How to simplify and improve incident and near miss reporting in wards: I.R.G.E. (Incident Reporting with Gravity Effect) system

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Abstract

In this paper, an improved system that allows a simplified reporting of errors and near misses in wards, and permits operators to accurately manage all data recorded, is presented. IRGE (Incident Reporting with Gravity Effect) System is based on the use of a paper form for reporting accidents and near misses. The severity of an error can be evidenced through the choice of a color similar to the well-known method used in the emergency medicine triage, thus leading to the most evident and immediate understanding of the magnitude of error. In addition, the system is provided with a report form for its users to be compiled with the highest completeness of information.

A dedicated software for the storage of records and data analysis has been created, which gives one the possibility of alerting key figures within the health facility promptly. The system allows us to store and share records among different care units and also among different hospitals, thus providing a basis for a national database. Moreover, through this system, it is possible to assess the "risk attitude" of the health facility monitored.

Key words: error, near miss, incident reporting system, risk management

Introduction

Any health organization needs instruments for monitoring risk management in order to ensure an adequate quality of the services it provides [1].

At the basis of any "definitive" approach to manage and eliminate errors in wards, there should always be a system of analysis and verification of the healthcare activity delivered. Thus, a key role is played by the activation of an "Incident Reporting" method within any health facility, that can highlight the most critical areas where managerial interventions are requested. Risk management, however, is costly and aims to guarantee an adequate economic investment. The knowledge and planning of interventions must be supported by real data.

Analysis of adverse events and near misses occurring in various hospital wards permits one to select the most appropriate intervention for preventing the occurrence of an error [2].

The Incident Reporting method can: (i) identify health processes at greater risk, (ii) check possible errors and their consequences in these processes, (iii) evaluate and define priorities for action on the basis on known events such as accidents, adverse drug reactions, infections, surgical errors, etc., and (iv) develop, on the basis of preventive self-evaluation of the risk potential, estimates of future risk and of its economic value, as well as help identify action plans in response to the risk [3].

This method was created, as almost all systems used to prevent errors, in the engineering industry, where many different *modus operandi* of reporting faults in processes or checking malfunctions of existing products [2,4,5].

The first incident reporting system was developed in 1971by ECRI Institute (USA), with the "International medical device reporting system" [6], though the one that proved to be most effective was developed by the Australian Patient Safety Foundation (APSF) in 1990. The

"Australian Incident Monitoring Study" (AIMS) made possible the storage and evaluation of all reported incidents in wards [7]. The system is based on the voluntary reporting of operators, using an appositely prepared form, with fixed and different items for different kinds of ward. Alerts are managed with a software that allows the storing of data, the build-up of statistics and which highlights anomalies on the basis of frequency, type and structure of incidents.

Over time, Incident Reporting has proved to be a useful method in the integrated management of clinical risk, and various health organizations have developed different kinds of systems, all based on similar assumptions. In fact, all of them use a report form, based on fixed items [8] to be answered or completely open text. In each case, the need not to blame the author [9] of error (the compiler of these forms) is always emphasized, as is the need to process all data by a software [3,10].

The aim of an Incident Reporting system is, through the entries therein, to record all adverse events and near misses that have or could have caused an error, thus obtaining reports that may be helpful to address which actions should be taken to correct these errors and assess their results.

Finally, over time the database becomes more complete, giving, then, an up-to-date series of information relative to best practices [10] which allow one to avoid errors in wards.

The project

In 2007, we performed a postal survey among hospitals in Campania region and found that 75% of them did not have a Clinical Risk Management unit, 59% did not have procedures to store information about errors and 77% of them any kind of mechanism for reporting "near misses" [11].

Following these results, we evidenced the need to create an information tool, simple and intuitive, that could facilitate the implementation of a protocol for reporting incidents and near misses, and could take into account the indications of the World Health Organization [9], that recommends the distribution of such tools if these could be used to identify problems, analyze their causes, plan and implement solutions and fully assess their effects.

Thus, we ideated a new procedure, called the IRGE (Incident Reporting with Gravity Effect) system, based on a paper form, for reporting incidents and near misses, and a dedicated software, to archive data from these paper forms and to perform data analysis, with the potential to alert system managers and to assess propensity to risk of the healthcare units [12].

