

An improved approach for failure mode and effect analysis involving large group of experts: An application to the healthcare field

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Abstract

Failure mode and effect analysis (FMEA) is a team-based technique for prospectively identifying and prioritizing failure modes of products, processes and services. Given its simplicity and visibility, FMEA has been widely used in different industries for quality and reliability planning. However, various shortcomings are inherent to the traditional FMEA method, particularly in assessing failure modes, weighting risk factors and ranking failure modes, which greatly reduce the accuracy of FMEA. Additionally, the classical FMEA focuses on the risk analysis problems in which a small number of experts participate. Nowadays, with the increasing complexity of products and processes, an FMEA may require the participation of larger number of experts from distributed departments or organizations. Therefore, in this article, we present a novel risk priority approach using cluster analysis and prospect theory for FMEA when involving a large group of experts. Furthermore, an entropy-based method is proposed to derive the weights of risk factors objectively by utilizing the risk evaluation information. Finally, we take an empirical healthcare risk analysis case to illustrate the proposed large group FMEA (LGFMEA) approach, and conduct a comparative study to evaluate its validity and practicability.

Keywords: Reliability Management; Failure mode and effect analysis (FMEA); Prospect theory; Cluster analysis; Healthcare risk assessment.

Introduction

Failure mode and effect analysis (FMEA) is a systematic reliability analytical technique to identify, analyze and reduce the failures of products, processes, and services (Stamatis 2003). It provides a group-oriented, structured, and stepwise tool to quantify the effects of potential failure modes, allowing a company to set priorities for risk-management activities. Since its

development in the 1960s in the aerospace industry, the FMEA technique has been rapidly adopted by the automotive industry and many other industries (Kim and Zuo 2018; Liu 2016). Compared with other reliability management tools, FMEA can prospectively examine a high-risk process and identify vulnerabilities to generate corrective measures to help improve reliability (Liu et al. 2016b; Peeters et al. 2018). Hence, a great deal of expenses, resources and time can be saved by analyzing fault scenarios before they have occurred and preventing the occurrence of causes or mechanisms of failures. Nowadays, FMEA has become an important tool in Lean/Six Sigma and concurrent engineering, and has been used not only in manufacturing systems (Certa et al. 2017a; Zhou et al. 2016), but also in healthcare risk assessment (Faiella et al. 2018; Liu et al. 2017a), maritime transport (Akyuz et al. 2016), food processing (Selim et al. 2016), photovoltaic systems maintenance (Villarini et al. 2017), etc..

In traditional FMEA, importance of each failure mode is ranked based on the risk priority number (RPN), which is derived by the product of three risk factors: occurrence (O), severity (S), and detection (D). Based on pre-established criteria, a ten-scale measurement is often employed to evaluate each of the three risk factors, ten being the number indicating the most severe, most frequent and least detectable failure mode, respectively. After computing RPNs, the failure modes are analyzed using a Pareto distribution. The failure modes with higher RPNs could be viewed as more important and should be given the top priority for risk mitigation. All the identified failure modes are collected on a standard table of FMEA, and recommended actions are suggested for the anomalous situations exhibiting the highest RPN values. The results of the risk analysis can be updated after undertaking mitigating measures and preventive actions, until a satisfying value of RPN is achieved for all the listed failure modes. However, the traditional RPN method, when used in real situations, shows some important drawbacks as cited in (Certa et al. 2017b; Chemweno et al. 2017; Chin et al. 2009; Jee et al. 2015; Liu et al. 2017c; Liu et al. 2016a; Pillay and Wang 2003; Song et al. 2014). In many cases, FMEA team members' judgments and assessments are ambiguous, vague and cannot be estimated with numeric values, so the exact values from 1 to 10 are not suitable to model practical risk analysis situations. Second, the weights given to the three risk factors are equal. But in the real-life

application, the weights for quantitative and qualitative risk factors may be different. Third, the multiplication of risk factors to obtain the RPN is a fundamental flaw in the traditional FMEA. The risk factors O, S, and D are evaluated based on ordinal scales, but their multiplication is not a meaningful measure in terms of the measurement theory. Therefore, in the past decade, many researchers have developed a lot of modified FMEA models to determine the ranking orders of failure modes, taking care of the limitations discussed above. For an excellent review of the drawbacks related to the conventional RPN method and the alternative risk priority models that have appeared in the literature, see Liu et al. (2013b).

Some scholars indicated that FMEA is a decision function performed by a cross-functional and multidisciplinary team (Carpitella et al. 2018; Liu et al. 2017b; Liu et al. 2017c). Guerrero and Bradley (2013) proved that groups outperform individuals in the prioritization of failure modes via an experimental study. However, current FMEA practices are dominated by critically analysis problems featuring few experts (five or less). Along with more complicity of products and processes, FMEAs are often implemented under distributed settings, such as offshore outsourcing. That is, FMEA might be used to coordinate an expert group that is dispersed across organizations and countries such that the incidence of failures can be reduced. In such situations, it is often the case that the risk analysis results by a small FMEA team are either hard or impossible to reflect the actual situation of a distributed organization. This causes a serious dilemma for FMEA practice: The FMEA has been broadly used in various areas but it is working worse than many people expected. To ensure the effectiveness of FMEA, large numbers of experts from distributed departments or institutions should be involved especially for complex products and services. Guerrero and Bradley (2013) made an important statement in their research that a super group can lead to the reduction of bias and errors for individual risk experts (i.e., “wisdom of crowds”). However, the decision makers participating in a large group FMEA (LGFMEA) (the FMEA team involves more than 20 experts) may have many differences in their attitudes, knowledge, and self-interests. Thus, it is regularly very difficult to reach a unanimous agreement among large FMEA team members. Consequently, it is of great theoretical significance and practical value to develop new risk priority models that effectively

handle challenges posed by the explosion of risk assessment data in LGFMEA.

