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A Fuzzy Bayesian Network Based on Fault Tree for Vaccine Safety Risks Analysis

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***Abstract*—Against the Covid-19 background, vaccine safety has aroused the wild attention of all social areas. However, the factors that cause vaccine safety risks are complicated and meanwhile, data is difficult to obtain, making it a challenge for analyzing vaccine safety risks quantitatively. This paper concretises the abstract issue of vaccine system safety by creatively proposing an analytical framework for the problem of uncertainty. First, the paper focuses on the whole process of vaccine safety, analyses risk factors affecting vaccine safety in development, approval, production, transportation, and supervision of vaccines in order to build a vaccine risk assessment system. The proposed framework is then used to construct a Bayesian network early warning system for vaccine risk. To address the difficulty of obtaining data, the probability of safety risks occurring throughout the process is calculated by combining expert knowledge and fuzzy set theory to obtain uncertainty data. In response to structural complexity, a comprehensive framework is constructed using fault trees and Bayesian networks to capture the correlation between risk factors. This analytical framework can provide guidance to governments and vaccine-related companies in their decision-making to prevent vaccine safety issues. Finally, sensitivity analysis revealed a high probability of vaccine risk in the transport process.**

Keywords—O.R. in Health Services, Bayesian Network, Vaccine safety system, Fault Tree, Fuzzy analytic hierarchy process

I. INTRODUCTION

Infectious diseases are characterized by their comprehensive transmitting mechanism, long duration and reoccurrence [1], high morbidity and mortality, and in some worst situations. COVID-19’ s high contagiousness and rapid spread is such an example, which has already caused a global public health emergency, resulting in 246 million infected people and over 4.98 million deaths as of October 29, 2021. At the same time, the epidemic hit the global economy immeasurably, especially the airline industry, leisure industry and catering industry, etc., which lost more than 50% of its value at the height of the epidemic. The world is in the grip of an extremely frightening public health emergency. The transport and facilities of emergency supplies for public health emergencies are therefore of particular concern. Factors affecting vaccine safety are complex and changeable. Meanwhile, the involved multi-variable data is opaque and difficult to obtain. Yet, we need to explore an objective approach to assess vaccine safety risks.

At present, the primary research focuses on the supervision and reporting of vaccine adverse events [2-6], analysis of the influencing factors of vaccine safety testing, and early warning [7, 8]. These researches lack quantitative analysis on the overall system, and they have not investigated the uncertainty and complexity of the vaccine safety system, thus unable to detect emergencies and issue warnings.

Method of transforming FT to BN has been widely used in system reliability estimation and risk assessment, such as reliability estimation of automatic sprinkler system [9], diagnosis system development of hydropower fault [10], vehicle offline fault diagnosis [11], and so on. However, an application in the field of vaccine safety remains a gap. In order to deal with the ambiguity and deficiencies of data in complex systems, extensive research has been conducted by using fuzzy set theory in different fields. Fuzzy numbers selected in applications are mostly triangular fuzzy numbers [12] or trapezoidal fuzzy numbers [13]. Celik used triangular fuzzy numbers and trapezoidal fuzzy numbers to quantitatively analyze technical failures in transportation accidents [14], deethanizer failure in petrochemical plant operations [15], abandoned oil Wells and gas Wells leakage risk [16]. Wang applied triangular fuzzy numbers and trapezoidal fuzzy numbers combined with FTA to the reliability analysis of crude oil tank fire and explosion [17].

The study aims to find a quantitative method for analyzing the risk of vaccine safety systems. The FT is used for qualitative analysis to identify the root cause of the risk events, and the fuzzy set theory combined with expert judgment is utilized to obtain unknown fault data of basic events (BEs). Theoretically, this article integrates the methods of vaccinology, probability theory and other disciplines to perfect the vaccine risk evaluation system, and identify the factors that affect the vaccine risk in each link, which has very important theoretical significance for improving a comprehensive and in-depth vaccine safety risk system. The practical significance is mainly to provide decision-making guidance for the government and vaccine-related companies and to prevent the occurrence of vaccine safety incidents.