The system is completed by a second paper form for patients and/or family members where they can report any failure or deficiency in the healthcare assistance received.

Reporting form: the event and the patient's advice

The paper form is based on three sections (Figure 1).

A section devoted to the description of the incident or near miss with an indication of the place and time in which it happened. A section indicating the severity of the consequences. A section devoted to the description of what has been done to correct the mistake or to prevent the near miss becoming an adverse event.

The section devoted to the description of the event is an open text, so the reporter can describe, with as much detail as possible, the type of event and the place where it occurred.

The second section allows one to report the severity of the error by choosing a value in a default list. We chose four degrees of severity only, like those represented by the well-known colors used in the emergency medicine triage [13]: white (bianco), green (verde), yellow (giallo) and red (rosso). White corresponds to "No effect on health", green to "Transient disorder that did not involve a longer hospital stay", yellow to "Deterioration of health status with lengthening the period in hospital and need for additional therapeutic interventions", and red to "serious and/or permanent damage to health or death".

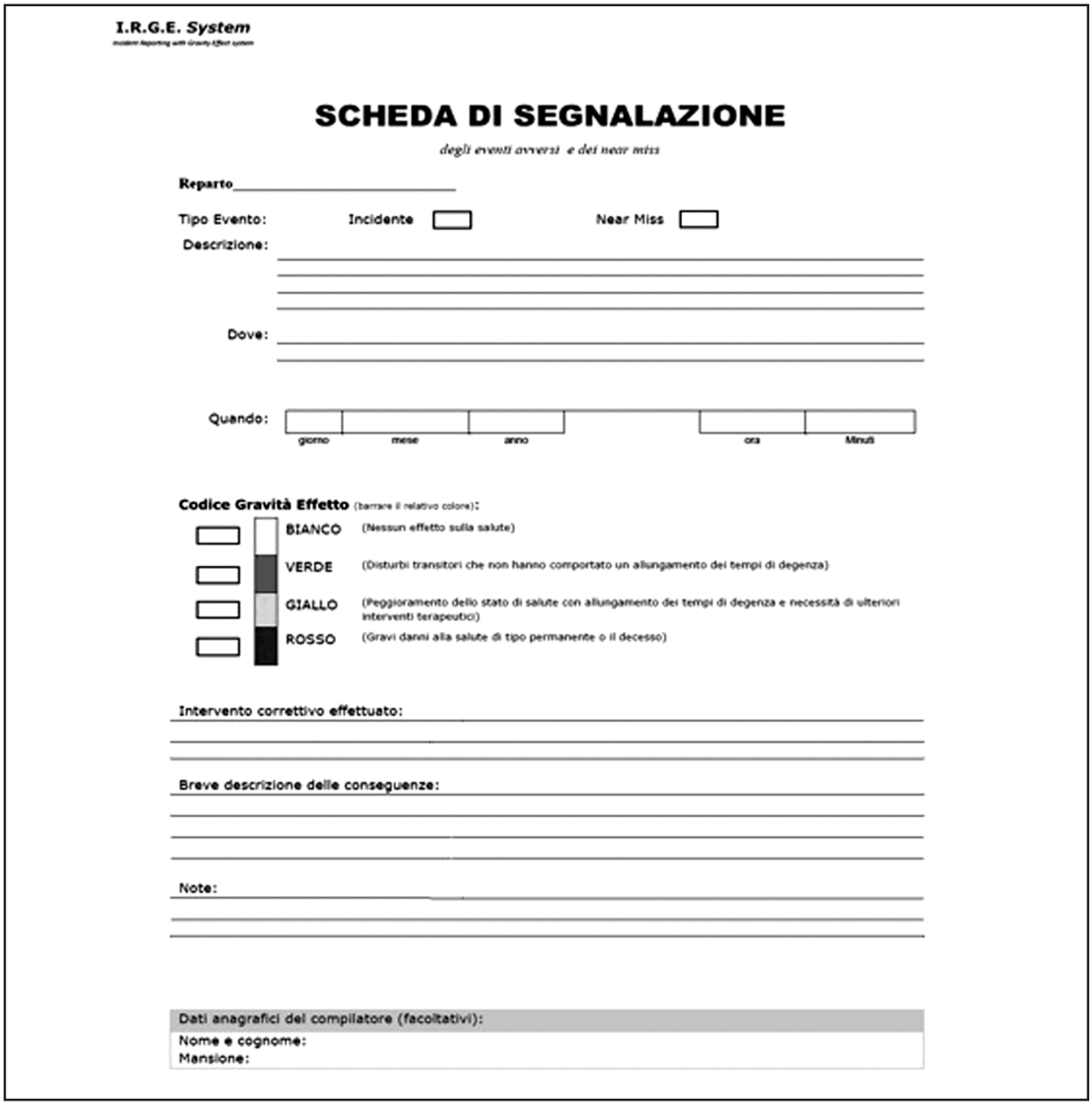
The choice of the color scale as an index of gravity was motivated by the fact that the paper form, as soon as it is delivered to the Risk Management unit, may be quickly understood and allows the selection of priorities for recording and consequential actions, like in emergency units where a patient is assigned a triage code.

