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ORIGINAL ARTICLE

FMECA methodology applied to two pathways in an orthopaedic hospital in Milan

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Key words

Risk management • FMEA methodology

Summary

Introduction. *Adverse events pose a challenge to medical management: they can produce mild or transient disabilities or lead to permanent disabilities or even death; preventable adverse events result from error or equipment failure.*
Methods. *IRCCS Istituto Ortopedico Galeazzi implemented a clinical risk management program in order to study the epidemiology of adverse events and to improve new pathways for preventing clinical errors: a risk management FMECA-FMEA pro-active analysis was applied either to an existing clinical support pathway or to a new process before its implementation.*
Results. *The application of FMEA-FMECA allowed the clinical risk unit of our hospital to undertake corrective actions in order to reduce the adverse events and errors on high-risk procedure used inside the hospitals.*

Introduction

Clinical risk management (CRM) has become an important part of hospital management. Reducing the probability of risk in hospitals is vital for improving health care quality, hospital staff-patient relationships, patient compliance and for limiting malpractice litigation. CRM is based on a systematic methodology designed to identify, analyse, evaluate, communicate, eliminate and monitor risks associated with hospital procedures, processes, and clinical or administrative guidelines. Risks are usually associated with diagnostic and therapeutic procedures performed in hospitals [1]: the objective of CRM is to decrease the probability of adverse events with a an unexpected and (or) potentially harmful effect on a patient's health status [2]. Preventing medical error has been targeted by public health strategies [3-7]; moreover, nationwide studies and campaigns have been conducted to raise awareness among hospital staff about different kinds of errors. Error classification can be based on different approaches to analyzing the origin of an error. Rasmussen [8] classified errors by taking human behaviour as their source, while Reason [8-12] defined errors as actions deviant from planned ones, showing the importance of latent errors. Responsible for the discovery and control of latent errors are health care managers and clinical directors, who often are unaware of these problems [13]. The role of hospital staff and its efforts to reduce errors are therefore crucial [10]. Enlisting the help of staff in risk awareness campaigns can ensure a campaign will be successful. The involvement of all staff is an essential element of hospital CRM programs since it allows the spread of risk awareness across all levels of an organization's hierarchy and forms a basis for implementing programs to control the occurrence of accidents or close calls during daily activities. The involvement of hospital staff should be organized to report errors, both evident and latent [14-16]. Reporting should be neither anonymous nor punitive, except for evident failure to comply with mandatory or recommended procedures. Incident reporting will include the frequency, severity, site and possible source of error in the organization model. However, reporting, registration and interpretation of errors are not sufficient alone to improve quality of care. The hospital staff need to be involved in preventing errors, recognizing the source of mistakes or failures of the organization and procedures. Risk analysis methods may be classified as reactive or proactive. Reactive methods are based on the analysis of reported adverse events through the use of incident reporting, administrative data, comparison with established quality indicators, and root cause analysis: when an adverse event occurs, a specific and accurate analysis of the steps leading to the failed procedure is performed. Reactive methods are adopted by hospital management to show the number and severity of errors and to modify procedures and organization. But direct staff involvement is no less important for enhancing risk awareness in risk culture – and it is for this purpose that proactive methods can be used.

A proactive analysis can be performed with Failure Mode and Effects Criticality Analysis (FMECA) methodology [17, 18]. Because it focuses on both process and product, FMECA permits evaluation of health system quality. The FMECA-based risk management approach is defined as a "bottom-up" process because, starting from a particular point (e.g. ordinary process activities, single components of a product), it locates defects or faults within a system.

The essential advantage of pro-active risk analysis methods is that they are used before errors or accidents occur. Preventive action, by analysing a process to locate a hazard, is by far the more effective way to improve health

care worker safety. Moreover, FMECA actively involves staff, since the operators of a department in question analyse, evaluate and quantify the risk in each step of the procedures they apply in daily clinical practice [15].
FMECA was chosen by the Joint Commission Accreditation of Healthcare Organizations (JCAHO) as the standard method for risk evaluation (Standard LD 5.2 Accreditation Manual, 2001 Edition).

