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Using fuzzy FMEA to increase patient safety in fundamental processes of operating room

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Abstract

Risk assessment is a standard tool in health care systems which are used to improve patient safety. Failure mode and effects analysis (FMEA) as a powerful risk assessment tool for safety and reliability widely applied by industries such as aerospace, nuclear, automotive, chemical, mechanical, medical technologies, and electronics. FMEA is popular technique, but it has some substantial deficiencies. In this paper, fuzzy logic is employed to overcome these shortages. The proposed methodology extended to five fundamental processes of operating room (OR): (1) patient admission in the operating room; (2) patient transmission into the operating room; (3) operating room, washing; (4) request for equipment repair in the operating room and (5) request for medical and pharmaceutical products. The FMEA team suggested corrective actions for failures with risk priority number (RPN) greater than 4. To observe the effectiveness of corrective action; two months after implementation of corrective actions, RPN was calculated, and results showed 8.23 percent reduction averagely.

Keywords: Risk assessment, FMEA, fuzzy logic; operation room, patient safety, fuzzy FMEA

1- Introduction

The "To Err Is Human" was published by the Institute of Medicine (IOM) in 1999. The aim of this report was to investigate medical malpractice in hospitals in the United States and describe the errors related to patient safety in healthcare systems. It imparted that

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health care systems are not as safe as possible and 44,000 to 98,000 people die in hospitals each year because of preventable medical errors (Kohn et al., 2000).

IOM report drew public and private organizations' attention to patient safety. They attempted to abate medical errors and enhance patient safety in the healthcare system (Altman et al., 2004).

Recent studies in the U.S. and Europe imply that despite all achieved successes in mitigating the harms of medical errors in healthcare systems and promoting the patient safety, there are many deficiencies in the safety of hospitals and they are the most consequential necessities and priorities in hospital settings (Maamoun, 2009, Thomas and Classen, 2014, Vintzileos et al., 2013).

Operating rooms occupy only small parts of hospitals. Indeed, four percent of the physical space of hospitals allocates to operating rooms and three percent of the hospital's staff work on it. Interestingly, 35 percent of claims of hospitals belong to this part (McLain, 1980). On the other hand, studies show that 40 to 50 percent of adverse events such as wrong site, wrong procedure, and wrong patient takes place in an operating room, a significant amount of which is preventable (McLain, 1980, Khoshbin et al., 2009, van Beuzekom et al., 2012, Marshall and Emerson, 2012).

Healthcare organizations are responsible and committed to providing a safe and confidential place to deliver efficient treatment for patients. In the past decade, organizations used various methods and techniques to reduce unpleasant consequences of medical malpractices in hospital settings. Errors could detect by conducting a timely and accurate method.

Risk assessment is a common way which most health care systems apply it to improve patient safety. Risk assessment consists of many models and approaches such as FMEA, Process and Effect Analysis (PHA), Fault Tree Analysis (FHA), Hazard and Operability Analysis (HAZOP), Root Cause Analysis (RCA) and Energy Trace and Barrier Analysis (ETBA).

The goal of this study is to demonstrate fundamental processes in the operating room and to implement FMEA techniques on these processes to recognize high-risk errors and decrease injuries happening in the operating room.

In actual situations, imprecision, ambiguity and uncertainty are inseparable parts of problems. While FMEA is conducted to evaluate the risk of processes or systems using its underlying parameters (occurrence, severity, and detection), unrealistic and deceptive impressions may be produced. Consequently, the RPN obtained by these parameters may disregard the prominence of results. The application fuzzy logic in the proposed methodology allows affording practical and eloquent information for these parameters and guarantees that identified failure modes don't be ignored because of a lower RPN.

The remainder of the paper organizes as follows. Failure modes and effects analysis will discuss in section 2. Next, in section 3, Fuzzy FMEA is explained. In section 4, a concise review of essential processes in the operating room will present. Part 5 consists of applying Fuzzy FMEA for fundamental processes. Then, results, discussions, concluding remarks and future research directions will propound.

2- Literature review

Numerous studies have strived to promote efficiency and effectiveness of FMEA by using fuzzy logic. Studies concerning fuzzy FMEA can be separated into two sections: (1)

fuzzy FMEA studies (2) amalgamation of fuzzy FMEA and other methods and approaches.

First, attempt to decrease limitation of the FMEA method using fuzzy logic was in 1995 by Bowles and Peláez. They represented FMEA parameters as members of a fuzzy set, combined by matching them against the rules in a rule base, evaluated with min-max inferencing, and then defuzzified to assess the riskiness of the failure. This approach resolves some of the problems in traditional methods of evaluation (Bowles and Peláez, 1995).

After Bowles and Peláez, application of fuzzy extends widely in various fields such as mechanics, nuclear, industrial engineering, electronics, medical and healthcare, agriculture, etc.

At the beginning of the 21st century, Xu et.al conducted fuzzy inference to FMEA on the turbocharged diesel engine system (Xu et al., 2000). First utilization of fuzzy FMEA in industrial engineering was in 2002 when Xu et.al used it for quality and reliability of engine systems (Xu et al., 2002). In 2004, Fuzzy FMEA applied to PWR chemical and volume control system (Guimarães and Lapa, 2004). Utilization of this approach for sewage plant (Yeh and Hsieh, 2007), product design system (Chin et al., 2008), CNC machine tool (Yang et al., 2010), improvement of the purchasing process in a public hospital (Kumru and Kumru, 2013) and risk measurement of supply chain of organic rice product (Rohmah et al., 2015) are a negligible portion of the studies.

Some studies were to reduce the number of fuzzy rules, i.e. Tay and Lim implement GRRS (Guided Rule Reduction System) as a general rule reduction to lessen the number of rules that need to be provided by users during the fuzzy RPN modeling process (Tay and Lim, 2006).

Kutlu and Ekmekçioğlu applied a combination of fuzzy FMEA and fuzzy TOPSIS-based fuzzy AHP since fuzzy approach, allowing experts to use linguistic variables for determining S, O, and D, is considered for FMEA by applying fuzzy ‘technique for order preference by similarity to ideal solution’ (TOPSIS) integrated with fuzzy ‘analytical hierarchy process’ (AHP) (Kutlu and Ekmekçioğlu, 2012).

