Risk Analysis on the Planning of Surgery: A Case Study in a Brazilian Public Hospital of Oncology

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Abstract
This study aimed to demonstrate the applicability of the Health Care Failure Mode and Effect Analysis tool (HFMEA) by reporting the experience in the planning of surgery. There was a reduction of errors, with reports of only three near miss in one year, indicating that the tool was highly effective.

Keywords: Risk management, Health care, Patient Safety.

INTRODUCTION

In recent years, there was a change in the focus on thinking about adverse events from an individual approach (blame a person by mistake) to a systems approach. The systems approach assumes that people make mistakes, and that the system around them should provide a safety net for these errors (De Vries et al. 2008). This change in approach is strongly based on the theory developed by Reason seeing that adverse events are rarely determined by a single mistake, be it human or technological; but more often they are the result of a sequence of errors and events in which the person responsible for the final error is just the latest causal link (Reason 1995).

After the report published by the Institute of Medicine of the United States, "To Err Is Human: Building a Safer Health System", some significant studies have been conducted on adverse events, some of them nationwide. In a review of the main studies on the occurrence of adverse events, that the general average incidence of adverse events in hospitals was found to be 9.2%, and the average of these possible events to be prevented was 43.5 %. Another important finding is that most of these events are related to surgery (52.9%) and drugs (15.7%) (Brennan et al. 1991; Baker et al. 2004; De Vries et al. 2008).

Some retrospective methods have been used to analyze the errors in healthcare services and to prevent them from happening again, such as the Root Cause Analysis (RCA) technique (Teixeira and Cassiani, 2010). However, to reduce harm to patients, the need to identify the risks prospectively and to predict possible errors was emphasized (Kessels-Habraken et al. 2009).

Several methods are available for prospective analysis and, despite the differences between these methods, they all aim to: identify, assess and eliminate or reduce risks before their occurrence: Root Failure Modes and Effects Analysis (FMEA); Failure Modes, Effects, and Criticality Analysis (FMECA); Heath Care Failure Modes and Effects Analysis (HFMEA); Hazard Analysis and Critical Control Point (HACCP) and others (Dückers et al. 2009; Lepage et al. 2009; Cagliano et al. 2011; Dunn et al. 2011; Adibi et al. 2012).

In healthcare service, risk management can be facilitated by accreditation programs (Wagner et al. 2013). Accreditation is an external quality review. Even though national accreditation bodies are available in many countries, the Joint Commission International (JCI) is among the oldest and most recognized agencies in the world. Accreditation has an advantage over excellence models since it focuses on specific needs for healthcare services (Abdallah 2014). Since 2001, the JCI has demanded that accredited hospitals perform at least one proactive risk assessment annually. The recommended tool is the Failure Modes and Effects Analysis - FMEA (Marx and Slonim, 2003). FMEA has been the most used technique in the healthcare industry to reduce risks to patients (Cagliano et al. 2011). Rosen et al. (2014) define FMEA as a method for engaging local staff in identifying real or potential breakdowns in processes or work systems and to develop strategies to mitigate risks. According the guide developed by JCI (Failure Mode and Effects Analysis in Health Care: Proactive Risk Reduction, 2010), FMEA is "one technique for systems improvement that can enhance safety. FMEA is a team-based, systematic, proactive, and reasoned-based technique that is used to prevent process and product problems before they occur". A limitation of this tool is that it does not jointly analyze multiple risk factors; the analysis is always individual (Marx and Slonim, 2003).

Recently, some studies began to be conducted to evaluate the effectiveness of the implementation of the healthcare industry tool, such as the research conducted by Alba Mesa et al. (2015), developed in Europe. They evaluate if application of FMEA to laparoscopy training could help surgeons acquire skills; and they concluded that application of FMEA principles helped to acquire non-technical skills necessary for safe laparoscopic surgery. According to Alba Mesa et al. (2015), the systematic implementation of FMEA can contribute to reducing the risk of human error and thus improve patient safety.