Based on the above discussions, we develop a novel risk priority approach for solving the LGFMEA problems characterized by unknown risk factor weights and linguistic assessment information. For the proposed approach, we first cluster failure mode assessments of large FMEA group using a cluster analysis method and each produced cluster is considered as a decision unit. Then we aggregate the risk assessments of various clusters fully considering conflict assessments and majority opinions of experts. Next, we propose an entropy-based method to derive the weights of risk factors objectively by utilizing the risk evaluation information. After that, prospect theory is used to generate the risk ranking of the failure modes that have been recognized. For doing so, the remainder of this paper is structured as follows. Section “Related literature” reviews the literature related to this study briefly. Section “The proposed LGFMEA model” develops the risk ranking model for FMEA within the large group context. Section “Case study” investigates the feasibility and validity of the proposed LGFMEA approach through a practical healthcare risk analysis example. Finally, section “Conclusions” summarizes the major research findings and outline future research directions.

Related Literature

This article is mainly related to two streams of literature. The first one is the literature on FMEA improvement. Currently, plenty of attentions have been paid to the limitations of the traditional FMEA and many useful risk ranking methods have been brought up, for example, by using mathematical programming (Chin et al. 2009), artificial intelligence (Jee et al. 2015; Liu et al. 2013a) and other methods (Kim and Zuo 2018; von Ahsen 2008). This paper is particularly related to previous researches on the application of multiple criteria decision making (MCDM) methods to enhance the performance of FMEA. In this aspect, Chang et al. (1999) used the fuzzy grey relational analysis (GRA) approach for finding the risk priority of product and process failures, Braglia et al. (2003) adopted the fuzzy technique for order preference by similarity to ideal solution (TOPSIS) method to prioritize the potential risks of failure modes in criticality analysis, and Seyed-Hosseini et al. (2006) applied the decision-making trial and evaluation laboratory (DEMATEL) technique for the priority ranking of failures in the system

with many subsystems or components. Liu et al. (2014) evaluated the risk of failure modes with an extended MULTIMOORA (MOORA plus the full multiplicative form) method under fuzzy environment, Adhikary et al. (2014) estimated the criticalities of failure modes by employing the grey-complex proportional assessment (COPRAS-G) tool, and Liu et al. (2016a) determined the risk priority of failure modes using an ELECTRE (ELimination Et Choix Traduisant la REalité) approach within interval 2-tuple linguistic setting. Besides, a systematic introduction of the modified FMEA models based on uncertainty theories and MCDM methods can be found in (Liu 2016). In this study, we contribute to the literature by applying a prospect theory-based method for the reprioritization of failure modes in FMEA. The new method overcomes the critical weak points of the traditional FMEA and provides more reasonable and credible solutions for facilitating risk management decision making.

The second related stream of research is the one on group decision making, which is one of the central topics in decision science. Given that many decisions within organizations are made in a group setting, group decision making problem has been studied extensively for making better decisions. For example, Yu (1973) presented a class of solutions for group decision problems of which each individual's utility function over a decision space is assumed to be known. Keeney (1975) suggested a group decision making method to address the complexities that there is uncertainty concerning the impact of alternatives and individuals have different preference attitudes toward risks. In Bodily (1979), the authors proposed a delegation process to set the weights of decision makers in a surrogate utility function for group decision making under uncertainty. Boje and Murnighan (1982) investigated the effects of two group decision making techniques on a set of problems in different group sizes, and found that pooled individual estimates are more accurate than those obtained from face-to-face verbal feedback and received written feedback. Hochbaum and Levin (2006) put forward an optimization framework for group-rankings decision, which allows for flexibility in decision protocols and considers imprecise beliefs and differentiation between reviewers according to their expertise. Altuzarra et al. (2010) employed a Bayesian based-framework for establishing consensus in the analytic hierarchy process (AHP)-group decision making, which permits automatic

identification of “agreement” and “disagreement” zones among the involved decision makers. However, few existing studies focus on the large group decision making problems (Cai et al. 2017, Liu et al. 2015), especially in FMEA. Our contribution to the group decision making literature is providing an algorithm to cope with the group decision making characterized by large numbers of participators in distributed groups and based on conflict assessments and majority opinions. This method is helpful to get representative collective assessments that are easily accepted by decision makers, and can relieve the influence of biased opinions and assessment differences on the final decision results.

The proposed LGFMEA model

A LGFMEA problem can be defined as a situation where a large number of experts from multiple groups are involved to make a high-quality risk analysis by identifying the most serious failure modes among a set of potential ones for corrective actions. Generally, when the number of experts in FMEA exceeds 20 (Liu et al. 2015; Zhou et al. 2017), the risk analysis process in which they participate can be considered as LGFMEA (as displayed in Figure 1). In this section, we develop a novel risk priority framework for LGFMEA, which is comprised of four parts: (1) cluster experts into small-groups according to their evaluations on failure modes; (2) aggregate different opinions of experts into group risk assessments; (3) determine the relative weights of risk factors; and (4) determine the risk priority orders of failure modes. A detailed diagrammatic representation of the proposed LGFMEA mode is shown in Figure 2.

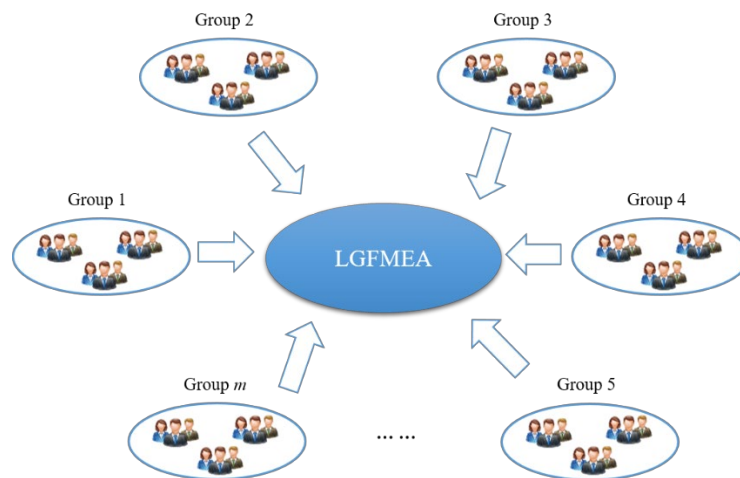


Figure 1. LGFMEA with experts from distributed groups.

