# Strategy research on risk Management of Medical Devices in Shanghai Quyang Hospital

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# ABSTRACT

**Title:** **Strategic Research on Risk Management of Medical Devices in Shanghai Quyang Hospital**

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Medical equipment is an indispensable component of disease prevention, diagnosis and treatment, health care, and rehabilitation for modern medical systems. Simultaneously, the role and value of medical devices also make clinicians more dependent on this. It is crucial to be aware that medical devices are affected by certain objective factors. During the life cycle, medical devices could face certain risks. The annual reporting rate of medical device risk events in China increases year by year, implying a trend of doubling year over year. As a key for a turn-around to improve medical quality, attaching importance to the adverse events of medical devices and controlling the potential risk factors in managing medical devices is essential. Risk management for medical devices is a critical management activity that ensures the safety and effectiveness of every medical device throughout its lifespan. This essential component belongs to the standards and standardized management procedures and needs to run through the whole lifespan of these medical devices. Given this information, this paper explored the strategies of medical device risk management. Through diligent research, this paper combined the findings of practical strategies with current research results and provided recommendations while using Shanghai Quyang Hospital as an example. Shanghai Quyang Hospitals' medical device risk management standards were further analyzed to find existing problems and put forward targeted improvement strategies accordingly. Providing these findings would help to ensure the highest safety of medical equipment for the majority of people. It would also help to alleviate the increasingly tense doctor-patient spear. The shield has a significant meaning.

**Keywords:** Hospital, medical equipment, risk management, strategy

# 摘要

题目：上海曲阳医院医疗器械风险管理的策略研究

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在现代医疗系统中，医疗器械是不可缺少的重要环节，在疾病预防、诊治、保健及康复等各个环节都被广泛应用。同时，医疗器械表现出的作用与价值也使得临床医师对此依赖性愈发变强，但需要注意的是医疗器械受到一些客观因素的影响，存在一定风险，也就是说任何的医疗器械都可能在生命周期发生相关不良事件。我国每年的医疗器械风险事件上报率逐年增加，隐有逐年倍增的趋势。足以说明，重视医疗器械不良事件，将医疗器械管理中存在、潜在的风险因素尽量予以控制，是提升医疗质量的关键。医疗器械的风险管理是保障医疗器械在使用期间安全、有效的重要的管理活动，属标准、规范化管理程序，需贯穿至医疗器械全寿命过程。鉴于此，本文将探讨医疗器械风险管理的策略，结合已有相关研究成果，以上海曲阳医院为例，分析其医疗器械风险管理现状，进一步分析其存在的问题，并据此提出有针对性的完善策略，以期从最大程度上保障广大人民的医疗用械安全，对缓解日益紧张的医患矛盾有着重要的意义。

**关键词**：医院　医疗器械　风险管理　策略

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# CONTENTS

# CHAPTER 1 INTRODUCTION

## 1.1 Research Background

With the progress of medical technology, modern diagnosis and treatment are highly dependent on a variety of advanced medical devices. More and more sophisticated technologies are integrated into medical devices, making medical devices a double-edged sword. While greatly improving the level of medical treatment and quality of service, corresponding medical risks are inevitable.

As an important part of medical risk management, medical device risk management is of great practical significance to protect the life safety, and health of patients.How to carry out effective risk management on medical devices, minimize the risks of medical devices in medical services, safeguard and protect the rights and interests of the public's life and health, to alleviate the increasingly tense doctor-patient contradictions, has become the focus of the government and relevant departments of hospitals.

## 1.2 Research Significance

Medical institutions to strengthen the medical device adverse event risk management work, can effectively avoid risk, expenses, caused by a reduction in risk of medical equipment for medical staff to provide a safe, harmonious working environment, give full play to the staff's enthusiasm and creativity, helps to ensure the quality of medical service, protect the patient's life safety,

Ensure that medical institutions provide safe and stable medical services, reduce medical disputes, and improve the social and economic benefits of medical services.In the medical institutions to establish scientific and perfect medical device adverse event risk management system, strengthen medical devices adverse events in the medical institution's internal risk management, to reduce or avoid repetition of similar medical device adverse events, reduce the patients, medical staff, and other personnel to use the risk of medical apparatus and instruments, to ensure the safety of the people by machinery,It is of great practical

significance to promote the healthy development of China's medical device industry.

## 1.3 Research questions

Based on the strengthening of medical device adverse event risk management in medical institutions, this paper proposes the following four research questions.

1. Are the risk management rules and regulations of Shanghai Quyang Hospital perfect?
2. Is the risk management organization of Shanghai Quyang Hospital sound?
3. Is the risk management method and process of Shanghai Quyang Hospital clear?
4. Is the risk management information system of Shanghai Quyang Hospital perfect?

## 1.5 Research Objectives

In this paper, a field survey of Shanghai Quyang Hospital was conducted. To make the research results more scientific and objective, and to be different from the universality of similar studies, the literature method and case analysis method were adopted. Shanghai Quyang Hospital was taken as a case, and an objective question survey document was adopted instead of a scale questionnaire.

First, in Shanghai QuYang hospital long-term work in the medical device adverse event risk management and clinical engineering and technical personnel of in-depth interviews, followed by questionnaires, finally through the analysis of the questionnaire data analysis, in-depth research hospital medical device adverse event risk management present situation, find out the risk of adverse events of medical equipment management work of the weak link,

The main factors affecting the risk management of adverse medical device events in medical institutions were summarized. Because of the existing problems, the risk management mode suitable for the adverse medical device events in Shanghai Quyang Hospital was given by referring to the advanced foreign risk management experience and the risk management concept of enterprise management.Provide countermeasures and suggestions for the risk management of adverse medical device events to the relevant management of Shanghai Quyang Hospital.

