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Adverse Events with Medical Devices in Anesthesia and Intensive Care Unit Patients Recorded in the French Safety Database in 2005–2006

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ABSTRACT

Background: French regulations require that adverse events involving medical devices be reported to the national healthcare safety agency. The authors evaluated reports made in 2005–2006 for patients in anesthesiology and critical care.

Methods: For each type of device, the authors recorded the severity and cause of the event and the manufacturer's response where relevant. The authors compared the results with those obtained previously from the reports (n = 1,004) sent in 1998 to the same database.

Results: The authors identified 4,188 events, of which 91% were minor, 7% severe, and 2% fatal. The cause was available for 1,935 events (46%). Faulty manufacturing was the main cause of minor events. Inappropriate use was the cause in a significantly larger proportion of severe events than minor events ($P < 0.001$) and was usually considered preventable *via* improved knowledge or device verification before use. Compared to with that in 1998, the annual number of reported events doubled and the rate of severe events decreased slightly (12–10%, $P = 0.03$). The rate of events related to manufacturing problems remained stable (59–60%, P = nonsignificant), and the rate of events caused by human errors was 32–42% ($P = 0.01$). There were no changes in the mortality rate (2% in both studies).

Conclusions: The number of adverse events related to medical devices indicates a need for greater attention to these complex pieces of equipment that can suffer from faulty design and manufacturing and from inappropriate use. Improvements in clinician knowledge of medical devices, and to a lesser extent improvement in manufacturing practices, should improve safety.

What We Already Know about This Topic

- Medical devices can improve patient safety but can also cause injury
- A 1998 review of mandatory reporting in France of adverse events related to medical devices revealed 11% severe events and 2% fatal events, leading to changes in device designs

What This Article Tells Us That Is New

- Review of reporting in France for 2005–2006 showed no change in fatal events but an increase in operator error as a cause of device-related adverse events

STUDIES of closed claims recorded in insurance company databases have established that medical devices play a crucial role in patient safety during anesthesia.[1–3] These findings prompted the development of new safety regulations such as a requirement to use end-tidal carbon dioxide and pulse oximetry monitoring. However, surveillance studies based on voluntary reporting in Australia,[4,5] Japan,[6] and the United Kingdom[7] have shown that medical devices also generate adverse events. The device itself may be faulty, in its design or manufacture, or a device free of defects may be used inappropriately.

Voluntary reporting is a limitation inherent in many earlier studies of adverse events related to medical devices.[8] In Europe, reporting to national and European databases has been mandatory for over a decade.[7,9] Thus, European databases probably constitute highly reliable sources of information. In a previous study of reports to the French database (maintained by the Agence Française de Sécurité Sanitaire des Produits de Santé [AFSSAPS]) in 1998, we identified 1,004 events, of which 20 (2%) were fatal and 111 (11%) were severe.[10] Inappropriate use of the device explained 35% of events overall, and more than 70% of events related to

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catheter ports and regional anesthesia devices. The blame fell on manufacturers for 30–40% of events, depending on the type of device. We identified several design faults that were corrected by the manufacturers and that prompted the French authorities to issue directives about problematic devices. Most of the events related to human errors that occurred because of inadequate clinician knowledge despite the existence of clear instruction manuals, indicating a need for further education about medical device safety.

The objective of this study was to determine whether the number, severity, and causes of adverse events related to medical devices used in anesthesiology and critical care have changed over time. To this end, we evaluated reports made in 2005 and 2006 to the same AFSSAPS database.

Materials and Methods

Reports to the AFSSAPS database of adverse events involving medical devices are made by completing a standardized form. The form collects the date of the event, the type of device involved, the nature of the event, the outcome in the patient, the investigation of the event, and the measures taken to avoid recurrences. Each reported event is evaluated by a panel of experts, who make recommendations about measures designed to avoid recurrences, such as further investigation to determine the cause of the event, contacting the manufacturer, restricting the use of the device, or mandating interventions to educate clinicians about the use of the device.

