HEALTHCARE BUSINESS PROCESSES RISKS IDENTIFICATION AND MANAGEMENT

Approach for Medication Administration Processes Re-engineering

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Abstract: Medication administration in healthcare institutions is one of the critical processes that need to be carefully considered from the risk management point of view. Medical administration errors are costly from several perspectives as they lead to injuries, illness or even death and finally, significantly increase hospital expense. In this article, we argue that efficient risk management approaches for medication administration business processes are needed. Risks should be identified and mitigated well before critical error occurs.
The presented work describes issues of healthcare business process risk individuation and propose a methodology for business process re-engineering to mitigate the identified risks. To show the potential impact of the approach, we illustrate the functioning of the methodology on the scenario derived from the application domain of the Nursy Rolly^{TM}industrial R&D project.

1 INTRODUCTION

Medication administration in healthcare institutions is a critical process that requires accuracy, timeliness and traceability. Medication administration errors have serious direct and indirect effects and are usually the consequence of a breakdown in a very complex system (Foote and Coleman, 2008) that includes both medical devices, healthcare organization and working practices. Errors can lead to injuries, illness or even death and increase significantly hospital costs. According to (The Joint Commission, 2011), medication error sentinel events resulting in death or permanent loss of function are 319 from 2004 till September 30th, 2011.

Risks of errors can be spread in any part of Medication Administration Business Process (MABP). Reasons of risks arising are usually due to bad design or bad execution of MABP. On one hand, an insufficient quantity of controls may leave the process liable of wrong interpretation and execution. On the other hand, a process with excessive controls may lead the operator to skip them in order to ease/speed activities.

An analysis of near miss[1] reports, as it is done in aviation, nuclear power technology, petrochemical processing, steel production, military operations and air transportation, can highlight risky situations and enable preventive actions (Barach and Small, 2000). Preventive actions, by introduction of IT Systems, if not planned carefully, can not be always effective in risk reduction or can introduce new risks. The question of potential risks early identification and introduction of preventive actions without creating new sources of risk in medication administration business process arise. The main challenges are in foreseeing and considering the necessary specificities for obtaining safe MABPs.

The goal of this work is to provide a solution to identify in advance the risks and enable risk managers and business process designers to mitigate the errors and improve medication administration business process. To achieve this, we adapt the Tropos framework (Castro et al., 2002; Bresciani et al., 2004) to

[1]A near miss is an unplanned event that did not result in injury, illness, or damage, but had the potential to do so (Kohn et al., 2000).

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our scenario. We employ the approach of Asnar et al. (Asnar et al., 2010) which is originally devised for analysing risks during the software requirements analysis phase. Our contribution is an approach that uses a goal-risk model as main artifact and a methodology that starts from operational goals extraction, goes to risk events identification, through problem analysis and to solution design.

The rest of the paper is organized as follows. Section 2 describes medication administration business process and the application of technologies to assist the nurse in performing the medication administration. In Section 3, we present the issues related to identifying the risky situations during MABP execution. A methodology to identify and treat risks on the process is proposed in Section 4. In Section 5 we apply the proposed methodology to the MABP. Section 6 is devoted to the proposed approach and related work discussion. Concluding remarks and future work are summarized in Section 7.

2 MEDICATION ADMINISTRATION BUSINESS PROCESS (MABP)

For this work, we take into account only the MABP running inside a hospital ward as illustrated in Figure 1. It is based in a real scenario modelled by a heterogeneous group of IT and healthcare professionals. The main actors involved in this MABP are: (i) Nurse, responsible for reading the physician order entries administering medicines to patients and (ii) Patient, who can decide whether to take or refuse a medicine. Another actor involved is the Physician, who is responsible for prescribing medicines to patients, however, we assume the prescription of medicines is done before the administration begins and we do not tackle its issues on this work;

The medication administration is performed during predetermined timeslots, e.g., at 8 a.m. and at 11 a.m. The nurse[2] assures she collected all medicines required to cover the patients needs and makes the rounds. Calculation of the required quantity of medicine for each round is performed by analysing the therapies prescribed to the patients the nurse is responsible for. If the nurse uses of a medication cart, she must load the medicines in the cart before starting the first round of the shift. The refill is usually done every shift when enough medicine for a whole shift is loaded. While in case of running out of a medicine, the refill of that specific medicine can be done at any time.