Liu et.al used fuzzy evidential reasoning (FER) and belief rule-based (BRB) methodology to fuzzy FMEA to propose a new risk priority model for prioritizing failures. The FER approach is used to capture and aggregate the diversified, uncertain assessment information given by the FMEA team members; the BRB methodology is used to model the uncertainty, and nonlinear relationships between risk factors and corresponding risk level; and the inference of the rule-based system is implemented using the weighted average maximum composition algorithm. The Dempster rule of combination is used to aggregate all relevant standards for assessing and prioritizing the failure modes that have been identified in the FMEA (Liu et al., 2013a).

Mandal and Maiti believed that fuzzy numerical approaches based on de-fuzzification suffer from the shortcoming of providing arbitrary priority ranks of failure modes even when their membership functions overlap. To overcome this shortcoming they developed a new methodology integrating the concepts of similarity value measure of fuzzy numbers and possibility theory. They applied similarity value measure to group together failure modes having similar amount of risk value (Mandal and Maiti, 2014).

Bozdag et al (2015) have studied the variation in one expert’s understanding (intra-personal uncertainty) and the variations in the understanding among experts (inter-personal uncertainty) together. They proposed fuzzy FMEA approach based on IT2 fuzzy sets, which has the ability to capture both intra-personal and inter-personal uncertainty (Bozdag et al, 2015).

In order to overcome insufficiencies traditional FMEA such as evaluation of failure modes, the weighting of risk factors, and the ranking of failure modes, Wang et al (2016) provide a new FMEA model which integrates COmplex PRoportional ASsessment (COPRAS) and Analytic Network Process (ANP) method is proposed to assess and rank the risk of failure modes under interval-valued intuitionistic fuzzy context. The proposed risk priority approach combines the advantages of interval-valued intuitionistic fuzzy sets (IVIFSs) in coping with uncertainty, vagueness and incompleteness, and the merits of COPRAS and ANP in solving multi-criteria decision making problems (Wang et al, 2016).

Since the determination of RPN is based on the risk factors like occurrence (O), severity (S) and detection (D), it has much irrationality and needs to be improved for more applications. Jing et al (2017) propose a FMEA model based on a novel fuzzy evidential method to overcome the aforementioned shortcomings of the traditional FMEA and better model and process uncertainties. The risks of the risk factors are evaluated by fuzzy membership degree. Consequently, a comprehensive way to rank the risk of failure modes is proposed by fusing the feature information of O, S and D with Dempster–Shafer (D–S) evidence theory. The advantages of the proposed method are that it cannot only cover the diversity and uncertainty of the risk assessment, but also improve the reliability of the RPN by data fusion (Jing et al, 2017).

Whereas in the conventional FMEA, sometimes the difference between some failure modes cannot be distinguished; therefore Fattahi and Khalilzadeh (2018) proposed new a novel fuzzy hybrid model for FMEA to evaluate various failure modes more precisely. In this method, fuzzy weighted risk priority number (FWRPN) is considered instead of RPN for each failure. The weights of the three factors and the weights of failure modes are computed by extended fuzzy AHP and fuzzy MULTIMOORA methods, respectively. The proposed fuzzy MULTIMOORA method calculates the weight of each failure based on three criteria of time, cost, and profit through fuzzy linguistic terms. After calculating FWRPN for each failure, corrective actions are performed for eliminating the identified failures or decreasing the effects of them. Then, corrected fuzzy weighted risk priority number (CFWRPN) is computed for each failure (Fattahi and Khalilzadeh, 2018).

3- Failure Modes and Effect Analysis (FMEA)

Many different tools have been created during the past decades to assess risks and prevent the occurrence of adverse events. Most of these tools detect anything might malfunction. FMEA is a risk assessment tool to find and decrease potential failure modes in processes (Thornton et al., 2011). Although at first FMEA was developed by engineers and it used in modeling high-risk procedures, now people frequently exert it in preventable assessments and safety improvements in the health care system (Shebl et al., 2012). FMEA as a powerful tool for safety and reliability is widely applied to industries such as aerospace, nuclear, automotive, chemical, mechanical, medical technologies and electronics (Liu et al., 2013b).

Different patient safety agencies e.g. Joint Commission (JC), Institute for Healthcare Improvement (IHI) and the Institute for Safe Medication Practices (ISMP) have acclaimed application and advantage of FMEA in health care (Shebl et al., 2012). In 2001, toward identifying and predicting weakness of the system, JC wanted deliverers to conduct preventable risk management procedures (Barton, 2009). To determine the failure causes, in 2003, JC forced health care centers and organizations to analyze high-risk process at least once a year by using FMEA (Paparella, 2007, Michell, 2013). Convectional FMEA is 10-step method (McDermott et al., 1996) as given below:

Step 1: Review the process. In the beginning, process components are discussed. The proper start point is to use a detailed process flow chart.

Step 2: Brainstorm potential failure modes. After an overall perception of the process, focusing on the potential failure mode will begin. A brainstorming session may help to gain many suggestions and ideas.

Step 3: List potential effects of each failure mode. When all potential failures were found, they will be reviewed to determine the potential effect of each failure.

Step 4: Assign a severity ranking for each effect (S). Here, each effect takes a severity ranking regarding table 1.

Table 1. Severity ranking (McDermott et al., 1996)

Ranking	Description	Definition
10	Hazardous without Warning (HWW)	Patient death
9	Hazardous with Warning (HW)	Patient disability
8	Very High (VH)	Serious impact on patient health
7	High (H)	High impact on patient health
6	Moderate (M)	Normal injury with medical care
5	Low (L)	Low injury with medical care
4	Very Low (VL)	Low injury without medical care need
3	Minor (M)	Slight effect
2	Very Minor (VM)	Very slight effect
1	Extremely Minor (EM)	No effect

Step 5: Assign an occurrence ranking for each failure mode (O). Based on Table 2 each failure is specified by an occurrence ranking.