For this study, we chose 2005–2006, which was the most recent period for which all events were closed after being fully or partly investigated or classified as not requiring an investigation (see Results section for details). We extracted all reports of adverse events involving medical devices in anesthesia and critical care that were filed during the study period. We examined the data available for each of the 4,188 events to record the following: type of healthcare institution, type of device, clinical severity of the event (classified as none or minor; severe, defined as prolonging hospitalization, requiring (re)operation, or causing permanent abnormalities; or fatal), cause of the event (inappropriate use of the device, use of an obsolete device, poor maintenance, faulty manufacturing, faulty design, or device breakdown), and whether the manufacturer corrected a design or manufacture problem because of the event. Each report was classified independently by one of three senior anesthesiologists (C.S., F.L., and P.Y.L.) and by another senior anesthesiologist (L.B.) who was a former AFSSAPS expert. Differences in classification were solved by consensus. Events for which the cause could not be determined with confidence based on the data in the standardized form (n = 2,253) were examined separately. Plausible causes were identified for 26% of these events.

The methodology for this study was the same as for our previous study of reports filed in 1998.[10] A few changes in database structure occurred between the two studies: rewarming devices were removed from the anesthesia and intensive care unit (ICU) sections of the database after 1998, whereas devices used in drainage, dialysis, and blood transfusion were assigned to the anesthesia and ICU sections after 1998.

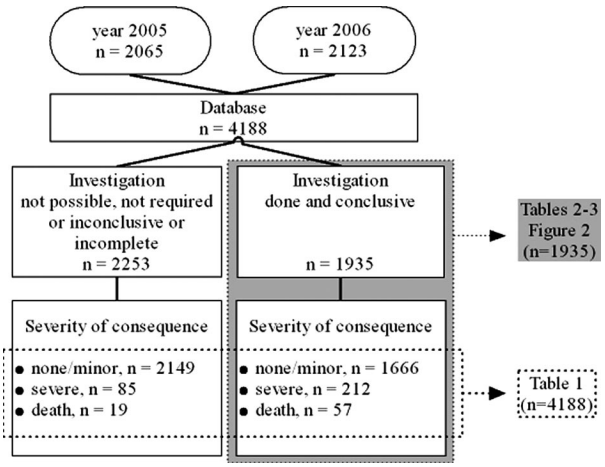

Fig. 1. Distribution of events by severity and result of the investigation (2005–2006).

Statistical Analysis

Data are reported as number (percentage) or median (interquartile range, 25–75). In most of our analyses, we pooled severe nonfatal events and fatal events into a single category, because together they constitute the main focus of concern. Differences between categories and time periods were assessed using the χ^2 test or the Fisher exact test, as appropriate. Bivariate correlations (Pearson) between pairs of continuous data were used to test for associations. To contrast two relevant categories of events, we assigned all events resulting from inappropriate use of the device, use of an obsolete device, or poor maintenance to a "human errors" category; and all events resulting from faulty manufacturing, faulty design, or device breakdown to a "manufacturing problems" category. All reported P values are two tailed. P values less than 0.05 were considered significant. Statistical analyses were performed using SPSS 15.0 (SPSS Inc., Chicago, IL).

Results

The database contained 2,065 events reported in 2005 and 2,123 in 2006, for a total of 4,188 events (fig. 1). A disagreement between the experts who reviewed the database was 4% for one pair of experts and 6% for the other pair. These disagreements were solved by consensus.

Of the 4,188 events, 3,228 (77%) were reported by healthcare institutions, 716 (17%) by manufacturers, and 254 (6%) by other sources. Healthcare institutions were distributed as follows: 627 university hospitals (19%), 1,899 public nonuniversity hospitals (59%), 644 private hospitals (20%), and 58 other healthcare facilities (2%). The median number of events per healthcare institution was 2 (interquartile range, 1). Severity was well documented for all 4,188 events. The distribution of severity by device category is reported in table 1, with the data from 1998[10] for purposes of comparison.

