Introduction

Increasing patient safety has a long history in anaesthesia. As early as 1984, mishaps and near mishaps monitoring was proposed as a means to enhance safety. However, with nowadays measurably safer anaesthesia, these critical events are very infrequent, and can no longer be used to help improve practice. Safety monitoring has thus been extended to sentinel events which are more frequent but less serious, and perhaps less relevant. This change has often been justified by common sense rather than by evidence. Unresolved issues include in particular how the data collected may best be used for safety monitoring and improvement, and whether changes could really be detected in these unspecific reporting systems.

Here we report on the organization of a computerized system for collection and analysis of significant anaesthetic events (SAEs). We routinely used with statistical process control for the incidence of SAEs, a method which is increasingly used in medical settings. Last we investigate the sensitivity of the reporting system to a planned change in the anaesthetic process.

Reporting and Control System

The reporting system was set up as part of a larger quality assurance initiative started in 1996 and described elsewhere. Thirty-two events were selected for monitoring, corresponding to anaesthesia induction, maintenance and recovery (Table 1). Eight events were associated with difficulties at various stages of intubation, 12 events were associated with problems in anaesthesia maintenance requiring the intervention of the anaesthetist (hypertension, bradycardia, . . . ), 5 with undesirable events related to anaesthesia (cutaneous reaction, nausea/vomiting, . . . ) and 7 to deviation from the normal course of anaesthesia (delayed departure from recovery room, unplanned blood transfusion, . . . ). All

Affiliations of the authors: Epidémiologie et Sciences de l’Information, INSERM U444, PARIS, France (P-YB, AJV), Département de Santé Publique, Hôpital Saint Antoine, AP-HP, PARIS, France (P-YB, AJV), Département d’Anesthésie Réanimation, Hôpital Tenon, AP-HP, PARIS, France (FB).
SAEs were in some sense indicative of sub optimal care in the anaesthetic process.

Reporting System

The monitoring and reporting system were designed under two constraints: i) it should increase as little as possible the workload of the staff, and ii) it should be accepted by the staff, to ensure exhaustive and accurate reporting. The first point led us to adopt a system in two steps: a paper form was used to monitor each procedure, from entrance of the patient in the operating theatre to departure from the recovery room. This paper form was later input in a computerized database. The second point led us to adopt a voluntary and anonymous system, and to assure the staff that the data reported would not be used for disciplinary purposes. We however organized for systematic reporting, asking the staff to start a paper form for all elective procedures.

On starting the procedure form, the type of procedure, anaesthesia and upper airways control were noted on the sheet. The results of the pre-anaesthetic evaluation regarding five risks (difficult intubation, allergic, thromboembolic, infectious, haemorrhagic) were obtained from the patient record. During anaesthesia and up to departure from the recovery room, each patient was monitored for the occurrence of SAEs, using tick boxes on the procedure form. The total duration of the procedure was recorded.

For the 6 first months of monitoring (Jan96-Jun96), only 10 SAEs were included for monitoring to test the feasibility of the system.

Database Architecture

A computerized application was developed using Microsoft ACCESS™ to record the paper forms (see Figure 1). A main table recorded details of the procedure, and a second table recorded all SAEs. A record in the procedure table consisted in the date, the starting and ending time of the procedure, the type of surgery, anaesthesia, and control for upper airways, and the presence of any patient specific risk identified during the pre-anaesthetic visit. An SAE record consisted in the code of the SAE.

Due to regulatory requirements, the identity of the patient undergoing a procedure could not be input in the database. Each procedure was thus uniquely identified by a number in the main table. SAE records were linked to the procedure record through the unique procedure identifier. To assure the quality of the data, all inputs were validated at entry time using controlled lists of codes for anaesthesia type, SAE type, etc.

A computer was set up in the recovery room and used by the anaesthetic nurses for the usual administrative data entry (independently of this project), and for input of the patients forms. All anaesthetic nurses were trained to use the system.