Based on the comprehensive risk management as the research theory frame, the COSO report, internal control and risk management theory, 《The medical equipment application of

risk management for medical equipment》 such as《the pharmaceutical medical instrument flight check method》as a real part of the framework, based on the empirical analysis of Shanghai QuYang hospital internal, looking for risk points,So as to improve the risk management of medical devices in Shanghai Quyang Hospital.

# CHAPTER 2 LITERATURE REVIEW

## 2.1 Current status of medical device risk management

Risk management is a management concept widely used in various fields of the current society. In the life cycle of medical devices, there is a certain probability of failure, and the risk of these failures cannot be controlled by the safety standards of medical devices. Therefore, it is necessary to implement risk management in the medical device industry.
Risk management runs through the life cycle before and after the launch of medical devices, which is an important measure to ensure the safety and effectiveness of medical devices systematically.

Progress in risk management of foreign medical devices In recent years, medical apparatus and instruments in a variety of disease prevention, diagnosis, treatment, and rehabilitation of more and more widely applied in the process, followed by a medical device adverse events occurred more frequently, medical apparatus and instruments of risk management as the medical risk management in medical institutions, an important part of that health authorities around the world are paying more attention to the risk management for medical equipment.In the field of medical device risk management, Europe and the United States and other developed countries started earlier than China, and have built a sound management system in-laws and regulations, management system, supervision concept, and supervision process.Since the end of the 20th century, some western countries began to try to implement risk management for medical devices with high risk.In 1997, the European Union issued the EN 144I risk analysis standard, which clearly defines the process of evaluating the safety of devices by identifying and evaluating the risks associated with the devices.(Dai & Zhang, 2019).

In 1998, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) two sub-technical committees set up a joint working group, drafting and issuing the ISO14971-L:1998 "medical device risk management for the application of medical devices", ISO14971 has both ISO and IEC logo, is the world's two largest organizations recognized by the new version of the medical device risk management standard, after the ISO revised several times, the latest version of ISO14971:2007 is a global guideline for risk management activities for medical devices.The standard states that the medical device manufacturer, following this procedure, can determine the hazards associated

with medical devices (including in vitro diagnostic medical devices), estimate and evaluate the associated risks, control these risks, and monitor the effectiveness of the controls.(Duan, 2019).

FDA shall carry out the policy of classification administration of medical apparatus and instruments, l976 in the United States Congress formally passed the food, drug, and cosmetic act amendment, to strengthen the regulation of medical devices, according to the level of risk and management by pre-IPO management for medical equipment is divided into three categories, this is the first country in the world legislation stipulated by the administrative departments of the government supervision and management of medical equipment(Lin, 2019).The post-marketing risk management model of post-marketing listed after risk identification,risk evaluation, and risk of post-marketing feedback of three modules, the entire management model associated directly with the pre-market approval of medical devices, and by the FDA's internal plan (in hindsight, education and training programs, etc.) and external partners to support the public health, reduce the medical apparatus and instruments of related damage,Enhance the system of the product.

Progress in risk management of domestic medical devices Medical apparatus and instruments of risk management in our country is still in its beginning stage, the current related rules and regulations of the file (Liu, 2020).in respect of the provision of the medical equipment, is safe and effective in terms of either directly or indirectly involved in the content about risk management, the measures for the administration of medical device registration (bureau no. 4) mentioned in the application of the third class medical device registration,China Food and Drug Administration shall determine the categories according to the degree of risk ".CFDA issued the industry standard YY/T 0316-2008 "Medical Device Risk Management for Medical Device Application" on April 25, 2008, which has been implemented since June 1, 2009. The standard is equivalent to 1SO14971, which stipulates the requirements of risk management and clarifies the process and method of risk management.The scope of medical device risk management is defined to cover all fields of scientific research, production, circulation, and use of medical devices. It is emphasized that medical device risk management includes the whole process of the life cycle of medical devices, including design, development, production, installation, use until disuse, and scrap disposal.The new version of YY/T 0316-2016 "Application of Medical Device Risk Management to Medical Device" has been implemented since January 1, 2017.Article 4 of the

2015 version of the GMP specification for medical devices stipulates that "manufacturers should carry out risk management throughout the whole process of design, development, production, sales and after-sales service"(Liu, 2019).

Under the acceptable level of new technology, medical device manufacturers can judge the safety of medical devices to ensure that the products meet the quality requirements after the market. In 2012, the State Food and Drug Administration issued the Work Procedures for Flying Inspection of Medical Device Manufacturers (Trial), and implemented the Measures for Flying Inspection of Drugs and Medical Devices since September 1, 2015, which played an important role in investigating problems, controlling risks and deterred illegal behaviors(Sun, 2019).Despite the guidance of a series of regulations and standards, there are still many deficiencies in the risk management of domestic medical devices. First, the risk management activities of some manufacturing enterprises are not implemented. On the surface, the enterprises manage according to the risk process required by the standards, but in fact, they do not have a deep understanding of the essence of risk management.