Table 1. Distribution of the Device-related Events Reported in 1998 and 2005–2006

Type of Device	All Events		Severe Events (Including Deaths)		Deaths	
	1998	2005–2006	1998	2005–2006	1998	2005–2006
Regional anesthesia	10 (1)	132 (3)	2 (0.2)	1 (≈0)	0 (0)	0 (0)
Catheter ports	82 (8)	197 (5)	30 (3.0)	58 (1.4)	0 (0)	0 (0)
Defibrillators	27 (3)	204 (5)	4 (0.4)	27 (0.6)	0 (0)	16 (0.4)
Medical gas supply	49 (5)	60 (1)	3 (0.3)	1 (≈0)	1 (0.1)	0 (0)
Incubators (neonatology)	25 (2)	26 (1)	7 (0.7)	5 (0.1)	0 (0)	0 (0)
Monitors	122 (12)	208 (5)	17 (1.7)	30 (0.7)	8 (0.8)	18 (0.4)
Infusion devices	309 (31)	1,843 (44)	29 (2.9)	138 (3.3)	6 (0.6)	19 (0.5)
Ventilation	372 (37)	659 (16)	32 (3.2)	62 (1.5)	5 (0.5)	16 (0.4)
Dialysis	—	343 (8)	—	32 (0.8)	—	5 (0.1)
Drainage	—	239 (6)	—	7 (0.2)	—	0 (0)
Transfusion	—	277 (7)	—	12 (0.3)	—	2 (≈0)
Rewarming	8 (1)	—	4 (0.4)	—	0 (0)	—
Total (%)	1,004* (100)	4,188* (100)	128* (12.7)	373* (8.9)	20 (2.0)	76 (1.8)

Data are represented as n (%). Percentages are computed by reference to the total number of events in the corresponding year.

* If only one considers devices studied during both periods (as required to build table 4), one should consider the following data: 996 instead of 1,004, 3,329 instead of 4,188, 124 instead of 128, 322 instead of 373.

Table 2 shows the events for which a cause was identified with confidence (n = 1,935, fig. 1), as well as the corrective measures taken by the AFSSAPS. The distribution of the two main categories of problems (human errors and manufacturing problems) for minor and severe events (including death) is plotted in figure 2. Minor events were chiefly related to

Table 2. Distribution of the Medical Device–related Events in Anesthesia or Critical Care Which Could Be Investigated in 1998 and 2005–2006

Type of Device	No. Investigated Events		Actions Taken by the AFSSAPS*	Causes†			
				Human Errors			
				Inappropriate Use (Including Inadequate Supervision)		Poor Maintenance/ Use of Obsolete Devices	
	1998 n	2005–2006 n	2005–2006 n (%)	1998 n (%)	2005–2006 n (%)	1998 n (%)	2005–2006 n (%)
Regional anesthesia	3	49	4 (8)	2 (66)	18 (37)	0 (—)	0 (—)
Catheter ports	32	105	2 (2)	22 (68)	86 (82)	0 (—)	0 (—)
Defibrillators	19	145	26 (18)	7 (37)	20 (14)	0 (—)	12 (8)
Medical gas supply	34	38	2 (5)	4 (12)	10 (26)	8 (23)	7 (18)
Incubators (neonatology)	16	20	1 (5)	6 (37)	7 (35)	6 (37)	4 (20)
Monitors	100	136	9 (7)	14 (14)	54 (40)	6 (6)	14 (10)
Infusion devices	74	694	20 (3)	27 (36)	274 (39)	7 (9)	17 (2)
Ventilation	193	347	17 (5)	31 (16)	105 (30)	11 (6)	17 (5)
Dialysis	—	183	20 (11)	—	59 (32)	—	8 (4)
Drainage	—	88	1 (1)	—	18 (20)	—	0 (—)
Transfusion	—	130	3 (2)	—	32 (25)	—	3 (2)
Total (%)	471	1935‡	105 (5)	113 (24)	683‡ (35)	38 (8)	82‡ (4)

Percentages are computed by reference to the number of investigated events in the corresponding year and category of device. As a consequence of a slight difference in the methods used between periods (see text), one or more cause were obtained for each incident in 2005–2006 (average 105% elucidated cause), whereas in 1998, a cause was not available in some investigated incidents (average 91% elucidated cause). Accordingly, horizontal sum of percentages may be less than 100% in 1998 and greater in 2005–2006.

