Journal of Applied Research and Technology

www.jart.icat.unam.mx

Journal of Applied Research and Technology 21 (2023) 772-786

Original

An intelligent model for improving risk assessment in sterilization units using revised FMEA, fuzzy inference, k-Nearest Neighbors and support vector machine

Amine En-Naaoui[a,b]* • Maryam Gallab[c] • Mohammed Kaicer[a]

[a]*Ibn Tofail University, Kenitra, Morocco*
[b]*National Institute of Oncology, Ibn Sina University Hospital Center, Rabat, Morocco*
[c]*MINES-RABAT School, Morocco*

Received 11 22 2022; accepted 02 19 2023
Available 10 31 2023

Abstract: Risk assessment is an essential decision-making issue in the healthcare sector. Our study aims to improve the process of risk assessment in healthcare organizations by adapting the failure mode and effects analysis (FMEA) to the studied context (revised FMEA), improving criticality calculating using fuzzy logic, and performing tolerance classification with machine learning algorithms.
The application area of the model is the sterilization unit of a university-tertiary hospital. The performance of the proposed model is evaluated as follows: we extensively explored the literature to compare fuzzy FMEA with classical FMEA. The results showed that the fuzzy approach is more effective than the classical. Furthermore, some SVM classifiers have been able to achieve 100% accuracy in both training and testing datasets, and the KNN classifier has achieved 97% and 75% of accuracy in training and testing data, respectively. This study will be applied to other hospital departments to generalize our model.

Keywords: risk assessment, FMEA, fuzzy inference system, support vector machine, k-nearest neighbor, sterilization unit

*Corresponding author.
E-mail address: amine.en-naaoui@uit.ac.ma (Amine En-Naaoui).
Peer Review under the responsibility of Universidad Nacional Autónoma de México.

1. Introduction

One of the main challenges managers face in improving healthcare organizations' patient safety and performance systems is Healthcare-associated Infections (HAI). HAIs are infections that develop following a medical intervention or contact in a healthcare setting (Wilson & Nayak, 2019).

Medical devices are one way by which healthcare-associated infections can be transmitted (Wilson & Nayak, 2019). For this reason, sterilizing reusable medical devices in the hospital is necessary for patient safety because this process is a fundamental means to fight against HAIs in hospitals.

Moreover, a fast delivery time reusable medical device for medical departments essentially depends on the performance of the hospital sterilization process (Kammoun et al., 2021). Hence, the sterilization process is a critical system that needs special attention from the top management of the hospital in order to improve the quality of service and reduce the criticalities of failure modes.

The International Organization for Standardization (IEC 31010, 2019) proposes 31 methods as universal tools used for risk assessment. Among these methods is FMEA.

The FMEA method is a method widely adopted to detect, evaluate and prioritize risks of the studied process based on a proactive approach.

The FMEA method is a powerful and effective tool for assessing risks (Wang et al., 2019). As a result, this method has been widely adopted in numerous sectors, specifically healthcare services. In fact, numerous studies applied the classical approach of FMEA so that it has proved its robustness in the healthcare context. Nevertheless, the classical approach suffers from several drawbacks that must be discussed and treated. For this reason, this paper proposes a model of risk assessment in order to enhance the FMEA method's effectiveness.

The fuzzy inference is the most adopted approach due to its several advantages (Qin et al., 2020). In fact, in the last decade, many studies adopted the FIS approach in the FMEA to enhance the efficiency of the risk assessment process in several sectors, such as, among others, gas and oil supply chain industry (Gallab et al., 2019), food manufacturing industry (Soltanali et al., 2022) (Di Nardo et al., 2022), and healthcare (Ahmadi & Mosallanezhad, 2018; Dağsuyu et al., 2016; Kumru & Kumru, 2013).

The risk assessment is a process that aims to determine if the identified risks, which is the premise for the risk assessment (Tian & Yan, 2013), are tolerable or not (ISO 31000, 2018). Otherwise, it is a logical approach to determine quantitative and qualitative value of risks and investigate potential consequences of probable accidents on people, materials, products, equipment, and environment (Fattahi & Khalilzadeh, 2018).

This process of assessing risks aims to solve two main problems: the problem of quantification and the problematic of classification. The FIS provides a powerful device to solve the quantification problem. However, there is no scientific rule to determine the threshold of the risk tolerance zone (Dağsuyu et al., 2016). Machine learning provides robust solutions for classification problems. The Support Vector Machine (SVM) and the k-Nearest Neighbors (KNN) are among the most used classification techniques.

- SVM: constitutes robust regression and classification capabilities (Soltanali et al. 2022).
- KNN: is a non-parametric method used for classification, considered one of the best-known classification algorithms (Chanal et al., 2022).

2. Materials and methods

2.1. Classical FMEA method

The related literature shows that the FMEA method was applied for the first time in the 1960s by NASA and the United States Army. After that, the method was extended to cover multiple sectors, such as aerospace, automotive, and healthcare.

The FMEA method consists of identifying the associated risks, their consequences on the functionality of the process, potential causes, and the corresponding actions needed to prevent or detect the cause (Shamayleh et al., 2020). Figure 1 presents the proposition of the steps that constitute the FMEA method's procedure.

Our study focuses on improving the risk assessment step in the FMEA procedure. In the approach of FMEA, the assessment of failure modes (risks) consists of the calculation of the criticality of each failure mode, named risk priority number (RPN), based on three parameters: the occurrence (O), the non-detection (D), and the severity (S). In the classical FMEA, the RPN is obtained by multiplying these three parameters (Fattahi & Khalilzadeh, 2018).

The point-scale used for O, D, and S are from 1 to 5, and the point-scale for the RPN is from 1 to 10. Then, the multiplication range goes from 1 to 125 (=5x5x5). Hence, the given results are multiplied by 10/125 in order to provide results of classical RPN (Equation 1).

$$RPN = \frac{10}{125} \times O \times D \times S \qquad (1)$$

Despite the meaningful use, many drawbacks and limitations are faced in the risk assessment step of the classical FMEA method, such as, among others:

- Ignoring weights of factors O, D, and S: have different weights in the system rather than equality (Meraj & Farhad, 2015).
- Different O, D, and S values can provide the same RPN value.

- It loses robustness and relevance in case of non-availability or scarcity of data.

Thus, developing a model to improve the FMEA method performance and surmount the cited drawbacks is essential. The FIS is used to perform this improvement.

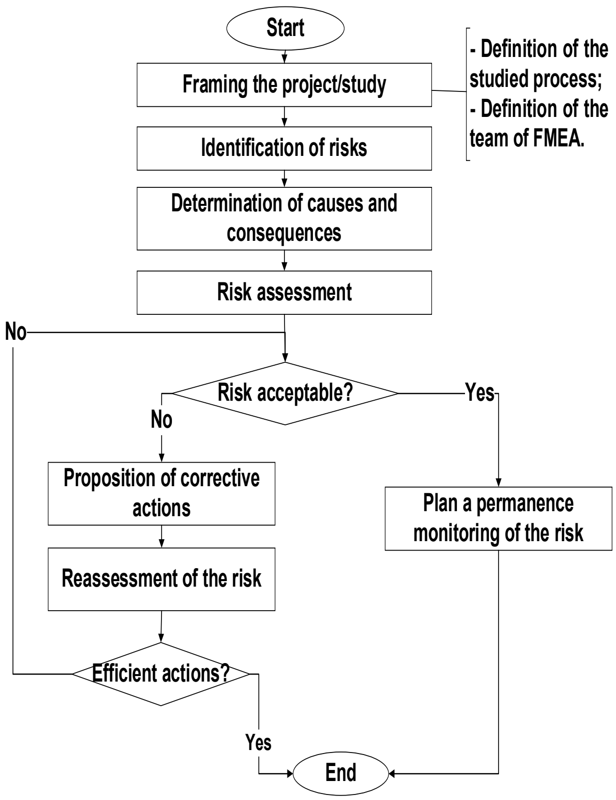

Figure 1. Procedure of FMEA method.