In practice, the application of risk analysis means is too formalized, which is only reflected in the organization and planning of the risk management of a certain type of medical devices, the establishment of a risk management plan, and the storage of the risk management document.Second, the linkage between departmental regulations is not strong enough, and the risk management and quality management systems are not systematically and effectively combined. Therefore, it is necessary to enhance the operability of regulations and urge production enterprises to consciously carry out risk management activities.Third, medical device risk management professionals are few, personnel quality, knowledge structure (Wang, Tian & Wang, 2019). can not meet the potential needs of medical device risk management.Part of the enterprise management personnel lacks risk management awareness, lack of corresponding management experience accumulation.

In the practical application, it is necessary to strengthen the training of relevant personnel in regulations and standards, improve the awareness and skills of risk management, master the risk management methods of each link, and accumulate and learn from practical experience.

## 2.2 Risk management

Concept of risk management Risk management is a social organization or individual to reduce the negative consequences of risk decision-making, through risk identification, risk estimate, risk evaluation, selection, and optimization based on the combination of various risk management techniques, to control the risk effectively and properly handle the risk caused by the consequences of loss of, to gain the biggest security at minimum cost(Wu, 2018).

The specific contents of risk management include:

(1) The object of risk management is a risk.

(2) The subject of risk management can be any organization and individual, including individuals, families, and organizations (including for-profit organizations and non-profit organizations).

(3) The process of risk management includes risk identification, risk estimation, risk assessment, selection of risk management techniques, and evaluation of risk management effects.

(4) The basic goal of risk management is to obtain maximum security at the minimum cost.

(5) Risk management has become an independent management system and an emerging discipline.

Process of risk management:

(1) Risk identification In the theory of enterprise risk management, risk identification is the first step of risk management, which refers to the process of judging, classifying, and identifying the nature of potential risks faced by enterprises. The main purpose is to reduce the uncertainty of risk. Risk identification is the basis of risk management, there are many variables in the risk management and uncertainty, any conditions and environmental changes are likely to change the nature of the original risk and generate new risk, so risk identification should be an ongoing, iterative process that will not happen overnight, need regularly in the whole management process from beginning to end.

(2) Risk assessment In enterprise management theory, risk assessment is a comprehensive analysis of risks based on risk identification, estimating the probability and severity of various risks, and further clarifying the overall level of risks, that is, quantitatively assessing the possible degree of impact or loss caused by risk events.

The work of risk assessment mainly depends on two aspects: the probability of risk

occurrence and the impact degree of risk. The method of qualitative analysis and quantitative analysis is mainly adopted. Qualitative risk analysis methods include questionnaire survey, group discussion, management interview, expert consultation, scenario analysis, policy analysis, industry benchmark comparison, investigation, and research, etc.
Quantitative risk analysis methods include statistical inference, computer simulation, failure mode, and impact analysis, fault tree analysis, and so on.

(3) Risk control In enterprise risk management, risk control means that according to the results of risk identification and risk assessment, risk managers take various measures and methods to eliminate the possibility of risk events or reduce the loss caused by risk events.
There are four common risk control methods in enterprise risk management: risk avoidance, risk reduction, risk-sharing, and risk-bearing.

(You, 2020) Risk avoidance: Risk avoidance refers to the method to avoid risks by actively withdrawing from activities that may produce risks when the potential threat of the project is too risky, the adverse consequences are too serious and there is no other strategy available.

Risk reduction: it refers to the method that the enterprise is unwilling to give up risks, and then takes measures to reduce the possibility or severity of risks, or reduce both at the same time; Risk sharing: refers to the method to reduce the possibility or influence degree of risk through sharing. Risk tolerance: it refers to the method of not taking any measures to interfere with the possibility or influence degree of risk. Risk control of medical devices in medical institutions refers to the process of developing risk control strategies and management measures to achieve the goal of risk management of adverse events of medical devices and to reduce the negative effects caused by various risks of medical staff in the process of using medical devices.

(Zhao, 2020)Medical devices carry specific safety risks while bringing health benefits to the public. In order to reduce the application risk of medical devices and ensure the safety and effectiveness of medical devices, it is essential to carry out risk management for medical devices after marketing. Medical device adverse events refer to the events that exceed the expected use effect and cause harm to human body or may cause harm to human body during normal use of qualified medical devices after they are approved to be on the market, which

may endanger life in serious cases. Medical device adverse event monitoring is a process of finding, reporting, evaluating and controlling suspicious adverse medical device events. Its purpose is to reduce or avoid the occurrence of harmful events or reduce the risk and degree of harm caused to human health. Medical device adverse event monitoring after appearing on the market for medical devices and then evaluation and recall mechanism to provide technical support, is an integral part of medical equipment safety supervision work of most national regulators have established medical device adverse event reporting system, actively collecting medical devices adverse events, so that the monitoring work smoothly. Medical device adverse event monitoring is an important means of medical device risk management. For medical device science after marketing, reasonable safety evaluation is an important means to guarantee the safety of the public and promote the improvement of product quality, and it is of great significance to warn the public how to use medical devices safely and effectively. Medical device adverse event reports after appearing on the market for medical equipment supervision, risk analysis, evaluation, recall, etc. provides a foundation, through the study of the hazard analysis of adverse event reports, the extraction of these risk factors, could help identify hidden trouble in security of medical equipment, and take the corresponding control measures, reduce the use of medical equipment safety risk. This paper is based on the human-machine-environment interaction model of medical device products