* Agence Française de Sécurité Sanitaire des Produits de Santé (AFSSAPS). † Figures for 1998 were recomputed from published data.[10] Absolute numbers were rounded to the nearest integer. ‡ If one considers categories of devices studied in both periods (as required to build table 4), the total of column is as follows: 1,534 investigated events instead of 1,935. For 1998 (same as in table 2): human errors = 113 + 38 = 151; manufacturing problems = 75 + 107 + 97 = 279. For 1995–1996 (a part of devices listed in table 2, that is, excluding dialysis, drainage, and transfusion): human errors = 574 + 71 = 645; manufacturing problems = 428 + 186 + 314 = 928.

manufacturing problems and severe ones to human errors ($P < 0.001$). The manufacturers acknowledged and corrected 59% of the manufacture and design problems.

Most of these human errors (table 3) seemed preventable by educational interventions focusing on improved knowledge of the device and procedure, on verifications to be performed routinely before using the device, and on the need to appropriately supervise the patient and device during surgery. Of the severe events related to manufacture problems, 77% led to corrective measures by the manufacturers.

For 2,253 events (54% of the database), the AFSSAPS experts determined that investigation for a cause (*i.e.*, the identification of who or what was responsible for the event) was not possible, inconclusive, or not required (fig. 1). Three main reasons were involved: (1) the problem was judged unimportant (58%) (*e.g.*, packaging problem or missing part in a catheter set), (2) the device could not be examined and/or tested by the manufacturer or a dedicated independent laboratory (35%) (*e.g.*, because it had been discarded, chiefly in the case of disposable devices such as plastics, or repaired locally before full investigation), or (3) the event was minor and consequently an investigation was deemed unnecessary (7%). This group of 2,253 incompletely investigated events had 104 severe events (including deaths) concerning infusion (57%), ventilation (11%), medical gas (4%), hemodialysis (11%), blood transfusion (2%), and catheter ports (6%).

By reviewing the standardized forms for these 2,253 incompletely investigated events, we were able to identify plausible causes for 596 (26%) events. These plausible causes could not be confirmed. They consisted of inappropriate use (n = 222, 10%), faulty maintenance or obsolete device (n = 5, <1%), faulty manufacture (n = 203, 9%), breakdown (n = 21, 1%), and faulty design (n = 32, 1%). Multiple causes were found in 113 (5%). The distribution of these plausible causes was very similar to the distribution of confirmed causes of the 1,935 fully investigated and resolved events that constitute the basis for our study (table 2).

We found a number of significant differences between the data for 2005–2006 and those for 1998 obtained in our earlier study. First, the number of events reported per year was twice as high in 2005–2006. Second, the proportions of events related to infusion devices, defibrillators, and regional anesthesia were higher in 2005–2006 than in 1998, chiefly because of an increase in manufacturing problems (table 1). Conversely, the proportion of events related to complex de-