There are three possible ways of the medication administration operation conclusion: (i) the patient wants to take the medicine and the nurse administers it; (ii) the nurse decides not to administer the medicine, e.g., the medicine is used to lower the blood pressure, and the patients blood pressure is very low, and the medicine is not administered because of the nurse decision; (iii) the patient decides to refuse the medicine by some reasons, e.g., the patient believes that the drug makes she feel sick.

In order to show the effects of introducing IT systems to the medication administration process, we present below the Nursy Rolly^{TM}project [3].

2.1 Nursy Rolly^{TM}- Smart Medication Cart

The main outcome of the Nursy Rolly^{TM}project is a system composed by a smart medication cart and several software applications and systems, to assist nurses during the medication administration process. The access to the cart is controlled by smart-card identification that grant even traceability. The cart includes a therapy system where physicians can prescribe a therapy, and where the nurses read the physician order entries. Accessing the therapy system from the cart, the nurse can be guided to administer medicines to the patients she is responsible for.

Several verifications are done during medication administration to assure the Six rights[4] of medication use (Pape et al., 2005). Every time a medicine is picked up from the medication cart and planned to be administrated, it has to be through barcode[5] reading. When barcode is read, all information about that specific medicine package is retrieved and controlled, i.e., such as, expiration date, equivalence. Every time a non equivalent medicine is selected instead of the medicine prescribed by the physician or expired medicine is checked, a near miss report is automatically generated. Just before administering the medicines to the patients, the nurse has to verify if the patient is exactly the person she prepared the medicines to. To do this, the patient bracelet has to be

[2] In this paper we only nominate the nurse as the responsible for performing MABP, even though we know that there are situations where other healthcare professionals assume this role.

[3] GPI S.p.A., "Nursy-Rolly^{TM}- the Smart E-Trolley" project number 10535.

[4] Six rights: right medication, right dose, right route, right patient, right time and right documentation.

[5] In several countries, e.g., Italy, a double barcode has been implemented. One represents the Medicine and the other one represents the single box of medicine.

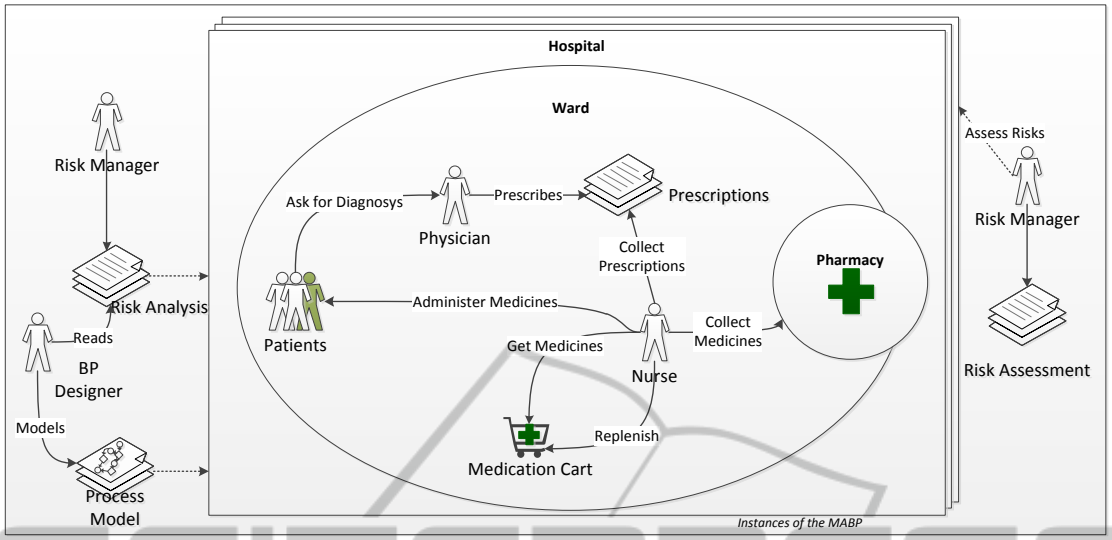

Figure 1: Scenario of the Medication Administration Business Process.