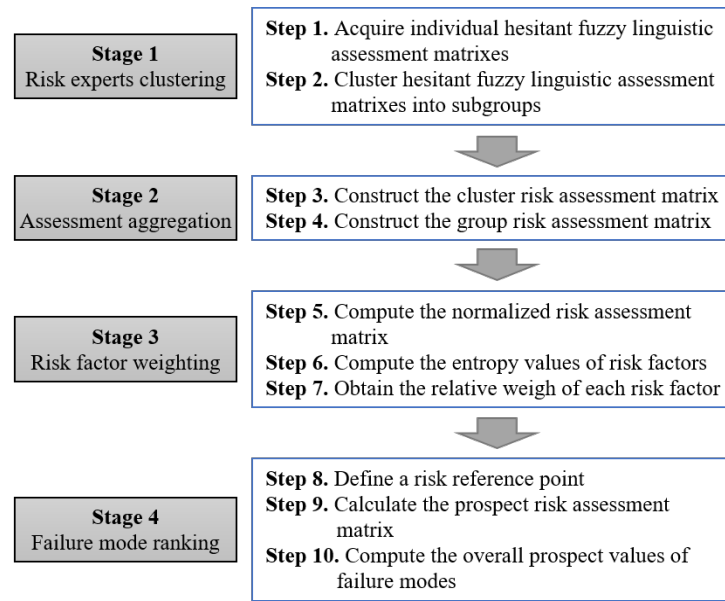


Figure 2. Flowchart of the proposed LGFMEA mode.

In a LGFMEA, without loss of generality, we assume that m failure modes $FM_i (i = 1, 2, \dots, m)$ are identified and needed to be evaluated by l experts or team members $TM_k (k = 1, 2, \dots, l)$ according to n risk factors $RF_j (j = 1, 2, \dots, n)$. Since risk factors are difficult to be precisely estimated in the actual risk assessment process, it is assumed that the experts provide their judgements on the failure modes using ambiguous linguistic terms. According to the approach illustrated in Figure 2, the detailed explanations of the proposed LGFMEA approach in prioritizing failure modes are given as follows.

Risk experts clustering

For the LGFMEA problem, a consensus process is required to deal with the enormous amount of risk assessment information obtained from experts. In the consensus process, participants seek to reach a mutual agreement with the expectation of gaining an acceptable whole group assessment. Because of the complexity of large groups and the difference among group members, clustering method is usually applied to derive the subgroups or so-called clusters in which experts have similar assessments. Then the subsequent analysis is much easier to manage based on the obtained clusters. Therefore, clustering analysis is an essential part of the proposed risk priority approach.

Several clustering methods such as the k -means algorithm (Wu and Xu 2018), the

hierarchical clustering method (Zhu et al. 2016), and the preference clustering method (Xu et al. 2015) have been utilized in the large group decision making literature. The similarity degree is a simple and popular used algorithm because its ease of implementation, efficiency, and empirical success (Cai et al. 2017). However, this clustering method has not yet been developed for LGFMEA. Therefore, in this part, a similarity degree-based clustering method is proposed to deal with the classification of risk assessments in large group environment.

Step 1. Acquire individual hesitant linguistic assessment matrices H^k

In practical situations, FMEA team members prefer to utilize linguistic labels to state their assessments on the risk of failure modes (Liu et al. 2016a; Zhou et al. 2016). Moreover, due to information insufficiency or limited expertise, experts may hesitate among different linguistic terms or require complex linguistic expressions to represent their opinions accurately (Huang et al. 2017; Liu et al. 2016b). Therefore, hesitant linguistic term sets (HLTSs) (Rodríguez et al. 2012) are used in this study to deal with the uncertain linguistic assessments provided by team members in LGFMEA.

For computing with words with the HLTSs, various linguistic assessments of experts need to be transformed into hesitant linguistic elements (HLEs) first. Let d_{ij}^k be the linguistic assessment values that team member TM_k provides for failure mode FM_i against risk factor RF_j ($i = 1, 2, \dots, m; j = 1, 2, \dots, n; k = 1, 2, \dots, l$). Then, the risk assessments over all failure modes versus each risk factor made by the k th expert form a hesitant linguistic assessment matrix H^k . That is,

$$H^k = \begin{bmatrix} h_{11}^k & h_{12}^k & \cdots & h_{1n}^k \\ h_{21}^k & h_{22}^k & \cdots & h_{2n}^k \\ \vdots & \vdots & \cdots & \vdots \\ h_{m1}^k & h_{m2}^k & \cdots & h_{mn}^k \end{bmatrix}, \quad (1)$$

where h_{ij}^k is an HLE converted from the linguistic assessment d_{ij}^k . For example, if an expert

evaluates the risk of failure modes using the following linguistic term set:

$$S = \{s_0 = \text{Very low}, s_1 = \text{Low}, s_2 = \text{Medium low}, s_3 = \text{Medium}, s_4 = \text{Medium high}, s_5 = \text{High}, s_6 = \text{Very high}\}.$$

Then different types of linguistic assessments given by the expert can be represented by HLEs as follows:

- A deterministic linguistic rating such as *Low* can be denoted by $\{s_1\}$;
- A hesitant linguistic rating such as *Medium high* and *High* can be expressed as $\{s_4, s_5\}$.

