A systemic methodology for risk management in healthcare sector

Anna Corinna Cagliano, Ph.D.[a]
Sabrina Grimaldi, Assistant Professor[b]
Carlo Rafele, Associate Professor[c]

[a] corresponding author
Department of Production Systems and Business Economics, Politecnico di Torino, corso Duca degli Abruzzi 24, 10129 Torino, Italy. Telephone: +39 0110907206. Fax: +39 0110907299. E-mail: anna.cagliano@polito.it

[b]Department of Production Systems and Business Economics, Politecnico di Torino, corso Duca degli Abruzzi 24, 10129 Torino, Italy. Telephone: +39 0110907289. Fax: +39 0110907299. E-mail: sabrina.grimaldi@polito.it

[c]Department of Production Systems and Business Economics, Politecnico di Torino, corso Duca degli Abruzzi 24, 10129 Torino, Italy. Telephone: +39 0110907286. Fax: +39 0110907299. E-mail: carlo.rafele@polito.it

Abstract

The recent biomedical, technological, and normative changes have led healthcare organizations to the implementation of clinical governance as a way to ensure the best quality of care in an increasingly complex environment. Risk management is one of the most relevant aspects of clinical governance and approaches put forward in literature highlight the necessity to perform comprehensive analyses intended to uncover root causes of adverse events.

Contributing to this field, the present paper applies Reason's theory of failures to work out a systemic methodology to study risks impacting not only directly but also indirectly on patients. Also, the steps of such approach are organized around Human Reliability Assessment phases, in order to take into account the human component of healthcare systems. This framework is able to foster effective decision making about reducing failures and waste and to improve healthcare organizations' maturity towards risk management.

The developed methodology is applied to the pharmacy department of a large Italian hospital. An extensive validation in different healthcare settings is required to fully prove benefits and limitations.

Keywords

Healthcare, risk management, clinical errors, patient safety

1. Introduction

In recent years healthcare systems have been involved in a number of different changes, ranging from technological to normative ones, all asking for increased efficiency. In addition, the biomedical progress in the last decades has contributed to raise the level of organizational complexity in hospitals, which is given by many different factors, such as multiple professional experiences, non uniform management models, patient specificity, surgery complexity, reduced inpatient days, and a growing number of healthcare service users due to an increase in average lifetime. As a result, medicine complexity, driven by innovations in both science and technology, stresses the need for new managerial models (Bridges, 2006). Thus, this context highlights the necessity to develop systemic approaches able to detect waste and errors and to suggest organizational and/or technological solutions for continuous improvement.

To this end, following the success of the application of Kaizen principles to the manufacturing sector (Liker, 2004; Liker and Hoseus, 2008), international healthcare organizations, such as The Joint Commission on Accreditation of Healthcare Organizations and The World Health Organization, have developed and adopted the concept of clinical governance. Clinical governance aims to ensure that patients receive the best quality of care. It includes systems and processes for monitoring and improving services, risk management, clinical audit, clinical effectiveness programs, staff management, education training and continuous personal development, and the use of information to support healthcare delivery (Sale, 2005). Among the different aspects of clinical governance, risk management is crucial since it addresses the clinical risk impacting on patients. Literature shows that clinical risk management does not always take a systemic perspective. Moreover, it does often not rely on the understanding of people acting in the investigated processes, nor gives it a valuable support to decision making.

This paper operationalizes Reason's theory of failures by developing a methodology to investigate healthcare processes and related risks impacting either directly or indirectly on patients.

The work provides a systemic approach based on expert knowledge and able to sustain continuous improvement. With the purpose of explaining how it works, the methodology is applied to the pharmacy department of a large hospital. However, more case studies are needed to completely assess the relevance of the framework to the healthcare sector.

The paper is organized as follows. Section 2 highlights the need for a systemic perspective on healthcare risk and presents Reason's theory of latent failures. Section 3 discusses the importance of errors to clinical risk, as well as the features characterizing a successful methodology for managing it. The proposed methodology and its application are presented in Section 4 and Section 5 respectively. Benefits and limitations of the approach, together with future research lines, are discussed in Section 6.

2. Healthcare risk: need for a systemic perspective

Similarly to any other complex system, the complexity of healthcare systems generates adverse events if not controlled (Vincent, 2006). An adverse event may be defined as an unintended injury or complication resulting in disability, death or prolonged hospital stay that is caused by healthcare management rather than by the patient's underlying disease process (Ross Baker et al., 2004). An intrinsic characteristic of medical care is the fact that, whenever it is delivered, patients run the risk to suffer from a disease as an unwilling consequence of treatments (Thomas et al., 2000). Thus, the probability of errors and adverse events in general cannot be eliminated in healthcare organizations. However, it can be controlled by the application to risk management phases of a recursive process of continuous improvement inspired by the Plan, Do, Check, Act (PDCA) paradigm (Tonneau, 1997). According to The Project Management Institute, risk management includes the processes concerned with risk management planning, identification, analysis, response, monitoring, and control. The aim is to increase the probabilities and impacts of positive events and to decrease the probabilities and impacts related to adverse events (Project Management Institute, 2004). Risk management has been adopted to cover all healthcare risks, both clinical and non clinical ones.

The present work focuses on clinical risk, which has been defined by different authors. Wilson and Tingle refer to clinical risk as clinical error to be at variance from intended treatment, care, therapeutic intervention or diagnostic result (Sale, 2005). Kohn, Corrigan, and Donaldson (1999) define clinical risk as the probability that a patient is affected by an adverse event voluntarily or involuntarily caused by medical treatments. However, clinical risk is not only due to medical activities directly impacting on patients but it is reliant on a larger set of activities and professionals. It can be determined by many factors relating to the system, the environment, and the interplay of individuals operating in the processes connected to the delivery of care (Kohn et al., 1999). This research takes such broader perspective on clinical risk, including all events that may affect patients' safety both directly and indirectly.

Within clinical risk, medical errors are particularly important since they may occur during multiple hospital processes, from therapy prescription, thorough preparation, distribution, and administration (Vincent, 2001). Several studies performed in US, Australia, New Zealand, and Europe (Davis et al., 2001; Leape et al., 1991; Vincent et al., 2001; Wilson et al., 1995) reveal that about fifty percent of adverse events taking place in healthcare systems may be

prevented. This highlights a strong need for understanding the triggering events of medical errors as well as their correlations in order to decrease the probability of occurrence of these errors by working on all their possible causes.

The theory of latent failures put forward by Reason is relevant to this end (Reason, 2002). According to such author, adverse events are seldom determined by a single error, being it either human or technological, but more often they are the result of a chain of errors and events where the person responsible for the final error is only the last causal link. In other words, adverse events are produced by many factors, such as organizational, professional, personal, and technical ones. Reason's model defines an adverse event as an unexpected release of energy that may be prevented by erecting barriers between the source of energy and the person or the object to be protected (Figure 1). In this situation, the word "barrier" refers to a wide range of preventive/protective measures including protection devices, security systems, working procedures, training, supervision, and emergency plans (Harms-Ringdahl, 2009). When there are deficiencies in these barriers, they are not able to block the unexpected flow of energy and originate an adverse event that may be classified as a "near miss" (almost an event), an "incident" (event without damage), or an "accident" (event with damage) according to its severity (Hollnagel, 2004). Deficiencies are represented by latent and active failures (Reason, 2001). On the one hand, latent failures alone are not able to cause full-blown symptoms, only if connected to other factors and under facilitating conditions they originate adverse events. On the other hand, active failures represent immediate triggering events, they are related to people acting in a system and their detection often implies the identification of an individual responsibility.