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This remainder of the paper is organized as follows: In Section 2, a fuzzy BN method based on FT is introduced, and the fuzzy analytic hierarchy process (FAHP) is used to reduce the subjectivity of expert judgment. Section 3 applies this method to the vaccine safety system, builds the BN for the vaccine safety system, inputs the prior information of the BEs, calculates the probability of the top event and the posterior probabilities of the BEs, and accordingly establishes appropriate preventive maintenance strategy. Section 4 draws the conclusion and discusses follow-up research.

II. Approach and Process

BNs can be constructed by introducing FT and then converting FT into the BN framework, making the structure more logical and scientific. In the end, the experience of experts is used to increase the horizontal links between BN nodes.

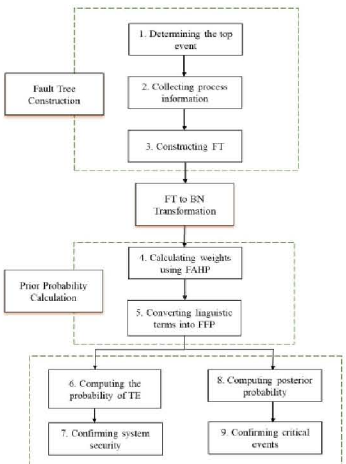

Fig. 1. The framework of the research approach

For the problem of missing data, consulting experts in related fields, and applying FAHP to overcome subjective problems, then using triangular and trapezoidal fuzzy numbers to transform expert predictions into a priori probability of failure. A framework of the research method and process proposed in this paper is shown in Fig.1.

A. Fault Tree Analysis (FTA)

FTA is a top-down, layer-by-layer deductive system fault analysis method [18], used to find the various possible causes of the top event until the base events are determined step by step. The potential risk fault is analyzed through the logical relationship, and preventive measures are taken.

In FTA, the top event is at the top of the FT, which is the least desirable for the analysis system. Generally, the foreseeable failure event that has a significant impact on system safety, reliability, and economy is considered as the top event. These events connect the causal relationship between the top event and BEs as intermediate events, and BEs located at the basis of the accident tree, which is the most fundamental cause of system failure, such as personnel errors, environmental factors, etc. These interrelationships are typically obtainable as logical AND/OR gates [19, 20].

The qualitative analysis of the FTA method is used to find all the failure forms of the top event, that is, the minimum cut set (MCS), and qualitatively determine the root cause of undesirable events in the system failure. Based on qualitative analysis, in quantitative analysis, we compute the probability of accident occurrence and base events' importance through the failure probability of BEs [21].

B. Bayesian Network (BN)

BN is a kind of directed acyclic graph based on probability theory and graph theory, which is used for expression and reasoning of uncertain knowledge. The BN with N nodes is expressed as $N = \langle V, R, P \rangle$, where V is a set of nodes, R is a set of directed edges, and P is a conditional probability distribution of nodes.

The start node of a directed edge is regarded as the parent node of the end node, and the end node is called the child node. A node with a parent node and no child nodes is called a root node, a node with a parent node and child nodes is called an intermediate node, and a node with child nodes without any parent nodes is called a leaf node.

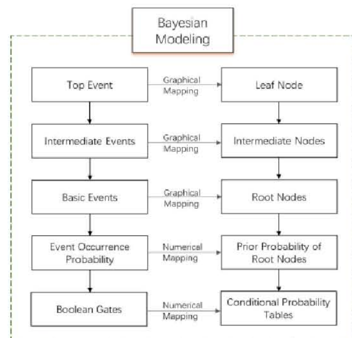

Fig. 2. Mapping FT to BN

As long as giving the prior probability of root nodes and the CPT of each parent node, the BN can realize bidirectional reasoning, and obtain decision information intuitively and concisely. Widely used in risk assessment and reliability assessment such as risk analysis of dust explosion scenarios [18],pressure drilling risk assessment [22], risk assessment of maritime piracy against offshore oil fields [23] and so on[24-26] .

C. Transformation from FT to BN

BN predictive analysis is similar to FTA, and can be used to figure out the probability of occurrence of any other node through the prior probability of root nodes or BEs and the CPT or logic gate between the nodes. However, the FTA has certain limitations: 1) The event has only two states of failure and non-fault. 2) Events are independent of each other. 3) The representation method of logical gates AND and OR is limited.

