Nursing Informatics 2014
K. Saranto et al. (Eds.)

doi:10.3233/978-1-61499-415-2-203

An Integrated Approach to Safety-driven and ICT-enabled Process Reengineering: Methodological Advice and a Case Study

M. LANGER[a1], R. CASTELLARI[a], P. LOCATELLI[b], E. SINI[c], M. TORRESANI[a], R. FACCHINI[b] and R. MOSER[b]
[a] *Fondazione IRCCS Istituto Nazionale dei Tumori di Milano, Italy*
[b] *Fondazione Politecnico di Milano, Italy*
[c] *IRCCS Istituto Clinico Humanitas di Rozzano, Italy*

Abstract. Patient safety is a central concern inside any healthcare environment. With the progress of Information and Communication Technologies (ICTs), new solutions have become available to support care and management processes. Analyzing process risks helps identifying areas of improvement and provides ICT-solutions design with indications on what portions of the process need primary interventions. Understanding the link between process reengineering, technology assessment of enabling technologies and risk management allows user acceptance and patient safety improvements. Fondazione IRCCS Istituto Nazionale dei Tumori (INT), offers a good example of process reengineering driven by the purpose of increasing patient safety, enabled by new technologies. A pillar of the evolution of ICT process support at INT is based on Radio Frequency Identification technologies, implemented to identify and trace items and people across processes. This paper will present an integrated approach, based on process reengineering methodologies and risk assessment studies, and methodological advice applied to a case of surgical kits management procedures.

Keywords. Surgical kit, patient safety, risk management, eHealth, traceability, RFId, AIDC, H-FMEA.

Introduction

Growing interest in safety culture has been accompanied by the need for assessment tools focused on patient safety improvement [1]. Aiming to constantly increase patient safety, a deep understanding of both clinical processes and new technologies is essential. In fact, literature shows how – especially in healthcare - most of the threats to patient safety are process-related, rather than clinical [2]. As a result, any instance of healthcare process reengineering has to be carefully planned, by evaluating implications *ex ante*. Process redesign and change implementation, often seen as the most important parts of any reengineering intervention, should only occur after a careful risk analysis, meant to inspect *as is* and *to be* scenarios [3]. Information provided by risk analysis becomes a valuable resource whenever the planned intervention focuses on the introduction of new ICT tools, exploiting their potential for

[1] Corresponding Author. Email: roberta.facchini@fondazione.polimi.it

quality and safety improvement, as well as cost reduction and service innovation [4]. Nonetheless, every innovation has to be adequately designed and developed, assessing the impact on processes and working practices: systematic reviews on the state of the art of ICT in healthcare show how the beneficial impact of most eHealth technologies is absent or, at best, modest [5], because of an incoherent approach to change planning and execution. This highlights the need for proper methodologies to form a solid work base for redesign and development.

1. Methods: Integrated Clinical Process Redesign

In recent years, the world of healthcare has been significantly influenced by the introduction of new ICT tools, solutions and support systems. A broad and continuative research initiative promoted from 2007 by the Politecnico di Milano School of Management, i.e. the "ICT in Healthcare" Observatory (IHCO), shows how, in 2012, more than 1.2 billion Euros have been assigned to innovation projects and digital management by Italian healthcare organizations [6]. The growing bond between ICT and healthcare is realized through innovation projects and technological solutions that directly improve patient safety and are carried on with great care for clinical risk management and through business process reengineering practices. This allows new solutions to not only improve processes by reducing existing risks, but also to prevent new hazards for patients and personnel. Therefore, any efficient clinical process reengineering focusing on patient safety can be divided into four primary aspects:

- Process reengineering. The theoretical Business Process Reengineering (BPR) framework is a structured approach for organizations transitioning from a current state to a desired scenario [7]. More specifically, it is a rethinking and redesign of business processes to achieve defined improvements in critical measures of performance such as costs, quality, service and responsiveness [8].
- Risk analysis. Many different risk analysis methodologies have been developed and perfected over the last decades. Out of the existing models, Failure Modes and Effects Analysis (FMEA) has become one of the most prominent and well-known risk management models [9], although many other risk analysis methodologies [10] have been developed to increase process safety (FMECA, H-FMEA, PRA, …).
- ICT enabling technology assessment. Clinical process evolution and improvement involves development and implementation of mature ICT tools supporting information management and process traceability. Some examples include Mobile&Wireless tools supporting healthcare and technical operations in mobility, delivering information and operation support directly at point of care, and ensuring traceability and robust identification of people and items throughout the process (Automatic Identification and Data Capture) [11].
- Change management and training. The value of proposed and planned change needs to be explained to staff in terms of patient safety, worker safeguard, information availability, to raise commitment and acceptance of change.

