

An Experience Feedback Committee for Improving Medication Process Safety: An Observational Study in a Hospital Pharmacy Department

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Abstract

Study objective: An experience feedback committee (EFC) is a management method for patient safety designed for a medical team. The aim of this study was to analyse the functioning of an EFC in a hospital pharmacy department and to explore its contribution to medication process safety.

Design: We conducted a transversal, observational study based on the analysis of all the written documents produced by the EFC between January 2012 and December 2013.

Setting: The study was conducted in the pharmacy department at Grenoble University Hospital in France.

Measurements: We analysed all the documents related to incidents reported, the reports of meetings and the reports of event analysis. Patient outcomes (degree of harm) were assessed according to the Conceptual Framework for the International Classification for Patient Safety. The main outcome was the corrective actions decided by the EFC.

Main Results: During the study period, there were 22 meetings attended by a total of 59 professionals including seven pharmacists. A total of 320 incidents were analysed. Most of them (92%) had no medical consequence for the patient. Twenty-two incidents were selected to be thoroughly analysed. One hundred and ten corrective actions were carried out including 32 training sessions, 32 guidelines written, 32 changes in organisation, nine changes in equipment and five changes in another category.

Conclusions: The EFC is an attractive method to involve healthcare professionals in quality and safety management.

Keywords: Patient safety; Medication process; Adverse events; Hospital pharmacy

Introduction

Despite efforts to improve patient safety for nearly 10 years, progress remains slow [1]. The main barriers are related to the sociology of healthcare organisations and the culture of health professionals. One of key issues 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 entity [2]. 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]. An EFC is a multidisciplinary team representing the diversity of the functions encountered in the medical entity. The EFC members usually meet monthly to examine reported incidents related to their medical department. They choose priority incidents that 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 also consider the near-miss events and the actions must concern latent factors that contributed to the occurrence of the near-miss event [3].

Adverse drug events (ADEs) refer to adverse events caused by medications, and they represent the most frequent cause of preventable adverse events [4]. Consequences can be substantial, including hospital admissions, prolonged hospital stay, additional resource utilization, and time away from work, as well as lower patient satisfaction. The substantial costs of ADEs for hospitals have

been assessed and justify investment in efforts to prevent these events [5]. Each part of the medication process (prescription, transcription, dispensing, administration and monitoring) has been targeted in order to prevent ADEs and potential ADEs and thus improve patient safety. To address each part of the process, several methods have been suggested and carried out such as computerized prescriber order entry (CPOE), decision support with CPOE and clinical pharmacists (for the prescription and transcription parts), bar code technology and automated dispensing cabinets (ADCs) (for the dispensing part) [6-11].

In this context, an EFC was implemented in the pharmacy department of our university hospital 6 years ago. The goal was to further improve the safety of the drug supply chain based on the analysis of adverse and near-miss events within the pharmacy department.

The objective of this study was to describe the functioning of the

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EFC in a pharmacy department and to consider its contribution to the management of medication process quality and safety.

Materials and Methods

Study design

This was a transversal, observational study based on the analysis of all the written documents produced by the pharmacy department EFC over 2 years, from January 2012 to December 2013.

Setting

The study was conducted in the pharmacy department of a university hospital. The drug management unit is composed of eight pharmacists and 13 technicians who deliver drugs to a total of 200 medical units in the hospital and 10,500 patients per year for ambulatory drug dispensations.

Pharmacy department EFC

The pharmacy department EFC was set up in March 2008 and worked through a written procedure in accordance with the method proposed by Air France Consulting [2,3]. The committee was composed of volunteer representatives of various professions within the pharmacy department and met once a month. All events concerning the pharmacy department were reported through a web-based information system. Committee meetings were conducted according to a standardised scheme: 1) reading the list of reported events, 2) choosing a priority event to investigate through a secret ballot, 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. Each investigation was carried out during the month following the EFC meeting by a designated person. The person in charge of the investigation performed the analysis using the ORION® method developed by Air France Consulting [3]. The main steps of the method were: collecting data; describing the chronological facts that occurred before, during and after the event; describing the failures; looking for causes of errors and latent factors that could have contributed to failures; setting up corrective actions; and writing a report of the analysis. Causes and latent factors were searched for in different areas: political aspects, organisational aspects, working conditions, team functioning, procedures, actors and the patient.