Control Charts

Control charts were used to monitor the monthly incidence of SAEs. Control charts are a preferred tool in statistical process control, allowing graphical detection of departure from expected performance. In control charts, a straight line represents the expected baseline level of performance, and a set of two other lines materializes the admissible interval of fluctuation around the baseline (see Figure 2). Each real

Table 1

<table>
<thead>
<tr>
<th>Definition of Significant Anaesthetic Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficult laryngoscopy</td>
</tr>
<tr>
<td>Difficult intubation</td>
</tr>
<tr>
<td>Difficult ventilation</td>
</tr>
<tr>
<td>Pharyngeal trauma</td>
</tr>
<tr>
<td>Dental trauma</td>
</tr>
<tr>
<td>Oesophageal intubation</td>
</tr>
<tr>
<td>Cardiac arrest</td>
</tr>
<tr>
<td>Death</td>
</tr>
<tr>
<td>Arythmia</td>
</tr>
<tr>
<td>Bronchospasm</td>
</tr>
<tr>
<td>Hypotension</td>
</tr>
<tr>
<td>Laryngeal spasm</td>
</tr>
<tr>
<td>Oedema (facial/quincke)*</td>
</tr>
<tr>
<td>Tachycardia</td>
</tr>
<tr>
<td>Bradycardia</td>
</tr>
</tbody>
</table>

*2 events, **3 events

SAEs were in some sense indicative of sub optimal care in the anaesthetic process.
measurement is then plotted on the graph: if it is outside the area of admissible fluctuations, it is declared abnormal and appropriate corrective action is taken.

The baseline and fluctuation levels were chosen according to the 6-sigma approach, where the average \( \mu \) and the standard error of the first 15 measurements serve as an estimate to compute the expected level (\( \mu \)) and the acceptable region (\( \mu - 3\sigma, \mu + 3\sigma \)). The frontiers of acceptance were adjusted for varying number of patients per month. Baseline values were updated at the end of the pilot phase.

**Statistical Analysis of the SAEs**

An automated EXCEL macro was developed to produce statistical analyses. The macro extracted all data from the computerized database. Descriptive statistics were produced for type of surgery and anaesthesia and for the duration of procedures. Pareto diagrams (bar charts sorted by descending frequencies) for SAEs were also produced. Finally, control charts were plotted, after computation of the acceptance region. It was possible to restrict analysis to only one type of SAEs in the control chart. Data were transferred on a monthly basis from the PC computer in the recovery room to another computer for analyses.

**Sensitivity of the System**

To investigate whether it was possible to detect slight changes in the anaesthetic process, we planned an intervention which effects should be detected using the monitoring system. This consisted in changing the prescription of anxyolitic drugs, during 2 months, from the usually prescribed benzodiazepin to clonidine. Clonidine is known to cause bradycardia, an SAE that is not favoured when using benzodiazepin. The intervention took place in May-June 1998. The effect of the intervention was assessed by comparing incidence of bradycardia during the intervention period to that of the whole year 98, intervention period excepted.

**Results**

All patients undergoing surgery were recorded in the database, totalling 8032 by the end of 1998. Figure 2 shows the monthly number of recorded patients, and the monthly incidence of interventions with at least one SAE.

The number of interventions was approximately 220 (± 40) per month, with pronounced decreases during August of each year. There was no learning curve for the completeness of declaration.

The most frequent SAE was hypotension (10.2% of the procedures), followed by bradycardia (4% of the procedures).

**Control Charts**

The bottom panel of Fig 2 shows a control chart for the incidence of SAEs. There was a marked change between the 6 first months (pilot phase, Jan96(Jun96) and the rest of the study period. During the follow-up, every SAE has been observed at least once. From July 96, the monthly incidence of interventions with at least one SAE has been approximately 25%. This corresponded to a total of 2106 SAEs during 1643 interventions, with an average of 1.3 SAE by intervention.

During the study period, only one month exhibited a very high incidence of SAEs detected by the control graph (Jan97). Detailed investigation did not evidence a systematic problem in the anaesthesia process at this time. The control chart also shows a declining trend in incidence during the last six months of monitoring. Investigation of the trends for the incidence for single SAEs showed that the overall decrease was mainly due to a decrease in nausea/vomiting, which could be related to changes in anaesthesia care (changes in drugs).
Sensitivity of the System

Figure 3 shows the bimonthly incidence of bradycardia and hypotension during the whole year 1998, comprising the period of intervention (May-June 1998). The first panel of the graph clearly evidences that the incidence of bradycardia was significantly higher (8% of the interventions vs. 4%) during the intervention. The incidence of hypotension was not modified during the same period.

