Risk assessment of medical devices used for COVID-19 patients based on a Markovian-based Weighted Failure Mode Effects Analysis (WFMEA)

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Abstract

Medical devices are critical in the healthcare system and their failures can significantly impress the safety of patients, medical staff, and clinical engineers. With increasing COVID-19 pandemic in recent months, it is more necessary to assess the risks of the devices to avoid infection for patients, death, and severe hurts due to inactive and breakdown devices. The aim of this study is to assess medical device risks in general and pandemic situations with three main factors of the Failure Model Analysis Effect include occurrence, detection, and severity. Some sub-factors are defined and weighted using the Fuzzy DEMATEL and Fuzzy Best-Worst Method. Consequently, the weighted FMEA score of each failure is calculated as the Weighted Risk Priority Number. Finally, steady-state probabilities of very low and low failures are calculated to consider the changes during the time. Results show that near half of the failures are scored in very low and low levels but in the long term, most of them transfer to medium level risk. It can be concluded that some preventive maintenance plans for these kinds of failures to avoid occurring the higher risk level for them in the future is necessary and the results can help medical device managers.

Keywords: Risk assessment, Medical devices, Weighted FMEA, Fuzzy DEMATEL, FBWM, Markov chain

1. Introduction

Medical devices play a critical role in the healthcare system to diagnose and treat. The failures of medical devices can significantly affect the safety of patients, medical staff, and clinical engineers in the clinical use of medical devices. The prioritization of medical devices is a crucial issue for healthcare systems. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) published a standard for medical devices which make hospitals in the

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United stated to use different risk management approaches for their medical equipment management programs [1].

As these medical devices affect patient life immediately and directly, risk evaluation and management for them is critical [2]. With the increasing COVID-19 pandemic in recent months, it is more necessary to assess the risks of the devices used for patients to avoid infection. Also, infectious diseases have severe results in public physical and mental health [3]. In this regard, different failures of these devices include general failures, and also those related to this pandemic should be considered and prioritized. Actually. Some failures will change over time. For example, some failures may be at a low level of risk now but they can be at higher levels within some period later. It is necessary to pay attention to these kinds of risks and predict them, in order to be ready for facing and controlling them [4,5]. Markov chain can help us to forecast later levels of failures during the time [6].

The FMEA (Failure Mode and Effects Analysis) is a tool for assessing the risks, failures, faults, or errors of different devices or services [7]. This tool is used for the risk assessment of identified failure modes. In the classical FMEA, there are three main factors for scoring Detection, Severity, and Occurrence and results in the risk priority number (RPN) that can score each device or service by that [8]. Some researchers use other criteria as sub-factors for FMEA to cope with its shortage and use the multi-criteria decision making (MCDM) for the factors or sub-factors weighting.

This paper presents a Markov chain-based weighted failure mode analysis approach to the medical device prioritization risks. In this study, all functional devices used for COVID-19 devices are described with their general and pandemic failures. Then they will assess based on three main factors of FMEA such as occurrence, detection, and severity. But due to coming up with FMEA shortcomings, some sub-factors will define each of the three main factors. Sometimes, the only three risk factors are difficult to be evaluated accurately, but some relative sub-factors can make the scoring easier. These sub-factors may have different impact levels on the main factor so they need to be weighted. Also, the weighting of sub-factors is calculated using the Fuzzy Best-Worth Method based on their internal relationship using Fuzzy DEMATEL. Consequently, the weighted FMEA score of each failure is concluded as WRPN. Finally, steady-state probabilities of very low and low failures are calculated to update their WRPN during the time and some corrective actions will propose. The main advantages of this study over the previous papers are (1) risk assessment for medical devices related to COVID-19 which have critical risks over the pandemic period and they are critical for the patient treatment, (2) using weighted FMEA with considering different sub-criteria based on general and pandemic situation, (3) Markov chain using for considering long term effect of RPN scores for very low and low-risk devices. Also, the main research questions of this study are as follows:

- What are the main failures (in general and in a pandemic) of medical devices related to COVID-19 patients?
- Which sub-factors are the most influential ones in the three main criteria of FMEA?
- How the medical device failures could be prioritized using WFMEA?

- How the medical device failures could be updated base on Markovian-based rescoring of WFMEA?

The rest of the paper is organized as follows: Section 2 presents a review of the literature around the field of this study. Different methods used with their explanation are described in Section 3. In Section 4, the case study and the results are discussed. Discussion is provided in Section 5, while some managerial implications are suggested in Section 6. Finally, the conclusion and future studies suggestions are expressed in Section 7.

2. Literature review

The prioritization of medical devices risk scores has become a necessary task for all healthcare organizations to provide maintenance programming. Furthermore, researchers focused on the risk assessment problem for medical devices in the recent decade. Therefore, this study is related to medical device risk assessment research streams. Some important and recent papers are discussed in this section.

Youssef and Hyman (2009) proposed a new medical device classification model rather than previous studies based on the complexity of medical devices. Their model includes two phases: Technical complexity of the medical device and use of the complexity of medical devices. The technical complexity of medical devices includes four criteria about the technical perspective of medical devices such as equipment maintainability and deterioration, while the use complexity of medical devices consists of nine criteria based on How difficult is the use of medical devices at the operation use and operational level such as data entry, setup process, retrieve, receive and send data, Integration of patient data and self-test [9]. Taghipour et al. (2011) used an analytical hierarchy process (AHP) for medical devices ranking through their criticality level. They considered six criteria for pairwise comparison of medical devices. These criteria include recalls, age, risk, mission criticality, equipment function, and maintenance requirements [10]. Corciova et al. (2013) determined and developed guidelines to have a program for medical devices quality assurance. They also suggested periodic inspection processes, maintenance guidelines and solutions, evaluation, and performance assessment for medical equipment. In their paper, they described a method that has five risk criteria in their scoring system concerning the patient, medical staff, and biomedical engineers in the healthcare system [11]. Tawfik et al. (2013) developed a fuzzy logic model for medical equipment classification. they recognized four criteria such as 1-the status of mission criticality, 2- equipment function, 3-maintenance needs, and 4- physical risks, to obtain and calculate the risk level for each medical device. Their outcome shows that, in some medical devices in the healthcare system, the same medical device class may acquire different risk scores. furthermore, they compared their classification schemes rather than other schemes in previous studies [12]. Cheng et al., (2014) tried to evaluate the flight operation risks. They considered several sub components for each risk and used fuzzy inference system for scoring them [13].

Onofrio et al. (2015) also evaluated the risks related to the design process of new devices in a medical device development company. They defined some medical devices, potential failure modes, functional effects, clinical harms, and causes of failure modes and ranked them based on FMEA to assess every medical device [14]. Jamshidia et al. (2015) Developed a new FFMEA approach. They defined some new criteria rather than previous studies include age, utilization, and use-related hazards. Then, they proposed a framework for medical devices prioritization which considered risks. So, they could help to avoid the high-risk failures [15]. Kirkire et al. (2015) investigate risk management in the process of medical devices. Their research aimed to explore risks in a dental product manufacturing company for minimizing failure events. These risks were analyzed using traditional Failure mode and effect analysis (FMEA) and fuzzy FMEA and categorized into different levels include critical, moderate, low, and negligible. Finally, a systematic approach for risk management was developed [16]. Cicotti and Coronato (2015) proposed a dynamic probabilistic risk assessment for medical devices. They combined the Event Sequence Diagram (ESD) and Markov decision process for considering risk scenario dynamics and stochastic manner. Finally, they implemented their approach in a case study [17]. Ardeshir et al., (2016) used FMEA for construction safety risk evaluation. They also used AHP and DEA for their analysis and prioritized the potential risks. Their results showed that falling from high locations was the most important risk in construction projects [18]. Vazdani et al., (2017) also used FMEA for environmental risk assessment. They first identified the risk in projects and then evaluated them by FMEA and classified them in three different categories including low-risk level, medium risk, and high-risk. Finally, they suggested some corrective actions to reduce the probabilities if the risks [19]. Wei Lo and Liou (2018) focused on risk assessment by using MCDM based FMEA. They weighted the FMEA factors by best-worst-method with gray variables. Then, the risks in an international electronics company as a case study [20].

