quantitative factors. Then, for each guideline, with the exception of stress ulcer prophylaxis and blood transfusion practices, we used unconditional multivariate logistic regression to estimate the adjusted odds ratios and 95% CIs to determine the association between selected factors and noncompliance.

To take into account clustering within units, the unit was defined as a random effect. For stress ulcer prophylaxis and blood transfusion practices, a polytomous multivariate logistic regression model was used because explanatory variables were categorized into three levels: compliance (reference), no compliance default (i.e., no prescription of stress ulcer prophylaxis or blood transfusion whereas guidelines recommend stress ulcer prophylaxis or blood transfusion), and no compliance excess (i.e., prescription of stress ulcer prophylaxis or blood transfusion whereas guidelines do not recommend stress ulcer prophylaxis or blood transfusion). For model building, we introduced selected variables from univariate analysis ($p < .20$). All analyses were performed using SAS version 9.2 (SAS Institute, Cary, NC)

Table 1. Selected guidelines in intensive care unit

Guideline (Reference)
Identified closest relative (7, 16, 17)
Plan of care (7, 16, 17)
Sepsis bundle (7, 18, 19)
Microbiological cultures prior to initial antibiotic (7, 20)
Antimicrobial agent adaptation (7, 20)
Transfusion practice (7, 21)
Semi-recumbent position in invasive ventilation patients (8, 20)
Endotracheal tube cuff pressure (8, 20)
Ventilator setting in acute respiratory distress syndrome (7, 9, 22)
Stress ulcer prophylaxis (7, 23)
Glucose control (7, 24)
Analgesia sedation monitoring (7, 10, 25)
Thrombosis prophylaxis and treatment (7, 26)

Table 2. Characteristics of the population hospitalized in the 66 intensive care units on the audit day, n = 625 (12)

Characteristics	Measure
Age, mean [SD], yrs	62 [16–74]
Sex, n (%)	
Men	391 (63)
Women	234 (37)
Cause of admission, n (%)	
Medical	393 (63)
Surgery	
Urgent	169 (27)
Nonurgent	63 (10)
Physiologic assessment, n (%)	
MacCabe 0	383 (61)
MacCabe 1	181 (29)
MacCabe 2	61 (10)
Diagnosis, n (%)	
Lung infection	175 (28)
Acute lung injury/acute respiratory disease syndrome	63 (10)
Trauma	49 (8)
Intracranial hypertension	43 (7)
Severe sepsis	35 (6)
Cardiogenic shock	35 (6)
Severe bleeding	32 (5)
Others	80 (13)
Variables at admission and within the intensive care unit stay	
Organ system dysfunction and risk prediction, median [Q1–Q3]	2 [2–3]
Pao_2 <60 mm Hg or need for mechanical ventilation, n (%)	502 (80)
Systolic blood pressure <90 mm Hg + signs of hypoperfusion or need for vasopressor, n (%)	418 (67)
Serum creatinine >300 µmol/L or urine output >500 mL/day or need for renal replacement therapy, n (%)	149 (24)
Glasgow Coma Scale score <6 without sedation or confusion, n (%)	236 (38)
Serum bilirubin >100 µmol/L or alkaline phosphatase >3 × normal value, n (%)	43 (7)
Hematocrit <21% or white blood cells <2000 mm^3 or platelets <40,000 mm^3, n (%)	82 (13)
Audit day assessment	
SOFA, median [Q1–Q3]	3 [1–6]
Patients with at least one organ (SOFA) score ≥3, n (%)	278 (44)
SOFA score ≥3, n (%)	
Lung	130 (21)
Heart and vessels	104 (17)
Brain	105 (17)
Kidney	41 (7)
Coagulation	33 (5)
Liver	17 (3)

SOFA, Sequential Organ Failure Assessment.

using a two-sided type 1 error rate of 0.05 as the threshold for statistical significance.

RESULTS

Patient Characteristics. The characteristics of the hospitalized population in the 66 ICUs on the audit day are shown in Table 2. The 28-day survival probability was .77 (.73–.80).