Table 2. Occurrence Ranking (McDermott et al., 1996)

Ranking	Description	Definition
10	Almost Certain (AC)	>1 in 2
9	Very High (VH)	1 in 3
8	High (H)	1 in 8
7	Moderately High (MH)	1 in 20
6	Moderate (M)	1 in 80
5	Low (L)	1 in 400
4	Very Low (VL)	1 in 2000
3	Minor (MI)	1 in 15000
2	Very Minor (VMI)	1 in 150000
1	Extremely Minor (EMI)	1 in 1500000

Step 6: Assign a detection ranking for each failure mode and/or effect (D). Current control on each process component is considered to assign a detection ranking. Using Table 3 is helpful to determine this ranking.

Table 3. Detection Ranking (Reid, 2005)

Ranking	Description	Definition
10	Extremely Minor (EMI)	Undetectable
9	Very Minor (VMI)	Controls will probably not detect
8	Minor (MI)	Controls as have a poor chance of detection
7	Very Low (VL)	Controls have low chance of detection
6	Low (L)	Controls may detect
5	Moderate (M)	Controls may detect
4	Moderately High (MH)	Controls have a good chance of detection
3	High (H)	Controls have very good chance of detection
2	Very High (VH)	Controls almost certain to detect
1	Extremely High (EH)	Controls will detect

Step 7: Calculate the risk priority number (RPN) for each effect. It is obtained by multiplying S, O, and D.

Step 8: Prioritize the failure modes of action**.** Order the failure modes from high-risk to low-risk.

Step 9: Take action to eliminate or reduce the high-risk failure modes.

Step 10: Calculate the resulting RPN as the failure modes are reduced or eliminated.

FMEA uses risk priority number to determine risk amount of process. Conventional RPN has several shortcomings (Liu et al., 2013b):

1. It disregards the relative importance among *O*, *S* and *D*. Assume severity of a failure effect A is 8, occurrence and detection of failure modes, respectively, be 1 and 1; and, the severity of failure effect B is 2, occurrence and detection, respectively be 2 and 3. Do both failures RPN have the same risk of health care?
2. Different combinations of O, S, and D may produce the same value of RPN, but their hidden risk implications may be entirely different.
3. The mathematical formula for calculating RPN is questionable and debatable.
4. RPNs are not continuous with many holes (e.g. RPNs exclude of prime numbers of greater than 10).

In this paper, to eliminate the shortcomings and extenuations of typical FMEA, fuzzy logic is exploited. Next an abridged introduction to fuzzy logic is presented.

4- Fuzzy logic framework as applied for risk assessment

Application of fuzzy logic in risk assessment is due to the following reasons; (1) it allows the analyst to evaluate the risk associated with item failure modes directly using the linguistic terms that are employed in assessing the criticality of failure; (2) ambiguous, qualitative, or imprecise information, as well as quantitative data, can be used in the assessment and they are handled in a consistent manner; (3) it gives a more flexible structure for combining the severity, occurrence, and detectability parameters(Bowles and Peláez, 1995).

Zadeh was the pioneer of fuzzy logic in 1965. Zadeh implied that classical logic is not compatible with complex systems and vague situations. He introduced fuzzy logic as an appropriate method to deal with uncertainty and ambiguity involved in complex systems.

A fuzzy logic system is unique in that it can simultaneously handle numerical data and linguistic knowledge. It is a nonlinear mapping of an input data vector into a scalar output, i.e. it maps numbers into numbers. In other words, fuzzy set theory and fuzzy logic establish the building-blocks of the nonlinear mapping (Mendel, 1995).

The definition of a fuzzy set *X* over the universe of discourse *A* is as follows:

$$X = \left\{ \left(\frac{\mu_x(x)}{x} \right) : x \in A \right\} \tag{1}$$

Where μ_x indicates a membership function of *X*, and the value $\mu_x(x)$ provides the grade of membership for $x \in A$. The value denotes the degree of *x* belonging to the fuzzy set *X* (Bede, 2012). In other words, membership function μ_x maps elements of the universe of discourse *A* to set $[0,1]$ (Deli and Çağman, 2015). That is:

$$\mu_x : A \to [0,1]. \tag{2}$$

There are several types of the membership function. In this paper, the triangular membership function is used as illustrated in figure 1 (for further information see Hans-Jürgen Zimmermann, 2001). Besides, its mathematical representation is as below (Shukla et al., 2010):

$$\mu_x(x,a,b,c) = \begin{cases} 0 & if\ x \le a \\ \dfrac{x-a}{b-a} & if\ a \le x \le b \\ \dfrac{c-x}{c-b} & if\ b \le x \le c \\ 0 & if\ c \le x \end{cases} \tag{3}$$

Here, the fuzzy rule-based system is composed of three parts which are called crisp input, fuzzy inference system, and crisp output. Crisp inputs contain severity ranking, occurrence ranking and detection ranking, which are based on expert knowledge and measured according to tables 1, 2 and 3.

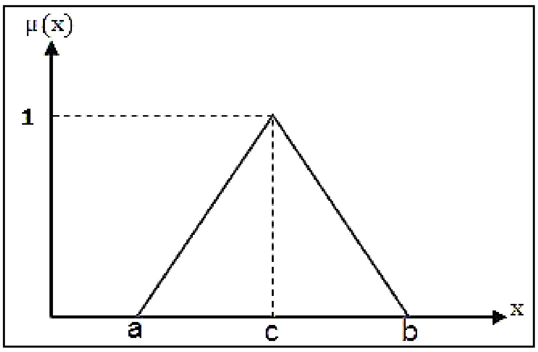

Fig 1. Triangular Membership Function

The proposed fuzzy-based inference system has four levels (Kumru and Kumru, 2013) including initialization, fuzzification, inference and defuzzification. These levels are described next.

4-1-Initialization

The first step for initializing the system is defining the linguistic variables. As you may know, linguistic variables are words or sentences in a natural or artificial language used to present the meaning of values (Zadeh, 1975).