Compared with FTA, BN has the following conveniences: 1) BN can be implemented to describe the polymorphism of things. 2) BN contains the interconnection between events. 3) BN uses probability to describe the logical relationship of faults, which is more general. 4) BN facilitates reasoning and can dynamically update the probability of event occurrence and the probability of system failure. Due to the similarity in reasoning mechanism of BN and FT, and BN possesses the above advantages compared to FT, we transform the FT into BN. The transformation process of BN structure from FT is described below (see Fig. 2): 1) Transform all events in FT into BEs of BN. 2) Use the probability of events in FT as the prior probability of the root node in BN. 3) Connect arrows in BN according to the definition of event relationship in FT. 4) Translate logic gates in FT into a CPT of corresponding nodes in BN.

Each node corresponds to a random variable and its distribution is determined by the conditional probability distributions of parent nodes. The conversion process of FT to BN involves only a linear thinking conversion, lacking the horizontal connection between the nodes. Therefore, it is necessary to determine whether the nodes are associated according to the experience of senior experts based on the whole process perspective. If two nodes are related, insert an arc and arrow to connect the two points in BN.

D. Calculating Priori Probability

In this research, the experts' judgment is employed to compute the unknown BEs values. The integration of fuzzy theory and subjective opinions can help assessors to overcome any ambiguity [27]. Next, we introduce a method that shows how to apply expert languages and weight them to obtain fault data.

1) Fuzzy Analytic Hierarchy Process (FAHP)

Satty proposed the analytic hierarchy process (AHP), a quantitative technique [28], which can be used to construct complex systems hierarchically. As a decision system, it helps determine the relative importance of different choices [29]. Classic AHP does not consider the ambiguity of human judgment, and it is challenging to check whether the judgment matrix is consistent. An improved analytic hierarchy process is introduced to determine the weighting factors of different experts.

Laarhoven proposed a method of comparative judgment using triangular fuzzy representation[30]. Buckley determined the fuzzy priority of the comparison ratio of the trapezoidal membership function[13]. Chang introduced triangular fuzzy numbers as the pairwise comparison scale of FAHP [12]. Lin and Wang presented a mixed-function based on triangular fuzzy numbers and trapezoidal fuzzy numbers[31]. Ahmed introduced 9 FAHP methods and made comparisons [32]. This paper selects the Fuzzy Extent Analysis (FEA) method proposed by Chang [12]. The steps of FEA are as follows:

Step1: Let $X = \{x_1, x_2, \dots x_n\}$ be an object set and $U = \{u_1, u_2, \dots u_m\}$ a goal set. We get m extent analysis values $M_{g_i}^j$ for each object by taking each object for each goal respectively, where $j = 1,2, \dots m$ and $i = 1,2 \cdots n$.

Step2: Fixed i, let $M_{g_i}^1, M_{g_i}^2, \dots M_{g_i}^m$ be values of extending the analysis of ith object for m goal. The value of fuzzy synthetic extent with respect to the ith object is defined as

$$S_i = \sum_{j=1}^{m} M_{g_i}^j \oplus \left[\sum_{i=1}^{n} \sum_{j=1}^{m} M_{g_i}^j\right]^{-1} \quad (1)$$

Where $S_i = (l_i, m_i, u_i)$, $l_i \le m_i \le u_i$, and l_i, m_i, u_i stand for the lower, modal and upper value of support of fuzzy number respectively.

Step3: The probability of $S_1 > S_2$ is defined as a triangular fuzzy function as:

$$P(S_1 \ge S_2) = \begin{cases} 1 & m_1 \ge m_2 \\ \frac{l_2 - \mu_1}{(m_1 - \mu_1) - ((m_2 - l_2)} & m_1 \le m_2 \ , \mu_1 \ge l_2 \\ 0 & otherwise \end{cases} \quad (2)$$

The i[th] object's weight is : $d^* u_i = min V \ S_i \ge S_k$ where $k = 1,2, \cdots n, k \neq i$.