Process risk analysis before and after process reengineering generates a strong link between the four aforementioned aspects: the implementation of ICT solutions requires business process reengineering, which has to be supported with information provided by a risk analysis regarding the process itself. Risk management tools can support

business process innovation by locating areas and aspects of the organizations where innovation is more needed or appears promising. By choosing the most suitable risk analysis methodology and modelling processes according to the required depth of analysis, this preliminary step can support the whole redesign process with a constant look on the intervention's outcome. Finally, keeping track of all risk analysis performed grants a clear vision of the results of the intervention, underlining differences and benefits from *as is* reality and *to be* target. Following chapters present a case study related to surgical kits management, highlighting the use of risk management tools within a redesign process as a resource to gather information.

2. Application: a Case Study

Founded in 1925, Fondazione IRCCS Istituto Nazionale dei Tumori in Milan, Italy (below INT) is regarded as a top Scientific Research and Treatment Institution in Oncology. In recent years INT has been introducing innovative ICT solutions to boost efficiency, traceability and quality of processes such as transfusion, therapy management, tissue banking and stem cell treatments. INT is working on these issues with an integrated view based on key levers: processes, organization and skills, technologies. At the same time, internal workgroups and external experts, such as Fondazione Politecnico di Milano (a research institution connected to the Technical University of Milan), study issues related to clinical risk management using different assessment methodologies. Among these, "ITACO – Identification and Traceability in Surgical Area within Hospital" is a project funded by the Regional Governments of Lombardy and Sardinia to explore current ICTs support to the Operating Theatre in order to increase patient safety. Essentially, process innovation goals are: improving productivity and efficiency while constantly maintaining high quality of care.

The project's main objective is to design new procedures and a coherent ICT framework for tracking medical tools. The project involves two technology partners and IRCCS Istituto Clinico Humanitas in Rozzano, a general hospital accredited by the National Health Service for outpatient and hospitalization near Milan, acting as a test bed for the framework and the ICT solution to be developed within the project.

As part of the project, research has been conducted in order to identify, evaluate and select the most proper risk analysis methodology. Given the importance of risk analysis, this choice was a crucial part of the whole redesign process adopted by INT in the project. The study compared different risk management models and evaluated specific characteristics of the application context, focusing on informative needs typical of business process reengineering. *Healthcare Failure Modes and Effects Analysis* (H-FMEA) [10] offers users analytical tools allowing the proactive identification and management of vulnerabilities in a healthcare system [12, 13]. H-FMEA offers a good starting point for a careful analysis inside risky processes in the healthcare environment, allowing both qualitative and quantitative analysis in order to approach process modelling with versatile and broad-spectrum perspectives. Every identified failure mode is associated with a Hazard Score that includes information regarding severity of effects and probability of occurrence of every error. Hazard Scores help comparing and prioritizing errors and consequently planning redesign interventions: the level of detail can be adjusted depending on the process needs.

The process of planning and managing surgical interventions and kit regeneration involves many different operators and includes a wide variety of operations and

procedures. The preparation of the intervention should ensure maximum concentration of efforts on the patient inside the Operating Theatre. Surgical intervention marks the most critical part of the entire process, as every good practice and correct process execution contributes to both clinical outcome and increased patient safety. Once the intervention has been completed, surgical kits are moved to the regeneration area, where tools are washed, cleaned and sterilized. The organizational redesign and new solution implementation have been supported by a holistic H-FMEA risk analysis, whose objectives include the *ex-ante* identification of risks and the *ex-post* evaluation of all benefits the solution is introducing and its impact on the process risk profile.

3. Results: Process Risk Analysis and ICT-enabled Solution Design

With the need to probe the process and identify dangerous events, the analysis team has modelled activities and operations and interviewed doctors, nurses and technicians working in INT. Analyzing risk profiles of every surgical kits management phase, fifty-two potential errors have been identified and ranked by Severity of consequences and Probability of occurrence. Clustering errors by origin, effects and types, seventeen Failure Modes (FM) have been identified as the most significant error types affecting the process. The resulting clusters and cumulated Hazard Scores are shown in Table 1. This helped identifying riskier areas where an intervention is more needed.

Table 1. Clustered failure modes in the surgical kits management process (Method: H-FMEA).