The third section allows one to record what action was undertaken to mitigate the effect of the error, or what has been performed to "intercept" it before it could cause damage: hence one can derive ideas for organizational or structural interventions to prevent the same type of error from recurring. In this section, there is also the possibility to describe, in a subjective way, health consequences of that mistake.

The paper form can be completed, on a voluntary basis, with a signature [9] (see the last section in Figure 1).

The system also includes a paper form designed to record alerts by patients and/or family members (Figure 2). In fact, from their reports, one can become aware of deficiencies and problems not taken into account by operators. These reports,

Figure 1. IRGE form.



I.R.G.E. System

SCHEDA DI SEGNALAZIONE

degli eventi avversi e dei near miss

Reparto_____

Tipo Evento: Incidente ☐ Near Miss ☐

Descrizione:

Dove:

Quando: giorno | mese | anno | ora | Minuti

Codice Gravità Effetto (barrare il relativo colore):

BIANCO (Nessun effetto sulla salute)

VERDE (Disturbi transitori che non hanno comportato un allungamento dei tempi di degenza)

GIALLO (Peggioramento dello stato di salute con allungamento dei tempi di degenza e necessità di ulteriori interventi terapeutici)

ROSSO (Gravi danni alla salute di tipo permanente o il decesso)

Intervento correttivo effettuato:

Breve descrizione delle conseguenze:

Note:

Dati anagrafici del compilatore (facoltativi):

Nome e cognome:

Mansione:

however, have to be carefully considered since, in most cases, they are motivated by "subjective" perceptions of health care received.

Software IRGE

I.R.G.E. is an information system that supports and facilitates the activities of Incident Reporting. The system is able to collect all data records in a centralized database storing electronic versions of the paper form [14].

Potentially I.R.G.E. is able to host reports from any number of hospitals and/or departments of the same hospital. The goal is to obtain a database of reported near misses and incidents that is as wide as possible (single institution, area/region, nation) in order to determine a quantitative measure of the quality of healthcare at any time.

One of the advantages of using an Incident Reporting system is its ability to assess the efficiency and effectiveness of preventive and/or corrective actions adopted to cope with an upsurge in a specific type of report. In general, given a certain action, the frequency of monitored events of a specific type should decrease, giving a signal of the effectiveness of corrective measures taken.

Moreover, the importance of the collected data to support the management activities and decisions has to be underlined as a useful tool when addressing the issue of available safety budget.

I.R.G.E. system provides several analysis tools to extract statistics from the data with different levels of detail. For example, specific statistics

Figure 2. Patient form.


I.R.G.E. System

SCHEDA DI SEGNALAZIONE

Gentile utente,

nell'ottica di migliorare le prestazioni del servizio sanitario offerte, ti invitiamo a segnalarci, attraverso la compilazione della presente scheda, le disfunzioni che a tuo avviso si sono verificate durante il tuo ricovero.

Descrizione:

Dove:

Quando: giorno mese anno ora minuti

Quale disagio hai dovuto subire?

Commenti aggiuntivi:

for a certain hospital or group of hospitals for a specific period of time (week, month or year) can be extracted.

The heart of the whole system is represented by a search tool that allows the operator to extract/filter information from the system and then apply analysis tools.