The normalized weight vector is as follows:

$$W = (d(u_1), d(u_2), \dots d(u_n))^T \quad (3)$$

2) Converting linguistic terms into fuzzy failure probabilities(FFP)

After calculating the expert weights, the expert languages are weighted to obtain the failure probability scores (FPS). The steps are as follows:

Step1: Obtain expert reviews and calculate the weighted average fuzzy number

The experts make the evaluation of BEs using linguistic variables, and the subjective opinions of a single expert are weighted and output to a single fuzzy set to form a fuzzy number for each BE.

$$Z_i = \sum_{j=1}^{n} w_j \cdot f_{ij}, \quad i = 1,2, \dots, m, \quad j = 1,2, \dots, n \quad (4)$$

where Z_i denotes the weighed fuzzy number of the ith BE, w_j represents the weighting factor of expert j, f_{ij} means the fuzzy number judged by the expert j on BE_i, m is the number of BEs, and n is the number of experts. The α-cut combines confidence , preference, or judgment of experts, which will yield an interval set of values[33]. The fuzzy number Z_i calculated is a subset of the solid line, and its membership function can be continuously mapped to the closed interval [0,1]:

$$f_z(x) = \begin{cases} f_Z^L(x) & a \le x \le b \\ 1 & b \le x \le c \\ f_Z^R(x) & c \le x \le d \\ 0 & otherwise \end{cases} \quad (5)$$

where $[a, d] \to [0,1]$, also, both $f_Z^L(x)$ and $f_Z^R(x)$ are liner.

Step2: Converting fuzzy numbers into fuzzy probability scores (FPS)

At this stage, we use the method of defuzzification to deal with the weighted fuzzy numbers. The conventional methods of defuzzification are the center of gravity (COG or centroid), the bisector of area, mean of maxima, leftmost maximum, and rightmost maximum [34]. In this paper, we adopt max-min aggregation methods, which were proposed by Chen [35]. First, defining the maximum and minimum fuzzy sets:

$$f_{max}(x) = \begin{cases} x, & (0 \le x \le 1) \\ 0, & (otherwise) \end{cases} \quad (6)$$

$$f_{min}(x) = \begin{cases} 1-x, & (0 \le x \le 1) \\ 0, & (otherwise) \end{cases} \quad (7)$$

Next, calculating the left and right scores $FPS_{\text{Right}}(Z)$ and $FPS_{\text{Left}}(Z)$ of the fuzzy number $f_z(x)$, as shown in Fig. 3. The formula is as follows [36] :

$$FPS_{Right}(Z) = {}^{sup}_{x}[f_z(x) \wedge f_{max}(x)] = d/[1 + (d - c)] \quad (8)$$

$$FPS_{Left}(Z) = {}^{sup}_{x}[f_z(x) \wedge f_{min}(x)] = (1 - a)/[1 + (b - a)] \quad (9)$$

Finally, obtain the final FPS according to the following formula:

$$FPS(Z_i) = [FPS_{\text{Right}}(Z_i) + 1 - FPS_{\text{Left}}(Z_i)]/2 \quad (10)$$

FPS is a definite score that represents the experts' belief in the likelihood of an event.

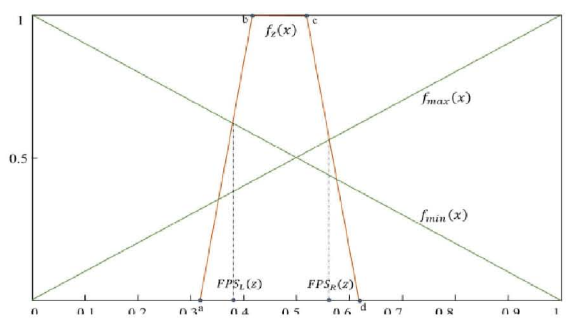

Fig. 3. The simplified computation of right and left FPS

Step3: Calculating fuzzy failure probabilities (FFP)

For further reasoning, we need to convert FPS to fuzzy failure rate that divides the frequency of failures by the total chance that the event may have, and the result is the incidence of accidents. Onisawa[37] proposed the following equation to compute failure probability from FPS:

$$\text{FFP} = \begin{cases} \frac{1}{10^K} & FPS \neq 0 \\ 0 & FPS = 0 \end{cases} \quad (11)$$

$$K = 2.301 \cdot [(1 - FPS) / FPS]^{\frac{1}{3}}$$

Therefore, by following the above processes, the failure probability of all BEs can be obtained. These failure probabilities can be used as the initial evidence node inputs and then we use the BN to perform forward reasoning and reverse reasoning.