Brun and Savio (2018) focused on risk assessment using integrated FMEA with pairwise comparison matrix and Markov chains in the construction industry. They aimed to assess potential risks to avoid or decrease work-related injuries and casualties. They listed different components of the system and calculated a weighted risk priority number (WRPN) for each component. Then, they used the Markov chain for low risk to consider the long term run due to tune the expert's opinion. They also considered the interdependence correction factor for calculating the corrected RPN [6]. Abdel-Basset et al. (2019) proposed a group decision-making framework for selecting medical devices. They used neutrosophic TOPSIS for ranking seven medical devices related to diabetics' patients based on seven criteria including: safety, cost, flexibility, quality, ease of use, maintenance requirements, and service life [21]. Mangeli et al., (2019) improved the FMEA analysis using the TOPSIS method and either Support Vector Machine (SVM). They first weighted the FMEA risk factors using TOPSIS (severity:0.479, occurrence: 0.335, and detection: 0.186) and then predicted the severity and occurrence of every failure modes by SVM with the accuracy of 87% and 95% [22]. Kim et al. (2020) provided a risk-based model for telemedicine systems security. They used the attack tree for identifying the telemedicine system's potential risks. Finally, they investigated these risks and threats to remote healthcare quality [23]. Song et al. (2020) developed a model aiming identification and also evaluation of human-related failures while medical devices are being used. They used the Swiss cheese model for identifying the potential failures and a new FMEA approach based on rough set and grey relational analysis for assessing the risks of the failure [24]. Parand F.A et al. (2020) also assessed medical device risks. They tried to obtain the risk value for each of the medical devices to know to which device they should allocate the budget for maintenance operations based on the ordered weighted averaging aggregation operator. This method is one of the fuzzy multi-criteria decision-making approaches [25]. Ostadi & Abbasi Harofteh, (2020) assessed the risks in a petrochemical plant construction using Monte Carlo simulation. First, they listed the risks and then identified the relation among these risks using system dynamic approach. Their results showed that the risks such as inflation, cost, temperature, rain, and labor are the most important risks [26].

Subriadi & Najwa (2020) used an improved FMEA and either traditional one for risk assessment of information technology and compared the results in the same case study. They listed the event risks for information technologies and calculated the RPN in two ways. Results showed that the consistency for traditional FMEA was 0.848 and for improved FMEA was 0.937 between different teams as an expert [27]. Moheimani et al., (2020) assessed the hospital agility based on a type-2 fuzzy flowsort inference system. Their results showed that 40% of 30 case studies hospitals are agile [28]. Qin et al., (2020) evaluated the risk using integrated FMEA and interval type-2 fuzzy evidential reasoning method. They weighted the FMEA risk factors by evidential reasoning and then calculated the RPN for each risk [29]. Bhattacharjee and Mandal (2020) compared the FMEA result and logistic regression model. They first calculated the RPN scores but believed that the equal weights of three factors of severity, occurrence, and detection are not appropriate for reality. So, they tried to predict the risk probability of every failure using interval number based logistic regression with 77.47% accuracy rate, 81.98 Receiver Operating Characteristic, and optimal cut-off of 0.56 [30]. Martinez-Licona & Perez-Ramos (2021) evaluated the risk of medical devices related to a hospital ICU as a case study using FMEA. These devices included a defibrillator, vital sign monitor, and volumetric ventilator and most of the devices had medium and high-level of risk probability [31]. Chen & Wang, (2021) evaluated the risks in public-private partnership projects. They used intuitionistic FAHP for prioritizing the criteria and then, Interval-Valued Hesitant Fuzzy Sets for calculating the risk level score [32]. Table 1 summarizes the researches reviewed.

As can be seen in Table 1, there are rare researches in the risk assessment field which is considered risk level alteration using Markov transition matrix while this issue is one of the most important issues in preventive maintenance planning is essential for the decision-making process. On the other hand, Defining the sub-factors for FMEA and weight them for calculating the WFME score can improve the traditional FMEA shortage which was rare in literature. Although several papers weighted the three factors of FMEA, a few of them had defined sub-factors and weight them either. this is the first research the developed the Markovian-based Weighted FMEA framework to study the medical devices risk assessment in a pandemic situation. This study can make insight into hospitals that serve COVID-19 patients to focus better on their devices and preventive maintenance plans using Markov chain which has been rarely addressed in the literature. So, the main contributions of this research comparing to previous studies are as follow:

i) Assessing the risk level for medical devices related to COVID-19 patients in the pandemic.
ii) Defining pandemic-related and general subfactors for FMEA three risk factors and validate them toward Structural Equation Model (SEM).
iii) Developing the WFMEA approach for weighting the sub-factors using Fuzzy BWM.
iv) Using Markov transition matrix as the Reprioritization Correction Factor (RCF) for calculating long-term changes in risk levels.

To the best of our knowledge, this is the first study that investigates the medical devices risk (general and pandemic-related) with identifying more risk factors for the main one (i.e., occurrence, severity, and detection) which are confirming by SEM. Then, weighted FMEA using FBWM is used. Finally, the prediction of each risk score is done using Markov chain.

3. Methods

In this section, the methodology of the current research is presented. This research applies the combination of Weighted FMEA, SEM, FDEMATEL, FBWM, and Markov chain to investigate the medical device's risks. Figure 1 shows the study steps. In the first step, we identify the different equipment used for COVID-19 patients. Then four failure types for each of them were listed by tan experts working them daily in the hospital. Remained steps are listed in Figure 1 and the approaches are explained in the following sections.

3.1 . SEM

The Structural Equation Modeling (SEM) method is a generalized linear regression. Linear regression is one of the most complex statistical techniques for data that is usually at the level of distance measurement. Linear regression is presented in two forms: simple regression and multivariate linear regression. In regression, the effect of independent variables on dependent variables is determined. Structural Equation Modeling is an approach for hypotheses test about the interrelationships of the observed and latent variables. In this research, structural equation modeling with the help of the partial least square method and PLS software is used to test the hypotheses and accuracy of the model. SEM techniques have become an integral part of the validation process and testing of links and relationships between structures. These relations can be investigated with variance or even covariance. The variance-based relations are calculated through Partial Least Squares (PLS) while the covariance-based relations are attained by LISREL. In this study PLS regression is considered. This technique was developed by Weld for analyzing multidimensional data in less structured environments.

PLS is a variance-based approach that requires fewer conditions than similar structural equation techniques such as LISREL. PLS has no sample size limit and the selected sample can be equal to or less than 30, in which case the results are also valid. When there are not many samples and measurement items or the distributions of the variables are not specified, PLS is more powerful. PLS modeling has two steps; In the first stage, the measurement model is examined by validity and reliability analysis and also confirmatory factor analysis, and in the second stage, the structural model is examined through the path between variables and identifying the model fit indices.

Model analysis in structural equation modeling with partial least squares (PLS-SEM) approach consists of two main steps:

• Check the model fit.

