A Simulation-driven Approach in Risk-aware Business Process Management: A Case Study in Healthcare

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Abstract: Risk management in business process is a key factor of success for organization as risks are part of every business activity. Errors may bring to increased costs, loss of quality as well as time delays, which in healthcare can bring to serious damages. This paper proposes a methodological framework to investigate risks in organizations by adopting a Business Process Management perspective that includes modeling and simulation of business processes. We applied our methodology to processes in the Blood Bank department of a large hospital. Our results show that a simulation-driven approach is an effective way to intercept and estimate real risks and to provide a decision support to guide the of department's managers.

1 INTRODUCTION AND RELATED WORK

One of the main issue of **Business Process Management** (BPM) concerns the analysis of risks related to a business process and the compliance of the process to norms, regulations or laws (Dumas et al., 2013; Van Der Aalst, 2013). Frequently, this forces organizations in redesign business processes, in the context of change management (Hayes, 2014).

The most common approach to the issue focuses on the detection of failures, mostly dealing with bad performance departments, stressing enforcement styles (Parker and Nielsen, 2011) as well as reconsidering project implementations (Hornstein, 2015). Following a different strategy from common business analysis (Chang, 2016), we applied an approach oriented towards the understanding of cases of success, as a way to address other departments of the same organization in process optimization.

Traditional BPM systems usually do not address the problem of risks that organizations face in their day-to-day operations. Risk is part of every business activity and therefore part of every business process. If a risk occurs it may cause loss of quality, increased costs, time delays, complaints and legal problems (Betz et al., 2011) as well as, in healthcare, serious and permanent damages up to death. So risks need to be managed and the applications of principles, frameworks and activities to manage them (commonly known as **Risk Management**) will create soon a whole range of new regulations. This will lead to two sets of problems: on one side these regulations have to be applied so we must pay attention to process compliance, from the other side new reorganizations must be implemented with the introduction of new procedures, i.e. for privacy control. A simulation-driven approach is a versatile tool to produce results that are relatively easy to interpret by comparing different scenarios to evaluate process changes (**What-if analysis**) (Vom Brocke et al., 2010; Di Leva and Sulis, 2017b).

This paper describes a methodology of risk-aware business process modeling based on process simulation. Our case study refers to Italian "City of Health and Science" of Torino, one of the biggest hospital in Europe[1]. In this context, we selected as a use case a well-performing department (accordingly with the Risk Manager office of the hospital), the Blood Bank (BB) department which collects blood or hemocomponents from blood donors and supplies several different hospitals located in the surrounding with blood products. The department's laboratory performs tests necessary for production of blood components (immunohematology, blood-borne infectious diseases) as well as for diagnostic, pre-transfusion testing and prevention of hemolytic disease of the newborn. This paper mainly refers to process modeling techniques used to analyze and support business processes which involve humans, documents, organizations, or applica-

[1]Cfr. Cittá della Salute e della Scienza, http://www.cittadellasalute.to.it

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tions (Van der Aalst et al., 2010; Di Leva et al., 2017). Such techniques include specific languages. One of the most used is the "de facto" standard for process modeling, the *Business Process Modeling and Notation* (BPMN) language (Allweyer, 2016; Smith and Fingar, 2003). In addition, several tools improve process analysis allowing the simulation of the process itself (Abo-Hamad and Arisha, 2013; Sulis and Di Leva, 2017). In our case, the iGrafxProcess tool (iGrafx, 2015) was used to implement the main phases of the BPM methodology, as well as process simulation and risk analysis. In the context of risk management (Sadgrove, 2016; McNeil et al., 2015; Haimes, 2015), most studies investigate specific use cases to describe benefits of new practices or tools (Tomiyama et al., 2009; DeRosier et al., 2002; Blake and McTaggart, 2016). In healthcare studies this kind of analysis is particularly important for the direct and indirect consequence of errors (Rose et al., 1992; Vincent et al., 2000; Fishman, 2013; Chartier, 2014). Some works focused on evidence based medicine (Vincent et al., 1998), while others treat favorable cases in public health (Braithwaite et al., 2017). In the broad spectrum of work related to the monitoring of business processes, it is possible to find several studies on compliance with laws, rules or regulations. This aspect is of particular importance in the case of processes related to patient health (Buddle et al., 2005; Racz et al., 2010; Adams, 2003; Vincent, 2017). In the following of the paper, we introduce the methodological framework that has been developed to analyze and improve business processes (section 2). The extended process model allows the simulation of actual (As-is) processes and the execution of What-if analysis of several scenarios which describe possible evolutions (To-be) of these processes. The methodology also takes into account aspects related to risk analysis and compliance of processes with current laws and regulations. Section 3 largely describes the exploration of the case study adopted in this paper: the whole process that describes the functioning of the hospital department is reconstructed and its compliance with current Italian laws and regulations is analyzed. This analysis is therefore proposed in order to introduce a new bank management system and analyze the changes that this hypothesis could have on the existing process. Finally, some concluding remarks will be discussed in section 4.