The VA National Center for Patient Safety (ICPS), responsible for developing the HFMEA technique, with the support of Tenet Health System (Dallas), defines it as a hybrid model (DeRosier et al. 2002). The HFMEA is a model of prospective analysis, adapted to healthcare services, combining the concepts found in the FMEA and HACCP, such as tools and analysis setting the root cause of the process, as well as using an interdisciplinary team, process flows, failure mode and identifying the cause of the failure mode, risk scoring matrix and decision tree algorithm to identify system vulnerabilities, in which actions and outcome measures are developed and managed.

This work aims to demonstrate the applicability and efficacy of the HFMEA technique in hospitals to reduce risks to patients. The study is based on a single case study preformed in a Brazilian public hospital of oncology, to mitigate the occurrence of incorrect description of surgical procedures in the planning stage.

The paper is divided into five sections. Section 2 presents the methodological approach used in the field research and the main steps of the HFMEA technique. Section 3 and 4 present their results and an analysis, respectively; and Section 5 presents the conclusions and limitations of the study.

METHOD

The single case study research methodology, a qualitative approach, was selected to develop this research. Case study methodology appears as an appropriate strategy when it comes to issues present in contemporary phenomena inserted in real-life contexts, and can be complemented by other exploratory and descriptive researches. The case study is used as a research strategy in organizational and managerial studies, uniquely contributing to understanding complex phenomena at individual, organizational, social and political levels and allowing maintaining significant characteristics of real life events (Yin 2003).

The unit of analysis was defined by convenience, especially considering the possibility of conducting the study. However, it is important to note that the hospital had interesting features for the work development. The institution selected is the Instituto do Câncer do Estado de São Paulo (ICESP), a large public hospital (499 beds), located in São Paulo (Brazil) and opened in 2008, with the prospect of being the largest oncology treatment specialized hospital in Latin America. The ICESP has obtained the accreditation of the national program (Organização Nacional de Acreditação - ONA), first in level I in 2010, and later at level II in 2011. In the late 2014, the institution was accredited by the Joint Commission International (JCI). The criteria for selecting the institution was the fact that it focuses on the continuous improvement of its processes and patient safety, demonstrated by the accreditations obtained.

The research focused on the application of the HFMEA technique. The process consisted of five steps and it was performed by a multidisciplinary team to proactively assess the health care processes (DeRosier et al. 2002). In summary, the five steps are: (i) to define the process for evaluation; (ii) to assign the team; (iii) to describe the process in a graphic form; (iv) to conduct a hazard analysis; and finally (v) to define actions and indicators for monitoring the results.

The evaluation process was defined based on both severity analyses, considering the current result of adverse events with severe patient outcome; and the probability analysis, carried out based on the general report of events and near miss history with potential sentinel event. Thus, the HFMEA conducted in 2014, examined the care process 'anesthesia and surgery' in the planning stage, in which the failure mode corresponded to the incorrect description of the surgical procedure.

The Risk Management team structured a multidisciplinary team of experts from the surgical ambulatory, anesthetic, management of beds, information technology and financial areas. Brainstorming meetings were conducted with a team of experts to analyze the risk and identified the potential causes of the failure mode; estimate the hazard score based on the severity and probability; applied the Decision Tree algorithm to identify system vulnerabilities and planned to stop or to proceed with HFMEA (DeRosier et al. 2002); improvement actions, responsibilities, schedule and outcome measures to control or to eliminate the risk. Finally, the evaluation of efficacy was conducted on a quarterly basis, to seek evidence of the implementation of improvements and to re-discuss the strategies to achieve the goal of partially implemented action plans.

The reference for probability, severity and risk rating scale was DeRosier et al. (2002). The scale rating was previously discussed and validated by the team. As shown in Table 1, there are four categories for assessing severity.

Table 1 – Probability rating scale – Source: DeRosier et al. (2002).

Category	**Description**
Frequent	Likely to occur immediately or within a short period (may happen several times in 1 year).
Occasional	Will probably occur (may happen several times in 1 to 2 years).
Uncommon	Possible to occur (may happen sometime in 2 to 5 years).
Remote	Unlikely to occur (may happen sometime in 5 to 30 years).