scanned. If the patient is not the supposed one, a near miss report is triggered, otherwise the administration of all the medicines prepared is done and the event is recorded.

3 MABP RISKS IDENTIFICATION ISSUES

The healthcare agencies encourage the adoption of technologies to assist the nurse. The scope of such technologies and tools is to avoid or mitigate risky situations during medication administration.

Design choices made during the development of new technologies and tools may not cover all the issues that are raised when the technology is in use. The reason is that specificities of the environment where technologies and tools are to be used is only learned during the actual introduction of the novelty to real working scenario.

The main challenges are in foreseeing and considering the features necessary for obtaining a safe MABP after the introduction of new technologies and tools. Healthcare business processes are very complex and highly dynamic. The possibility of providing system risk analysis based on requirements obtained just from parts of the business process, but not from the whole process is challenging. At this point, one has to consider the fact that the organizations differ from hospital to hospital and from department to department.

Given a business process *MABP* implementing technologies such as therapy software, and controls such as barcode reader to confirm the patient identify and right medicine. A set of problems P identified during risk analysis, e.g., process deviations, process violations, stock mismatch. This naturally leads to posing the question of "How to identify the specificities for new redesigned medication administration business process $MABP'$ to cover the issues raised and to mitigate the risks?".

Below, we discuss some of the problems that might appear during the medication administration, even after the implementation of new technologies.

New controls implemented could introduce new risks to the process. Besides the new technology can even not cover all the risky aspects in the administration process. We would like to discover these aspects inspecting the software features with our methodology. The need of scanning every patient's bracelet every time a medicine administration is done, may lead the nurse to skip if she is in a hurry. These **deviations** from the original business process model may lead to errors.

Example 1. *Nurse Maria is in a hurry, she administers the medicines to all her patients (including patient Katrin) without using the bracelet scanning to check their identities. After an hour, the patient Katrin dies. The autopsy reveals an insulin intoxication, however the therapy plan for patient Katrin does not contain insulin prescribed.*

The fact that it was possible to skip (disable) the identity checking, enabled the risk of error in switching patients therapy plans.

Example 2. *According to Pietro's therapy plan, nurse Maria should administer the medicine X to him. However, the medicine X is not available in the de-*

partment. The head nurse has required the correct medicine but the hospital store has sent an equivalent one. The nurse administers the equivalent medicine but cannot record the administration because it has a different code.

The features designed and implemented by the technology may not avoid **violations** of a correct business process.

Example 3. *Maria reads on Carlo's therapy plan and administers 600 mg of medicine Y to him. After half an hour the patient feel sick because of an overdose. The physician prescribed an incorrect dose but the nurse couldn't notice it because the previous dose was administered by the nurse of the previous shift.*

Example 4. *Maria administers a medicine to patient Roberto and a few minutes later, the patient dies. The physician and the nurse did not read the allergies report or the physician did not check allergies before inserting the order entry.*

Even though a physical audit in the cart content is not done, a mismatch between physical stock of medicine and logical stock registered in the medication cart system can be discovered. Two situations of mismatch can happen, with different causes and implications: (i) more drugs in the logical than in the physical stock, (ii) more drugs in the physical than in the logical stock.

More Drugs in the Logical than in the Physical Stock. The fact that a medicine is missing, can be due to the fact that it was forget to register a case of fallen or spilt of a medicine, or due to the fact that some medicine was administrated without being the event registered.