Data collection

All written documents from the pharmacy EFC were analysed. Reported events were classified according to the source of the report, the type of event using an in-house classification dedicated to the activity of a pharmacy department and the consequence for the patient using the International Classification for Patient Safety [12]. 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 reports of event analysis 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 Microsoft Excel®.

Results

The committee set up 22 meetings during the study period, attended

by a median of 7 professionals [IQR, 6–9] per meeting. This included a median of 3 pharmacists [IQR, 3–4] for a median of 1.5 technicians [IQR, 1–2] per meeting. A total of 320 events concerning the pharmacy activities were examined by the EFC with a median of 13 events [IQR, 8–18] per meeting. Events were exclusively (100%) reported by one of the department's professionals. Thirty percent of the incidents reported occurred outside of the department, e.g. involving a medical unit or patient Table 1. Events related to pharmacy most frequently involved globalised distribution (22%), generally due to a defect in the drug supply chain. In 21% of the cases, the events were related to storage problems. The majority of events (92%) had no consequence for the patient. Nevertheless, these events were likely to generate additional workload. In 11 cases (3%), the reported event was a mild adverse event for the patient: a drug dosing error in five cases, no drug delivery in three cases, drug delivery delay, a drug delivery error and lack of information at drug delivery. One event was classified as moderate: it concerned a prescribing and dispensing error of Haldol decanoate instead of Haldol at a continuous intravenous dosage to control emesis in the treatment of a cancer disease. It was administered for 3 days.

A report was written for each meeting. 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 systematic for each meeting. The analysis of an event was reported in every meeting, was systematically written according to the defined plan and presented orally.

The events analysed were related to drug delivery for an outpatient (nine events); globalised distribution (six events); procurement, emergency or nominative delivery, and storage (two events each); and narcotic delivery (one event).

All analyses of events implied a search for their causes. From three to nine proposals for actions per event were reported, for a total of 114 actions. The EFC retained 110 actions (Table 2) including 32

Characteristics of incidents reported	N=320	
	n	(%)
Reporting professional		
Working in the pharmacy department	320	(100.0)
Working outside the pharmacy department	0	(-)
Place where incident occurred		
Within the pharmacy department	223	(69.7)
Outside the pharmacy department	97	(30.3)
Type of incident		
Globalized distribution	71	(22.2)
Storage	67	(20.9)
Emergency or nominative delivery	55	(17.2)
Retrocession	54	(16.9)
Procurement	26	(8.1)
Narcotic delivery	26	(8.1)
Communication	7	(2.2)
Other	6	(1.9)
Returns of care units	5	(1.6)
Logistics	3	(0.9)
Degree of harm for the patient		
None	308	(96.3)
Mild	11	(3.4)
Moderate	1	(0.3)
Severe	0	(-)
Death	0	(-)

Table 1: Characteristics of the incidents reported.

training actions, 32 instances requiring writing up a guideline, 32 changes in organisation, nine changes in equipment and five changes in another category (e.g. obtaining information about a drug from a pharmaceutical company). The professional in charge of the action was a professional working in the department in all cases except one (involving drug preservation outside the area of the pharmacy department), and was always designated. The time to accomplish the action was defined in only nine cases (8.2%).

A cost analysis has been performed to assess the cost of an EFC. Considering an average cost of 40€ per hour, 10 meetings of 2 hours each per year attended by a median of 7 professionals, this leads to 5,600€ per year. To this amount must be added the time spent for organizing the EFC, preparing the meetings, declaring and analysing events: an approximate estimation from 5% to 10% of the working time of a pharmacist seems to be reasonable. Therefore, 3,750€ to 7,500€ must be added to reach a global cost for an EFC ranging from 9,350€ to 13,100€ per year that can be converted to approximately 12,000\$ to 16,000\$ per year.