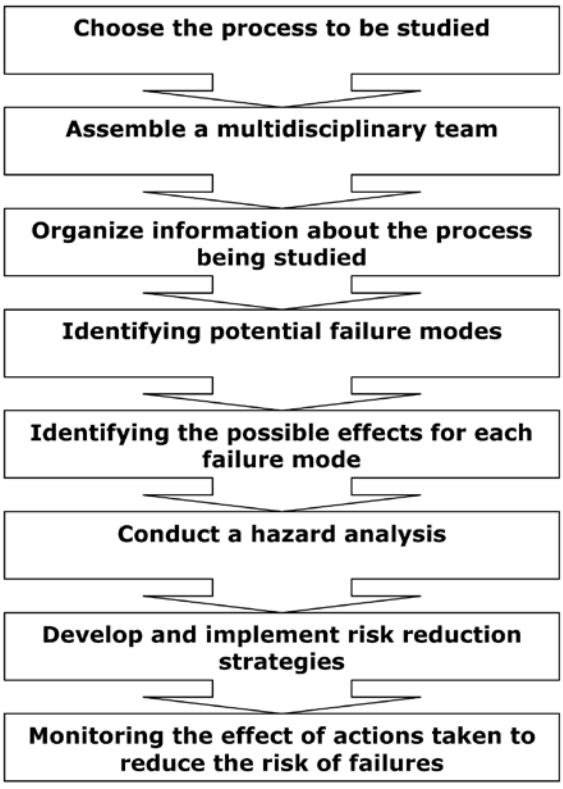
Methods

The awareness that the human factor cannot be completely eliminated from the occurrence of adverse events and that enabling the operator to minimize the chance of committing an error is a fundamental duty of an organization for correct risk management. At the IRCCS Galeazzi, Milan, a risk management FMECA-FMEA pro-active analysis (Fig. 1) was applied to several pathways of the quality system.
This methodology was applied to an existing clinical support pathway and to a new process before it was implemented. All execution errors of the analysed processes had been preventively considered; this made it possible to introduce tests, controls, and countermeasures to limit errors.

Step 1: Selection of the process for analysis

The Institute identified the processes it defined as critical based on the severity of potential harmful events and the potentially dangerous outcomes for patient safety. We will consider the analysis of the blood and hemoderivatives supply and dosing procedure (an existing procedure) and of the physical retention usage in accidental drops prevention pathway (a new pathway). The former was examined and modified also because of the occurrence of a potentially fatal event at the Institute; the latter, which pertains mainly to orthopedic services or units with patients with locomotor apparatus illnesses, identified all potential causes of error or harm to patients before it was implemented by the Quality System.

Fig. 1. The FMEA process covers the following steps. (Modified from Spath, AORN J 2003).



Step 2: Assembly of the FMEA team

For proper application of the methodology, the assembly of a team of experts to analyse the process and identify the potential critical sources of errors was fundamental. The pathways were analysed by blood bank service persons in charge of servicing orders for blood products and by head nurses of the hospital's orthopedic and rehabilitation departments for the physical retention pathway.

Step 3: Analysis of the selected process

The processes were broken down into subprocesses and simple tasks. The processes were described in terms of what actually happens in daily practice and not what should happen. Flow charts for both procedures were drafted to simplify the process analysis.

Step 4: Identification of potential drawbacks and breakdowns

The teams identified in each subprocess and simple task the potential drawbacks, i.e. the potential risks, that, should they occur, could be harmful for patient safety. This analysis needs to show all potential failures of a procedure (Tab. I).

Step 5: Identification of potential consequences

After the error modes were identified, the consequences of each were evaluated. This step is fundamental for evaluating all potential consequences, from the slightest to the most serious.

Step 6: Identification of potential causes

Each drawback was associated with one or more potential causes.

Step 7: Evaluation of severity, probability of occurrence and detectability of each cause

The team evaluated for each pathway subprocess the severity, probability of occurrence and detectability of each drawback/error found in the previous steps.
Severity is defined as the damage or injury a patient may sustain from occurrence of the potential drawback; probability is the possibility or the frequency with which a drawback will occur; detectability refers to the possibility of the operators and the control measures to track a drawback/error. The scale to evaluate severity, probability, and detectability was taken from Spath (Tab. II).

Tab. I. Example of application of FMECA to the Blood and Hemo-derived demand and dosing Procedure.