• Test the relationships between structures [33].

3.2 . Fuzzy DEMATEL

Fuzzy DEMATEL examines the relationships between criteria and sub-criteria and identifies all the influential and influential criteria (or in other words, causal criteria) by the relationship matrix [34]. This method is one of the multi-criteria decision-making methods. As the name implies, all calculations are performed in a fuzzy environment. However, assume $\tilde{a} = (l, m, u)$ is a triangular fuzzy number. The Graded Mean Integration Representation (GMIR), which is shown by $R(\tilde{a})$, is defined using Equation (1) below [35]:

$$R(\tilde{a}) = \frac{l + 4m + u}{6} \quad (1)$$

The steps of FDEMATEL are as follows:

- Step 1: Form a group of experts to gather their group knowledge to solve the problem. However, determining the criteria to be evaluated as well as the design of linguistic scales is in this step. In this research, we use linguistic scales which are given in Table 2.
- Step 2: Create a fuzzy matrix with the initial direct relations by gathering expert opinions. To measure the relationships between criteria/sub-criteria, we need to put them in a matrix and ask experts to compare them in pairs based on how much they influence each other. In this survey, experts will express their views based on Table 2. Assuming we have n criteria and p expertise; we have P numbers of the fuzzy matrix $(n \times n)$, each corresponding to the opinions of an expert with triangular fuzzy numbers. Finally, the average of these matrices is applied to calculations.
- Step 3: Normalize fuzzy matrix of direct relations. To this, linear scale conversion is used as a normalization formula to convert scale to comparable scales using the Equations (2-3):

$$\tilde{a}_{ij} = \sum_{j=1}^{n} \tilde{z}_{ij} = \left(\sum_{j=1}^{n} l_{ij}, \sum_{j=1}^{n} m_{ij}, \sum_{j=1}^{n} r_{ij} \right) and r = \max_{1 \le i \le n} \left(\sum_{j=1}^{n} r_{ij} \right) \quad (2)$$

$$\tilde{X} = \begin{bmatrix} \tilde{X}_{11} & \cdots & \tilde{X}_{1n} \\ \vdots & \ddots & \vdots \\ \tilde{X}_{m1} & \cdots & \tilde{X}_{mn} \end{bmatrix} and \tilde{X}_{ij} = \frac{\tilde{Z}_{ij}}{r} = \left(\frac{l_{ij}}{r}, \frac{m_{ij}}{r}, \frac{r_{ij}}{r} \right) \quad (3)$$

- Step 4: Calculate the fuzzy matrix of total relations. In this step, we first calculate the inverse of the normal matrix and then subtract it from the matrix I, and finally multiply the normal matrix by the resulting matrix as Equations (4 – 6).

$$\left[l_{ij}^{"}\right]=X_1\times\left(1-X_1\right)^{-1} \tag{4}$$

$$\left[m_{ij}^{"}\right]=X_m\times\left(1-X_m\right)^{-1} \tag{5}$$

$$\left[r_{ij}^{"}\right]=X_r\times\left(1-X_r\right)^{-1} \tag{6}$$

- Step 5: Creation and analysis of causal diagram. To do this, we first calculate the sum of the elements of each row (D_i) and the sum of the elements of each column (R_i) of the fuzzy matrix above. D_i indicates the level that each factor affects the other factors in the system. Also, R_i indicates the effectiveness of each factor from the other factors. Consequently, $D+R$ and $D-R$ are calculated. More value of $D+R$ results that this factor is more interactive with other system factors. On the other hand, if $D-R$ is positive, the variable is causal, and if it is negative, it is not a cause. The causal diagram can be plot based on $D+R$ and $D-R$. Interested readers can gain more detail about the steps of FDEMATEL from the paper of [36].

3.3 . Fuzzy BWM

FBWM is one of the new multi-criteria decision-making methods. The basis of this method is to measure the criteria by comparing pairs. In the FBWM, the weight of the criteria is determined by determining the priority of the best criterion over other criteria and the preference of all criteria over the worst criterion. Advantages of this method compared to other multi-criteria decision-making methods are:

- Requires fewer comparative data;
- This method leads to more stable comparisons and provides more reliable answers.
- This approach can easily combine with other MADM methods [37].

The steps of FBWM are as follows [38]:

- Step 1: Determining the Best and Worst (Most Important and Less Important): This step can be determined using expert opinions or a fuzzy Delphi method.
- Step 2: Pair comparison of the best criterion with other criteria and other criteria with the worst criterion: In this step, pairwise comparison vectors with the following transformation in Table 3.

Considering $\tilde{A}_W$ and $\tilde{A}_B$ are the comparison vectors of other-to-worst and Best-to-other as Equations (7 – 8).

$$\tilde{A}_W = \left(\tilde{a}_{1w}, \tilde{a}_{2w}, \ldots, \tilde{a}_{nw}\right) \tag{7}$$

$$\tilde{A}_B = \left(\tilde{a}_{B1}, \tilde{a}_{B2}, \ldots, \tilde{a}_{Bn}\right) \tag{8}$$

- Step 3: Creating a fuzzy BWM model: In this step, you can calculate the factors using the nonlinear under-weight planning model based on Equation (9).

$$\begin{aligned} &\min\ \tilde{\xi}^* \\ &s.t.\begin{cases} \left|\dfrac{(l_B^w, m_B^w, u_B^w)}{(l_j^w, m_j^w, u_j^w)} - (l_{Bj}, m_{Bj}, u_{Bj})\right| \le (k^*, k^*, k^*)\forall j \\ \left|\dfrac{(l_j^w, m_j^w, u_j^w)}{(l_W^w, m_W^w, u_W^w)} - (l_{jW}, m_{jW}, u_{jW})\right| \le (k^*, k^*, k^*)\forall j \\ \sum_{j=1}^{n} R\left(\tilde{w}_j\right) = 1 \forall j \\ l_j^w \le m_j^w \le u_j^w \forall j \\ l_j^w \ge 0 \forall j \end{cases} \end{aligned} \tag{9}$$

Step 4: In this method, after solving the model in Equation (9), a formula is used to calculate the Consistency Ratio (CR) to check the validity of the comparisons. First, based on the comparison vector of best-to-worst criteria, the Consistency Index (CI) is determined (according to Table 4). Then, the consistency ratio calculated applying Equation (10) [38]. The smaller value for CR (close to zero) is better.

$$CR = \frac{\xi^*}{CI} \tag{10}$$

3.4 . Weighted FMEA

Risk assessment is a logical method for determining the quantitative and qualitative score of hazards and examining the potential consequences of potential accidents on people, materials, equipment, and the environment. The Failure mode and effect analysis (FMEA) method is one of the most common methods of risk assessment in industries in which possible failures and risks during the project are identified and the amount of risk is calculated. FMEA was first used by the aerospace industry in the 1960s and rapidly was used in the automobile industry and other industries gradually. FMEA is a systematic tool used to identify, evaluate, prevent, eliminate or control failures and their potential effects on a system, design process, or service. Furthermore, the defects can be rooted out and prevented from occurring [39].

The main factors in FMEA which should be scored are Severity (S), Occurrence (O), and Detection (D). Severity means the severity of the risk or the degree to which it is new is the potential risk effect on individuals. There are four scores for severity that are expressed on a scale of 1 (Minor effects) to 4 (Dangerous). Occurrence determines how often a potential cause or mechanism of danger occurs. The probability of occurrence is measured on a scale of 1(Unlikely) to 4(Very often). Finally, detection is the possibility of discovering the occurrence of a hazard that has scored from 1(Almost certain) to 4 (rarely) [40].