2 THE METHODOLOGICAL FRAMEWORK

This section introduces our methodological framework that is based on a Risk-aware Business Process Management (RBPM) methodology (Suriadi et al., 2014; Jakoubi et al., 2010), including some considerations will be presented on the application of the methodology in the medical field.

2.1 Risk-aware Business Process Management methodology

Our methodology consists of three phases:

- *Context Analysis*: this phase aims to fix the overall strategic scenario of the enterprise and to determine the organizational components which will be investigated.
- *Functional Analysis and Process Engineering*: the initial purpose of this phase is the determination of the activities that are carried out in the corporate functions involved in the process and the causal relationships existing among them. The process is then reconstructed starting from external input/output events and/or objects: this provides the **Process Diagram** (sometimes referred to as a process map or flowchart) that uses the Business Process Model and Notation (BPMN) (Allweyer, 2016) specification language to describe the process. The process model must therefore be validated with stakeholders involved in the process, using animation and simulation of its specific, obtaining the so called **As-is model**. This phase includes the analysis of each cause of errors, such as failures, "near-miss" and behavior that does not comply with the regulations.
- *Risk Analysis and Compliance Verification*: the purpose of this phase is to trace back from the problems highlighted in the previous phase and to introduce corrective actions to reduce risks to an acceptable level or to make activities compliant with laws and regulations. In this way it is possible to generate a new version of the As-is model (the **To-be model**) which must be verified by comparing it with the previous version.

2.2 Risk and Compliance Management in the Medical Field

The **Clinical Risk Management** (CRM) in hospitals includes processes, methods, tools and activities used in handling risks in patient care to increase the safety of patients and those involved in their care.

A CRM process has to describe the procedure for handling risk and consists of:

- *Risk identification:* to perform risk identification the hospital can take into account notifications

from reporting errors (usually stored into an incident reporting data base), such as events that caused problems to patients and complaints. Even results of inspections and audits can provide useful indications.

- *Risk analysis:* the goal of this step is to determine the causes of risks and factors that favor errors as well as their effects on the safety of patients.
- *Risk assessment:* decision-makers must determine what kind of risks should be treated with priority.
- *Risk treatment:* a risk can be treated by introducing preventive measures and/or accepting risk with or without supervision.

Within a framework of continuous development the hospital management has to asses the risk management system regularly to ascertain whether the risk handling process achieved the desired goals.

Risk management methods and tools can be proactive or reactive. Proactive methods are used in absence of adverse events while reactive methods are always preceded by an event. Proactive methods include Failure Mode and Effect Analysis (FMEA) (Chiozza and Ponzetti, 2009), Cause and Effect analysis ("fishbone" diagram) (Nicolini et al., 2011), Scenario analysis (Dumas et al., 2013) and are based on a systematic data collection. Reactive methods apply a systematic investigative technique to analyze adverse events that aims to achieve a comprehensive identification of both systemic aspects as well as individual causes, e.g. London protocol (Vincent et al., 2016).