Here, the linguistic variables of severity, occurrence, detection and RPN respectively are defined as [HWW, HW, VH, H, M, L, VL, M, VM, EM], [AC, VH, H, MH, M, L, VL, M, VM, EM], [EM, VM, M, VL, L, M, M, H, VH, EH] and [EMI, VMI, VL, L, M, MH, H, VH, EH]. The illustration of the linguistic variables for severity, occurrence, detection and RPN is given in figures 2-5 regarding a 10-level triangular membership function.

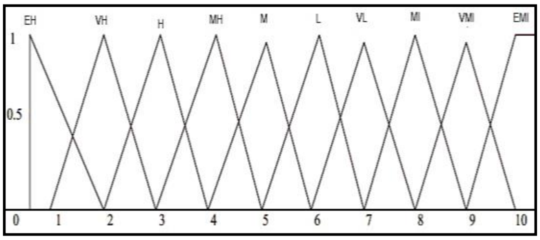

Fig 2. Severity membership functions in system

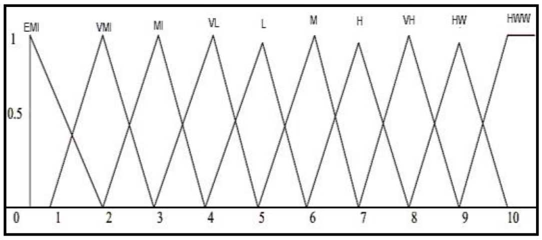

Fig 3. Occurrence membership functions in system

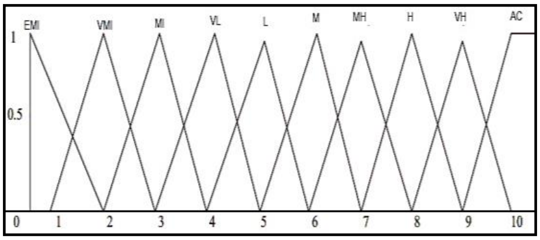

Fig 4. Detection membership functions in system

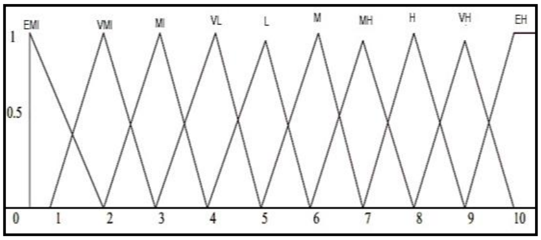

Fig 5. RPN membership functions in system

Next, the rule base is constructed. It is composed of 1000 fuzzy IF_THEN rules to cover all possible situations. The general form of fuzzy rules is as follows (Sumathi and Paneerselvam, 2010):

$$IF\ x_1\ is\ A_1\ AND\ x_2\ is\ A_2\ , \ldots.\ AND\ x_n\ is\ A_n\ THEN\ y\ is\ B.$$

Some example rules are given below:

(1) IF (Occurrence is EMI) AND (Severity is EMI) AND (Detection is EMI) THEN (RPN is EMI),

(2) IF (Occurrence is EMI) AND (Severity is EMI) AND (Detection is VMI) THEN (RPN is EMI),

And until to:

(999) IF (Occurrence is AC) AND (Severity is HWW) AND (Detection is VH) THEN (RPN is EH),

(1000)IF (Occurrence is AC) AND (Severity is HWW) AND (Detection is EH) THEN (RPN is EH).

To calculate the consequent of a fuzzy rule more conveniently, a slack parameter called effect analysis as observed in table 4 is used. Suppose we want to obtain the consequences of fuzzy rule (RPN) while occurrence is EH, severity is EH and detection is EH. First, we combine occurrence and detection to obtain effect analysis by using table 5. As shown in table 4, the result is indicated by the EH. Now to attain the RPN, we combine effect analysis, here it is EH, and detection, which is EH. According to Table 5, the consequent is EH. This procedure is the same for all of the other rules.

Table 4. Fuzzy rules (Effect Analysis)(Kharola and Singh, 2014)

Effect Analysis		Occurrence Ranking									
		AC	VH	H	MH	M	L	VL	MI	VMI	EMI
Severity Ranking	HWW	EH	EH	VH	VH	H	H	MH	MH	M	M
	HW	EH	VH	VH	H	H	MH	MH	M	M	L
	VH	VH	VH	H	H	MH	MH	M	M	L	L
	H	VH	H	H	MH	MH	M	M	L	L	VL
	M	H	H	MH	MH	M	M	L	L	VL	MI
	L	H	MH	MH	M	M	L	L	VL	MI	MI
	VL	MH	MH	M	M	L	L	VL	MI	MI	VMI
	MI	MH	M	M	L	L	VL	MI	MI	VMI	VMI
	VMI	M	M	L	L	VL	MI	MI	VMI	VMI	EMI
	EMI	M	L	L	VL	MI	MI	VMI	VMI	EMI	EMI

Table 5. Fuzzy rules (RPN)(Kharola and Singh, 2014)

RPN		Effect Analysis									
		EH	VH	H	MH	M	L	VL	MI	VMI	EMI
Detection Ranking	EH	EH	EH	VH	VH	H	H	MH	MH	M	M
	VH	EH	VH	VH	H	H	MH	MH	M	M	L
	H	VH	VH	H	H	MH	MH	M	M	L	L
	MH	VH	H	H	MH	MH	M	M	L	L	VL
	M	H	H	MH	MH	M	M	L	L	VL	MI
	L	H	MH	MH	M	M	L	L	VL	MI	MI
	VL	MH	MH	M	M	L	L	VL	MI	MI	VMI
	MI	MH	M	M	L	L	VL	MI	MI	VMI	VMI
	VMI	M	M	L	L	VL	MI	MI	VMI	VMI	EMI
	EMI	M	L	L	VL	MI	MI	VMI	VMI	EMI	EMI

4-2-Fuzzification

The first step is to take the crisp inputs and determine the degree to which these inputs belong to each appropriate fuzzy set. This crisp input is always a numeric value limited to the certain range of values. Once the crisp inputs are obtained, they are fuzzified using the designated fuzzy membership functions(Shukla et al., 2010).