Major activity:											
Main activity	**Kind of error**	**Causes of error**	**S***	**P°**	**D#**	**RPN§**	**Action**	**S**	**P**	**D**	**RPN**
Assessment of patient ability to receive blood transfusion	Error in assessment of patient ability to receive blood transfusion	Failure to folllow the procedure (pathway)	8	10	10	800	Make sure the procedure is followed and it is clearly stated in the clinical notes	8	2	10	160
Blood Pressure measurement	Error in blood pressure measurement	Failure to folllow the procedure (pathway)	8	10	10	800	Make sure the procedure is followed and it is clearly stated in the clinical notes	8	1	10	80
Body temperature assessment	Error in body temperature assessment	Failure to folllow the procedure (pathway)	8	10	10	800	Make sure the procedure is followed and it is clearly stated in the clinical notes	8	1	10	80

* Severity; ° Probability; # Detectability; § Risk Priority Number

Step 8: Evaluation of the Criticality Index

After these three characteristics are taken for each potential injury, each was assigned a risk priority number (RPN) calculated with the formula RPN = severity X probability X detectability. Measured against this scale, the Criticality Index has a range from 1 to 1000. By calculating the RPN the team identified those pathways and processes that required corrective actions to reduce problems within the system.

Tab. II. FMECA occurrence, severity and detection ranking (modified from Spath, AORN J 2003;78:16-37).

	Ranking
Probability (P)	
Remote (No known occurrence)	1
Low (Possible but no known data eg. may happen sometime in 5 to 30 years)	2-4
Moderate (Documented but infrequent)	5-6
High (Documented and frequent)	7-8
Very high (Documented, almost certain error eg. may happen several times in 1 year)	9-10
Severity (S)	
Slight annoyance. (No injury nor increased length of stay nor increased level of care)	1
Moderate system problem	2-3
Major system problem	4-5
Minor injury	6
Major injury Increased length of stay or increased level of care	7
Terminal injury (e.g. permanent loss of function)	8-9
Death	10
Detectability (D)	
Very high (System will always detect error)	1
High (Error likely to be detected before product reaches patient)	2-3
Moderate (Moderate likelihood of detection before error reaches patient)	4-6
Low (Low likelihood that error will be detected before product/service reaches patient)	7-8
Remote	9
None (Detection not possible at any point within system)	10

Fig. 2a. RPN for the Blood and Hemo-derived demand and dosing Procedure, before the application of FMECA-FMEA analysis.

