A Proactive Risk Assessment Framework to Enhance Patient Safety in Operating Rooms

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Abstract. Patient safety, as a main aspect of quality of care, has been a major issue over the last decades in the healthcare industry. The number of preventable medical errors in hospitals has been noticeably high. These errors are more likely to occur in intensive care units including Operating Rooms (ORs). Moreover, preventable errors such as operating on a wrong body part have serious consequences. This paper fills an important gap by proposing a framework for proactive risk assessment of operations in ORs through the identification and monitoring of appropriate Leading Safety Indicators (LSIs) to evaluate the safety of operations and generate warning/predicting signals for potential failures. These LSIs are identified across the six layers of the Rasmussen's Risk Management Framework, which each represents a main group of involved decision-makers. These layers in our context, from top to bottom, are: government; regulators; hospital; surgery division management; surgery personnel; and work processes.

Keywords: Proactive risk assessment · Patient safety · Operating Rooms (ORs) · Healthcare industry · Leading Safety Indicators (LSIs) · Wrong Site Surgery (WSS) · Jens Rasmussen

1 Introduction

Experts estimated that between 44,000 and 98,000 Americans die every year from preventable medical errors that occur in hospitals [1]. This number exceeds the deaths attributable to motor vehicle accidents (43,458), breast cancer (42,297) and AIDS (16,516) - three causes that receive far more public attention [1]. Adding the financial cost to the human tragedy, medical error easily rises to the top ranks of urgent, widespread public problems.

High error rates with serious consequences are most likely to occur in intensive care units, Operating Rooms (ORs) and emergency departments due to the tightly coupled and interactively complex nature of their operations [1].

Among the above-mentioned healthcare settings, ORs deal with high risk operations. The occurrence of the errors and adverse events is due to the lack of effective management as well as other technological and human and organizational factors-related failures. For instance, lack of communication and training as well as inadequate standard

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procedures are some of the contributing causes of preventable medical errors in OR settings. These have resulted in issues such as wrong side/site surgery, wrong procedure and anesthesia management, which have been noticeable in ORs endangering the life of patients and imposing tremendous amount of cost to healthcare facilities. Therefore, reducing failures and adverse events in the healthcare industry; ORs in the context of this study, and enhancing the quality of care is of paramount importance in this industry.

The IOM Committee on Quality of Healthcare in America has proposed six aims to improve the quality of care in healthcare settings including hospitals [2]. These aims are: safety, effectiveness, patient-centeredness, timeliness, efficiency and equity. In this study, we will focus on safety (hereafter referred to as patient safety), as a critical quality concern, which aims to avoid harm and injuries to patients from the care that is intended to help them.

Our extensive literature review indicates a gap in the existence of enough proactive risk assessment frameworks and methodologies to enhance patient safety in the healthcare industry. Most of the developed frameworks in this context have been mainly reactive/retrospective, and not proactive. Proactive frameworks contribute to predicting and in one step further, preventing errors and failures in a system. Therefore, our research fills a vital need for the development of more robust risk assessment frameworks to identify and analyze the risks of failures in healthcare settings and improve the quality of care by preventing medical errors.

This study proposes a proactive risk assessment framework in order to improve patient safety, as a crucial component of quality of care. This framework is specifically developed for the analysis and improvement of patient safety in operating rooms – one of the primary places where high rates of error occur. As stated before, the proactive (versus reactive) characteristic of this framework will enable healthcare practitioners to measure, analyze, control and enhance patient safety through predicting and preventing the occurrence of errors.

The proactive perspective of the proposed framework in this study has been developed by defining appropriate Leading Safety Indicators (LSIs) to evaluate and monitor both internal and external socio-technical factors in a healthcare setting that can contribute to causing an error or failure in the system. The role of these leading indicators, in contrast with lagging indicators, is to identify sources of failure (e.g. putting patient safety at risk in the context of our project) before they occur.

The structure of this paper is as follows: A brief literature review of existing risk assessment methodologies in the healthcare industry is provided in the next section. Section 3 describes the proposed methodology of this research. The analysis of the results of the developed methodology is discussed in Sect. 4. Section 5 provides the conclusion, which is followed by future research and directions in Sect. 6.

2 Brief Literature Review

The healthcare industry has only recently applied risk assessment methodologies compared to many other safety-critical industries such as nuclear power plants, transportation sector and oil and gas industry. Further, there are even fewer studies that proactively analyze and address the risks associated with healthcare delivery and more specifically, patient safety.

