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The diagnostic-therapeutic process. Workflow analysis and risk management with IT tools.

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Abstract— **The aim of this work is to study the impact of an Information Technology (IT) tool on clinical risk management and Adverse Drug Events prevention in patient care. In this study we propose the workflow analysis and the application of Failure Modes Effects and Criticality Analysis (FMECA) as potential tools to assess the effectiveness of a specific IT tool in mitigating clinical risk. The study is made up of two different parts: the first one shows the decomposition and representation of the workflow of hospital departments using standardized tools from Project Management. The next phase shows the application of FMECA to the workflow, in order to identify critical issues and evaluate the risk reduction obtained using a specific IT tool, compared to the use of current resources.**

I. Introduction

Drug prescription and administration in patient care strongly impact on the occurrence of risks in medical settings for that they can be sources of Adverse Drug Events (ADEs). An ADE is defined as "an injury resulting from the use of a drug". Under this definition, the term ADE includes harms caused by the drug (adverse drug reactions and overdoses) and harms from the use of the drug (including dose reductions and discontinuations of drug therapy)" [1]. ADE can occur because of prescription, transcription, preparation, distribution and administration errors.

Information Technology (IT) is considered a promising approach to reduce these risks. Specific IT solutions, (such as workflow management systems, Computerized physician order entry (CPOE), patient and asset tracking systems, drugs administration devices), have been designed to assist doctors and nurses in patient care activities and improve patient security even if they are often still not enough suitable to real processes. [2]-[11]

Approaches to ADE reduction are of worldwide interest: the British Department of Health recommends the wider use of electronic prescription systems to reduce the risk of medication errors [11]. On the other hand, several studies also conclude that IT tools could even introduce new risks that must be taken into account while planning to adopt these systems for clinical risk reduction scopes.

Koppel et al. [12] claim that a leading CPOE system often facilitated medication error risks. As CPOE systems are implemented, clinicians and hospitals must attend to errors that these systems may cause in addition to errors they prevent.

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Hence the effectiveness of IT tools in the management and reduction of clinical risk is highly dependent on the ability of systems to adapt themselves to all the activities that take place within the healthcare processes. Therefore the development of effective and exportable IT tools requires a deep knowledge of workflows that take place in hospitals wards and departments. Our approach consists in the use of workflow analysis in order to develop a representation of all the processes involved in patient healthcare and to provide a model of healthcare assistance. FMECA has been then applied to the processes analyzed in order to identify failure modes, as possible ADE sources, and to assess the effectiveness of a specific IT tool in mitigating the risk associated to them.

This manuscript is structured as follows: Section II describes the methods and tools used to represent the workflow and to run risk analysis. Section III describes the parameters used to evaluate the risk . In section IV the results obtained are shown and discussed.

II. Materials and Methods

We performed our study by analyzing two hospital departments: an Intensive Care Unit and a ward in the Department of Internal Medicine. Both departments are located in the Ospedale Santa Maria Nuova in Florence, Italy.

Workflow analysis of hospital department has been done through direct observation of healthcare assistance inside the hospital departments. The workflow has been decomposed, according to the Breakdown Structure Description, and represented using principles taken from the Project Management Body of Knowledge Guide (PMBOK Guide), an ANSI Standard (ANSI/PMI 99/001/2004), in order to identify clearly the tasks that are involved in the workflow and to map the resources used in each one of them [13]. Failure Mode and Effect Analysis (FMECA) has been then applied to identify the failure modes related to each task and to evaluate the level of risk associated to each one of them through the Risk Priority Number (RPN). [14]

The impact of a specific IT system on risk management has been tested. The IT tool considered is PHARMA, a Web information system developed at the department of Electronics and Telecommunication of the Università degli Studi Firenze (Italy), designed to support the healthcare staff in the secure cooperative execution of drug prescription, transcription and registration tasks [10]. The details about the functions of this software are omitted in this paper, since they have been discussed in [10]. The effectiveness of PHARMA in mitigating the risk related to each task has been assessed repeating the RPN estimation by considering that tool adopted by the department and comparing the results

obtained with the one related to current resources (see below, section II.A).