III. Vaccine Safety System Analysis

As we all know, a vaccine is a particular medicine. The development, approval, production, transportation, and supervision of vaccines not only require operational efficiency and entire process of vaccines from the production end to the injection end to be within the temperature range necessary for safety. Vaccine safety is the safety of the result and the safety of the process in the whole process. The safety of the process is an essential guarantee for the safety of the result.

A. Hazard analysis

Hazard and operability methodology is a process of hazard analysis technique used worldwide for studying not only the hazards of a system[38]. We surveyed the literature to collect the factors influencing vaccines' safety, compiled the factors influencing the safety of vaccines at various links, and corrected them by issuing questionnaires and consulting relevant experts to determine the factors affecting the safety of vaccines.

Risk events during the research and development process include unreasonable clinical design and irregular laboratory management. There may be insufficient professional standards or attitudes of review and approval experts and personnel in the review and approval process. In the production process, risk events include backward production equipment, environmental pollution, raw material problems, and poor packaging. In the transportation process, there may be improper distribution plans, loss of goods, bad weather, improper loading and unloading, traffic accidents, transportation equipment failure, inadequate monitoring, pre-cooling failure, hardware failure, damaged insulation box, damage to cold storage, refrigeration unit failure, backup power supply failure, review problems, information system failure, or personnel operation failure. In the monitoring process, there may be problems with incomplete recovery of vaccines.

B. Fault tree analysis

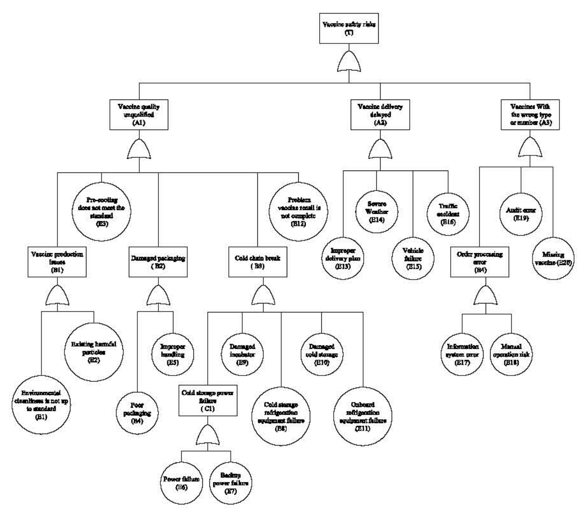

Fig. 4. Fault tree for vaccine safety

To apply the FT to analyze the whole process of the vaccine, first, we defined the undesirable system fault events and used them as the top events, then looked for the direct cause that can make the top event happen as the intermediate cause. In the vaccine safety system, there are three types of secondary intermediate events: 1) The quality of the vaccine does not meet the requirements: the vaccine production link is contaminated or the temperature is too high during transportation. 2) The quantity and type do not meet the requirements: the vaccine is not delivered to the third-party manufacturers in the prescribed quantity, which results in the lack of vaccine and cannot be vaccinated according to the prescribed time and dose. 3) Delay in delivery of vaccine: failure to deliver to the designated place at the prescribed event may result in the inability to vaccinate in time. We analyzed the next level of intermediate events down by layer until the BEs are found. The FT of the vaccine safety system constructed is shown in Fig. 4.

C. *Mapping Fault Tree to Bayesian Network*

There are some base events in the FT that can be regarded as the same situation, and they are merged when they are transformed into BN. Besides, some BEs with a relatively small probability of occurrence need no further discussion, and it is not considered when constructing the BN model. Also, add some horizontal connections as appropriate based on expert opinions: bad weather can cause traffic jams. The BN of the vaccine safety risk system is shown in Fig.5.