Some proactive risk assessment methods for addressing patient safety focus primarily on hazards – or "risk factors" that increase the probability of errors or injuries [3–6]. One primary applications of the proactive risk assessment methods is drug delivery and medication error (e.g. [5]). In addition, the Agency for Healthcare Research and Quality (AHRQ) sponsored a study for proactive risk assessment of surgical site infections in ambulatory surgical centers [7]. These studies, however, have not focused on patient safety in operating rooms. Thus, our research addresses a critical gap in risk analysis methods that proactively improve patient safety in operating rooms. The development of our proactive risk assessment framework enhances patient safety and quality of care in the healthcare industry, with the specific focus on the safety of operations in ORs.

3 Project Methodology

3.1 Introduction to Methodology

The foundation of the proposed methodology in this study is based on a seminal model originally developed by Rasmussen [8]. This hierarchical framework consists of six layers, with each representing a main group of involved decision-makers, players or stakeholders in a studied system [8]. These six layers, from top to bottom, are: government, regulators and associations, company, management, staff and work (Fig. 1). The analysis of the framework includes assessing the activities of key players in each layer. More importantly, this framework captures the interactions between those key players within the stated layers [9, 10].

Here, we have applied the Rasmussen's framework in the context of a healthcare delivery system and more specifically, operating rooms as the scope of this study. The six layers in the modified framework from top to bottom, are: government; regulators; hospital; surgery division management; surgeons, nurses, anesthesiologists, operating rooms technicians and other related personnel; and work and processes in operating rooms (Fig. 1).

The Rasmussen's framework and several other similar approaches have been primarily used as retrospective methods for risk analysis and accident investigation. In contrast, this study uses the framework to develop a *proactive* risk assessment methodology. For this purpose, we have identified appropriate leading safety indicators for each of the stated layers of the Rasmussen's framework. The role of these leading indicators, in contrast with lagging indicators, is to identify sources of failure (e.g. putting patient safety at risk in the context of our project) before they occur. One simple example of such indicators is the number of hours of training for surgery crew. The value of this indicator can be measured at regular intervals and compared with existing standards. A warning is issued if the actual number of hours of training does not match the target value.

A clear statement of objectives is in general the foundation for any decision. Attributes clarify the meaning of each objective and are required to measure the consequences of different alternatives. Five desirable characteristics of attributes are as follows:

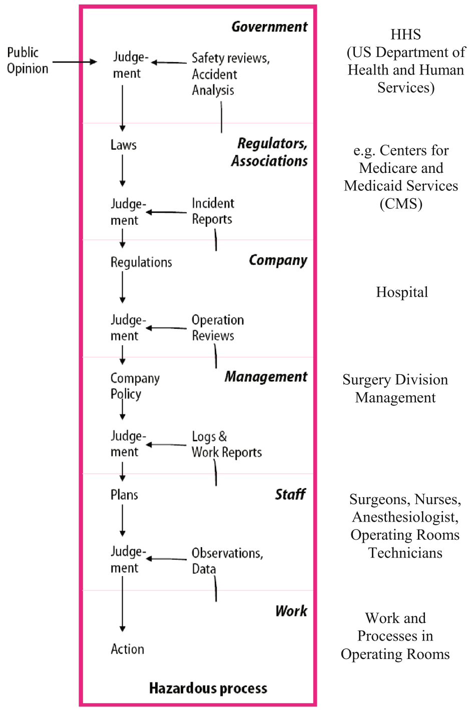

Fig. 1. Risk management framework to analyze contribution of multiple decision-makers in operating rooms. The right hand-side layers have been designed and customized for this study [10].

unambiguous, comprehensive, direct, operational and understandable [11]. Leading safety indicators, which are considered as attributes, ought to possess these characteristics.

Based on the described approach, there have been two main phases in developing our proactive risk assessment framework: (1) Defining context-specific LSIs for each of the layers of the discussed model in Fig. 1 and (2) validating this model and the defined LSIs through interviews with experts in medical fields and OR settings.

Figure 2 illustrates the process of defining the aforementioned leadings safety indicators. In this process, the first step is to identify the main issues in the context of the studied system, which are patient safety-related issues in operating rooms in the scope of our project. The next step is determining the main contributing causes, including root causes, of the identified issues in order to be able to define related leading safety indicators based on those causes. The determined root causes are then connected to associated involved decision makers (layers) of the Rasmussen's Risk Management Framework (RMF), which was described in the beginning of this section. In parallel, an extensive literature review of existing LSIs in the healthcare industry and other safety-critical industries, such as oil and gas, nuclear power and chemical processing, is conducted. Finally, appropriate leading safety indicators are defined to address identified root causes of issues in ORs by adjusting some of the related existing LSIs or introducing new indicators. It is noteworthy that due to page limitation, we will only state and explain two of the main categories of our developed LSIs and their associated subcategories.