Medical institutions for medical equipment in the process of control the risk of adverse events, often do not use a single method, but according to the medical apparatus and instruments, as a result of risk assessment according to the different situation with different methods or a combination of several kinds of method to control the risk of medical equipment, (Dai, Cui & Sun, 2019).to ensure that the risk control effect to achieve the best effect. Modern medical institutions are highly dependent on the diagnosis and treatment of patients with medical devices. In vitro diagnostic reagents are now under the management of medical devices. Its main purpose is to provide a priori service for medical treatment, and it is a basic tool for detecting whether patients are sick and the extent of their illness. As an emerging field, in vitro diagnostic reagents industry has broad market prospects, but huge profits are bound to be accompanied by huge risks, the accuracy of the results will directly affect the diagnosis of doctors and the health and life safety of patients, so it is particularly important to carry out effective risk management on it. This study established a set of effective methods for risk management of similar diagnostic projects based on the manufacturer of in vitro diagnostic reagents, which is primarily responsible for the risk of

medical devices (Du, Li, Shi, & Li, 2019).The main research work completed is as follows: 1. Firstly, according to the development process and characteristics of the in vitro diagnostic reagent project, the risk is prelim identified according to different stages of its life cycle by using the work decomposition flow chart method, and 8 major risk categories such as technical risk and management risk in the project implementation stage are summarized. Second, through the expert survey, qualitative analysis of risk factors, determine the probability and distribution of risk events, and the severity of the impact on the project after the occurrence, summarize the product competitiveness, comprehensive quality of personnel and other 14 main risk sources, to provide a basis for reasonable choice of risk countermeasures. Thirdly, starting from the five stages of risk of in vitro diagnostic medical device project, the risk hierarchical structure model of this kind of project is established. Analytic Hierarchy Process (AHP) method is used to evaluate each risk factor, determine the weight of each risk factor, and summarize the risk factors that should be paid attention to in vitro diagnostic reagent project. The results of qualitative and quantitative analysis show that the evaluation method is reasonable and practical.

(Han, Yang, & Dong, 2019). The hospital medical risk management in developed countries has been gradually scientific, institutionalized, and standardized, but the overall level of hospital medical risk management in China is relatively low, the system construction lags, the new management theory and the application of methods are still immature. Medical equipment is an important technical support tool for the development of medical science, a material basis for the development of medical technology, and an important symbol of hospital modernization. Medical equipment acts directly or indirectly on human body and is closely related to human health and life safety. Therefore, the quality and safety management of medical equipment is an important part of hospital management. Safety is the top priority in the use and management of medical equipment, which runs through the whole safety life cycle of equipment research and development, production and manufacturing, planning and purchase, use and scrap. In order to strengthen the supervision and management of medical equipment, ensure the safety and effectiveness of medical equipment, and protect human health and life safety, the State Council specially formulated the Regulations on the Supervision and Administration of Medical Devices, which was adopted at the 24th executive meeting of the State Council on December 28, 1999 and came into force on April 1, 2000.(Li, J. & Zhuang, Z. 2019).The State Food and Drug Administration (SFDA) has issued the ISO according to the International Organization for Standardization (ISO)14971:2007 "Medical

Device Risk Management for Application of Medical Devices" standard, YY/T0316-2008 "Medical Device Risk Management for Application of Medical Devices" standard, has played a great role in guiding and standardizing the risk management of medical equipment, and has great significance for ensuring the safety and effectiveness of medical equipment. This paper introduces the classification of safety risks of medical equipment, analyzes the causes of safety risks, and puts forward the preventive measures.

With the further development of the medical system reform and the increasingly tense doctor-patient relationship, patient safety has attracted more and more attention. The importance of medical risk management in hospital management in China has become increasingly prominent, and its application has become more and more widespread. The theory and method have gradually formed and improved. Medical service is a kind of high technology industry, but also a high-risk industry. Medical risk is a common problem faced by governments all over the world. Medical devices have been widely used in the process of disease prevention, diagnosis, treatment, health care and rehabilitation. As modern scientific and technological products, they have become an important part of the field of modern medicine. But medical apparatus and instruments of fake and inferior products still exist at present, an increasing incidence of medical device adverse events, the existence of this phenomenon is related to the quality of medical work in China, more related to the patient's life and health, safety, so to improve current medical equipment management system, improve the management level of domestic medical equipment has become a top priority. Methods: In this paper, comparative analysis method, synthesis method, induction method and other methods were adopted, and a large number of literature related to American and European medical device laws and regulations were consulted. In addition, we interviewed important insiders of medical devices in China's medical institutions, and extensively collected information on the actual management of medical devices in China. Through elaborating the specific situation of medical device management in China, the problems existing in the process of medical device management in China are analyzed, and the importance of standardizing medical device management is deepened. Results: By consulting information. The main problems existing in the management of medical devices in China are as follows: the supervision of medical devices has achieved some achievements, but still needs to be improved; The risk of medical devices has not been paid enough attention, and the awareness of risk management of hospital devices is insufficient. Hospital instrument maintenance, maintenance is not comprehensive, the safe and effective operation of the

instrument needs more guarantees; The professional skill level of clinical engineering and technical personnel is different, and the loss of senior talents is serious. Based on theory and investigation, the existing problems and possible solutions of medical device management in China are pointed out. Conlusions: Although medical device management in the United States and the European Union has just started, it is worthy of reference in the aspects of government regulatory system, regulatory implementation mode, post-listing regulatory measures, laws and regulations and hospital risk management.There are many problems in the management of medical devices in China.