#	Failure Mode	Hazard Score
1	Inefficient resource dimensioning in planning	14
2	Inefficient information management	10
3	Inefficient surgical kits planning	10
4	Incorrect cart loading	4
5	Surgical kits corruption	9
6	Incorrect surgical kit withdrawal	2
7	Incorrect damaged / broken tool management	8
8	Incorrect surgical kits and tools sorting	12
9	Incorrect kits carriage and decontamination	14
10	Incorrect tools washing	21
11	Incorrect surgical kits and tools identification	39
12	Incorrect washing cycle management	17
13	Incorrect surgical kits reassembly	19
14	Incorrect packaging	9
15	Insufficient personnel	4
16	Incorrect sterilization cycle management	28
17	Incorrect sterilization conservation	4

Out of all considerations, a few elements of interest have immediately been noted:

- Instruments identification shows the highest exposition to risk (*Table 1* – FM No.11). The wide range of manual operations during kit regeneration and a control system based almost exclusively on good practices - not supported by dedicated tools - produces a high-risk profile.

- The sterilization process, doesn't feature any single relevant error, but, being this the last activity in the surgical kit regeneration process, it suffers from all failure modes generated as part of previous operations (*Table 1* – FM No.16).
- While washing is almost completely automated and usually performed by dedicated machines, few instruments could potentially leave this phase in inadequate hygienic conditions (*Table 1*, FM No.10).

The analysis then focused on un-clustered errors identified during interviews. By rigidly adopting the H-FMEA methodology, the analysis team studied the most relevant among recorded errors, basing on severity of consequences and probability of occurrence. More specifically, three errors presented a Hazard Score that exceeded the relevance threshold suggested by the methodology:

- Missing identification data. Incomplete surgical kits, missing tools or incorrectly reassembled sets have to be immediately identified and, when possible, corrected, to keep process flowing at its usual rate. Fortunately, the technicians' experience and knowledge about kit composition help in quickly identify and assign instruments, although the need for a more reliable system is still strong.
- Insufficient number of surgical kits during planning. High variability of surgical operations and the impossibility of planning emergency interventions can cause staff to consider the scarcity of kits as inevitable. Experience has proven to be the best resource to manage unforeseen events or unplanned kit processing.
- Unwashed instrument. This failure mode confirmed observations from the previous analysis. A manual control procedure keeps unclean tools under control and arranges a second cleaning process in case of need.

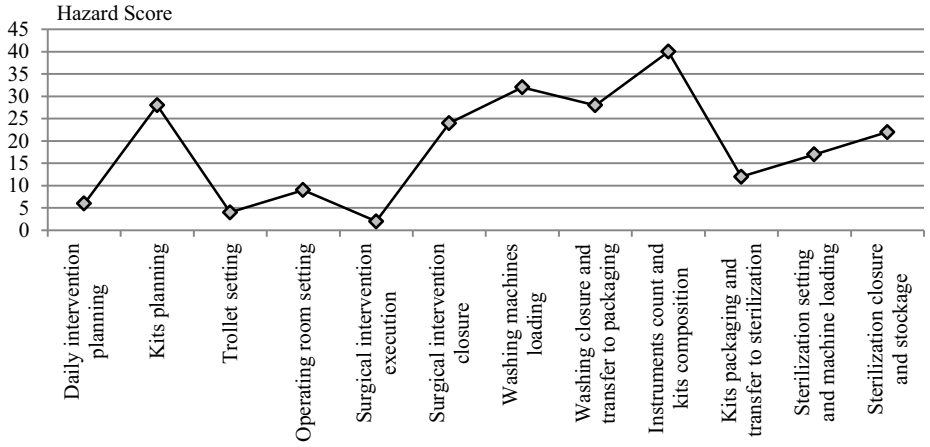

Figure 1. Activity-by-activity clustered failure modes (Method: H-FMEA).

In order to fully understand the implications of approaching a cyclical process where all operations impact on subsequent activities, another study has been performed with an activity-by-activity focus: in general, the core part of the surgical kit regeneration process shows a higher exposition to risks. Washing, packaging and

sterilization processes, which are all part of the regeneration phase, include many manual operations and are more prone to errors. Planning kit allocation is an extremely critical activity, as errors occurring in this phase can cascade throughout the whole process. Interviews with technicians highlighted the amount of troubles the personnel has to deal with on daily basis. Many difficulties encountered everyday refer to inefficient kits planning, as unexpected kits transfers or splitting due to unforeseen events can cause troubled during compositions and packaging. This confirms the criticality of identifying kits and instruments and suggests the need for a tracking system.

