

Experimentation of an Anaesthesiologic Incident Monitoring System in Emilia-Romagna Region (Italy) Hospitals

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Abstract

Objectives: This study describes the experimental implementation of incident reporting in the anaesthesia services of Emilia-Romagna Region Hospitals. Its principal objectives are to assess the applicability and feasibility of this tool in a regional context, to sensitize theatre staff to acknowledge events that may compromise patient safety and to identify areas to be improved.

Materials and method: The study is conducted by Emilia-Romagna Health Agency. It involves 44 theatre units of 16 regional "Aziende Sanitarie" (a trust that rules community services and hospitals). Theatre staff has been invited to spontaneously and even anonymously report incidents and near miss using a dedicated form. The tools arranged and offered to each Aziende Sanitarie were a training set for staff, a reporting form adapted to the anaesthesia context and an internet database to register the reported incidents.

Results: In the first 5 months of the study (march 04-july 04), 173 reports of anaesthesiological incident were collected. In 62% of the cases accidents were reported by physicians; the incidents mainly involved patients with low anaesthesiological risk (ASA I/II, 56% of cases), submitted to general anaesthesia (68%), in the preoperative period (38%). In 15% of the cases the patient suffered of a damage; the most frequent events were classified as "inaccuracy or inadequacy" (34%); human errors were considered the most frequent cause (48%).

Discussion: Despite the short observation period, preliminary results confirm that the incident reporting system brings useful information that can be used in high risk health services such as anaesthesia to identify areas to be improved.

Key words: Incident reporting. Anaesthesia. Quality Improvement. Internet.

Resumen

Objetivos: Se describe la aplicación experimental de un sistema de comunicación de incidentes en los servicios de anestesia de los hospitales de la región Emilia-Romagna. Sus objetivos principales han sido la evaluación de la aplicabilidad y factibilidad de esta herramienta en un contexto regional con objeto de sensibilizar a los profesionales sanitarios del área quirúrgica respecto al reconocimiento de las complicaciones que pueden comprometer la seguridad de los pacientes y de identificar los aspectos susceptibles de mejora.

Materiales y método: El estudio ha sido realizado por la agencia de salud de la región Emilia-Romagna. Han participado 44 unidades quirúrgicas de 16 Aziende Sanitarie (agencias que controlan los servicios sanitarios tanto comunitarios como hospitalarios) regionales. Se invitó a los profesionales sanitarios a que comunicaran de manera espontánea y también anónima cualquier incidente observado utilizando un formulario específico. Las herramientas proporcionadas a cada Aziende Sanitarie fueron: un pequeño curso de formación para el personal sanitario, un formulario de comunicación adaptado al contexto de la anestesia y el programa a través de internet para la comunicación de los incidentes observados.

Resultados: Durante los primeros 5 meses del estudio (marzo de 2004 a julio de 2004) se recogieron 173 comunicaciones de incidentes anestesiológicos. En el 62% de los casos, los incidentes fueron comunicados por médicos; los problemas afectaron fundamentalmente a los pacientes con bajo riesgo anestesiológico (ASA I/II, 56% de los casos), intervenidos con anestesia general (68% de los casos) y durante el período preoperatorio (38%). En el 15% de los casos, el paciente presentó algún tipo de lesión; los incidentes más frecuentes fueron clasificados como imprecisión o inadecuación (34%); las causas más frecuentes fueron los errores humanos (48%).

Discusión: A pesar de la brevedad del período de observación, los resultados preliminares confirmaron el hecho de que el sistema de comunicación de incidentes ofrece información útil que se puede utilizar en los servicios sanitarios de riesgo alto, tales como los de anestesia, con objeto de identificar las áreas susceptibles de mejora.

Palabras clave: Comunicación de incidentes. Anestesia. Mejora de la calidad. Internet.

Introduction

In 2001, the Emilia-Romagna Region Health Agency adopted a "Risk management in Healthcare Facilities" program with the objective to favour an holistic approach to risk, taking into consideration its multiple elements.

Emilia Romagna-Region has 4 million inhabitants and 17 Aziende Sanitarie that administers community services and/or hospitals. Public hospitals are 67; private sector brings other 45 small ones. Beds/inhabitants ratio is 4,5‰.

This objective can be reached on one side by the integration of Quality, Safety and Environmental Management Systems, and by the regional side through helping the clinical organization to adopt "new" tools, useful to:

- Prevent clinical risks.
- Enhance premises and occupational safety.
- Manage complaints and claims.

Since 2001, some risk management methods and practical tools have been experimented and afterwards disseminated in the regional context. The scope was to prevent or reduce, in a systematic way, various risks in health care facilities.