2.2. Fuzzy FMEA

Fuzzy inference is one of the popular tools used to solve the constraints/problems of the classical FMEA method. The adoption of FIS to reduce the limitations of the FMEA method was in 1995 by Bowles and Pelæz. Later, fuzzy FMEA has been widely applied. In fact, several works propose fuzzy inference approaches in purpose to increase risk assessment efficiency in order to overcome weaknesses the classical FMEA (Na'amnh et al., 2021). The fuzzy FMEA approach proved high effectiveness due to several reasons (Ahmadi & Mosallanezhad, 2018): it allows the analyst to evaluate the risk associated with item risks 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.

The FIS is the system that transforms crisp inputs using the theory of fuzzy logic (Zadeh, 1965). Generally, the algorithm of the fuzzy inference applied to the FMEA method is presented as follows:

- Definition of the linguistic variables (initialization).
- Construction of the membership functions (initialization).
- Construction of the rule base (initialization).
- Conversion of the crisp input data to fuzzy values using the membership functions (fuzzification).
- Evaluation of the rules in the rule base (inference).
- Combination of the results of each rule (inference).
- Conversion of the output data to non-fuzzy values (defuzzification).

2.3. KNN technique

Risk assessment is a process that aims to decide whether the risk assessed is tolerable or not by determining class zones. Therefore, the problem searched by the risk assessment is a classification problem. One of the most influential and well-known techniques for classification problems is the KNN technique.

The KNN algorithm is a very simple and easy-to-implement algorithm. It is used mainly for classification purposes and comes under supervised machine learning types (Das et al., 2022).

The KNN algorithm consists of classifying each point depending on its distances from points of data. The studied point is classified with the category of the K (where K is a natural number) nearest neighbors' points (Ali et al., 2019). Several means can be selected to calculate the distances, such as, the Euclidean Manhattan and Minkowsky equations.

The KNN is an algorithm composed of the following steps (Das et al., 2022):

Step 1: Choosing the number K of neighbors.

Step 2: Taking the K-nearest neighbor of the new data point, according to the selected distance.

Step 3: Counting the number of data points in each category among the K neighbors.

Step 4: Assigning the new data point to the category where the most neighbors were counted.

2.4. SVM technique

The support vector machine (SVM) is classified as one of the supervised learning methods (Okabe & Otsuka, 2021).

SVM is a sophisticated and popular machine learning method that was proposed by Vapnik in 1982 and extended to solve classification problems and has become exceedingly popular for neuroimaging analysis in recent years (Pisner & Schnyer, 2020). It is a supervised learning method used for regression and classifications. The SVM algorithm consists of optimizing the linear threshold (named separation hyperplane) between points of the 2 classes. In case of nonlinear separation, the SVM is done using the projection of the dataset to a higher dimensional space where a determined hyperplane (support vector) separates the categories of the training data (Bajaj et al., 2023).

In case of a multi-class problem, 2 tricks are adopted, "one-vs-one", which is a binary classification, and "one-vs-all", which is based on the separation of one class from the rest.

Performing the SVM algorithm is performed by following these steps (Gholami & Fakhari, 2017):

Step 1: Preparation of the datasets: training data and test data.

Step 2: Selection of the adequate Kernel function: several kernel functions can be used as the linear, the gaussian, the cubic, etc.

Step 3: Execution of training algorithms (training data).

Step 4: Classification/prediction of unseen data (test data).

Step5: Evaluation of the SVM classifiers' performances.

2.5. The proposed model

Limited resources allowed to hospitals, especially in low-income countries, leads managers to prioritize the treatment of intolerable risks based on the RPN value of each risk and if the risk is easy to be treated or not. For this reason, another parameter is added to the three parameters defined in FMEA (O, D, and S), which is the control level (C).

That, values of fuzzy R^2PNs are trained using KNN to provide a decision of tolerance about each risk. Figure 2 presents the design of the developed model.

The present model consists of the following three sequential steps: calculating fuzzy RPN, calculating fuzzy R^2PN, and classifying the risk using SVM and KNN. Two fuzzy inference systems are developed: the first FIS (fuzzy inference System1) is developed to compute the value of RPN, and the second FIS (fuzzy inference System 2) is developed to compute values of R^2PN. Obtained results are classified using several machine learning classifiers. These classifiers are based on SVM and KNN techniques.

2.6. Application area: the hospital sterilization unit

The operation rooms and the medical departments use reusable instruments (RI) permanently. This multitude of uses for patients makes RI a way by which infections can be transmitted from one patient to another (Wilson & Nayak, 2013). For this reason, the sterilization unit plays a pillar role in the hospital. Then, we select a sterilization unit for this study,the central sterilization unit of Ibn Sina Hospital of Rabat-Morocco (CSU).

As a part of the quality management system requirements, the CSU has implemented a risk assessment plan covering the processes of the unit: disinfection and cleaning, (2) packaging, (3) autoclaving (sterilization); (4) storage and distribution; and (5) resources support (maintenance, human resources…).

The risk assessment plan has been developed using the FMEA method procedure (Figure 1), and the evaluation of the risks has been performed according to the developed model.

3. Results

3.1 Calculating fuzzy RPN and fuzzy R^2PN values

In our case, five variables are used: O, D, and S as initial inputs, RPN as the output of FIS 1 and input of FIS 2, C as the input of FIS 2, and R^2PN as the output of FIS 2. The scale-point used for the inputs is from 1 to 5 (O, D and S), and the scale-point used for the outputs is from 1 to 10 (RPN, C and R^2PN).

The linguistic variables are: For the factors O, D, S, and RPN are defined as: [very low (VL); low (L); medium (M); high (H); very high (VH)], for the parameter C are defined as: [low (L); medium (M); high (H)] and for R^2PN are defined as: [low priority (LP); priority medium (PM); high priority (HP)].

In the present study, the membership function form adopted in all input and output variables is the triangular form, which has the following mathematical formula (Equation 2):

Let X be a nonempty set. Let A be a set in X. And let μ_A be the triangular membership function ($\forall x \in A\ \mu_A(x) \epsilon [0,1]$):

$$\mu_A(x) = \begin{cases} \frac{x-a}{b-a} & \text{if } a \leq x \leq b \\ \frac{b-x}{c-b} & \text{if } b \leq x \leq c \\ 0 \text{ otherwise} & \end{cases} \tag{2}$$

where a, b, c and d real numbers (a < b < c).

In concertation with the experts of the studied process (a hospital sterilization unit, see paragraph $4: application), the membership functions have been constructed based on the triangular form defined in mathematical function (2). With the same experts, a dataset of rules has been listed to construct the rule base of each developed FIS (FIS 1 and FIS 2). The different membership functions of the two FISs are illustrated in Figures 3,4,5 and 6.

