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Abstract. Healthcare processes, such as sterilization, are extremely dynamic, complex, and multidisciplinary, making risk management in healthcare facilities particularly challenging. Risk-aware business process management is a new paradigm for better understanding such processes by identifying and evaluating the risks that go along with them. This paper focuses on analyzing the vulnerability of a hospital sterilization service through the use of a new framework, called *e-BPRIM*, which consists of the digitalization of the Business Process-risk management - Integrated Method (*BPRIM*). The *e-BPRIM* framework promotes and supports risk-aware process management with *AdoBPRIM*, a modeling environment using the ADOxx meta-modeling platform. The main *e-BPRIM* components will be introduced and then used to study the robustness of a given sterilization process taking into consideration several potential risks.

Keywords: *BPRIM*, Risk-aware Business Process Management, Modeling Method, ADOxx, Sterilization service.

1 Introduction

In terms of risk analysis, the hospital sterilization service is one of the most significant services. Because of the high-level risk structure and the potential of contagion, managing sterilization services is complex. These services collaborate with other hospital services and serve as a focal point in the fight against germs and infections, which is critical to make the service safe. Any risk that this service may face is critical since it affects all of the hospital's other services [1, 2]. Sterilization

services are in charge of producing sterile medical devices. The organization of this process may differ from one hospital to another but in general, we find common steps, which are crucial to the functioning of the service [3, 4]. Each step could be a source of risk. Therefore, it is imperative for health facilities to manage the ensuing vulnerability to deal with hazardous situations.

Risk management (RM) is recognized as a relevant method to mitigate process vulnerability by a holistic understanding of the causality of risks and reducing the likelihood of their occurrences and their consequences. In the healthcare domain, there are multiple risk management methods [5].

These techniques, however, do not consider the complexity of risks, their close relationship to process activities, and therefore the effect of organizational and human aspects. Given these findings, healthcare facilities should really study novel risk management techniques that incorporate all-risk concepts and their interdependence with process activities. To fill the gap of existing approaches, in this paper we propose to explore the potential of a Risk-aware Business Process Management (R-BPM) approach [6, 7] to address risks associated with the complicated sterilization service.

The present work is organized as follows. First, in Section 2, we provide an overview of healthcare risk management methods and a brief review of related work on R-BPM. In Section 3, we present the adopted framework. Section 4 is devoted to illustrating the use of this framework to study various potential risks that might arise from a particular sterilization process. Finally, the paper concludes with some directions for further research.

2   Background and Related Work

2.1   Healthcare Risk Management

A risk in the healthcare domain can have serious and long-term repercussions, including death.[3, 8]. Such risks must be controlled using risk management principles. The goal of the RM approach is to protect healthcare providers from adverse events. In this way, RM contributes significantly to reducing uncertainties and creating rich opportunities for various healthcare sectors. The development of RM helps healthcare facilities reduce harm due to the likely occurrence of faulty processes through error identification, rooting, and strategy development. Implementation of RM in healthcare facilities improves healthcare resource allocation, process management, decision making, reduced organizational losses, patient safety, continuous quality improvement, customer satisfaction, organizational performance, hospital reputation, and creating a better community [9, 10].

Risk management is one among the emerging approaches in management systems, and various papers have examined risk management in healthcare facilities. In [2, 11, 12], a comparative analysis of the most relevant risk management approaches currently in use in the healthcare field is provided.

However, this sector lags far behind other sectors of the industry in the use of these techniques. Today, in the healthcare sectors, there is a consensus that the knowledge, experience, and expertise of other industries in RM can improve the quality of services provided by the healthcare sectors [9]. Therefore, it seems essential to review the choice of RM techniques. These tools need to be customized according to the complexity of the healthcare system and the causes of events that affect the sector [9]. In consequence, in order to improve patient safety, healthcare facilities need to implement effective policies to detect, prevent and control risks associated with the complex processes of healthcare. To address this issue, we advocate exploring new research fields, notably integrated risk within business process management.

