Patient safety: the experience of an Italian teaching hospital

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Abstract

Introduction

The risk management project of The University Hospital "A. Gemelli" aims to define the necessary procedures to manage clinical risk, by identifying the structures involved within this process, so that all of the personnel can contribute to a measurable improvement in the safety of both patients and staff.

Methods

The Risk Management Program is comprised of 5 long-term phases:

Phase 1 - Strategy Definition and Communication: a clear and shared Risk Management Strategy is indispensable to guarantee a coordinated action plan, in order to focus all of the interventions towards the achievement of common and measurable results.

Phase 2 - Risk Management System Governance: all of the organisational structures have been activated in order to effectively manage the Risk Management System. The system has been introduced to interact within all areas of the hospital and to transfer information.

Phase 3 - Promotion within the Organisation: this phase fosters the aims of the project within the whole organisation, by stressing the concept of "learning from errors". This is crucial if organisational and healthcare workers are to understand the true aims of risk prevention and protection and offer to contribute to the process.

Phase 4 - Risk Assessment: a data survey system was created and institutionalized. This phase begins with an analysis of the information flow, in order to estimate the probabilities that certain risks occur, and ends with defining the interventions to undertake. Risk assessment makes it possible to forecast the consequences of certain risks and thus prioritise those for prevention.

Phase 5 - Risk Management: this consists of planning and implementing all of the actions necessary to prevent risks, protect and finance (in terms of prevention) A. Gemelli University Hospital.

Results

The results achieved are remarkable especially when one considers the organisation of a complex clinical risk management system within a large university hospital. An information flow that examines and identifies risks from surveying the data has been created. Preventative activities have been planned in the laboratories, transfusion and pharmacotherapy sectors as outlined in the risk map, together with clinical audit activities. Furthermore, all of these issues have been highlighted across all sectors with the creation of an accredited ECM training program as well as the implementation of an anonymous survey. These initiatives have not only increased the interest in Risk Management issues, but have also fostered the integration of different groups and their working methods.

Conclusions

Introducing risk management processes to A. Gemelli University Hospital represents a step from the promotion and dissemination phase to that of a formal organic risk management system in medicine. This initiative, involving the participation of all personnel, has produced a measurable improvement in safety of both patients and staff.

Key words: risk management, clinical risk, survey system, safety

Introduction

At present in Italy, issues such as patient safety and clinical risk management are strongly debated. Risk management is considered to be a valid tool to improve quality and to prevent the consequences of adverse events. An adverse event is one which occurs at a certain point in time and causes injury.

Clinical risk can be defined as the probability that a patient may be the subject of an adverse event caused by a medical treatment(s) during

his/her stay in hospital, that has lead to harm, even if unintentional. These treatments may lead to an extended hospital stay, worsening of health conditions or some cases death.

Clinical governance policies aim to continuously improve healthcare safety by examining and redesigning activities and processes in order to make them less prone to errors. This involves both cultural and technical change. Creating such a culture of safety also involves redesigning working conditions and interactions between healthcare workers.

New risk management policies are becoming increasingly imperative, as a large number of errors lead to an increase in mortality and morbidity, higher healthcare costs, a decrease in patient satisfaction and an increase in cases seeking compensation.

Understanding how to better directly manage one's own risks is possible by introducing methodologies which:

- analyse the internal resources, both professional and organizational;
- identify risks which can be directly managed;
- identify preventative actions;
- identify risks which should be directly managed by insurance companies;
- identify the most effective procedures to manage adverse events that have occurred within the organization

A risk management program has been created at A. Gemelli University Hospital. Its objectives are: to draw up a risk map, to design a safety plan for healthcare procedures, to facilitate communication between healthcare workers, to disseminate information and discussions on errors and incidents, to choose an information collection system for sentinel events, to perform corrective actions and to prevent medical litigation and insurance actuarial risk, and finally inform the writing up of an annual report on risk management improvement.

A. Gemelli University Hospital's Risk Management Program is based on the principles of gradual introduction of methodologies, promotion of a risk culture and the creation of competencies within the organization.

Methods

The Risk Management Program is comprised of five phases:

- Phase 1: Strategy Definition and Communication
- Phase 2: Constitution of Risk Management System Governance
- Phase 3: Promotion within the Organisation
- Phase 4: Risk Assessment
- Phase 5: Risk Management

Phase 1: Strategy Definition and Communication

A clear and shared risk management strategy, which is imperative to guarantee a coordinated action plan, has been designed after contemplating the complete project in its entirety, its formal approval by the University Hospital High Directorate, the draft of a formal document to progressively record risk management actions and the communication within the organization of the actions performed as well as the results achieved.

