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Research Article

ST-PRA+FMEA Hybrid Risk Analysis Application for Catastrophic Events at Hospitals

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Abstract

Healthcare; albeit with low frequency, is an industry more prone to critical errors, than other industries due to its matrix structure and the numerous factors involved such as patients, professionals, and other external factors. Since multiple factors also mean multiple error sources, methods such as system analysis, process evaluation and error-and near-error notifications are implemented to pinpoint factors that could cause daily errors, and more specifically, to prevent any harmful end use effects to patients. Though unusual, catastrophic external factors (Earthquakes, fires, floods and civic occurrences) have the potential to cause difficulties in hospital due processes as well as shortages, thus requiring measures other than the usual practices.

The purpose of this study is discovering the best way out of a cathastrophic event using analytic tools to decide on an intervention by removing the greatest risk by a single and powerful shot. In this study, the management and maintenance of patient security was carried out via quantitative analysis; the ST-PRA method was used, along with the FMEA scale developed by our hospital to determine risks and intervention priorities/actions generated by the ST-PRA(Sociotechnical-Probabilistic Risk assessment) method for a hospital with 780 beds the operation of which was impacted by demolition and construction hazards in 2015. Through a hybrid ST-PRA + FMEA method, the "zero error – zero collateral effect" goal was attained.
Keywords: ST-PRA, Patient Security, FMEA, Risk Analysis.

Hastanelerde Felaket Getiren Olaylar İçin ST-PRA+FMEA Hibrit Risk Analizi Uygulaması

Öz

Sağlık hizmetleri, frekansı düşük olmakla birlikte etkileri yönünden en ağır hataların görülebildiği endüstrilerden biri kabul edilmektedir. Diğerlerinden farklı olarak karmaşık matris bir yapıdadır ve işleyişine hem profesyoneller hem hastalar hem de dışsal pek çok etki bir arada hükmeder. Çoklu etki çoklu hata kaynağı anlamına da geldiği için günlük düzende hataya neden olabilecek etkenlerin ayrıştırılması ve özellikle kişilere ulaşan etki görülmeden engellenmesi amacı ile sistem analizleri, süreç değerlendirmeleri, hata veya neredeyse olay bildirimleri gibi yöntemlerden yararlanılmaktadır. Ancak nadiren görülse de katastrofik dış etkiler (deprem, yangın, sel, toplumsal olaylar vb) hastane işleyiş sisteminde beklenmedik zorlanmaların ve kesintilerin ortaya çıkabilmesine neden olma potansiyeli taşırlar. Boyle anlarda standartları ve işleyişi korumak için her zaman ki yöntemlerden farklı çalışmalara ihtiyaç duyulabilir.

Bu çalışmamızda da 2015 yılında çevresel bir yıkım ve inşaat çalışması nedeni ile 780 yataklı bir eğitim araştırma hastanesinin öngörülmemiş şekilde karşı karşıya kaldığı beklenmedik hasta güvenliği tehditlerine karşı durumu kontrol altına almak için risklerin kantitatif olarak ortaya konmasını sağlamak amacı ile ST-PRA yöntemi, bu yöntemin belirlediği risklerin müdahale önceliklerinin ve müdahale şeklinin kararlaştırılmasında ise hastanemiz tarafından geliştirilen FMEA ölçeği kullanıldı. Uygulanan Hibrit ST-PRA +FMEA yöntemi ile hedef olan "sıfır hata-sıfır yan etki" sonucuna ulaşılmasını sağlandı.

Anahtar Kelimeler: ST-PRA, Hasta güvenliği, FMEA, Risk analizi

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1. Introduction

An individual in need of health care services faces numerous unfamiliar processes, personal interactions and seemingly incomprehensible technologies. Besides the failure potential of each technological tool, each stage of the processes themselves has unique failure potentials. The identification of the probability of such failure modes before they impact patients is referred to as patient safety.

The most challenging aspect here is that the interactions among these complex processes as well as the social, societal, environmental circumstances have failure potentials that could affect patient safety on many levels at the same time; and most health care professionals responsible for maintaining patient safety lack sufficient knowledge of the steps of each process and their effects beyond their own area of expertise (Slomin, 2014; Marx, 2003). Any external factors additionally challenging service could worsen the ramifications (Modaresse, 2006). Therefore, the use of rational, comprehensible and accessible methods for assessing patient risk is crucial. There are cases and fields where assessment methods fall inadequate due to the matrix structure of health care services, regardless of whether they are retrospective (failure analysis, root cause analysis, examination of near-misses) or prospective (FMEA, Risk analysis). Marx and Slonim defined the ST-PRA (Sociotechnical-Probabilistic Risk assessment) method in 2003, instead of the PRA method which also is a hybrid, mathematical engineering model (Modaresse, 2006) that integrated risk analysis and decision supporting systems where FMEA and RCA methods were inadequate for matrix interactions, and was formerly utilized for risk mapping processes in nuclear substance production and aviation fields.