3.5 . Markov chain

A Markov chain is a stochastic model depicting possible events sequence in which the probability of each event depends on the previous event only [41]. Based on this, in this study, we define a matrix P which shows the probability of being in a special risk level and transfer to other levels in one period later as Equation (11):

$$P = \begin{bmatrix} \frac{p_{11}}{p_{1T}} & \frac{p_{12}}{p_{1T}} & \frac{p_{13}}{p_{1T}} & \frac{p_{14}}{p_{1T}} & \frac{p_{15}}{p_{1T}} \\ \frac{p_{21}}{p_{2T}} & \frac{p_{22}}{p_{2T}} & \frac{p_{23}}{p_{2T}} & \frac{p_{24}}{p_{2T}} & \frac{p_{25}}{p_{2T}} \\ \frac{p_{31}}{p_{3T}} & \frac{p_{32}}{p_{3T}} & \frac{p_{33}}{p_{3T}} & \frac{p_{34}}{p_{3T}} & \frac{p_{35}}{p_{3T}} \\ \frac{p_{41}}{p_{4T}} & \frac{p_{42}}{p_{4T}} & \frac{p_{43}}{p_{4T}} & \frac{p_{44}}{p_{4T}} & \frac{p_{45}}{p_{4T}} \\ \frac{p_{51}}{p_{5T}} & \frac{p_{52}}{p_{5T}} & \frac{p_{53}}{p_{5T}} & \frac{p_{54}}{p_{5T}} & \frac{p_{55}}{p_{5T}} \end{bmatrix} \quad (11)$$

The second phase supposes that this matrix will remain constant after a long time. This is called a steady-state probability. It is calculated by multiplying the matrix P more and more until it converges. So that the risk distribution at the steady-state is as vector V in Equation (12) [6]:

$$V = (V_1, V_2, V_3, V_4, V_5) \quad (12)$$

4. Results

4.1. Identifying devices for COVID- 19 patients and their failures in the case study

The effective way to deploy the methodology is to select a real case study. For this purpose, we used a private hospital in Iran which services COVID-19 patients in the pandemic period and has ten active departments dedicated to COVID-19 patients includes three ICU departments, two CCU departments, and five inpatients departments. The devices used include a Digital X-Ray machine, CT SCAN 16Slice, Ventilator, Patient Monitor, Echo Cardiograph, Syringe Pump, ECG, Real-Time PCR, Cell Counter, Elisa Reader.

These important and functional devices which are used for COVID-19 patients are listed. Table A in Appendices shows these devices and their probable failures in Supplementary Material.

4.2. Define factors and Sub-factors of FMEA and Validating them using SEM

In FMEA, the risk priority orders of the identified failure modes are scored by a risk priority number (RPN). The RPN is calculated from the multiplication of the three risk factors occurrence (O), severity (S), and detection (D). but in this study, we considered some sub-factors with related ranges for each of three factors due to focus on more parameters for calculating each factor score. These are extracted from the literature or some from expert opinion. The sub-factors are described as follows:

- **Occurrence**
  - O1: Visibility: the failure occurrence probability especially hidden ones [15].
  - O2: Mean time between failures in the normal situation: the interval between two consecutive failures in a normal period [42].
  - O3: Mean time between failures in a pandemic: the interval between two consecutive failures in the pandemic period.
  - O4: Repeatability in the normal situation: frequency of a failure occurrence with the same cause during the same period in the normal situation [43].
  - O5: Repeatability in Pandemic: frequency of a failure occurrence with the same cause during the same period in the pandemic situation.

Also, Table 5 shows the different ranges and related levels of O1-O5.

- **Detection**
  - D1: Probability of non-detection: the probability of when a failure will not be detected [44].
  - D2: Detection Method: the degree of automation for a medical device failure detection method [15].
  - D3: Detection costs: the average cost of failure detection.
  - D4: Detection Speed: the average time to detect the failure.
  - D5: Detection accuracy: how much the detection is valid.

Table 6 shows the different ranges and related levels of D1-D5.

- **Severity**
  - S1: Patient general Safety: general safety level of the patient during failure occurrence [45].
  - S2: patient safety from Infection risk: infection risk level of the patient During and after failure occurrence.
  - S3: The potential risks for patients, operators, and nurses in the normal situation
  - S4: The potential risks for patients, operators, and nurses in the pandemic situations.
  - S5: Repair meantime: the average time for repairing a medical device [46].
  - S6: Economic loss: includes maintenance cost and the cost related to delayed treatment [47].

Table 7 shows the different ranges and related level of S1-S6.

To check the validity of the sub-factors selecting, two parts of fitting the measurement and structural models should be done.

- Fitting of measurement models

The model drawn in SmartPLS software is as shown in Figure 2. It shows the strengths of the relations between each level of the model both the main factors and FMEA analysis and the sub-factors with related factors.

One of the study indicators in fitting the measurement model is the factor load. The strength of the relationship between the factor (hidden variable) and the visible variable is indicated by the factor load. The factor load is a value between zero and one. If the factor load is less than 0.3, a weak relationship is considered and ignored. The factor-load of between 0.3 and 0.6 is acceptable, and if greater than 0.6 it is highly desirable. Therefore, relationships with a factor load of less than 0.3 will exclude from the model. Fortunately, Table 8 shows the factor loads which were depicted in Figure 2. Based on this, all variables have a factor load of more than 0.3 and all of the, are acceptable.

Cronbach's alpha rate and hybrid reliability coefficient are also used to measure the combined reliability of the model. Also, to derive convergent validity in the model, the mean of extracted variance (AVE) index is used. These values are shown in Table 9 which are the software outputs.

Therefore, according to the stated values, it can be seen that the validity and reliability and in general the fit of the measurement model are proved.

- Fitting the structural model

T-test and R2 criterion are used to check the structural model fit. Table 10 shows the software outputs for the z significance test. It should be noted that the test in the model of this research has been tested at 95% confidence level. In the t-values test, the values must be greater than 1.96, otherwise, the test will be rejected. As can be seen in Table 10, the value of the z statistic for all variables is greater than 1.96.

In structural equation modeling, the R2 criterion is related to the endogenous (dependent) variables of the model. R2 is a criterion that indicates the effect of an exogenous variable on an endogenous variable and three values of 0.19, 0.33, and 0.67 are considered as the criterion values for weak, medium, and strong values of R2. Table 11 shows the R2 values for the model-dependent variables.

In this section, it can be seen that the stated criterion R2 has the standard limit and the desired value and as a result, is valid.

- The overall fit of the model

To test the overall fit of the model, two basic hypothesis tests have been used. T-test hypothesis test and path coefficient test, which were examined separately during the fit of the measurement model and the structural model. In this model, several statistical hypotheses have been examined that the effect of occurrence, severity, and detection on FMEA results. In Table 12, according to the Z test statistics as well as the path coefficient, the hypothetical tests are examined.

As can be seen, according to software outputs and hypothetical tests, all the risk factors and their sub-factors affect the FMEA score and thus the factors and sub-factors of the research are proven.

4.3. The interrelationship between sub-factors using Fuzzy DEMATEL

In this section, the interrelationships among the sub-factors of O, D, and S are identified by the FDEMATEL method. Moreover, since determining the best and the worst criteria is hard work especially when the decision-makers have different points of view, in this research, we apply the output of the FDEMATEL to specify the best and the worst criteria. In this way, the criteria with the highest D+R are considered as the best, and the criteria with the lowest D+R are defined as the worst. Table B1-B3 in Appendices shows the average of experts' opinions based on fuzzy numbers. Also, the crisp counterpart of the relation matrix is presented in Table B.4-B.6 in Appendices. Finally, the best and the worst criteria have been determined in Table 13 - 15.

