Original Research Article

Human cause reliability evaluation and application of medical devices based on the improved FMEA method——Take the color ultrasound instrument as an example

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Abstract: To improve the safety and reliability of medical devices in use, This paper combines the human factor reliability evaluation method based on SHELL model and an improved FMEA method based on fuzzy set and ordered weighted geometric average operator (OWGA), The improved method in this paper is compared to the traditional method, Solve the problem of relying on expert experience and consistent risk factor weights in traditional methods, And introduced the scenario parameter α that can represent the attitude in the risk ranking, Built a human cause reliability assessment model with FMEA as the core, Taking the color Doppler ultrasound instrument in a hospital as an example, To ify the validity and reliability of the method in this paper, Provide targeted risk control measures for hospitals or device companies, Raise the risk awareness, Convenient for doctors and patients while reducing the occurrence of adverse events.

Keywords: Improve the FMEA method; Medical equipment; Orderly weighted geometric average; Fuzzy set theory; SHELL model

1. Introduction

Failure mode and Effect analysis (failure mode andeffect analysis, FMEA) is a tool to identify the cause and mode of possible failure of the product in advance, and adopt the corresponding scheme to eliminate risks. This method can find the possible faults before the accident and correct the potential dangers, so as to achieve the purpose of reliability analysis and safety assessment. FMEA was first used in the early 1950s in the early 1950s, and in the 1960s, it continued to be used in space development, and has since been widely used in the automotive, medical equipment and other industries.

With the vigorous development of modern medical technology, the application of medical devices is gradually increasing. Meanwhile, the reliability of medical devices is particularly important. In recent years, hospitals have gradually paid more attention to the after-sales service of medical devices, which also encourages enterprises to continue to pay attention to the after-sales service satisfaction after the sale of the devices. However, the operators in the hospital departments do not understand the failure mode and effect analysis of the medical devices, leading to many unnecessary adverse events[1]. Therefore, the analysis of the failure mode and effect analysis of medical equipment can not only significantly improve the reliability of medical equipment, but also reduce the occurrence of adverse events, Nowadays, the use of various medical devices in each department has no clear definition, there will be the operator for the device use or attention is not clear, so in medical device adverse events, human factors caused by extremely high, so, in the analysis of medical device adverse events, through the human reliability evaluation perspective is an integral part[2]. Human factor reliability assessment is a technique that analyzes the impact on the device from the perspective of human operation error, which can be aware of the potential human error and its cause before human error occurs; At the same time, it can shorten the distance between the operator and the engineer, making the corresponding fault solution more convenient.

From the above knowledge, The importance and necessity of the application of the FMEA to the medical device industry, While the traditional FMEA, The calculation method is to score ten grades of the three risk factors of the product (from 1 to 10), That is the severity of the fault (Severity, S), frequency of failure (Occurrence, O) and the fault detection rate (Detection, D), Risk priority number is calculated after obtaining three points (Risk Priority Number, RPN), That is, RPN = S * O * D, After ranking from risk priority to large to small, Identify the key fault modes, And improve the reliability of the equipment according to the corresponding improvement method. It can be seen that the traditional FMEA has the following problems: it can be seen that the three risk factors of S, O and D require expert scoring, while the inconsistent background, professionalism and judgment criteria cause the experts can not rate the risk factors accurately; secondly, in the calculation of RPN, S, O and D have equal weights by default and fail to assign each risk factor, so the ranking of RPN cannot accurately express the reliability degree.

In order to solve the above problems, Wang Liren and Liu Hushen[3]The application of fuzzy set and COPRAS improves the limitation of RPN sorting in traditional method; Liu[4]Add fuzzy mathematics and grey correlation theory in the traditional FMEA method, it can achieve qualitative analysis and quantitative prediction in the fault model evaluation, and get the corresponding improvement measures[5]In the traditional FMEA method, fuzzy set theory and gray correlation theory are combined. And C agliano et al[6]Based on the theoretical basis of Reason and combined with the risk of FMEA, the human factor reliability evaluation index of medical device was obtained. Zhen class[7]On the basis of human factor reliability theory, VIKOR is used to determine the risk priority order of fault mode.