As explained previously, all membership functions used in this study are based on the triangular form (Equation 2). Values of constants (a, b, c) assigned to each input/output variable in order to obtain ranges are given as follows:

- **Input variables O, D and S (Figure 3):** VL (a=1, b=1, c=2); L (a=1, b=2, c=3); M (a=2, b=3, c=4); H (a=3, b=4, c=5); VH (a=4, b=5, c=5).
- **Input/output variable RPN (Figure 4):** VL (a=1, b=1, c=3); L (a=1, b=3, c=5); M (a=3, b=5, c=7); H (a=5, b=7, c=9); VH (a=7, b=10, c=10).
- **Input variable C (Figure 5):** L (a=1, b=1, c=5); M (a=2, b=5, c=8); H (a=5, b=10, c=10).
- **Output variable R^2PN (Figure 6):** low priority (a=1, b=1, c=5); priority medium (a=2, b=5, c=8); high priority (a=5, b=10, c=10).

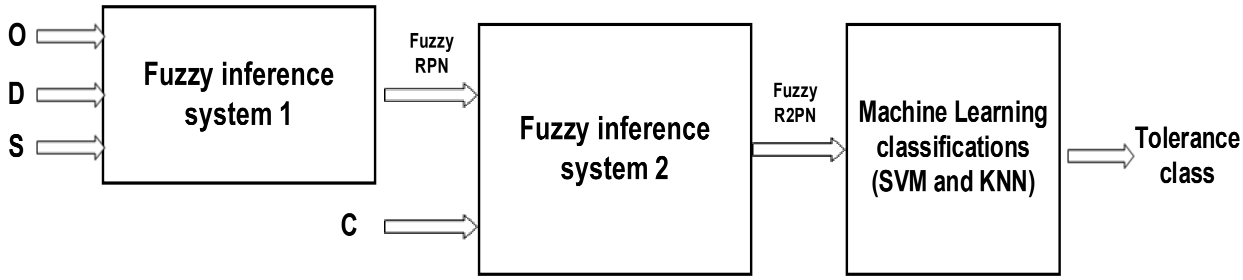

Figure 2. Structure of the developed model.

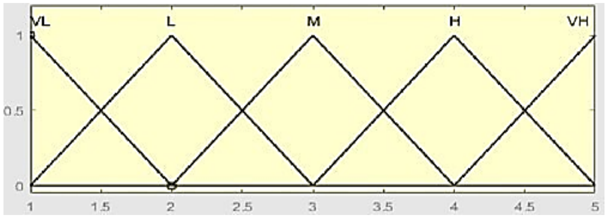

Figure 3. Input variables “O, D and S.”

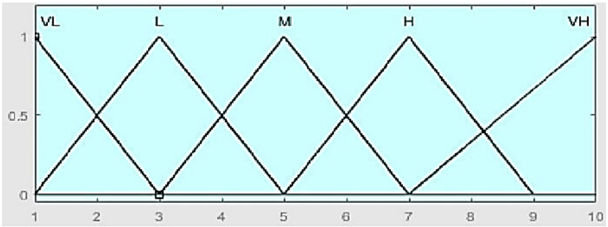

Figure 4. Input/output variable “RPN (fuzzy RPN).”

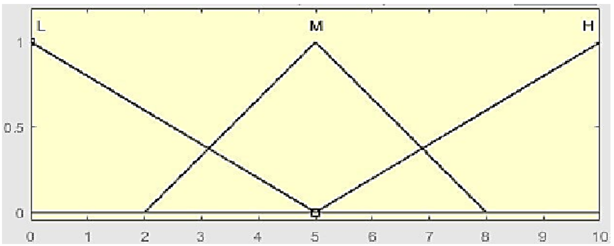

Figure 5. Input variable “C.”

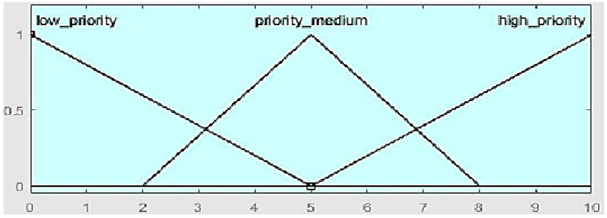

Figure 6. Output variable “R^2PN.”

Table 1. Results of classical RPN, fuzzy RPN and fuzzy R^2PN.

1	2	3	4	5	6	7	8	9	10	11
Risk code	O	D	S	O x D x S	Classical RPN	Fuzzy RPN	fuzzy RPN Classification	Level of control 1	fuzzy R^2PN	fuzzy R^2PN Classification
R1	1	5	5	25	2	9,03	VH	2	8,17	HP
R2	2	1	4	8	0,64	5	M	4	4,42	PM
R3	1	3	4	12	0,96	5	M	8	8,17	HP
R4	1	1	4	4	0,32	5	M	7	6,44	HP
R5	3	1	5	15	1,2	9,03	VH	8	8,17	LP
R6	1	4	3	12	0,96	3	L	3	2,02	HP
R7	2	3	5	30	2,4	9,03	VH	9	8,23	LP
R8	2	2	1	4	0,32	1,64	VL	10	1,77	HP
R9	2	3	5	30	2,4	9,03	VH	8	8,17	HP
R10	1	5	4	20	1,6	7	H	3	6,15	PM
R11	2	4	5	40	3,2	9,03	VH	4	8,22	PM
R12	2	4	3	24	1,92	5	M	8	8,17	PM
R13	1	1	2	2	0,16	1,64	VL	10	1,77	HP
R14	2	1	4	8	0,64	5	M	10	8,37	HP
R15	1	1	3	3	0,24	3	L	9	1,69	LP
R16	4	1	4	16	1,28	9,03	VH	7	7,98	HP
R17	3	2	4	24	1,92	7	H	6	8,22	HP
R18	1	1	4	4	0,32	5	M	5	5	PM
R19	2	5	4	40	3,2	7	H	4	7,27	LP
R20	2	3	4	24	1,92	7	H	7	7,98	LP
R21	2	4	3	24	1,92	5	M	8	8,17	LP
R22	1	2	3	6	0,48	3	L	4	1,78	HP
R23	1	1	4	4	0,32	5	M	10	8,37	HP
R24	1	1	4	4	0,32	5	M	9	8,31	HP
R25	1	1	4	4	0,32	5	M	6	5,58	PM
R26	1	2	3	6	0,48	3	L	7	2,02	LP
R27	3	1	2	6	0,48	3	L	7	2,02	HP
R28	4	1	2	8	0,64	3	L	4	1,78	HP
R29	2	3	4	24	1,92	7	H	6	8,22	LP
R30	5	1	4	20	1,6	9,03	VH	8	8,17	HP
R31	2	1	4	8	0,64	5	M	7	6,44	HP
R32	2	3	2	12	0,96	3	L	3	2,02	HP
R33	1	5	5	25	2	9,03	VH	8	8,17	LP
R34	3	2	5	30	2,4	9,03	VH	9	8,23	PM
R35	5	1	2	10	0,8	3	L	2	1,83	PM
R36	4	1	5	20	1,6	9,03	VH	4	8,22	HP
R37	2	2	4	16	1,28	5	M	9	8,31	HP
R38	3	4	3	36	2,88	7	H	5	8,37	HP
R39	1	1	3	3	0,24	3	L	2	1,83	LP
R40	2	3	4	24	1,92	7	H	1	5	LP
R41	1	1	5	5	0,4	7	H	9	8,31	LP
R42	1	1	5	5	0,4	7	H	7	7,98	HP
R43	1	2	5	10	0,8	7	H	6	8,22	LP
R44	1	1	3	3	0,24	3	L	3	2,02	HP
R45	2	1	3	6	0,48	3	L	4	1,78	LP
R46	5	1	2	10	0,8	3	L	3	2,02	HP

2 lists of rules have been constructed: Appendix I and Appendix II provide the rules lists associated with FIS 1 and FIS 2, respectively. These lists of rules have been constructed based on experts of the FMEA team. After the construction of rules, the fuzzy inference engine step is conducted.