With regard to clinical risk prevention, a Patient Safety Reporting System has been experimented in 2002; five trusts have collected data on incidents with damage to the patient and near miss from 39 selected clinical units. Reporting was spontaneous and a standardized report form was used.

This was based on the form adopted by the Australian Incident Monitoring System (AIMS).

The Incident Reporting Systems allow the collection of data and information on critical events in a standardized frame, so that they can be analyzed. Corrective actions and improvement strategies or actions may thereafter be implemented to avoid future reoccurrence.

Establishing an Incident reporting system is considered in literature as a baseline for any risk management initiative^{1,2}.

At the national level of healthcare, the Australian Incident Monitoring System (AIMS)^{3,4} is the most relevant surveillance system. It was introduced in 1996 in South Australia and it was extended afterwards in many healthcare facilities in the rest of this country and in New Zealand.

In Italy presently, there is no national or regional safety patient incident monitoring system. Such a system for blood and derivatives transfusion is under study. The Emilia-Romagna pilot study⁵ suggests that it is necessary to adopt a simplified format applicable to all clinical specialities.

Thus in 2004 a new trial, supported by new tools, has been launched: its principal objectives were to assess the applicability and feasibility of a monitoring systems of anaesthesiological incidents at the regional level, to sensitize theatres' staff to acknowledge events that may compromise patient safety and to identify at the local and the regional level areas to be improved.

Materials and method

The ongoing study involves 44 operating blocks (one or more operating rooms in each) and all the regional Aziende Sanitarie.

The study was preceded by preparatory phase, started in may 2003. Figure 1 shows the timeline of the activities that allowed data collection from march 2004.

The planning and the coordination of the trial was made by the Regional Health Agency. In may 2003 several anaesthetist and the clinical directors of their units were invited to take part of the project committee. They were involved in developing the study design and the methods for its implementation. In January 2004 the staff training began and was concluded by June 2004. As soon as the training was over, each Unit, started to produce reports; and to register the reported events in the ad hoc database available on internet. This occurred in march 2004.

The tools and conditions to support the trial were: 1) a trial protocol for which the units adhered on a voluntary basis; 2) a staff training set; 3) a standardized and agreed reporting form; 4) a data base available on Internet with safe access to register the reported events; 5) the involvement of the Aziende leaderships and of the anaesthesiological units' clinical directors.

Each study site had at its disposal the same training project and materials, reporting form and database to input the signaled events, to classify them and their causes and to produce some basic reports.

Staff sensitization and training

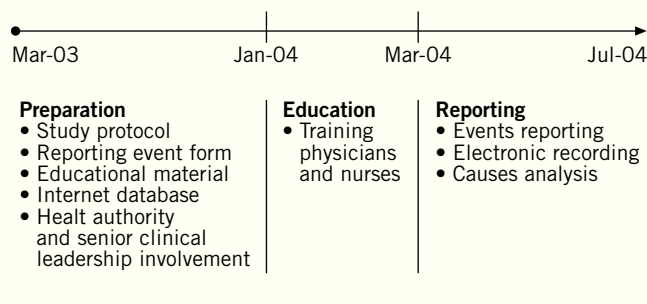
Cultural change and staff training are fundamental steps to approach the topic of safety in healthcare organizations^{6,7}.

Sensitization and training of anaesthetists and theatre nurses has been performed in each Azienda using the materials provided by the Regional Health Agency and integrated by local details when necessary.

About one thousand persons participated in the training event. This was of "blended" type (class room sessions and self-training on CD-ROM support). This training methodology was chosen to guarantee access to the training for a big number of persons and to favor uniform learning process at the regional level.

The training objectives were to sensitize staff to the fundamental risk management concepts, to enhance their capacity to identify anaesthesiological incidents and to train them to compile the reporting form.

Figure 1. **Timeline of the study. Study activities and approaches are shown over three periods defined as preparation, education and reporting.**



The reporting form

All the events were spontaneously described on a standardized form by the anaesthesiologists and theatre nurses.

The signaling sheet was prepared on the basis of the results of a previous study⁵. It contains space for narrative description of how, when and where the incident occurred, which factors have influenced it, which reduced the consequences and the corrective actions that have been undertaken, the type of anaesthesia and the surgical procedure performed, patient age and ASA physical status (American Society of Anaesthesiologist Physical Status Classifications). The sheet may be signed or anonymously compiled and confidentially delivered to the unit clinical responsible. The senior clinical evaluates the event consequences on a gravity scale (table 1) and its future risk on the basis of probability of re-occurrence and seriousness of results ratio (fig. 2). The incident analysis is completed by answering questions that investigate the organizational and economic costs, the identified causes and the corrective actions suggested.

The database

The events signaled are directly loaded through a safe access into the electronic data base by the staff of the Clinical Units participating to the study.