Compliance refers to the ability of an organization to comply with the obligations laid down by laws and regulations. It must become part of the organization culture and integrate into its processes. Compliance risk can be characterized by the likelihood of occurrence and the consequences of non-compliance with the organizations obligations.

A compliance framework has to provide the organizational processes for implementing, monitoring and continually improving compliance management throughout the organization. Obviously this kind of framework is based on detailed knowledge of the data about errors that occur in the process. For the purpose of transparency and safety of care, which includes prevention and management of risk related to the provision of health services, one of the techniques used to date and encouraged by most States in the world is the reporting of adverse events and sentinel events[2].

[2]https://www.jointcommission.org/sentinel_event_policy_and_procedures/

3 THE BLOOD BANK (BB) CASE STUDY

Blood banking is the process that takes place in the hospital to make sure that donated blood, or blood products, are safe before they are used in blood transfusions and other medical procedures. Blood banking includes typing the blood for transfusion and testing of infectious diseases. The process begins with the arrival of a Blood request by using a special form (we refer to "request" in the rest of the article). In our case, the BB department consists of three functional units: Acceptance, Laboratory and Distribution. In Acceptance requests coming from the other hospital departments (for example, the Emergency Department) are verified: staff should confirm if the information on the tube label and on the transfusion request form are identical. In case of any discrepancy or doubt, a new sample should be obtained. The request and the test tube with the patient's blood is then sent to the Laboratory. When a patient's blood sample arrives at the Laboratory, a certain set of standard tests are performed, including, but not limited to, the following:

- Typing: AB0 group (blood type),
- Rh typing (positive or negative antigen),
- Screening for any unexpected red blood cell antibodies that may cause problems in the recipient.

In Distribution, if a unit of blood (or a component) is required, it is taken from the blood deposit and sent to the requesting department through the appropriate staff. In this paper we decided to show only the Acceptance subprocess for reasons of space, but the same analysis was carried out for all three (Acceptance, Laboratory and Distribution) subprocesses and full results are provided. We started by reconstructing the actual Acceptance subprocess as illustrated in Figure 1. The BPMN language has been used and our tool allows to insert, after the control gateways, monitors - blocks M1, M2, M3, M4 and M5 - that count all the transactions that correspond to errors. As shown in the process diagram, requests are received (**Receive Request**), the staff adds requests in the local management system and applies an identifying barcode (**Manage Request**). Then checks are carried out on the correctness of data on the request and the patient's blood tube (**Check**). If errors are detected (monitor M1) the correct data is re-entered. The gateway *Blood_components?* checks if only blood tests are necessary or blood components are also required. In the latter case the doctor of the Blood Bank (BB doctor) verifies the correctness of the request (**Evaluate Request**) and, if he has any doubts, calls the doctor

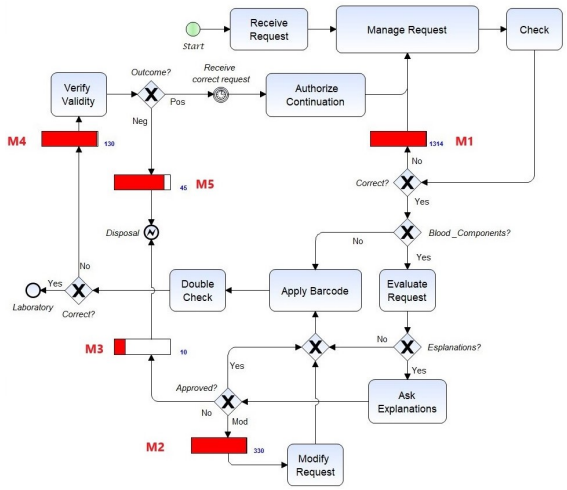

Figure 1: Subprocess of Acceptance of requests with counters of errors.

