Introduction

Despite efforts to improve patient safety for nearly 10 years, progress remains slow [1]. The World Health Organization and leaders in the field of quality and patient safety called for profound changes in healthcare systems. The main barriers are related to the sociology of healthcare organisations and the culture of health professionals. A key issue is to achieve the involvement of physicians and clinical teams in healthcare safety management.

In France, specific structures, called Experience Feedback Committees (EFCs), have been created to analyse adverse events within a medical department [2,3]. Originating from civil aviation security systems, the method has been adapted to healthcare facilities and successfully implemented in radiotherapy units by the company Air France Consulting [3,4]. An EFC is a team composed of diverse professionals who represent the diversity of the functions encountered in the medical department. The EFC members usually meet monthly to examine reported incidents related to their medical department. They choose priority incidents which need to be analysed and propose corrective actions. The main principles of this method are that patient safety must be managed within a medical team, the team must focus on near-miss events and the actions must concern latent factors that contributed to the occurrence of the near-miss event [5].

An EFC was implemented in the anaesthesiology department of our university hospital. Patient safety in anaesthesia has improved over the last 50 years [6]. In 1999, the National Institute of Medicine reported that anaesthesia mortality rates decreased from two per 10,000 cases to one per 200,000–300,000 cases [7]. Various tools have been deployed in anaesthesiology to improve patient safety and this specialty can be considered a leader in the management of patient safety analysis [8–11]. However, there are still incidents warranting the pursuit of scrutiny [10,12].

The objective of this study was to describe the functioning of the EFC in an anaesthesiology department and to consider its contribution to the management of health care quality and safety.
Materials and Methods

Study design

This was a descriptive study based on the written reports of the anaesthesia department EFC over 2 years, from its beginning in October 2009 until September 2011. According to the French law, ethics review board approval was not required for this observational study because no personal data was collected.

Setting

The study was conducted in a 1347-bed acute-care university hospital. The anaesthesia department is composed of 82 medical doctors and 84 nurses who intervene in a total of 63 medical units in the hospital.

The hospital has a voluntary internal reporting system for adverse events and near-misses. The events are reported to a central safety unit on a standardised reporting form. This unit is composed of a medical doctor, a pharmacist and a quality engineer. It animates a weekly meeting involving representatives of the administration and the people in charge of specific risk areas such as the risks associated with drugs (pharmacovigilance), nosocomial infections (infection vigilance), healthcare materials and devices (medical device vigilance), transfusion (haemovigilance), etc. Reports of events are classified by severity and risk areas, recorded in a computer program and presented in the weekly meeting. The central safety unit directly investigates the most serious events and those involving several hospital departments. Others are transmitted to the operator most suitable for the problem and to executives of relevant departments. For departments with an EFC, the central safety unit addresses the reports of events concerning the department to the EFC leader every month.

Anaesthesia Department EFC

The Anaesthesia Department EFC was set up in October 2009 and works through a written procedure in accordance with the method proposed by Air France Consulting [2,5]. The Committee is composed of volunteer representatives of various professions within the anaesthesia department. A few days before the committee meeting, the EFC leader receives a file with event reports concerning the anaesthesia department. Committee meetings are conducted according to a standardized scheme: 1) reading the list of reported events, 2) choosing a priority event to investigate, 3) choosing the professional responsible for the investigation, 4) reviewing the analysis report from the previous month, 5) choosing corrective actions and 6) monitoring on-going actions. The investigation is carried out during the month following the EFC by a designated person. The person in charge of the investigation performs the analysis using the ORION® method developed by Air France Consulting [13]. The main steps of the method are collecting data, describing the chronological facts occurring before, during and after the event, describing the failures, looking for causes for errors and latent factors that could have contributed to the failures, setting up corrective actions and writing a report of the analysis. Causes and latent factors are searched for in different areas: political, organisational, working conditions, team functioning, procedures, actors and the patient.

Data collection

All written documents from the anaesthesia EFC were analysed. Reported events were classified according to the source of the report, the type of event and the consequence for the patient using the International Classification for Patient Safety [14]. Written reports from meetings were analysed using a standardised form which followed the theoretical steps and contents of an EFC meeting (as described above). The event analysis reports were examined using a standardised form which followed the theoretical steps and contents of the ORION® method.

Data analysis

Qualitative data were described using total numbers and percentages. Quantitative data were described with median and interquartile range (IQR). The analysis was performed using Statview.