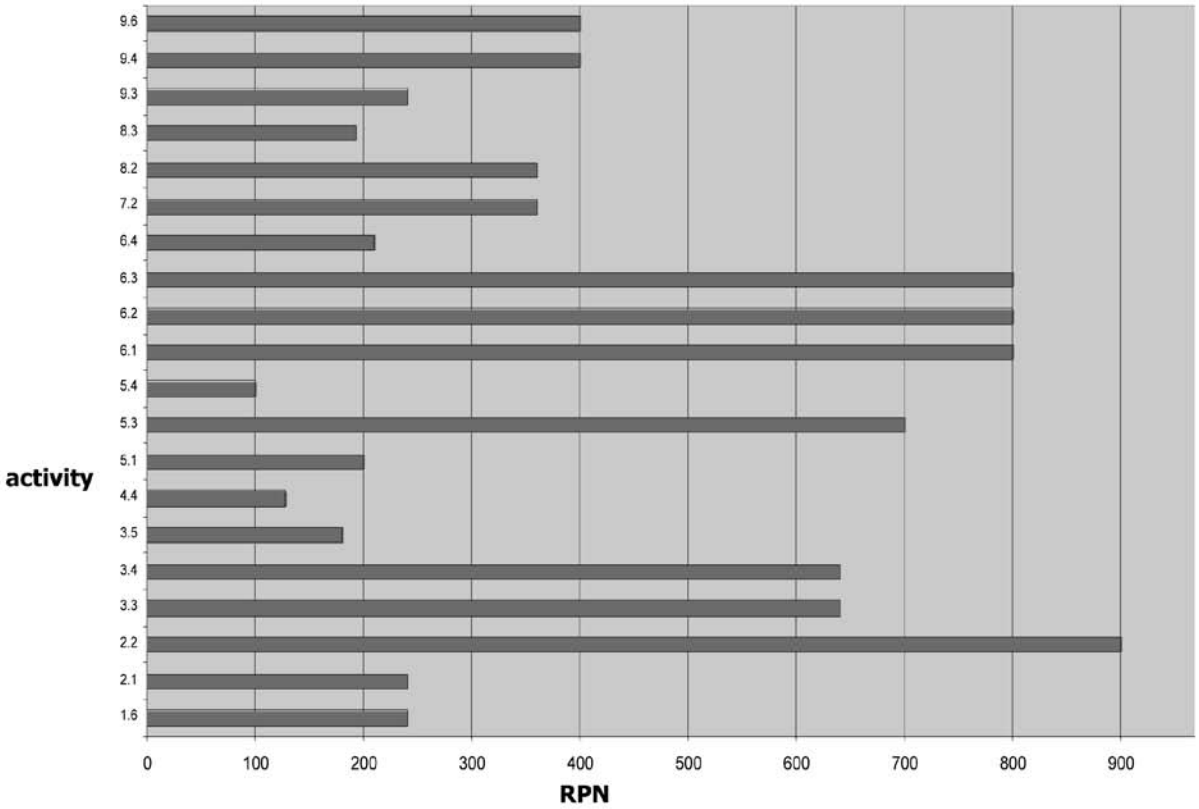
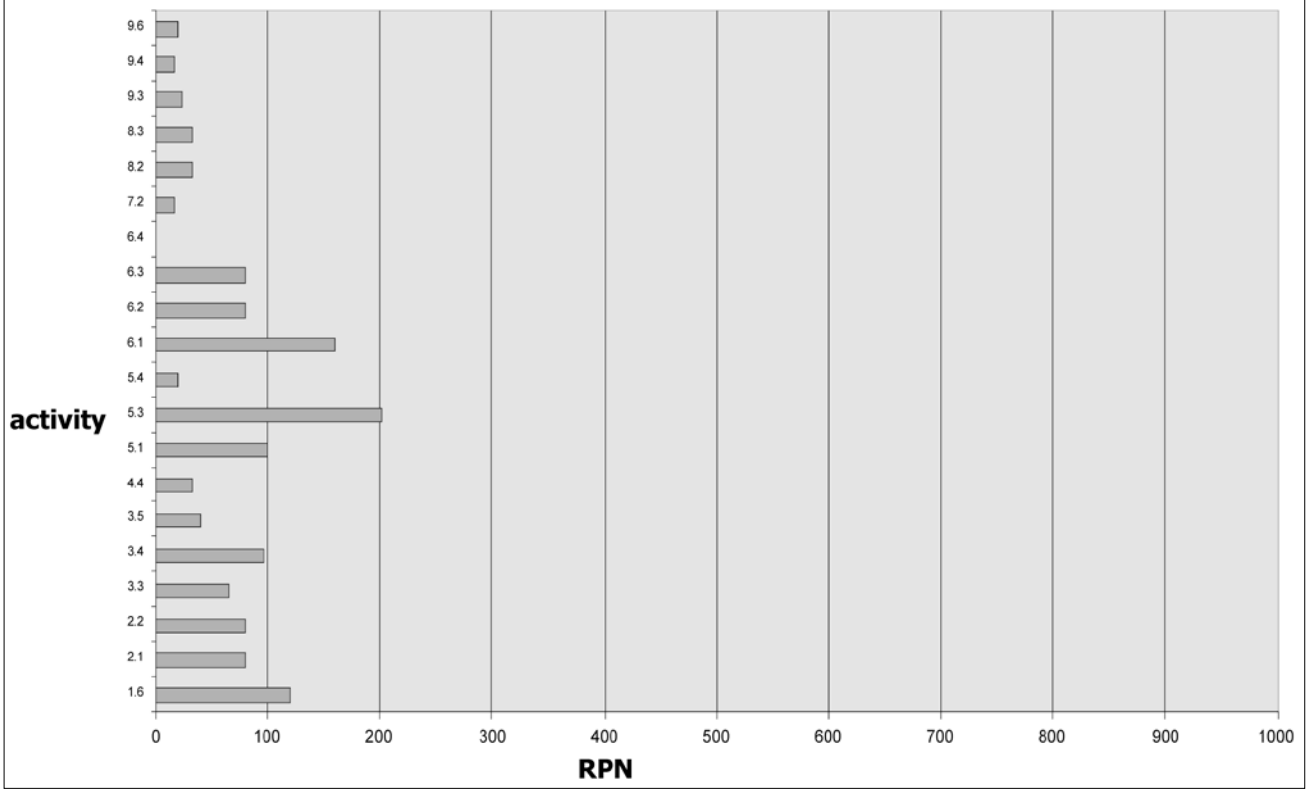


Fig. 2b. RPN for the Blood and Hemo-derived demand and dosing Procedure, after the application of FMECA-FMEA analysis.