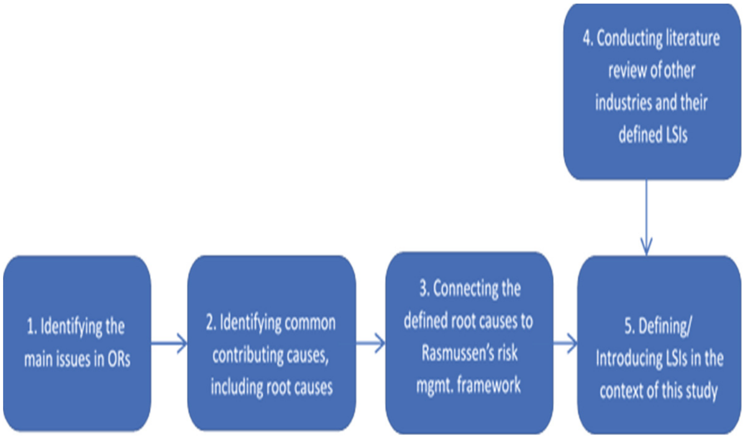

Fig. 2. The process of defining LSIs to monitor safety of operations; patient safety in this context, in ORs

3.2 Methodology Description

As described in Sect. 3.1, the illustrated process in Fig. 2 was performed to define leading safety indicators to evaluate the safety of operations in a healthcare setting; i.e. operating rooms, and monitor both internal and external socio-technical factors that can contribute to causing an error or a failure in the system and compromise patient safety.

In the first step, we have identified the main patient safety-related issues in operating rooms and categorized them. This step has been completed through an extensive literature review. In addition, we have contacted some experts at the University of Southern California (USC) Keck Medical School and through their subject matter opinion, we have validated those main identified issues in ORs as well as their root contributing causes, which will be described as the next step in this section. The described identified issues are as follows [12, 13]:

- Wrong site surgery [14, 15]
- Wrong side surgery [14, 15]
- Wrong patient surgery [14, 15]
- Wrong procedure [14, 15]
- Retained Foreign Object in Body (RFOB) [14]
- Blood management (Transfusion mishaps)
- Anesthesia management

Among the above-mentioned identified issues, we have focused on four major problems with more common contributing and root causes, which are: wrong site, side and patient surgery and wrong procedure. As the next step of our process to define LSIs depicted in Fig. 2, root causes of the four aforementioned issues were identified. The following is the list of some of the main root contributing causes of those issues:

- Communication failures [16]
- Inadequately designed procedures/systems [16]
- Noncompliance with existing procedures [16]
- Lack of compliance monitoring of existing systems [16]
- Lack of, or inadequate "time-out" [16]; as the name shows, time-out is the last step before starting the surgery. According to Stahel, Mehler, Clarke and Varnell [17], "The "time out" represents the final recapitulation and reassurance of accurate patient identity, surgical site, and planned procedure."
- Inadequate orientation and training [16]
- Team issues: informal norms, hierarchy problems [16]
- The challenge with people feeling free to speak up [16]
- Lack of consistency in surgery team members [12]
- Lack of clarity in roles and responsibilities [12]
- Inaccurate/incomplete scheduling information [16]
- Lack of scheduling to a procedure code, based on the specialty of surgeries [12]
- Changes to the schedule until the morning of the surgery [12]
- Moving patient's surgery up and down the schedule [12]
- Lag time between the decision to do a surgery and the actual surgery [12]
- Operational delay [12]
- Production/time pressures, including case urgency [16]
- Consent – availability, legibility, accuracy and consistency with other documents [16]
- Inadequate patient identification and assessment [16]
- Inadequate pre-operative/pre-procedural verification process [16]
- Incomplete physical history [16]
- Failure to have complete information available (x-ray, lab, or pathology reports) [16]
- Failure to correlate available information [16]
- Inconsistent, absence of, or unclear site marking (Lack of standardized marking) [12, 16]
- Room set-up, positioning, prepping and draping variation [16]
- Lack of appropriate order of steps for the procedure [12].

In the next step, each of the identified root causes were connected to related layers of the Rasmussen's risk management framework in order to identify both internal and external (to a healthcare facility) involved decision makers and players, who can contribute to causing errors and need to be monitored closely.