Step 2. Cluster hesitant linguistic assessment matrices into subgroups

Determining an appropriate clustering threshold is critical to cluster the hesitant linguistic matrices of all risk experts H^k ($k = 1, 2, \dots, l$). Motivated by the method of (Cai et al. 2017), we determine a clustering threshold based on the similarities between individual hesitant linguistic assessments as

$$\lambda = \min_{p,q=1,2,\dots,l,p \neq q} SD(H^p, H^q) + \frac{2}{3} \left(\max_{p,q=1,2,\dots,l,p \neq q} SD(H^p, H^q) - \min_{p,q=1,2,\dots,l,p \neq q} SD(H^p, H^q) \right), \quad (2)$$

where $SD(H^p, H^q)$ is the similarity degree between the hesitant linguistic assessment matrices H^p and H^q , and can be computed by

$$SD(H^p, H^q) = \frac{1}{mn} \sum_{i=1}^m \sum_{j=1}^n \frac{E(h_{ij}^p)E(h_{ij}^q)}{(E(h_{ij}^p))^2 + (E(h_{ij}^q))^2 - E(h_{ij}^p)E(h_{ij}^q)}. \quad (3)$$

It is easy to know that $0 \leq \lambda \leq 1$. If $SD(H^p, H^q) \geq \lambda$, then H^p and H^q are placed into the same cluster (or subgroup). As a result, the k hesitant linguistic assessment matrices H^k ($k = 1, 2, \dots, l$) can be divided into L small-scale clusters G_K ($K = 1, 2, \dots, L$) by means of the proposed clustering method. The number of experts in cluster G_K is defined as l_K and $\sum_{K=1}^L l_K = l$.

Note that the number of clusters should be no less than three in the LGFMEA so as to avoid the extreme situation in which only two clusters exist and their opinions are absolutely opposite in the risk analysis. In addition, the clustering results are assumed to be reasonable if each of the L clusters has more than one expert ($L \geq 2$). Otherwise, if only one expert in a single cluster, then the expert is advised to exit the LGFMEA process since the consensus levels with the other

experts are low (Xu et al. 2015).

Risk assessment aggregation

After clustering the hesitant linguistic assessment matrices into subgroups, this stage is to aggregate the risk assessment of each cluster to attain a cluster risk assessment matrix, and aggregate the risk assessments of all clusters to establish a group risk assessment matrix.

Step 3. Construct the cluster risk assessment matrix R^K

In the same cluster G_K , the similarity degree between experts is sufficiently high, which means that the risk assessments of failure modes in each cluster are basically coherent. So we suppose that the risk experts in a cluster have equal weights in the hesitant linguistic assessment aggregations. Therefore, the cluster risk assessment matrix $R^K = [r_{ij}^k]_{m \times n}$ corresponding to cluster G_K can be obtained by

$$r_{ij}^K = \frac{1}{l_K} \sum_{k \in I_K} E(h_{ij}^k), \tag{4}$$

where $E(h_{ij}^k)$ is an expected value for the HLE h_{ij}^k .

Step 4. Construct the group risk assessment matrix R

Once obtaining the cluster risk assessment matrices $R^K (K = 1, 2, \dots, L)$, this step is to determine the group risk assessment matrix $R = [r_{ij}]_{m \times n}$ by

$$r_{ij} = \sum_{K=1}^L v_K r_{ij}^K, \tag{5}$$

where v_K signifies the weight of the K th expert cluster.

From Eq. (5), it is known that the weight of each expert cluster should be computed first prior to aggregating the risk assessments. In this study, the clusters' respective weights are yielded in terms of the following two methods. First, because of the complexity and uncertainty of LGFMEA problems, the team members with different experiences, knowledge and backgrounds cannot achieve absolute consistent regarding failure modes' assessment. So risk assessment conflicts among clusters should be taken into account to aggregate the cluster risk assessment information. The cluster weight vector can be derived based on the conflict degree

between the cluster risk assessment matrix R^K and the ideal risk assessment matrix R^* , which is defined as

$$\varepsilon_K = \frac{1}{mn} d(R^K, R^*), \quad (6)$$

where $d(R^K, R^*) = \sqrt{\sum_{i=1}^m \sum_{j=1}^n (r_{ij}^K - r_{ij}^*)^2}$ is the Euclidean distance between R^K and R^* . Inspired by the relevant literature (Yue 2011), the average matrix of the L cluster risk assessments is considered as the ideal risk assessment matrix R^* .

A larger value of ε_K indicates that a higher assessment conflict between the cluster G_K and the ideal risk assessments. In general, the less conflict level of the cluster G_K , the more weight should be placed on it. Hence, we use Eq. (7) for determining the first type weights of clusters $v_K^{(1)} (K=1, 2, \dots, L)$.

$$v_K^{(1)} = \frac{1 - \varepsilon_K}{\sum_K (1 - \varepsilon_K)}. \quad (7)$$

Based on the majority principle, another method can be used here for specifying the cluster weights. The larger the cluster is, the greater impact the group risk assessments would have. In other words, if the number of experts in a cluster is larger than other clusters, then it can be seen that the cluster plays a more important role in the LGFMEA and should be assigned a higher weight. On the contrary, if a cluster comes to be smaller than other clusters, then this cluster should be assigned a lower weight. Accordingly, the second type weights of clusters $G_K (K=1, 2, \dots, L)$ are computed through the following formula:

$$v_K^{(2)} = \frac{(l_K)^2}{\sum_K (l_K)^2}. \quad (8)$$

In real-life situations, both the risk assessment conflict and the majority principle should be taken into consideration. Therefore, the above two types of weights can be combined to determine the cluster weights comprehensively. For example, the ultimate weighting vector of clusters $v = (v_1, v_2, \dots, v_L)$ is derived by

$$v_k = \alpha v_k^{(1)} + (1 - \alpha) v_k^{(2)}, \quad (9)$$

where α is a parameter representing the relative importance between the two types of weights, $0 \leq \alpha \leq 1$.

