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MEDICAL DEVICE QUALITY RISK JUDGMENT METHOD BASED ON RFID TAG IDENTIFICATION

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Abstract: In order to better improve China's medical level and ensure the use quality of medical devices, the quality risk judgment method of medical devices is optimized by integrating the current international medical quality index system, combined with the RFID tag identification principle, combined with the RFID tag identification principle for feature collection, and the medical device quality risk early warning model is constructed, The risk index evaluation is carried out to accurately describe the characteristic dynamic response of medical information. Finally, the quality risk judgment method of medical devices based on RFID tag identification is repeatedly verified in combination with Delphi method, The quality risk judgment method of medical devices based on RFID tag identification has high accuracy and practicability in the process of practical application, and fully meets the research requirements.

Keywords: RFID tag identification; medical apparatus and instruments; Risk judgment;

0 Introduction

This paper briefly introduces the research background and significance, and describes the current situation and progress of medical device risk management[1]. The organizational structure for the research and development of medical devices and the development process of medical devices are sorted out in detail[2]. A risk management group composed of experts in the relevant fields identifies the possible risk factors by means of interview and brainstorming, identifies the list of 16 risk factors in five categories that may arise in the research and development of medical devices, conducts an empirical study of the list of risk factors by means of questionnaire survey, and ensures the accuracy and objectivity thereof[3]. Formulate reasonable risk response measures according to different risk types and according to mitigation, avoidance, sharing and acceptance strategies, and monitor the response to risks. The risk management of the research and development project of the HIFU treatment system is used as a case study to carry out risk management according to the above theoretical methods, analyze and control the risks therein, and verify the feasibility and operability of the theoretical research[4]. This paper is an exploratory study on the application of risk management indicators and methods in the process of medical device R&D from the perspective of project, and its research results have some guiding and reference value for the medical device R&D work, and are also helpful to the further deepening of project risk management theory.

1 Method for determining quality risk of medical devices

1.1 quality identification process of medical devices based on RFID tag identification

RFID is a communication technology, which can identify targets and read and write relevant data through wireless signals. It has the following characteristics: larger data storage capacity,

higher reading and writing efficiency and more convenient data update; Faster data reading and writing, wider target range and low requirements for reading and writing conditions; The package is easy to use and can be embedded in the product[5]. High data reliability, strong uniqueness and good encryption effect; It can adapt to various harsh environments such as high temperature and humidity and general acid-base environment, with long service life. The flow diagram of the management platform is shown in the figure 1 below.