Researchers have demonstrated that the ST-PRA is capable of establishing a system sensitive to multiple failures compared to the Failure Effects Analysis (FMEA) method, which investigates the steps of a single process (Franklin, 2012); and Root Cause Analysis (RCA), which investigates a single occurrence (Slomin, 2014; Marx, 2003; Modaresse, 2006). On the other hand, this method has certain disadvantages compared to other methods such as its dependence on software for application in the healthcare industry and that the lack of familiarity on the part of healthcare personnel (Slomin, 2014). Nevertheless, the logic the logic underlying this method provides useful and convenient clues for the healthcare institutions for identifying risks.

2. Material and Method

Our hospital experienced a certain external exposure in the year 2015 that led to a probable interruption to services and more importantly, the potential to severely harm patients. The ST-PRA method was utilized by the hospitals top management and patient safety personnel to quantitatively identify the risks to ensure fast, accurate and sustainable decisions, their flawless implementation, and demonstrating sound evidence via objective and scientific reasoning throughout; whereas the FMEA was utilized to agree upon the prioritization and method of interventions defined by this method.

Distinct from other methods, the ST-PRA enables us to define the probability of results generated on the same output by the interaction of multiple failures of varying levels of importance resulting from separate processes on the same grounds, and to evaluate any effects of these processes. It enables the construction of a three-dimensional risk map in an industry which is open to numerous internal and external factors along with human-system-technology network. On the other hand, since the ST-PRA is basically a mathematical engineering model, there are challenges to applying this method in fields where human factors play a major role such as the healthcare industry.

Though identified as the most convenient method for identifying the multiple risks of the catastrophic events taken as the basis of our study, the FMEA was chosen for the sensitivity analysis and definition of interventions with respect to risk priorities, which were the last stages of the ST-PRA after the construction of the fault tree.

The ST-PRA consists of 6 steps as defined by Slonim [(1).] These steps are: the identification of risks based on data located at the center (data gathered from literature, site visits and technical assessments, focus group meetings, etc.), review of interactions among processes and risks, the construction of the fault tree and the review of its validity by expert teams, the presentation of AND/OR questions for each risk factor identified and process steps for probabilities, i.e, the multiple failures, evaluation of structural sensitivity, listing interventions and execution of risk prevention interventions. (Figure 1)

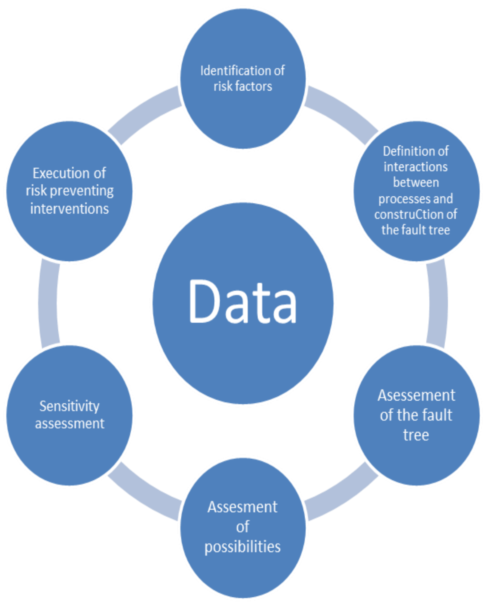

Figure 1: Risk Management circle

According to the method utilized during our study, all of the steps of the initial data collection, identification of risk factors, determination of process-risk factor interactions and construction of the fault tree, and consequent review of AND/OR outputs were carried out based on same operational principles. On the other hand, each risk was quantified by utilizing the FMEA risk priority coefficient table consequent to the review of the fault tree by the focus groups, and an RPN (risk priority number) was allocated to each of these risks. Method for the Hybrid ST-PRA (Figure 2)