Risk factor weighting

Solving risk factor weights is a critical step in FMEA because the variation of weight values may lead to different risk ranking orders of the identified failure modes. Vast majority of FMEA methods in the literature assumed that the weights of risk factors are given beforehand or determined subjectively. In the real world, however, it may be hard or even impossible to define the important weight of each risk factor, because of the complexity of practical risk analysis problems and the inherent subjective nature of human thinking. The entropy theory (Shannon and Weaver 1947) is a measurement index used to measure the amount of information implied in data. It is well suited for measuring the relative contrast intensities of criteria to represent the intrinsic information transmitted to the decision maker. Therefore, the entropy method has been widely used in many fields for estimating the relative weights of evaluation criteria (Gitinavard et al. 2017; Liu et al. 2017d). For the LGFMEA problem, we propose an entropy-based method to objectively compute the weights of risk factors by utilizing the evaluation information of experts. The calculation process of risk factor weights based on the entropy method is shown as below.

Step 5. Compute the normalized risk assessment matrix P

The group risk assessment matrix $R = [r_{ij}]_{m \times n}$ is normalized to get the normalized risk assessment matrix $P = [p_{ij}]_{m \times n}$ by

$$p_{ij} = \frac{r_{ij}}{\sum_{i=1}^m r_{ij}}, \quad (10)$$

where p_{ij} is the normalized value of r_{ij} , representing the projected outcome of risk factor RF_j concerning failure mode FM_i .

Step 6. Compute the entropy values of risk factors

The entropy with respect to each risk factor is calculated via

$$E_j = -\left(\frac{1}{\ln m}\right) \sum_{i=1}^m p_{ij} \ln p_{ij}, \quad j = 1, 2, \dots, n, \quad (11)$$

where m is the number of failure modes and guarantees that the value of E_j lies between 0 and 1.

Step 7. Obtain the relative weigh of each risk factor

According to the entropy theory (Shannon and Weaver 1947), E_j indicates the discrimination degree of the overall risk assessment information contained by RF_j . The smaller the entropy value E_j , the bigger the difference across failure modes under the risk factor (i.e., it provides decision makers with more effective information), and then a higher weight should be assigned to the risk factor RF_j . Therefore, the entropy weight of RF_j is defined as (Liu et al. 2017):

$$w_j = \frac{1 - E_j}{\sum_{j=1}^n (1 - E_j)}, \quad j = 1, 2, \dots, n. \quad (12)$$

As a result, we can obtain the weight vector $w = (w_1, w_2, \dots, w_n)$ of all the risk factors RF_j ($j = 1, 2, \dots, n$) with $w_j \in [0, 1]$ and $\sum_{j=1}^n w_j = 1$.

Failure mode ranking

The prospect theory was first proposed by Kahneman and Tversky (1979) for behavioral decision making under uncertainty, which considers decision maker's personality, psychological attitude and risk preference, as well as environmental and other factors in the decision making process. Due to its characteristics of simple computation and clear logic, the prospect theory has been broadly used as behavioral model of decision making in different areas (Ren et al. 2017; Wang et al. 2017). In this study, the prospect theory is adopted to determine the risk ranking of failure modes, and the specific steps are described as follows.

Step 8. Define the risk reference point r_0

The risk reference point is normally assigned based on previous risk analysis experience or directly inferred according to the risk assessments of experts. With the group risk assessment matrix $R = [r_{ij}]_{m \times n}$ determined in the second stage, the preference point r_0 can be computed by

$$r_0 = \frac{1}{mn} \sum_{i=1}^m \sum_{j=1}^n r_{ij}. \quad (13)$$

Step 9. Calculate the prospect risk assessment matrix V

The prospect values of failure modes against each risk factor v_{ij} ($i=1, 2, \dots, m, j=1, 2, \dots, n$) are determined by the value function $v(r_{ij})$ to construct the prospect risk assessment matrix $V = [v_{ij}]_{m \times n}$. The value function is expressed in the following equation:

$$v(r_{ij}) = \begin{cases} (|r_{ij} - r_0|)^\alpha, & r_{ij} \geq r_0, \\ -\lambda (|r_{ij} - r_0|)^\beta, & r_{ij} < r_0, \end{cases} \quad (14)$$

where $\alpha \in [0, 1]$ and $\beta \in [0, 1]$ are diminishing sensitivity coefficients specifying the concavity and convexity of the value function, respectively. The decision maker is more prone to risk if the values of α and β are higher. λ is the loss aversion coefficient indicating the degree of severe feelings toward loss, and when $\lambda > 1$, the decision maker exhibits a greater sensitivity to losses.

Step 10. Compute the overall prospect value of each failure mode

Finally, the overall prospect values of the m failure modes can be determined by

$$V_i = \sum_{j=1}^n w_j v_{ij}, \quad i = 1, 2, \dots, m. \quad (15)$$

The larger the value of V_i , the higher risk the failure mode FM_i . Therefore, all the identified failure modes can be ranked in accordance with the descending order of their overall prospect values and the most important failures can be selected.

Note that the parameters α , β , and λ are involved in the value function defined in Eq. (14). The determination of them plays a crucial role in the risk ranking process. Some researches have been carried out to define the three parameter values appropriately (Abdellaoui et al. 2007; Tversky and Kahneman 1992). Through experiments, Tversky and Kahneman (1992) suggested that the diminishing sensitivity coefficients $\alpha = \beta = 0.88$ and the loss aversion coefficient $\lambda = 2.25$, which are more suitable to describe the behavior of most decision makers. If necessary, these parameters can be adjusted based on the specific problems we are dealing with.

Case study

In this section, we consider the risk analysis of blood transfusion as an example to illustrate the

applicability and performance of our proposed LGFMEA approach and particularly the potentials of prioritizing failure modes within the larger group context.

Background description

Blood transfusion is a procedure routinely performed in healthcare organizations, which saves lives and reduces morbidities in many clinical diseases and conditions. But blood transfusion is a costly and complex procedure associating with certain risks such as transmission of infectious disease, clerical error, hemolytic reactions and transfusion-related lung injury. This has led to a trend towards safer transfusion practices, minimizing the risk of errors in the blood transfusion. Identification and prevention of blood transfusion failures is of great importance to the transfusion safety. In this study, we applied the proposed LGFMEA model to analyze the risks in blood transfusion to improve patient care and safety. Through brainstorming, a total of nineteen potential failure modes were recognized within the whole blood transfusion process (Lu et al. 2013). Among them, eight failure modes $FM_i (i = 1, 2, \dots, 8)$ with their RPN values bigger than 100 are considered for further discussions. These failure modes, the causes for them and their effects are summarized in Table 1.