From a technical standpoint, particular attention has been devoted to the aspects of interoperability, or the system's ability to communicate, share information and work with other information systems. At any time, all data or part of them can be exported in formats like PDF, Excel, plain text, xml and others. This feature allows users to analyze the same data with other external software. In any case, it is always possible to export the results offered by the system by designing an appropriate web service.

System access

I.R.G.E. system is accessible via browser from any computer connected to the Internet. Obviously, only authorized users can use the software services and, for this reason, each user has a personal account consisting of username / password to be entered in the first login page [15] (Figure 3).

The system has an access control function. In brief, as the system is able to collect data from many hospitals and/or many departments, each user, based on permissions provided, can access a limited subset of all information stored in the system on the basis of permits to him/her provided [16,17].

When a user makes a successful access, the system recognizes the user's role/permission and shows only the appropriate information and services. For example, a generic user has access only to information of a specific ward, while the hospital manager may have access to all records related to the hospital under his/her control (Figure 4). I.R.G.E. system administrator has access to all configuration parameters for the maintenance of the server hosting the web application.

Report input data in the system

The report form is equivalent to the electronic paper form, so the information is exactly the same, with the particularity that the electronic version introduces a syntax check of the information

Figure 3. Login page.

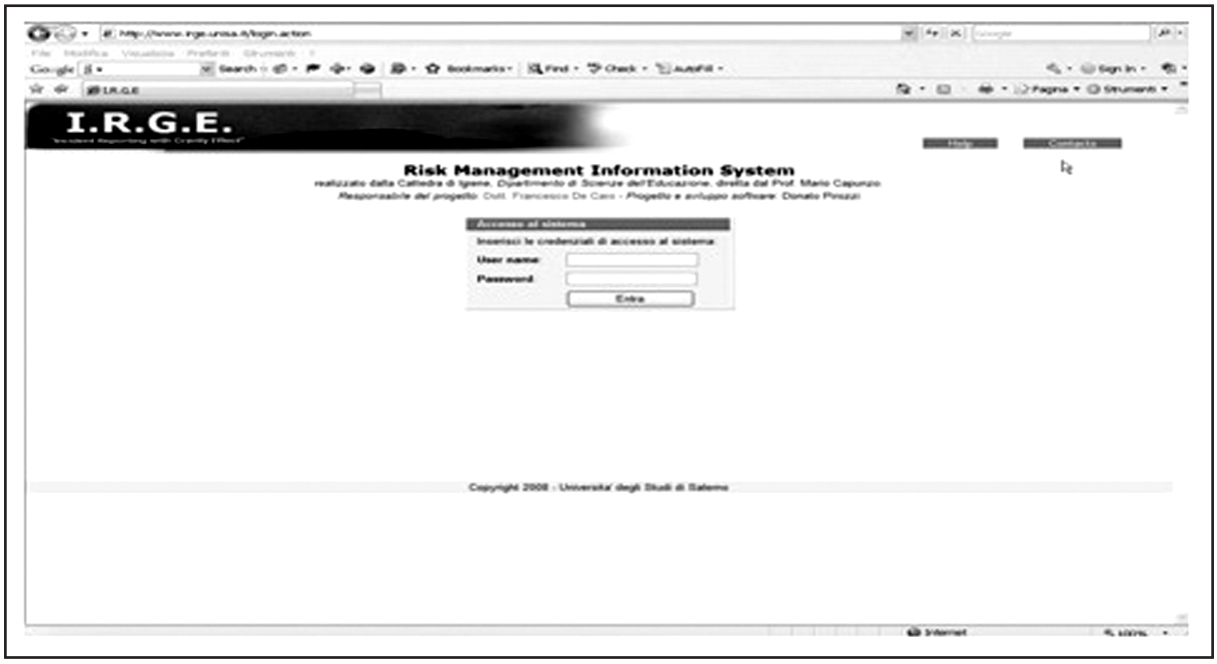
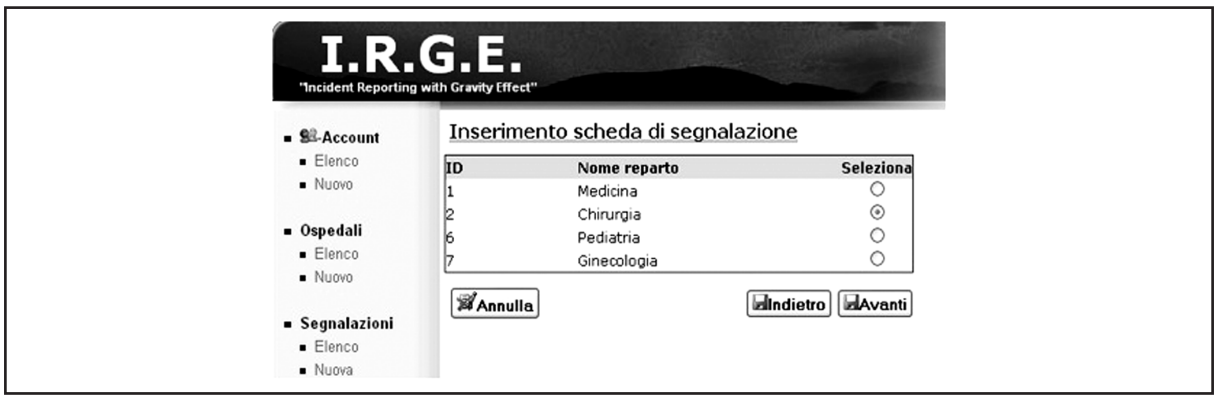