4-3-Inference

The inference engine is the heart of any fuzzy inference system. Two important actions happen inside it: evaluating the output of each rule in the rule base and aggregating the results obtained from different rules. There exist different inference methods including Mamdani, Takagi-Sugeno (TS) and Tsukamoto inference ones. Mamdani fuzzy inference method uses fuzzy sets as the rule consequent while TS method uses functions of input variables as the rule's consequent and the Tsukamoto inference method uses a fuzzy set with a monotonically membership function as the rule's consequent(Sumathi and Paneerselvam, 2010). In this paper, Mamdani inference method considering minimum input method and maximum aggregation method is exploited.

4-4-Defuzzification

At the end of inference, the aggregated outputs as a result of applying the rules are obtained. Hence, these results have to transform to crisp data. This transformation is called defuzzification. Various methods are used to defuzzify the outputs. The most prominent methods are the center of gravity (COG) or centroid, weighted average method and mean max method. Here in this paper, COG is selected as a defuzzification method. Mathematically, COG is shown as:

$$COG = \frac{\int \mu_A(x).xdx}{\int \mu_A(x)dx} \quad (4)$$

The overall structure of the proposed fuzzy modeling framework is illustrated in figure 6. In order to implement the proposed approach depicted in figure 6, we used the methodology presented in figure 7. As it can be seen, the methodology has the following distinguished phases: developing conventional FMEA process (first six steps), calculating fuzzy RPN as defined in section 3 and conducting remaining steps of conventional FMEA for failures with RPN greater than four.

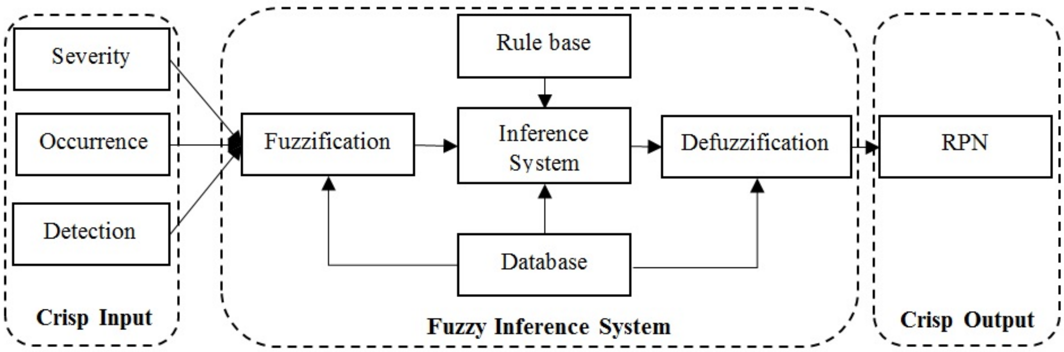

Fig 6. Overall structure of the fuzzy modeling framework

5- Case Study

The case study was exploited at the Abadan Imam Khomeini hospital. In the formed FMEA team, there exist six members, who are working in the OR, including a matron, an anesthetic expert, two surgeons and two nurses. The FMEA team selected five fundamental processes in OR comprising (1) patient admission in OR; (2) patient transmission to OR; (3) washing the OR; (4) request for equipment repair in the OR and (5) request for medical and pharmaceutical products.

Although all of the possible effective major failures were found by brainstorming, here just 24 of the most notable failures are considered. After listing these failures, identifying failures' effects, and failure causes, we should rank severity, occurrence, and detection of each failure. Table 6 presents all of the above-mentioned information.

Then, according to the proposed methodology based on fuzzy FMEA, severity, occurrence and detection rankings are used to determine RPN. Meanwhile, all of the detailed calculations to determine fuzzy RPN were done using the Fuzzy toolbox of MATLAB.

Finally, corrective action is suggested for each case whose RPN is greater than four and for the other common corrective action is considered.

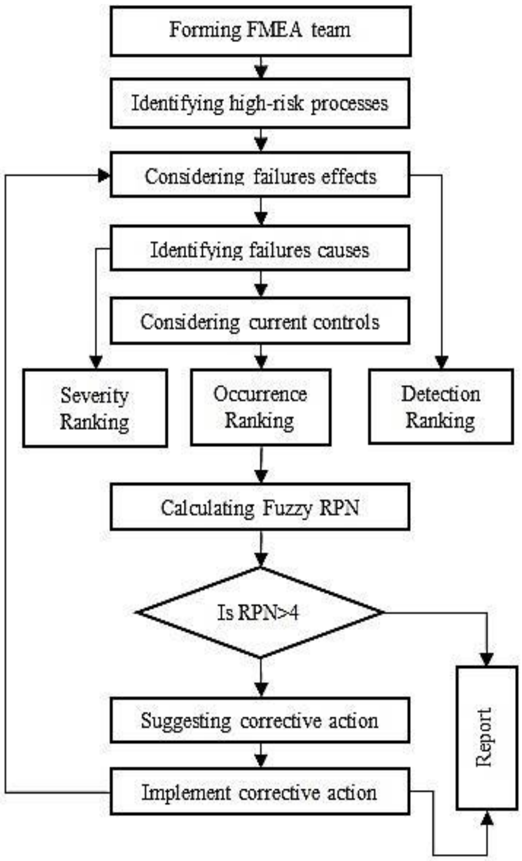

Fig 7. Proposed methodology process

6- Results

According to table 6, almost 63 percent of failures need corrective action. Riskiest failure among the failure is E02 and E03 whose RPN is 6.46. Figure 8 shows failure modes regarding their RPN.