Phase 2: Risk Management System Governance

In this phase all the necessary organizational units were initiated in order to successfully manage the Risk Management System. An effective risk management process starts with the clear definition of duties and responsibilities of the professionals involved. This resulted in the formation of a Risk Management Committee and a more restricted Risk Management Board.

Phase 3: Promotion within the organization

This phase fosters the project's aims within the hospital, particularly the concept of "learning from errors". Without promoting the project at this stage the organisation and workers may have misunderstood the objectives of the project in terms of prevention and protection and in turn may not have offered their indispensable collaboration.

This phase consisted of two main activities:

a) An ECM Course "*Errors in Medicine*". This course, held between September 2004 and January 2005, provided guidelines for preventing medication errors, by focusing in particular on principles such as "total quality management" and by promoting a culture which considers errors not as failures, but as opportunities to improve the healthcare system.

b) An anonymous questionnaire on errors in medicine. This intranet based questionnaire tested the healthcare professionals' knowledge of medication errors at A. Gemelli University Hospital. Its focus was to explore not only the degree of awareness regarding this issue, but also to gather opinions on the causes of errors and on effective measures that could be taken to prevent and manage them, including the psychological impact on the individuals who had experienced them. This initiative had a dual scope: firstly, to highlight the cultural background of this subject, which maybe different for each operator, secondly to inform the design of ad-hoc training programs.

Phase 4: Risk Assessment

A specific process for information flow was designed to gather all of the useful information required to identify risks. The main task was to merge, in one database, all of the information that was available in the different areas. Homogenous data collection was crucial to keep the data current as well as to ensure the comparability of the data. Unique reference times were used, years 2002, 2003 and 2004 (Figure 1).

The available data were progressively integrated to increase the precision of risk identification.

The information flow forms the basis for the ongoing assessment of the probability and consequences of certain risks. While risk assessment implies the identification of the economic impacts and the probabilities that certain risks will emerge.

The main task is to do a quantitative risk assessment, using statistic techniques to evaluate the distribution of the losses caused by certain incidents.

This process provides two important types of information:

1)the expected value of the losses, which allows for the determination of the effective cost of the insurance policies adopted;

2)the value of potential losses, particularly in those cases where adverse events have occurred. This allows the organisation to understand if it can face the risks within its own resources (self insurance), as well as to identify the necessary maximum rate of insurance coverage. From this it is possible to identify contracts which the organisation can provide directly and to save money in terms of insurance payouts.

The statistic analysis consists of calculating the distribution of:

- the frequency of accidents;
- the seriousness of accidents;
- the potential annual losses.

The qualitative technique, which is essentially employed in pure risk screening activities, refers to a successive quantitative assessment of more serious risks.

Qualitative assessment is made in brainstorming sessions or by filling out a form.

This technique includes:

1)a scale of probabilities that an adverse event can occur;