Figure 4. Ward selection page.



and has some functions to facilitate and foster the integration of data (Figures 5 and 6). For instance, for the selection of the date, a calendar is available, or as one fills in the field "when," the recommended choices are automatically shown, taken from data previously recorded in the system.

Tools

Reasonably, the system provides a list of the most recent ten to twenty uploaded reports, to provide explicit feedback on the latest data added. Obviously, the amount of system information stored in the system is large, so it is necessary to have a tool that allows to filter data and obtain only the information of interest.

It is possible to filter data in relation to a specific period of time, for example from a starting to an ending date, so all reports of one or more months, or a whole year, can be selected.

The system also allows to group data by type of event, severity and ward. Moreover, search tool allows the operator to insert a specific "key word" description, and obtain all records containing that keyword, like in the most common search engines. Obviously, all search parameters can be combined to obtain a more accurate filtering (Figure 7).

Clearly, the search tool takes into account only reports which the user is allowed to access. Should the user have access only to the records of Department X, the search filter will only apply to data from Department X.

- ***Query tool.*** Once the search filter is set, I.R.G.E. shows all records that meet the search parameters.
- ***Analysis tool.*** The operator may decide to export the data into another format, and use different tools to perform statistical analysis. The formats supported are PDF, Excel, plain text, HTML and XML. In a second step, the system can gather and manipulate the extracted data and allow one to create several types of

Figure 5. Event/Near miss page section 1.

Figure 6. Event/Near miss page section 2.

Figure 7. An example of research tool use.

graphs: histogram, pie, bar chart, and so on.

- ***Alert functions.*** An Alert function can notify hospital and/or safety managers when the number of alerts for a given degree of severity reaches a certain level of attention, thus requiring a corrective action to be undertaken. Different warning mechanisms can be activated. The Basic alert mechanism is called Simple Alarm Threshold. In practice, for each color and for each severity level, the system calculates the number of events determining alerts. In Figure 8 an example of that is shown, where for near miss recordings, there are two reports of yellow severity and a red alert. The mechanism is activated when the number of reports of at least one color exceeds the threshold. The activation of the alarm is immediately visible in the system, as there is a continuously flashing warning sign indicating the type of alert. Linked to the alarm is also relevant information taken directly from the reports, that provides an immediate view of the problem. In addition, alarm information is sent via both email and SMS to the decision makers. Initially, managers may ignore the alarm,

Figure 8. Threshold alert configuration example.