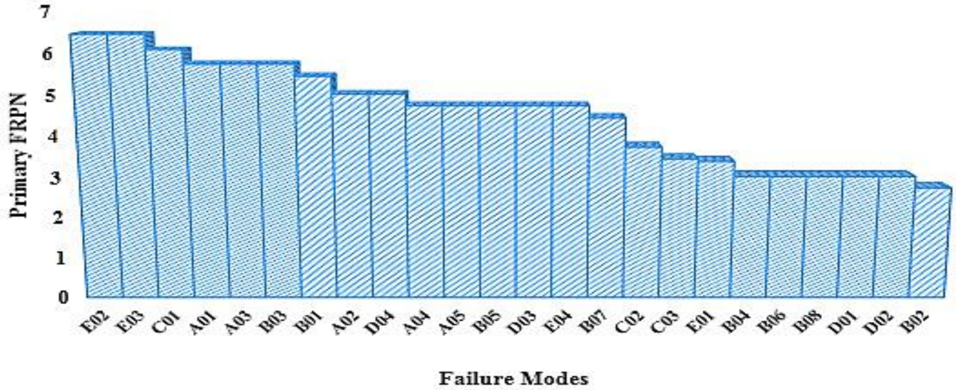

Fig 8. Failures RPN

To decrease the risk of those 63 percent of failures, corrective actions were executed for a two-month period. After two months, severity, occurrence, and detection ranking were reassigned. The findings were surprising. The severity, occurrence, and detection rankings were amended 7.35 percent, 6.45 percent, and 8.27 percent, respectively.

In reassigning the rankings, A04 had the most changes (improvements) in severity; E01 had it in occurrence and B07 had it in detection. Figures 9, 10 and 11 show the obtained improvements in percentage on failure modes in a two-month period for severity, occurrence, and detection, respectively.