Legend to Figures 2a and 2b.
The blood and hemoderivatives supply and dosing procedures were broken down into subprocesses and simple tasks (FMEA-FMECA pro-active analysis): here we show those pathways and processes that required corrective actions to reduce problems within the system and the patients.

Step 1	Data to be included in the buffy-coat request form
1.6	On the buffy-coat request form the medical doctor has to clearly report the degree of urgency. Specifically, it has to be indicated whether the buffy-coat: 1) Is scheduled for a specific date; 2) Has to be available for a period of 48 h during and after the surgical procedure; 3) Is urgent.
step 2	Blood sample collection
2.1	Verify the identy of the patient undergoing the blood sample collection.
2.2	Collect the blood sample during the two hours preceding the scheduled time of the of the buffy coat request.
step 3	On buffy-coat receival
3.3	Fill the form for the assignment of the buffy coat to a given patient, providing all the required information, such as patient and operator ID (identity) and starting time of the procedure.
3.4	The filled form has to be delivered immediately to the blood bank and has to specifically report the starting and ending time of the transfusion.
3.5	At the end of the procedure, the operator has to sign the blood bank register. This represent an additional checking point that allows the identification of the operator, in case of an error occurs.
Step 4	Additional controls to prevent errors in blood transfusion to patients
4.4	Report on the patient's medical record the buffy coat identification code.
Step 5	Blood transfusion unit preparation
5.1	It is enforced not to add solutions or drugs to the buffy coat during the preparation phase.
5.3	Thawing the plasma fraction in water bath at 37°C in order to avoid damage to the transfusion bag.
5.4	Use specific shielded catheters to avoid clot formation.
Step 6	Patient preparation to the transfusion
6.1	Verify the eligibility of the patient for blood transfusion by checking blood pressure and temperature. Assuring that the patient has observed the appropriate fasting regimen before the transfusion.
6.2	Checking blood pressure.
6.3	Checking temperature.
6.4	Assuring that the patient has observed the appropriate fasting regimen before the transfusion.
Step 7	Provide assistance to the patient during transfusion
7.2	Check the patient vital parameters and report them on the medical record.
Step 8	End of the transfusion
8.2	Check the vital parameters of the patients and report them on the medical record.
8.3	Report the ending time of the transfusion.
Step 9	Procedure to adopt in case of variation of the vital parameters during the transfusion
9.3	Collect blood sample from the patient soon after variation of the parameters had occurred.
9.4	Collect urine sample from the patient soon after variation of the parameters had occurred.
9.6	Collect blood, urine and fecal samples a few hours after the adverse reaction, to ascertain the absence of a hemolytic reaction.

Step 9: Definition and application of improvement measures

Improvement measures were identified according to the subprocesses with the highest RPN.

Step 10: Evaluation of intervention effectiveness

After the corrective actions were undertaken, the team recalculated the RPN of the subprocesses and found a decrease in the Criticality Index. For both procedures an "ad hoc" control system was instituted to identify all accidents or near-accidents related to the analysed procedures.

Active control of adverse events

For a complete evaluation of the effectiveness of the corrective actions, the team set up an active control system that involved the entire staff: any health care worker involved in an adverse event is to report it to the administration so that an investigation can be carried out to identify the cause, mode of error and possible changes needed for preventing its recurrence. To ensure complete investigation of an adverse event, the administration implemented a nonpunitive reporting system so that all necessary data can be obtained from the health care worker involved. In this way, all adverse events or

near-miss events arising from an operator's procedural error can be identified.

Results

At present, because of its experimental design, the study results are still preliminary. It was seen, however, that application of the FMEA/FMECA methodology to the existing blood supply and management protocol helped to modify the procedure by adding further control systems to minimize the possibility of a transfusion reaction from incompatbile ABO. As illustrated in Figures 2a and 2b, the difference in the estimated risk index before and after modifications indicated a significant decrease in the likelihood of injury to patients.
Final results await evaluation after continued application of the planned procedures together with application of those analyzed. The Institute involved the entire staff in the active control of identified sentinel events.