2 popular techniques are well-known to perform the fuzzy inference engines: Mamdani-type and Sugeno-type. The most used fuzzy inference engine is the Mamdani-type (Kumru & Kumru, 2013). The Mamdani is easily implemented and widely used in various fields (Zulfikar et al., 2017). For this reason, the present study adopts the Mamdani min/max approach for the two FISs used in this model.

Defuzzification is the process of obtaining a single number from the output of the aggregated fuzzy set. It transfers fuzzy inference results into a crisp output (Masoum & Fuchs, 2015). There are several techniques for defuzzification, such as the center of gravity (COG), the mean of maximum and the center of gravity for singletons. The most popular technique is COG (Kumru & Kumru, 2013), also used in this study. The mathematical formula of the COG is expressed in Equation (3) as follows.

$$\mathrm{COG} = \frac{\int \mu_A(x)\,x\,dx}{\int \mu_A(x)\,dx} \tag{3}$$

3.2. Classification of risks using machine learning

a. KNN classification

The assessed and prioritized risks are assigned to 3 priority classes: low priority (acceptable), priority medium (periodic monitoring), and high priority (urgent). The KNN technique has been adopted to perform this classification. The present study selects the value of K=5 because this value is the most used (Das et al., 2022).

The principle of KNN is that the classification algorithm first selects k closest samples for a test sample from all the training samples and then predicts the test sample with a simple classifier (Zhang et al., 2018). For this reason, the available dataset has been divided randomly into two categories: 80% (n=36) for data and 20%(n=36) for the testing data (n'=10). .

The selected technique used to calculate the distance between points of the training data is the Euclidean distance, which is a distance commonly used. The mathematical formula of the Euclidean distance can be expressed in Equation (4) as follows:

$$d(x,y) = \left(\sum (x_i - y_i)^2\right)^{\frac{1}{2}} \tag{4}$$

where d (.,.) is the Euclidean distance and x and y are two points of the training data.

b. SVM classification

Similarly, the assessed and prioritized risks are assigned to 3 priority classes: low priority (acceptable), priority medium (periodic monitoring), and high priority (urgent).

In the present study, six kernel functions are performed: the linear, the quadratic, the cubic, the fine gaussian, the medium gaussian and the coarse gaussian. The approach adopted for the multi-class problem is the "one-vs-one" approach. As the KNN technique, the dataset has been divided randomly into two categories: 80% for training and 20% for the testing sets.

46 risks have been identified and assessed in the CSU. Based on experts' estimations and the developed model, we obtained each risk's fuzzy RPN. The description of the risk scenarios of each risk code is provided in Appendix III.

Each risk has been analyzed to estimate its level of control and how easily it can be treated. Hence, a level of control has been assigned to each risk based on experts' and workers' judgments. The combination of fuzzy RPN and C provides the value of R^2PN. In order to perform the SVM and the 5-NN classifications, each data set was split randomly into 80% for training data (n=36) and 20% for the testing data (n'=10).

Table 1 and Table 2 present the results of the studied case study: The FMEA team identified 46 failure modes associated with the activity of the sterilization unit in the Ibn Sina hospital (Table 1, Column 1 in Table 1 & Appendix III). The team assigned each risk value to input factors O, D, and S using experiences in the CSU (Table 1, Columns 2, 3, and 4 in Table 1). The values obtained of the 46 RPNs using classical FMEA (Table 1, Column 6). The fuzzy approach of risks is then obtained (Table 1, Column 7) with classifications (Table 1, Column 8) using FIS 1 process. The FMEA team provides values of C (Column 9) to obtain values and classifications of R^2PN (Table 1, Column 10 and Column 11, respectively) using the FIS 2 process.

After that, each result of risk prioritization is obtained using fuzzy approach (FIS 2). Finally, the types of data are generated randomly (80% training data and 20% testing data) (Table 2, Column 3) using machine learning models (SVM kernel functions and KNN) to learn from training data and predict the testing data (Table 2, Columns 3-10).

The proposed model is evaluated using the outputs of the present case study in order to prove its performance.

Table 2. Results of machine learning classifiers.

1	2	3	4	5	6	7	8	9	10
Risk code	fuzzy R^2PN Classification	Type of data	Machine learning classifiers						
			Linear SVM	Quadratic SVM	Cubic SVM	Fine gaussian SVM	Medium gaussian SVM	Coarse gaussian SVM	5NN
R1	HP	Training	HP	HP	HP	HP	HP	HP	HP
R2	PM	Training	PM	PM	PM	HP	PM	HP	PM
R3	HP	Training	HP	HP	HP	HP	HP	HP	HP
R4	HP	Testing	HP	HP	HP	HP	HP	HP	HP
R5	LP	Training	LP	LP	LP	LP	LP	LP	LP
R6	HP	Training	HP	HP	HP	HP	HP	HP	HP
R7	LP	Training	LP	LP	LP	HP	LP	LP	LP
R8	HP	Training	HP	HP	HP	HP	HP	HP	HP
R9	HP	Training	HP	HP	HP	HP	HP	HP	HP
R10	PM	Testing	PM	PM	PM	PM	PM	PM	LP
R11	PM	Training	HP	HP	PM	PM	PM	HP	HP
R12	PM	Testing	PM	PM	PM	PM	PM	PM	HP
R13	HP	Training	HP	HP	HP	HP	HP	HP	HP
R14	HP	Training	HP	HP	HP	HP	HP	HP	PM
R15	LP	Testing	LP	LP	LP	LP	LP	LP	PM
R16	HP	Training	HP	HP	HP	HP	HP	HP	HP
R17	HP	Training	HP	HP	HP	HP	HP	HP	LP
R18	PM	Training	PM	PM	PM	PM	PM	HP	HP
R19	LP	Training	LP	LP	LP	LP	LP	LP	HP
R20	LP	Training	LP	LP	LP	LP	LP	LP	PM
R21	LP	Testing	LP	LP	LP	LP	LP	LP	LP
R22	HP	Training	HP	HP	HP	HP	HP	HP	HP
R23	HP	Training	HP	HP	HP	HP	HP	HP	HP
R24	HP	Training	HP	HP	HP	HP	HP	HP	LP
R25	PM	Training	PM	PM	PM	HP	PM	HP	HP
R26	LP	Test	LP	LP	LP	LP	LP	LP	HP
R27	HP	Training	HP	HP	HP	HP	HP	HP	LP
R28	HP	Test	HP	HP	HP	HP	HP	HP	HP
R29	LP	Training	LP	LP	LP	LP	LP	LP	HP
R30	HP	Training	HP	HP	HP	HP	HP	HP	LP
R31	HP	Test	HP	HP	HP	HP	HP	HP	HP
R32	HP	Training	HP	HP	HP	HP	HP	HP	HP
R33	LP	Training	LP	LP	LP	LP	LP	LP	HP
R34	PM	Training	PM	PM	PM	HP	PM	HP	LP
R35	PM	Training	PM	PM	PM	HP	PM	PM	LP
R36	HP	Training	HP	HP	HP	HP	HP	HP	LP
R37	HP	Training	HP	HP	HP	HP	HP	HP	HP
R38	HP	Testing	HP	HP	HP	HP	HP	HP	PM
R39	LP	Training	LP	LP	LP	LP	LP	LP	HP
R40	LP	Testing	LP	LP	LP	LP	LP	LP	HP
R41	LP	Training	LP	LP	LP	LP	LP	LP	LP
R42	HP	Training	HP	HP	HP	HP	HP	HP	HP
R43	LP	Training	LP	LP	LP	LP	LP	LP	LP
R44	HP	Training	HP	HP	HP	HP	HP	HP	HP
R45	LP	Training	LP	LP	LP	LP	LP	LP	HP
R46	HP	Training	HP	HP	HP	HP	HP	HP	LP

3.3. Evaluation of the model performance

The present study proposes a model for risk assessment using revised FMEA, fuzzy approach, the SVM and the KNN techniques. This model aims to improve the effectiveness of the risk assessment process in hospital sterilization units. Hence, we need to check out the model's performance in this case to prove the achievement of the desired objective.