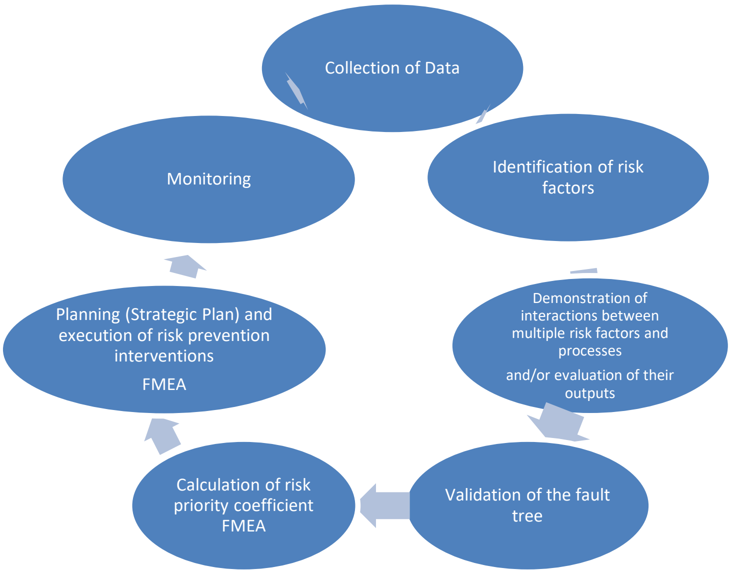

Figure 2: Steps of the Method

The study comprised 7 steps. First of all, it was demanded that the demolition and construction work that threatened all units of the hospital be terminated, and this goal was achieved.

Step 1: A multidisciplinary board was urgently called for a meeting. This board consisted of the Head Physician, Head of Infection Control Committee and committee members, Head of Administrative and Financial Affairs, Management of Maintenance Services, Director of Quality Management, Technical Services Engineer in Charge, Hospital Biomedical Service in Charge and Environmental Engineer, Operation Theaters' Manager, Intensive Care Units' Manager, Press Council, Managers of Internal and Surgical Clinics and Legal Counsel.

This board made an assessment of the situation and established an expert committee for the construction of the fault tree.

The goal was defined as the establishment of a graphical representation of failure mode estimates for processes that might be the cause or collaborator of a specific risk, and to monitor the execution status of interventions through simple monitoring methods.

Step 2: The ST-PRA study was initiated to identify the possible risks. All technical data, literature data, reports related to the field (quality reports, technical reports, safety reports), hospital processes and interaction maps were examined.

Step 3: Risk assessment took place for each step of the process to determine any intersection points and inherent risks of processes at varying levels of importance.

For instance; the interactions between emergency and in-patient units' operations were considered along with operating theater processes and patient transfer processes while assessing the risk of dust from the construction permeating the surgical buildings.

AND/OR questions were presented to identify all adverse factors that might contribute to the outcomes of the event by determining interactions among multiple risk factors. The probability of occurrence of both cases is demonstrated in the process flow (Figure 3).