Take in **Fig. 1.** Reason's model (adapted from Barach, 2002)

The existence of both direct and indirect causes for adverse events in any social-technological complex system, as highlighted by Reason's theory, stresses the need for taking a systemic perspective to risk, in order to have a global view on how the interrelations among technical, human, and organizational factors cause or prevent negative events. This necessity is even more evident for clinical risk, since healthcare systems are human intensive and their ultimate goal is providing a medical service ensuring the safety of the entire population.

3. Managing clinical risk by working on errors

A systemic perspective is not the only feature characterizing a successful methodology for managing clinical risk. Preventing risk requires to understand how to strengthen those procedural, administrative, physical, and individual barriers intercepting and blocking the energy flow responsible for deviations. To this end, it is useful to work on what constitutes such energy flow, that is, according to Reason's theory, on errors.

Error taxonomies put forward in literature provide relevant insights on how to cope with adverse events occurring in the healthcare sector. Several classifications of errors have been developed (Baysari et al., 2008; Baysari et al., 2009; Cosby, 2003; Shorrock, 2002; Wieman and Wieman, 2004). Among them, Predictive Human Error Analysis (PHEA) is one of the most detailed (Embrey, 1992; Hollnagel, 1998). PHEA groups error modes according to the following activities: planning, execution, control, information retrieval, communication, and selection. For example, in a healthcare setting, prescription errors may be related to planning, if the proper drug is not prescribed, to execution, if physicians' handwriting is not easy to be interpreted, or to communication, if errors occur when transcribing therapies. This scheme suggests that errors usually have roots grounded in different areas, thus assuming multiple viewpoints is essential to manage them.

Our research builds on Lucas (1997) and Reason's (2001) perspectives for approaching error reduction. These authors look at errors by taking into account four dimensions, namely organizational (systemic), individual, technical, and psychological ones. The present work focuses only on the first three perspectives since the last one is related to merely psychological issues.

The *organizational perspective* states that error determinants are to be found within the system at issue. To be more precise, errors are made by people but their behaviours are highly influenced by the working environment and the organizational processes. Active failures, such as cognitive, skill set (interpretive and procedural), task-based and personal impairment (Cosby, 2003), have to be traced back to latent failures residing for instance in planning and working procedures (e.g. poor shift programming exposing anaesthetists to many consecutive working hours, with the consequent risk of a decreased level of attention; lacking of integration among informative systems leading to scarce communication among the actors of the healthcare delivery process).

The *individual perspective* focuses on the characteristics of people responsible for errors, such as motivation, personality, and interpersonal relationships. Also, it encourages learning

from errors by discussing them and communicating possible safety problems and adverse events (McDonald and Mayer, 2008). Thus, this perspective stimulates the emergence of the experience developed by people while working in a given system, of the "big message" coming from experts. In other words, such perspective promotes expert knowledge elicitation, a formal process of obtaining information able to make a person's knowledge and believes explicit (Garthwaite et al., 2005). Expert knowledge elicitation has been widely applied not only to risk identification but also to risk assessment being translated into probability distributions (O'Hagan and Oakley, 2004). In a healthcare system, characterized by human-based activities, managing criticalities by means of an individual perspective allows to fortify barriers against the flow of energy associated with adverse events. In this case, experts are represented by nurses, physicians, radiographers, pharmacists, receptionists, cleaners, porters or other professional figures.
Finally, according to the *technical perspective*, adverse event reduction can only be pursued by means of strong automation, because the technical components of a system are more reliable than human beings (Lucas, 1997). However, similarly to what happened in the manufacturing industry about forty years ago (Janssen et al., 1995; Norman, 1990), healthcare systems require a gradual introduction of technological innovations such as Computer Physician Order Entry or Electronic Patient Records. Technology is a powerful tool to increase safety in healthcare processes, but without a well structured organization it may make existing working practices more complicated, resulting in fewer benefits than expected. Therefore, an accurate analysis of processes to understand criticalities and waste is necessary before their reengineering through technology.

The relevance of Lucas and Reason's approach has been witnessed by many authors (Harms-Ringdahl, 2009; Henriksen et al., 2008; Paz Barroso and Wilson, 2000; Wiegmann and Shappell, 2001). However, adopting one of these perspectives alone is not so beneficial. Instead, a combination among the first three ones leads to an effective methodology to clinical risk management. Thanks to the individual perspective, human resources will make emerge that sunk information necessary to adopt a systemic standpoint and to comprehend the links between causes and effects of adverse events. This enables the definition of appropriate measures for error reduction, also based on technical innovation.
The present work suggests a risk management methodology integrating all the three error perspectives by Lucas and Reason into an inductive approach able to perform a

comprehensive investigation of clinical processes in order to identify criticalities (ineffectiveness) and waste (inefficiency).

4. A systemic methodology for clinical risk management

4.1 Overview of the methodology

Lucas and Reason's perspectives to error reduction allow to describe the relevant characteristics of our methodology:

- The suggested approach complies with the organizational/systemic perspective since it first identifies the most critical parts of the entire clinical system as well as those barriers that are most vulnerable and prone to cause adverse events. After that, the methodology focuses on a specific healthcare process and on the analysis of the associated criticalities, in order to identify, assess, and control risks related to the activities of such process both directly and indirectly impacting on patients.
- The individual perspective is assured by involving the actors of the investigated process in every step of the methodology, in order to create that background of information necessary to handle all risk management phases.
- The technical perspective is addressed since our methodology supports decision making in order to define the most effective and efficient organizational and/or technological improvements, according to the maturity of single organizations towards risk.

The practical translation of these features was inspired by Human Reliability Assessment (HRA), an approach aimed to identify errors and weaknesses by examining both a system and people working in it. HRA takes a systemic perspective by looking at the human contribution to technical and organisational settings (Embrey, 2000). In this way, it provides a class of techniques that are very powerful to improve reliability and safety in the healthcare sector. The main phases of HRA include data collection, task description, task simulation, human error identification and analysis, and human error quantification (Lyons et al., 2004). Following them, we propose a methodology structured according to four progressive steps, namely:

1. Context analysis.
2. Process mapping.
3. Risk identification and assessment.

4. Failure modes and waste analysis (FMEA-Waste analysis).

Our methodology integrates and organizes project, risk, and waste management approaches, thus enabling them to contribute to a systemic analysis of risk, which is not possible when they are applied in isolation. It is important to highlight that a project and a process have resembling structures, even though a project is temporary and unique while a process is usually ongoing and repetitive (Project Management Institute, 2004). As a matter of fact, a project may be defined as a set of activities aimed to produce a given outcome (Harvard Business School, 2004) and a process is a set of interrelated activities whose goal is transforming inputs to create outputs (Johansson et al., 1993). In the case of healthcare processes the activities will be directed towards the correct delivery of care to patients. Therefore, the similarity of structure between a project and a process allows us to apply project management tools to the investigation of risk in healthcare processes. In addition, healthcare processes are characterised by several cross-functional projects, such as those related to innovation. Furthermore, the fourth step of the methodology makes use of a HRA technique, Failure Modes and Effects Analysis (FMEA), which is by far one of the most extensively adopted in the healthcare sector in the last decades. It has been employed in many fields, such as reducing risk in blood transfusions (Burgmeier, 2002), intravenous drug infusions (Apkon et al., 2004), improving drug distribution systems (Lyons, 2009; McNally et al., 1997), and drug prescription in hospitals (Saizy-Callaert et al., 2001). Moreover, FMEA has been recently endorsed by the healthcare industry and the Joint Commission on Accreditation of Healthcare Organizations as a tool for reducing risk to patients (Brown et al., 2008; Ookalkar et al., 2009; Stalhandske et al., 2003).