2.2   Risk-aware Business Process Management

For several years, a major research focus has been on the merging of the two traditionally distinct areas of risk management and business process management into a single concept known as Risk-aware Business Process Management (R-BPM) [6]. This integration helps to improve the efficiency of risk identification, detection, and evaluation in business processes [6, 7].

One of the key methodologies in the R-BPM field is the Business Process-Risk Management Integrated Method (BPRIM) [7]. The method emphasizes the need for risk management throughout the business process management (BPM) lifecycle. BPRIM proposes a three-pronged integrative approach: (1) a conceptual unification of risk and business process based on the coupling between the ISO /DIS 19440 conceptual model and a new conceptual model for risk, (2) a common modeling notation of risk and business process that extends the Event-driven Process Chains notation, and (3) a synchronized lifecycle based on the coupling between BPM and RM lifecycles.

3   Adopted Framework Description

In this work, we adopt a framework based on the *BPRIM* method, called *e-BPRIM*. The latter consists of the digitalization of *BPRIM*. The *e-BPRIM* framework promotes and supports risk-aware process management with *AdoBPRIM*, a modeling environment based on the *ADOxx* meta-modeling platform [13]. An overview of the adopted framework is given in [11, 14]. The *e-BPRIM* framework suggests three main components: a *modeling procedure*, a *modeling language*, and *mechanisms & algorithms*. These latter form, according to [15], the main components of a modeling method.

In the following subsections, we present a short description of the *e-BPRIM* modeling method and the *AdoBPRIM* modeling tool.
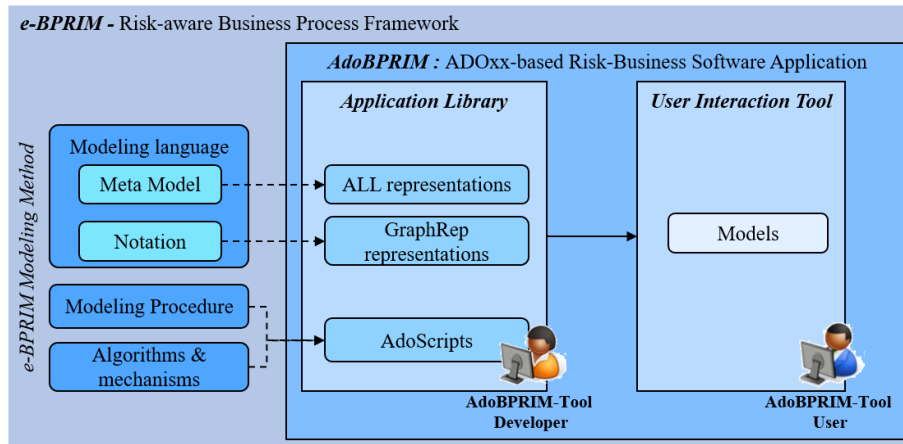
Fig. 1. e-BPRIM framework overview

3.1 *e-BPRIM* Modeling Method

e-BPRIM Modeling Procedure. As mentioned before, *BPRIM* [7] proposes an integration of the two lifecycles of business process management and risk management. The *BPRIM* lifecycle distinguishes between four main phases (1-Contextualize, 2-Asses, 3-Treat and 4-Monitor), each of which is divided into steps. Considering information exchanged between the first three steps, a set of eleven viewpoints was identified. The *e-BPRIM* modeling procedure introduces then the sequence to be applied while creating and working with these multiple viewpoints. The complete modeling procedure can be found in [11, 14].

- The contextualization phase starts with the establishment of a "Process Landscape" viewpoint which specifies the value-added processes of the system under study. Next, the "Organizational Chart" viewpoint is defined which aims to identify roles and expectations, thereby establishing a greater understanding of the organization's structure. This definition serves firstly to produce the "Context" viewpoint and secondly to establish the "Business Process" viewpoints.
- The Assessment phase starts with the creation of the "Risk Taxonomy" viewpoint which serves to generate the "Risk-extended Business Process" viewpoints which assign previously identified risks to individual activities of the "Business Process" viewpoints. Next, the "Risk Analysis", "Risk" and "Risk Relationship" viewpoints are defined to analyze each previously identified risk. This analysis serves to evaluate and list the analyzed risks in a two-dimensional risk matrix forming the "Risk Mapping" viewpoint.
- The Treatment phase aims to identify critical risks and treat them by defining control mechanisms in "Risk Treatment" viewpoints.