of the ordering department for an explanation (**Ask Explanations**). At this point (*Approved?* gateway) one of three things can happen: 1) the BB doctor is convinced of the correctness of the request, 2) the request is changed in agreement between the two doctors (**Modify Request**), and 3) the request is considered unsuitable and disposed of (the subprocess is closed with an error report *Disposal*). For cases 2) and 3) the M2 and M3 monitors count the errors detected in the request. If no blood components are requested or the request is deemed suitable or modified, an identifying barcode is applied on the test tube (**Apply barcode**) and a final check is carried out by two people together (**Double Check**), at least one must be a graduate (doctor or biologist) who eventually puts a signature of approval on the request. If no errors are detected (*Correct?* gateway) the request and the test tube are sent to the Laboratory, otherwise (Monitor M4) a check is made with the requesting department (**Verify Validity**). Once an agreement is reached, the requesting department sends a modified request back with the correct data that is re-entered into the system (after a certain delay, timer *Receive correct request*), otherwise the request is considered unsuitable and deleted (monitor M5).

3.1 Process Simulation

In our RBPM methodology the process diagram is integrated with a description of how each activity deals with a transaction, how long does it take, and what are the necessary resources to execute the activity. Furthermore, it is necessary to specify how the transactions (in our case the requests) are introduced in the model and for how long the simulation has to last.

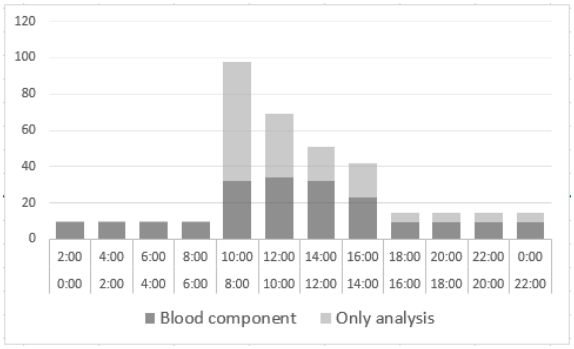

Figure 2: The BB daily workload.

The simulation environment is based on the iGrafx Process tool which is very suitable for process mapping and simulation modeling in business process management projects. We perform input data analysis by considering data about the functioning of the BB department in 2017. Moreover, we interviewed interviewing physicians, nurses, administrative workers and managers of he department. The model has been refined several times and finally validated by workers and managers of the department.

In particular, for the Acceptance subprocess the generator that corresponds to the initial event *Start* introduces about 350 requests a day distributed according to the time table of Figure 2 for a total amount of about 85,000 requests received from the Blood Bank during the initial 8 months of 2017. This scenario has been simulated and, as shown in Table 2, the total number of errors detected in the subprocess after 8 months of simulation is 1,829 (sum of the M1 - M5 monitors). This number must be compared with the number of errors reported by the BB staff during the same period. These errors are stored (together with the causes that generated them) in a self-reporting database (managed by the local system) and shown in Table 1. In this table the causes of error have been divided according to the units of the Blood Bank where they can occur, corresponding to Acceptance, Laboratory and Distribution, and the columns **TErr**, **Causes**, **Errors** and **C** respectively represent the Type of Errors, Causes, Errors and Complaints in these three units. The number of self-reported errors for the Acceptance is 701. This means that about 62% of errors has not been self-reported.

For the Laboratory and Distribution units, similar results are obtained, as shown in Table 2 in which the columns **Rep**, **Det**, **DetButNotRep** and **Com** respectively represent the errors Reported, Detected, Detected but not Reported and the Complaints in the three units of the Blood Bank and for the whole process. The table provides the starting point for two important conclusions:

Table 1: Table of reported errors, detected errors and complaints.

Dep	TErr	Causes	Err	Com
Acceptance	**Internal Acceptance**		511	10
		Incomplete data	134	
		Switching Errors	20	
		Insert Error	349	10
		Other	8	
	Internal Check in Acceptance		127	
		Cross check (request-test tube) missing	14	
		Signature check missing	31	
		Doctor check missing	82	
	Inappropriate Request		63	
		Data: inappropriate/reconsidered	16	
		Quantity: inappropriate/reconsidered	26	
		Urgency: inappropriate/reconsidered	21	
Laboratory	**Internal Test**		18	
		Not performed	11	
		Insert missing	6	
		Other	1	
	Internal Assignment		93	4
		Barcode check missing	9	
		Unsuitable reservation	79	
		Wrong labeling		3
		Wrong assignment		1
		Computer transmission problem	5	
Distribution	**Internal Distribution**		78	8
		Wrong document delivery	1	1
		Wrong number of unit delivery	27	1
		Late delivery	43	
		Wrong blood component delivery		1
		Error on the medical report	3	
		No correspondence bag/data	2	5
		Various	2	
	External Output			4
		Wrong Department Delivery		2
		Switching Errors		2