The following section gives a detailed description of each step of the developed methodology.

4.2 Description of the steps of the methodology

1. Context analysis

Context analysis is aimed to select and become familiar with the critical healthcare process to be investigated. Also, this is the phase when the various actors responsible for the process at issue get involved into the working group committed to perform the analysis.

Thanks to expert knowledge elicitation and careful consideration of documents, such as working procedures, organizational charts, responsibility maps, and shift plans, the working team gets a first knowledge of process activities and related flows of both quantitative data

and clinical and organizational information. This forms the base for the identification of criticalities, which are investigated more in depth by means of two of the traditional tools employed in risk identification: checklists and interviews (Grimaldi and Rafele, 2008). Checklists are a useful way of keeping trace of the lessons learnt from previous events and may be purposefully employed in self-assessment processes and reviews (Bartlett et al., 2004). On the other hand, interviews are often used for risk identification sessions when it is not possible to make the working team meet together. They are usually conducted into a confidential environment, where the interviewee is encouraged to express his idea honestly and without fear of reprisal or blame.

2. Process mapping

In this second step of the methodology, typical project risk management tools are used to obtain a more in depth definition of single process activities, also including the identification of actors in charge for them. The process is divided into phases that are analysed and in turn decomposed into activities, until a satisfactory level of detail has not been reached. In order to accomplish this task effectively, the Activity Breakdown Structure (ABS) may be used. The ABS is a tree structure coming from the Work Breakdown Structure (WBS) (Project Management Institute, 2001), but it is process-oriented instead of being product-oriented. The lowest level of the ABS contains elementary process activities. However, since WBS and ABS have been developed in the context of project planning, they lack the time dimension. Therefore, this has been included in the proposed methodology by making use of process flow charts (Graham, 2004). Flow charts allow to locate activities in the lowest ABS level according to a logical-time sequence by means of priority links. In addition, activities in a flow chart may be spatially placed within a matrix structure where horizontal lanes represent different process phases and vertical lanes correspond to actors performing activities. This structure is called cross-functional flow chart (Damelio, 1996).

All the pieces of information related to single activities represented by flow charts are summed up by process sheets (Figure 2). These tables contain the following details:

- name or code of both process phase and activity at issue;
- actors performing the activity;
- inputs (information, materials, preliminary actions, orders, etc.);
- detailed description of operations required by the activity;

- duration and frequency;
- controls to monitor activity progress;
- tools necessary to perform both the activity and related controls;
- outputs (other activities, information, and data).

Take in **Fig. 2.** Process sheet

3. Risk identification and assessment

The third phase of the proposed approach moves from the understanding of the analysed process to the identification of related risks, again by using project risk management tools. First of all, risk sources are identified by using the Risk Breakdown Structure (RBS), defined as a source-oriented grouping of project risks that organizes and defines the total risk exposure of the project. Each descending level represents an increasingly detailed definition of sources of risk to the project (Hillson, 2002; Project Management Institute, 2004). In the present methodology RBS levels are determined based on the knowledge of the process at issue gained during the first two steps, Context analysis and Process mapping, and also according to the experience of the members of the working team. The number of levels should be set so that the RBS is both comprehensive, that is it includes all possible risk sources, and easy to understand and use to control risks.

A first general classification divides risk sources into internal and external ones. The risk sources in the first class may be successfully prevented and managed, whereas those in the second class are out of the process actors' control and can be treated only with assurance coverage or by avoiding them, for example by modifying activities where they may occur. Internal risk sources are of particular importance since they can be controlled. According to Roth (1993), they originate from those elements representing the foundations of a healthcare delivery system. These are related to the three processes enabling healthcare systems to transform inputs into outputs, namely clinical, management, and ancillary processes (Vissers, 1998) (Figure 3).

Take in **Fig. 3.** Roth's model (adapted from Roth, 1993)

Roth's model has been used in this work as a guide to find out the main areas of a healthcare delivery system where internal risk sources could be identified:

- *human resources*, with their various tasks, their individual knowledge and professional skills. They operate in a specific organizational structure able to plan and program the activities forming clinical processes;
- *physical and technological supports* used by resources to perform their activities. They may be either medical or related to information or plant technology;
- *communication/information*, as the basis of the relationships among resources and between them and technological supports. It plays a strategic role in managing healthcare complexity. In fact, similarly to any other complex system (Gandolfi, 1999), in the healthcare one interactions among professionals are more important than individual competencies and activities to determine the success of a clinical treatment;
- *physical structure*, with all the tools necessary to support clinical, technological, and managerial processes within a healthcare delivery system.

It can also be noticed that there is a correlation between the foundations of a healthcare delivery system and the barriers required to intercept and block adverse events according to Reason's theory. As a matter of fact, adverse events are caused by the simultaneous action of deficiencies in the different processes characterizing a healthcare delivery system. Therefore, by integrating both Roth's and Reason's theories, the barriers existing in a generic healthcare system may be classified as follows:

- O – Organization;
- T – Technology;
- C – Communication;
- S – Structure.

These represent the macro areas forming the second RBS level as far as internal risk sources are concerned (Figure 4).

Take in **Fig. 4.** RBS structure

The risk sources in the lowest RBS level are linked to the activities in the lowest ABS level by means of the Risk Breakdown Matrix (RBM) (Hillson, 2003; Hillson at al., 2006). The RBM allows for risk identification by simply putting crosses into its cells meaning that given risk sources impact on given activities.

As a further step, depending on the quantity of information elicited from experts, risk evaluation is performed by estimating probabilities of occurrence and impacts with either qualitative or quantitative scales. The first time the proposed methodology is applied to a case, available information will not be sufficient to make a quantitative risk evaluation viable. Only after iterating the present method a number of times, a healthcare organization will have developed that risk culture making possible to deepen the analysis through quantitative techniques such as reactive (after an adverse event) or proactive (before an adverse event) indicators (Körvers and Sonnemans, 2008).

The RBM gives a classification of risky events enabling to select the most critical ones, which require a more detailed analysis in order to define an adequate risk response supporting continuous improvement efforts. For this purpose, the proposed methodology integrates FMEA as a Human Reliability Assessment technique (Lyons et al., 2004) to further investigate the critical links among risk sources and activities.

4. Failure modes and waste analysis (FMEA-Waste analysis)

Even if a great number of sheet structures to support FMEA have been proposed in literature, the present methodology suggests specific FMEA tables in order to have a more effective integration among FMEA and the RBM. Such tables have been conceived with the aim of highlighting not only the ineffectiveness of a system but also its inefficiency. To this end, the study of failure modes has been enhanced by a waste analysis driven by the seven classes of waste defined by the Toyota Production System (Ohno, 1988). These sources of waste have been adapted to healthcare process analysis (Gray, 2007; Zidel, 2006) as follows:

- *Overproduction*: doing more than customer requirements. For example, a similar behaviour may be a consequence of mixing drugs in anticipation of patient needs or of hospitalizing patients when they could be given medical care at their homes.
- *Waiting times*: whenever no activity is performed, waiting for the next event happening, such as waiting for bed assignment, waiting for discharge, waiting for treatment, waiting for diagnostic tests, waiting for supplies, waiting for approval, waiting for a physician or a nurse, and long waiting times between cases in operating rooms.
- *Transportation*: moving medications, patients, and supplies without adding value to the process.