A. Data collection and workflow analysis

The schematization of the workflow of a particular department has required firstly the acquisition of a high level of knowledge about the specific procedures adopted to treat patients inside it. In this study observation and analysis of the care processes was carried out for one year at the Intensive Care Unit (ICU) and at the Department of Internal Medicine of the Santa Maria Nuova Hospital in Florence (Italy). The first one used some very basic IT tools, such as spreadsheets and word processors, together with a few vertical software. The second department was provided with a more powerful dedicated commercial software.

The observations allowed to collect information about all the activities of the department, by working alongside the medical and nursing staff during the performance of their duties. In this way it has been possible to determine the main sub-processes and tasks that constitute the workflow, as well as their relations and the way they happen in time. Resources (documents, data, technologies, personnel) have been identified and their absorption by each task has been analyzed. Observations focused also on understanding the structure and storage of clinical data and documentation and on identifying activities in which data management is particularly critical and increases the probability of occurrence of adverse events for patients.

B. Processes representation

According to the principles of the PMBOK Guide an "operative function" is a kind of work that is made continuously and repetitively and can be described trough different processes [13]. Considering the workflow of each department as an operative function, we have described it with the eight processes: Health care planning, Drug delivery, Nursing care, Invasive procedures, Radiological and ultrasound investigations, Organic derivatives test, Blood test, External consulting.

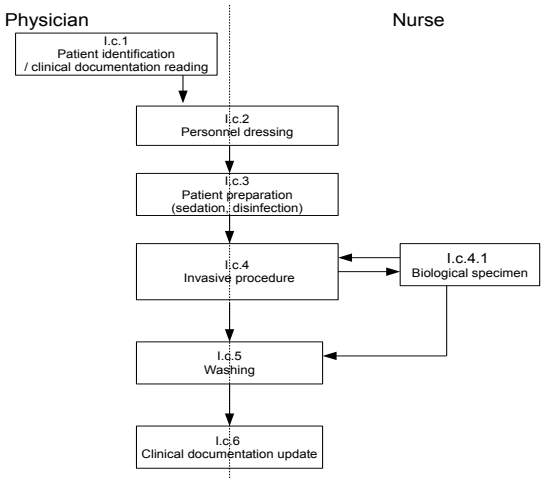

Figure 1. Workflow for the invasive maneuvers

Each process is composed of different tasks and is represented through a flow chart. Each block of the flowchart represents a task and is located in an area identified by the actor that execute the task. All the resources (actors, clinical documentation, technological tools) have been mapped for each task. In Figure 1. an example of a workflow for the invasive maneuvers in the ICU department.

16 different processes (8 for ICU and 8 for Internal Medicine) have been analyzed and mapped using this technique (planning, drugs administration, nursing care, invasive procedures, radiological, blood test, culturing, external consulting), for a total of 137 tasks.

III. FMECA OF THE WORKFLOW

FMECA has been applied to the workflow in order to identify the failure modes related to each task that can represent a possible source of ADEs for patients. Failure modes identification for each task has been performed using data and statistics found in literature and all the information gained from the observations in each department. Each failure mode has been linked to its possible effects and has been identified by a unique code.

The Risk Priority Number has been used to estimate the level of risk of a specific failure mode. RPN is obtained multiplying the level of Occurrence(O), Severity(S), Detectability (D) as shown in the following formula:

$$RPN = O \, x \, S \, x \, D \quad (1)$$

The scales adopted for these the parameters O, S have been taken from [15], while the D scale was built using some of the level of Detectability proposed in [14].

For each failure mode different types of RPN have been estimated.