To determine risk ranking of the failure modes, a total of 28 eligible subjects in a university teaching hospital were invited and asked to conduct the risk evaluation based on a web-based questionnaire system. As a consequence, 20 usable surveys were collected from the hospital. In the following, the risk assessment data of the 20 respondents, denoted as $TM_k (k = 1, 2, \dots, 20)$, are used to demonstrate the proposed LGFMEA approach. These experts from different departments include managers of blood transfusion department, doctors, nurses, and staff from quality control department. Moreover, they possess professional knowledge of healthcare risk assessment and have worked in related fields for more than three years. All the experts rated the risk of each failure mode with respect to the risk factors, O, S and D, and express their judgements by using the linguistic term set \dot{S} ,

$$\dot{S} = \left\{ \begin{array}{l} s_0 = \text{Almost None (AN)}, s_1 = \text{Extremely Low (EL)}, s_2 = \text{Very Low (VL)}, \\ s_3 = \text{Low (L)}, s_4 = \text{Medium Low (ML)}, s_5 = \text{Medium (M)}, s_6 = \text{Medium High (MH)}, \\ s_7 = \text{High (H)}, s_8 = \text{Very High (VH)}, s_9 = \text{Extremely High (EH)} \end{array} \right\}.$$

Note that a ten-point linguistic term set is used here in order to make a comparison of the ranking results of the proposed approach with those derived by the traditional FMEA. In actual applications, the linguistic term set \dot{S} can be determined according to the specific problem considered and the opinions of FMEA team members. In this case study, the linguistic assessments of the eight failure modes under each risk factor provided by the 20 experts are presented in Table 2.

Table 1. FMEA of the blood transfusion process.

No.	Failure modes	Failure causes	Failure effects
1	Insufficient and/or incorrect clinical information on request form	Request form filled out incorrectly/incompletely; patient provided incorrect blood group	Normal process is interrupted; transfusion cannot be performed within appropriate time frame
2	Blood plasma abuse	Blood plasma still used in volume expansion, as nutritional supplement and to improve immunoglobulin levels	Blood resources wasted, risk of transfusion-related reaction and infection increased
3	Insufficient preoperative assessment of the blood product requirement	Improper evaluation of the disease or potential blood loss	Adverse event if compatible blood cannot be prepared in time after emergency cross-matching procedure
4	Blood group verification incomplete	Importance of performing blood group testing on two separate occasions not recognized; use of another sample collected separately or historical records	ABO-incompatible transfusion reaction if no historical blood type or another sample for verification
5	Preparation time before infusion >30 min	Delivery of blood products to clinic department takes too long; Infusion is not started in time	Blood components not transfused within 30 min, resulting in reduced quality and associated potential risks to the patient
6	Transfusion cannot be completed within the appropriate time	Transfusion not started when blood products are sent to clinic area; inappropriate transfusion time	Transfusion is delayed and patients receive uncertain quality blood products
7	Blood transfusion reaction occurs during the transfusion process	Patient not monitored during the transfusion process	Emergency treatment is delayed, putting the patient's life in danger
8	Bags of blood products are improperly disposed of	Staff unfamiliar with procedures for waste bags	Contamination of environment, traceability cannot be guaranteed if required later

Table 2. Linguistic assessments for the failure modes.

Risk experts	Risk factors	Failure modes							
		FM ₁	FM ₂	FM ₃	FM ₄	FM ₅	FM ₆	FM ₇	FM ₈
TM ₁	O	M	L	VL	L	L	VL	ML	L
	S	MH	L	L	EH	M	M	VH	L
	D	ML	L	L	M	L	L	ML	L
TM ₂	O	L	H	H	AN	M	M	EL	EL
	S	H	MH	MH	EH	M	M	M	L
	D	VH	MH	MH	EL	VL	VL	VL	VL
TM ₃	O	M	L	EL	AN	H	H	AN	L
	S	H	MH	H	EH	L	VL	EH	H
	D	EL	VL	VL	AN	L	AN	ML	M
⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮	⋮
TM ₁₉	O	H	M	MH	MH	M	M	MH	H
	S	MH	MH	M	H	MH	MH	MH	MH
	D	M	H	H	H	MH	L	MH	ML
TM ₂₀	O	L	MH	M	MH	M	M	MH	ML
	S	ML	H	MH	H	H	MH	M	VL
	D	ML	ML	ML	ML	M	ML	MH	EL

Results

To solve the healthcare risk analysis problem and identify the most serious failures for corrective actions, the LGFMEA approach proposed in this paper is implemented as follows.

Based on the data of Table 2, we first transform the linguistic assessments of each expert into HLEs to obtain the hesitant linguistic assessment matrices H^k ($k = 1, 2, \dots, 20$). Taking the expert TM₉ as an example, the hesitant linguistic assessment matrix H^9 obtained is shown in Table 3. Then, by Eqs. (2)-(3), the clustering threshold is computed as $\lambda = 0.801$, and the large group can be divided into three smaller clusters according to the introduced clustering method, i.e.,

$$G_1 = \{H^2, H^4, H^6, H^7, H^8, H^{10}, H^{12}, H^{13}, H^{14}\},$$

$$G_2 = \{H^{15}, H^{16}, H^{17}, H^{18}, H^{19}, H^{20}\}, G_3 = \{H^1, H^5\}.$$

Note that the hesitant linguistic assessment matrices H^3 , H^9 and H^{11} are excluded from the risk analysis because their similarity degrees with other experts' hesitant linguistic assessments are low than the clustering threshold.

Table 3. Hesitant fuzzy linguistic assessment matrix H^9 .