4.4. Weighting sub-factors based on the output of FDEMATEL output and FBWM

In this section, we report the obtained results from the implementation of the FBWM for each risk factor. It should be noted that the pairwise comparison is a collection using questionnaires that are distributed to five experts who were managers and experts of medical devices. The average opinions of three groups of experts are given in Tables C.1-C.6 in Appendices. For the occurrence factor, based on expert's opinions, O1 is the best, and O2 is the worst. The achieved results are given in Table 16. The results of FBWM for sub-factors of detection are given in Table 17. For this mode, as DEMATEL results shown, select D2 as the best and D5 as the worst sub-factor. Table 18 shows the results of FBWM for the sub-criteria of severity risk factors. In this mode, S5 and S1 as the best and worst criteria.

Based on the sub-factor weights obtained above, the score of each failure will calculate in the next section.

4.5. Weighted RPN for failures

In this step, a weighted RPN can be calculated using the sub-factors weights through Equation (13):

$$WRPN = \left(\sum_{i=1}^{5} O_i \times \alpha_i\right) \times \left(\sum_{i=1}^{5} D_i \times \beta_i\right) \times \left(\sum_{i=1}^{6} S_i \times \gamma_i\right) \qquad (13)$$

Where:

O_i: Occurrence of Failures

α_i: Occurrence sub-factors weights

D_i: Detection of failures

β_i: Detection sub-factors weights

S_i: Severity of failures

γ_i: Severity of sub-factors weights

Based on Equation (13), Table 19, shows the results of weighted FMEA for failures of the devices. After analyzing the results obtained in Table 19, the experts specified different ranges to categorize the failures into five categories of risk failures such as very low, low, medium, high, and very high. In Table 20, different levels of risk failures and their related WRPN ranges are described.

4.6. Estimating Very low/ Low/ risks failures in the long term

Based on Table 20, there are seventeen failures that are very low and low risks. Experts decided to update their WRPN scores during the time to consider some inadequate information for these types of failures. This correction factor involves the long-term possible effect of these failures. It means that it can estimate whether a failure remains in its current level or increase in next periods.

However, the probability of each very low and low failure risk is evaluated in long term. To do this, the one-step transition probability will be defined as Matrix P explained in Section 3.5. the one-step transition matrix of all very low and low failures is shown in Tables D.1-D.17 in Appendices. The probabilities of remaining the failures in a unique risk level in the next periods are described as a steady-state vector of V_i , which is shown in Table 21 for very low and low failures.

By calculating the steady-state, a Reprioritization Correction Factor (RCF) can be defined for recalculating the WRPN for very low and low failures. This correction factor relates to the sum of the probabilities of high and very high probabilities at the steady-state of each failure based on (Brun & Savino, 2018). So, we calculate $P_{h,Vh}$ as Equation (14) in Table 22:

$$P_{h,vh} = V_4 + V_5 \tag{14}$$

Besides, the RCF factor is specified based on different ranges of C as Table 23. Updated WRP are calculated in Table 24.

5. Discussion

The medical devices risk assessment problem aims to score different failures of devices and it includes a failure modes evaluation process that considers qualitative and quantitative criteria. Dealing with this problem, there are many different tools and techniques which are useful.

Since FMEA is a popular method for evaluating the risks, it is important to use it but in a way that its shortage cover by defining more factors besides Occurrence, Detection, and Severity. However, the least important of failures initially is maybe at a higher risk level over time. So, a pattern that shows dynamics of risk levels priority is necessary especially for very low and low-risk failures, which can be attained through Markov chains. These chains can suggest tracing and predicting the pattern of constantly changing processes. For example, now when we are in the initial months of the pandemic, some failures like the display screen of the ventilator or the slip rings of CT scan are in very low and low-risk levels, but when the times they are disinfected become more and more, it is the probability that their risk levels increase. It is obvious that as the COVID-19 continues and the infected patients increase, the risk levels of the failures which are not that important today are changing. So, if the changes in risk levels are not considered, sudden serious failures are probable to lead to death on severe injuries to patients or either device operators. But using the Markov chains, the risk level scores can be calculated more accurately.

Also, there are some factors when decision-makers try to use FMEA such as Occurrence, Detection, and Severity. In this study, we defined some sub-factors for each of them when some of them imply the general situation, and some of them are especially related to the pandemic situation.

Based on Table 16, visibility of failure occurrence has the most weight, and also mean time between failures in the general situation has the least weight between the sub-factors of occurrence based on the expert opinion. It means that when a failure occurred it is more critical to be visible for operators to react through its repairing or avoiding more hurt. However, based on Table 17, the method of failure detection has the most weight, and also detection accuracy has the least weight between the sub-factors of detection based on the expert opinion. It means that detecting the failure is very hard in most cases and is the most important sub-factors. Usually, if a failure can be detected it is accurate based on expert opinion and historical data. So, the detection accuracy is the least important sub-factor.

Finally, as Table 18 shows in severity factor, mean time to repair is the most important sub-factor where the patient general safety is the least important one. it can be concluded that most of the time when a medical device faces failure, it doesn't hurt the patients by itself directly, but the time last for repairing cause to more danger for patients need that device.

Based on Table 19, most of the failures categorized in very low and low-risk levels (12 /17) are the general failures related to all medical devices except Digital X-ray machines and ECG. For the medium, high, and very high category the pandemic-related failures are more than general ones. It shows that the expert and operators of these medical devices are aware of the pandemic-related failures and notice them as more important than general ones. Figure 3 shows the general and pandemic-related failures in each of the five risk categories.

6. Managerial implication

In this section, we try to extract several managerial insights based on the results of the study as follow:

1. This paper proposed an integrated Markovian WFMEA model for risk evaluation for medical devices used for positive COVID-19 patients in hospitals. It can provide an

appropriate perspective to hospital medical device managers for preventive maintenance plans based on the results obtained.

2. Figure 2 showed that there are several sub-factors defined for the occurrence risk factor (Visibility, mean time between failures in the normal situation, mean time between failures in a pandemic, repeatability in the normal situation, repeatability in pandemic) had the highly desirable relationship with occurrence (factor loads were more than 0.6). In addition, the sub-factors of detection risk factors (probability of non-detection, detection Method, detection costs, detection speed, detection accuracy) also had a highly desirable relationship with detection (factor loads were more than 0.6). Finally, for the severity risk factor, the defined sub-factors were patient general safety, patient safety from Infection risk, the potential risks in the normal situation, the potential risks in a pandemic situation, repair meantime, economic loss. All of them had highly desirable relationships except patient safety from Infection risk which had an acceptable relationship (factor load of between 0.3 and 0.6). So, the medical device managers could consider the sub-factors for more accurate risk evaluation and not only the three main risk factors.
3. Based on Table 16, the most important sub-factor of occurrence risk factor was visibility (optimal weight: 0.3148588), and the least important was a mean time between failures in the normal situation (optimal weight: 0.09515465). Based on Table 17, the most important sub-factor of detection risk factor was the detection method (optimal weight: 0.3460532) and the least important was detection accuracy (optimal weight: 0.08667522). Based on Table 18, the most important sub-factor of severity risk factor was repaired meantime (optimal weight: 0.3187820) and the least important was patient general safety (optimal weight: 0.09662019). The managers should be certain about the more important sub-factors and then decide for their maintenance plans considering their prioritizations for higher risk management levels.
4. The failures with medium, high, and very high-risk levels are important to be considered, too. Based on Table 19, 23 failures of all 40 failures had a high or very high score which is more than half of the failures. Managers should focus on them seriously since they can hurt patients directly.
5. When medium, high, and very high-risk levels failures are very important for a hospital, it is necessary to predict the risk levels of very low and low-risk levels in the future, too. Among 17 failures with very low and low-risk levels, 13 of them transfer to medium risk

levels based on Table 24. Managers should plan for preventive maintenance schedules, especially for these failures.