- *Overprocessing*: performing unnecessary activities leading to an inefficient use of resources, with the consequence of rising process costs. Examples of such behaviour include using high skilled resources for repetitive activities that could be performed by less trained people, employing unnecessary auxiliary staff, such as technical, catering or laundry personnel, conducting redundant tests, and subjecting patients to multiple bed moves.
- *Queues/Stock*: everything waiting for an event, thus increasing costs and taking up room, such as medical devices, drugs, and other materials bought by specific departments and stocked for a long time, patients in emergency departments waiting for hospitalization, patients waiting for undergoing diagnostic tests, and prescriptions awaiting transcription.
- *Movements*: unnecessary movements that may generate a waste of time or, in some cases, even hurt people, such as repetitive searching for documents and supplies and nurses taking care of patients at multiple hospital floors.
- *Process defects, errors, and re-work*: generally defined as activities not adding value either to the process or to patients, such as medication errors, wrong-site surgery, improper labelling of specimens, using multiple sticks for blood draws, and injuries caused by either defective drugs or patient intolerances to specific treatments.

FMEA and waste analysis are integrated into FMEA and Waste tables, which add the adverse events identified by the RBM to the process sheets developed in the second phase of the methodology.

Each failure mode associated with an activity is characterized in FMEA tables by the following pieces of information (Figure 5):

- failure mode code;
- failure mode description;
- risk sources, classified into internal and external ones, as discussed in the third step of the proposed methodology;
- description of causes determining the failure;
- effects;
- most effective methods to detect the failure;
- suggested improvement actions and degree of success of already taken measures.

Take in **Fig. 5.** FMEA table

It is important to observe that causes determining failures can also be other failure modes. In this context, the 5 Whys method may be applied (Zidel, 2006). This is an approach enabling to explore cause and effect relationships by asking five questions, in order to determine the root causes of a failure mode. When multiple failure modes need to be considered to define patients' exposure to risks, our methodology links them through the logical AND operator. Also, failure mode effects are classified into immediate and final ones. The first ones include all those effects impacting on the analysed organization, thus increasing costs and waste, but not affecting patients. The second ones are those impacting on patients, both directly and indirectly through correlation with other failure modes.

Waste tables (Figure 6) rely on six of the healthcare sources of waste defined based on the Toyota Production System principles: overproduction, waiting times, transportation, overprocessing, queues/stock, and movements. The seventh source of waste, process defects, errors, and re-work, concerns all those situations in which the occurring of failure modes may cause an activity to be performed again, with consequent greater cycle times and costs. This kind of waste is not considered by Waste tables since it is already extensively analysed among failure modes in FMEA tables.

As for failure modes, sources of waste may be classified into internal (related to organization, technology, communication, and structure) and external ones.

Take in **Fig. 6.** Waste table

Finally, both FMEA and Waste tables detail people in charge of detecting failure modes and waste and possible improvement actions. In addition, both the tables allow to keep trace of the success of corrective actions already undertaken. This because FMEA and waste analysis are not static approaches to be performed only once, but, on the contrary, they are recursive processes to be applied overtime to constantly monitor how system outcomes react to both internal strategies and external inputs.

5. Applying the Methodology to a Hospital Pharmacy Department

In order to exemplify how the developed methodology should be used to analyse healthcare processes, its application to the drug management process at a hospital pharmacy department is detailed.

This case was selected since drug and other material management is one of the most cross-functional processes taking place in a hospital. In fact, it involves many activities performed by different departments, including central pharmacy and operating rooms, starting from when materials are sourced from suppliers until they are employed to deliver care to patients. As a consequence, effectiveness and efficiency are strongly influenced by the way such process is globally managed. Some authors proved that logistics and sourcing costs represent a big portion of the total costs for a hospital (Linch, 1991). Moreover, adverse events due to incorrect drug administration (Adverse Drug Events) are common causes for injury among hospitalized patients and may be originated by any part of the drug management process (Cohen, 2007). Thus, we chose to analyse the logistics process of a pharmacy department since adverse events taking place downstream in the drug management process may find their root causes within this converging point for materials in a hospital.

The present case study focuses on a 1,372 bed teaching hospital located in Torino (Italy). This is the oldest operating hospital in town, and the largest in Piedmont Region of Italy, spread over 142,000 square meters, 14 clinical departments, and 5,822 employees, with 1,030 physicians and 2,063 nurses among them (Cagliano et al., 2009). Also, this is one of the most complex hospitals in Italy as far as organizational flows are concerned. To be more precise, the application of the proposed clinical risk management approach was aimed to study central pharmacy's drug supply to the hospital wards, with the purpose of identifying possible sources of risk for patients and understanding failure modes and waste, thus stimulating an improvement in the overall level of service.

1. Context analysis

First of all, the working team in charge of analysing the logistics process of the Pharmacy Department was formed. It included both the authors and hospital representatives.

Expert knowledge elicitation was performed by interviewing pharmacists and logistics managers. Gathered information, as well as provided documentation, allowed to analyse all the procedures currently in place for the portion of drug process managed by the Pharmacy.

In addition, operational activities were directly observed. In this phase the working team was able to uncover the main issues that were deepened by the later steps of the methodology.

2. Process mapping

The ABS and the flow charts describing both operational and informational flows revealed three phases in the investigated process. First, after physicians prescribe therapies, floor personnel in charge of material management requests necessary drugs and medical devices to the Pharmacy Department mainly thorough a computerized procedure (Material Request Issue by Floors). Second, in the Pharmacy Department, after approval by the chief pharmacist, requested materials are picked from shelves and placed into baskets to be delivered to floors by means of trolleys. In a similar way, orders are placed to suppliers after validation by the chief pharmacist. Incoming products are inspected to check their compliance with orders (Pharmacy Request and Material Management). Third, before leaving the Pharmacy Department, outgoing packages are checked by pharmacists, afterwards they reach the destination wards together with a copy of the order, and finally the material receipt confirmation is signed by ward personnel and filed in the Pharmacy Department (Material Request Fulfilment).

Phases were in turn decomposed into activities to form an ABS (Figure 7). We decided to develop process sheets only for critical activities (see the application of the fourth phase of the methodology).

Take in **Fig. 7.** ABS for drug management process

3. Risk identification and assessment

The previous phases of the methodology served as a basis to identify risks related to the process under consideration, particularly by combining the information gathered during Context analysis and Process mapping with the experience of the working team components about both risk and healthcare process management.

In such a way, sources of risk were identified and classified according to a RBS. This structure was then intersected with elementary activities in the ABS to give the RBM for the drug management process at the Pharmacy Department. Developed RBS and RBM are presented in Figure 8 and Figure 9 respectively.

Take in **Fig. 8.** RBS for drug management process

Take in **Fig. 9.a.** RBM for drug management process (part 1)

Take in **Fig. 9.b.** RBM for drug management process (part 2)

Take in **Fig. 9.c.** RBM for drug management process (part 3)

A first correlation between sources of risk and elementary activities was established by putting crosses in the corresponding RBM cells. The limited information available to the working team in this first application of the methodology did not allow to quantify risks by evaluating their probabilities of occurrence and their impacts on activities. However, the fourth step of the methodology may be applied also with a qualitative risk evaluation.

4. Failure modes and waste analysis (FMEA-Waste analysis)

The analysis of the RBM and further interviews to the Pharmacy management revealed that 8 out of the 22 identified elementary activities may be considered critical so that it is worth investigating them by means of FMEA and Waste tables. They are namely Computerized Material Request Creation, Material Request Check and Validation, List Fulfilment & Material Picking, Material Packing, Material Storing, Outgoing Package Sample Quality Inspection, Material Delivery to Floors, and Product Transaction Registration.

First, failure modes (FM) and kinds of waste (W) impacting critical activities were numbered according to the following notation: FM1, FM2,..., W1, W2,... After that, they were put in the corresponding RBM rows, under the sources of risk generating them (Figure 9). A same failure mode or kind of waste may appear multiple times in a RBM row if it may affect an activity as a consequence of more than one source of risk.