As presented previously (see paragraph 3: Proposed model), the model calculates the RPN and R^2PN with a fuzzy inference approach and then classifies the risks according to the defined priority classes using the SVM and KNN techniques. Thus, the objective achievement consists of improving the performance of the two parts of the model.

According to the related literature, the fuzzy logic approach proves a significant ability to improve the efficiency of the FMEA method, then the performance of the risk assessment process, specifically in the healthcare sector. The advantages provided by the fuzzy logic to FMEA. These advantages are, among others:

- The assessors do not need to correct or accurate the value of the parameters (Chanamool & Naenna, 2016). The assessors' approximative point of view does not provide a realistic image of the criticalities of risks.
- The fuzzy logic is instrumental in the case of the lack of data (Dağsuyu et al., 2016). In the CSU, there was no available data concerning the failure modes or the adverse events in the unit (we have just created a non-conformity register to provide data).
- It combines the three factors (O, D, and S) in the modeling process (Kumru & Kumru, 2013).

For this reason, the FISs provide a high-efficiency level to the FMEA in the phase of measurement of criticalities.

Several metrics are used to evaluate the performance of the machine learning algorithms, such as the root mean square error (RMSE), the efficiency, and the coefficient of variation (Soltanali et al., 2022). One of the most commonly and the simplest tools and metrics used for machine learning performance evaluation is the confusion matrix, the accuracy (ACC), the precision (PRE), the recall (REC) and the f-score (FS) (Ali et al., 2019), which are extracted from the confusion matrix. The selected metrics are defined as follows (Ali et al., 2019):

- ACC: the ratio of the number of correctly classified objects to the total number of objects evaluated.
- PRE: the ratio of correctly predicted positive data objects to the total predicted positive data objects.
- REC: the number of correct positive results divided by the total number of relevant samples.
- FS: the weighted average of the precision and recall.

Six kernel functions are used to perform the SVM classification: linear, quadratic, cubic, fine gaussian, medium gaussian and coarse gaussian kernel functions. Each SVM model (kernel function) is evaluated using the metrics extracted from the confusion matrixes (Acc, Pre, Rec and FS) of training data and testing data. Results are illustrated in Table 3.

According to the results of the measured metrics in Table 3, the most performant SVM classifiers are the SVM models, which use the cubic and the medium gaussian kernel functions (all metrics are equal to 100% for training and testing data). The linear and the quadratic can be judged as the performant classifiers. The metrics associated with the training dataset exceed 90%. Nevertheless, despite the good results in the training step, the fine gaussian and the coarse gaussian kernel functions provide unperformed results in the testing data.

Table 3. Evaluation of SVM classifiers' performances.

SVM Kernel function	Training dataset (n=36)				Testing dataset (n'=10)			
	ACC	PRE	REC	FS	ACC	PRE	REC	FS
Linear	97%	92%	98%	95%	100%	100%	100%	100%
Quadratic	97%	92%	98%	95%	100%	100%	100%	100%
Cubic	100%	100%	100%	100%	100%	100%	100%	100%
Medium Gaussian	100%	100%	100%	100%	100%	100%	100%	100%
Fine Gaussian	100%	100%	100%	100%	50%	55%	45,8%	50%
Coarse Gaussian	92%	75%	94%	83%	70%	75%	83%	79%

Table 4. Evaluation of 5-NN models' performance.

	Training dataset (n=36)				Testing dataset (n'=10)			
	ACC	PRE	REC	FS	ACC	PRE	REC	FS
5-NN classification	97%	92%	98%	94%	75%	83%	69%	97%

Similarly, the KNN classifier model is evaluated using the metrics extracted from the confusion matrixes (Acc, Pre, Rec and FS) of training data and testing data. Results are illustrated in Table 4.

According to the results of the measured metrics given in Table 4, the proposed KNN classifier in this study can be judged performant. The metrics associated with the training dataset exceed 90%. The metrics associated with the training data show that the classifier model is relatively performant in predicting new data.

4. Discussion

The present study proposes a model to perform the risk assessment process. The proposed model uses FMEA as a method for risk assessment. However, the healthcare sector suffers from limited resources and budgets, especially in low-income countries. For this reason, another parameter has been developed: the level of control C, which is used in this study to maximize practical treatment actions, and then opportunities for systems improvements. In this study, the new FMEA using O, D, S and C parameters is called revised FMEA.

The fuzzy inference is a very popular approach widely used to perform FMEA. In the present study, the fuzzy inference approach has been used twice in the proposed model: in the first step, it was used to compute RPN values of RPNs, and in the second step, it was used to compute the values of R^2PN.

The machine learning models, the SVM and the KNN have been integrated to provide an ability to learn and improve the model's prediction capacity.

The application area of proposed model is the case of a sterilization unit of a university hospital in Morocco. A review paper published by Kaicer et al. (2021) shows the complete absence of any indexed research that proposes the use of artificial intelligence, including machine learning algorithms, for risk management in the Moroccan healthcare sector. Hence, this work will initiate other techniques of artificial intelligence in the healthcare sector. The evaluation of the obtained results allows us to judge that the proposed model is highly performant and adaptable to the application field's context.

5. Conclusion

The model can be applied in any medical department with minor adaptations. Nevertheless, the risk management system is not limited to risk assessment. Other processes, such as the identification and the analysis, need to be highlighted and improved. Thus, it is recommended to think about models that enable the performance of such processes to design a robust and intelligent risk management system that can play the role of a “qualified decision-maker” in the healthcare sector.

Conflict of interest

The authors have no conflict of interest to declare.

Acknowledgements

We offer our thanks to the central administration of the Ibn Sina University-Hospital Center, to the administration of Ibn Sina Hospital and all workers of the Central Sterilization Unit of Ibn Sina Hospital Specifically Pr. J EL HARTI (and the manager of the unit) and M BELESMAK (nurses head) for supporting us in collecting data provided in this study.

Funding

The authors received no specific funding for this work.

References

Ali, N., Neagu, ., & Trundle, P. (2019). Evaluation of k-nearest neighbour classfier performance for heterogeneous data sets. *SN Applied Sciences*, *1*, 1-15.
https://doi.org/10.1007/s42452-019-1356-9

Ahmadi, A., & Mosallanezhad, B. (2018). Using fuzzy FMEA to increase patient safety in fundamental processes of operating room. Journal of Industrial and Systems Engineering, 11(3), 146-166.