Eligibility and Compliance. Figure 1 presents the number of patients eligible for each guideline. Sixteen patients were not eligible for any guidelines, mainly due to the time of admission and/or discharge. The eligibility rate for the bundle of 13 clinical guidelines ranged from 27% (antimicrobial treatment adaptation) to 80% (identified closest relative; Fig. 1). The compliance rate ranged from 24% (sedation monitoring) to 96% (identified closest relative and bacteriological sampling before onset of antibiotics). The median number of eligible clinical guidelines per patient was 7 (4–10). The median compliance rate per patient was 75% (60–100).

Implementation of the Complete Bundle. Full compliance was reported in 24% (20–27) of the studied cohort. The rate of full compliance in the patients with less than three eligible clinical guidelines was >80%. The full compliance rate dropped <20% in the patients with at least three clinical eligible clinical guidelines (Fig. 2). We then defined the median rate of compliance according to the total number of eligible clinical guidelines per patient. Among the patients with more than three eligible clinical guidelines and without full compliance, the median rate of compliance in the patients ranged from 77% (69–77) in the patients in whom all 13 guidelines were eligible to 55% (55–73) in those eligible for 11 guidelines (Fig. 2).

Factors Associated With the Noncompliance to Each Guideline. To determine the factors associated with noncompliance to each guideline, a model was adjusted for clustering within units by entering the unit as a random effect (Table 3). A low severity score was associated with noncompliance to antimicrobial treatment adaptation and an excess of ulcer prophylaxis use. In contrast, a high severity score was associated with noncompliance to semi-recumbent position in mechanically ventilated patients of patients. Other factors affecting noncompliance with guidelines were age, case mix, length of ICU stay, and history of respiratory disease.

No global time related effect was found between prior ICU stay and compliance rates (data not shown). In the univariate analysis, prolonged ICU stay was associated with an increase in compliance rates to clinical guidelines related to "identified closest relative" (11 ± 28 days vs. 4.5 ± 15 days, $p = .005$), "stress ulcer prophylaxis" (10 ± 25 days vs. 7 ± 18 days, $p = .03$), and "initial cultures" (10 ± 14 days vs. 5 ± 7 days, $p = .02$).

Specific Points. Among the 67 patients with septic shock, the compliance rates for the mean arterial pressure goal, the preload assessment, and the plasma lactate measurement were 70%, 78%, and 55%, respectively. The central venous oxygen saturation, which was not included in our sepsis bundle, was reported in 16% of the eligible population. With respect to stress ulcer prophylaxis, noncompliance was related to either an excess of care administration (18%) or an absence of care administration (14%). With respect to blood transfusion practices, noncompliance was due to an excess of care administration in 11% of patients and an absence of care administration in 3%. Compliance rates for pain and sedation were 28% and 56%, respectively, in eligible populations.

DISCUSSION

To the best of our knowledge, this is the first large-scale study exploring compliance to a global bundle of ICU guidelines. In the present study, compliance with 13 clinical guidelines ranged from