The data base offers automatic aggregation of data and reports in real time to three levels clients: to the clinical unit, to the Azienda Sanitaria Direction and to the Regional Health Agency.

The objective is to build a data base that can help the local level (Clinical Units and Aziende Sanitarie) and the central government level (Health Agency) to monitor “undesirable events” in anaesthesia and to establish in which area to intervene with improvement activities.

The result of the experimentation period from 1st March 2004 and 31st July 2004 are below presented.

Results

In the period 173 reports have been inputted into the regional database.

Table 2 shows the available categories of the electronic reports.

Figure 2. Assessment of future risk.

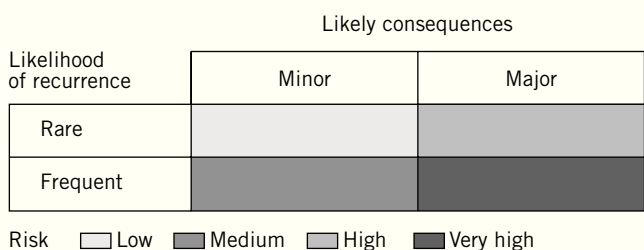


Table 1. Impact ranking

Unsafe condition – no event occurred	Level 1
Near miss – event occurred but intercepted before reaching patient	Level 2
No harm – event which reached patient without injures	Level 3
Minor consequences – minor injures without need of treatment	Level 4
Moderate consequences – moderate diagnostic investigations or moderate treatment	Level 5
Between moderate and major consequences – need of major treatment	Level 6
Major consequences – protraction of recovery/unplanned transfer to ICU	Level 7
Catastrophic consequences – permanent inability/contribution to death	Level 8

Anaesthetist have signaled 62% of the events (n = 108), nurses 30% (n = 52) and in 8% of the cases the event reporter has not qualified himself.

The reported events occurred during the preoperative period (n = 65; 38%); the maintenance (n = 35; 22%); the induction (n = 26; 15%); the waking up phase (n = 12; 7%) and the postoperative period (n = 8; 5%) follow in the order. In 13% of the cases the anaesthesiological phase has not been indicated.

The place of occurrence in most cases (58%) was the operating theatre; the induction room was cited in 20% of cases (n = 35), the recovery room in 4% (n = 6), intensive care unit in 2% (n = 3), elsewhere in 2% (n = 4) and in 7% of cases the place of the reported event was not recorded.

In 68% of the cases patients underwent general anaesthesia (n = 117); in other 25 cases (14%) loco-regional anaesthesia, 7% (n = 12) local anaesthesia and 6% (n = 10) other anaesthesiological procedures.

Table 2. Features of the event reporting system

- Demographic/background information for each event
- Open ended narrative description to document incident details
- 4 major event classification: inexactness, omission, retard, other event type
- 4 major event classification further classified into 29 subtypes
- Contributing factors: patient, staff, system
- Reducing factor
- Impact ranking (1-8)*
- Future risk assessment (likely consequences and likelihood of recurrence)
- Root causes: human error, error system, failure of environmental and equipment, other causes
- Actions undertaken
- Recommendations for improvement

*See table 1 for detailed definitions of the level of impact.

The surgical procedures during which the events occurred involved the following disciplines: Orthopedics (n = 43; 25%); General Surgery (n = 37; 21%); Obstetrics and Gynecology (n = 26; 15%); Urology (n = 19; 11%); ORL (n = 13; 8%) Neurological Surgery (n = 10; 6%); Ophthalmology (n = 8; 5%); Cardiology and ITU (n = 3; 2%) and Vascular Surgery (n = 4; 2%); in 5% of cases this information was non registered.

The events that caused a damage to the patient were 25 (15%); in 19% of cases the incident involved the patient but did not cause injuries, in 36% (n = 63) it was signaled as a condition of harm and in 30% (n = 52) a near miss.

Among the patient that suffered a damage, 8% (n = 14) had minor consequences, 3% (n = 5) had moderate consequences, 2% (n = 3) moderate to important, 1% (n = 2) important, 1% (n = 1) severe consequences (table 1).

The events were classified in 4 major categories: inaccuracy or inadequacy (34%; n = 59), delay (23%; n = 39), omission (12%; n = 21) and other types of events –to identify areas of particular interest– (31%; n = 54). The most frequent events inside these major categories were inaccuracy/inadequacy in drugs prescription/administration (25%), delay in surgical procedures (49%) and omissions of care (31%). Among the “other types of event” the most frequent was the malfunctioning of devices or equipment (35%).

Factors reducing the consequences of the events were identified in 69% of the cases; among these the commonest are the early detection of the incident (55%; n = 65), good luck (17%; n = 20), the appropriate treatment (14%; n = 17), the adequate planning and the presence of protocols (9%; n = 11); other factors accounted for 5% of cases (n = 6).