(Liu, 2017). According to the report "Errors are Human Nature: Building a Safer Health Care System" published by the Institute of Medicine (IOM) in 1999, 44,000 to 98,000 people in the United States die from medical errors every year, more than car accidents, breast cancer and AIDS, and the economic losses caused by these errors are $17 billion to $29 billion each year. The total misdiagnosis rate is about 27.8% among the more than 2 billion medical visits in China every year. At present, many countries tend to establish a protective mechanism to prevent accidents to reduce medical risks. Our country hasn't been set up on the authority of the medical risk monitoring and early warning system, both in government and academic research unit did not fully grasp the medical risk management of the national relevant data, it is difficult to time for medical institutions to evaluate the level of medical risk, more can't through the corresponding early warning mechanism timely warning signal.

How to timely find and effectively deal with all kinds of risks in the process of medical service, and constantly improve the quality of medical service, has become an important and urgent task faced by hospital management. First of all, this paper expounds the risk, medical risk and medical risk management connotation and the characteristic, and analysis of the current medical risk management in our country the problems and solutions, three in the United States, Japan, and Australia to study the medical risk management in the developed countries, based on proposed foreign mature experience for our reference value; Secondly, using the theoretical knowledge of risk management, this paper makes an in-depth analysis of the current situation and existing problems of medical risk management in the First Affiliated Hospital of Harbin Medical University (hereinafter referred to as the First Clinical Medical College).Medical risk management is directly related to the patient's life and health safety and is also an important part of hospital management. In recent years, to reduce medical errors, avoid medical disputes, reduce the occurrence of adverse events in the process of medical

diagnosis and treatment, and realize the effective control of medical risks, medical institutions often use effective risk management tools for medical risk management.In this study, based on literature investigation, failure mode and effect analysis (FMEA) was selected as a theoretical model, and the case study method was used to study the risk management of intervention surgery in hospitals based on the FMEA model.A study found that the FMEA model results in the medical risk management for medical documents writing reflect is more perfect, more number of medical quality index statistics is accurate, complete and in patients with such confinement is reduced on average, cases to reduce medical dispute occurs, the existing problems and its reason mainly includes medical personnel lack of strict technical access specification,There are defects in risk prevention and control in the medical process, weak awareness of risk prevention and control among medical staff, unsound medical safety monitoring mechanism, and lack of standard records of operative medical records.Based on the case study, this research analyzes the feasibility of medical risk management based on the FMEA model framework and its content, and from strengthening the construction of hospital medical adverse event reporting system, improve the medical risk management of form a complete set of rules and regulations, establish a medical risk management organization, and other aspects put forward the countermeasures and Suggestions, to promote the medical risk management of medical institutions ability,To strengthen the awareness of medical risk prevention and control of medical staff, further, improve and optimize the medical service process, and finally achieve the purpose of continuous improvement of medical quality and continuous improvement of patient satisfaction. (Zhai, 2020).

Any medical device approved for marketing is only a product with an acceptable risk-benefit ratio. Due to the objectivity and universality of the risks of medical devices, medical device companies must carry out risk management on medical devices to control the risks at an acceptable level. The purpose of this paper is to analyze the current situation and problems of product quality risk management in medical device enterprises in China, and to study the measures to strengthen product quality risk management in medical device enterprises in China, so as to improve the safety of medical device products. In this paper, through a large number of literature review, expert consultation, information analysis and case analysis, from the latest risk management theory, combined with the advanced countries medical equipment enterprise quality management and risk management system implementation experience, explore the medical equipment companies in product design and development, complaint management, management review, and corrective and preventive implementing risk

management in the process of the four methods, and put forward The improvement of medical device supervision laws and regulations and supervision mechanism in China. The results show that the quality risk management level of medical device enterprises in China is low. Therefore, we should establish and improve the quality management and risk management system, learn from the practical experience of quality management and risk management system of advanced countries, integrate risk management into the quality management system, and effectively implement risk management. China's medical device regulatory authorities should strengthen the supervision of medical devices, improve the legal system, improve the regulatory mechanism, and promote the implementation of product quality risk management.

"Theory and Practice of Medical Risk Management" proposed to construct a medical risk management countermeasure system integrating medical risk early warning, medical risk disposal, and social sharing of medical risk through a systematic study of the problems related to medical risk management. Improve the efficiency of risk management, broaden the idea of risk management to provide a method and suggestions. Medical devices, as modern scientific and technological products directly or indirectly used in the human body (Sun, 2019). play an important role in the diagnosis, prevention, monitoring, treatment or mitigation of diseases, and become an important means of diagnosis and treatment in the medical field. Its safety and effectiveness are directly related to human health and even life. Therefore, in order to ensure the safety and effectiveness of medical devices, it is crucial for manufacturers to carry out quality risk management comprehensively and effectively. At the end of the 20th century, risk management theory was applied in the medical device industry. The risk management of medical devices is mainly through the establishment of some standards, such as medical device GMP, to standardize the medical device manufacturers and provide a framework for risk management. Based on the new medical device GMP perspective to enterprise quality risk management analysis and research countermeasures. Begin with medical devices GMP in this paper, the first chapter, introduce the developed countries and areas to its definition and the drafting background and definition in our country, by new and old medical equipment compared to highlight the advantages of the new GMP, then introduce the quality risk management and risk analysis tools and processes, using risk management analysis tools, from different angles is put forward under the new medical equipment GMP perspective, five One kind of risk management method: five elements analysis, root cause analysis, source analysis, purpose main line analysis, data authenticity method; The second chapter to

enterprise registered quality management system verification in zhejiang province as the research object, collecting a large amount of data, using data classification summary, horizontal comparative analysis of 2017 registration system for verification of defect items, observe a higher frequency of defective item, longitudinal comparison ordinary medical apparatus and instruments, 2015201, 6201, sterile medical devices implanted medical devices, in vitro diagnostic reagents with the same defect type and conduct trend analysis, observe the trend of each defect item, and analyze the change trend of quality risk.(Sun, Li, Lou , & Chen, 2020).