As can be seen from Table 2, there are four categories for assessing risk severity, highlighting the consequence only for the patient in case an adverse event occurs. The consequence to other people involved, facility, organization image or any other dimension were not analyzed.

Table 2 – Severity rating scale – Source: DeRosier et al. (2002).

Category	**Patient outcome**
Catastrophic Event	▪ Death or major permanent loss of function (sensory, motor, physiologic, or intellectual) function, surgery/procedure on the wrong patient or wrong body part
Major Event	▪ Permanent lessening of bodily functioning (sensory, motor, physiologic, or intellectual), disfigurement, surgical intervention required, increased length of stay for 3 or more patients, increased level of care for 3 or more patients
Moderate Event	▪ Increased length of stay or increased level of care for 1 or 2 patients
Minor Event	▪ No injury nor increased length of stay nor increased level of care

To conclude the risk estimation and prioritization, the Risk Priority Number (RPN) or Hazard Score was calculated. The Hazard Score was obtained by multiplying the results of severity and probability analyses. As shown in Table 3, results equal to or greater than eight are considered high and unacceptable, and need more attention.

Table 3 – HFMEA™ Hazard Scoring Matrix™ – Source: DeRosier et al. (2002).

		Severity of Effect			
		Catastrophic	Major	Moderate	Minor
Probability	Frequent	16	12	8	4
	Occasional	12	9	6	3
	Uncommon	8	6	4	2
	Remote	4	3	2	1

Note: The table cells highlighted in gray represent high risk and in white represents both moderate and low risk.

RESULTS

As can be seen from Table 4, six potential causes of failure were identified in ‘description of the surgical procedure’ sub-process, whereas five of them had a high risk (scores greater than or equal to eight). For causes classified as high risk, all were verified to represent a point of weakness, that is, they are so critical that the occurrence of this failure will result in the system fault or an adverse event to the patient. These causes also presented no effective control measures (barrier) to eliminate or to substantially reduce the incidence of an adverse event. In addition, none of the five causes could be detected before the completion of the task. With this

result, it was necessary to set an action for each of the five potential causes classified as high risk, critical tasks, without an effective means of control or the possibility of detection before they occurred.

The actions on the causes were classified into three options, namely, eliminating, accepting or controlling the potential cause, as suggested by DeRosier et al. (2002). The details of the actions were not mentioned in the Table and will not be presented in this paper, because they were considered very specific to the sub-process analyzed in the related institution. However, among them, we can mention as an example the review of surgical procedures registered by specialists; awareness of the medical staff to ensure the surgical indication flow after staging; and the description of the update flow of registered procedures.

Table 4 – Risk analysis in the 'description of the surgical procedure' sub-process.

Potential causes	**Severity [1]**	**Probability [2]**	**Hazard score**	**Single point of weakness?**	**Is there a control measure?**	**Detectability?**	**Process next step of HFMEA (action)?**	**Action (C - Control, A - Accept or E - Eliminate)**
1. Does not find the desired surgical procedure due to the absence of the procedure in the registration record and, for this reason, another alternative available is selected from the current list	4	4	16	Yes	No	No	Yes	E
2. Registering the list of surgical procedures based on the Government's pay table, being limited and generating divergence in practice, such as surgical terminology	2	4	8	Yes	No	No	Yes	E
3. Lack of knowledge of how to use the search tool for procedures	2	4	8	Yes	No	No	Yes	E
4. Lack of attention in the selection procedure due to the large volume of care and inadequate management of outpatient schedule	2	3	6	No	Stop			---
5. Early indication for surgical procedure for performing routing	2	4	8	Yes	No	No	Yes	C
6. Lack of a standard or a flow to update the descriptions of registered procedures	2	4	8	Yes	No	No	Yes	C

Notes:
[1] Severity: Catastrophic = 4; Major = 3; Moderate = 2; Minor = 1.
[2] Probability: Frequent = 4; Occasional = 3; Uncommon = 2; Remote = 1.

The evaluation of technique efficacy was based on measuring the results from the analysis of notifications of subsequent events related to the description of incorrect surgical procedure. The risk of adverse events was reduced to only three events in one year, classified as near miss, whose immediate action was to perform the flow for procedures register update. Therefore, the application of HFMEA promoted the mitigation of the initial high risk of incorrect description of surgical procedures, ensuring a higher safety healthcare process.