In the final step, appropriate leading safety indicators were defined in order to enable healthcare practitioners to eliminate the root contributing causes of the discussed issues in ORs and prevent the occurrence of those issues. To achieve this goal, different approaches were taken. We have studied the improvement strategies to eliminate those root causes that were identified earlier. Those improvement suggestions were proposed by hospitals and healthcare facilities in different published studies and articles. We have used those strategies and transferred them into appropriate LSIs to fulfill the explained purpose.

In addition, as Fig. 2 illustrated, we conducted an extensive literature review of existing leading safety indicators in the healthcare industry and other safety-critical industries, including oil and gas, nuclear power and chemical processing. Some of those LSIs that in some way were related to the identified root causes were selected and used. Some other identified LSIs from the literature review were reformed and redefined in a way that can be related to OR operations, patient safety and the identified root causes. Finally, we have defined and introduced some (additional) original LSIs based on our extensive research and our discussions and meetings with experts at the USC Keck Medical School.

As an example, inadequate orientation and training was identified as one of the root causes of wrong site, side and patient surgery and wrong procedure. Training constitutes a critical category for a leading safety indicator, as it is corroborated by several references (e.g. [18–20]). This main category of an indicator can have different aspects, such as technical and non-technical training [18], training completed on schedule [21], overdue training [22] and lack of knowledge and lessons learned [20]. More details about the aspects and subcategories of the training, as a leading safety indicator, are provided in the next section.

Up to this point in our research, we have validated the main identified issues in operating rooms as well as their root contributing causes by contacting the stated experts at the USC Keck Medical School. In addition, we have consulted with them about the validity and practicality of our defined LSIs. Some of these defined LSIs have been validated by our experts. This however, is an ongoing process, which has been stated as part of our future research as well.

4 Model Discussion and Results

We explained the process of defining leading safety indicators with the purpose of enhancing patient safety in operating rooms through monitoring and eliminating the sources and root causes of failures and issues in these healthcare settings.

This section describes two (due to page limitation) of the main categories of leading safety indicators, which have been developed by following the discussed process in the previous section. These two categories are: training; and engineering and inherently safe design. Each of these LSIs consists of defined subcategories, which are elaborated in the following subsections.

In addition to providing categories and subcategories of LSIs, each subcategory has been connected to the relevant layers of the Rasmussen's risk management framework, which was explained in the methodology section, in order to indicate involved decision makers and players that can influence or be influenced by that LSI. These relevant layers have been stated separately for each indicator in a bracket.

4.1 LSI#1: Training

Training is an essential factor that contributes to workplace safety in any safety-sensitive industry. For instance, lack of training and expertise was identified as one of the main contributing cases of the BP Deepwater Horizon accident in 2010 [19]. The healthcare industry and operating room settings are not exempt from this. Due to this significance, training has been considered as one of the main LSI categories in this study.

This LSI can include both technical and non-technical training. Technical training is related to elements such as the know-how of working with equipment as well as following existing procedures, which are indicated below as some of the subcategories for this class of LSI. Non-technical training is more related to components that enable management and personnel to work together as a team and incorporate safety into their activities and operations.

According to Morrison [18], some statistical analyses showed that training hours was the leading indicator with the strongest correlation to lagging indicators, such number of incident. In another word, conducting more hours of training contributed to fewer safety incidents in healthcare settings. The effectiveness of training sessions however plays a more critical role in promoting safety comparing to the number of hours of conducted training.

The Following shows an extensive list of the defined subcategories of LSIs for training:

- *Inadequate training* [23] [Rasmussen's RMF layers: management, staff]: Inadequate training can play a critical role in contributing to incidents and near-misses in ORs and compromising patient safety. Training can be inadequate with regards to the number of training sessions, the goal of those training sessions or their quality.
- *Number of overdue trainings*: [Rasmussen's RMF layers: hospital, management, staff]: High number of overdue trainings indicates that safety can be at risk.
- *Numbers of workers in each personnel category whose training is overdue* [24]: [Rasmussen's RMF layers: staff]
- *Percentage of process safety required training sessions completed on time or (Number of Individuals who Completed Planned Training Sessions On time)/(Total Number of Individual Training Sessions Planned)* [25] [Rasmussen's RMF layers: hospital, management, staff]
- *Whether staff are well-trained in the use of new equipment* [26] [Rasmussen's RMF layers: staff]: This was mentioned as one of the latent risk factors in the context of patient safety in ORs. This LSI is an important component of any training as it was discussed in the earlier part of this section.
- *Number of hours for new equipment training*: [Rasmussen's RMF layers: regulators and associations, hospital, management]: Utilizing new equipment without providing adequate hours of training will increase the risk of errors in OR operations.
- *Lack of evidence-based practice* [23] [Rasmussen's RMF layers: hospital, management]: Setting principals of the evidence-based practice and application of them should be used as one of the LSIs to provide safety in the ORs.
- *Number of hours of training about new procedures and academic articles:* [Rasmussen's RMF layers: regulators and associations, hospital, management]: The higher

the number of training hours on new procedures and academic articles, the lower the risk of errors will be.