Discussion

Application of FMECA to the pathway of patient control by means of constraint tools showed that the methodology was highly specific. The wide differences in the RPN of the same evaluated steps of the procedure between two different rehabilitation departments were related to different approaches and different evaluation by different teams. After receiving specific training and information, nurses and rehabilitation therapists found it easy to calculate the RPN and to accept and carry out the FMECA. The characteristics of the rehabilitation patients were very similar because they are transferred from the orthopedic departments after hip or knee replacement or surgery for bone fracture. There are no comparative studies on FMECA application in different wards of the same hospital or between similar wards of different hospitals.
The application of FMECA to a well-established procedure, such as blood transfusion orders, showed a dramatic effect of changes on high-risk steps as measured by RPN. The methodology could play a specific role in the revision and reinterpretation of clinical practice protocols. It should be underlined that blood transfusion order protocols are regulated by national laws and norms. The possible deviant behaviour of physicians and nurses are minimized. The changes we made to the old pathway introduced some additional controls on steps that significantly decreased the RPN. The use of FMECA should also be considered for evaluating the effectiveness of mandatory procedures to be used in different hospitals or in different health care facilities.

Conclusions

The clinical risk unit of our hospital generated a greater interest of health care workers in risk management, most likely because the reporting system was nonpunitive and because staff were directly involved with the team of experts in applying the FMEA/FMECA methodology. Through staff interest and involvement, valuable epidemiological data on new hazards within the facility have been obtained so that the administration, by central analysis (eg. FMECA), can institute recommended best practices and new pathways for staff to follow in order to monitor progress in the prevention of error and to improve patient safety.

References

[1] Kohn LT, Corrigan JM, Donaldson MS, eds. *To err is human: building a safer health system*. Committee on Quality of Health Care in America, Institute of Medicine. Washington, D.C.: National Academy Press 1999.

[2] Cinotti R. *La Gestione del Rischio nelle Organizzazioni Sanitarie. First edition*. Roma: Il Pensiero Scientifico Editore 2004.

[3] Cineas. *Quando l'errore entra in ospedale. Risk management: perché sbagliando s'impari. Le mappe del rischio, i costi, le soluzioni*. Dossier realized from Cineas and Zurich Consulting 2002.

[4] Leape LL, Lawthwters AG, Brennan TA, Johnson WG. *Preventing medical injury*. QRB Qual Rev Bull 1991;19:144-9.

[5] Ministero della Salute; Commissione Tecnica sul Rischio Clinico (D.M. 5 marzo 2003): Rapporto "*Risk management in sanità. Il problema degli errori* " (marzo 2004).

[6] Spath PL. *Using failure mode and effects anlysis to improve patient safety*. AORN J 2003;78:16-37.

[7] Wilson RM, Runciman WB, Gibberd RW, Harrison BT, Newby L, Hamilton JD. *The Quality in Australian Health Care Study*. Med J Aust 1995;163:458-71.

[8] Rasmussen J, Duncan K, Leplat J. *New technology and human error*. Chichester, England: Wiley 1987.

[9] Reason J. *Human error*. Cambrige University Press 1990.

[10] Reason J. *Human error: models and management*. BMJ 2000;320:768-70.

[11] Reason J, Carthey J, de Leval MR. *Diagnosing "vulnerable system syndrome": an essential prerequisite to effective Risk management*. Qual Health Care 2001;10(Suppl 2):21-5.

[12] Reason J. *Combating omission errors though task analysis and good reminders*. Qual Saf Health Care 2002;11:40-4.

[13] Vincent C, Taylor-Adams S, Chapman EJ, Hewett D, Prior S, Strange P, et al. *How to investigate and analyse clinical incidents: clinical risk unit and association of litigation and risk management protocol*. BMJ 2000;320:777-81.

[14] Leape LL. *Reporting of adverse events*. N Engl J Med 2002;347:1633-8.

[15] Ministero della Salute; Commissione Tecnica sul Rischio Clinico (D.M. 5 marzo 2003). Rapporto "*Risk management in sanità. Il problema degli errori*" (marzo 2004).

[16] Nashef S. *What is a near miss?* Lancet 2003;361:180-1.

[17] Cohen MR, Senders J, Davis NM. *Failure mode and effect analysis: a novel approach to avoiding dangerous medical errors and accidents*. Hosp Pharm 1994;29:319-24.

[18] Di Denia P, Forni C, Rolli M. *La metodologia FMECA: uno strumento di risk management per la riduzione degli errori nelle strutture sanitarie*. Rischio Sanità 2003;8:23-7.

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