Failure modes	Risk factors		
	O	S	D
FM ₁	{s ₁ }	{s ₇ }	{s ₀ }
FM ₂	{s ₀ }	{s ₁ }	{s ₁ }
FM ₃	{s ₁ }	{s ₃ }	{s ₁ }
FM ₄	{s ₀ }	{s ₈ , s ₉ }	{s ₀ }
FM ₅	{s ₁ }	{s ₄ }	{s ₆ }
FM ₆	{s ₀ }	{s ₅ }	{s ₁ }
FM ₇	{s ₂ }	{s ₇ , s ₈ }	{s ₁ }
FM ₈	{s ₀ }	{s ₇ }	{s ₁ }

In the second stage, the cluster risk assessment matrices R^K with respect to the three risk assessment clusters G_K ($K = 1, 2, 3$) are determined by using Eq. (4), and presented in Table 4.

Based on the clustering results and via Eqs. (6)-(9), the two types of cluster weights and the ultimate cluster weights are yielded as shown in Table 5. By applying Eq. (16), we obtain the group risk assessment matrix $R = [r_{ij}]_{8 \times 3}$ as reported in Table 6.

Table 4. Cluster risk assessment matrices for the failure modes.

Clusters	Risk factors	Failure modes							
		FM ₁	FM ₂	FM ₃	FM ₄	FM ₅	FM ₆	FM ₇	FM ₈
G ₁	O	4.89	5.17	4.44	1.44	5.11	5.33	2.67	2.56
	S	7.22	5.89	6.33	8.56	5.56	5.78	7.00	5.44
	D	5.33	5.11	5.67	3.56	5.33	5.56	4.22	4.56
G ₂	O	8.00	7.80	7.20	6.40	7.20	8.40	7.20	7.80
	S	8.20	8.20	8.00	9.60	8.40	8.40	9.20	7.20
	D	5.40	8.20	9.00	7.60	7.00	5.80	6.00	6.80
G ₃	O	6.50	5.00	5.50	5.00	6.00	5.50	4.00	4.00
	S	7.00	3.50	3.50	9.50	6.00	6.00	8.50	6.00
	D	5.50	3.50	3.50	7.50	3.00	3.00	3.00	3.50

Table 5. Two types of cluster weights and ultimate cluster weights.

	G ₁	G ₂	G ₃
$v_K^{(1)}$	0.354	0.298	0.348
$v_K^{(2)}$	0.669	0.298	0.033
v_K	0.512	0.298	0.191

Table 6. Group risk assessment matrix of failure modes.

Failure modes	O	S	D
FM ₁	6.122	7.471	5.385
FM ₂	5.919	6.122	5.724
FM ₃	5.466	6.290	6.247
FM ₄	3.598	9.047	5.512
FM ₅	5.903	6.487	5.385
FM ₆	6.278	6.601	5.141
FM ₇	4.271	7.941	4.519
FM ₈	4.393	6.073	5.023

Subsequently the entropy method is applied to compute the objective weights of risk factors. We first calculate the normalized risk assessment matrix $P = [p_{ij}]_{8 \times 3}$ according to Eq. (10), then acquire the entropy value of every risk factor through Eq. (11), and the relative weights of risk factors are derived with Eq. (12). The above computation results are provided in Table 7.

Table 7. Normalized risk assessment matrix and objective weights of risk factors.

Failure modes	O	S	D
FM ₁	0.146	0.133	0.125
FM ₂	0.141	0.109	0.133
FM ₃	0.13	0.112	0.145
FM ₄	0.086	0.161	0.128
FM ₅	0.141	0.116	0.125
FM ₆	0.15	0.118	0.12
FM ₇	0.102	0.142	0.105
FM ₈	0.105	0.108	0.117
E_j	0.992	0.995	0.998
w_j	0.556	0.315	0.129

Finally, we adopt the prospect theory to determine the risk ranking of the considered failure modes. Using Eq. (13), the reference point for the healthcare risk analysis is acquired as 5.872. The prospect risk assessment matrix $V = [v_{ij}]_{8 \times 3}$ is calculated based on Eq. (14), and the overall prospect values of the failure modes $V_i (i = 1, 2, \dots, 8)$ are determined using Eq. (15). Table 8 shows the calculation results in detail. Therefore, the risk priority of the eight failure modes is $FM_6 \succ FM_1 \succ FM_4 \succ FM_3 \succ FM_7 \succ FM_8 \succ FM_2 \succ FM_5$, and FM6 is the most severe failure mode. Accordingly, preventive measures can be arranged to enhance the reliability and safety of the blood transfusion process.

Table 8. Results of the prospect theory and risk priority ranking.

Failure modes	O	S	D	V_i	Ranking
FM ₁	0.296	5.869	-9.9	0.74	4
FM ₂	4.782	4.926	-10.446	2.865	3
FM ₃	-10.031	5.242	5.203	-3.252	6
FM ₄	-6.942	7.132	-10.494	-2.962	5
FM ₅	4.77	5.37	-10.296	3.017	2
FM ₆	5.036	5.411	-9.982	3.219	1
FM ₇	-8.073	6.382	-8.895	-3.621	7
FM ₈	-8.275	5.092	-9.721	-4.246	8

Discussions

This part compares our proposed LGFMEA model with some related risk ranking methods to investigate its effectiveness and advantages. First, as the proposed approach aims to enhance

the risk evaluation capability of the traditional FMEA, a comparison with the RPN method is performed. Besides, Guerrero and Bradley (2013) found that synthesized group ranking methods, i.e., average and median of individual scores, perform as well as or better than the group consensus method, and the median is preferred in the super group risk assessment. Therefore, the average and the median methods are also selected for the comparative experiments. Table 9 summarizes the risk ranking results of the eight failure modes determined by using these methods.

Table 9. Ranking comparisons.