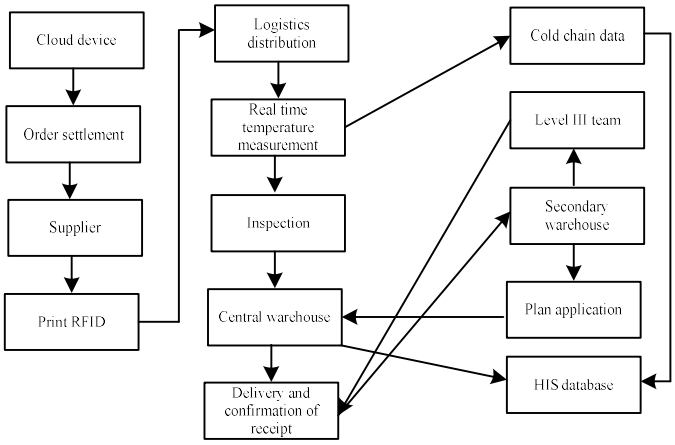

Fig.1 Flow diagram of fine management platform

The medical device risk management standard indicates that risk management can be a part of the quality management system[6]. The quality management system is of great significance for risk management, and the structure of risk management standards is also easy to integrate risk management into the quality management system. Therefore, medical devices should not oppose and separate the risk management and quality management system, but integrate the risk management into the quality system and operate effectively, so as to facilitate the systematicness and integrity of risk management[7]. In the medical device quality management system standard, the requirements of risk management are specified, and the medical device so14971 standard is required as the guide to carry out risk management. The combination of risk management and quality management system will make the quality management system more efficient, fundamentally control the risk of medical devices within an acceptable range and ensure the safety of medical devices. There are many interactive relationships between the quality management system and the risk management process: many risk management activities can be carried out through the implementation of the quality management system to reduce duplication of work and improve effectiveness; Many risk management tools are also quality management tools[8]. The interrelated parts of medical device quality management and risk management include management responsibilities, document control and records, personnel qualification training and resources, policies and post marketing monitoring. Based on this, the process of medical device quality risk management system is constructed, as shown in Figure 2:

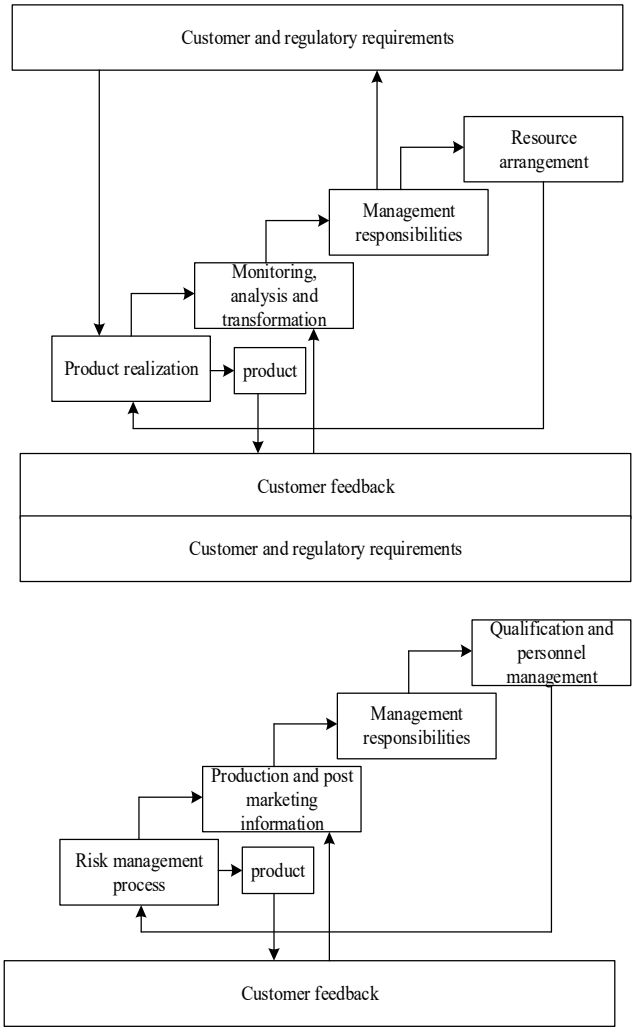

Fig. 2 Flow chart of medical device quality risk management system

The inherent risk of medical devices refers to the damage to people, environment and property caused by design, materials, technology and various electromagnetic radiation. According to the risk degree, medical devices can be divided into class I, class II and class III. The risk degree is mainly determined by the structural characteristics, use form, use state, contact with human body and other factors of the device[9]. According to the severity of nonconformities, the quality risk of medical devices is divided into three levels: medical device quality risk of medical device correction system, medical device quality risk of medical device I, medical device quality risk of medical device II and medical device quality risk of headquarters[10]. Medical devices can be classified according to their own situation. The frequency classification is divided into five levels: very low, low, medium, high and very high. The classification standard of frequency is shown in the table 1.

Table 1 Classification Standard of nonconformity frequency

Frequency				
a	Very low	≤1 in 150,000	>6%	≤6.8ppm
b	low	>1 in 150,000	>0.26%	>6.8ppm

c	secondary	>1 in 150,000	>0.0067%	>66.8ppm
d	high	>1 in 500	>0.00068%	>2600ppm
e	Very high	>1 in 30	≤0.00068%	>60,000ppm

According to the severity of nonconformity, it is divided into five levels, and the risk assessment can be carried out by the method of design or process failure mode.