Discussion

This study showed that healthcare professionals of the pharmacy department involved in the EFC were routinely involved in the management of reported events. The committee was active throughout the study period and produced improvement actions. This study also showed that the department may be the appropriate level for the management of the drug supply chain safety, and that the method based on EFC was applicable to other disciplines than radiotherapy or clinical department [3,13].

A key feature is that the EFC is deliberately based on a systematic approach to patient safety and allows the direct involvement of healthcare professionals in risk management. Regular committee meetings integrate the analysis of adverse events into the department's routine. The essential contribution of an EFC is to provide a formal framework for analysis of adverse events. ORION© [3] is a method for analysing the root causes of an adverse event, using the Reason model [14]. It is close to the method of Association of Litigation and Risk Management (ALARM) [15,16] and includes the same steps. However, the ORION method is somewhat simpler than ALARM and, a priori, easier to use by healthcare professionals who are non-specialists in risk management.

In this study, we observed that healthcare professionals stuck with the theoretical method of conducting an EFC as well as with the ORION© method's steps when analysing the events. The search for potential causes leading to the event was systematic. Corrective actions were systematically set up and monitored, but deadlines for carrying them out were almost never specified. The healthcare professionals' involvement in the method may be explained by the fact that they perceived the potential benefits for their own practice. We can consequently hypothesise that the ORION method is simple

enough for non-specialists in risk management or that the actors are sufficiently trained in its use. Indeed, professionals in the pharmacy department were among the earliest adopters of this method because it was still in an experimentation phase at Grenoble University Hospital. However, professionals were not available for all meetings. We noticed that 59 professionals were involved in EFCs over the 2-year period for a median of seven participants per meeting, including three pharmacists.

Among the patient safety management features, 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 [17,18]. 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 reported incidents and some incidents were probably not reported. However, every month, the committee had enough incidents to discuss. The existence of an EFC in a department may improve incident reporting. Indeed, the professionals of the department can perceive the potential benefit of reporting events when they observe that corrective actions are set up based on the analyses of these events.

The fact that the drug supply chain is connected to several medical units and patients explains why the ultimate number of reported events seems relatively high. Among the events reported, many did not warrant a thorough analysis by the team. Most of events reported in the pharmacy department, whatever their type (globalised distribution, storage, emergency or nominative delivery, etc.), implied the intervention of several professionals involved in the drug supply chain. However, many events were related to a single, simple problem that could be solved by a direct intervention.

Our study has a few limitations. First, it is a single observation in a particular setting, but we know that the EFC method works in other settings such as radiotherapy or emergency departments [3,13]. Second, the design did not allow assessing the impact of EFCs on patient safety outcomes. The effectiveness of EFCs was estimated through the implementation of corrective actions.

Indeed, this EFC was introduced as a real life experience for healthcare professionals from a hospital pharmacy department committed into risk management. The main points assessed here were the involvement of care providers in healthcare safety management on a routinely basis and the use of a root cause analysis method (ORION©) to explore adverse events.

Concerning the cost analysis of an EFC ranging from 9,350€/year to 13,100€/year (12,000\$/year to 16,000\$/year), this points out that an EFC has a real cost but it is the price we have to pay to contribute routinely to medication process quality and safety.

To go a step further, as it has been demonstrated that this setup can work on a routinely basis, more data will be needed to compare hospital pharmacy department with EFC with other system or a hospital without EFC.

To conclude, 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.

Characteristics of actions retained	N=110	
	n	(%)
Type of action		
Training	32	(29.1)
Guideline	32	(29.1)
Organisation	32	(29.1)
Equipment	9	(8.2)
Other	5	(4.5)

Table 2: Characteristics of the corrective actions set up.

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The manuscript does not contain clinical studies or patient data.

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