e-BPRIM Modeling Language. As shown on the left side of Fig. 1, the *e-BPRIM* modeling language is composed of abstract and concrete syntax. The abstract syntax is described by a meta-model based on the *BPRIM* conceptual model, called *e-BPRIM* meta-model. The concrete syntax is based on the *BPRIM* modeling notation and describes the graphical representation of each *e-BPRIM* meta-model concept, called *e-BPRIM* notation. It needs to be noted, that the *e-BPRIM* meta-model can be divided into eleven meta-models corresponding to the eleven viewpoints of *e-BPRIM*. A comprehension description of them all of them can be found in [11, 14].

e-BPRIM Mechanisms & Algorithms. The *e-BPRIM* mechanisms & algorithms support the steps of the *e-BPRIM* modeling procedure and provide functionalities (i.e. operations) to use and evaluate viewpoints. In the following, we present a short description of some *e-BPRIM* operations:

- The decomposition operation *(Op₁)* divides a system into smaller subsystems, each of which is accountable for part of the problem domain.
- The reuse operation *(Op₂)* allows the reusing of one or several concepts from one or more existing viewpoints.
- The synthesis operation *(Op₃)* allows the collection of data from several perspectives and create a synthesis viewpoint.

A detailed overview of the e-BPRIM framework can be found in [11, 14], including a detailed description of the meta-model, viewpoints and all functionalities.

3.2 *AdoBPRIM* Modeling Tool

For realizing a software prototype dedicated to the *e-BPRIM* modeling method, called *AdoBPRIM*, we have resorted to meta-modeling platforms that strongly support the implementation of a modeling method as a tool with little programming effort while providing an environment for storage, user interaction, and model creation automatically [15, 16]. A comparative surveyof existing meta-modeling platforms can be found in [7, 11].

In our case, the ADOxx [13] meta-modeling platform was chosen to implement the prototype, as it has been successfully used in research and practical projects for more than 15 years [16]. ADOxx enables the easy definition of modeling languages, their graphical representations and required mechanisms and algorithms. For this purpose, ADOxx provides a number of domain-specific languages for implementing modeling methods. In our case, we used: (a) ADOxx Library Language to specify *e-BPRIM* viewpoints meta-models, (b) GraphRep Language to define the graphical representation of *e-BPRIM* meta-model concepts, and (c) ADOScript language to implement mechanisms & algorithms working on *e-BPRIM* viewpoints.

In order to realize an ADOxx-based software prototype dedicated to the *e-BPRIM* modeling method, the *AdoBPRIM* tool developer uses the generic concepts and languages of ADOxx. Afterwards, the tool environment is set up for *AdoBPRIM* users to create *AdoBPRIM* models (see the right side of Fig. 1). The *AdoBPRIM* modeling

tool has been developed as a project within the Open Models Laboratory [16], where a free download and further information can be found[1].

4   Case Atudy: A Hospital Sterilization Service

In this section, we present the application of the *e-BPRIM* framework on a given hospital sterilization service to analyze its robustness. The sterilization delivery process made the subject of several works aiming to provide a deeper understanding of the functioning of the process and identifying the best practices [3, 4, 17].
Sterilization service plays a prominent role in healthcare facilities. In the medical field, it is an indispensable process. Nonetheless, this process is fraught with risks. Transmission of infectious diseases such as Creutzfeldt-Jakob disease, human immunodeficiency viruses, hepatitis C, and hepatitis B are among these risks. Contamination of medical devices (MD) during surgical procedures and poor sanitation of these MD are the causes of this transmission [4].