1.2 Medical device quality risk assessment algorithm

According to the structural characteristics, it can be divided into passive and active medical devices; Medical devices can be divided into contact with human body and non-contact with human body according to whether they are in contact with human body[11]. If the production of medical devices fails to comply with the requirements of the management specifications for the means of production of medical devices, the produced devices will be inconsistent with the registered or filed product technical requirements, affecting the safety and effectiveness of medical devices[12]. In the risk factor importance ranking hierarchy, the highest level criterion is the risk factor importance of each stage. At present, the method of logistic multiple regression model is still the most widely used in the screening of risk factors and the control of confounding factors in RFID tag identification[13]. It is widely used and not limited to medicine. And has a complete set of methods for model construction and evaluation. Firstly, the general form of the conceptual formula of the method is:

$$logit\,\mathrm{prob}\left(y_{ij}=1|\ X_{ij}\right)=\alpha+\beta X_{ij}\text{-}L\left(y_{ij}\right) \quad (1)$$

Where, α is one of the previously screened indicators, β is the outcome variable, X_{ij} is the occurrence of index outcome[14]. It is usually represented by $L\left(y_{ij}\right)$. Further, calculate the standardization rate

$$\hat{p}_{ij}=\frac{\exp\left(\hat{u}+\hat{\beta}x_{ij}\right)}{1+\exp\left(\hat{a}+\hat{\beta}x_{ij}\right)}=L^{-1}\left(\hat{\alpha}+\hat{\beta}X_{ij}\right) \quad (2)$$

Taking the hospital as the unit, the actual observed occurrence and the predicted occurrence are recorded as y_{ij}, and the ratio conversion is carried out after summation, multiplied by the incidence P of all statistics[15]. Then the formula for the standardized incidence of fixed effects in the second hospital is:

$$SR_i=\left(\sum_{j=1}^{n_i}y_{ij}\Big/\sum_{j=1}^{n_i}\hat{p}_{ij}\right)*p \quad (3)$$

In the second layer, the criteria should consider three aspects: the probability of risk factors, the loss when risk occurs and the uncontrollability of risk factors. In normal risk assessment, only risk probability and risk loss are considered for the importance of risk factors, but this will lead to a certain evaluation deviation[16]. Considering that the risk response measures adopted for the risk factors that can be effectively controlled (reduced, avoided, accepted and shared) and the uncontrollable risk factors in the medical device R & D project will be quite different, when ranking the risk factors, the uncontrollability of the risk factors will be used as the evaluation

criterion of a grade with the risk probability and risk loss[17]. The third level is the risk types of medical device R & D projects, including technical risk, management risk, market risk, policy risk and financial risk. The fourth level is the risk factors included in different risk types.

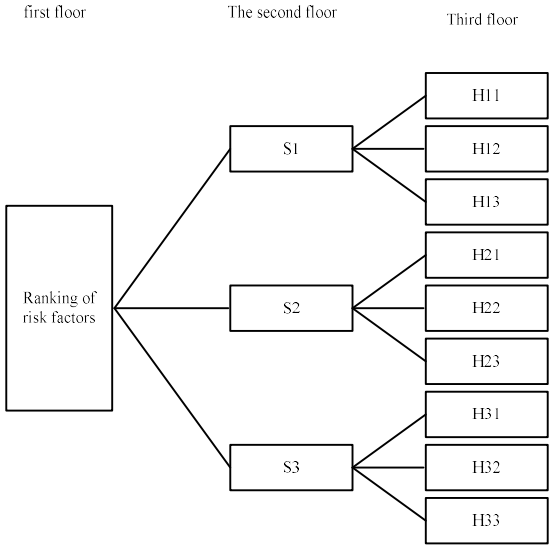

Fig. 3 Schematic diagram of hierarchical structure model

The paired comparison matrix refers to the influence degree of each index of this layer on an index of the upper layer, which is expressed by numerical value, showing the relative influence degree of two indexes on an index of the upper layer a_{ij}. The construction method of paired comparison matrix is to compare the indexes related to the risk factor in this layer in the form of matrix.