Example 5. *Nurse Maria is preparing the medicines for the Patient Carlo and by mistake, drops a pill. She takes another pill from the package and continuous the administration without registering the event of discarding the medicine was dropped. The logical and physical stocks are not equivalent any more.*

More Drugs in the Physical than in the Logical Stock. An excessive number of medicine in the medication cart, other than it is supposed to be, based on the logical stock can represent the case where the nurse has put the medicines in the cart without loading them with the software procedure because they were patient medicines.

Example 6. *Maria is about to load the medicine Z for patient Carlo in the cart and she realizes that the department does not have that specific medicine in the stock. However, she knows that Carlo brought his own medicine when he was admitted to the hospital. She puts the drug box into the cart without registering the event in the software, because the box does not have the barcode label anymore.*

The possible points of failure in the business process design can be related to **corner cases** as it is in the software verification/test community. Situations where a patient needs a medication immediately may achieve a level of emergency where there is no sense of following all the controls.

Example 7. *Patient Pietro faints. Maria measures his blood pressure and calls the physician. The physician orally prescribes a medicine and Maria administers it to Pietro. As it was an emergency, nothing was recorded on the software at that moment.*

4 MABP RE-ENGINEERING APPROACH

To assist the business process designer on the task of re-modelling medication administration business process to mitigate risks identified by the risk manager, we propose a methodology based on the work of Asnar et al. (Asnar et al., 2010). Although their approach is originally devised for analysing risks during software requirements analysis phase, it suits well to our need of careful analysis to find risk not managed yet.

The proposed methodology uses a Goal-Risk (GR) model defined in (Asnar et al., 2010), which consists of three layers representing *asset*, *events* and *treatment*. The GR model has to be designed following the proposed methodology, which consists of 4 main steps illustrated in Figure 2: (1) Operational Goals Extraction, (2) Risk Events Identification, (3) Problem Analysis and (4) Solution Design.

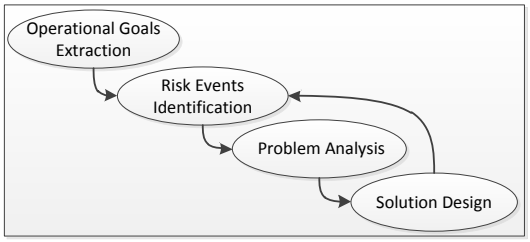

Figure 2: Proposed Methodology.

4.1 Operational Goals Extraction

The first step of the proposed methodology is devised to extract the operational goals from MABP and modelling them into the *Asset* layer. Every operation identified in the business process is translated to a goal. To have a higher detailed model of operational goals, the goals can be refined to subgoals using an AND/OR decomposition. For example, a goal "Correct Administration" could be refined to subgoals such as

"Confirm Patient Identity" and "Confirm the Right Medicine".

Goals can have also relationship among each other in order to contribute positively or negatively to their fulfilment. These relationships can be modelled using a contribution relation. The contribution relation employs the concepts of Satisfy/Deny and the quantifiers '-', '−', '+' and '++'. For example, the goal "Allow Patient to Refuse Medicine" can contribute negatively to the goal "Correct Administration".

4.2 Risk Events Identification

After operational goals individuation, we can start to identify risk events. Making use of a goal-risk approach, it is possible to find risk events by analysing the relation between goals. When two different goals have a negative impact to each other, it automatically takes to a risky situation where Satisfying a goal may imply to Denying the other. For example, the goal "Allow barcode reader disabling" contributes negatively to the goal "Confirm Patient Identity", a risk event of "Wrong Patient" can be detected.

After identified, events have to be modelled in the *event* layer, as it is shown in Figure 3. The events are characterized with two properties: likelihood and severity. Likelihood is modelled as a property of an event, i.e., satisfy or deny, and severity is denoted as the sign negative or positive of an impact relation. In this way it is possible to model the impact each event has on fulfilling operational goals.