Bajaj, N. S., Patange, A. D., Jegadeeshwaran, R., Pardeshi, S. S., Kulkarni, K. A., & Ghatpande, R. S. (2023). Application of metaheuristic optimization based support vector machine for milling cutter health monitoring. *Intelligent Systems with Applications*, *18*, 200196.
https://doi.org/10.1016/j.iswa.2023.200196

Chanal, D., Steiner, N. Y., Petrone, R., Champagne, D., & Péra, M. C. (2021). Online Diagnosis of PEM Fuel Cell by Fuzzy C-Means Clustering, Reference Module in Earth Systems and Environmental Sciences.
https://doi.org/10.1016/B978-0-12-819723-3.00099-8

Chanamool, N., & Naenna, T. (2016). Fuzzy FMEA application to improve decision-making process in an emergency department. *Applied Soft Computing*, *43*, 441-453.
https://doi.org/10.1016/j.asoc.2016.01.007

Dağsuyu, C., Göçmen, E., Narlı, M., & Kokangül, A. (2016). Classical and fuzzy FMEA risk analysis in a sterilization unit. *Computers & Industrial Engineering*, *101*, 286-294.
https://doi.org/10.1016/j.cie.2016.09.015

Das, C., Sahoo, A. K., & Pradhan, C. (2022). Multicriteria recommender system using different approaches. In *Cognitive Big Data Intelligence with a Metaheuristic Approach* (pp. 259-277). Academic Press.
https://doi.org/10.1016/B978-0-323-85117-6.00011-X

Di Nardo, M., Murino, T., Osteria, G., & Santillo, L. C. (2022). A new hybrid dynamic FMECA with decision-making methodology: a case study in an agri-food company. *Applied System Innovation*, *5*(3), 45.
https://doi.org/10.3390/asi5030045

Kaicer, M., El Harti, J., Hachimi, H., Idrissi, F. K., Darouichi, A., & Lamarti, S. M. (2021). Risk Management in Moroccan Healthcare Organizations: An Overview. *Turkish Journal of Computer and Mathematics Education*, *12*(5), 930-936.
https://doi.org/10.17762/turcomat.v12i5.1735

Fattahi, R., & Khalilzadeh, M. (2018). Risk evaluation using a novel hybrid method based on FMEA, extended MULTIMOORA, and AHP methods under fuzzy environment. *Safety science*, *102*, 290-300.
https://doi.org/10.1016/j.ssci.2017.10.018

Gallab, M., Bouloiz, H., Alaoui, Y. L., & Tkiouat, M. (2019). Risk assessment of maintenance activities using fuzzy logic. Procedia computer science, 148, 226-235.
https://doi.org/10.1016/j.procs.2019.01.065

Gholami, R., & Fakhari, N. (2017). Support Vector Machine: Principles, Parameters, and Applications, in Samui, P. et al (eds), Handbook of Neural Computation, Elsevier, 2017, pp. 515-535.
https://doi.org/10.1016/B978-0-12-811318-9.00027-2.

IEC 31010:2019 (2019). Risk management — Risk assessment techniques. https://www.iso.org/standard/72140.html

ISO 31000:2018 – Risk management.
https://www.iso.org/standard/65694.html

Kammoun, A., Hachicha, W., & Aljuaid, A. M. (2021). Integrating quality tools and methods to analyze and improve a hospital sterilization process. In *Healthcare* (Vol. 9, No. 5, p. 544). MDPI.
https://doi.org/10.3390/healthcare9050544

Kumru, M., & Kumru, P. Y. (2013). Fuzzy FMEA application to improve purchasing process in a public hospital. *Applied soft computing*, *13*(1), 721-733.
https://doi.org/10.1016/j.asoc.2012.08.007

Masoum, M. A. S., Fuchs, E. F., Masoum, M. A. S., & Fuchs, E. F. (2015). Optimal placement and sizing of shunt capacitor banks in the presence of harmonics. *Power quality in power systems and electrical machines*, 887-959.
https://doi.org/10.1016/B978-0-12-800782-2.00010-5

Na'amnh, S., Salim, M. B., Husti, I., & Daróczi, M. (2021). Using artificial neural network and fuzzy inference system based prediction to improve failure mode and effects analysis: A case study of the busbars production. *Processes*, *9*(8), 1444.
https://doi.org/10.3390/pr9081444

Okabe, T., & Otsuka, Y. (2021). Proposal of a validation method of failure mode analyses based on the stress-strength model with a support vector machine. *Reliability Engineering & System Safety*, *205*, 107247.
https://doi.org/10.1016/j.ress.2020.107247

Pisner, D. A., & Schnyer, D. M. (2020). Support vector machine. In *Machine learning* (pp. 101-121). Academic Press.
https://doi.org/10.1016/B978-0-12-815739-8.00006-7

Qin, J., Xi, Y., & Pedrycz, W. (2020). Failure mode and effects analysis (FMEA) for risk assessment based on interval type-2 fuzzy evidential reasoning method. *Applied Soft Computing*, *89*, 106134.
https://doi.org/10.1016/j.asoc.2020.106134

Rafie, M., & Namin, F. S. (2015). Prediction of subsidence risk by FMEA using artificial neural network and fuzzy inference system. *International Journal of Mining Science and Technology*, *25*(4), 655-663.
https://doi.org/10.1016/j.ijmst.2015.05.021

Shamayleh, A., Awad, M., & Farhat, J. (2020). IoT based predictive maintenance management of medical equipment. *Journal of medical systems*, *44*, 1-12.
https://doi.org/10.1007/s10916-020-1534-8

Soltanali, H., Khojastehpour, M., Pais, J. E. D. A. E., & Farinha, J. T. (2022). Sustainable food production: an intelligent fault diagnosis framework for analyzing the risk of critical processes. *Sustainability*, *14*(3), 1083.
https://doi.org/10.3390/su14031083

Tian, J., & Yan, Z. F. (2013). Fuzzy analytic hierarchy process for risk assessment to general-assembling of satellite. *Journal of applied research and technology*, *11*(4), 568-577.
https://doi.org/10.1016/S1665-6423(13)71564-5

Wang, L., Hu, Y. P., Liu, H. C., & Shi, H. (2019). A linguistic risk prioritization approach for failure mode and effects analysis: A case study of medical product development. *Quality and Reliability Engineering International*, *35*(6), 1735-1752.
https://doi.org/10.1002/qre.2472

Wilson, A. J., & Nayak, S. (2019). Disinfection, sterilization and disposables. *Anaesthesia & Intensive Care Medicine*, *20*(11), 603-608.
https://doi.org/10.1016/j.mpaic.2019.09.013

Wilson, A. J., & Nayak, S. (2013). Disinfection, sterilization and disposables. *Anaesthesia & Intensive Care Medicine*, *14*(10), 423-427.
https://doi.org/10.1016/j.mpaic.2013.07.004

Zadeh, L. A. (1965). Fuzzy sets. *Information and control*, *8*(3), 338-353.
https://doi.org/10.1016/S0019-9958(65)90241-X

Zhang, S., Cheng, D., Deng, Z., Zong, M., & Deng, X. (2018). A novel kNN algorithm with data-driven k parameter computation. *Pattern Recognition Letters*, *109*, 44-54.
https://doi.org/10.1016/j.patrec.2017.09.036

Zulfikar, W. B., Jumadi, Prasetyo, P. K., & Ramdhani, M. A. (2018). Implementation of mamdani fuzzy method in employee promotion system. In *IOP Conference Series: Materials Science and Engineering* (Vol. 288, p. 012147). IOP Publishing.
https://doi.org/1088/1757-899X/288/1/012147