Table 2. Continued

Manufacturing Problems					
Faulty Manufacture		Device Failure		Faulty Design (Hardware and/or Software)	
1998 n (%)	2005–2006 n (%)	1998 n (%)	2005–2006 n (%)	1998‡ n (%)	2005–2006 n (%)
1 (33)	19 (39)	0 (—)	0 (—)	0 (—)	12 (24)
2 (6)	12 (11)	0 (—)	0 (—)	0 (—)	9 (9)
2 (10)	30 (21)	8 (42)	49 (34)	2 (10)	50 (34)
4 (11)	13 (34)	4 (11)	4 (11)	10 (28)	8 (21)
0 (—)	0 (—)	1 (6)	7 (35)	3 (18)	2 (10)
8 (8)	16 (12)	39 (39)	23 (17)	36 (36)	37 (27)
16 (21)	267 (38)	3 (4)	20 (3)	9 (11)	91 (13)
42 (21)	71 (20)	52 (26)	83 (24)	37 (19)	105 (30)
—	105 (57)	—	10 (5)	—	47 (26)
—	58 (66)	—	1 (1)	—	12 (14)
—	88 (68)	—	3 (2)	—	15 (12)
75 (16)	679‡ (35)	107 (23)	200‡ (10)	97 (20)	388‡ (20)

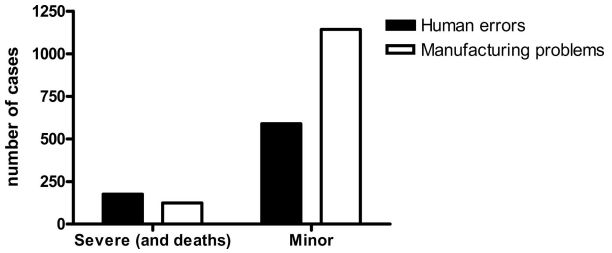

Fig. 2. Distribution of human errors and manufacturing problems according to the level of severity (2005–2006). There is a significant difference in the distribution regarding severity ($P < 0.001$).

vices such as ventilators and ventilation-related devices, monitors, medical gas supply, and incubators was smaller in 2005–2006, as shown in table 1. Third, the proportion of reported severe events was slightly but significantly smaller in 2005–2006 than in 1998 (table 4), although the mortality rate was comparable (2.0 and 1.8%, respectively; table 1). Fourth, the proportions of events related to inappropriate use of the devices were significantly higher in 2005–2006, contrary to faulty manufacturing (table 4). Of note, in 2005–2006, at least one cause per investigated case was identified. It contrasts with 1998, where no cause was found despite investigation, in an average of 9% of events. This improvement may be explained by an increase in the investigative efficiency of AFSSAPS experts, which was made possible by increasing manpower and organizational resources dedicated to matériovigilance since 1998. We believe that this slight discrepancy between periods, in terms of investigation completeness, is not large enough to induce a bias.

In 2005–2006, the AFSSAPS took 105 corrective measures relevant to our study topic (permanent or temporary withdrawal of the device from the market, 45%; recommendation to users, 13%; and information to users, 42%). No data on corrective measures are available for 1998. The distribution of the corrective measures by device category in 2005–2006 is shown in table 2. When we examined the 11 categories of medical devices, we found that the number of corrective measures correlated with the number of manufacturing problems ($r = 0.72$, $P < 0.01$) but not with the number of human errors ($r = 0.49$, $P = 0.10$). In 2005–2006, a single general guideline was issued by the healthcare authorities in the field of anesthesia and intensive care on interactions between medical equipments and implanted devices (defibrillators, pumps, nerve stimulators, and others); and two additional guidelines were issued about monitoring blood glucose levels at the bedside. Eleven statements to users were issued to increase the awareness of selected problems relevant to device monitoring, including two in the field of anesthesia and intensive care.

Table 3. Main Types of Inappropriate Use Responsible for the Severe Events Related to Inappropriate Use of a Device