The purpose of this section is to demonstrate the usage and the capabilities of the *e-BPRIM* modeling method with the *AdoBPRIM* modeling tool for understanding the sterilization process and analyzing related risks. To this end, the following presentation focuses to demonstrate how an *AdoBPRIM* user should address the environment tool to create models (i.e. instances of *e-BPRIM* viewpoints). For greater clarity, we exclusively work on selected *e-BPRIM* viewpoints namely the "Process Landscap", "Business Process", "Risk Taxonomy", "Risk-extended Business Process", "Risk Analysis", and "Risk Mapping" viewpoints.

It also needs to be noted, that to build *AdoBPRIM* models, we based ourselves on the works of Di Mascolo et al. [2–4, 18]. In these works, a real case study was carried out in the sterilization service of the University Hospital of Grenoble. In their research, the authors looked at documents from the French and international standards on the sterilization process, as well as medical documents on sterilization best practices and the findings of a survey done in the Rhône-Alpes region on sterilization services.

4.1   *AdoBPRIM* Modeling Tool

Following the *e-BPRIM* modeling procedure, an *AdoBPRIM* user starts with the contextualization phase by creating:

A "Process Landscape -- (PL)" model (i.e. instance of the "Process Landscape" *e-BPRIM* viewpoint). The latter aims to describe an overview of the value-added processes of the system under study. In our case study, this model describes the sterilization process. In the top of Fig. 2, we illustrate the organization of a hospital sterilization process according to the works carried out in [2–4, 18]. We can then identify eight sub-processes of the hospital sterilization process namely: (1) Pre-

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[1]   *e-BPRIM*   project   space   within   OMiLAB   [online]: https://austria.omilab.org/psm/content/BPRIM, last visited: 14.04.2021

disinfect and transfer MD, (2) Rinse MD, (3) Wash MD, (4) Dry MD, (5) Pack the MD, (6) Sterilize MD groups, (7) Transfer MD to the surgical block, and (8) Store the groups of MD.

A "Business Process -- (BP)" model (i.e. instance of the "Business Process" *e-BPRIM* viewpoint). The latter aims to provide a deeper understanding of the functioning of each identified sub-process in the PL model. This model depicts a collection of interconnected and collaborative activities that produce a particular service or product. Data and organizational elements can also be introduced. This model can provide a full overview of the system as well as process improvement. In our case study, each identified hospital sterilization sub-process can be described by a BP model. For example, at the bottom of Fig. 2, the ``Wash medical devices" process is described in greater detail. This up-down description is ensured through the decomposition operation *(Op₁)* provided by the *AdoBPRIM* modeling tool functionalities (see Fig. 2).

4.2   Assessment Phase of a Sterilization Service

After the first phase of the *e-BPRIM* modeling procedure, the *AdoBPRIM* user can then start the assessment phase by creating:

A "Risk Taxonomy -- (RT)" model (i.e. instance of the "Risk Taxonomy" *e-BPRIM* viewpoint). The latter aims to provide an inventory of potential risks. In our case study, to identify and classify risks that can appear in the sterilization service, we refer to the works carried out in [2–4, 17, 18]. These works used a risk classification inspired by the Ishikawa method. They then differentiate between five risk classes namely: (1) Equipment Risk, which includes all risks associated with the equipment used during the manufacturing process (washer-autoclave-dryer-sink), (2) Entity Risk, which includes all the risks associated with MD, (3) Human Risk, which includes risks associated with the personnel working in the sterilization service, (4) material risk, which includes risks associated with the materials used to ensure the correct functioning of the activities (washing, packaging, etc.), and (5) Environment Risk, which includes risks associated with the system's indoor environment, such as the work area, and the risks associated with the system's external environment. In regards to the Entity Risk class, five main risks can be identified namely: Non-functional MD, Deteriorated MD, MD non-compliant, Mixing of MD, and Contaminated MD. In the left side of Fig. 3, we illustrate this classification through an RT model.
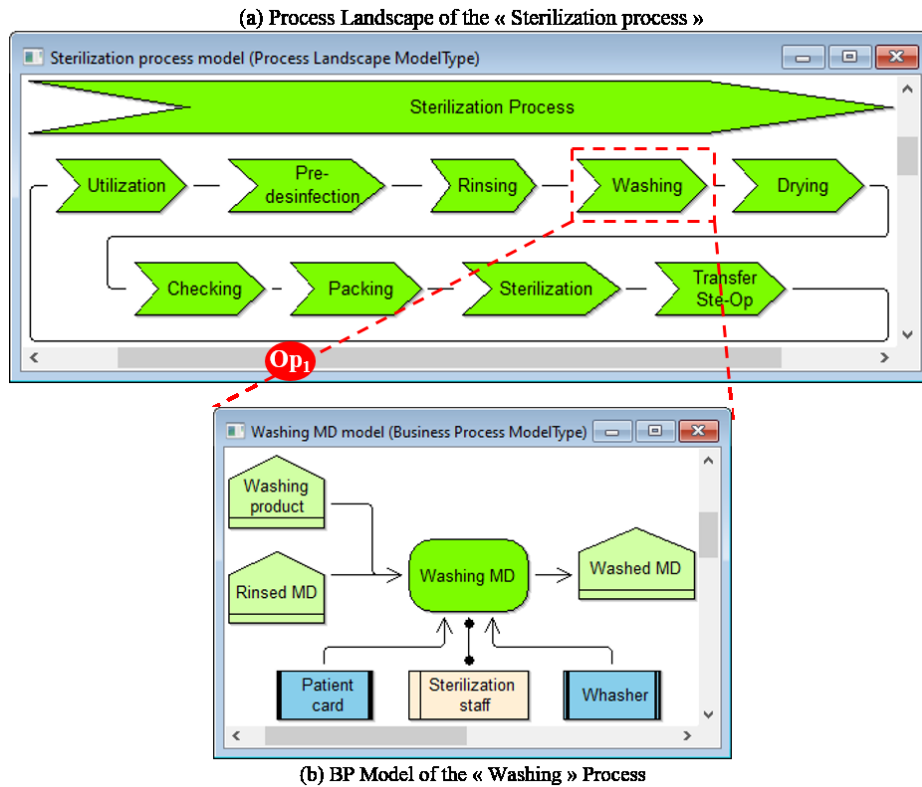
(a) Process Landscape of the « Sterilization process »

(b) BP Model of the « Washing » Process

Fig. 2. Sterilization process mapping (Screenshot from *AdoBPRIM*)

A **"Risk-extended Business Process -- (R-BP)" model** (i.e. instance of the "Risk-extended Business Process" *e-BPRIM* viewpoint). The latter aims to assign individual activities of the BM model to potential risks from identified risks in the RT model. This model ensures the identification of: (1) process activities that are exposed to risks, and (2) Risk factors and situations that can influence the likelihood and/or the severity of a risk. In our case study, as shown on the right side of Fig. 3, we can assign the "Contaminated MD" risk (identified in the RT model) to the "Washing MD" activity. The reuse of an object in different models is ensured through the operation (Op$_2$) provided by the *AdoBPRIM* modeling tool functionalities (see Fig. 3).

A **"Risk Analysis -- (RA)" model** (i.e. instance of the "Risk Analysis" *e-BPRIM* viewpoint). The latter aims to analyze each identified risk in the RT model. For this purpose, the model enables: (1) definition of the risk scenario by describing potential risk causes and consequences, and (2) risk level calculation using a qualitative risk analysis method, specifically the Bowtie method [19].
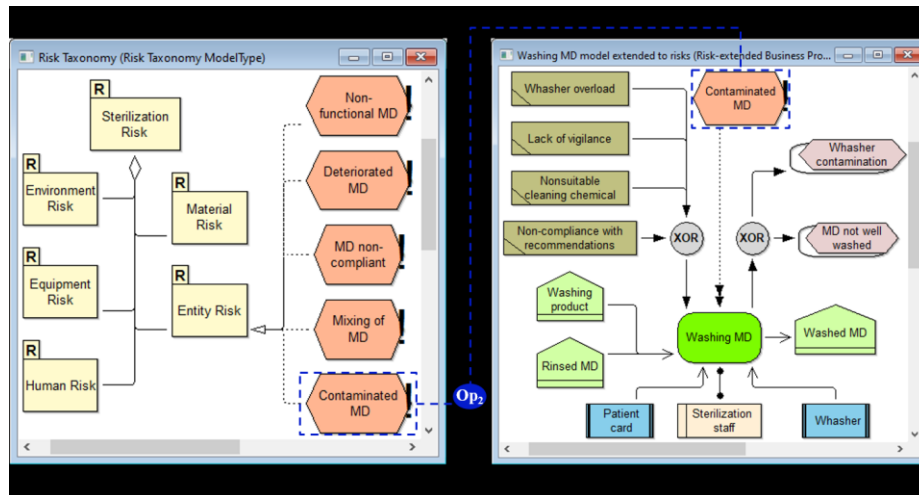
Fig. 3. Washing process extended to risks (Screenshot from AdoBPRIM)