The extension of the INT enterprise-wide RFID traceability platform [7], in fact, could help physicians, nurses and technicians by providing a simple-to-use resource for surgical kit management. Moreover, an integrated management system would help reducing errors and keeping risks under control, with benefits for patient safety. This can be achieved thanks also to all information gathered directly from the field during risk analysis, regarding process specifications impact on design and development of the ICT solution. In particular, risk analysis has proven its potential in suggesting specific needs for the overall process and highlighting areas where improvement appeared strongly needed. Combining the results of risk analysis with personnel interviews, the design and development team could build a customized solution enabling surgical kits tracking and monitoring. The developed solution is based on three components:

- ITACO's Web application integrated with the Operating Theatre Information System and with RFId readers. Personnel have access to information recorded on events from any workstation.
- RFId badge for unique identification of surgical operations. This badge identifies surgical events from set-up to kits regeneration.
- RFId tags applied to surgical equipment for unique identification. These tags allow unique and automatic identification of objects involved in the process.

The result is a centralized kit-item management system supported by Mobile devices and RFId technology, enabling quick and precise identification. Right now the solution focuses on surgical kits RFId identification, tracking, and monitoring and it will support daily planning activities. This will help in preventing errors from inefficient planning. In addition, the real-time knowledge about every kit allocation and status can resolve a previously hazardous phase, such as planning, into an information-rich activity. This new ICT tool has been entirely custom-built from specific needs highlighted during process analysis and is now ready for implementation: system testing in the INT's Surgical Area started in December 2013.

Doctors and nurses can access the system with both their personal account and their personal RFId badge plus a PIN. This control procedure allows the system to monitor each access and keep track of every action performed. A dedicated rewritable badge is associated to every surgical intervention before operations begin. This physical support acts as the central element that gathers information during the intervention and serves as an immediately accessible tool for information checking. Specialized nurses and Operating Theatre supervisors possessing access privileges keep track of every surgical kit and prosthesis brought into the operating room before and during intervention. In order to keep these procedures as simple as possible, kits - and, in the future scenario, prosthesis - are provided with RFId tags that are scanned for immediate check-in in OR. Authorized personnel records unforeseen events in real time during intervention resulting in unplanned introduction or removal of surgical kits. During the closing phase of surgical interventions, as used kits leave the room and head

towards the regeneration ward, staff confirms the correct displacement of kits. The central system is notified and automatically updates used surgical kits status: therefore, used kits cannot be reintroduced inside operating rooms until regeneration process is completed. During washing, packaging and sterilization procedures, every item status is updated as soon as kits are once again ready for usage. Surgical kit's information tracking and status monitoring allow efficient day-by-day planning for near future interventions and support nurses and technicians during daily activities. The dedicated intervention badge is reset in prevision of subsequent surgical operations. Deleted information on the badge is still stored in the central system to keep track of interventions.

4. Discussion: Focus on Patient Safety

This RFId-enabled solution developed at INT will target the most significant failure modes and problems exposed during risk analysis of the process, some of which would not have been easily detected and prioritized with a traditional BPR approach. Thanks to the developed solution patient safety will be increased thanks to a reliable kits management system. A *to be* analysis of the resulting scenario is yet to be performed (early 2014), but preliminary observations already suggest that patient safety can be significantly increased with the adoption of this custom solution that, as aforementioned, has been designed directly from the needs of the process.

However, the relevance of kit management in the Surgical Area environment requires an extremely careful adoption of this pervasive ICT tool: analyzing the *to be* scenario will not only verify effects of the new ICT solution, but will also keep unwanted hazards under control, reducing risks spawned by system introduction. In fact, ICT can be a source of new hazards that need to be assessed before reengineered processes fulfilment.

For example, network failures can represent a dangerous threat: at INT, an emergency procedure uses the memory of RFId tags to provide constant offline support to every personnel during daily activities. Moreover, in the unlikely event of an unreadable RFId tag, information appears in clear on every badge. In case of malfunctioning of the RFId technology, staff can still operate and eventually refresh tag contents with RFId readers/printers. In case a staff badge goes missing, information stored on the badge can be read thanks to a centralized data storage system: any unidentified badge can be therefore identified and returned to the owner.