$$A = \begin{pmatrix} a_{11} & a_{12} & \cdots & a_{1n} \\ a_{21} & a_{22} & \cdots & a_{2n} \\ \cdots & \cdots & \cdots & \cdots \\ a_{n1} & a_{n2} & \cdots & a_{nn} \end{pmatrix} \quad (4)$$

Based on the constructed hospital medical quality risk early warning index system, a third class hospital is selected as the empirical research object to evaluate its medical quality risk[18]. Therefore, the risk early warning index system established in this study can be applied and tested, so as to better guide practical activities, and contribute to the improvement of the theoretical system and new research problems[19]. According to the weighted sum of the occurrence frequency of risk events, the comprehensive index, i.e. the risk value, is expressed by "R", where u represents the weight of an index (as shown in the table) and P represents the probability value of the index (the actual occurrence value of index events collected on site).

$$R = A\sum_{i=1}^{4} U_i \left(\sum_{j=1}^{n} U_{ij} * P_{ij} \right) \quad (5)$$

When $R < 0.35$, it is a green warning, indicating that there is no medical risk or the risk is very small, and normal medical activities can be carried out: when $0.35 \leq R < 0.65$, it is a yellow warning, indicating that the medical risk is relatively large. Medical institutions should improve

supervision, timely feed back information and need to take corresponding measures in time: when $R \geq 0.65$, it is a red warning, indicating that the medical risk is the largest, Strong measures need to be taken immediately to prevent the occurrence of medical risk events or minimize the harm of risk events[20]. This paper tries to put forward specific countermeasures, as shown in the figure 4:

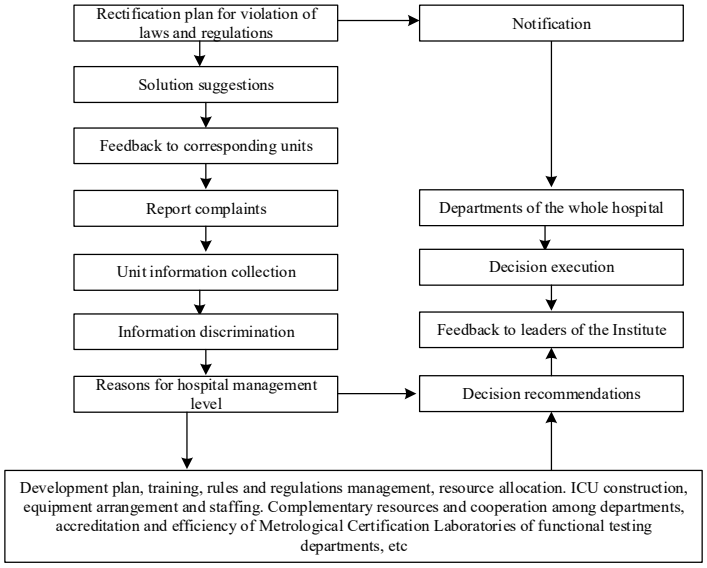

Fig. 4 Quality risk early warning process of medical devices

Based on the RFID tag identification principle, the quality tag in the medical device quality information evaluation system is set as DKT. The quality index content label is set to SKT. Tags without potential threats are SNKT. The characteristic label of practice quality judgment is GKT. The label that does not master the judgment of practice quality is GNKT. There are two formulas:

$$\begin{aligned} \{\mathrm{SNKT}\} &= \{\mathrm{DKT}\} - \{\mathrm{SKT}\} \\ \{\mathrm{GNKT}\} &= \{\mathrm{SKT}\} - \{\mathrm{GKT}\} \end{aligned} \quad (6)$$