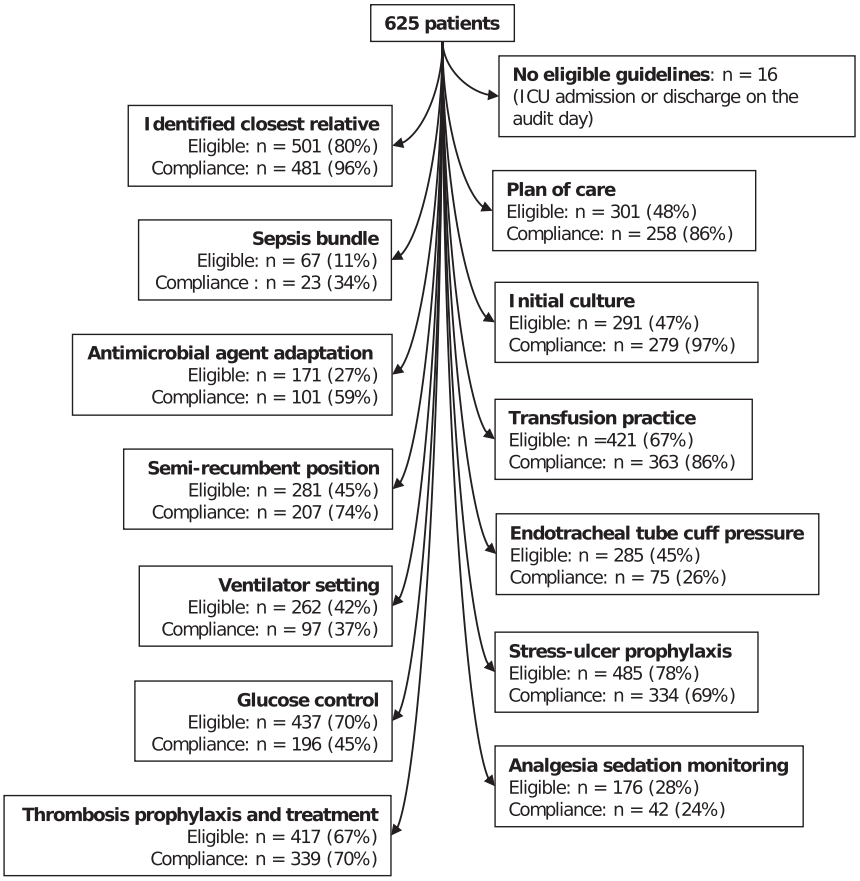
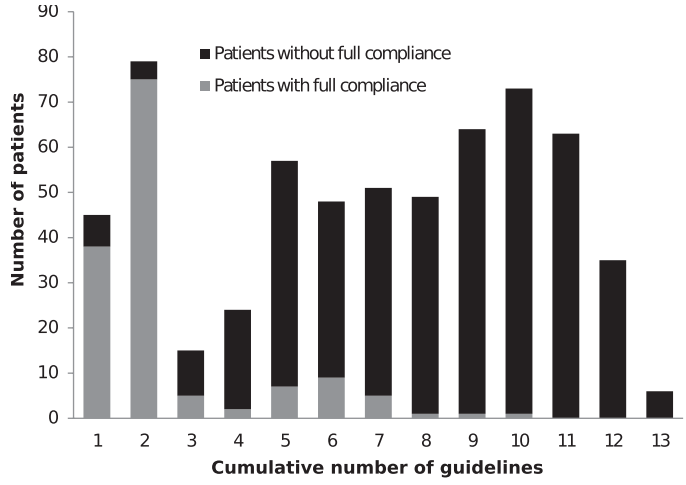


Figure 1. Flowchart of inclusion for each guideline with eligibility and compliance rates. *ICU,* intensive care unit.



n	7	4	5	19	43	35	36	43	56	65	51	26	6
Median (%)	0	50	67	75	60	67	71	63	67	60	55	63	77
25% Quartile	0	50	33	75	60	67	57	63	56	60	55	58	69
75% Quartile	0	50	67	75	80	83	79	75	78	70	73	75	77

Figure 2. Patients with and without full compliance according to the cumulative number of eligible guidelines. The x-axis represents the cumulative number of guidelines. The *grey bar* indicates the number of patients in whom the compliance is 100%. The *black bar* indicates the number of patients in whom the compliance is <100%. The table below the diagram represents the number of patients (n) eligible for one to 13 guidelines without full recommendations, the median rate of compliance per patient according to the number of eligible guidelines with 25%–75% quartiles.

24% to 96% (median value = 75%). Full compliance was inconsistent in patients in whom at least three guidelines should have been applied. Regardless of the number of eligible guidelines, about 50% to 77% of eligible guidelines were applied at the bedside. Overall, only 24% (20–27) of patients in our cohort received fully compliant care. At variance with previous studies (27, 28), there was little correlation between a specific center and its overall rate of adherence to guidelines.