To overcome the above defects, this paper proposes an improved FMEA method based on fuzzy set theory and OWGA operator[8]. This method quantifies the evaluation information of risk factors through fuzzy set theory and sorts the possible failure modes in the product by OWGA operator. At the same time, the human factor reliability evaluation is applied to the improved FMEA method, and the method is demonstrated on a medical device to obtain the reliability and feasibility of the human factor evaluation method for medical device reliability evaluation

2. The FMEA method based on the fuzzy set theory and the OWGA operator

From the previous above, When using the FMEA method, Potential failure mode, causes and available detection methods, After that, the experts will score and evaluate from the three dimensions of S, O and D, As the experts score, How to reduce the subjectivity and quantitative evaluation in the process of expert scoring, In this paper, the evaluation terms of the three dimensions are regarded as fuzzy language variables, Based on the background knowledge and work experience of the experts, Complete and refine the fuzzy set of language terms for the three variables, Determine the fuzzy number, Then, after determining the weights by using the OWGA operator, To derive the corresponding risk priority, Determine the key faults, And follow the specified steps to solve the fault possibility, The reliability, stability and safety of the product are greatly improved.

2.1. Introduction of the fuzzy-set theory

2.1.1. Establish a fuzzy language term set

The characteristic of fuzzy set theory lies in the ability to quantify the subjective identification, qualitative and uncertain information of experts. There are many ways of quantification. The fuzzy language terms in this paper use the commonly used triangular fuzzy number for quantification processing. The triangular blur number is expressed as A= (a, b, c), and its membership function is expressed as:

$$\mu_A(x)=\begin{cases}0, x\leqslant a;\\ \dfrac{x-a}{b-a}, a<x\leqslant b;\\ \dfrac{c-x}{c-b}, b<x\leqslant c;\\ 0, x>c.\end{cases} \tag{1}$$

Where a, b and c indicate negative values, possible values and the most optimistic values.

At the same time, in the medical industry, medical experts and engineers usually use “low” and “very high” to express the corresponding grade. In order to make the evaluation results of experts more standard and unified, this paper establishes a fuzzy set of risk factors, as shown in Table 1.

Table 1. Set of fuzzy language terms.

Language terminology	severity (S)	incidence (O)	Difficult measure (D)
Very low (VL)	The probability of the system is extremely high	Very low incidence	Very low failure difficulty detection rate
low (L)	The probability of normal operation of the system is relatively high	Lower incidence rate	Low failure difficulty detection rate
secondary (M)	The system occasionally works normally	Occasional incidence	Occasionally detected fault difficult detection rate
tall (H)	The probability of the system is low	A higher incidence rate	High failure difficulty detection rate
very high (VH)	The probability of normal operation of the system is very low, which may endanger the safety of patients	An extremely high incidence rate	Very high failure difficulty detection rate

2.1.2. Deblur

In order to achieve more intuitive analysis and evaluation information, the above triangular fuzzy number needs to be deblurred. This paper combines the characteristics of the medical industry and its simplicity and practicality, and the weighted average method is used to remove the blur. The specific formula is as follows:

$$F_j=\frac{(c_j-a_j)+(b_j-a_j)}{3}+a_j \tag{2}$$

2.1.3. Termination of expert weight

Due to the different background, technology and expertise of the experts in the FMEA team, the differences between the assessors will also cause the differences in the final failure mode risk of the experts. Therefore, the weight of the experts should be determined , which can be obtained after normalization. After determining the expert weight, the corresponding triangular blur number can be determined. For example, there are n experts, the ability of the th expert is β_i(Percentage), where the j th fuzzy evaluation term of a variable of the fault mode is $x_{ij}=(a_{ij}, b_{ij}, c_{ij})$, (i =1, 2, …, n; j =1,2,3,4,5) then the triangular number of this variable can be summarized by Equation (3) ~ (5):

$$a_j=\sum_{i=1}^{n}\boldsymbol{\beta}_i a_{ij} \tag{3}$$

$$b_j = \sum_{i=1}^{n} \boldsymbol{\beta}_i b_{ij} \tag{4}$$

$$c_j = \sum_{i=1}^{n} \boldsymbol{\beta}_i c_{ij} \tag{5}$$

among. $\sum_{i=1}^{n} \beta_i = 1, \beta_i \in (0,1)$

2.2. Introduction of the QWGA operator

The traditional FMEA method fails to consider the weight of the three risk factors of S, O and D, and also considers the situational parameters, so that the calculation of RPN cannot reflect the actual situation and makes the final evaluation biased. This paper introduces the OWGA operator, which not only overcomes the problem of equal weight of the three risk factors in the traditional method, but also adds the context parameter α to consider the attitude of the evaluator.