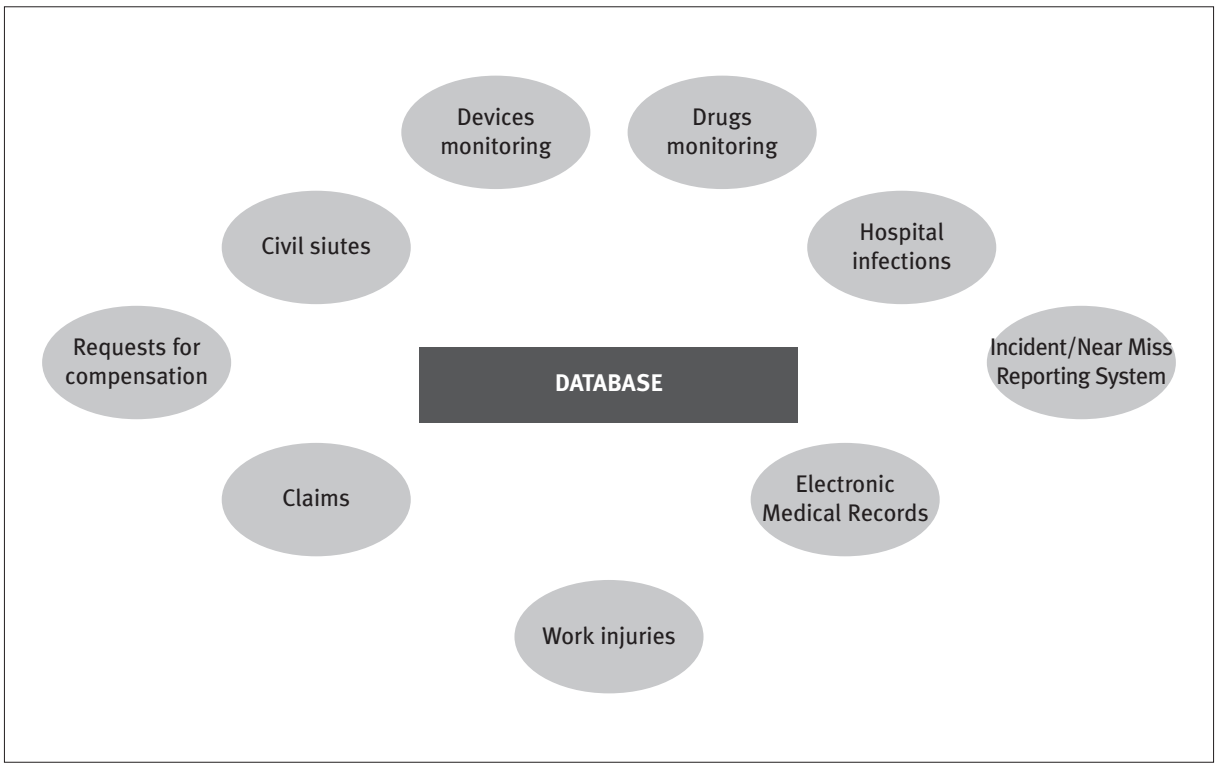
2)a scale of economic consequences of an adverse event;

3)a scale of estimations of each combination of possible economic impact (risk rating);

4)an indication of the behaviour to assume with respect to each single risk rating.

Australian risk management standards, which have been adopted as international standards, involve five classes of probabilities, five classes of impacts and four classes of risk ratings.

Figure 1. Data gathered in the Risk Assessment Database



Risk assessment can forecast the possible consequences of the risks identified and therefore highlight the most urgent risks as well as the necessary interventions.

In the A. Gemelli University Hospital's Risk Management Project, assessment is the Risk Management Board's main activity. The risk assessment phase ends with the definition of interventions to be made, the actions to continue in order to identify risks and finally the activities to perform in order to monitor the whole risk management process.

Finally, the results achieved are then formalized and disseminated. One way that this has been achieved has been through the production of a risk management manual that shows the data collected, the evaluation performed and the final assessment.

The manual also contains the Risk Management Program's strategic guidelines and the actions which will be undertaken.

Phase 5: Risk Management

To manage risks means to take decisions aimed at improving the risk profile of a healthcare organization. More precisely, risk management consists of planning and implementing all those actions which can prevent, finance and protect an organisation from risks.

The risk management phase strongly affects healthcare activities, but it is not limited to them: risk management involves all risks which can emerge within an organization.

By classifying risk management methods one can help to identify the necessary actions required.

Management interventions which affect the healthcare organization's risk profile:

A. Gemelli University Hospital's Risk Management Program includes several interventions, both general and specific for each area. The following areas of priority have been identified:

- Informed Consent;
- Clinical Records Quality;
- Blood Transfusion Risk;
- Risk in Diagnostic Areas;
- Pharmacological Risk;
- Complaint Management;
- Alarming Events Audit.

Results and Discussion

Phase 2, Risk Management System Governance, produced excellent results, by guaranteeing cooperation between the hospital's units and by operatively supporting the project activities.

On the other hand, Phase 3, Promotion within the Organization, demonstrated poor feedback from healthcare workers who were requested to fill in the questionaire, however this may be due to other more pressing issues at that time, rather than a lack of interest in the subject.

Dissemination processes included internal communication activities such as:

1)the establishment of a bulletin, that includes all of the information related to A.Gemelli University Hospital's risk management activities;
2)a dedicated intranet area for risk management, which contains circulars, results, activities performed and other useful information on medical risk management.

In Phase 4, Risk Assessment, data collection was completed. The data proved to be both significant and heterogeneous enough to enable the hospital's main risks to be outlined. At present the *Health Technology Assessment Unit* (the *Health Technology Assessment Unit - HTA-U* - has been established in 2001 within A. Gemelli's University Hospital Medical Directorate with the special scope to introduce Health Technology Assessment methodologies to the hospital's management processes) is focusing on the design of a database which will contain all of the data collected and automatically carry out the next process of analysis.