5. Conclusions: Application of the Integrated Approach in Other Projects

The aforementioned approach, being non-process specific and posing as a general model for ICT-enabled business process reengineering, can be transferred and adopted by any innovation project, inside and outside INT. The interest in patient safety and quality assurance at INT doesn't end with project ITACO. This is part of a series of initiatives based on state-of-the-art identification and Mobile&Wireless technologies by which INT has worked on improving blood transfusion safety, chemotherapy administration risk, and is now focusing on stem cells aphaeresis, preservation and administration. Recognizing the great need (and opportunities) of innovative ICT tools supporting the stem cells process, the Italian Ministry of Health funded the research

project “Safety, Traceability and Reliability of Collection, Processing and Transplantation of Haematopoietic Stem Cells (HSCs) and Therapeutic Cells (TCs): Integrated Procedures and Tools to Support Operations, Clinical Care and Banking” led by INT, and involving A.O. Ospedale “Ca' Granda" Niguarda in Milan (the largest public hospital in Milan), IRCCS Istituto Clinico Humanitas, and Fondazione Politecnico di Milano. INT’s approach based on the four aforementioned aspect has been applied to this project as well. Clinical process analysis has been already integrated with risk assessment (focused on stem cells processing and stocking) in order to highlight riskier activities and problems to address during the design of new ICT solutions. In fact, risk analysis is now in progress to understand the needs of every involved individual, from doctors and nurses to patients.

The development of project ITACO has proven that reengineering processes with ICT-enabled solution can be supported with a careful risk assessment process, in order to understand the needs of the organization. While no single risk analysis methodology can be considered superior to others, H-FMEA [10], its original version FMEA [9], and the FMECA variant can all be considered excellent starting points for process analysis and risk evaluation. What is constant is the importance of a risk culture inside processes impacted by ICT-enabled solutions: while technology can be one of the most important means and goals of reengineering, analyzing and keeping track of risks keeps the goal in sight and helps designing and developing new safety-driven and ICT-enabled solutions.

References

[1] Nieva V.F, Sorra J. “Safety culture assessment: a tool for improving patient safety in healthcare organization”. BMJ Quality & Safety Health Care. 2003.
[2] Bates D.W. “Using information technology to reduce rates of medication errors in hospitals”. British Medical Journal - British Medical Association. 2000.
[3] Crowe T.J., Fong P.M., Bauman T.A., Zayas-Castro J.L. “Quantitative risk level estimation of business process reengineering efforts”. Business Process Management Journal. 2002.
[4] Shekelle P.G., Morton S.C., Keeler E.B. “Costs and benefits of health information technology”. Agency for Healthcare Research and Quality - Evidence Report / Technology Assessment. 2006.
[5] Black A.D., Car J., Pagliari C., Anandan C., Cresswell K., et al. “The impact of eHealth on the quality and safety of healthcare: A Systematic Overview”. The University of Edinburgh. 2011.
[6] Locatelli P., Restifo N., Gastaldi L., Sini E., Torresani M. “The evolution of hospital information systems and the role of electronic patient records: from the Italian scenario to a real case”. Studies in Health Technology and Informatics. 2010.
[7] Locatelli P., Restifo N., Facchini R., Sini E., Torresani M., “Closing the safety loop in therapy management through ICT: mobile and wireless scenario for bedside support”. IADIS International Journal on Computer Science and Information Systems. 2012.
[8] Varun G., Malhotra Manoj K. “Business process reengineering: a tutorial on the concept, evolution, method, technology and application”. Journal of Operations Management. 1997.
[9] Stamatis D.H. “Failure modes and effects analysis: FMEA from theory to execution”. ASQ Quality Press. 2003.
[10] DeRosier J., Stalhandske E., Bagian J., Nudell T. “Using healthcare failure mode and effect analysis (HFMEA)”. Journal on Quality Improvement. 2002.
[11] Swedberg C. “RFID system tracks surgical instruments in Denmark”. RFID Journal. 2013.
[12] Stalhandske E., MPP, MHSA, DeRosier J., PE, CSP, Wilson R., MS, Murphy J., APR, MS. “Healthcare FMEA in the Veterans Health Administration”. Patient Safety & Quality Healthcare. 2009.
[13] Linkin D.R., Sausman C., Santos L., Lyons C., Fox C., Aumiller L., Esterhai J., Pittman B., Lautenbach E. “Applicability of healthcare failure mode and effects analysis to healthcare epidemiology: evaluation of the sterilization and use of surgical instruments”. Clinical Infectious Diseases – Oxford Journals. 2005.