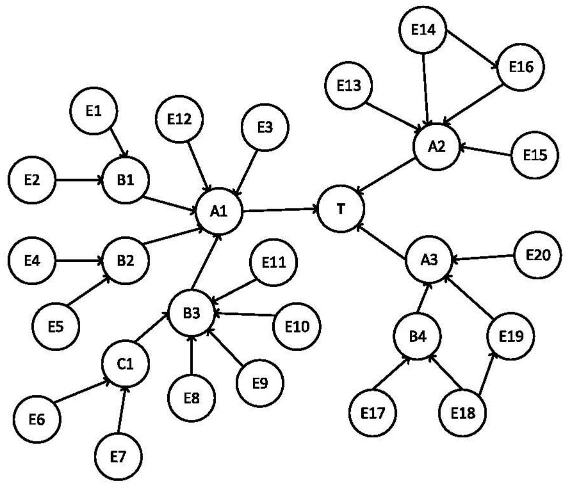

Fig. 5. Bayesian Network based on FT in Fig.4

D. *Calculating Priori Probability*

Using the failure rate as the BE input, two-way reasoning can be performed. However, due to insufficient data, it is difficult to assign accurate values to all BEs. Therefore, this paper combines FAHP and fuzzy set theory to obtain the input prior probabilities.

1) Calculation of expert weights based on FAHP

This article employed the Delphi method to collect experts from five fields: vaccine development, vaccine production, vaccine transportation, and vaccine supervision. Although each expert has rich experience, each expert's understanding of the difference in the probability of different BEs may cause significant changes in systematic reasoning and prediction. Table 2 shows their background information, and the weight of each expert was calculated according to the FAHP steps in Section 2.4.1 above:

TABLE I. EXPERTS' PROFILES

No.	Institution	year	Edu.	Title	Job field	W_i
1	Teaching and Research Unit	18	Doctor	Senior	Develop-ment	0.3077
2	Biopharmaceutical companies	3	Master	Primary	Production	0.0879
3	Administrative department	9	Bachelor	Vice-senior	Supervi-sion	0.1758
4	Medical and health institutions	8	Master	Primary	Transporta-tion	0.1758
5	Public health department	17	Bachelor	Middle	Vaccina-tion	0.2527

2) Converting linguistic terms into Fuzzy Failure Rates(FFR)

Fuzzy set theory can be implemented to deal with the uncertainty of failure probability expressed in language [39]. Saaty discussed that the proper number for expert judgment is between five and nine[40]. Through email, consulting experts about the possibility of BEs. The terms representing the probability of BE occurrence are divided into seven levels: very high (VH), very high (H), fairly high (FH), medium (M), and fairly low (FL), very low (L), very low (VL). This paper took the membership function of triangular fuzzy numbers and trapezoidal fuzzy numbers as a mapping relationship between the experts' language definition, as shown in Fig. 6.

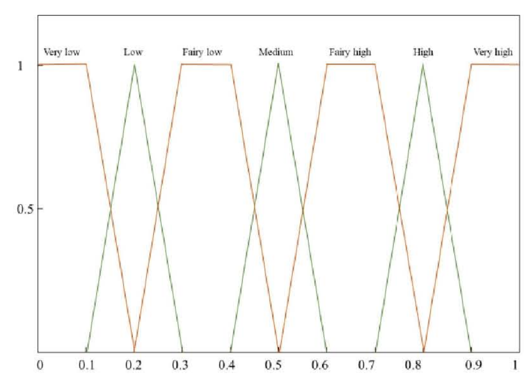

Fig. 6. Fuzzy membership functions

The expert comments obtained for each BE are shown below. According to the method proposed in Section 2, firstly, we calculated the weighted average fuzzy number, then turned the fuzzy number into fuzzy probability scores, and finally converted FPS into FFP. The result is shown in Table 3.