Discussion

This computerized system for significant anaesthetic events monitoring proved to be well accepted by the staff. The incidence of SAEs was constant over time, and the system was able to detect controlled changes in the anaesthetic process.

The system provided a lot of information, beginning with baseline values for SAEs, most of which were unknown. The figures obtained here compare with those in other reporting systems for comparable events.7-9 This was neither unexpected nor guaranteed, because the recognition of most SAEs requires the subjective judgement of an anaesthetist. To alleviate this concern, computer only methods have been proposed for detection of SAEs, using automated scanning of patients vital measurements.10 Surprisingly, less SAEs were detected using this approach, owing for the most part to low specificity. At present, it seems that detection of SAEs must still rely on the anaesthetist, especially to retain events of clinical significance.

The SAE incidence was fairly constant over time, with a plateau at 25% of the interventions, but exhibited a decreasing trend over the last six months. While this was mainly due to a reduction in incidence of a single SAE (nausea/vomiting), it can not be ruled out that this resulted from less complete reporting. However, during the same period, the incidence of other SAEs did not change, as exemplified for hypotension, the most frequent SAE, in Figure 3. Contemporaneous changes in the medications of the patients may have caused a decrease in the incidence of nausea/vomiting.

As of today, setting up such monitoring systems has been justified by common sense rather than on proved efficacy.7 Before judging if these systems contribute to patient safety, it is advisable to test whether they are able to respond to change. We investigated this issue by devising an intervention that should change the incidence of bradycardia, and analysed reports for change in the incidence. It is remarkable, given all the sources of variability found in a surgical ward (patient case-mix, changes in staff) that the corresponding change could be evidenced so clearly. Inspection of the preceding and following months showed that the observed increase in bradycardia, taking place during the two months of intervention, could not be explained by chance variation only. The system proved to be sensitive to changes, thereby establishing its capacity to raise alerts in case of changes in performance. With approximately 220 procedures per month, the time required to raise an alert was approximately 1 month. This duration would be sufficiently short in practice to allow investigation of the unwanted changes while these may still be operating.

In medicine, “fault free performance is expected always.”11 In this context, voluntary and anonymous reporting systems are more likely to be accepted. A concern is that the data collected in these systems may provide a partial view of the reality, because serious events tend to be reported more often than merely undesirable events. We tried to resolve this issue by routinely starting a form with each procedure. Also, nurse anaesthetists could be in charge of the form, under the supervision of the anaesthetist. As is advised in quality improvement project, allowing the whole team to take part in data collection and analysis helped the acceptance of the system.

Today, a number of issues still limit the quantification of the impact of the described system on patient
safety. First, it must be recalled that to test that the frequency of cardiac arrests was halved (starting at 1 in 2000 procedures), the number of subjects required corresponds at least to 5 years of data collection, given the volume of activity in the anaesthetic department. The second issue is even more critical, and is best understood by comparison with earlier systems. When mishaps and near mishaps were monitored, a cause and a cure could generally be found for every observed default. For example, “laryngoscope bulb failure” has a readily understood cause, and a cure in the use of fiberoptic intubation. The issue is not as simple when the observed default is “hypotension.” Indeed, hypotension has numerous causes, may sometimes be unavoidable, and the best ways to avoid it during anaesthesia are not clear. This does not forbid the use of such SAEs as an overall performance measure, but it surely prevents the design of simple interventions to reduce their incidence.

We believe that this problem could be overcome by a finer study of SAEs, especially in the form of cascades of SAEs, whose cause may be identified with higher certainty. This demands that the staff reports SAEs in greater detail than described here, for example including the precise time of each SAE. There is at present no study implementing this strategy, and it is not known how such a system would be accepted by professionals.

Reprinted from the Proceedings of the 2001 AMIA Annual Symposium, with permission.

References