Compliance rates for clinical guidelines related to "identified closest relatives," "plan of care," "red blood transfusion practices," and "initial microbiological cultures" are >80%. On one hand, a strong level of evidence may explain these rates of adhesion (29, 30). On the other hand, a strong legislative framework can motivate the physicians to follow guidelines, as it seems the case regarding blood cell transfusions.

Guidelines related to "stress ulcer prophylaxis," "thrombosis prophylaxis and treatment," and "semi-recumbent position" are applied in around 70% of our cohort. Results regarding the guidelines related to both "stress ulcer prophylaxis" and "thrombosis prophylaxis and treatment" can be explained by a lack of evidence in the ICU setting (31, 32). Regarding the guideline related to the "semi-recumbent position," on the audit day, 30% of patients eligible for this recommendation were in a supine position. Nevertheless, in the prevention of ventilator-associated pneumonia, this recommendation is based on a strong level of evidence (33, 34). One may underline that the rate of compliance obtained in the present study is close to that obtained after active implementation of a bundle for preventing ventilator-associated pneumonia (35).

Guidelines related to antimicrobial agent adaptation after pathogen identification and glucose control had average compliance rates. The appropriate usage of antimicrobial agent is critical for the survival of patients (36). It is surprising that the adherence to this recommendation was not optimal. In the ICU, glucose control remains a controversial issue. The literature is heterogeneous (37–41), which may explain the average level of compliance. Guidelines on glucose control changed between the study conception and its current publication. The best practice was clearly in flux, and units would likely now be in better compliance with less restrictive goals (39).

Compliance rates for other guidelines are <40%. Interestingly, this includes

Table 3. Factors associated with noncompliance (multivariate analysis)

Clinical Guidelines (Number of Patients)	Factors Associated With Noncompliance	Compliance n (%) or median [Q1–Q3]	No Compliance n (%) or median [Q1–Q3]	Adjusted Odds Ratio [95% Confident Interval]	*p*
Identified closest relative (n = 501)	Duration between admission and audit day				
	≥5 days	378 (97)	10 (3)		
	<5 days	103 (91)	10 (9)	4.1 [1.5–1.3]	.007
Plan of care (n = 301)	[a]Age (yrs)				
	<56	72 (95)	4 (5)	1	
	[56–68]	64 (86)	10 (14)	3.5 [0.9–13.9]	
	>68	122 (81)	29 (19)	6.7 [1.8–24.5]	.014
	Admission				
	Medicine	184 (88)	25 (12)	1	
	Nonurgent	25 (89)	3 (11)	1.2 [0.2–5.3]	
	Surgery				
	Urgent surgery	49 (77)	15 (23)	3.4 [1.3–8.7]	.042
Sepsis bundle (n = 67)	No associated factor				
Initial microbiological cultures (n = 291)	No associated factor				
Antimicrobial treatment adaptation (n = 171)	[b]Simplified Acute Physiology Score II decrease (one unit)	51 [41–59]	47 [36–59]	1.02 [1.001–1.04]	.004
Blood transfusion practices (n = 421)	No associated factor				
Semi-recumbent position (n = 279)	[c]Organ failure number (by increase one unit)	3 [2–3]	3 [2–4]	1.4 [1.1–1.9]	.015
Endotracheal tube cuff pressure (n = 285)	No associated factor				
Ventilator setting (n = 262)	[d]Prior history of respiratory disease				
	No	79 (42)	107 (58)	1	
	Yes	18 (24)	58 (76)	2.4 [1.3–4.4]	.005
Stress ulcer prophylaxis (n = 485)	[e]Organ failure number (by decrease one unit)	2 [2–3]	Default 3 [2–3] Excess 1 [1–2]	Excess (multivariate) 1.9 [1.4–2.4]	<.0001
Glucose control (n = 437)	No associated factor				
Analgesia sedation monitoring (n = 176)	No associated factor				
Thrombosis prophylaxis (n = 417)	No associated factor				