A. Types of RPN considered

Firstly a RPN "A priori" (RPN_a) has been calculated estimating the level of O, S, D excluding the contribution of the information tools currently available to the department. A second RPN (RPN_r) describes the level of risk related to the use of the current resources and procedures of the department. RPN Pharma (RPN_p) has been obtained with O, S, D estimated considering the adoption in the department of the software PHARMA. [10]

B. Threshold of acceptable risk

A specific RPN threshold value (RPN_{th}) has been chosen, using an ALARP ("as low as reasonably practicable") approach, to determine the highest acceptable risk level for each failure mode. RPN_{th} has been obtained by the combination of three value O, S, D chosen as :

- Occurrence = 3 (occasional occurrence)
- Severity = 3 (slight damage to the patient)
- Detectability = 3 (high detectability of failure modes)

According to the adopted scales the RPN_{th} obtained is 27.

IV. RESULTS AND DISCUSSION

For each type of RPN discussed above it has been calculated the RPN related to the whole workflow of a department by summing all the RPN associated to the failure modes identified. Figure 1. and Figure 2. report the three RPN values obtained respectively for the ICU and the Department of Internal Medicine.

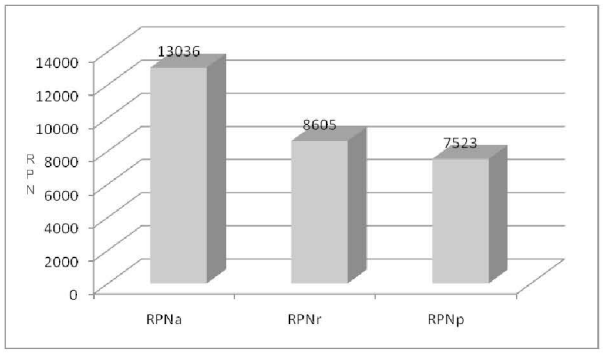

Figure 2. RPNs ICU workflow

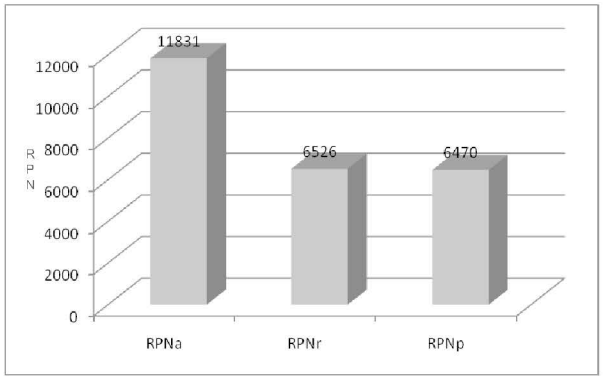

Figure 3. RPNs Internal medicine Department Workflow

Current resources or the hypothetical use of PHARMA involve in both cases a considerable reduction of the overall risk for each department a-priori.

The relative improvement of PHARMA compared to the one related to the existing resources, however, is extremely low (8%) in the case of intensive care unit. This may suggest that the design of the software and its implementation have not been based enough on the analysis of the diagnostic-therapeutic process and its related risks. The paper-based data management and storage still used in the ICU department and most of the problems associated with it can be largely resolved through electronic data management provided by PHARMA. The IT tool optimizes the preservation of documents and the correct document-patient association.

At the same time the lack of knowledge of the process that affects the design of PHARMA, prevents the software to ensure the completeness of the medical record (absence of particular types of documents and information therein), complicating the inclusion of data for specific processes.

In the case of the Department of Internal Medicine, there is an absence of reduction of the RPN due to PHARMA compared to the one related to the existing resources. The software currently used in department has a more complete documentation and a greater adaptation to the process than PHARMA. If we then consider the department of internal medicine as paradigmatic for many other wards with similar characteristics, it is even more evident that it is important to investigate the adoption of risk mitigation changes for the software PHARMA.

The number of failure modes identified for the ICU is 239, while for the department it is 235. For the ICU the number of failure mode with RPNp > RPNth has been 96. For the Internal Medicine department we had 77 failure mode with RPNp > RPNth.

C. Definition of improving interventions for PHARMA

The results obtained demonstrated how PHARMA has not a strong impact on risk management in both cases, hence it still cannot be considered an effective tool in mitigating risk and it needs to be improved. Improvements have been proposed only for failure modes having values of RPNp> RPNth. Examples of this improvements are: link between active principles and commercial drug names, mandatory filling of the field "number of bed", gain in usability.