Type of Device	Nature of the Problem (Severe Cases Including Deaths)	Type of Event	Percentage of Severe Events
Regional anesthesia	Epidural catheter migration and meningitis	P	100
Catheter ports	Pinch-off	K	54
	Catheter not firmly secured to the port at insertion	P	15
	Section of catheter during insertion	P	10
	Rupture of catheter after > 5 yr	S	5
Defibrillators	Misunderstanding of message displayed by semiautomatic defibrillator	K	19
Medical gas supply	Fire at home and oxygen therapy	S	100
Incubators (neonatology)	Variable (settings and poor handling of the neonate)	K	40
Monitors	Improper response to alarms	K	30
	Faulty operation of the device	P	30
	Silenced alarms	P	22
Infusion devices	Error in infusion rate	P	24
	Disconnection and migration in vascular bed	P	13
	Significant vessel lesion during insertion	P	9
	Unrecognized leaks with bleeding	S	7
	Faulty purging with embolism	P	4
Ventilation	Faulty assembly of valves or tubings	P	25
	Faulty operation of the device	P	21
	Poor understanding of ventilation mode	K	13
	Silenced alarms	P	4
	Poor maintenance	P	4
Dialysis	Inappropriate use and poor maintenance	K/P	19
	Faulty asepsis	P	11
	Mishandling of alarms	K/P	8
Drainage	Inappropriate use	P	14
Transfusion	Inappropriate use	P	43

K = inadequate knowledge; P = procedural error; S = inadequate patient or device supervision or monitoring.

Table 4. Comparison of Characteristics of Events Recorded in 1998 and in 2005–2006

Characteristics	1998 n/Total (% of Total)	2005–2006 n/Total (% of Total)	*P* Value
Severe event (including deaths)*	124/996 (12)	322/3329 (10)	0.03
Event due to human errors† using the device*	151/471 (32§)	645/1534 (42‖)	0.01
Event due to manufacturing problems‡ in the device*	279/471 (59§)	928/1534 (60‖)	NS

* The denominator is the total number of events studied during both periods (this criterion excluded rewarming devices in 1998; and transfusion, dialysis and drainage in 2005–2006) (the numbers shown in this table originate from the a subset of data in tables 1 and 2; see footnotes in these tables for explanation). † Human errors group inappropriate use (including inadequate supervision) and poor maintenance or use of obsolete devices. ‡ Manufacturing problems group faulty manufacture, device failure, and faulty design. § The sum of these percentages do not reach 100% as in 1998, as some investigated events had not cause identified (in average 9%). ‖ The sum exceeds 100% (in average 105%) as in some instances, more than one cause was found in 2005–2006.

Discussion

This study adds to recent information on adverse events involving medical devices used in anesthesia and critical care.[10,11] Over a 2-yr period, 76 patients died from device-related events and 297 others experienced severe events. Human errors explained more than one-third of the events overall and was the main cause of severe events, whereas manufacturing problems explained most of the minor events. Compared with 1998, the number of events reported per year was twice as high in 2005–2006; the proportion of fatal events was unchanged, but the proportion of severe events was significantly smaller. Adverse events related to inappropriate use of devices increased between the two study periods. Clearly, there is a need for increased attention to educational interventions aimed at decreasing device-related events caused by human errors.

A number of points regarding the methodology of this study deserve comment. First, several facts suggest high reliability of the AFSSAPS database used for this study. Reporting is mandatory throughout the country, the database is managed by a public regulatory agency staffed by experts in healthcare quality, reports are handled confidentially, and healthcare providers involved in the adverse advents are not open to prosecution. These characteristics would be expected to encourage reporting and favorably compare with those of many nonmedical reporting systems.[12] Second, we used the same methodology in this study and in our earlier study. This allowed us to compare nationwide data obtained 8 yr apart. We found a 2-fold increase in the number of reported events over this interval. However, we cannot determine from our data the extent to which this increase reflects improved reporting, as opposed to increased absolute event rates or increased numbers of exposed patients.