2.2.1. OWGA operators

$A = \{a_1, a_2, \ldots, a_n\}$ Definition: For a set of elements, the OWGA operator is:

$$f(a_1, a_2, \cdots, a_n) = \prod_{j=1}^{n} b_j^{\,w_j} \tag{6}$$

Where the element b j in the vector represents the element in the set ranked in position j by size. $\mathbf{B} = (b_1, b_2, \ldots, b_n)^{\mathrm{T}}$ $A = \{a_1, a_2, \ldots, a_n\}$

2.2.2. Determine the weight

To be able to determine the optimal weight in the case of maximum entropy, Fuller et al[9]The OW G A equation is derived as a polynomial equality using Lagrange multipliers. By their method, the weight vector is calculated according to equation (7) ~ (9):

$$\ln w_j = \frac{j-1}{n-1}\ln w_n + \frac{n-j}{n-1}\ln w_1 \Rightarrow w_j = \sqrt[n-1]{w_1^{n-j} w_n^{j-1}} \tag{7}$$

$$w_n = \frac{((n-1)\alpha - n)w_1 + 1}{(n-1)\alpha + 1 - nw_1} \tag{8}$$

$$w_1[(n-1)\alpha + 1 - nw_1]^n = [(n-1)\alpha]^{n-1} \cdot [((n-1)\alpha - n)w_1 + 1] \tag{9}$$

w_j Where: is the weight; n represents the number of attributes; is the context parameter. α

When the FMEA method obtains RPN, the OWGA operator is used, and the situational parameter α is introduced to reflect the optimism of the evaluator[8]. That is, α =1 is the case in optimal optimism; α =0 is the worst optimism; α =0.5 is the decision in moderate cases. Therefore, it can reflect the decision of the evaluator more truthfully and effectively.

3. Case analysis

Color doppler ultrasound diagnostic instrument is one of the essential hospital ultrasound and clinical department, it can be convenient, quick and no harm diagnosis or auxiliary diagnosis of a variety of diseases, but also in anesthesiology clinical department for patients do nerve block or targeted interventional surgery, has become the doctors' third eye. In order for doctors to be able to diagnose diseases for patients more clearly, the reliability of color Doppler ultrasound diagnostic instrument is particularly important. Therefore, this paper takes the color ultrasound instrument of a clinical department of a hospital as an example to analyze the failure mode of high-risk people to reduce the failure frequency of color ultrasound instrument.

3.1. Determine the analysis object

There are many images not clear in a hospital, which is one of the medical devices with more frequent accidents. Therefore, the color ultrasound instrument of the anesthesiology department of the hospital was determined as the research object of FMEA, and the fault mode of the person was studied.

3.2. Construct the FMEA group

Since three risk factors for failure are obtained based on expert experience in operation or maintenance, Therefore, the research objects are 1 professional manufacturer of color ultrasound instrument, 2 teachers of the hospital equipment department and 2 operators of the department, Form an expert panel, Capabilities β i of the members evaluated according to Table 2, Draw the expert weights (0.3, 0.25, 0.2, 0.1, 0.1) After that time, FMEA team members identify the fault mode, the impact of the fault mode, the possible causes and the three risk factors of S, O and D, Complete the corresponding FMEA and record the form.

3.3. Identify the human cause fault mode

Qualitative analysis of human cause reliability Through the study of human cause events, it identifies the external manifestations and internal error mechanism of human cause error, and finds out the factors leading to these events based on the analysis, so as to provide support for the quantitative analysis of human cause reliability. In the qualitative analysis of human cause reliability, SHELL model is widely used. The model analyzes human (center live ware) and software (L-Software), hardware (L-Hardware), environment (L-E nvironment), combined with the overall analysis. The medical device system based on SHELL model analyzes the factors based on the characteristics of medical device accidents.

3.4. Calculate the risk priority number

In order to complete the quantitative calculation of the fault mode risk of human cause error mode, three steps are mainly completed.