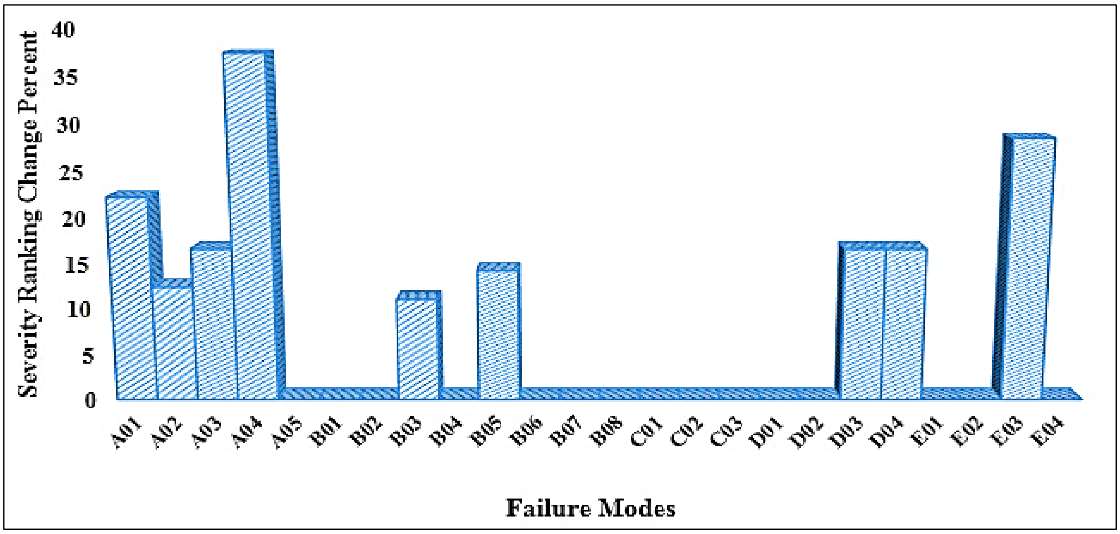

Fig 9. Severity improvement in a 2-month period

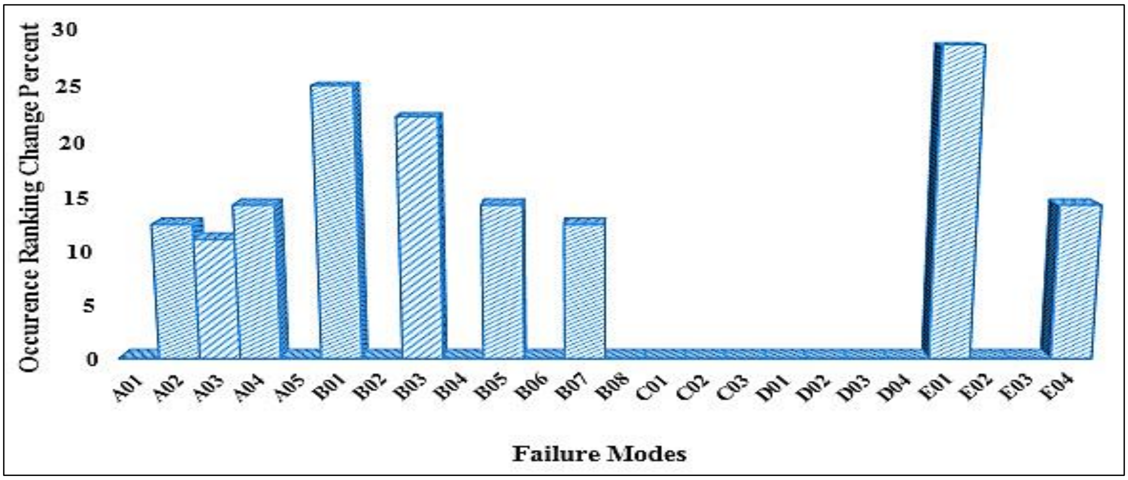

Fig 10. Occurrence improvement in a 2-month period

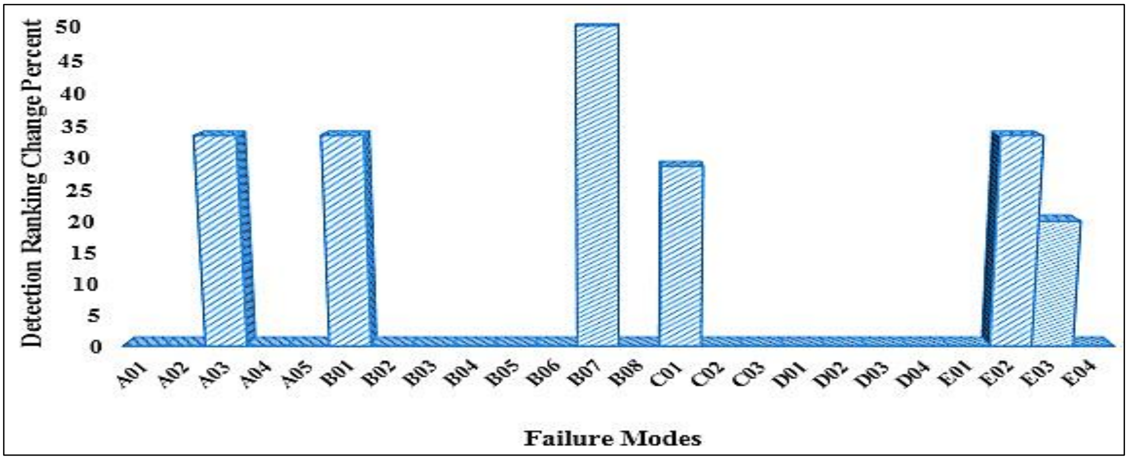

Fig 11. Detection improvement in a 2-month period.

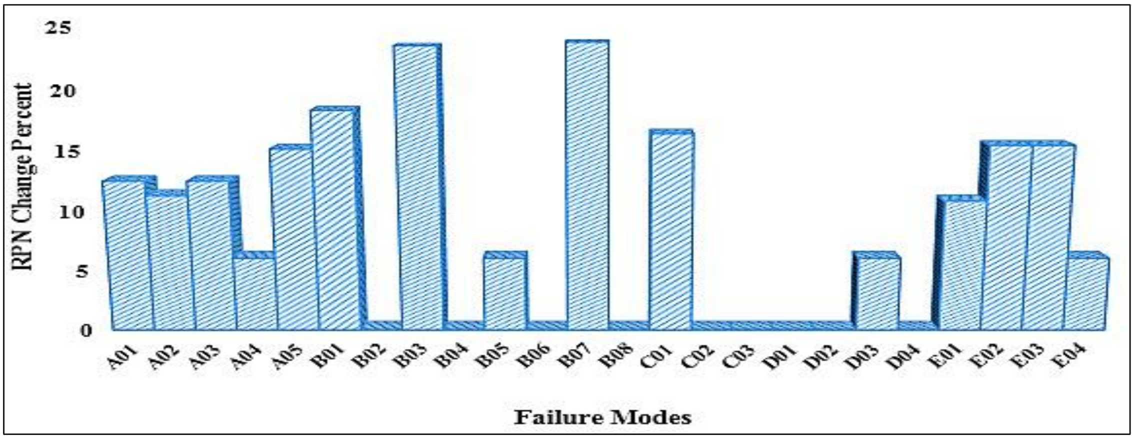

Fig 12. RPN improvement in a 2-month period.

After reassigning, RPN recalculated to find how much corrective actions were effective. In fact, a two-month is a short time to discuss the effectiveness of corrective actions in failures improvement; but, totally, according to figure 12, we can observe that the majority of failures has been improved considerably. Moreover, RPN improvements on average are 8.32 percent, which indicates favorable risk reduction amount.

6-1-Fuzzy FMEA versus conventional FMEA

As mentioned, since conventional FMEA has several shortages, in this paper, it was attempted to overcome these deficits. In order to present an inclusive prospect, consider failures A01 and B07. Severity, Occurrence, and Detection for A01 are 8, 8 and 1, respectively. On the other side for B07, these parameters are 4, 8 and 2, respectively. Based on conventional FMEA, A01 and B07 are considered as an equivalent threat to patient safety because both failures' RPN is 64. This is not acceptable in sensitive locations such as health care systems.

In the proposed fuzzy FMEA, such issues have been omitted. According to Table 4, RPN for declared failures, A01 and B07 is 5.03 and 4.46, respectively. This shows the superiority of fuzzy FMEA. Fuzzy FMEA reflects the corresponding relation between FMEA parameters and keeps the prominence of each parameter while standard FMEA is not able to consider it. Application of fuzzy FMEA can characterize each failure using membership function; it can also bunch expert perceptions up using IF-THEN rules, and it can ease the risk assessment process and increase reliability.

7- Conclusion

In this paper, FMEA was used for assessing risk and preventing adverse events in OR to improve patient safety. Conventional FMEA uses RPN to prioritize the risk. Literature review shows that such prioritization has severe limitations. We used fuzzy modeling to overcome the limitations of conventional FMEA. Fuzzy FMEA was conducted for five fundamental processes in OR in a real hospital and it identified all of the critical failures in these processes. After calculating RPN, for failures by RPN greater than four, corrective actions were suggested. Two months later, after implementing the corrective actions, the recalculated RPN showed impressive improvements. In future studies, the executing of fuzzy FMEA in other hospital units and wards and combination of fuzzy FMEA and Multi-Criteria Decision Making methods such as AHP, ANP, etc can be valuable.

Table 6.a. FMEA worksheet of basic processes

Process	Label	Failures	Effect	Causes	Severity	Occurrence	Detection	Fuzzy RPN	Corrective actions	Severity	Occurrence	Detection	Fuzzy RPN
patient admitting in OR	A01	Inaccessibility of empty OR	• Patient waiting for a preoperative position • Patient dissatisfaction • Exhaustion of patients • Patient companions concerning	• Surgeon delay • Prolonged surgery	9	8	1	5.75	Set accurate scheduling in accordance with surgeons presence	7	8	1	5.03
	A02	Lack of proper places for waiting for patient	• Patient dissatisfaction • Exhaustion of patients • Patient companions concerning	• Patients delivery without surgeon entrance time setting • Surgeons delay despite scheduling	8	8	1	5.03	Construct proper places by considering the patient privacy and security	7	7	1	4.46
	A03	Wrong side surgery	• Nurses confusion • Time wasting • Serious injuries • Patient death	• Lack of personnel attention to patient case • Disobedience of surgeons from notation standards	6	9	3	5.75	Hold medical communication with patient training for staff in order to diagnose right surgery	5	8	2	5.03
	A04	No information insertion in related form (form No.6)	• Nurses confusion • Time wasting	• Lack of OR personnel attention • Crowded units • No control of mentioned way by OR personnel	8	7	2	4.75	Staff training and create process specified checklist	5	6	2	4.46
	A05	Lack of preoperative process care	• Doing additional works in OR • Time wasting • Patient concerning	• Inconsiderateness and laches of nurses • Patients delivery without surgeon entrance time setting • Surgeons delay despite scheduling	7	5	1	4.75	Create process specified checklist	7	5	1	4.03