O, S, D parameters have been then re-estimated assuming the application of the proposed actions and the usage of the modified PHARMA in the departments. Then a new RPN has been evaluated: the (RPNc). However for some failure modes that have RPNp above the threshold it is not possible to identify any interventions to optimize the software in order to mitigate the associated RPN: often these failure modes are derived from risk inherent to the process or they can be solved only using other new hardware/software tools **Errore. L'origine riferimento non è stata trovata.Errore. L'origine riferimento non è stata trovata.Errore. L'origine riferimento non è stata trovata.**. Figure 4. and Figure 5. show the values of RPNc for each department compared to the previous RPNp

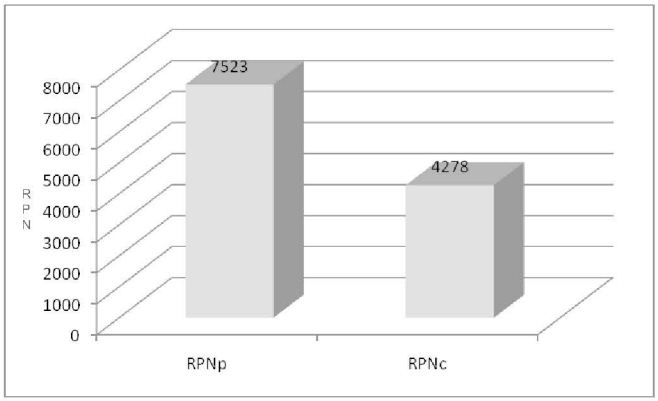

Figure 4. RPNc for ICU

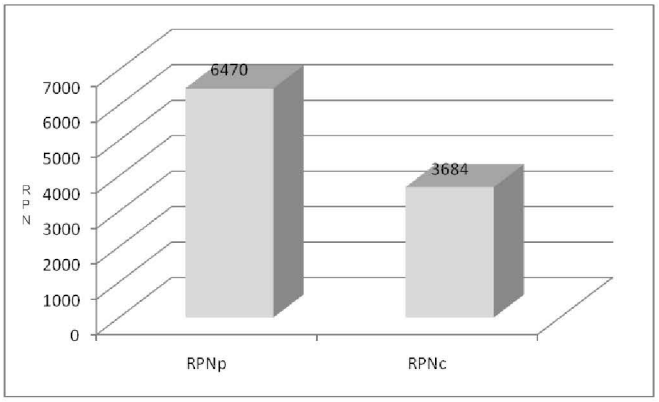

Figure 5. RPNc for Internal Medicine

In both cases we can notice important reduction of the value of RPN.

The number of failure modes with RPNc > RPNth reduced to 34 (-56%) for the ICU and to 44 (-54%) for the Internal Medicine

V. Conclusion

Considering patient care as an "operative function" brought to the possibility of applying the principles of the PMBOK Guide into the representation of medical processes. The description of the diagnostic-therapeutic processes of an intensive care unit and a department of internal medicine obtained is innovative and original and the decomposition of the workflow for each department brought to the building of a model that can be used to verify the suitability of any IT system to the diagnosis and treatment processes.

The FMECA, although affected by the subjectivity of the operator in particular in the estimation of the RPN, is a standardized powerful proactive risk assessment tool. The definition of a threshold for risk acceptance allowed us to identify and prioritize the improvements for the studied IT tool in order to reduce the risk within the limits of acceptability.

This work has shown how a software whose design has not been based on care processes' knowledge is less performing regarding its effects on the overall clinical risk. The results obtained demonstrated how the use of Workflow analysis and FMECA represents a powerful approach in the development of an IT system designed for clinical risk management and ADEs prevention. Future development of this work can be represented by an extension through a multidimensional FMECA to assess the risks related to other subjects (Physicians and nurses, hospital, patient's family etc..).

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