Results

The committee set up 16 meetings during the study period, attended by 26 professionals. This included 13 medical doctors, six head nurses, five nurses and two quality engineers. A total of 156 events concerning the anaesthesia activities were examined by the EFC with a median of eight incidents [IQR, 7–12] per meeting. Events were more often (79%) reported by one of the department’s professionals (Table 1). Fifteen per cent of the incidents reported occurred outside the department, e.g. involving the pharmacy, patient transport or medical

<table>
<thead>
<tr>
<th>Characteristics of reported incidents</th>
<th>N=156</th>
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</thead>
<tbody>
<tr>
<td>Reporting professional</td>
<td></td>
</tr>
<tr>
<td>Working in the anaesthesia department</td>
<td>123   (78.8)</td>
</tr>
<tr>
<td>Working outside the anaesthesia department</td>
<td>33    (21.2)</td>
</tr>
<tr>
<td>Place where incident occurred</td>
<td></td>
</tr>
<tr>
<td>Within the anaesthesia department</td>
<td>133   (85.3)</td>
</tr>
<tr>
<td>Outside the anaesthesia department</td>
<td>23    (14.7)</td>
</tr>
<tr>
<td>Type of incident</td>
<td></td>
</tr>
<tr>
<td>Medical device/equipment</td>
<td>36    (23.1)</td>
</tr>
<tr>
<td>Clinical administration</td>
<td>28    (17.9)</td>
</tr>
<tr>
<td>Medication/IV fluids</td>
<td>26    (16.7)</td>
</tr>
<tr>
<td>Clinical process/procedure</td>
<td>24    (15.4)</td>
</tr>
<tr>
<td>Resources/organizational management</td>
<td>15    (9.6)</td>
</tr>
<tr>
<td>Behaviour</td>
<td>12    (7.7)</td>
</tr>
<tr>
<td>Infrastructure/building/fixtures</td>
<td>9     (5.7)</td>
</tr>
<tr>
<td>Nutrition</td>
<td>3     (1.9)</td>
</tr>
<tr>
<td>Blood/blood products</td>
<td>2     (1.3)</td>
</tr>
<tr>
<td>Documentation</td>
<td>1     (0.6)</td>
</tr>
<tr>
<td>Degree of harm for the patient</td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>147   (94.2)</td>
</tr>
<tr>
<td>Mild</td>
<td>7     (4.5)</td>
</tr>
<tr>
<td>Moderate</td>
<td>0     (-)</td>
</tr>
<tr>
<td>Severe</td>
<td>1     (0.6)</td>
</tr>
<tr>
<td>Death</td>
<td>1     (0.6)</td>
</tr>
</tbody>
</table>

devices. Events related to anaesthesia most frequently involved medical devices (23%), which were unavailable, defective or not well maintained. In 18% of the cases, the events were related to clinical administration problems including patient transfer, appointment, admission and discharge problems. The majority of events (94%) had no consequence for the patient. Nevertheless, these events were likely to generate extra workload or to disrupt the operating program, e.g. delay surgery or a blood transfusion. In seven cases (4%), the reported event was a mild adverse event for the patient: desaturation in three cases (equipment problem during surgery, lack of monitoring after a surgery), hypothermia in a patient after leaving the recovery room because he was not well covered, a broken tooth during panendoscopy, a medication error (cisatracurium injected instead of midazolam), and a patient who had a cyst and was operated with local anaesthesia despite great pain. One event was more severe, i.e. the patient underwent cardiac arrest: he had abnormal laboratory values and the anaesthetist called but did not respond. In one case, the patient died due to pneumothorax occurring during a gastrostomy performed under local anaesthesia.

A report was written for 13 meetings. The analysis of these reports showed that the different steps of the EFC meeting were generally respected. The choice of a priority event to analyse and the monitoring of previous actions were missing in five meetings. The analysis of an event was reported in ten cases, was written according to the defined plan in six cases and was presented orally in four cases.

The events which were the subject of the analysis were: a total electrical failure in an operating room, no response to an emergency call, a lack of information on an anaesthesia document, a lack of transition in a recovery room, a return from the operating room without medical records or orders, misuse of a respirator soda lime tray, poor communication between caregivers after pleural drainage; medication error: epidural injection of oxytocin instead of fentanyl and lack of monitoring during a transfusion.