Appendix

Appendix I. The rule base of the FIS 1

1. If (Occurrence is VL) and (non-Detection is VL) and (Severity is VL) then (RPN is VL)
2. If (Occurrence is L) and (non-Detection is VL) and (Severity is VL) then (RPN is VL)
3. If (Occurrence is M) and (non-Detection is VL) and (Severity is VL) then (RPN is VL)
4. If (Occurrence is H) and (non-Detection is VL) and (Severity is VL) then (RPN is L)
5. If (Occurrence is VH) and (non-Detection is VL) and (Severity is VL) then (RPN is L)
6. If (Occurrence is VL) and (non-Detection is L) and (Severity is VL) then (RPN is VL)
7. If (Occurrence is L) and (non-Detection is L) and (Severity is VL) then (RPN is VL)
8. If (Occurrence is M) and (non-Detection is L) and (Severity is VL) then (RPN is VL)
9. If (Occurrence is H) and (non-Detection is L) and (Severity is VL) then (RPN is L)
10. If (Occurrence is VH) and (non-Detection is L) and (Severity is VL) then (RPN is L)
11. If (Occurrence is VL) and (non-Detection is M) and (Severity is VL) then (RPN is VL)
12. If (Occurrence is L) and (non-Detection is M) and (Severity is VL) then (RPN is VL)
13. If (Occurrence is M) and (non-Detection is M) and (Severity is VL) then (RPN is L)
14. If (Occurrence is H) and (non-Detection is M) and (Severity is VL) then (RPN is L)
15. If (Occurrence is VH) and (non-Detection is M) and (Severity is VL) then (RPN is L)
16. If (Occurrence is VL) and (non-Detection is H) and (Severity is VL) then (RPN is L)
17. If (Occurrence is L) and (non-Detection is H) and (Severity is VL) then (RPN is L)
18. If (Occurrence is M) and (non-Detection is H) and (Severity is VL) then (RPN is L)
19. If (Occurrence is H) and (non-Detection is H) and (Severity is VL) then (RPN is M)
20. If (Occurrence is VH) and (non-Detection is H) and (Severity is VL) then (RPN is M)
21. If (Occurrence is VL) and (non-Detection is VH) and (Severity is VL) then (RPN is L)
22. If (Occurrence is L) and (non-Detection is VH) and (Severity is VL) then (RPN is L)
23. If (Occurrence is M) and (non-Detection is VH) and (Severity is VL) then (RPN is L)
24. If (Occurrence is VH) and (non-Detection is VH) and (Severity is VL) then (RPN is M)
25. If (Occurrence is H) and (non-Detection is VH) and (Severity is VL) then (RPN is M)
26. If (Occurrence is VL) and (non-Detection is VL) and (Severity is L) then (RPN is VL)
27. If (Occurrence is L) and (non-Detection is VL) and (Severity is L) then (RPN is VL)
28. If (Occurrence is M) and (non-Detection is VL) and (Severity is L) then (RPN is L)
29. If (Occurrence is H) and (non-Detection is VL) and (Severity is L) then (RPN is L)
30. If (Occurrence is VH) and (non-Detection is VL) and (Severity is L) then (RPN is L)
31. If (Occurrence is VL) and (non-Detection is L) and (Severity is L) then (RPN is VL)
32. If (Occurrence is L) and (non-Detection is L) and (Severity is L) then (RPN is L)
33. If (Occurrence is M) and (non-Detection is L) and (Severity is L) then (RPN is L)
34. If (Occurrence is H) and (non-Detection is L) and (Severity is L) then (RPN is L)

35. If (Occurrence is VH) and (non-Detection is L) and (Severity is L) then (RPN is M)
36. If (Occurrence is VL) and (non-Detection is M) and (Severity is L) then (RPN is L)
37. If (Occurrence is L) and (non-Detection is M) and (Severity is L) then (RPN is L)
38. If (Occurrence is M) and (non-Detection is M) and (Severity is L) then (RPN is M)
39. If (Occurrence is H) and (non-Detection is M) and (Severity is L) then (RPN is M)
40. If (Occurrence is VH) and (non-Detection is M) and (Severity is L) then (RPN is M)
41. If (Occurrence is VL) and (non-Detection is H) and (Severity is L) then (RPN is L)
42. If (Occurrence is L) and (non-Detection is H) and (Severity is L) then (RPN is L)
43. If (Occurrence is M) and (non-Detection is H) and (Severity is L) then (RPN is M)
44. If (Occurrence is H) and (non-Detection is H) and (Severity is L) then (RPN is M)
45. If (Occurrence is VH) and (non-Detection is H) and (Severity is L) then (RPN is M)
46. If (Occurrence is VL) and (non-Detection is VH) and (Severity is L) then (RPN is L)
47. If (Occurrence is L) and (non-Detection is VH) and (Severity is L) then (RPN is M)
48. If (Occurrence is M) and (non-Detection is VH) and (Severity is L) then (RPN is M)
49. If (Occurrence is H) and (non-Detection is VH) and (Severity is L) then (RPN is H)
50. If (Occurrence is VH) and (non-Detection is VH) and (Severity is L) then (RPN is H)
51. If (Occurrence is VL) and (non-Detection is VL) and (Severity is M) then (RPN is L)
52. If (Occurrence is L) and (non-Detection is VL) and (Severity is M) then (RPN is L)
53. If (Occurrence is M) and (non-Detection is VL) and (Severity is M) then (RPN is M)
54. If (Occurrence is H) and (non-Detection is VL) and (Severity is M) then (RPN is M)
55. If (Occurrence is VH) and (non-Detection is VL) and (Severity is M) then (RPN is H)
56. If (Occurrence is VL) and (non-Detection is L) and (Severity is M) then (RPN is L)
57. If (Occurrence is L) and (non-Detection is L) and (Severity is M) then (RPN is L)
58. If (Occurrence is M) and (non-Detection is L) and (Severity is M) then (RPN is M)
59. If (Occurrence is H) and (non-Detection is L) and (Severity is M) then (RPN is M)
60. If (Occurrence is VH) and (non-Detection is L) and (Severity is M) then (RPN is H)
61. If (Occurrence is VL) and (non-Detection is M) and (Severity is M) then (RPN is L)
62. If (Occurrence is L) and (non-Detection is M) and (Severity is M) then (RPN is M)
63. If (Occurrence is M) and (non-Detection is M) and (Severity is M) then (RPN is M)
64. If (Occurrence is H) and (non-Detection is M) and (Severity is M) then (RPN is H)
65. If (Occurrence is VH) and (non-Detection is M) and (Severity is M) then (RPN is H)
66. If (Occurrence is VL) and (non-Detection is H) and (Severity is M) then (RPN is L)
67. If (Occurrence is L) and (non-Detection is H) and (Severity is M) then (RPN is M)
68. If (Occurrence is M) and (non-Detection is H) and (Severity is M) then (RPN is H)
69. If (Occurrence is H) and (non-Detection is H) and (Severity is M) then (RPN is H)
70. If (Occurrence is VH) and (non-Detection is H) and (Severity is M) then (RPN is VH)
71. If (Occurrence is VL) and (non-Detection is VH) and (Severity is M) then (RPN is M)
72. If (Occurrence is L) and (non-Detection is VH) and (Severity is M) then (RPN is M)
73. If (Occurrence is M) and (non-Detection is VH) and (Severity is M) then (RPN is H)
74. If (Occurrence is H) and (non-Detection is VH) and (Severity is M) then (RPN is H)
75. If (Occurrence is VH) and (non-Detection is VH) and (Severity is M) then (RPN is VH)
76. If (Occurrence is VL) and (non-Detection is VL) and (Severity is H) then (RPN is M)
77. If (Occurrence is L) and (non-Detection is VL) and (Severity is H) then (RPN is M)
78. If (Occurrence is M) and (non-Detection is VL) and (Severity is H) then (RPN is H)
79. If (Occurrence is H) and (non-Detection is VL) and (Severity is H) then (RPN is VH)
80. If (Occurrence is VH) and (non-Detection is VL) and (Severity is H) then (RPN is VH)
81. If (Occurrence is VL) and (non-Detection is L) and (Severity is H) then (RPN is M)
82. If (Occurrence is L) and (non-Detection is L) and (Severity is H) then (RPN is M)
83. If (Occurrence is M) and (non-Detection is L) and (Severity is H) then (RPN is H)
84. If (Occurrence is H) and (non-Detection is L) and (Severity is H) then (RPN is VH)
85. If (Occurrence is VH) and (non-Detection is L) and (Severity is H) then (RPN is VH)
86. If (Occurrence is VL) and (non-Detection is M) and (Severity is H) then (RPN is M)