Minor events contributed 91% of all events in our study. This proportion is higher than those found in two earlier studies (54%[11] and 69%[7]) but similar to the 89% proportion in another study.[13] Most of the minor events in our study were related to manufacturing problems, particularly in the categories of infusion devices and disposable devices. The reports of these events to the relevant manufacturers led to corrective measures in up to 50% of cases. Thus, surveillance of device-related events can help to improve the quality of care. However, the reports also confirmed problems previously described in the literature, such as the mechanical limitations of disposable laryngoscope blades,[14] poorly designed Luer-lock stopcocks that cannot be unscrewed, and insufficient runtime of batteries for portable ventilators or monitors.[7]

Severe events are of special interest, given their potential to cause harm to the patient. We found that the proportions of severe events related to inappropriate use were highest for catheter ports and monitors. Most of the severe events involved migration of catheter ports, infusion devices, and regional anesthesia catheters. Catheter ports led to catheter migration *via* the pinch-off syndrome, in which the catheter is fractured by the scissor movement of the clavicle on the first rib. Instances of pinch-off syndrome were identified in our earlier study and many other publications, most of which suggest proper insertion and control radiographs as preventive measures.[15–18] Manufacturers have improved their information about this adverse event, apparently to limited effect. Neither the French healthcare safety agency nor learned societies in France have issued warnings about the pinch-off syndrome. Similarly, little is done to increase awareness among users about measures for preventing migration of intravenous or regional anesthesia catheters. Another common severe event related to inappropriate use was alarm silencing or delayed response to alarms due to poor understanding of alarm function. This is a well-documented adverse event that highlights the problem of designing unambiguous alarms, free of artifacts.[19]

Human errors accounted for 39% of the fully investigated events in our study. This proportion should be compared with previous data. For instance, a study of closed malpractice claims recorded from 1961 to 1994 found that 75% of events related to gas delivery equipment were ascribable to human errors.[1] A detailed study of 359 events that occurred during anesthesia showed that human errors explained 82% of the preventable events, when compared with only 14% for equipment failure.[20] Inappropriate use of devices and inadequate knowledge and training among healthcare providers were further addressed by Cooper[21] in 1984, who stressed that human errors were paramount. In nonmedical fields, training and technical knowledge have also been shown to affect the adverse event rate. For instance, the number of crashes per model of aircraft correlated negatively with the

number of flight hours on the model,[22] irrespective of pilot experience with other models.[23] To improve the safety of medical devices, a number of laws have been passed, with differences across countries. In France, hospitals must check medical devices at delivery and choose the settings recommended by the manufacturer.[24] Healthcare providers who plan to start using a new medical device must first receive onsite training by the manufacturer's commercial engineers. However, in practice, this training is often limited in scope and duration and is seldom available to all users. In addition, training delivered at introduction of the new device is not repeated for newly hired healthcare providers, who may make up a large proportion of the staff, given the high job turnover rates in many hospitals. French regulations also require that devices used for anesthesia (intubation, ventilation, defibrillation, gas supply, suction, and others) be checked according to a standard checklist every morning when the operating room is opened. It also imposes limited checking procedures (ventilator settings and alarms) before two consecutive anesthesias. However, these regulations do not apply to the same devices used in the ICU instead of the operating room. Germany has stricter regulations that include formal training of all users.[25,26] Our finding that events related to inappropriate use increased over an 8-yr period suggests that formal training may indeed be indicated, although at present, no studies of the impact of this measure are available.

The French Society for Anesthesia and Intensive Care, which encouraged this study, is acutely aware of the continuing major role for human errors in adverse events related to medical devices, particularly as it contrasts with substantial decreases in anesthesia-related mortality[27] despite a marked increase in the number of anesthetized patients.[28] At least two approaches may hold promise for decreasing human errors. First, in each department of healthcare institutions, selected staff members could receive high-level training about the medical devices used in their department, delivered by the manufacturers. These staff members (for instance, one nurse and one physician) would then be available for questions about devices, initial training of existing staff and newly hired staff, refresher courses, and selection of new devices for purchase based on an assessment of risk–benefit ratios under the specific conditions in the department. Second, efforts to improve knowledge of device-related safety among healthcare providers would be expected to decrease events related to human errors. In France, a task force was created to develop didactic reports on the risks associated with the main technologies used in ICUs. These reports were published in 2008 as a supplement to the main French journal on anesthesia and critical care.[29] It is still too early to measure the impact of this intervention. Finally, manufacturers should be further encouraged to include as many safeguards as technically possible when designing devices.