TABLE II. EXPERTS' OPINIONS, CORRESPONDING FUZZY NUMBER, FPS, FFR OF BEs

Events	Linguistic judgments of experts					Defuzzi-fication	FPS	FFP
	1	2	3	4	5			
1 Environme-ntal cleanliness is not up to standard	VL	L	FL	M	L	26.00%	0.05%	0.05%
2 Existing harmful particles	VL	VL	FL	L	FL	23.45%	0.04%	0.04%
3 Pre-cooling does not meet the standard	H	L	FH	VH	M	65.35%	1.37%	1.37%
4 Poor packaging	M	M	FH	M	H	59.29%	0.93%	0.93%
5 Improper handling	H	FH	M	FL	M	57.19%	0.81%	0.81%
6 Power failure	M	FL	FL	L	M	41.61%	0.27%	0.27%
7 Backup power failure	VL	L	M	H	M	40.30%	0.24%	0.24%
8 Cold storage refrigeration equipment failure	M	L	FL	H	FL	46.55%	0.39%	0.39%
9 Damaged incubator	FH	H	M	H	FH	64.84%	1.33%	1.33%
10 Damaged cold storage	H	M	FH	VH	H	74.72%	2.49%	2.49%
11 Onboard refrigeration equipment failure	M	H	FH	M	M	54.80%	0.69%	0.69%
12 Problem vaccine recall is not complete	VL	L	M	FL	L	20.67%	0.02%	0.03%
13 Improper delivery plan	M	FL	L	M	FH	47.45%	0.42%	0.42%
14 Severe Weather	H	FH	M	H	VH	74.50%	2.46%	2.46%
15 Vehicle failure	VL	L	M	H	FL	36.78%	0.18%	0.18%
16 Traffic accident	L	L	M	FL	L	29.92%	0.09%	0.09%
17 Information system error	VL	L	L	FL	VL	17.74%	0.01%	0.01%
18 Manual operation risk	L	M	FL	L	VL	24.28%	0.04%	0.04%
19 Audit error	L	M	VL	FL	L	25.28%	0.05%	0.05%
20 Missing vaccine	FL	L	VL	L	L	24.67%	0.05%	0.05%

E. Computing and Analysis

By inputting the prior information of the vaccine safety system to analyze the BN, the probability of failure can be calculated effectively, and an appropriate preventive maintenance strategy can be established accordingly.

1) Computing probability of TE

Using Netica software, we inputted the prior probability data and CPT into the BN constructed in Fig. 7. The updated value of the system unreliability is 0.113.

After finding the MCS by using the Boolean method, calculate unreliability of the system in FT according to the following equation [19] :

$$P(T) = 1 - \prod_{i=1}^{20}(1 - p_i) \quad (11)$$

Where p_i represents the prior probabilities of BEs. The result is 0.1134, which is almost the same as the unreliability calculated in BN.

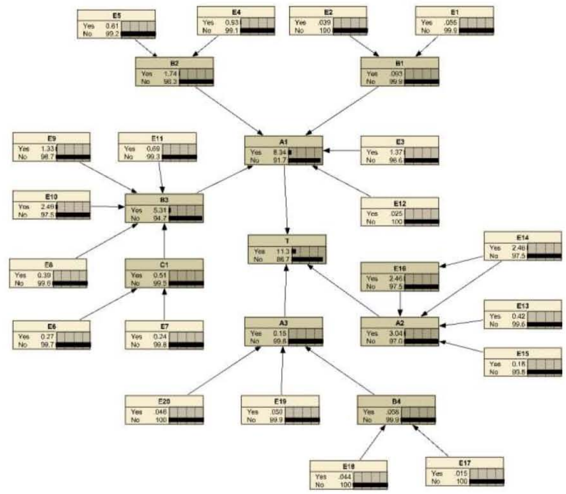

Fig. 7. Calculation the unreliability of the vaccine safety system in Netica

2) Sensitively analysis

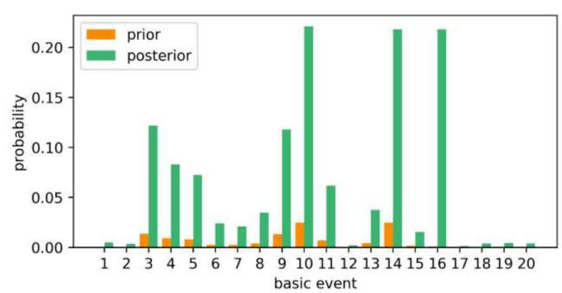

Fig. 8. Comparison of the prior-posterior probability of basic events

Assuming that the system fails, the vaccine safety risk (T) is set to 1, and the posterior probability derived from the BN reverse inference is used as an index to evaluate the degree of each basic event affecting the vaccine safety risk. For events with a significant prior probability, the posterior probability is not necessarily significant, and the impact on system security is not necessarily massive; However, the BE with a sizeable posterior probability, which has an enormous impact on system security, is a crucial target for prevention and improvement. Fig. 8 gives the numerical comparison of the posterior probability and the prior probability.