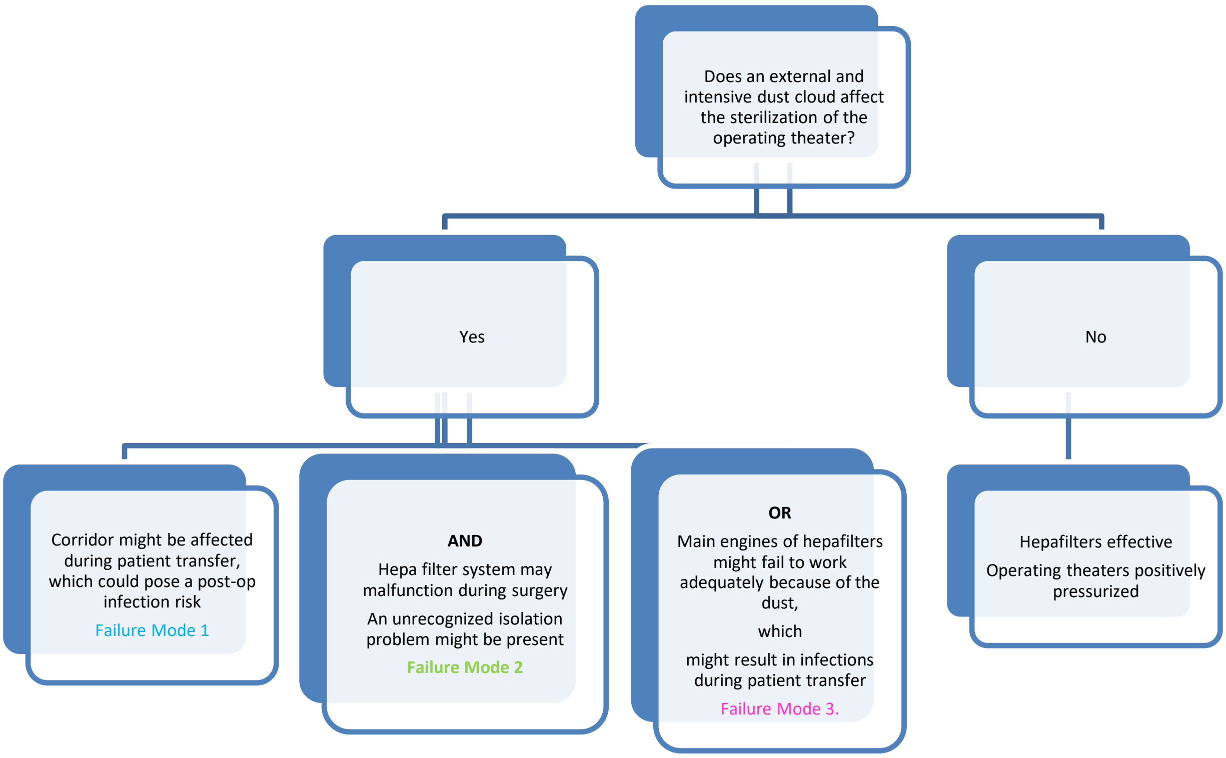

Figure 3: And/Or Outputs

Step 4: Evaluation and validation of the fault tree: All risks and process interactions identified were presented to the focus groups. For instance, the intensive care focus group consisted of intensive care senior physicians, senior nurses, infection control team, technical team and biomedical team. The fault tree was evaluated by reviewing each step of the process. The process flow maps, technical reports and quality audit reports of the hospital were utilized for this purpose, along with data from the literature.

Step 5: This step was the differentiating step from the standard ST-PRA. The FMEA scale was used for the sensitivity assessment and risk prioritization listing that ST-PRA suggests.

The focus group and risk assessment team calculated a risk priority number for each of the process steps and each of the risks defined (http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx, 2017) (Table 1) Color coding was also applied for each risk and the coding approached red as risk increased. (Table 2) Table 1 and Table 2 are given to clearly demonstrate how the death of a patient would affect risk priority number even when all other variables remained constant.

Table 1: Calculation of risk priority coefficient (Case: Material transfer between two buildings)

Probability	Variable	Table Value	Scor(over 100)	Relative Coefficient	Weighted score
Frequency of the work	everyday	5	100	0,25	25
Education level of the staff	good	2	40	0,25	10
Equipment technology	insufficient	4	80	0,083	6,64
Sufficiency of equipment as number and quality	insufficient	4	80	0,083	6,64
Duration of work	more than 10 hours	5	100	0,083	8,3
Working environment	very insufficient	5	100	0,083	8,3
Standardized operational process documents	Very sufficient	1	20	0,083	1,66
Past incidence	moderate	3	60	0,083	4,98
TOTAL					71,52
Severity	**Variable**	**Table Value**	**Scor(over 100)**	**Relative Coefficient**	**Weighted score**
Damage to staff and patient	Minor harm	2	40	0,8	32
Damage to the environment and society	none	1	20	0,05	1
Damage to the reliability and brand of the hospital	very high	5	100	0,05	5
Damage to the building	none	1	20	0,05	1
Damage to the equipment	Yok	1	20	0,05	1
TOTAL	none				40
İn the case of death the dummy variable is assumed to be 100					100
Detectability	**Variable**	**Table Value**	**Scor(over 100)**	**Relative Coefficient**	**Weighted score**
Work related knowledge level of the staff	very good	5	100	0,25	25
Frequency of external audit	annually or rare	1	20	0,25	5
Past incidence	rare	2	40	0,25	10
work frequency	everyday	5	100	0,25	25
TOTAL					65
				RÖS	44,01230769