DISCUSSION

As indicated by the results, the HFMEA technique applied to the prioritized sub-process was effective, as it achieved the initial objective of mitigating the occurrence of incorrect description of the surgical procedure. Before the risk analysis, from 2011 to 2014, there had been a near miss and two adverse events without damage, both with serious damage potential (incorrect surgical procedure). After 2014, there was only three near miss report showing the reduction of risk to the patient.

Additionally to the effectiveness of the technique, it worth noting that the team had found it easier to apply the technique since it has well-defined steps, including clear standards on how to proceed. The categories clearly defined for assessing the probability, severity and risk, as well as the decision tree, made the process easier and reduced both the subjectivity and lack of standard in risk assessment.

Another important point was the need of both the team and multidisciplinary experience to develop the work. There is a need of deeply understanding the process analyzed in order to ensure the quality of the assessment and to achieve the results expected.

Moreover, this study highlights the importance of support from the senior management, both for team mobilization, and for implementing actions to eliminate, to reduce or to control risks. The fact of the deployment tool being linked to the Accreditation program has significantly contributed to involving all the areas in the implementation of the new tool. Depending on Accreditation, there is an even greater mobilization of all the professionals seeking to improve the processes for quality of health care services and patient safety. At the same time, several improvement projects were conducted with a strong contribution to the implementation of HFMEA to reduce risks. According to Manzo et al. (2012), the movement toward quality reflects the need for fundamental changes in organizations to obtain the titles of excellence.

Finally, it is also relevant to discuss the need and the opportunity to train the staff. Trainings were provided before starting the implementation of HFMEA. Manzo et al. (2012), in their study on the implications of Hospital Accreditation in day-to-day health professionals, highlighted the constant need to invest in continued education for making the changes viable in the organization internal and external processes, and to respond to the demands arising from certification programs and from health professionals. Thus, the Accreditation may represent an important personnel training strategy within hospitals.

CONCLUSION

On the one hand, the effort to reduce adverse events, both by reducing the severity and the probability of their occurrence, is a duty of hospitals. On the other hand, the recent research has increasingly given transparency to the reality of health services, with emphasis on events that could have been avoided, showing that there is still a significant gap requiring further work. For this challenge, risk management techniques have a great contribution and through this study sought to demonstrate the effectiveness of one of them, the HFMEA technique.

It is worth mentioning that the techniques are only means which need capable people committed to the result, as well as adequate resources for implementation and maintenance, to be effective. One must keep in mind that the entire system must be efficient and that a fault can be fatal to a patient.

Furthermore, a growing trend of recognizing the importance of greater engagement of patients in their care is observed, along with the need of transparency in the healthcare service process. Risk management can significantly contribute to raising awareness of managers, of patients and of all the parties involved about potential risks of processes.

This study limitations are related to the HFMEA technique. A limitation to be considered in its deployment is that it does not jointly analyze multiple risk factors, the analysis is always individual. According to Reason (REASON, 1995) in charge of major studies on errors in healthcare, the notion that mistakes can be active or latent justifies the model of "barriers" to prevent the error from affecting the patient. One must make a distinction between active faults (causing immediate adverse results) and failures of latent or delayed actions, which can exist for a long period before combining with local triggering events and penetrating system defenses. Reason assumes that it is impossible to eliminate human and technical failures. To err is human, but certainly there are some mechanisms to prevent the error and to mitigate the occurrence of adverse events, reducing the risks to patients.

A limitation of the technique leads to a deeper analysis of the whole system and what barriers are designed to prevent the occurrence of adverse events, considering that the error which may affect the patient causing the damage is only the last link in a chain.

For future research, the suggestion is to conduct a quantitative analysis of the risks classified as high, that is, tolerance levels above the acceptable. Another suggested study is evaluating the care system as a whole, after the implementation of HFMEA for each process and its sub-processes, making sure there are enough barriers in the process to reduce or to eliminate risks to patients considering the possibility that a sequence of errors can result in an adverse event.

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