Configurazione Alert Based on Threshold: Near Miss

Colore gravità:	bianco	verde	giallo	rosso
Valore attuale:	2	1	2	1
Data ultimo allarme:				
Low Threshold:	20	15	7	4
High Threshold:	25	18	9	5

but they are asked to provide and record a brief justification of why the alarm was not taken into account. In fact, there is a second threshold, higher than the previous one, after which the system "hangs up" in the sense that the managers can no more use the software until he/she provides a description of the corrective action taken to "turn off" the alarm. All transactions made in the system, are continuously recorded, together with date and time of each alarm with its related information, manager's actions, corrective action undertaken, and additional data that can be analyzed later. For each color, the administrator can configure both thresholds, taking into account that the first threshold (low threshold) is lower than the second one (high threshold). The mechanism of Simple Threshold Alarm is based solely on the number of detection of any color code and, in fact, every report is different from the standpoint of content, so one should be aware that an alert can be repeated several times. Basically, an evolution of this function will be the introduction of alarms based on the analysis of content of reports, such as description, location, etc.

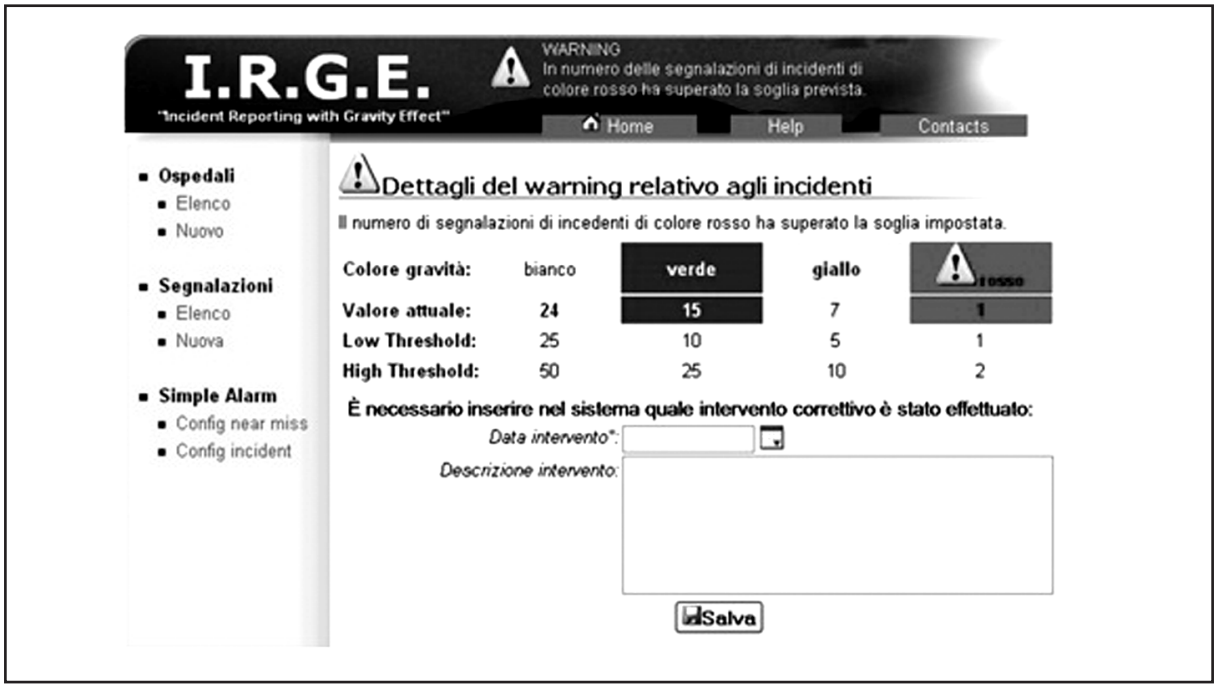
- ***System security.*** All information stored in the system and all data traveling from/to the server, are critical and sensitive. In all systems connected to a network, information exchanged between the user and the centralized system can be intercepted by someone else. To avoid this, the basic idea is to adopt all possible safety techniques widely known and used in other business domains, such as banking websites. Technically, all exchanged information can be encrypted. At each stage of the session, the user can view in their status bar, an icon of a padlock, indicating a secure connection. Moreover, all information stored in the central system can be encrypted, making it incomprehensible, so that in the presence of attacks, any snatched information will be unusable.

Operating mode

I.R.G.E. system is an information system aimed at understanding the errors and near misses that occur in practice and clinical care in order to optimize remedial measures and, therefore, must necessarily be shared by all operators working in the healthcare facility monitored.