Table 2: Table of reported errors, detected errors and complaints.

	Rep	Det	DetButNotRep	Com
Acceptance	701	1,829	62.0%	10
Laboratory	111	700	84.0%	4
Distribution	78	400	80.5%	12
BB Process	890	2,929	70.0%	26

- The BB staff has a poor attitude for reporting errors as they are discovered in the process. This is partly due to the workload that at certain times of the day is particularly heavy. The consequence of this fact is that the management of the bank has little information about the actual causes of errors. As a result, improvement initiatives clearly suffer from this deficiency.
- The Complaints column shows that the number of errors not detected in the BB process is very low, this indicates that the current process is very efficient. In any case, as the consequences of certain errors can be very serious the need to improve the process is always present and an FMEA analysis is under way to address the most dangerous cases.

3.2 Compliance of the BB Process

The efficiency of the BB process is the result of continuous improvement initiatives. In particular, several checks on the correctness of data have been introduced in order to detect the greatest possible number

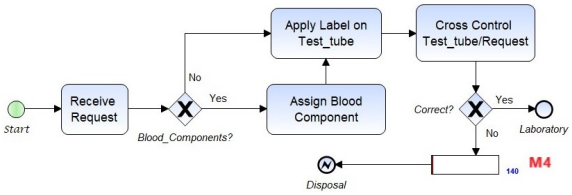

Figure 3: Acceptance subprocess with only mandatory controls and detected errors.

of errors. It may therefore be instructive to compare, for example, the current Acceptance sub-process with what would be if only the rules prescribed by law were applied. In our case, in the Acceptance subprocess the Italian law only imposes to check that the surname, name and date of birth of the patient reported on the request are the same as reported on the test tube. Figure 3 shows how the subprocess of Acceptance would be with only the mandatory controls by Italian law.

Therefore, at the arrival of the request (**Receive Request**) if a blood component is required, it is assigned by the BB doctor (**Assign Blood Component**). In both cases, a label identification is applied on the test tube (**Apply Label on Test_tube**) and then the data on the request and the test tube is checked (**Cross Control Test_tube/Request**). If no errors are detected (*Correct?* gateway) the request and the test tube are sent to the Laboratory, otherwise (Monitor M4) the request is disposed. As shown in Figure 3, only a limited number (140) of errors would be detected in this Compliant subprocess (the simulation of the two versions of the subprocess was performed under the same conditions). This number must be compared with the number of errors detected in the current subprocess (1,829) and this means that about 92% of the errors would not be detected (lost errors). Table 3 illustrates the results obtained for the whole BB process if only mandatory obligations are implemented. In this table the columns **Current**, **Compliant** and **Lost** respectively represent the errors detected in the current and the compliant processes, and the percentage of lost errors. These results clearly indicate that the controls required by law are absolutely insufficient.

Table 3: Comparison of current and compliant processes.

	Current	Compliant	Lost
Acceptance	1,829	140	92%
Laboratory	700	53	92%
Distribution	400	43	89%
BB Process	2,929	236	92%

3.3 Process Improvement

The need to introduce several controls into the Acceptance subprocess stems from the fact that the process relies only on the (hand-filled) paper request which may contain errors and therefore needs to be checked several times to ensure that patient and test tube data are correctly uploaded to the local management system.