Table 2: Case: Material Transfer Incorporating Risk of Death

Probability	Variable	Table Value	Scor(over 100)	Relative Coeffic	Weighted score
Frequency of the work	everyday	5	100	0,250	25,000
Education level of the staff	good	2	40	0,250	10,000
Equipment technology	insufficient	4	80	0,083	6,640
Sufficiency of equipment as number and quality	insufficient	4	80	0,083	6,640
Duration of work	more than 10 hours	5	100	0,083	8,300
Working environment	Very insufficient	5	100	0,083	8,300
Standardized operational process documents	very good	1	20	0,083	1,660
Past incidence	moderate	3	60	0,083	4,980
TOTAL					**71,520**
Severity	**Variable**	**Table Value**	**Scor(over 100)**	**Relative Coeffic**	**Weighted score**
Damage to staff and patient	death of a person	5	100	0,800	80,000
Damage to the environment and society	none	1	20	0,050	1,000
Damage to the reliability and brand of the hospital	very high	5	100	0,050	5,000
Damage to the building	none	1	20	0,050	1,000
Damage to the equipment	none	1	20	0,050	1,000
TOTAL					88,000
İn the case of death the dummy variable is assumed to be 100					**100,000**
Detectability	**Variable**	**Table Value**	**Scor(over 100)**	**Relative Coeffic**	**Weighted score**
Level of knowledge about the work	very good	5	100	0,250	25,000
Frequency of external audit	annually or rare	1	20	0,250	5,000
Past incidence	rare	2	40	0,250	10,000
work frequency	every day	5	100	0,250	25,000
TOTAL					**65,000**
				RÖS	110,0307692

Step 6: 24 sub-risks that affected 6 main processes were attained. RPNs attained by the joint meeting of the patient safety committee, facility safety committee and infection control committee was assessed and a strategic plan was set out. Interventions determined in this plan were monitored within determined periods by assigned teams. (Table 3).

Table 3: Strategic Plan

<table>
<tr><th>Process</th><th>Operating Theater Process</th><th>Intensive Care Process</th><th>Oncology Unit</th><th colspan="2">Emergency Room; Eye Clinic; Infectious Diseases Clinic</th></tr>
<tr><td>Potential Failure Mode</td><td>Preventive measures towards dust and particles remaining inadequate; Ventilation problems; Failure Mode 1; Failure Mode 2</td><td>Ventilation problems; Failure Mode 3</td><td>Intensive construction dust in the environment; Presence of infective agents such as Aspergillus and etc.</td><td>Physical harm to patient and relatives resulting from construction</td><td>Dust; Noise</td></tr>
<tr><td>Related Effect</td><td>Aspergillus infection; Increase in Post-op infection cases</td><td>Increase in intensive care infections; Aspergillus infection</td><td>Patients with compromised immune systems becoming vulnerable to various infections,mainly lung infections</td><td>Falls from the construction sites and related injuries.</td><td>Asthma, lung and hearing problems</td></tr>
<tr><td>Underlying Cause</td><td>Construction dust; Blockage of filters; Positive pressure becoming inadequate</td><td>Construction dust; Clogging in filters; Positive pressure becoming inadequate</td><td>Increased number of infectious agents in air, compared to normal conditions</td><td colspan="2">Construction site being unfenced</td></tr>
<tr><td>Controls in Place</td><td>Operating theater safety procedure; Infection control procedure; Disaster plan</td><td>Operating theater safety procedure; Infection control procedure; Disaster plan</td><td>No procedure exists related to air and municipality services surrounding the hospitals</td><td colspan="2">None</td></tr>
<tr><td>RPN</td><td>93.7</td><td>93.7</td><td>90.3</td><td colspan="2">73</td></tr>
<tr><td>Suggested Intervention</td><td>Terminate the process and plan</td><td>Terminate the process and plan</td><td>Terminate the process and plan</td><td colspan="2">Install temporary signage and barricades</td></tr>
<tr><td>Executed Intervention</td><td>A road map was established during a joint meeting of patient safety, facility safety and infection committee and a monitoring team were established; an aerometer and an air fogging device were supplied; it was decided that particle measurements for air filters should be conducted every other day.</td><td>A road map was established during a joint meeting of the patient safety, facility safety and infection committee and a monitoring team was established; an aerometer and an air fogging device were supplied; it was decided that particle measurements for air filters should be conducted every other day; windows were isolated, ventilation of the intensive care unit was sealed for protection.</td><td>Meeting with the company</td><td colspan="2">Implementation of water curtains surrounding the buildings, implementation of a sound curtain surrounding the construction site, prohibition of access to the construction site.</td></tr>
<tr><td>Period</td><td>First hour</td><td>First hour</td><td>3 hours later</td><td colspan="2">On the same day</td></tr>
</table>

Step 7: Field monitoring. was conducted according to the strategic plan. Monthly prevalence tracking was conducted. Monitoring activities were maintained for 6 months.