Anesthesia and critical care is often compared with other industries that require risk management strategies, especially aviation. In both anesthesia and critical care and aviation, death rates have decreased over the years,[30]†† whereas annual operational volumes have increased.[27]†† However, the aviation industry has reported a 40% decrease in human errors between the mid-1980s and 2000,[30]†† in contrast to our finding of a rise between 1998 and 2005–2006. Several hypotheses can be put forward to explain this difference. Aviation has benefited from a steady increase in automation and from improvements in instrument interfaces. Although the need for better monitoring[3] and well-designed interfaces[31,32] has long been recognized in anesthesia and critical care, much of our equipment is not amenable to full automation. Instead, final decisions remain based on clinical judgment, and monitors track a limited number of parameters that are not tightly interrelated. Thus, the instruments used today in ICUs can be compared with those used in aviation in the 1960s, and today's aircrafts are more predictable than patients.[33] Furthermore, checklists have long been used in aviation but are only now receiving serious attention in medicine. The efficacy of checklists for preventing severe morbidity was suggested long ago[34] but has been only recently proven in anesthesia[35] and surgery.[36] Our study suggests that checklists and/or procedural guidelines might decrease adverse events related to inappropriate ventilator settings, faulty ventilator tube connections, faulty drainage tube and catheter port insertion, poor handling of devices, and inadequate monitoring of devices. Current ventilators run partly automated checks, but the anesthesiologist must inspect all ancillary equipment. Manually checking equipment is a time-consuming task[37] that is often omitted.[38,39] The British Medical Defense Union reported that failing to check the equipment before anesthesia and silencing the alarms were among the most common violations among anesthetists.[40] In a study of adverse events in an ICU, violations of standard practice explained 28% of human errors, about the same proportion as lack of knowledge and inexperience (27%).[11] This high rate of failure to comply with standard safety precautions reflects a broader failure to develop a culture of patient safety. Indeed, a survey showed that responses suggesting absence of a safety climate were given three times more often by healthcare providers than by naval aviation professionals.[41]

Our study has the limitations inherent in the use of a reporting database. Underreporting may have occurred, and we have no data for estimating the extent of this issue. In the construction industry, despite a policy of mandatory accident and injury reporting, half the cases go unreported.[42] In medicine, underreporting may be even more prevalent; thus, one study found that only 6% of drug-related adverse events were reported.[43] The many factors that contribute to underreporting include fear of litigation or blame[44] and absence of a strong culture of safety.[42] Furthermore, failure to report events related to rule violation is more common among physicians than among nurses.[45] However, a comparison of the

†† International Civil Aviation Organization. Annual report. Available at: http://www.icao.int/annualreports/. Accessed May 2009.

characteristics of different reporting systems in nonmedical industries[12] suggests that the AFSSAPS reporting system may encourage reporting. Favorable characteristics of this system include the mandatory and confidential nature of reporting. The system also requires a detailed description of each event and uses a broad definition of events (*i.e.*, any event involving a physician or a nurse that led to patient injury or that might have led to patient injury had it not been promptly recognized). Healthcare professionals involved in the events are not subject to litigation, and they receive feedback about the results of the investigation and any corrective measures. The 2-fold increase in the reporting rate observed over an 8-yr period in our study may reflect the development of a stronger culture of safety, with a decrease in underreporting. We hope that our report will help to shift this focus a step forward by drawing attention to user-related problems. We also hope that our study will increase awareness among users about the need for accurate reporting and for making disposable devices available for investigation after adverse events. An inability to investigate events limits the efficiency of reporting systems.

In conclusion, our study shows that adverse events related to medical devices in anesthesia and critical care remain of considerable concern. The rate of inappropriate use of medical devices clearly address the need for improved education among healthcare providers about the safe use of the ever-growing range of medical devices; checklists and didactic reports disseminated in widely read specialist journals may help in this regard. Medical devices should receive the same attention to safety that is given to drugs.

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