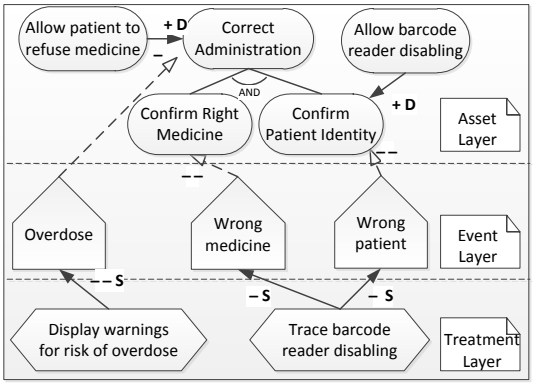

Figure 3: Goal-risk model.

4.3 Problem Analysis

The next step of the suggested methodology is devoted to analyse the problem(s) found in the business process *MABP*. With the layers *asset* and *event* modelled and including operational goals, events and their relationships, it is possible to compute the fulfilment of the operational goals with help of the Tropos goal risk framework (Asnar et al., 2010). In this way, it allows us to understand the problem and see which operational goals are not fulfilled because of the risk events present in the business process.

4.4 Solution Design

After the problems are identified and analysed, the last step of the proposed methodology is performed. To design a solution for the problem, we use the *treatment* layer in the GR model. The *treatment* layer allows us to introduce treatments/countermeasures/mitigations with the purpose of tackling the issues identified in the previous steps.

Just like the goals in the *asset* layer, the treatment elements can be decomposed using AND/OR relationship. A treatment can impact in a risk either by reducing its likelihood or by attenuating its severity. To reduce the likelihood, a treatment is modelled using a contribution relation. To attenuate the severity of an event, the alleviation relations are used, with the purpose of reducing the impact sign to a lesser value.

Every situation may have different requirements for safety. Some specific hospitals or specific departments can demand a more intensive work on the treatment layer to cover a higher number of risks than others. The example illustrated in Figure 3 shows the treatments inserted to mitigate the risk events identified.

5 METHODOLOGY APPLICATION

We consider the medication administration business process presented in Section 2 and apply the proposed MABP Re-engineering methodology. The application was done in collaboration with the Project Manager and the Software Analyst (with healthcare expertise) involved in the Nursy Rolly^{TM}project.

We start from the first phase of the methodology, when at the beginning operational goals are extracted and then modelled in *asset* level, as it is done in Figure 4. The operational goals identified are listed as follows: (i) Assure patient's safety, (ii) Prescribe the medicines correctly, (iii) Perform correct administration, (iv) Allow barcode reader disabling, (v) Allow patient to refuse medicine, (vi) Perform the round on time, (vii) Administer the right medicine, (viii) Administer to the right patient, (ix) Administer via the right route, (x) Administer the right dose, (xi) Administer at the right time, (xii) Perform the right documentation after the administration.

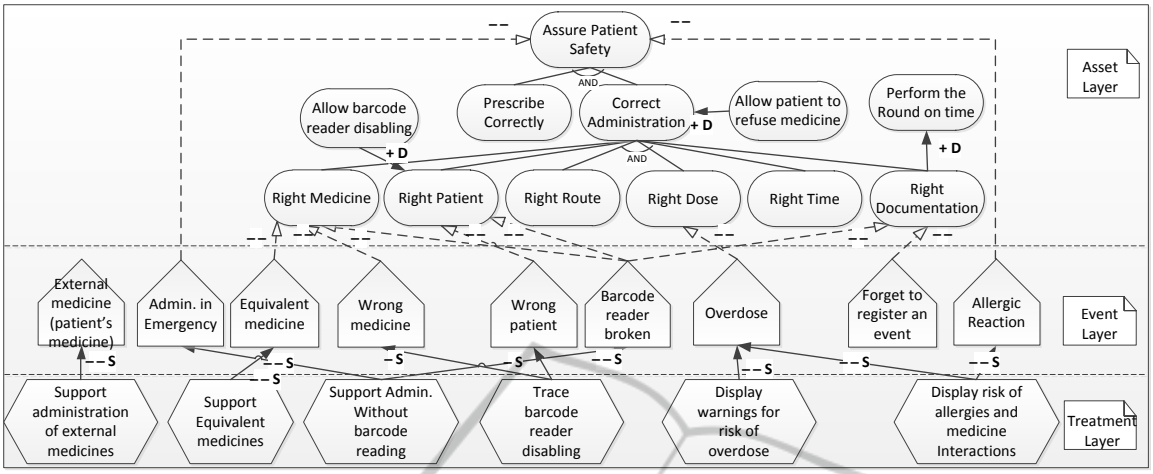

Figure 4: Goal-risk model for the Medication Administration Process.