The description of the application of the fourth step of the proposed methodology to the case will focus on List Fulfilment & Material Picking. Several failure modes and kinds of waste were defined for this activity.

Figure 10 and Figure 11 show the process sheet and the FMEA table for List Fulfilment & Material Picking activity. As far as the effects of failure modes are concerned, the symbol X means that the failure mode at issue has some kind of effect, whereas the logical AND operator indicates that a failure mode, together with other failure modes, has a final effect on patients. Following the discussion of some of the identified failure modes. First of all, the misunderstanding of units expressing the quantities of materials wards order to the Pharmacy

Department is due to the fact that relevant information is often communicated verbally, and double-checking is sometimes impossible because of the heavy workloads to which resources working in this hospital department are subjected. The effects may be both immediate and final. As an improvement action, two different pharmacy operators should always double-check units. Moreover, the picking of the wrong items to be delivered to floors is given by both technological and organizational issues. These may include the wrong identification of either warehouse location or package to be picked. Also this failure mode may have both immediate and final effects according to the risk source generating it, and can be prevented by the use of optical barcode reading. Finally, loosing picking lists is determined by organizational issues, such as the high number of picking lists received by the Pharmacy Department every day. Related effects do not affect patients but process time and costs, since they imply that picking lists are prepared again. As a consequence, improvement actions having picking lists follow a precise path within the Pharmacy Department are highly recommended.

Take in **Fig. 10.** Process sheet for List Fulfilment & Material Picking

Take in **Fig. 11.** FMEA table for List Fulfilment & Material Picking

The analysis of List Fulfilment & Material Picking activity revealed the following kind of waste: useless motions by pharmacy operators (Figure 12). It is determined by both organizational issues (e.g. poor coordination among workers) and technological ones (e.g. wrong picking lists). The effect is the same: operators do not follow optimized paths, thus taking longer to pick items, with the risk of getting in one another's way. As a solution, it is suggested to have a pharmacist, or another professional figure, monitor picking paths.
It can be observed that for this activity, as well as for the other ones being analyzed, the number of failure modes is far greater than the number of kinds of waste. As a matter of fact, many potential sources of waste are related to the class 'Process defects, errors, and re-work', which, as explained before, is addressed by FMEA tables. Therefore, they are considered as failure modes. It is the case of loosing picking lists, which asks for additional operational activities such as reintegrating the stock of products that have been wrongly picked and delivering the correct materials to floors.

Take in **Fig. 12.** Waste table for List Fulfilment & Material Picking

6. Discussion

Based on the results of its application to the drug management process at a hospital pharmacy, strengths and weaknesses of the developed approach to clinical risk management are here discussed.

First of all, the systemic feature of the suggested methodology is assured by the adoption of the RBM. The RBM frames all risk sources into the specific activities characterizing the process at issue. Furthermore, it gives a global view of criticalities, making it easy to define correlations among different failure modes in order to trace at the root all the determinants of adverse events. This is crucial in healthcare since the occurring of an adverse event that may hurt hospitalized patients is often linked to multiple interrelated failure modes giving rise to a failure mode chain. For example, in the drug management process, the administration of a wrong medicine may be due to a picking error by the pharmacy operator that has not been detected before the drug arrives at the patient's bed (Hollnagel, 2004). The systemic perspective of the RBM enhances the effectiveness of FMEA because it supports a more comprehensive understanding of the relationships between causes and effects of failure modes. Furthermore, the RBM provides not only a systemic but also a schematic representation of criticalities, thus making the proposed methodology a valid communication tool for organizational members.

In addition, the methodology revealed to be extremely flexible since it is able to work at different levels of detail according to the specific case and the information available.

In the developed clinical risk management approach, first process criticalities are identified by means of a reactive analysis based on past adverse events. Usually, such events have not been recorded, thus expert knowledge elicitation is used to encourage the emergence of process actors' experience about inefficiencies and ineffectiveness. As a further step, thanks to the mapping of the discrepancies in the system barriers (failure modes and kinds of waste), the RBM methodology, integrated with FMEA and waste analysis, is able to make operators aware of both risks and waste existing in a healthcare process. Therefore, in a sense, the proposed methodology also constitutes a valid tool for stimulating a structured analysis of criticalities, which is absolutely important in a highly human based context like the healthcare one.

Moreover, the present framework could support decision makers in setting correct priority areas for intervention and may be a part of Health Technology Assessment programs. This is guaranteed by the identification of improvement actions in the last step of the method.

Finally, the developed clinical risk management method may be applied overtime to review the effectiveness of the implementation of corrective actions to limit risks and waste. To this end, the RBM and FMEA and Waste tables will be updated, and, if necessary, new corrective actions will be developed and adopted. As a consequence, the RBM and FMEA and Waste tables also prove to be useful means of communication among people involved in the improvement process.

The implementation of the methodology in the case hospital revealed great difficulty in gathering all the pieces of information necessary to fully apply the four steps, due to a scarce aptitude for risk management and, as a consequence, for supporting such a comprehensive organizational analysis by both personnel and informational systems. As a matter of fact, this first application to the logistics process of a pharmacy department was limited to risk identification, without performing any quantitative evaluations. To this end, it stimulated an increase in the level of maturity towards risk of the studied organization, thus enabling future deeper analyses.

Overall, the application of the proposed methodology may serve as a first step towards a deeper understanding of risk and waste in healthcare processes and the definition of the most appropriate measures to reduce them. It may be the foundation of a quantitative risk evaluation by numerically determining the probabilities of occurrence of risks as well as their impacts on process activities.

However, in order to prove the full benefits and limitations of the suggested approach and understand if it requires further conceptual refinements, an extensive application to a variety of healthcare settings is needed.

The flexibility of our methodology potentially allows the integration with risk management approaches already established in the healthcare sector, such as for instance Fault Tree Analysis (FTA), Hazard and Operability Study (HAZOP), and Incident Reporting (Armitage et al., 2007; Lyons, 2009). These techniques may work at the level of single RBM cells by performing either qualitative (e.g. HAZOP, Incident Reporting) or quantitative analyses (e.g. Montecarlo simulation), according to the availability of data and the degree of organizational maturity towards risk management. Also, multiple RBM cells may be considered in order to understand the root causes of a failure mode or of a kind of waste. FTA could be applied for this purpose, since it is not limited to the investigation of a single system but usually crosses system boundaries. To be more precise, FTA would break down the top event to find out the parallel and sequential combinations of basic faults responsible for it. To this end, the use of logical operators to link failure modes in FMEA tables is a first attempt to correlate different

risky events. Moreover, the role that Key Performance Indicators (KPIs) could have in the approach as pre-warning signals anticipating the occurrence of adverse events should be investigated. In particular, RBM cells could be associated with proper metrics able to capture the impact of the symptoms of a risk source manifestation on the performance of a given activity.

Although combing the mentioned approaches with our methodology increases the knowledge about the origins of patients' exposure to risks and allows a better planning of proper countermeasures, it may require healthcare organizations additional efforts to develop new skills about the management of risk and safety. Nevertheless, we believe that this stream of research deserves future attention because it contributes to enhance the suitability of the methodology discussed in the paper for a variety of settings.

7. Summary

The growing healthcare complexity requires management approaches taking into account multiple points of view. Based on Reason's theory of failures, the paper suggests a methodology giving a systemic perspective on clinical risk by integrating existing tools coming from different fields, such as process mapping, project risk management, and quality management. Moreover, because of the human-centred nature of healthcare systems, the steps of such methodology have been developed according to Human Reliability Assessment methods.