Failure modes	Traditional FMEA					Average	Median	Proposed method
	O	S	D	RPN	Ranking			
FM ₁	6	6	5	180	2	1	3	4
FM ₂	5	7	5	175	5	4	4	3
FM ₃	5	6	6	180	2	2	1	6
FM ₄	4	7	6	168	6	6	8	5
FM ₅	6	6	5	180	2	5	2	2
FM ₆	7	6	5	210	1	3	4	1
FM ₇	4	7	5	140	7	7	6	7
FM ₈	3	6	4	72	8	8	6	8

First of all, the top two failures obtained by the proposed FMEA are FM₅ and FM₆ and the last two failures are FM₇ and FM₈, which are in agreement with the ones determined by the RPN method. This demonstrates the validity of the suggested risk priority model for prioritizing failure modes. However, the ranking orders of four of the eight failure modes derived by the proposed approach and the RPN method are different. Particularly, the priority orders of FM₁, FM₃ and FM₅ cannot be discriminated in terms of the traditional FMEA. The possible reasons mainly lie in the shortcomings of the conventional RPN method. First, the failures FM₁ and FM₃, where O, S and D are rated as 6, 6, 5 and 5, 6, 6, respectively, have exactly the same RPN value 180. Thus they are assumed as having the same priority in terms of the RPN method. In the reality, the two failure modes should have different risk levels because their O and D values are different. Accordingly, FM₁ is ranked higher than FM₃ when the proposed approach is leveraged. Second, based on the numeric scale from 1 to 10, the O, S and D scores for FM₁ and FM₅ are consistent and the two failures can not be differentiated according to the RPN method.

This ranking could be unreasonable especially when FMEA team members' assessment data are vague and uncertainty and exact values cannot reflect their judgments sufficiently. According to the proposed FMEA, FM₅ is given a higher priority compared to FM₁. Third, the influence of risk factor weights used in the proposed FMEA approach can be seen in the rankings for the failure modes FM₂ and FM₃, where O, S and D are 5, 7, 5 and 5, 6, 6, respectively. Using the RPN method, FM₃ is ranked higher than FM₂. But by applying the presented approach, FM₂ has a higher priority in comparison with FM₃ since the weight of S is bigger than that of D (cf. Table 7). Finally, only five experts are involved in the RPN-based risk analysis, which may lead to a lack of precision in the final ranking result.

The ranking of failure modes determined by the average and median methods are based on the super expert group. But from Table 9, it is observed that the prioritization of failure modes via the proposed approach is quite different from the ones derived from the average and median methods. The Spearman rank correlations between risk priority rankings of the proposed FMEA and the average and median methods are calculated as 0.524 and 0.374, respectively. Explanations of these inconsistency of risk ranking results are as follows. First, the average method is a fully compensatory method, which allows low assessment of some experts for a failure mode to be compensated by high assessments of other experts. This is not always practically satisfied, especially when the risk assessments of experts are of great difference in the large group context. Second, the median method cannot discriminate the failure modes well from each other. For example, the risk priority orders of four failure modes (FM₂, FM₆, FM₇ and FM₈) cannot be distinguished via the median method. Third, the relative important among risk experts are not taken into consideration in the average and median methods. But, in practical situations, different experts generally act as different roles in the risk analysis process since they come from different fields and have different knowledge, experience, and backgrounds. Therefore, biased risk ranking results may be obtained when the average and median methods are used.

According to the comparative experiments above, the proposed FMEA approach based on cluster analysis and prospect theory provides a useful and practical way for risk evaluation

when involving large group of experts. In summary, the prominent advantages of the proposed LGFMEA model are as follows:

- By the use of HLTs, FMEA team members can use flexible and richer expressions to evaluate the failure modes on each risk factor more accurately. Thus, the linguistic ratings of failure modes can be appropriately represented to directly account for the uncertainties in complex or ill-defined situations.
- Based on the cluster analysis method, the proposed FMEA is able to obtain a relatively satisfactory failure mode ranking within the context of larger group. Therefore, it useful for modeling LGFMEA problems where the scale of FMEA groups is larger and the type of FMEA groups is complex due to the complexity and insufficient information of failure modes.
- Importance weights of risk factors are taken into account in determining the risk priority of failure modes. Particularly, an entropy-based is proposed to objectively determine risk factor weights by comprehensively utilizing the risk assessment information in FMEA.
- The proposed method can compensate the weaknesses of the conventional RPN method and get a more accurate and credible risk priorities of failure modes by using the prospect theory, thus providing useful and practical information for risk management decision making.

Conclusions and future directions

In this article, we developed a novel risk priority approach for the LGFMEA with unknown risk factor weights and linguistic assessment information. The proposed FMEA model is initiated by clustering the large group experts from different sectors and professional fields via a similarity measure-based clustering method. Then, a group risk assessment matrix was constructed by taking conflict degree and majority principle into account simultaneously to improve the consistency of group opinions. Next, an entropy-based objective weighting method was suggested to derive the weights of risk factors with the collective risk evaluation information. In addition, the prospect theory was modified to derive the risk ranking of the failure modes identified in FMEA. After designing the proposed risk priority approach, we

tested and evaluated it via an empirical healthcare risk analysis case study. The example analysis revealed that the proposed model is feasible and effective, which is conducive to improve the rationality and accuracy of large-group risk analysis in distributed settings. In particular, the importance of our LGFMEA approach stems from the increasing dispersal of product design and produce activities in terms of geography and different organizations.

In the future, we will further extend our research in the following directions. First, the work presented in this article does not consider non-cooperative behaviors and minority opinions of experts, which may be happening in real world settings, particularly among large and diversified group members. Thus, our proposed FMEA could be enhanced in the future, making it more applicable to distributed large group-based FMEA problems. Second, different attitudes of FMEA team members have a direct impact on the risk ranking results, but they are not reflected in the introduced LGFMEA model. In the future, we can consider expert attitude as an important influencing factor in the large group risk analysis. Third, it will be interesting to further extend our approach to manage the large group risk analysis problems with incomplete assessment information, because experts may not able to evaluate all failure modes due to their limitations in knowledge, experience, and interests. In addition, future research should be conducted in developing a web-based risk management system that is helpful and convenient for domain experts located in different places to perform LGFMEA via a web interface.

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