4. Conclusions and Recommendations

5 physical interventions were made within the first 24 hours following rigorous investigations and meetings with the construction company (Concrete covering of trenches, water curtains, sound curtains, securing ventilations of intensive care units, supplementary window isolation for risky areas, request for fore pilefor securing the policlinic building). Harm to patients being treated within this period was prevented by successive monitoring provided within three and seven day periods. However, the policlinic building, a structure unattached from the main hospital building, needed to be evacuated due to cracks that formed despite all preventive measures taken; and the building was out of service until it was secured.

Priority was given to the evaluation of monitoring and infection control data and daily reports obtained from teams during the process tracking procedure. Operating theater infection rates, surveillance, post-op infection rates and intensive care infection rates were monitored. No incidences of hospital-related infections were observed in patients that underwent surgery, or that were being treated in the intensive care or oncology units during this period; and no interruptions, errors or harm to patients were found in the aforementioned processes during the monitoring period of 6 months.

The advantages of the strengths offered by each method were both taken where; ST-PRA's strength was building a multi-dimensional failure map, FMEA's strength was the familiarity of the healthcare personnel with it, and the FMEA scale's strength was the rapid identification of risk priority numbers. A risk priority coefficient was defined for each of the risk factors followed by identifying interventions within the strategic plan for quantitatively ranking the risks, and a flowchart for control of priority zones was readily available for utilization by the teams without any delay. The execution of all of these assessments altogether made rapid interventions possible by managing the limited time effectively, along with the establishment of scientific and legal bases required by the management.

The FMEA and PRA are industrial analysis methods that were adopted to the healthcare industry within the scope of patient safety. Though the FMEA is suggested as a mandatory annual analysis method within certain intervals by IHI (Institute for Healthcare Improvement) and WHO (World Health Organization) (http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx , 2017; World Health Organization, 2005) it has major shortcomings compared to PRA.

The FMEA is based on the principle of assessing the effects of a single risk factor by constructing process maps and is inadequate for investigating multiple risk combinations that might be generated in complex systems (Marx, 2003; Modarres, 2006; Franklin 2012). However, what is important is not preventing single or individual failures but the prevention of catastrophic effects resulting from accumulated failures generated by multiple failures coinciding (Slomin, 2014; Marx, 2003; Modarres, 2006; Franklin 2012). Another difference between the two methods is the FMEA's suggestion of process maps (http://www.ihi.org/resources/Pages/Tools/Quality-Improvement-Essentials-Toolkit.aspx , 2017; World Health Organization, 2005; DeRosier, 2002; Catchpole, 2007; Van Tilburg, 2006), whereas the PRA makes conclusions based on the error maps Slomin, 2014; Marx, 2003; Modarres, 2006. The most undesirable and probable result is considered, factors that might result in this outcome are assessed, the presence of two factors together is considered through "AND" options, and generation of another factor in case one factor is removed is considered through the "OR" output. In some cases, these two might occur at the same time. The success of the analysis for both methods depends on the teams having adequate knowledge of the processes and the presence of sufficient data for facilitating the evaluation. On the other hand, the objective of all methods is to curtail major risks by utilizing the easiest and most efficient method at once within the current system. In other words, the objective is to decide on an intervention by removing the greatest risk by a single and powerful shot (Slomin, 2014; Marx, 2003; DeRosier, 2002; Catchpole, 2007; Van Tilburg, 2006; Burke, 2006).

The uniqueness of this study is the immediate prevention of a catastrophic event's effects on a 780 bed capacity hospital that could directly affects patients, despite being unrelated to medical interventions, by the joint utilization of risk analysis methods used consistently in hospitals for the prevention of medical errors; and attaining the desired patient and personnel safety results. The ST-PRA's multi-directional risk analysis requires certain statistical assessments to be conducted during its 5th step. Birnbaum and Fussel-Vesely measurements (Slomin, 2014) are utilized for carrying out the critical analyses, defining target occurrences and for deciding on the interventions to be implemented. The priority of risks is calculated by the software. In contrast, the underlying logic of the ST-PRA was utilized in our study to differentiate all risks and integrated risks resulting from process interactions as needed, and to create preventive interactions with respect to all these risks; however the risks were then based on FMEA models that healthcare personnel frequently use, and quantitative assessment was consequently performed through this model to attain Risk Priority Numbers (RPN). Priority zones and priority interventions were defined by utilizing the strategic plan generation module of the FMEA based on RPNs.

As a result of this study, the joint usage of the multi-dimensional assessment logic of ST-PRA to identify risks in hospitals along with the FMEA scale to calculate risk priorities could be proposed as an effective method for attaining "zero failure, zero side effects" results even under catastrophic circumstances.

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