In the process of RFID tag identification, it is assumed that the trust of user $\mathrm{U_A}$ in local domain a is calculated. At this time, it is necessary to consider: the behavior of the user when accessing the local domain; When accessing extraterritorial resources, extraterritorial will evaluate their access behavior. However, in order to prevent malicious evaluation outside the territory, it is necessary to consider the trust between the two domains to prevent users from performing well in the early stage of access and malicious attacks in the later stage of access. In view of the above three situations, it is concluded that the calculation formula of domain A's trust in user $\mathrm{U_A}$ is

$$T_A(u_A)^i = \begin{cases} 0.5 & i = 0 \\ \dfrac{C_{D_1}(u_A) \times T(A \to D_j) + T_A(u_A)^0}{2} & i = 1 \\ \dfrac{C_{D_1}(u_A) \times T(A \to D_j) + \sum_{n=1}^{i-1} T_A(u_A)^i \times F(c, t_n - t_{n-1})}{2} & i \square 2 \end{cases} \quad (7)$$

Of which: $T_A(u_A)^i$ Indicates the user's trust in local domain a after the user's *i*-th access; $C_{D_j}(u_A)$ indicates the evaluation of domain D_j on user $\mathrm{U_A}$ after user $\mathrm{U_A}$ accesses domain D_j

resources; $T\left(A \to D_j\right)$ Indicates the trust of domain a to domain D_j; $F(c, t_n - t_{n-1})$ is the time decay function, which indicates that in the context C, the user can access any two times t_n and t_{n-1} decay rate in time. Where $F(c, t_n - t_{n-1})$ meets:

$$F\left(c, t_n - t_{n-1}\right) = \frac{1}{1 + \frac{t_n - t_{n-1}}{R(c, A, B, \cdots)}} \quad (8)$$

Where $R(c, A, B, \ldots)$ is the attenuation rate, which is determined by the system according to the specific situation. Suppose that to calculate the trust degree of user a in domain a in domain B, we need to consider not only the evaluation of user a in domain B, but also the recommended trust degree of user a in other domains except domain a and domain B. When users send resource access requests, they submit some of their own attributes to pep, but each attribute has different sensitivity. In order to obtain the most real risk prediction results of medical devices, the normalized statistics of sensing data fully comply with the application principles of support vector machine risk prediction and dynamic game supervision. While coordinating the data transmission pressure in the model prediction system, it also controls the improper diffusion of data boundary caused by the over fitting of risk information. On the premise that other influencing factors remain unchanged, the normalized prediction statistical operation is only related to the support strength of sensor nodes and the information over fitting application coefficient. The so-called sensor node support strength refers to the average transmission promotion ability of risk prediction organizations at all levels, which is often expressed as $\overline{j}$, as a restrictive index vector in the data sensing environment, it does not change with the increase of the total amount of medical device risk prediction data. The information over fitting application coefficient can be expressed as $\dot{\mu}$,affect the specific processing and implementation depth of medical device risk prediction data, and directly determine the final implementation result of normalized prediction statistical behavior. Simultaneous $\overline{j}$, $\dot{\mu}$, The normalized prediction statistical formula of medical device risk prediction data can be expressed as:

$$P = \sqrt{\frac{\int_{\hat{e}}^{\breve{e}} y \cdot \overline{j}}{4\dot{\mu}R^2} q\chi^2} \quad (9)$$

Among them, $\hat{e}$ represents the lower limit boundary coefficient of risk prediction data normalization statistics, $\breve{e}$ represents the upper limit boundary coefficient of risk prediction data normalization statistics, y represents the sensing offset difference of the data node, R represents the real value of statistical processing of medical device risk prediction data, q represents the simulation prediction vector, χ represents the prediction processing basis vector of the sensing data.

1.3 Realization of medical device quality risk judgment

The quality system meets the requirements of laws and regulations and the quality policies and objectives of medical devices, in the quality management system, combined with the RFID tag identification principle. According to the processes of quality management system and risk management system, 18 main processes can be classified as shown in Table 2.