In the RA model, a risk event is expressed by three elements: Likelihood (L), Severity (S), and Risk level (R). With:

- *Likelihood* describes the occurrence probability level of risk situations and risk events. To propagate and calculate the likelihood of a risk event, we based our work on the qualitative approach of the Bowtie method [19] and used the qualitative scales as presented in [20].
- *Severity* describes the impact level of a risk event on values and stakeholders of the system under study.
- *Risk level* is calculated in Equation (1) as the product of likelihood and severity levels.

$$\text{Risk level (R)} = \text{Likelihood (L)} * \text{Severity (S)} \tag{1}$$

In our case study, we focus the analysis on the "Contaminated MD" risk (identified in the RT model). The analysis result is given at the bottom of Fig. 4. In this model, the risk event likelihood of "Contaminated MD" is the result of previous risk situations and factors. The risk factors: "Non-suitable cleaning chemical", "Non-compliance with recommendations", "Lack of vigilance" and "Washer overload", influence directly the likelihood of risk situations: "MD not well washed" and "Washer contamination". The final risk event is impacting two values namely: "Human and social" and "Well-being" values. These two values are of interest for two stakeholders "Healthcare facility" and "Patient".

A "Risk Mapping -- (RM)" model (i.e. instance of the "Risk Mapping" *e-BPRIM* viewpoint). The latter aims to produce a two-dimensional risk matrix that shows the risk level of each analyzed risk. The risk position in the matrix will be according to likelihood and severity levels as calculated in its RA model. For our case study, Fig. 5 illustrates the mapping of different analyzed risks. For example, according to the

analysis result, provided in Fig. 4, we can see the risk "R2" (corresponding to the "Contaminated MD" risk) placed in the position (5, 3).
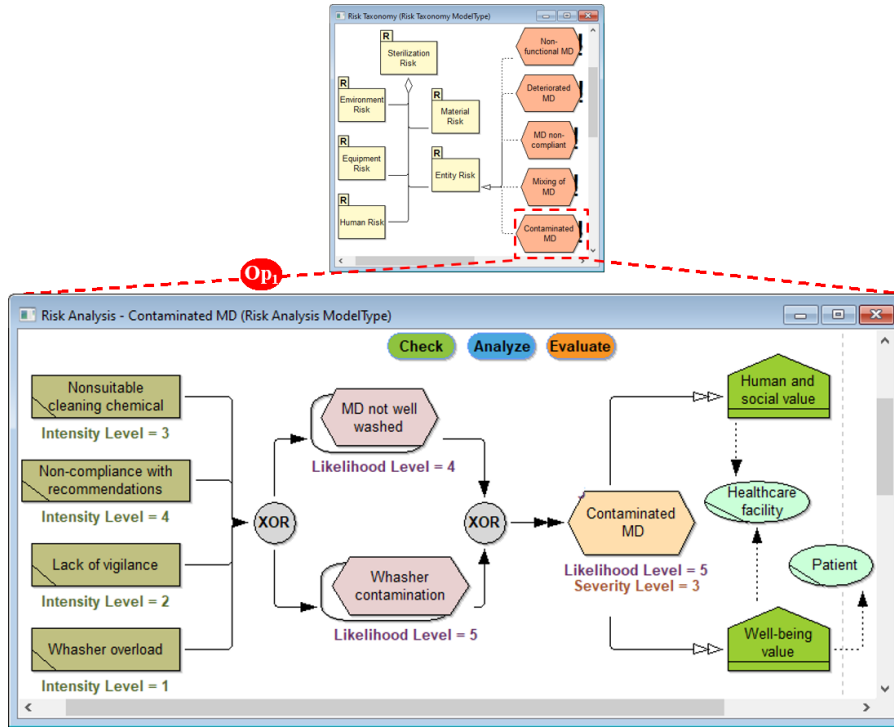