The first application to the logistics process of a pharmacy department in a large hospital highlighted that our method can effectively support not only risk analysis, but also decision making, thus increasing organizations' maturity towards clinical risk. Future research efforts will be focused on an extensive test of the presented approach in various healthcare contexts.

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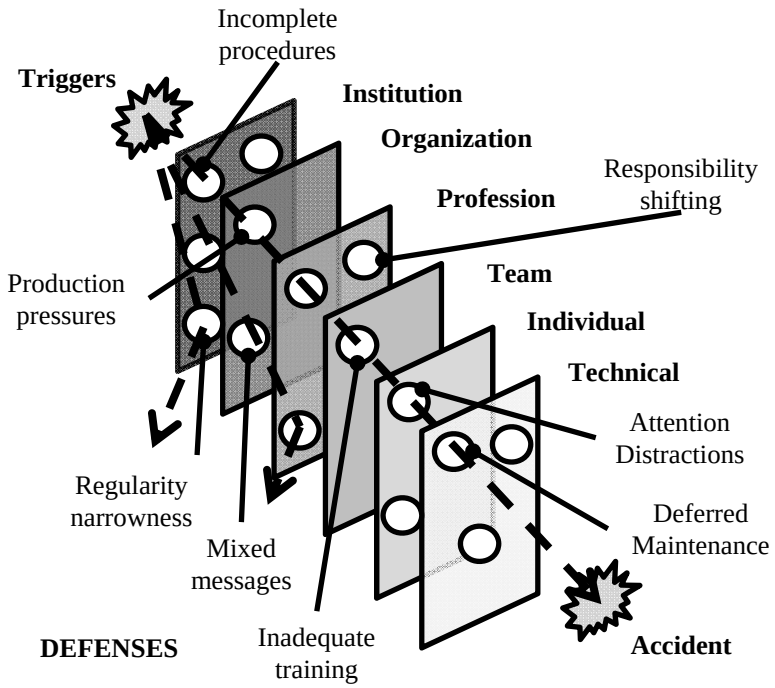
Incomplete
procedures
Triggers
Institution
Organization
Responsibility
shifting
Profession
Production
pressures
Team
Individual
Technical
Attention
Distractions
Regularity
narrowness
Deferred
Maintenance
Mixed
messages
DEFENSES
Inadequate
training
Accident

Fig. 1

PHASE	ACTIVITY	
	Process Actors	
	Inputs	
	Description	
	Duration and Frequency	
	Tests	
	Tools	
	Outputs	

Fig.2

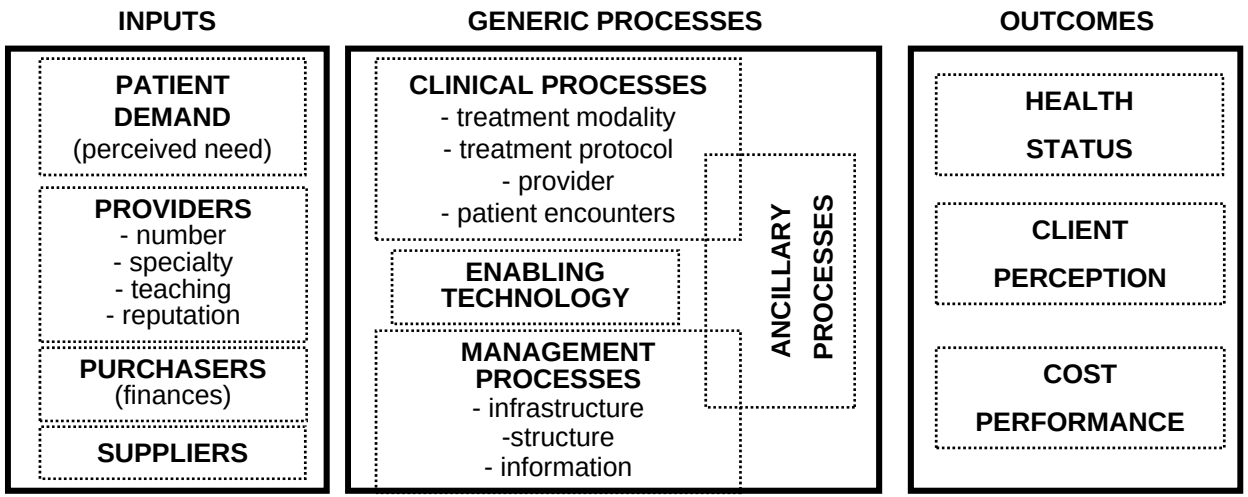
INPUTS
PATIENT DEMAND
(perceived need)
PROVIDERS
- number
- specialty
- teaching
- reputation
PURCHASERS
(finances)
SUPPLIERS
GENERIC PROCESSES
CLINICAL PROCESSES
- treatment modality
- treatment protocol
- provider
- patient encounters
ENABLING TECHNOLOGY
MANAGEMENT PROCESSES
- infrastructure
-structure
- information
ANCILLARY PROCESSES
OUTCOMES
HEALTH STATUS
CLIENT PERCEPTION
COST PERFORMANCE

Fig.3

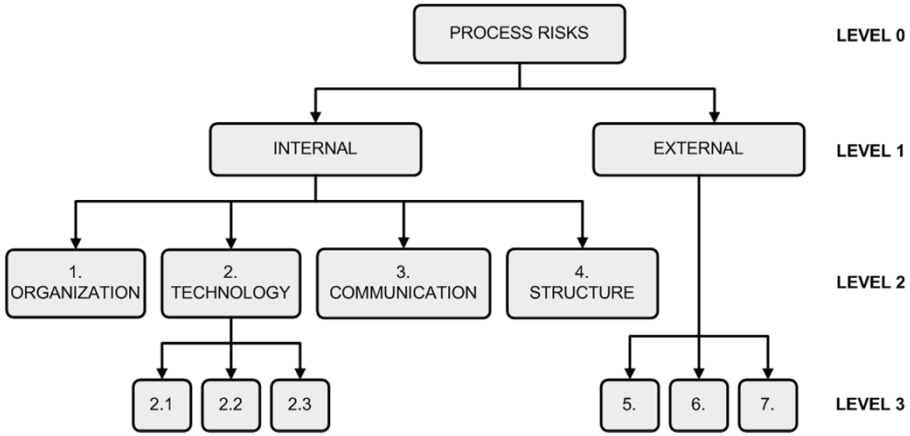
PROCESS RISKS
LEVEL 0
INTERNAL
EXTERNAL
LEVEL 1
1. ORGANIZATION
2. TECHNOLOGY
3. COMMUNICATION
4. STRUCTURE
LEVEL 2
2.1
2.2
2.3
5.
6.
7.
LEVEL 3

Fig.4

COD	FAILURE MODE DESCRIPTION	RISK SOURCES	CAUSE DESCRIPTION	EFFECTS		METHODS TO DETECT ERRORS	SUGGESTED IMPROVEMENT ACTIONS AND TAKEN MEASURES
				Immediate	Final		

Fig.5

COD	CLASSIFICATION AND DESCRIPTION OF MODES OF WASTE	SOURCES OF WASTE	DESCRIPTION OF SOURCES OF WASTE	EFFECTS OF WASTE	METHODS TO DETECT WASTE AND PEOPLE IN CHARGE OF THIS TASK	SUGGESTED IMPROVEMENT ACTIONS	TAKEN MEASURES