As outline in the projects plan, based on the positive results obtained, the possibility to empower the database with an Incident/Near Miss Reporting System in particular high risk areas should be considered.

The Incident Reporting System is meant to collect anonymous event notices (incidents and near misses) from the health care workers. This allows for those events that fortuitously have not caused any injuries or claims to be identified. Limitations include the level of participation by healthcare workers.

Their collaboration is crucial, as corrective actions cannot be undertaken if the information is not disclosed. Another aspect is the public utility of the data collected: the outcomes of the notices collected and the disciplinary actions undertaken must be communicated. This contributes to the creation of an atmosphere of trust within the system and encourages participation.

The incident/near miss reporting systems are based on a communication form, based on templates from international experience. It includes the following headings: place and time, description of the event, classification and evaluation of the event.

Phase 5, Risk Management, achieved valuable results in terms of prevention and protection from risks, particularly in the areas more prone to

Figure 2. Quality in Use of Consent

Nosographic			
Type of consent (blood transfusion, surgery, etc...)			
	Present	Absent	Notes
Patient's name and surname			
Description (or diagnosis) of the disease			
Short description of the therapy			
Improvements expected			
Most relevant and frequent complications			
Most frequent and invalidant sequela			
Patient's clear signature			
Signature of eventual witnesses			
Time, date and signature of the clinician informing the patient			
Module approval from the CE			
Date of compilation	Responsible for the compilation		

medical litigation. Within this phase two interventions on Clinical Records Quality and Informed Consent management emerged as crucial. The first analysis of a group of clinical records highlighted the following necessary improvements:

1) to implement uniform Informed Consent standards according to precise guidelines and modes of dissemination (Figure 2);
2) to establish formal modes to approve the standards;
3) to include regular activities to monitor the standards' use.

This phase demonstrated not only good clinical record management, in terms of entering administrative data, information on the diagnosis of the patient and of the course of the disease, but it also emphasized the necessity for the clear identification of the editor of the clinical record.

With respect to clinical risk management, three workgroups were formed in September in order to analyse the processes and plan preventative actions in three clinical risk areas: blood transfusions, laboratories and pharmacotherapies.

The workgroups' objectives are:

a) to draw up a document containing
   - a description of the processes and sub-processes of their activities;
   - the identification of potential weaknesses and possible areas of risk (risk identification);
   - risk prioritization;
   - proposals for interventions to prevent errors on the basis of the identified priorities;
   - proposals for methods to detect errors such as indicators, data sources, detection responsibilities and reporting systems.
b) to disseminate all available data on the errors detected within the areas analysed.

In the course of the risk assessment and risk management activities, particular events have emerged whose seriousness justifies the decision to include an Alarming Events Audit in the 2005 project. The occurrence of serious events makes it possible to investigate their causes and then carry out effective actions to avoid their repetition.

The audit process will be structured as follows:

- the event is made anonymously: all details which can help identify the people involved, are deleted;
- the event is analysed and discussed by external professionals;
- conclusions are compared with practice in order to identify other similar events;
- solutions to avoid the repetition of such an event are proposed;
- solutions are presented to and discussed by the Risk Management Unit.

At present 4 experimental audits have been planned, these are emergency surgery management, drug error, newborn exchange and blood transfusion error.

The long standing process of improving quality of healthcare services at A. Gemelli University Hospital is based on the following principles:

- to take care of patients, by respecting their dignity, their needs, their sufferings and their hopes;
- to offer excellent services and performance in terms of effectiveness, appropriateness, equity, safety, timeliness, efficiency and accessibility;
- to foster innovation and guarantee transparent professional behaviour, by sharing both general and specific objectives and by overcoming sectional interests in order to continuously improve the organization;
- to stimulate continuous learning and professional training, both scientific and technical;
- to ensure wide dissemination of the information, the knowledge of strategic and operational objectives, the results achieved and the experiences gained;

- to foster involvement, collaboration, multidisciplinary activities, team-working, and shared responsibility;
- to recognize and highlight everyone's efforts;
- to turn intentions and values into actions, with the crucial support of the Medical Directorate and the active participation of all professionals.

The risk management project continues this process of quality improvement.

In conclusion, the application of a Risk Management System within a hospital has the following advantages:

- improving the quality of care by reducing healthcare risks and by guaranteeing patient safety;
- protecting healthcare professionals from charges of malpractice and reducing cases of litigation;
- improving the organization's image.

The process of improvement requires the continuous study of clinical risks as well as the identification of systems which can identify, avoid and reduce errors, in order to continuously improve patient safety.