The clinical directors with their analysis have identified 295 conditions as incidents' causes, being possible for each event more than one cause (table 3): human errors 48%; (n = 142), system errors 36% (n = 105), premises or equipment problems 7% (n = 22) and miscellaneous causes 9% (n = 26).

Among the human errors (total 142) the most frequent concerns preventive controls (31%, n = 45); among system errors in the first rank are the those linked to the use of protocols and procedures (58%; n = 61); among premises and equipment problems those linked to building, installing and materials (77%; n = 17), among the miscellaneous causes were prevalent those linked to patient's conditions.

The incidents signaled were analyzed by the clinical director of each unit; they have evaluated their future risk on the basis of the probability of re-occurrence and seriousness of results ratio (fig. 2). Evaluating the incidents with these 2 parameters, 21% of incidents (n = 36) were judged at low risk (low probability/ minor consequences); 43% (n = 74) were judged at intermediate risk (high probability/ minor consequences), 15% (n = 27) at high risk (low probability/major consequences) and 21% at very high risk (high probability/major consequences). This evaluation of future risk allows to identify priorities for intervention.

The incident analysis is completed answering the questions that investigate organizational and economic costs, causes individualized and corrective actions suggested.

Table 3. Taxonomy of root causes

Category of causes	Total events n* (%)
<i>Human error</i>	142 (48)
Previous check	45 (31)
Coordination	23 (16)
Vigilance	33 (23)
Actions	17 (12)
Knowledge-based	7 (5)
Skill-based	7 (5)
Ruled-based	5 (4)
Qualification	4 (3)
Extern	1 (1)
<i>System error</i>	105 (36)
Protocols and procedures	61 (58)
Transmission of knowledge/information	23 (22)
Managements priorities	12 (11)
Culture of safety	9 (9)
Extern	0 (0)
<i>Failure of environment and equipment</i>	22 (7)
Building, installing or in materials	17 (77)
Designing (projecting and planning)	3 (14)
Extern	2 (9)
<i>Other causes</i>	26 (9)
Related to patient	19 (73)
Unclassified causes	7 (27)
Total	295 (100)

*For each event more than one cause could be signed.

Discussion

Preliminary data emphasize the medical staff willingness to signal events; such results differ from previous studies^{8,9}. In our case this may be explained by the early involvement of the Aziende leaderships in order to establish common objectives and by the participation of the clinical directors in the project planning, at the regional level, and as teachers, in the training process at the local level. Involvement and commitment of both kind of leaderships are essential to implement risk management activities in health care facilities¹⁰.

The events inputting in the internet data base allows a continuous and updated informative feed back at the local and at the regional level; that is a further essential condition to develop and maintain a spontaneous incident reporting system¹¹.

This preliminary experience confirms that such a system permits to give evidence and even to quantify risk situations to patients safety that may happen during anaesthesia activities; this is true even if it is mainly a qualitative tool and the way the data was obtained cannot be considered significant from the epidemiological point of view.

The limits of the data drawn from an incident signaling systems are known, particularly the absence of those elements that guarantee the suitability of the statistical sample: the number of incidents reported vary not only with relation to their "real" total number, but even with relation to the staff skill to acknowledge them, and the staff willingness to make them public¹².

For example, most incidents (56%) involved patients in good health conditions (ASAI/II), undergoing general anaesthesia (68%). The interpretation of these results must be pursued by correlating these incidents to the number and general typology of patients admitted to the hospital for surgical procedures¹³ or to the under-reporting of the incidents occurring during emergency cases¹⁴.

At the local level, the clinical units have now ongoing audits on the signaled events to deepen the causes analysis and to introduce improvement actions; at the regional level the codification of events started, with the scope to classify them into an anaesthesia specific taxonomy. Moreover, a survey and an analysis of the problems arise during the use of the experimentation tools has been started in order to better identify them before their dissemination to the Regional Health Service.

An efficient system of Incident reporting, when diffused and systematically and continuously applied, may be an informative tool that helps decision making to improve the health services quality locally, and to govern the health system, at the central level.

Nonetheless, it is necessary to continue the study for a further period and to reach a "critical mass" of registrations that will enable an evaluation of effectiveness and applicability of such a system for anaesthesiological incidents.

A data collection on clinical activities volume and surgical case mix is now ongoing in each unit; this will enable to correlate, the number of incidents with activity indicators and to perform a deeper analysis of risk adjustment of the events.

The Regional Health Agency puts as next objectives the dissemination of the incident reporting system to the entire Regional system of health care facilities and to develop, together with the involved health staffs, suitable strategies to reduce the incidence and the impact of signaled events.

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