Fig.6

PROCESS PHASE	PROCESS ACTIVITY	
	DESCRIPTION	CODE
1. Material Request Issue by Floors	Starting the Computerized Material Request Procedure	ABS 1.1
	Computerized Material Request Creation	ABS 1.2
	Material Request Check and Validation	ABS 1.3
	Sending Material Requests to Pharmacy	ABS 1.4
2. Pharmacy Request and Material Management	Material Request Receiving	ABS 2.1
	Material Request Validation by Pharmacists	ABS 2.2
	Substituting Therapeutic Equivalents for Unavailable Products	ABS 2.3
	Defining Picking Lists	ABS 2.4
	List Fulfilment & Material Picking	ABS 2.5
	Material Packing	ABS 2.6
	Checking Reorder Levels for Products	ABS 2.7
	Receiving Incoming Materials	ABS 2.8
	Material Storing	ABS 2.9
	Incoming Material Data Entry	ABS 2.10
	Filing Incoming Material Documents	ABS 2.11
	Returning Products to Suppliers	ABS 2.12
3. Material Request Fulfilment	Preparing Trolleys for Delivery to Floors	ABS 3.1
	Outgoing Package Sample Quality Inspection	ABS 3.2
	Material Delivery to Floors	ABS 3.3
	Checking Pending Material Requests	ABS 3.4
	Material Receiving by Floors	ABS 3.5
	Product Transaction Registration	ABS 3.6

Fig.7

LEVEL 0	LEVEL 1	LEVEL 2	LEVEL 3	LEVEL 4	RBS CODE
RBS for Pharmacy Logistics Process	Internal Risk Sources	1. Organization	Organizational Structure	Planning Activities	RBS 1.1
				Planned Work Schedule	RBS 1.2
				Workload	RBS 1.3
			Human Resources	Working Procedures Knowledge and Compliance	RBS 1.4
				Training/Know How	RBS 1.5
				Availability of Personnel in Charge of Supervising Activities	RBS 1.6
				Controls	RBS 1.7
				Planned Work Schedule Knowledge and Compliance	RBS 1.8
			Operations	Determining the Kinds of Products	RBS 1.9
				Determining Product Quantity	RBS 1.10
				Computerized Procedures	RBS 1.11
				Transcription	RBS 1.12
				Stocking Products	RBS 1.13
				Moving Products	RBS 1.14
		2. Technology	Information System	Continuity of Service	RBS 2.1
				Intranet	RBS 2.2
				Data Transfer	RBS 2.3
				Data Backup and Network Records	RBS 2.4
				Managing Antivirus	RBS 2.5
			Equipment	Handling Systems	RBS 2.6
				Revolving Shelves	RBS 2.7
				Elevators	RBS 2.8
				Computers and Palmtops	RBS 2.9
				Boxes for Delivering Products	RBS 2.10
		3. Communication	Information Exchanges	Information Exchanges According to Procedures	RBS 3.1
				Variations in Quantity	RBS 3.2
				Variations in Quality	RBS 3.3
			Communicating Variations and Decisions	Communicating Variations	RBS 3.4
				Feedback	RBS 3.5
				Decision Making	RBS 3.6
		4. Structure	Layout	Ordinary Maintenance Plans	RBS 4.1
				Extraordinary Maintenance Plans	RBS 4.2
				Workplace Safety	RBS 4.3
			Networks	Service Interruptions	RBS 4.4
				Service Continuity	RBS 4.5
	External Risk Sources	5. Product Supplying	Delivery Lead Times		RBS 5.1
			Delivery Points		RBS 5.2
			Quality of Delivered Products		RBS 5.3
			Documentation Management		RBS 5.4
			Delivered Items		RBS 5.5
		6. Finance	Supplier Assets		RBS 6.1
			Contract Specifications		RBS 6.2
		7. Environment	Guidelines by Regional Council		RBS 7.1
			Social Issues		RBS 7.2
			Epidemiological Events		RBS 7.3
			Natural Events		RBS 7.4

Fig.8

PROCESS PHASE	PROCESS ACTIVITY		RBS FOR PHARMACY LOGISTICS PROCESS													
			ORGANIZATION													
			Organizational Structure			Human Resources					Operations					
	CODE	DESCRIPTION	Planning Activities	Planned Work Schedule	Workload	Working Procedures Knowledge and Compliance	Training/ Know How	Availability of Personnel in Charge of Supervising Activities	Controls	Planned Work Schedule Knowledge and Compliance	Determining the Kinds of Products	Determining Product Quantity	Computerized Procedures	Transcription	Stocking Products	Moving Products
			RBS1.1	**RBS1.2**	**RBS1.3**	**RBS1.4**	**RBS1.5**	**RBS1.6**	**RBS1.7**	**RBS1.8**	**RBS1.9**	**RBS1.10**	**RBS1.11**	**RBS1.12**	**RBS1.13**	**RBS1.14**
Material Request Issue by Floors	ABS1.1	Starting the Computerized Material Request Procedure				x		x					x			
	ABS1.2	Computerized Material Request Creation				FM1	FM1				W1	W1				
	ABS1.3	Material Request Check and Validation				W1	x	W1	FM1; W1		W1	x	FM1			
	ABS1.4	Sending Material Requests to Pharmacy		x		x		x	x	x			x			
Pharmacy Request and Material Management	ABS2.1	Material Request Receiving						x			x		x	x		
	ABS2.2	Material Request Validation by Pharmacists		x			x	x	x		x	x	x			
	ABS2.3	Substituting Therapeutic Equivalents for Unavailable Products					x	x			x	x	x			
	ABS2.4	Defining Picking Lists				x	x	x					x			
	ABS2.5	List Fulfilment & Material Picking	W1	W1	W1		FM4; FM6	FM7	FM4	W1					FM2	
	ABS2.6	Material Packaging	W1	W1	W1		FM2	FM4	FM1	W1		FM1				
	ABS2.7	Checking Reorder Levels for Products	x			x	x	x	x		x	x				
	ABS2.8	Receiving Incoming Materials	x	x	x	x	x	x	x	x		x				x
	ABS2.9	Material Storing	FM1		FM1	FM2	FM1; FM2;FM 3		FM2			FM2			FM2	
	ABS2.10	Incoming Material Data Entry					x	x					x	x		
	ABS2.11	Filing Incoming Material Documents					x	x								
	ABS2.12	Returning Products to Suppliers		x			x	x	x	x						
Material Request Fulfilment	ABS3.1	Preparing Trolleys for Delivery to Floors		x	x		x	x		x					x	
	ABS3.2	Outgoing Package Sample Quality Inspection						FM2	FM2		FM2	FM2				
	ABS3.3	Material Delivery to Floors		FM4;W1				FM2		FM2						FM5
	ABS3.4	Checking Pending Material Requests						x	x				x			
	ABS3.5	Material Receiving by Floors		x				x	x	x						
	ABS3.6	Product Transaction Registration						x	FM1							