Then we start second phase of the methodology where we analyse the relation between goals, and based on the negative impact one goal applies to another, we identify the risk events. The risk events are then modeled in *event* layer, as it is illustrated in Figure 4. From the identification of risk events, the following list is created: (i)Administration of an external medicine (patients brings her own medicine), (ii) Administer medicine in case of emergency, (iii) Administer an equivalent medicine, (iv) Select a wrong medicine, (v) Select a wrong patient, (vi) The barcode reader breaks, (vii) Overdose, (viii) Forget to register an event, (ix) Allergic Reaction.

In the third phase of the methodology, we perform the problem analysis. We take into account the operational goals that have their satisfaction compromised by the occurrence of risk events. We also individuate the risk events that causes direct impact on the operational goals satisfaction.

In the last phase of the methodology, we design the solution to mitigate the risks. The solution is concentrated in the creation of treatments to minimize the likelihood of a risk event happening. The treatments created are: (i) Support administration of external medicines (patients brings her own medicine), (ii) Support equivalent medicines, (iii) Support Administration without barcode reading, (iv) Trace barcode reader disabling (register the situation when the barcode is disabled), (v) Display warnings for risk of overdose, (vi) Display risk of allergies and medicine interaction.

6 RELATED WORK

We have followed the idea of using a Goal-Risk model to identify and mitigate risk of errors during medication administration process. We have adapted the Tropos goal risk framework (Asnar et al., 2010), which was originally proposed for analysing risks during requirements analysis phase of software engineering. They work analyse risks along with stakeholder interests, and identify countermeasures, to be introduced as part of information system's requirements.

Other work related to risk management in health care scenario is a platform called ReMINE (Arici et al., 2010). They consider vulnerabilities in hospital processes that may result in adverse events causing harm to patients. The authors propose risk control rules to enable real time control of clinical processes.

Yet in the healthcare scenario, there is the work (Rebuge and Ferreira, 2012). It considers healthcare processes including medical treatment processes and generic organizational processes. The authors apply process mining techniques that leads to detection of regular behaviour, process variants, and exceptional medical cases.

Despite it is from a different community of research, we also consider the work of (Pape, 2003) as related to ours, because it aim at reducing errors during medication administration process. They focus on human factors and work redesign to create safer procedures. They apply airline safety practices to increase the level of attention the professional has to attend when performing the most critical steps of medication administration process.

7 CONCLUDING REMARKS

One of the most thought challenging issues in risk management is that of risks investigation and management in healthcare business processes. The research on complex business processes risk management is well under way. While the existing approaches address the issue of risk management of the already running business process and try to correct the errors occurred during the execution. We consider that risks should be identified and mitigated well before critical error occurs.

The main contribution of the paper is to consider issues of medication administration process risk individuation and propose a methodology for business process re-engineering to mitigate the risks identified.

With the application of our methodology, it is possible to detect the risks present in the medication administration business process. Knowing the risks, the treatments necessary to avoid or mitigate them can be properly planned. Furthermore, when treatments are introduced, any additional risk that might appear can be considered and treated as well.

The research presented in this work is still in progress. This work prods for more investigation of medication administration and of the medication administration processes management. In the next future, we plan to dive into the details of a framework implementing the proposed business process re-engineering approach and then to experiment in a real hospital ward in Bassano, Italy. Furthermore, as future work, we would like to extend the methodology by introducing the management of metrics and indicators of risk, and a suitable visualization for the information collected.

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