Methods The commonly used project management techniques were applied to the establishment of a medical device risk management system. In short, the complicated risk management system was divided into several project groups. Each group established clear goals and made overall planning. Including the relevant scheme design, in the process of specific discussion from the project management and the definition of medical device risk management system to start with the analysis. A group of related concepts such as medical risk management and medical risk is explained and compared.(Wang, Tian & Wang, 2019). Medical risk management is a kind of comprehensive management. Thereafter, this paper discusses the causes and classification of medical risks in China, aiming to make medical risk managers more targeted and effective in risk management. Finally, according to the current situation of medical risk management in China, and using the risk management methods and principles of enterprises and financial industry for reference, some suggestions on medical risk management in Chinese hospitals are put forward, mainly from the aspect of system reform. For the production and operation process of an enterprise, it is a kind of micro economic risk, which is accompanied by the existence of every link of enterprise production and operation activities. In the complex and changeable market environment, financial risk will have a great impact on the production and operation process of every enterprise and the level of profit, so it is very important for enterprises to conduct financial risk management before, during and after the event, so that enterprises can remain invincible in the fierce market competition. As one of the most important industries in China's manufacturing industry, the medical device industry plays a key role in China's economic growth, because health is more and more concerned by the country and the people, and as a basic industry in the health industry, the development of the medical device industry has also attracted the attention of the country. Although it started late in China, it plays an important role in the development of our country.(Wang, T., Zhao, L. L., & He, D. 2019)..The research elements of

medical risk in China include the object, consequence, process and cause of medical risk. Research category of medical risks include the risk prevention and treatment, the causes and influence factors of sharing mechanism, specialized subject disease medical risks, concept and the connotation, characteristics, education and training, management experience at home and abroad, and process management system, management and early warning system and assessment model, internal management practice of medical institutions, the present situation, the management method, the risk of medical equipment, medical risk types, Object, category, research method and so on. Conclusion At present, domestic medical risk research focuses on risk control, and discusses how to resolve risks from the perspective of results. Most of the research is case-by-case, and the research is not systematic and in-depth enough.The definition of medical risk has not formed a unified understanding.Therefore, it is suggested that: (1) the systematization of domestic medical risk research should be strengthened;② Standardize the understanding of the meaning of medical risk;(3) actively carry out the early warning of medical risks (Yuan, X. 2020).

Medical risk is everywhere "has become the consensus of medical and health, the medical risk is not only the economic interests of the rights and interests and hazardous to the health of patients, but also can give the hospital, the normal work of the medical personnel and medical development bring adverse effect, correct understanding and active prevention of medical risk, as far as possible to reduce the medical risk of harm, to safeguard patients rights, It is of positive significance to carry out clinical work better.In this paper, the concept of medical risk, characteristics of adverse effects, and causes for preliminary analysis, to explore the medical risk prevention measures, to improve the management mechanism, improve the quality of medical services.Science and technology have been widely used in all aspects of social life, medical equipment has become an important condition in the process of clinical medical diagnosis, and the dependence of clinical departments on medical equipment has been gradually strengthened, which means that the position of the armory department has been improved and ushered in a new opportunity and development opportunity.But it also means that the armoury will also face unprecedented severe challenges.In this case, it is particularly important to define the position of hospital armory department.Hospital armory department must recognize the situation, comprehensive and detailed positioning of their own work, clear their new positioning in the new situation, away from the old way of thinking, with a new look to meet the challenge.At the same time, it is necessary to clarify the changing trend of the management function of the hospital armory department under the new situation,

to adapt to these changes and establish various effective working systems with a positive attitude in order to better meet the new needs of the development of the hospital.

## 2.3 Enterprise risk management

The conceptual framework I used in this study was the Committee of Sponsoring Organizations integrated enterprise risk management framework (2017). The Committee of Sponsoring Organizations of the Treadway Commission (COSO) jointly sponsored and funded by the American Accounting Association, American Institute of Certified Public Accountants, Financial Executives International, Institute of Management Accountants, and the Institute of Internal Auditors, commissioned the COSO integrated 5 enterprise risk management framework (COSO, 2017). Published in 2004, and updated in 2017, the COSO framework is a process that business leaders may implement to protect

their entity and enhance shareholder value (COSO, 2017). There are five interrelated components of the COSO framework: (a) governance and culture; (b) strategy and objective-setting; (c) performance; (d) review and revision; and (e) information, communication, and reporting (COSO, 2017).(Baldrige Performance Excellence Framework, 2017) Understanding how nonprofit business leaders implement enterprise risk management strategies, as related to each of the five interrelated components of the COSO framework, may assist other organizational leaders in the process of maintaining and improving organizational sustainability. I determined the potential relevance of using the COSO framework as a lens to explore the strategies nonprofit business leaders use to maintain and improve organizational sustainability(Moldavanova & Goerdel, 2018; Peterlin, Pearse, & Dimovski, 2015).

Overall, enterprise risk management (ERM) as a discipline.A business process is evolving, but not yet mature for strategic use.ERM is actually more about corporate reputation management.

Because once unforeseeable risks occur, they will disrupt or even cause business loss, thus causing a major blow to corporate reputation and brand.

Therefore, active, active and regular risk management and integration with corporate strategy can not only help prevent the occurrence of adverse events, but also help reduce the impact caused by the occurrence of risks.