Table 2 Correspondence between quality management and risk management process

Risk management system process	Quality management system process	Corresponding important process	Explain
Literature and airborne	Literature and airborne	Document control and quality control	-
Governance work	Governance work	Governance review, quality objectives and direction	-
Qualification and staff control	Resource arrangement	Training and resource arrangement	-
Risk management	Product realization	Design and product R & D, external product management, elimination, process management, confirmation of purchased products, and product integration	Risk management runs through the whole product law and is used in many product quality processes
Production and post market news	Supervision and improvement	Internal audit, customer communication, correction, prevention and improvement, nonconforming product management and complaint	-

The specific methods of implementing RFID tag identification risk management within the framework of quality system, as well as the risk management practice of medical devices. From the perspective of RFID tag identification and quality risk prevention of medical device products, select the product design and development process to control the product risk at the lowest level in the design process; From the perspective of risk monitoring, study the risk information feedback, investigation and analysis measures in the complaint management process, select the management review process from the perspective of risk communication, communicate and review the risk information within the organization, select the correction and prevention process from the

perspective of RFID tag identification risk correction, and study the specific methods to integrate the risk management process into the correction and prevention process. If the feature dimension of the sensing space is too high, the so-called "information disaster" response event will occur. The most direct consequence is that the risk prediction data of medical devices based on RFID tag identification have over fitting behavior. The most fundamental reason for this phenomenon is that when the sensing dimension increases, the density of data samples for risk prediction of traditional Chinese medicine devices inserted into the browsing table will become more and more sparse. With the increasing feature dimension of the sensing space, the probability level of the risk data training sample falling into the support vector machine risk prediction and dynamic game supervision model will become infinitely smaller, so it is easier to find a category standard and divide the original medical device risk prediction data into multiple hyperplane subjects. However, the more sample data in the over fitting processing state, the more obvious abnormal feature States will be presented for these risk information. These features show a relatively good occupancy state in the data browsing table, but the training node may have an incomplete utilization transmission state, which will aggravate the original over fitting problem of medical device risk prediction data. Figure 5 shows the risk data in the whole RFID tag identification and repair process.

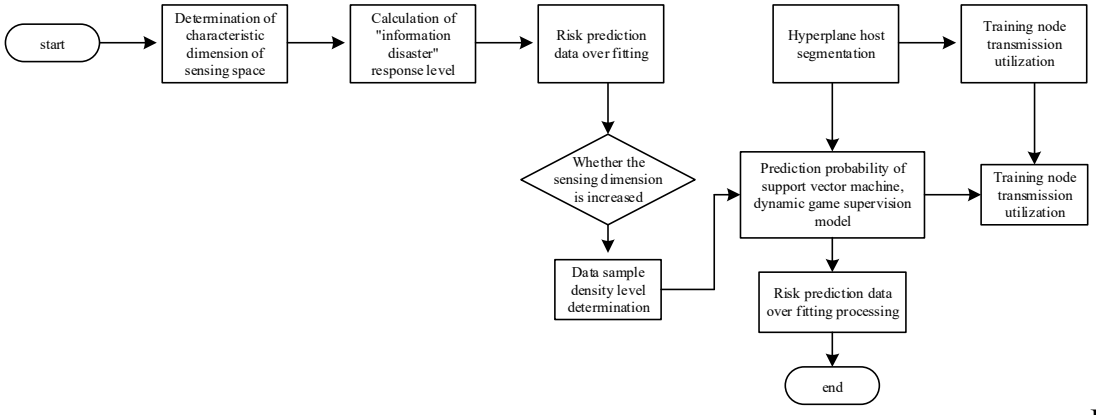

Fig. 5 Flow chart of medical device risk data over fitting processing

The necessity of medical device risk identification is that all appropriate personnel know the remaining risks, even after the implementation of risk control measures. RFID tag based identification methods, such as warning tag, user manual, customer notice, etc., shall be used for the communication of necessary RFID tag identification risk information at the same time. In the process of management review, according to the organizational characteristics and the risk degree of products, design the types and different depths of internal communication, such as the mode and specific frequency of communication, so that relevant personnel in the medical device can understand the problems and risks in the implementation of the quality system and the residual risks after the implementation of risk control measures, ensure that problems and risks are fully communicated within the organization. As the most important form of internal communication in the medical device quality management system, medical devices have established a strict management review process, and its specific imitation is worthy of learning from medical devices in China. The flow chart of medical device management review is shown in the figure 6 below.