7. Conclusion and Future studies

This study tried to consider different devices related to COVID-19 patient failures and assess their risks as one of the important issues affecting hospital costs and more important patient safety. Therefore, risk assessment, especially for expensive equipment, can be important for hospitals. Also, due to the pandemic and high volume of COVID-19 patients, a device failure may result in death or severe injury to a patient. In this regard, we used weighted FMEA by describing more sub-factors and weighted the using Fuzzy DEMATEL and FBWM. Markov chain is also used for considering long-term impacts and reprioritize devices for facing the risk in the future. Considering a hospital serves the COVID-19 patients in Iran as a case study, the proposed approach was executed and results showed that near half of the device failures are scored medium risk level or more. Although the remained half is very low and low level, there are some probabilities for each of them during the time as the pandemic situation is going worse. So, based on the reprioritization correction factor based on the Markov transition matrix, most of these very low and low-risk failures may lead to a medium level, and planning for avoiding the serious problem is necessary. The limitations of the model proposed in this study are i) other hospitals should assess their medical devices risks and cannot use the same results of this study, ii) calculating the risk levels needs questionnaire and the expert and this is not an intelligence-based model. So, future researches can combine the Markov transition matrix with artificial intelligence methods and proposed a prediction artificial intelligence approach to investigate the device risks and comparing the results with the current study. Also, researchers can consider risk assessment for other medical devices for different patient categories, and also other risk assessment tools can be investigated.

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Tables captions

Figures captions

Tables

Table 9

Paper	Method	Markov chain	Pandemic situation
Onofrio et al. (2015) [14]	FMEA	×	×
Jamshidia et al. (2015) [15]	new FFMEA with more criteria definition	×	×
Kirkire et al., (2015) [16]	Traditional and Fuzzy FMEA	×	×
Cicotti and Coronato (2015) [17]	Event Sequence Diagram (ESD)	✓	×
Vazdani et al., (2017) [19]	FMEA	×	×
Wei Lo and Liou (2018) [20]	Gray BWM based FMEA	×	×
Brun and Savio (2018) [6]	Weighted FMEA		×
Mangeli et al., (2019) [22]	FMEA and TOPSIS	×	×
Kim et al. (2020) [23]	Attack tree	×	×
Bhattacharjee and Mandal (2020) [30]	FMEA and Logistic regression model	×	×
Parand F.A et al. (2020) [25]	Ordered weighted averaging aggregation operator	×	×
Fabiola and Sergio (2021) [31]	FMEA	×	×
This study	Weighted FMEA with more criteria definition using integrated DEMATEL and FBWM methods	✓	✓

Table 10

Linguistic terms	Linguistic values	Triangular fuzzy numbers
No influence (No)	(1, 1, 1)	$\tilde{1}$
Very low influence (VL)	(2, 3, 4)	$\tilde{3}$
Low influence (L)	(4, 5, 6)	$\tilde{5}$
High influence (H)	(6, 7,8)	$\tilde{7}$
Very high influence (VH)	(8, 9,9)	$\tilde{9}$

Table 11

Linguistic terms	Membership function
Equally important (EI)	(1, 1, 1)

Weakly important (WI)	(0.667, 1, 1.5)
Fairly important (FI)	(1.5, 2, 2.5)
Very important (VI)	(2.5, 3, 3.5)
Absolutely important (AI)	(3.5, 4, 4.5)

Table 12

	(EI)	(WI)	(FI)	(VI)	(AI)
$\tilde{a}_{BW}$	(1, 1, 1)	(0.667, 1, 1.5)	(1.5, 2, 2.5)	(2.5, 3, 3.5)	(3.5, 4, 4.5)
CI	3.00	3.80	5.29	6.69	8.04

Table 13

O1	O2	O3	O4	O5	Level	Number
Visibility	Mean time between failures in normal situation	Mean time between failures in pandemic	Repeatability in normal situation	Repeatability in pandemic		
Not visible at all	<1months	<3 days	Same failures in 1 months	Same failures in 3 days	Very high (VH)	5
Visible while using the device	1-6 months	<3-6 days	Same failures in 1-6 months	Same failures in 3-6 days	High (H)	4
Visible between two inspection intervals	6 months to 1 year	A week to a month	Same failures in 6 months to 1 year	Same failures in a week- a month	Moderate (M)	3
Visible while inspecting	1 year -2 years	1-2 months	Same failures in 1-2 years	Same failures 1-2 months	Low (L)	2
Visible before an inspection	>2 years	>2 months	Failure is unlikely >2 years	Failure is unlikely >2 months	Remote (R)	1

Table 14

D1	D2	D3	D4	D5	Level	Number
Probability of non-detection	Detection method	Detection costs	Detection Speed	Detection accuracy		
Low or No Detectability	No failure detection method.	750-1000 $	5-10 working days	<20%	Very high (VH)	5
Fair detectability	No failure detection method but the failure can fairly detected without method.	500-750 $	3-5 working days	20%-40%	High (H)	4
Likely to Detect	The failure detection method usually is used.	200–500 $	1-3 working days	40%-60%	Moderate (M)	3
Good degree of Detectability	There is a not-automated failure detection method.	100–200 $	1h to 1 working days	60%-80%	Low (L)	2
High degree of Detectability	There is an automatic failure detection method.	0–100 $	Less than 1 h	80%- 100%	Remote (R)	1

Table 15

S1 and S2	S3 and S4	S5	S6	Level	Number
Patient general Safety	Potential risk for the device operator	Mean time to repair	Economic loss		
Death	Serious Infected	Order a new device	≥ 60 % of the device price	Very high (VH)	5
Severe injury	Infected	Several days for repair	$30\% \leq S6 < 50\%$ of the device price	High (H)	4
Moderate injury	Moderate infected	1 day- 4 days	$20\% \leq S6 < 30\%$ of the device price	Moderate (M)	3
Minor injury	Minor infected	1h-1 day	$10\% \leq S6 < 20\%$ of the device price	Low (L)	2
Less or no effect	No infection	< 1h	$0 \leq S6 < 10\%$ of the device price	Remote (R)	1

Table 16

Hidden Variable	Obvious Variable	Factor Load
Occurrence	O1	0.847
	O2	0.897
	O3	0.932
	O4	0.959
	O5	0.883
Detection	D1	0.960
	D2	0.861
	D3	0.623
	D4	0.879
	D5	0.960
Severity	S1	0.741
	S2	0.593
	S3	0.690
	S4	0.893
	S5	0.889
	S6	0.849

Table 9

Hidden variable	**Cronbach's alpha coefficients** $\boldsymbol{\alpha \geq 0.7}$	**Combined reliability coefficient** $\boldsymbol{\alpha \geq 0.7}$	**Mean extraction variance** $\boldsymbol{AVE \geq 0.5}$
Occurrence	0.946	0.957	0.818
Detection	0.910	0.936	0.749
Severity	0.873	0.903	0.614