1) The first phase is devoted to specific training of all personnel on the purpose and procedures of the system so that they can learn how to use it properly: at this stage, it should be emphasized to everyone that the system aims to improve the health organization, and personnel assured that recordings will never be used for punitive or discriminatory actions. A predetermined number of sheets (5-10) is given to each operator, with the recommendation to compile them for any adverse event or error which he/she becomes aware of, stressing the need not to subscribe to the alert (protection of anonymity).
2) In the health facility, a special mailbox is placed, wherein to insert an anonymous paper form completed.
3) The Medical Director is responsible for the local management system and receives a user account (username and password) (figure 3) to access the IRGE software with the role of Local Administrator of the system. It is evident that the Medical Director may delegate this role to an employee for the management of the system.
4) The Local Administrator daily collects the paper forms and transfers data to the software. At this stage, by the simple observation of the color chosen to signal the seriousness of the error, corrective actions could be undertaken to mitigate the effect of the error and avoid it in future.
5) At this stage it is possible to proceed in the following ways:
   a. The Administrator analyzes data using the different options provided by software: severity, type, department, etc., and, if deemed necessary, starts the corrective procedures.
   b. The number of events reaches the alarm threshold prescribed for each type and the software alerts the administrator through

Figure 9. Alarm and corrective action page.



the means configured (email, sms). Thus, the system manager is immediately made aware of the number of occurring events and that corrective action, for which the software has a section, is required (Figure 9). As described before, reports in the software generate a database, accessible to the Local Administration but also, at higher-level, to Administrators having responsibility for different hospital structures and who thus manage a wider numbers of events.

Future developments

We believe that more advanced techniques could be applied to data reports, especially data mining algorithms to extract new knowledge from these reports. For example, it is reasonable to think that there are relationships between different alerts, dependant on a "cause and effect" relationship. So, we could design an analysis tool supporting root cause analysis [2].

Simply, many near misses coded green or yellow, are alerts for possible future accidents. We believe that a correct analysis of data collected through the report forms could be used to formulate appropriate corrective and preventive action.

Results of one year application of the system

IRGE system was implemented in one pilot project lasting one year, between 2008 and 2009, at one hospital, hosting 700 beds, located in Abruzzo (Italy). Four operating units, namely 1- Anesthesia (including operating room, day-surgery, sterilizing room), 2-Clinical pathology, 3-Ophtalmology, 4- Infectious Disease unit, used IRGE system to report errors and near misses. The Medical manager was the Local Administrator of the process, who daily collected the paper forms and transferred data to the database. All the operative steps were conducted as described in the previous section 4.4. During the experiment, 24 incidents and 6 near misses were reported. In detail, 10 of the 24 incidents did not modify the health of the patient, 9 caused transitory disturbances without lengthening the hospital stay, 5 worsened the health and lengthened the hospitalization requiring additional care also. For what concerns near misses: 1 would have not caused any consequence, 1 would have caused transitory disturbances, 1 would have caused a worsening of health and 3 would have caused a permanent health detriment. In particular, the latter events were associated to wrong surgical sites. In this way the Medical manager was able to undertake specific actions in order to eliminate malpractice of which he/she was not previously aware.

Conclusions

I.R.G.E. system can be a useful tool for clinical risk management: it gives the possibility to report errors and near misses in a single paper form and indicates the seriousness and corrective actions undertaken. It comes with a data analysis tool, flexible and adaptable to use in any context, usable as an

active support to decision-making and assessment of risk tolerance of the stru1ctures monitored, by comparing the number of events occurring and the number of corrective actions undertaken. Moreover, it can be used as an instrument for assessing quality parameters of a given medical facility and also as a good indicator of "risk attitude". This claim could be evidenced as support when negotiating insurance policies, that are usually stipulated using generic and unspecific parameters [18].

Acknowledgements

This research was in part funded by the University of Salerno and Italian University and research Ministry (MIUR).

The product presented in this paper has been the object of a presentation at the 43° Congresso Nazionale della Società Italiana di Igiene, Medicina Preventiva e Sanità Pubblica (S.I.T.I.). Bari, Fiera del Levante, 1-4 ottobre 2008.

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