The causes of the events were reported in eight cases and were related to organisation, work conditions and team functioning. One to four proposals for actions were reported per event, for a total of 20 actions. The EFC retained 12 actions including five training actions, four instances requiring writing up a protocol, two changes in organisation and a modification of the environment. The professional in charge of the action was a professional of the department in six cases, from another department in four cases (technical units or the haemovigilance unit), and was not designated in two cases. The time to accomplish the action was defined in only one case.

Discussion

This study shows that the healthcare professionals involved in the EFC have a continuing implication in the management of reported events. The committee is active and produces improved actions. This study also shows that the department may be the appropriate level for the management of patient safety and that the method is applicable to other disciplines than radiotherapy [3,4].

A key feature is that the EFC is deliberately based on a systematic approach to patient safety. ORION is a method for analyzing the root causes of an adverse event, based on the Reason model [15–17]. It is close to the ALARM method and includes the same steps. It is somewhat simpler than ALARM and, a priori, easier to use by healthcare professionals, nonspecialists in risk management. However, the essential contribution of an EFC is to provide a formal framework for the use of this method by a team. Regular committee meetings integrate the analysis of adverse events into the routine of the department. The EFC allows the direct involvement of healthcare professionals in risk management.

In this study, we observed several differences compared to the theoretical way of conducting an EFC. Indeed, the analysis of events did not always follow all the steps of the ORION© method. The search for potential causes leading to the event often lacked depth. Also, the corrective actions were not always planned and monitored. These deviations from the method can be partly explained by the professionals’ lack of availability.

Indeed, the investigations require a great deal of time, especially to assemble professionals involved in the event and stakeholders, to explore the causes and to produce an analysing report. Consequently, we observed that for eight participants at each meeting 26 individuals must be involved over the 2-year period. We can also hypothesize that the ORION method is too complex or that the actors are not sufficiently trained in its use. This suggests that the training of participants must be reinforced.

Among the features of patient safety management, reporting adverse events is of particular importance. It raises awareness of all the possible weaknesses in the care system as well as in the monitoring of the effectiveness of corrective actions [12,18]. Several studies have shown that healthcare professionals, particularly physicians, agree with the importance of incident reporting and the concept of learning from errors [19,20]. Nevertheless, in practice, many incidents are not reported [20–23], due to numerous barriers such as non-ergonomic reporting tools, workload, fear of punishment and lack of feedback to the report [22–25]. In the present study, we were not able to estimate the rate of incidents reported. Certainly, there were incidents that were not reported. However, every month, the committee had enough incidents to discuss. Corrective actions were regularly taken. Within the EFC, reported incidents are analysed within the team. Healthcare professionals can therefore be informed more easily of the corrective actions and are more likely to observe their effects. Consequently, the existence of an EFC in a department may indeed improve incident reporting.

Among the events reported, many did not warrant a thorough analysis by the team. Several events were related to a single, simple problem that can be solved by a direct intervention on the part of the head nurse or head physician. Other events fell within a specific effector. For example, the reports concerning failures of medical devices are directly sent to the person in charge of medical device vigilance. Also, some of the events were not within the scope of the team’s possible actions. For example, the reports relating lack of staff or lack of beds are the consequence of hospital policy that has
prioritized the reduction of spending for budgetary reasons. This explains why the ultimate number of investigated events seems relatively low.

The main advantage of the EFC is that it included the management of adverse events in the routine of a team. The committee is multiprofessional and promotes teamwork. We believe that it may encourage reporting adverse events because professionals are more readily informed of the outcome of their reporting. The main drawback is the lack of availability of personnel.

The EFC is located at the basic level of the safety management system that can be described as a triple-loop model inspired by models of self-learning organisations [2,26]. The basic level is represented by the healthcare professionals who have to identify and analyse incidents in order to improve their working methods [26]. At the hospital level, all reported incidents are addressed to the transverse structure of risk management, so that a comprehensive status of all clinical activities within the hospital can be constructed, the events that involved several departments can be investigated and decision makers can be provided with action plans to reduce risks. At the country level, care system regulators (state agencies, insurance organisations) receive information on safety issues whose analysis can lead to national actions such as the withdrawal of health products [24].

Within this framework, the EFC is a tool that allows the direct involvement of healthcare professionals in managing the quality and safety of healthcare. It can be a way to encourage adverse event reporting and to develop a safety culture among healthcare professionals.

References