3.4.1. Establish fuzzy language number sets and fuzzy number collection

Based on the opinions of the experts of the FMEA team, establish and perfect the fuzzy language number, after the expert independent language term evaluation of each risk factor, according to the five fuzzy language terms formula (2) ~ (4) for each risk factor after the corresponding triangle fuzzy number, as shown, after the fuzzy number by formula (5), the results are shown in the Table 4**.**

Table 4. Number of triangular blur.

FMEA member	β	VL	L	M	H	VH
1	0.3	(0,1,2.6)	(1.8,3,4.8)	(3.8,5,7.4)	(6.7,8,8.8)	(8.3,9.5,10)
2	0.25	(0,1,2.4)	(1.6,3,4.7)	(3.9,5,7)	(6.6,8,8.7)	(8.4,9.6,10)
3	0.25	(0,1,2.5)	(1.5,3,4.7)	(4,5,6.8)	(6.6,8,8.5)	(8.5,9.6,10)
4	0.1	(0,1,2.1)	(1.7,3,4.6)	(4,5,6.9)	(6.5,8,8.8)	(8.6,9.7,10)
5	0.1	(0,1,2.3)	(1.5,3,4.5)	(3.9,5,7)	(6.6,8,8.9)	(8.7,9.5,10)
sum	1	(0,1,2.45)	(1.6,3,4.7)	(3.9,5,7)	(6.6,8,8.7)	(8.5,9.6,10)

Table 5. The clear number

Evaluation language	VL	L	M	H	VH
Clear number	1.1	3.1	5.3	7.8	9.3

3.4.2. Evaluation human fault mode

The FMEA team independently completed the evaluation of S, O, D for each fault mode, following the results of the previous step. The results are shown in Table 5**.**

Table 6. Results of the evaluation.

risk factor	**FM1**	**FM2**	**FM3**	**FM4**	**FM5**	**FM6**
S	8.0	7.9	8.5	6.5	2.5	3.8
O	6.2	3.8	2.6	3.1	3.0	6.2
D	1.6	0.9	8.7	0.2	2.2	0.7

risk factor	**FM7**	**FM8**	**FM9**	**FM10**	**FM11**	**FM12**	**FM13**
S	3.1	8.2	7.4	4.3	6.8	1.8	1.3
O	5.4	3.6	2.5	6.1	6.0	2.3	2.3
D	3.2	5.5	0.3	0.2	1.5	3.5	0.6

3.4.3. Calculate the risk priority number

Based on the modification method proposed in this paper, the weights of the three risk factors S, O and D are calculated using Equation (8) ~ (10), and the RPN values of the three factors are aggregated using Equation (6). For example, assume α =0.6, derived from Equation (9):

$\omega_1 \times (2 \times 0.6 + 1 - 3 \times \omega_1)^3 = [(2 \times 0.6)^2 \times (2 \times 0.6 - 3) \times \omega_1 + 1]$, Then. $\omega_1 = 0.4384$

Get by formula (8)

$$w_3 = \frac{((3-1) \times 0.6 - 3)w_1 + 1}{(3-1) \times 3 + 1 - 3 \times w_1} = 0.3232。$$

Then use the formula (7) to get

$$w_2 = \sqrt[3-1]{w_1^{3-2} w_3^{2-1}} = \sqrt{w_1 w_3} = 0.2384。$$

Finally, based on Equation (6), the aggregate value f under the OWGA weight is available. For example, according to the table, the S, O and D values of FM1 are 8.0,6.2 and 1.6, while when α =0.6, the weight is finally available ω = [0.4384, 0.2384, 0.3232] ,

$$f(8.0,6.2,1.6) = 8.0^{0.4384} \times 6.2^{0.2384} \times 1.6^{0.3232} = 4.47$$

Therefore, according to formula (7) to (9), the weights under different scenario parameters, as shown in Table 6 and the aggregate values under different α can be obtained according to the above calculation steps as shown in Table 7.

Table 7. The best weight vectors for the different scenario parameters.