The VALUE proposition of the ERM is evolving.The traditional view of risk is more defensive, that is, risk reduction, risk management to an acceptable level, risk elimination, asset protection, value preservation, these are important, but risk management can also be "active attack", through which new value is created and optimized.

Risk leads you to innovate, to be first, to offer differentiated products and services, and to do better than your competitors.So risk and opportunity are two sides of the same coin.


Fig. 2.1 COSO risk management

Coso-erm framework or corporate reputation management framework As can be (see Figure 2.1).

COSO risk management is integrated, including five components.

Each of these five parts contains a different set of guiding principles, a total of 20. Each of the 20 principles plays an important role in an effective ERM framework, but they are integrated and interdependent.

The COSO-ERM framework enables organizations to achieve their strategic objectives and grow with confidence by providing them with more predictive flexibility and adaptability when managing disruptive events or contingencies.

## 2.4 Medical device risk management

Refers to the risk management of medical device industry according to the nature of the medical instrument and the intended use, identification of all relevant hazards, hazard situation caused by the adverse events of medical equipment, for each risk evaluation, when considered unacceptable risk measures to reduce or control risks, complete control will continue to repeat after evaluation of the residual risk of harm or damage to,This evaluation and necessary controls are repeated until all risks are considered acceptable.

No medical device can be risk-free and safe. The approval of a medical device on the market can only indicate that it has been studied and evaluated before the market and that it is considered to be an acceptable product with risks compared with known benefits, but relative to the life cycle and use a range of the whole product,Scientific risk management of adverse events in the clinical use of medical devices after marketing can maximize the control of potential risks of medical devices and ensure the safe and effective use of medical devices.

These problems in medical device risk management are not only restricted by the reality and regulations but also lack of device use and relevant objective data. These constraints also exist in all countries in the world.For example, the U.S. FDA's CDRH panel in a report on the safety of post-market medical devices also found that the United States has the same two aspects of problems.Due to these constraints and the lack of objective data, both at home and abroad, through a review of relevant pieces of literature and important reports, suggestions on the risk management of in-use medical devices are mainly based on qualitative analysis. This is the case at home, and internationally, such as the United States, the United Kingdom, and the European Union are no exception.As a special product, the safety and effectiveness of medical devices are closely related to people's health and even life. The risks of medical devices also include damage to social property and environment.As a medical device manufacturer, it is necessary to carry out comprehensive and effective medical device risk management activities from the perspective of responsibility to patients, users and other relevant personnel, as well as from the perspective of meeting regulatory requirements.Based on the perspective of the manufacturer, this paper studies how to integrate the requirements of risk management into the quality management system by relying on the internal quality

management system established and implemented according to the YY/T0287-2003 standard and implementing the YY/T0316-2008 standard, so as to establish a complete set of risk management system covering the whole product life cycle.Firstly, this paper reviews the research status at home and abroad.The YY/T0316-2008 standard clauses are analyzed, the process and methods of risk management activities are clarified, and several common risk analysis tools are compared to determine their application scope;From the Angle of the manufacturer on how different categories of medical devices in risk analysis, risk evaluation, risk control and so on has carried on the analysis of the event, trying to find the inherent law, discuss operable risk analysis tool, the key point in the process of risk analysis, evaluation and risk control and the need to pay attention to the problem are discussed and summarized.Finally, the feasibility of the risk analysis tool and the effectiveness of the risk control measures are verified through the empirical study on the risk management of the poly lactic acid anti-adhesion membrane product.The research of this paper will be beneficial to the construction or improvement of the risk management system of medical device manufacturers.

The theory and method of risk management were applied to medical devices at the end of the 20th century, marked by the release of the international standard ISO14971-1:1998.China will be the International Standard Organization (International Organization for Standards) Forstandards for risk management of medical devices (hereinafter referred to as "ISO") are equivalent to the recommended industry standards of China's pharmaceutical industry. Under the background of the attention paid to the safety of pharmaceutical products, this paper studies the application of risk management in the field of medical devices in China.Starting from the application of risk management in the field of medical devices, this paper focuses on the perspectives of government regulatory authorities and manufacturers of medical devices as two stakeholders.Literature research, questionnaire survey, field study, comparative study and case study are mainly used.According to ISO14971 and risk management theory is introduced the application of risk management for medical equipment, in the domestic scholars on the established after the research of this article research scope and research train of thought, namely the study of risk management in the application in the field of medical apparatus and instruments in our country, first introduced the domestic and foreign medical device regulations for medical devices in the risk management and demands of the medical device Machinery, the application of the risk management standards, and the huge influence at home and abroad of the casualties were retrospective analysis of medical

equipment, the application of the risk management in the field of medical apparatus and instruments, after a comparative study of liaoning province food and drug administration review center conducted field research, at the same time to 75 in liaoning province based on a questionnaire survey of the medical device manufacturing enterprise.Through an 18-month survey, it is found that the risk management awareness and level of staff in large enterprises are stronger than those in small and medium-sized enterprises.