[a]Adjusted for gender male, no prior history of toxic abuse, decrease in number of organ system dysfunctions, short duration between admission and audit day; [b]adjusted for prior history of cardiovascular disease; [c]adjusted for short duration between admission and audit day; [d]adjusted for increased age, long duration between admission and audit day; *e*adjusted for decrease of Simplified Acute Physiology Score, short duration between admission and audit day, prior history of cardiovascular disease, MacCabe = 1, type of admission in urgent surgery.

guidelines targeting specific populations of patients with septic shock and acute lung injury. It is important to note that most of these guidelines may evolve in the future. With respect to septic shock, the present "bundle" included a predefined mean arterial pressure goal, a preload assessment, and a plasma lactate measurement. The absolute compliance rate was 34%, which is higher than in previous studies (42, 43). The Surviving Sepsis Campaign group obtained 31% compliance at the end of the implementation process (43). However, these previous studies used much more complex guidelines than the bundle used in the present study.

With respect to the recommendation on ventilator settings, barriers to low tidal volume ventilation were reported elsewhere (44). Organizational and clinician barriers mainly included knowledge deficits. Our study design makes it impossible to assess these issues. The risk factors for noncompliance seem related to the past medical history of respiratory disease. Our data does not allow us to clearly understand this association. The compliance rate for the sedation monitoring bundle (24%) is lower than that reported in a previous study (47%) (45). However, this study was dedicated to pain assessment, and one may suppose that centers with an interest in this field were preferentially included (45). This may suggest that studies centered on a specific topic may not accurately reflect global practices.

The major strength of the present study was the use of a global approach toward guideline compliance, independent of specific diseases. The effect of a focused assessment on a specific issue, like severe sepsis or ventilator-associated pneumonia, can mask poor compliance in other fields. As underlined in the present study, the compliance rate in patients with multiple eligible guidelines remains low. This raises questions about guideline prioritization. In addition, most audits of care practices occurred after an educational process. Such results may thus reflect only an inflated, transient effect due to an active policy. In contrast with previous studies (11, 35, 44, 45), our findings are based on an external audit performed by a trained resident. Other studies relied on involved physicians, who self-assessed their own practices. This methodology is obviously highly prone to bias because of the gap that can be observed between practice and perception (46).

An ancillary analysis using an alternative statistical approach (a model including center as a fixed effect in order to test the specific effect of each center) suggests a low specific effect of each center on the adherence to guidelines (data not shown). If this hypothesis were to be confirmed, it would indicate that the diffusion and appropriation of guidelines are consistent among centers. A global policy including for instance caregiver education and multiprofessional approach should be required in order to improve the compliance rate to guidelines.

The major limitation of the present study is the lack of consensus about certain guidelines. The guidelines in this

study, however, were elaborated by a group of five intensivists, reviewed by a large group of coinvestigators, and validated by an independent steering committee of three senior physicians. In addition, one may wonder whether various guidelines did not overlap. The independent steering committee carefully checked this potential issue. Our study was not designed to explore patient outcomes, and our cross-sectional approach is irrelevant in determining a relationship between recommendation compliance and outcomes. A high level of compliance has been associated with improved outcomes (42, 43), but conflicting results are available, making this an issue of further exploration in future studies (47, 48). Compliance does not always mean that patient care is improved. Furthermore, in our study, the effect of each recommendation could affect patient outcomes in different ways (for instance, contacting next-of-kin vs. deep venous thrombosis prophylaxis vs. transfusion guidelines). In brief, not all guidelines are equally important in improving patient outcomes. One additional point should be underlined. The study was performed in 2009, and due to organizational issues, the publication occurred at a later time. Because guidelines are quite dynamic and may undergo regular revision, this may have impacted some of our findings.

In conclusion, in this large survey performed in 66 ICUs, the median compliance rate for the relevant guidelines was 75%. Complete compliance was observed in <30% of ICU patients and seems more difficult to obtain in patients eligible for at least three guidelines. These findings are independent of center performance. The results of this study suggest the need to refine the application of clinical guidelines in ICUs.

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