α	**ω_1**	**ω_2**	**ω_3**
0.5	0.3333	0.3333	0.3333
0.6	0.4384	0.3232	0.2384
0.7	0.554	0.292	0.154
0.8	0.6819	0.2358	0.082
0.9	0.8263	0.147	0.026
1	1	0	0

Table 8. The aggregate values under the OWGA weights.

fault-pattern	α=0.5	α=0.6	α=0.7	α=0.8	α=0.9	α=1
FM1	4.24	4.97	5.75	6.57	7.36	8
FM2	2.94	3.67	4.53	5.53	6.69	7.9
FM3	5.76	6.46	7.17	7.83	8.39	8.7
FM4	1.58	2.21	3.04	4.06	5.27	6.45
FM5	2.55	2.63	2.71	2.80	2.89	3
FM6	2.47	3.07	3.80	4.59	5.43	6.2
FM7	3.72	3.94	4.26	4.56	4.92	5.4
FM8	5.44	5.91	6.43	6.97	7.56	8.2
FM9	1.77	2.42	3.28	4.38	5.76	7.35
FM10	1.73	2.40	3.25	4.24	5.29	6.1
FM11	3.93	4.54	5.18	5.82	6.40	6.8
FM12	2.44	2.61	2.79	3.00	3.23	3.5
FM13	1.16	1.33	1.56	1.79	2.04	2.3

3.5. Risk prioritization and improvement

The failure modes are ranked from high to low based on the risk priority number (RPN) calculation. A higher RPN value indicates a greater potential risk for this failure mode. In this article, all failure modes can be sorted, and the specific results are detailed in Table 8**.** The results of the traditional FMEA method and this method are listed in the table. It can be seen that when considering the order weighting, the traditional ranking results are the same as this method at α =0.5. Therefore, different evaluators can analyze the corresponding failure mode under different situational parameters, and obtain the high-risk failure mode after RPN sorting. Based on the results, medical device companies and hospital departments can take corrective measures to develop more perfect and targeted methods to reduce the failure rate and eliminate patient pain.

Table 9. Final ordering.

fault-pattern	Traditional RPN ranking	α=0.5	α=0.6	α=0.7	α=0.8	α=0.9	α=1
FM1	3	3	3	3	3	3	3
FM2	6	6	6	5	5	4	4
FM3	1	1	1	1	1	1	1
FM4	12	12	12	10	10	9	7
FM5	7	7	8	12	12	12	12
FM6	8	8	7	7	6	7	8
FM7	5	5	5	6	7	10	10
FM8	2	2	2	2	2	2	2
FM9	10	10	10	8	8	6	5
FM10	11	11	11	9	9	8	9
FM11	4	4	4	4	4	5	6
FM12	9	9	9	11	11	11	11
FM13	13	13	13	13	13	13	13

4. Conclusions

Due to the irrationality of the traditional FMEA algorithm, this paper proposes the improvement method based on fuzzy set theory and OWGA weighting, and based on the failure mode and effect analysis of the color ultrasound instrument in the hospital anesthesiology department, it can be concluded that compared with the traditional FMEA method, this method has the following advantages:

a) Apply fuzzy set theory, establish fuzzy set term set based on expert experience, use Delphi method to collect the scores of experts for each risk factor, complete deblur, optimize the accuracy of evaluation results and improve the reliability of evaluation;

b) Introduce OWGA operator for weight analysis, considering the orderly weighting of three risk factors, to some extent solving the problem of traditional methods not considering the weight of risk factors, making the ranking of RPN more objective;

c) The introduction of situational parameters, so that different evaluators can analyze in different situations, so that the evaluators can get the optimal ranking and develop the optimal solution, so as to reduce the occurrence of medical accidents.

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References

[1] Shi Dongmei & Ma Xiaoyan Analysis of related factors of causing adverse medical events 3,269+272, doi:10.16281/j.cnki.jocml.2016.02.053 (2016).

[2] Cooper, S.E., Brown, W.S.& Wreathall, J.A Human Reliability-Centered Approach to the Development of Job Aids for Reviewers of Medical Devices That Use Radiological Byproduct Materials.probabilitstic Safety Assessment and Manage-men (2006).

[3] Based on fuzzy set and COPRAS 31,69-78 (2017).

[4] Liu Oo, Wang Zhu & Li Ping Comparcomparative improvement of medical equipment and application of industrial engineering and management 16,133-138,doi:10.19495/j.cnki.1007-5429.2011.06.026 (2011).

[5] FMEA method of door-peak fuzzy set theory and grey correlation theory, 109-112 + 117 (2008).