87. If (Occurrence is L) and (non-Detection is M) and (Severity is H) then (RPN is H)
88. If (Occurrence is M) and (non-Detection is M) and (Severity is H) then (RPN is H)
89. If (Occurrence is H) and (non-Detection is M) and (Severity is H) then (RPN is VH)
90. If (Occurrence is VH) and (non-Detection is M) and (Severity is H) then (RPN is VH)
91. If (Occurrence is VL) and (non-Detection is H) and (Severity is H) then (RPN is H)
92. If (Occurrence is L) and (non-Detection is H) and (Severity is H) then (RPN is H)
93. If (Occurrence is M) and (non-Detection is H) and (Severity is H) then (RPN is VH)
94. If (Occurrence is H) and (non-Detection is H) and (Severity is H) then (RPN is VH)
95. If (Occurrence is VH) and (non-Detection is H) and (Severity is H) then (RPN is VH)
96. If (Occurrence is VL) and (non-Detection is VH) and (Severity is H) then (RPN is H)
97. If (Occurrence is L) and (non-Detection is VH) and (Severity is H) then (RPN is H)
98. If (Occurrence is M) and (non-Detection is VH) and (Severity is H) then (RPN is VH)
99. If (Occurrence is H) and (non-Detection is VH) and (Severity is H) then (RPN is VH)
100. If (Occurrence is VH) and (non-Detection is VH) and (Severity is H) then (RPN is VH)
101. If (Occurrence is VL) and (non-Detection is VL) and (Severity is VH) then (RPN is H)
102. If (Occurrence is L) and (non-Detection is VL) and (Severity is VH) then (RPN is H)
103. If (Occurrence is M) and (non-Detection is VL) and (Severity is VH) then (RPN is VH)
104. If (Occurrence is H) and (non-Detection is VL) and (Severity is VH) then (RPN is VH)
105. If (Occurrence is VH) and (non-Detection is VL) and (Severity is VH) then (RPN is VH)
106. If (Occurrence is VL) and (non-Detection is L) and (Severity is VH) then (RPN is H)
107. If (Occurrence is L) and (non-Detection is L) and (Severity is VH) then (RPN is H)
108. If (Occurrence is M) and (non-Detection is L) and (Severity is VH) then (RPN is VH)
109. If (Occurrence is H) and (non-Detection is L) and (Severity is VH) then (RPN is VH)
110. If (Occurrence is VH) and (non-Detection is L) and (Severity is VH) then (RPN is VH)
111. If (Occurrence is VL) and (non-Detection is M) and (Severity is VH) then (RPN is VH)
112. If (Occurrence is L) and (non-Detection is M) and (Severity is VH) then (RPN is VH)
113. If (Occurrence is M) and (non-Detection is M) and (Severity is VH) then (RPN is VH)
114. If (Occurrence is H) and (non-Detection is M) and (Severity is VH) then (RPN is VH)
115. If (Occurrence is VH) and (non-Detection is M) and (Severity is VH) then (RPN is VH)
116. If (Occurrence is VL) and (non-Detection is H) and (Severity is VH) then (RPN is VH)
117. If (Occurrence is L) and (non-Detection is H) and (Severity is VH) then (RPN is VH)
118. If (Occurrence is M) and (non-Detection is H) and (Severity is VH) then (RPN is VH)
119. If (Occurrence is H) and (non-Detection is H) and (Severity is VH) then (RPN is VH)
120. If (Occurrence is VH) and (non-Detection is H) and (Severity is VH) then (RPN is VH)
121. If (Occurrence is VL) and (non-Detection is VH) and (Severity is VH) then (RPN is VH)
122. If (Occurrence is L) and (non-Detection is VH) and (Severity is VH) then (RPN is VH)
123. If (Occurrence is M) and (non-Detection is VH) and (Severity is VH) then (RPN is VH)
124. If (Occurrence is H) and (non-Detection is VH) and (Severity is VH) then (RPN is VH)
125. If (Occurrence is VH) and (non-Detection is VH) and (Severity is VH) then (RPN is VH)

Appendix II. The rule base of the FIS 2

1. If (fuzzy RPN is VL) and (level of Control is L) then (priority actions is low priority)
2. If (fuzzy RPN is L) and (level of Control is L) then (priority actions is low priority)
3. If (fuzzy RPN is M) and (level of Control is L) then (priority actions is low priority)
4. If (fuzzy RPN is H) and (level of Control is L) then (priority actions is priority medium)
5. If (fuzzy RPN is VH) and (level of Control is L) then (priority actions is high priority)
6. If (fuzzy RPN is VL) and (level of Control is M) then (priority actions is low priority)
7. If (fuzzy RPN is L) and (level of Control is M) then (priority actions is low priority)
8. If (fuzzy RPN is M) and (level of Control is M) then (priority actions is priority medium)
9. If (fuzzy RPN is H) and (level of Control is M) then (priority actions is high priority)
10. If (fuzzy RPN is VH) and (level of Control is M) then (priority actions is high priority)
11. If (fuzzy RPN is VL) and (level of Control is H) then (priority actions is low priority)

12. If (fuzzy RPN is L) and (level of Control is H) then (priority actions is low priority)
13. If (fuzzy RPN is M) and (level of Control is H) then (priority actions is high priority)
14. If (fuzzy RPN is H) and (level of Control is H) then (priority actions is high priority)
15. If (fuzzy RPN is VH) and (level of Control is H) then (priority actions is high priority)

Appendix III: description of risk scenarios

R1	Stab wounds
R2	leaking liquid
R3	Hygiene rules non-respected
R4	Wearing jewelry
R5	no respect of protection rules and procedures
R6	non-declaration of non-functional MD
R7	inefficient brushing
R8	Aggressive brushing
R9	MD passed with no brush
R10	immersion duration not respected
R11	dilution concentration not respected
R12	Small MD lost in sewers
R13	inefficient rinsing
R14	inefficient drying
R15	error of cycle selection
R16	airlock opened from 2 sides
R17	inefficient control of wholeness
R18	use non-functional box
R19	use non-functional paper
R20	Bad operation of packaging
R21	inefficient control of MD constitution
R22	losing MD or part of MD
R23	no applications of indicators
R24	inefficient welding
R25	error of cycle selection
R26	using expired BD
R27	Non-functional autoclave machine (breakdown)
R28	breakdown of consumables
R29	inhomogeneous loading
R30	indicators not putted
R31	error of cycle selection of sterilization process
R32	blocked autoclave machine
R33	explosion of autoclave (overpressure of autoclave)
R34	burns of autoclave nurse (when getting out MD package from autoclave)
R35	inefficient control of indicators results
R36	crushes between MDs
R37	deadlines of sterile MD not respected
R38	client s confusion
R39	lateness in delivery of MD
R40	inadequate conditions of transport
R41	Absence of area cleaning
R42	Inefficient cleaning
R43	ineffective waste management
R44	ineffective maintenance intervention
R45	Non-reactivity for an intervention request
R46	Non-satisfaction of a procurement demand