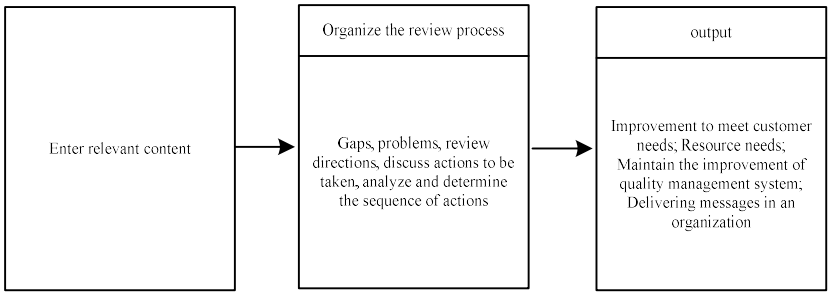

Fig. 6 Process of medical device management review

The management review is conducted at different levels, from low to high, and the review information, such as review decisions and action items, are distributed from high to low. Based on this, the risk identification and judgment of medical device quality are realized, the identification accuracy is guaranteed, and the review process is simplified.

2 Analysis of experimental results

In order to verify the practical application effect of medical device quality risk determination method based on RFID tag identification, experimental detection is carried out. Reliable and effective sample data is the basis to ensure the results of scientific quantitative analysis. After sorting out the obtained data, the reliability is verified by reliability analysis. Reliability refers to the consistency of the results obtained when the same method is used to measure the same object repeatedly. Reliability reflects the reliability and delicacy of the measurement method. The measurement results of the measurement procedures have reference value only if they have high reliability. The methods of reliability analysis mainly include test-retest reliability method, duplicate reliability method, half reliability method and Cronbach coefficient reliability method. Among them, Cronbach coefficient reliability method is the most commonly used method, and its formula is:

$$a = (k/(k-1)) * (1-(\sum s12)/ST2)(10)$$

Where, K is the total number of questions in the scale, SI2 is the intra question variance of the score of question I, and ST2 is the variance of the total score of all questions. It can be seen from the formula that coefficient and evaluates the consistency between the scores of various questions in the scale, which belongs to the internal consistency coefficient. The scholar Devellis (1991) believe that the reliability coefficient of the total scale should be above 0.8, between 0.70 and 0.80 is acceptable, and the subscale should be above 0.70, between 0.60 and 0.70 is acceptable. If it is below 0.6, the questionnaire should be redesigned. The internal consistency results of the primary indicators obtained from the sample data through SPS statistical analysis software are shown in the table 3.

Table 3 Internal consistency analysis results of primary indicators

Variable name	CRONBACH'S ALPHA	Number of test items
Technology crisis	0.795	5
Crisis management	0.729	5
Market crisis	0.863	4

Policy crisis	0.836	4
Financial crisis	0.798	3

As shown in the table 3, the coefficients corresponding to the first level indicators of the compliance survey of the medical device risk assessment project exceed 070, of which the Cronbach's alpha coefficient of market risk and policy risk is higher than 0.80, indicating that its internal consistency is very good; The coefficients of technical risk, management risk and financial risk are greater than 0.70, indicating that their internal consistency is good, all within the acceptable range, and the survey results are effective. It is known that TSV (risk data judgment sensitivity) index can directly reflect the transmission sensitivity of risk prediction data. Under normal circumstances, the lower the TSV index value, the lower the transmission sensitivity of risk prediction data, and vice versa. By comparing the traditional neural network method with the method in this paper, Figure 7 shows the specific changes of TSV index and given detection time.