- *Number of hours for safety training:* [Rasmussen's RMF layers: regulators and associations, hospitals, management]: Safety a crucial subject in the category of training has to be provided by considerable training on that.
- *Number of near-misses due to lack of trainees' technical understanding and/or experience, inadequate training and absence of skills in a team* [24] [Rasmussen's RMF layers: hospital, management]: Number of near misses due to lack of experience or inadequate training is a lagging indicator by itself. However, the trend of this number over time can be considered as a leading indicator; e.g. an increasing trend over time can indicate a serious problem with the training system.
- *Safety becomes the first agenda in every meeting* [12] [Rasmussen's RMF layers: regulators and associations, hospital, management, staff]: The importance of safety should always be reminded. Therefore, this topic should become the first agenda in every meeting.

4.2 LSI#2: Engineering and Inherently Safe Design

International Association of Oil and Gas Producers (OGP) [24] identified the engineering and inherently safe design as one of its key performance indicators. The context of safe design is also applicable to the healthcare industry and OR settings. Our research indicates that the design of operating rooms and their layout; e.g. lights and equipment such as monitors, tables, and cords on the floor, based on the science of ergonomics is crucial. Results of a conducted survey between surgeons in a hospital indicated that 97% of the surgeons confirmed the importance of ergonomic design of the ORs [27]. Surgeons stated that these deficiencies can lead to potential hazards for patients and personnel, potentially on a frequent basis [27]. The following are the defined subcategories of LSIs for the engineering and inherently safe design based on our research and analysis:

- *Quality of images and the readability of information shown by installed controls and displays (scale of 1–5)* [Rasmussen's RMF layers: regulators and associations, hospital, management, staff]: Almost all surgeons use monitors and other controls to see images, identify exact problems, and perform the surgery based on that. Therefore, the quality of the displays and controls has to be adequate in order to avoid any errors and mistakes.
- *Proper layout and instalment of controls or displays in the operating room (scale of 1–5)* [Rasmussen's RMF layers: hospitals, management]: The layout and installment of monitors and other equipment is critical in order to make the flow of each surgery more comfortable and also make the screens more visible from different standing point angles.
- *Number of incidents or near-miss events where errors were identified due to design* [24] [Rasmussen's RMF layers: hospital, management]: Number of incidents occurred due to design is a lagging factor itself. However, the trend of this number over time can be considered as a leading indicator; e.g. an increasing trend over time can indicate a potential problem.

- *Design and ergonomic status of lights, monitors, table, cords on the floor and other equipment* [27] [Rasmussen's RMF layers: regulators and associations, hospital, management]: Besides the layout design, the design of lights, monitors, cords on the floor and other equipment matters significantly for the safety of patients and OR staff.

5 Conclusion

The high rate of fatalities due to preventable medical errors in the healthcare industry indicates the urgent need to improve patient safety, as a major aspect of quality of care, in this industry. This study proposed a proactive risk assessment methodology, which was specified in the context of OR operations, to fill an existing gap in this domain.

Operating rooms, as one of the intensive care units with high risk of operations, have dealt with major issues such as wrong side, site and patient surgery; wrong procedure; Retained Foreign Object in Body (RFOB); blood management and anesthesia management. In this study, we mainly focused on wrong side, site and patient surgery as well as wrong procedure in ORs and analyzed their contributing and root causes.

The proposed methodology integrated the risk management framework of Rasmussen [8] and its associated layers with context-specific leading safety indicators in order to address the above-mentioned issues in ORs and their contributing root causes. Such integration creates a proactive capability for our proposed methodology comparing to the retrospective characteristic of the stated risk management framework by Rasmussen and several other developed risk analysis models in the literature. It is noteworthy that although the introduced methodology in this study has been developed in the context of patient safety in operating rooms, it can be generalized and applied to enhance patient safety in other healthcare settings.

6 Future Research

One of the main future research directions for this study is to work on developed leading safety indicators in order to expand and refine them. In addition, LSIs for other categories of patient safety-related issues in operating rooms, rather than wrong side, site and patient surgery as well as wrong procedure, and their contributing causes will be developed. For this purpose, more meetings with previously contacted subject matter experts will be held. Moreover, we plan to contact other healthcare facilities and hospitals to gather more information and improve our research results.

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