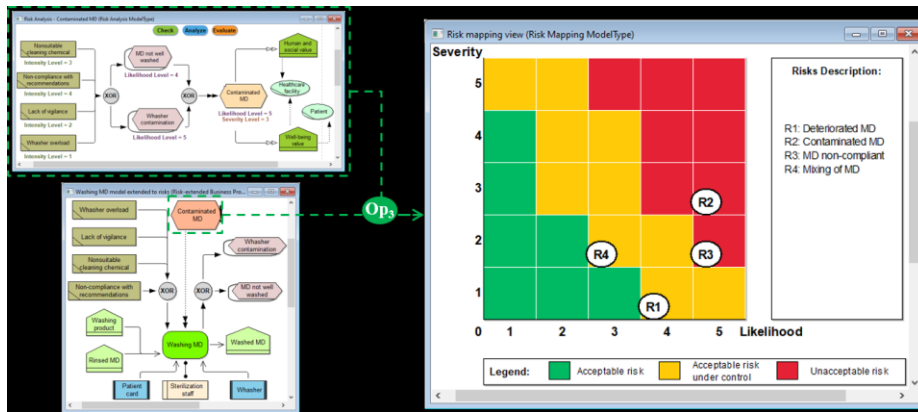**Fig. 4.** Analysis of the "Contaminated MD" Risk (Screenshot from *AdoBPRIM*)

Fig. 5. Analysis of the "Contaminated MD" Risk (Screenshot from *AdoBPRIM*)

5   Conclusion

Addressing the vulnerability of hospital sterilization service is at the heart of guardianships in healthcare facilities due to the contagious nature of their environment which could affect the safety of patients and staff. In order to support healthcare professionals in moving forward on this issue, several risk management methods are proposed. Investigations and literature analysis that we conducted on some of them, shows a statement of their limits. Indeed, none of them qualifies the dynamics of risk, any more than the detailed explanation of the contexts generating the latter.

To progress towards a more efficient approach, we present, in this work a new R-BPM framework called *e-BPRIM*, which is a recent achievement of our long-term research in this area. It consists of the digitalization of the *BPRIM*, an R-BPM approach based on the coupling of two typically separate approaches – risk management and business process management – to improve the risk-awareness of an organization's business processes.

To assess the usefulness and relevance of this framework, we analyzed the vulnerability of a hospital sterilization service through the use of *AdoBPRIM*, the dedicated tool for *e-BPRIM*. Thanks to this later, a completed risk map is given with a reliable basis for risk assessment and the investigation of each of the identified risks. This comprehensive map gives us valuable insights into the hospital sterilization service. All developed models enable to improve a hospital's understanding of its risk profile, clarify thinking on the nature and impact of risks taking into consideration both, the organization as a whole, and the context of the risk situation and its relationship to the activities of the sterilization service. This allows vulnerability to be mitigated or coped with more effectively.

Our study has thus shown that R-BPM approaches can overcome some of the limitations of conventional methods. Obviously, *e-BPRIM* framework is not limited to analyzing hospital sterilization service vulnerabilities, it could be used to investigate other healthcare processes which are vulnerable to risks such as the medication-use process. The generic character of the *e-BPRIM* meta-model gives it a wider potential of use, even in other sectors such as the financial services industry or the energy industry. At this stage, it is worth mentioning that the current version of *AdoBPRIM* is of a relatively young maturity level and is focusing on the design-time stage. Aware of these limitations, we are working on a new version of *AdoBPRIM*, which will add new features such as simulation capabilities to study risk propagation and to assess the effectiveness of the risk mitigation activities.

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