Table 10

Hidden Variable	Obvious Variable	T_0
Occurrence	O1	31.048
	O2	43.277
	O3	60.075
	O4	133.903
	O5	70.342
Detection	D1	158.604
	D2	30.476
	D3	12.550
	D4	53.984
	D5	161.461
Severity	S1	17.241
	S2	9.562
	S3	14.570
	S4	83.124
	S5	69.420
	S6	41.141

Table 11

Hidden Variable	**R2 Value**
Occurrence	0.655
Detection	0.425
Severity	0.898

Table 12

Hidden Variable	Path coefficient	T_0	Result
Occurrence	0.652	27.043	Acceptance
Detection	0.809	42.056	Acceptance
Severity	0.948	196.148	Acceptance

Table 13

Criteria	**D+R**	**The best**	**The worst**
O1	2.866	O1	O2
O2	2.210		
O3	2.571		
O4	2.797		
O5	2.661		

Table 14

Criteria	**D+R**	**The best**	**The worst**
D1	7.874	D2	D5
D2	9.127		
D3	7.093		
D4	8.169		
D5	6.99		

Table 15

Criteria	**D+R**	**The best**	**The worst**
S1	2.522	S5	S1
S2	2.695		
S3	2.5651		

S4	3.828		
S5	6.571		
S6	4.780		

Table 16

Criteria	O1	O2	O3	O4	O5
Optimal weights	0.3148588	0.09515465	0.2917890	0.1441147	0.1540829

ξ^*=0.50000 CI=6.69 → CR=$\frac{0.50000}{6.69} = 0.0747$

Table 17

Criteria	D1	D2	D3	D4	D5
Optimal weights	0.2292430	0.3460532	0.2265062	0.1115224	0.08667522

ξ^*=0.3594849 CI=8.04 → CR=$\frac{0.3594849}{8.04} = 0.0447$

Table 18

Criteria	S1	S2	S3	S4	S5	S6
Optimal weights	0.09662019	0.1029543	0.2250613	0.1232335	0.3187820	0.1333488

ξ^*=0.7948322 CI=8.04 → CR=$\frac{0.7948322}{8.04} = 0.0988$

Table 19

Failure No	Occurrence					Detection					Severity						WRPN	Category
	O1	O2	O3	O4	O5	D1	D2	D3	D4	D5	S1	S2	S3	S4	S5	S6		
Weights	0.314	0.095	0.291	0.144	0.154	0.229	0.346	0.226	0.111	0.866	0.096	0.102	0.225	0.123	0.318	0.133		
1-1	2	2	3	2	4	4	2	3	4	2	1	1	1	3	3	3	16.2	High
1-2	3	2	3	3	4	2	3	2	2	2	2	2	1	4	3	3	17.7	High
1-3	1	3	5	3	4	3	1	1	1	1	1	2	1	4	2	2	12.9	Medium
1-4	2	3	3	4	3	2	3	1	2	1	1	1	1	3	2	1	15.6	High
2-1	1	2	1	2	2	1	2	2	2	1	2	2	1	3	2	3	4.7	Very Low
2-2	4	4	4	4	1	2	2	1	2	2	1	1	1	1	2	1	8.2	Low
2-3	1	2	1	3	4	3	2	2	2	1	1	1	1	1	2	2	5.7	Low
2-4	1	3	2	5	1	4	4	2	3	3	1	1	1	2	3	1	13.8	Medium
3-1	2	1	2	1	2	2	3	1	3	3	5	5	1	3	3	4	12.5	Medium
3-2	2	3	2	3	5	5	5	1	1	1	3	1	1	4	1	1	13.9	Medium
3-3	1	2	1	2	1	2	2	1	1	1	1	1	1	2	2	1	3.3	Very Low
3-4	1	2	1	2	2	4	5	3	3	3	4	3	1	3	3	4	17.6	High
4-1	3	1	3	1	4	3	3	1	2	2	2	1	1	2	2	1	9.6	Low
4-2	4	1	3	1	5	3	2	1	1	1	1	1	2	2	1	1	7.6	Low
4-3	4	4	4	5	5	4	3	1	1	2	4	1	1	3	2	2	21.0	Very High
4-4	2	3	2	3	2	3	3	1	1	1	1	1	1	3	2	2	13.8	Medium
5-1	1	1	1	1	5	4	4	3	3	3	1	1	1	2	2	3	9.8	Low
5-2	2	2	1	2	1	3	3	1	1	2	1	1	1	3	4	3	8.5	Low
5-3	2	3	2	3	2	2	4	2	2	1	1	1	1	3	2	2	19.7	High
5-4	1	1	1	1	2	5	3	3	3	3	1	1	1	3	4	3	11.5	Medium
6-1	1	1	1	1	4	1	1	1	2	1	3	1	1	2	2	2	2.8	Very Low
6-2	1	1	1	1	4	2	2	1	2	2	5	1	1	2	2	1	4.7	Very Low
6-3	2	2	1	2	4	3	3	1	2	1	1	1	1	2	2	3	7.7	Low

6-4	1	2	1	3	4	4	2	2	1	1	1	1	1	2	2	2	6.5	Low
7-1	2	1	2	1	4	4	3	2	2	2	3	1	1	2	5	5	18.1	High
7-2	3	2	2	2	1	3	2	1	1	1	1	1	1	2	5	5	11.4	Medium
7-3	4	3	4	3	4	3	2	1	2	1	1	1	1	2	2	2	16.2	High
7-4	3	3	3	4	4	4	2	3	1	1	1	1	1	2	5	2	20.7	Very High
8-1	2	1	1	1	3	1	1	3	2	1	1	1	1	1	4	3	5.6	Low
8-2	1	1	1	1	1	1	1	2	2	1	1	1	1	3	2	2	2.2	Very Low
8-3	2	4	2	4	5	2	1	3	4	3	1	1	1	3	3	2	12.9	Medium
8-4	1	2	1	2	4	2	2	2	2	2	1	1	1	4	4	4	13.6	Medium
9-1	2	1	3	3	5	4	4	3	3	4	1	1	1	4	3	2	21.9	Very high
9-2	1	1	2	1	4	4	3	3	2	1	1	1	1	3	2	3	9.4	Low
9-3	2	2	2	4	4	2	2	2	2	1	1	1	1	3	2	3	17.3	High
9-4	1	3	2	2	4	2	2	2	2	1	1	1	1	3	2	3	14	Medium
10-1	3	3	2	4	4	1	1	3	2	1	1	1	1	3	3	4	10.7	Medium
10-2	1	1	1	2	3	1	1	2	1	1	1	1	1	3	1	2	2.4	Very Low
10-3	1	5	1	4	5	5	5	3	3	4	1	1	1	3	2	3	18.8	High
10-4	2	2	1	3	4	1	1	1	1	1	1	1	1	3	2	2	9.2	Low

Table 20

WRPN	Category
0<WRPN< 5	Very low risk
5<WRPN< 10	Low risk
10<WRPN< 15	Medium risk
15<WRPN< 20	High risk
WRPN> 20	Very high risk

Table 21

Failure	The probability at steady-sate					Total
	Very low	Low	Medium	High	Very high	
2-1	0.004	0.002	0.004	0.02	0.97	1
2-2	0.002	0.001	0.037	0.24	0.72	1
2-3	0	0.006	0.014	0.16	0.82	1
3-3	0.005	0.005	0.005	0.015	0.97	1
4-1	0.014	0.023	0.074	0.22	0.669	1
4-2	0	0.02	0.33	0.15	0.5	1
5-1	0	0.031	0.013	0.09	0.866	1
5-2	0	0.01	0.17	0.12	0.7	1
6-1	0.006	0.024	0.03	0.22	0.72	1
6-2	0	0.04	0.08	0.06	0.82	1
6-3	0	0.005	0.005	0.05	0.94	1
6-4	0	0	0.01	0.24	0.75	1
8-1	0	0.07	0.13	0.25	0.55	1
8-2	0	0.01	0.03	0.1	0.86	1
9-2	0	0	0.08	0.08	0.84	1
10-2	0	0.005	0.015	0.16	0.82	1
10-4	0.002	0.003	0.005	0.05	0.94	1