The simulation-based approach in the RBPM methodology is very useful for verifying the possible evolution of the processes currently under investigation (**What-if analysis** of possible future scenarios). A **scenario** can be considered as a description of a possible future situation. Scenarios are not meant to be a complete description of the future, but rather a tool to consider the basic elements of a possible future and to draw analysts' attention to the key factors that can help to effectively improve the process (Di Leva and Sulis, 2017a). In the RBPM approach the specification of the scenarios to be analyzed is very simple if they can be defined as changes to be made to the As-is model.

A new web-based version of the local management system is currently under development. The new system provides for integration with the hospital management system in which the patient and test tube data will be uploaded by the requesting department. A simplified paper request and the test tube will then arrive at the Blood Bank, and both will already have the correct control barcode inserted. At the same time, these data will be automatically loaded on the local system for which the problems related to the local insertion of data are eliminated.

Figure 4 shows how the Acceptance subprocess could be modified. At the arrival of the request (**Receive Request**) the data will be acquired and checked (**Acquire Request**) for blood components. If a blood component is required, as well as for the As-is model (Figure 1), the BB doctor verifies the correctness of the request (**Evaluate Request**) and, if he has any doubts, calls the doctor of the ordering department for an explanation (**Ask Explanations**). At this point the request could be 1) approved, 2) modified (**Modify Request**) or 3) deleted. For cases 2) and 3) the M2 and M3 monitors count the errors detected in the request.

The simulation of the two models As-is and To-be allows a comparison between the two scenarios in relation to the detected errors. Table 4 shows the results for the whole process. In this table the columns **As-is**, **To-be** and **Elim** respectively represent the errors detected by the current As-is subprocess, by the To-be subprocess and the percentage of errors that would

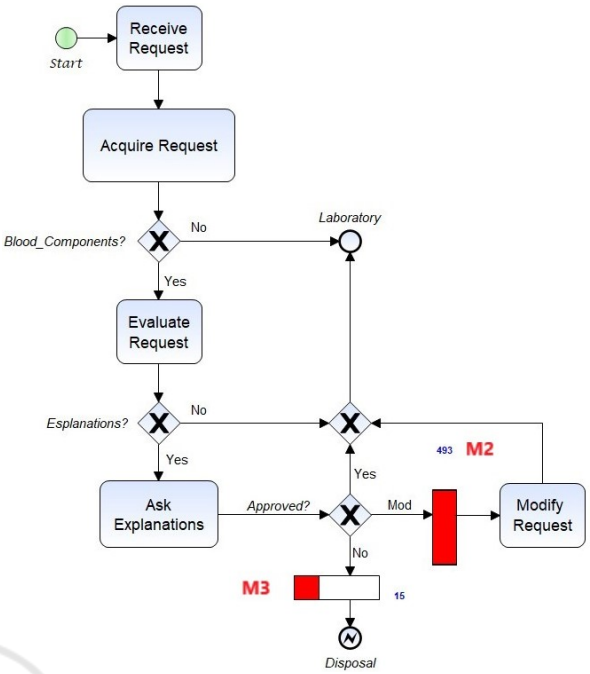

Figure 4: To-be model of the Acceptance subprocess.

Table 4: Comparison between the As-is and the To-be model.

	As-is	To-be	Elim
Acceptance	1,829	509	72%
Laboratory	700	494	29%
Distribution	400	335	16%
Process	2,929	1,337	54%

be eliminated from the restructuring. These results in Table 4 clearly indicate that the introduction of the new local system greatly reduces (54%) the number of errors that would be detected in the Blood Bank. This leads to a much more efficient process in terms of processing time of requests and costs for the organization.

4 CONCLUSIONS

In this paper, we described a model-based approach (RBPM framework) to design and reason about an organization's business environment. The framework includes a methodology to model, validate and analyze business processes, and an extended process model that allows the simulation of actual (As-is) processes and the execution of What-if analysis of scenarios which describes possible evolutions of these processes. In this way managers can get useful suggestions for deciding on the most appropriate restructuring actions to improve the efficiency of the organization.

The paper illustrates, through a complete case study, the possibilities offered by the RBPM framework to accurately analyze the effective functioning of the organization under analysis and to model possible evolutions towards a more efficient organization.

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