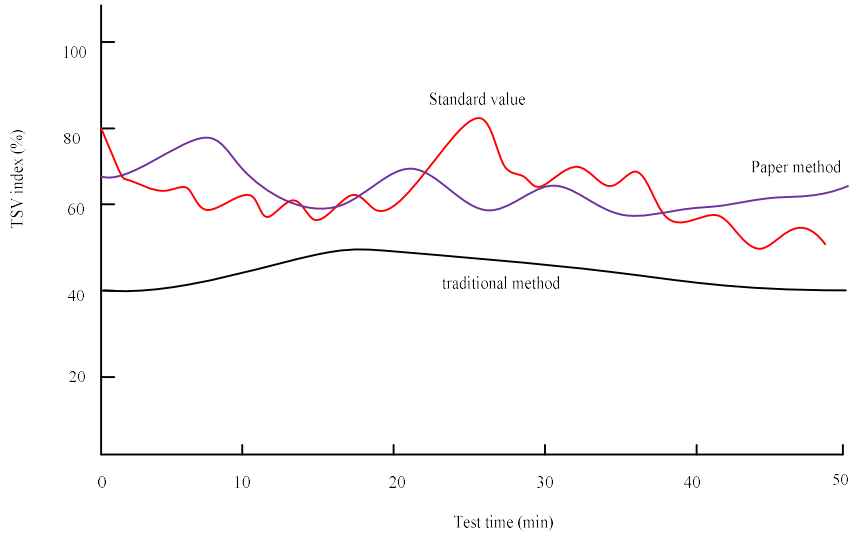

Fig. 7 Comparison Chart of risk data judgment sensitivity

To sum up, compared with traditional methods, this method has significantly higher sensitivity to the quality risk stability of medical devices in the process of practical application, and is relatively closer to the expected value. Further make statistical analysis on the compliance survey data of risk factors of all medical device R & D projects, including data volume, maximum value, minimum value, mean value and standard deviation. As shown in the table 4:

Table 4 Statistical analysis of compliance of risk factors

Index item	Data volume	Minimum value	Highest value	Mean value	Standard deviation
Technological reform	70	5	7	5.9	0.835582
Uncertain technical future	70	4	7	5.9	0.835582
Technology is complex and the important technology is not expected	70	5	7	5.9	0.60285
Insufficient r & d facilities	70	5	7	5.8	0.895282

Human resources risk	70	5	7	6.1	0.835865
Lack of information or communication	70	5	7	6	0.765282
Lack of quality or experience of managers	70	5	7	6.3	0.92825
Insufficient attention of leaders	70	5	7	5.6	0.725825
The product is replaced by new technology	70	5	7	6.3	0.528548
Insufficient demand due to price	70	6	7	6.5	0.358528

From the mean value of compliance of all risk factors in the table, it can be seen that the current medical device quality risk judgment method proposed in this paper has high consistency in the evaluation of compliance of risk factors, and it also proves that the survey data has high authenticity. It shows that the risk factors of these medical device R & D projects are common risk factors of medical device R & D projects. The list of risk factors has high accuracy and objectivity, which lays a foundation for subsequent risk assessment.

3 Conclusion

Based on the latest risk management theory and the implementation experience of medical device quality management and risk management system in advanced countries, this paper discusses the methods of risk management in the four processes of product design and development, complaint management, management review, correction and prevention, The research conclusion of this paper is that the level of risk management of medical devices in China is low, and the quality management and risk management system should be established and improved. Learn from the practical experience of quality management and risk management system in advanced countries, integrate risk management into quality management system, and implement risk management more effectively; It is hoped that the medical device industry will pay more attention to the quality risk management of medical device products. Risk management theory is abstract, difficult to implement and specific, and has high requirements for medical device regulatory authorities. Although the international experience has proved that it is necessary and beneficial to establish a medical device quality management and risk management system, the extensive and effective implementation of medical devices in China and the strengthening of medical device supervision capacity still need to go through a necessary development process, which requires great efforts from relevant parties to achieve results. Therefore, at present, we should vigorously strengthen publicity, pay attention to index accumulation, carry out corresponding investigation and research, improve the quality risk management level of China's medical device products as soon as possible, and make China's medical device product quality risk management ability to a new level.

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