Table 6.b. FMEA worksheet of basic processes

Process	Label	Failures	Effect	Causes	Severity	Occurrence	Detection	Fuzzy RPN	Corrective actions	Severity	Occurrence	Detection	Fuzzy RPN
patient transmission to OR	B01	Wrong-patient	• Drowse surgery processes for another patient • Increased risk for the patient (serious injury or even death) • Patient concerning • anxiety to the patient and surgeon	• Lack of clinical presence of nurse with patient • Lack of coordination with patient carrier • Lack of attention to patient case	5	8	3	5.46	Evaluation of patients' records and facts before transmission	5	6	2	4.46
	B02	Late delivery of patient	• Drowse surgery processes for another patient • Patient and surgeons concerning and exhaustion • anxiety to the patient and surgeon	• Lack of proper training of nurses and patient	4	4	1	2.75	-	4	4	1	2.75
	B03	Not having the surgery testimonial	• Drowse surgery processes for another patient • Claims and complaints against hospital	• Delinquency of OR personnel	9	9	1	5.75	Preoperative evaluation of patients' records and cases	8	7	1	4.40
	B04	Not having patient images and tests	• Drowse surgery processes for another patient • Irregularities and disturbances in preoperative processes	• Delinquency of OR nurses in patient case checking	4	6	1	3.03	-	4	6	1	3.03
	B05	Invalid patient IV	• Create problems in the treatment process	• Inaccuracies of nurses in IV therapy	7	7	2	4.75	Complete review of IV	6	6	2	4.46
	B06	Not wearing special	• Inaccessibility to right side in anesthesia and surgery	• Lack of OR personnel controls	4	4	2	3.03	-	4	4	2	3.03
	B07	Not keeping the patient in NPO situation	• Surgery cancellation or delays in it. • The aspiration • Patient death	• Lack of OR personnel control of patient feeding	4	8	2	4.46	Monitor all patient activities by OR nurses	4	7	1	3.40
	B08	Wrong patient case	• Wrong surgery • Prolonged surgery process • Serious injuries (death or disabilities)	• Delinquency of OR nurses	4	6	1	3.03	-	4	6	1	3.03

Table 6.c. FMEA worksheet of basic processes

Process	Label	Failures	Effect	Causes	Severity	Occurrence	Detection	Fuzzy RPN	Corrective actions	Severity	Occurrence	Detection	Fuzzy RPN
Operation room washing	C01	Non-guideline based OR washing	• Remaining germs and infection in different parts of OR	• Lack of precision and the attention of the OR service staff to process of washing • Inadequacy of washing materials	3	3	7	6.09	Following and checking washing process by head OR or matron	3	3	5	5.09
	C02	Inadequacy of washing materials	• Remaining germs and infection in different parts of OR	• Untimely washing materials delivery • Delays in washing materials requests	3	4	4	3.75	-	3	4	4	3.75
	C03	Inadequacy of OR service staff	• Prolonged washing process • Staff exhaustion • Improper and unpleasant washing	• No replacement service personnel in case of illness or permission	5	3	2	3.46	-	5	3	2	3.46
request for equipment repair in the OR	D01	Timely calibration	• injuries caused by System malpractice during processes	• Lack of appropriate presence of company for calibration • Lack of proper planning for calibration	5	4	1	3.03	-	5	4	1	3.03
	D02	Timely PM	• System malpractice during using that results injuries	• Lack of proper planning for PM	5	5	1	3.03	-	5	5	1	3.03
	D03	Lack of facilities for repair	• Prolonged repair process • Delay in surgery process	• Lack of proper planning for repairing of facilities	6	7	2	4.75	Set a modern codified planning for OR equipment repair and a checklist for facilities requests	5	7	2	4.46
	D04	Postponement of repair process	• Delay in surgery process	• Outdated facilities • Lack of proper planning for	6	8	2	5.03	Set regular scheduling for calibration of OR equipment	5	8	2	5.03

				delivery of services for repairing									

Table 6.d. FMEA worksheet of basic processes

Process	Label	Failures	Effect	Causes	Severity	Occurrence	Detection	Fuzzy RPN	Corrective actions	Severity	Occurrence	Detection	Fuzzy RPN
request for medical and pharmaceutical products	E01	Prolonged pharmaceutical products provision	• OR personnel confusion • Surgeries cancellation • Increasing surgeries qualities	• Lack of medicine in storage • Lack of timely detection of drug shortages • Failure to submit a timely request for medication	4	7	1	3.40	-	4	5	1	3.03
	E02	Purchasing of close expiration date drugs	• Occurrence of adverse events to patients	• Lack of procurement unit attention to the expiration date	7	6	6	6.46	Note the officer of acquisition to prevent of purchasing close expiration date items and return purchased drugs.	7	6	4	5.46
	E03	Purchasing of pharmaceutical products less than requirement	• Surgery cancellation • Increasing surgeries qualities	• Lack of procurement unit attention to the quantity of requirement	7	6	5	6.46	Determine the amount of drugs and medical items requirement tailored to number of operation and note the officer of acquisition to purchase requested amount	5	6	4	5.46
	E04	Untimely Purchasing of pharmaceutical products	• OR personnel confusion • Surgery cancellation • Increasing surgeries qualities	• The request process Difficulties • Lack of procurement unit attention to the requirements	7	7	2	4.75	Deliver purchasing application to the acquisition unit before run out of medical items and drugs	7	6	2	4.46

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