Table 22

Failure	$P_{h,Vh}$
2-1	0.99
2-2	0.96
2-3	0.98
3-3	0.985

4-1	0.88
4-2	0.65
5-1	0.95
5-2	0.82
6-1	0.94
6-2	0.88
6-3	0.99
6-4	0.99
8-1	0.8
8-2	0.96
9-2	0.92
10-2	0.98
10-4	0.99

Table 23

$P_{h,Vh}$	RCF
$P_{h,Vh} < 0.30$	1
$0.31 < P_{h,Vh} < 0.45$	1.5
$0.46 < P_{h,Vh} < 0.60$	2
$0.61 < P_{h,Vh} < 0.85$	2.5
$P_{h,Vh} > 0.86$	3

Table 24

Failure	WRPN	Risk level	RCF	Updated WRPN	Updated risk level
2-1	4.7	Very low	3	14.1	Medium
2-2	8.2	Low	3	24.6	Medium
2-3	5.7	Low	3	17.1	Medium
3-3	3.3	Very low	3	9.9	Low
4-1	9.6	Low	3	28.8	Medium
4-2	7.6	Low	2.5	19	Medium
5-1	9.8	Low	3	29.4	Medium
5-2	8.5	Low	2.5	21.25	Medium
6-1	2.8	Very low	3	8.4	Low
6-2	4.7	Very low	3	14.1	Medium
6-3	7.7	Low	3	23.1	Medium
6-4	6.5	Low	3	19.5	Medium
8-1	5.6	Low	2.5	14	Medium
8-2	2.2	Very low	3	6.6	Low
9-2	9.4	Low	3	28.2	Medium
10-2	2.4	Very low	3	7.2	Low
10-4	9.2	Low	3	27.6	Medium

Figures

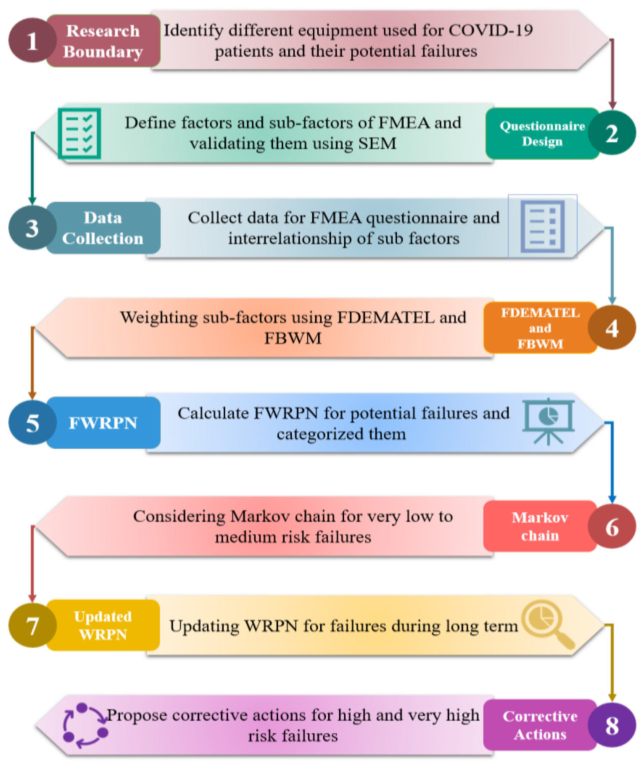

Figure 3

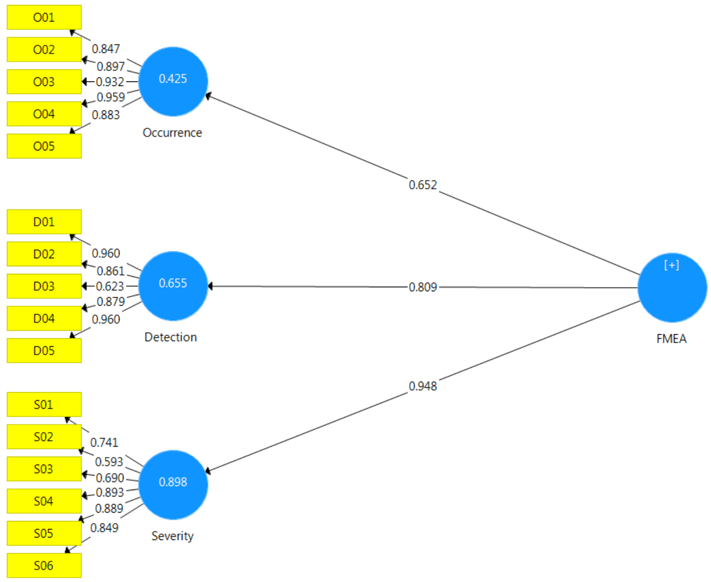

Figure 4

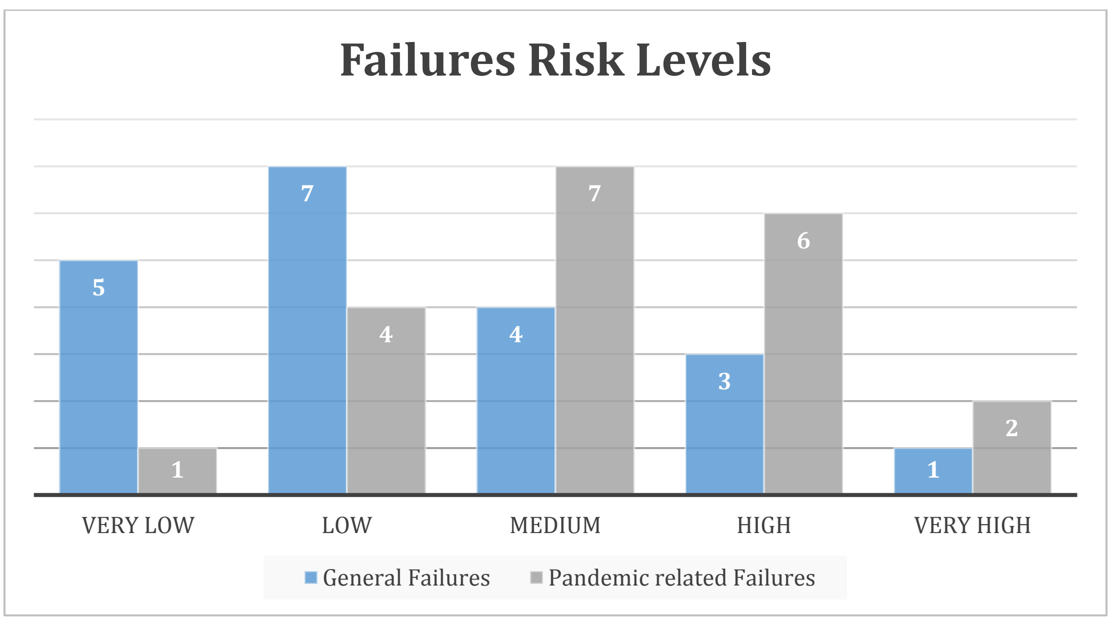

Figure 3