Fig.9a

PROCESS PHASE	PROCESS ACTIVITY		RBS FOR PHARMACY LOGISTICS PROCESS															
			TECHNOLOGY										COMMUNICATION					
			Information System					Equipment					Information Exchanges			Communicating Variations and Decisions		
	CODE	DESCRIPTION	Continuity of Service	Intranet	Data Transfer	Data Backup and Network Records	Managing Antivirus	Handling Systems	Revolving Shelves	Elevators	Computers and Palmtops	Boxes for Delivering Products	Information Exchanges According to Procedures	Variations in Quantity	Variations in Quality	Communicating Variations	Feedback	Decision Making
			RBS2.1	RBS2.2	RBS2.3	RBS2.4	RBS2.5	RBS2.6	RBS2.7	RBS2.8	RBS2.9	RBS2.10	RBS3.1	RBS3.2	RBS3.3	RBS3.4	RBS3.5	RBS3.6
Material Request Issue by Floors	ABS1.1	Starting the Computerized Material Request Procedure		x							x							
	ABS1.2	Computerized Material Request Creation	W1	x		x	FM1				x							
	ABS1.3	Material Request Check and Validation		x		x	x				x		FM1; FM2	x	x	W1	x	x
	ABS1.4	Sending Material Requests to Pharmacy		x	x	x	x				x							
Pharmacy Request and Material Management	ABS2.1	Material Request Receiving	x	x			x				x							
	ABS2.2	Material Request Validation by Pharmacists		x		x							x	x	x	x	x	x
	ABS2.3	Substituting Therapeutic Equivalents for Unavailable Products											x	x	x	x	x	x
	ABS2.4	Defining Picking Lists	x			x					x							
	ABS2.5	List Fulfilment & Material Picking							FM2; FM6				FM1; FM3				FM1; FM5	
	ABS2.6	Material Packaging											FM3					
	ABS2.7	Checking Reorder Levels for Products	x	x									x				x	x
	ABS2.8	Receiving Incoming Materials						x								x	x	
	ABS2.9	Material Storing						FM3										
	ABS2.10	Incoming Material Data Entry	x	x	x	x												
	ABS2.11	Filing Incoming Material Documents																
	ABS2.12	Returning Products to Suppliers						x										
Material Request Fulfilment	ABS3.1	Preparing Trolleys for Delivery to Floors						x				x						
	ABS3.2	Outgoing Package Sample Quality Inspection																FM1
	ABS3.3	Material Delivery to Floors						FM1		x		FM3						
	ABS3.4	Checking Pending Material Requests		x													x	
	ABS3.5	Material Receiving by Floors						x				x						
	ABS3.6	Product Transaction Registration	FM2		FM3	FM3					FM2;FM3							

Fig.9b

PROCESS PHASE	PROCESS ACTIVITY		RBS FOR PHARMACY LOGISTICS PROCESS															
			STRUCTURE					EXTERNAL RISK SOURCES										
			Layout			Networks		Product Supplying					Finance		Environment			
	CODE	DESCRIPTION	Ordinary Maintenance Plans	Extraordinary Maintenance Plans	Workplace Safety	Service Interruptions	Service Continuity	Delivery Lead Times	Delivery Points	Quality of Delivered Products	Documentation Management	Delivered Items	Supplier Assets	Contract Specifications	Guidelines by Regional Council	Social Issues	Epidemiological Events	Natural Events
			RBS4.1	RBS4.2	RBS4.3	RBS4.4	RBS4.5	RBS5.1	RBS5.2	RBS5.3	RBS5.4	RBS5.5	RBS5.6	RBS5.7	RBS5.8	RBS5.9	RBS5.10	RBS5.11
Material Request Issue by Floors	ABS1.1	Starting the Computerized Material Request Procedure	x	x		x	x											
	ABS1.2	Computerized Material Request Creation	x	x		x	x											
	ABS1.3	Material Request Check and Validation	x	x		x	x											
	ABS1.4	Sending Material Requests to Pharmacy	x	x		x	x										x	
Pharmacy Request and Material Management	ABS2.1	Material Request Receiving				x	x											
	ABS2.2	Material Request Validation by Pharmacists				x	x										x	
	ABS2.3	Substituting Therapeutic Equivalents for Unavailable Products													x		x	x
	ABS2.4	Defining Picking Lists				x	x											
	ABS2.5	List Fulfilment & Material Picking	FM6															
	ABS2.6	Material Packaging													x			x
	ABS2.7	Checking Reorder Levels for Products															x	
	ABS2.8	Receiving Incoming Materials			x			x	x	x	x	x	x	x		x		x
	ABS2.9	Material Storing	FM3		FM3										FM2			x
	ABS2.10	Incoming Material Data Entry				x	x				x	x						
	ABS2.11	Filing Incoming Material Documents																
	ABS2.12	Returning Products to Suppliers									x	x	x	x				
Material Request Fulfilment	ABS3.1	Preparing Trolleys for Delivery to Floors																
	ABS3.2	Outgoing Package Sample Quality Inspection																
	ABS3.3	Material Delivery to Floors	FM1			FM1											x	x
	ABS3.4	Checking Pending Material Requests																
	ABS3.5	Material Receiving by Floors																
	ABS3.6	Product Transaction Registration				FM3	FM2											

Fig.9c

PHASE	ACTIVITY *2.5 List Fulfilment & Material Picking*	
2. Pharmacy Request and Material Management	Process Actors	Warehouse personnel
	Inputs	Picking lists (both computer and paper based)
	Description	Warehouse personnel prepare materials requested by floors according to picking lists. This task is performed by following a logistics path allowing optimizing the sequence of picking operations
	Duration and Frequency	According to the defined schedule
	Tests	Matching between requested quantities and delivered ones.
	Tools	Revolving shelves Forklifts
	Outputs	Material Packing

Fig.10

COD	FAILURE MODE DESCRIPTION	RISK SOURCES	CAUSE DESCRIPTION	EFFECTS		METHODS TO DETECT ERRORS	SUGGESTED IMPROVEMENT ACTIONS AND TAKEN MEASURES
				Immediate	Final		
FM1	Misunderstanding of units expressing requested quantities	C	Verbal communication only	X	AND	Floor personnel	Two different pharmacy operators should always double-check units
			Lack of both verbal and written communication	X	AND	Floor personnel	Two different pharmacy operators should always double-check units
			Scarce communication among Pharmacy warehouse personnel	X	AND	Floor personnel	
FM2	Picking of the wrong items to be delivered to floors	T	Wrong identification of warehouse location	X	---	Floor personnel/visual check	
		O	Products difficult to be identified (e.g. similar packages; same packages, but different dosage)	---	AND	Floor personnel	Use of optical barcode reading
FM3	Documentation not updated according to changes in quantities requested by floors.	C	No communication about changes in quantities requested by floors	X	---	Administrative control	
FM4	Lack of controls on the matching between requested and delivered quantities	O	Unavailability of personnel in charge of controlling	X	AND	Pharmacy warehouse personnel	
			Lack of staff training	X	---	Pharmacy warehouse manager	Training courses. Having operators be supported by qualified personnel.
FM5	Loosing picking lists	O	High number of picking lists received by the Pharmacy Department every day	X	---	Pharmacy warehouse personnel	Having picking lists follow a precise path within the Pharmacy Department
			Confusion	X	---		
FM6	Machine breakdowns	T	Inadequate maintenance service	X	---	Maintenance plans	Careful ordinary maintenance plans
			Unwary operations	X	---	Pharmacy warehouse manager	Training warehouse personnel to deal with machine breakdowns effectively
			Inadequate staff training	X	---	Pharmacy warehouse manager	Training warehouse personnel to deal with machine breakdowns effectively
FM7	Staff unavailability	O	Unexpected absences	X	---		

Fig.11

COD	CLASSIFICATION AND DESCRIPTION OF MODES OF WASTE	SOURCES OF WASTE	DESCRIPTION OF SOURCES OF WASTE	EFFECTS OF WASTE	METHODS TO DETECT WASTE AND PEOPLE IN CHARGE OF THIS TASK	SUGGESTED IMPROVEMENT ACTIONS	TAKEN MEASURES
W1	Useless motions by pharmacy operators	O	Poor coordination among warehouse personnel	Not optimized picking paths. Inadequate task assignment	Pharmacy warehouse personnel. Pharmacists	Having a pharmacist, or another professional figure, monitor both picking paths and task assignment	
		T	Wrong picking lists	Not optimized picking paths, thus operators take longer to pick items	Pharmacy warehouse personnel. Pharmacists	Having a pharmacist, or another professional figure, monitor picking paths	

Fig.12