Given the value of the posterior probability of each BE calculated based on the BN, we can get the importance of BEs:

$I_P(10) > I_P(14) = I_P(16) > I_P(3) > I_P(9) > I_P(4) > I_P(5) > I_P(11) > I_P(13) > I_P(8) > I_P(6) > I_P(7) > I_P(15) > I_P(1) > I_P(19) > I_P(20) > I_P(18) > I_P(2) > I_P(12) > I_P(17)$

The results show that the posterior probabilities of E10, E14, E16, E3, and E9 are very high. All of the above-mentioned incidents occurred in the transportation of vaccines, which shows the importance of transportation to the vaccine safety system. Vaccine transportation is divided into incubator transportation and refrigerated truck transportation. Both E10 and E9 are risk events that are often encountered in incubator transportation. Therefore, the risk of incubator transportation is high. Severe weather, traffic accidents, and failure to meet pre-cooling standards are key factors leading to substandard vaccine quality. Also, the posterior probability of E4, E5, E11, E13 is fairly high.

After clarifying the importance of each BE influencing the top event, corresponding measures can be taken to strengthen the safety of the vaccine system's safety. For example, to deal with the failure of vehicle-mounted refrigeration equipment, the relevant unit should formulate a strict preventive protection plan to ensure the regular operation of the refrigeration device of the refrigerated vehicle, to ensure that the temperature is always maintained at the required set value, and to reduce fluctuations. The problem of improper distribution planning can be solved by reasonably planning the time and route of distribution and querying the road condition information promptly.

In 2011, up to 2.8 million doses of childhood vaccines were lost in five countries due to a break in the cold chain[41] . The problem of transport not only hinder the ability to provide needed immunizations but also yield finance waste of government. According to the World Health Organization(WHO), as of November 2021, about 7 billion vaccine doses have been administered globally. DHL estimated that the delivery of 10 billion vaccine doses globally would require approximately 15,000 flights and 15 cooling boxes[42]. This achievement is the result of the complicated supply chain network in which transport plays a crucial role. However, an expanding population of getting Covid-19 vaccines and diversity of delivery strategies may result in stock-out, ineffective vaccines, inadequate cold-chain capacity, all of which have performance of vaccine and cost implications. By comparing with the reliability analysis of FT, the results of BN inference are verified. A sensitivity analysis was further conducted to identify critical subsystems and components of vaccine safety issues. The sensitivity analysis can be used as an essential reference for future diagnostic analysis and maintenance strategies.

IV. Conclusion

Vaccines play an important role that cannot be ignored in protecting human health and preventing infectious diseases. Constructing a vaccine safety network and a risk warning system can effectively detect vaccine safety.

For the problem that the structure of the vaccine safety system is enormous, complex, and difficult to construct, in this paper we drew on the analysis method of system reliability to conduct a hazard analysis on the vaccine safety system and then constructed a system failure FT. Based on the similarity between the BN and the FT and the advantages of BE, this paper converts the FT into a BN according to the regular conversion rules. For the problem that the data of failure events is difficult to obtain, we consulted experts and used FAHP to minimize the subjectivity of expert evaluation. By combining fuzzy sets and expert evaluation, we computed the prior probability of BEs. After that, the two-way inference function of BN was used to comprehensively evaluate the vaccine safety system's reliability, reveal the main causes of vaccine safety problems, and provide a basis for formulating specific measures to improve the reliability of the vaccine safety system.

The analysis method proposed in this paper can solve similar problems: the structure is difficult to obtain and the data depends on the language of experts. In addition, the research on vaccine risks in this article will help the government and vaccine-related companies to identify factors affecting vaccine safety risks in advance and take effective measures in advance to avoid the occurrence of risk events, which has important practical significance for protecting human health and consolidating social stability.

We consider the follow-up work to continue to study the vaccine safety system and collect big data for analysis. At the same time, we have a plan to extend the method used in this article to analyze the safety of related special foods or medicines.

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