There are many kinds of risks in daily life, which may cause harm to people, or even endanger their life or health.Experts at the "Third National Academic Conference on Injury Prevention and Control" pointed out that accidental injuries are currently the top cause of death in China for people under 34 years of age.Any clinical activity, even the simplest or seemingly trivial, carries risks."Medical risks are everywhere" has become a consensus in the medical community.Modern diagnosis and treatment are highly dependent on a variety of advanced medical devices. More and more sophisticated technologies are integrated into medical devices, making medical devices a double-edged sword. While greatly improving the level of medical treatment and service quality, corresponding medical risks inevitably accompany them.From the perspective of medical institutions, this paper puts forward countermeasures and suggestions on the risk of medical devices in China.Objective To explore the existing problems of medical device risk management in China, and to put forward countermeasures and suggestions from the perspective of medical institutions.Methods Based on the risk management theory of enterprise management and the actual situation of medical device risk management in medical institutions, the basic system and work flow of medical device risk management in China were put forward.Results To establish a perfect medical device risk management system and rigorous management process in medical institutions can improve the level of medical device risk management in hospitals.

Conclusion To do a good job in the risk management of medical devices in medical institutions can guarantee the safety of medical devices for the majority of the people to the greatest extent, and it is of great significance to alleviate the increasingly tense contradiction between doctors and patients.Hospital clinical diagnosis and treatment are highly dependent on a variety of medical equipment, the quality of medical equipment itself has a significant impact on hospital diagnosis and treatment services, but also related to the life safety of patients to a certain extent.This paper demonstrates the concept of risk management of medical device, then analyzes the whole life span and stakeholders of medical device, and

discusses on the risk classifications of medical device in medical institutions. Combined with the actual conditions of our hospital, the methods for risk management of medical devices in medical institutions are also discussed in this paper.

In the use of medical device risk management as an important measure to effectively guarantee the quality of medical devices, it has always been a management content that hospitals can not be ignored, but from the actual situation of the current use of medical device risk management, there are still some problems, the effect of itself is restricted to a certain extent.Because of the above problems, this study mainly focuses on the existing problems in the risk management of in-use medical devices for a systematic analysis, based on which several optimization measures and suggestions are put forward for reference only.In China's medical institutions, there have been many accidents in the process of using medical devices.In recent years, these medical accidents not only did not decrease, but also showed an increasing trend, and the medical risk showed a significant increase.Therefore;Risk management is carried out in medical device management in China to ensure the clinical safety of medical devices.Medical apparatus and instruments of risk management, this paper has carried on the simple study of modern diagnosis and treatment are highly dependent on a variety of advanced medical equipment, more and more advanced technology integration in medical equipment, medical apparatus, and instruments for the medical workers are of great convenience, improve the clinical curative effect and the efficiency of medical equipment in use process still has a certain risk,If the risk management is not done well, it will affect the development of the whole hospital work.This paper analyzes the problems existing in the risk management of medical devices and discusses the effective countermeasures to improve the level of risk management of medical devices.Medical device adverse event monitoring, provide the regulatory basis for medical device supervision and regulation department, maximum limit control the potential risks of medical equipment, reduce or avoid repetition of similar medical device adverse events, reduce the patients, medical staff and other personnel to use the risk of medical apparatus and instruments, to ensure the safety of the people use machinery.

Objective To analyze the current situation and international research focuses on the study of medical device risk management. Methods To retrieve medical device risk management literature information cited from 2002 to 2011 in Pub Med such as high-frequency Me SH; analyze current situation and research focuses of medical device risk management by using,

bibliographic item co-occurrence matrix builder (BICOMB), and graphical clustering toolkit (gCluto) for quantitative analysis, high-frequency Me SH term papers cluster visualization analysis. Results A total of 7 073 published studies were retrieved, basically suggesting a gradually increasing trend of the number of published papers. The top 3 numbers of frst authors' papers referred to three countries: the United States, Britain and Germany, while China ranked . The top 3 numbers of journal articles referred to the United States, Britain and Holland, while China ranked twenty-second. Twenty journals published more than 50 papers, and all these journals were clinical journals.

The management of implantable medical devices has been attached great importance at home and abroad. The definition, nomenclature, classification and unique identification code (UDI) of implantable medical devices are basic scientific problems that need to be studied and defined in depth.When a medical device is approved for marketing, it only indicates that, according to the results of market evaluation studies, its known risks and known benefits are an acceptable product with acceptable risks. Relative to the life cycle and use range of the whole product, this is only a phased conclusion of product risk assessment.Some low-incidence long-term effects or the actual frequency or extent of known risks may not be discovered or recognized until the product is on the market and has been used by large numbers of people for a long time.Implantable medical devices have developed rapidly in China in recent years.But at the same time, due to the highest degree of risk of implanted medical devices (generally classified into the third class), a large number of medical errors and adverse events have occurred in clinical application.Therefore, the risk analysis and control of medical devices are becoming more and more important.

This paper analyzes the current situation and existing problems of ADR monitoring in the grass-roots drug administration departments and puts forward reasonable countermeasures and suggestions according to the problems.This paper analyzes the problems existing in the use of medical devices by nurses, mainly including the lack of understanding of the daily maintenance and the importance of maintenance of medical devices, the lack of relevant knowledge, and the imperfect management system, which lead to the shortening of service cycle, high maintenance rate and the increase of maintenance cost.To ensure the safety and effectiveness of the use of medical instruments, reduce the medical cost and ensure the quality of medical treatment, it is proposed to further strengthen the education of nurses, improve their understanding, establish and perfect the management system and strengthen the training.

Because of the related problems in the procurement of medical equipment and consumables in some hospitals, the corresponding countermeasures and improvement measures are put forward to enhance the supervision level of the procurement and use of medical devices in hospitals.

From the perspective of risk management, this paper comprehensively analyzes the medical device regulations in China, finds out the deficiencies and needs to be improved, and puts forward suggestions for the development of medical device risk management in China's public health policies, so as to strengthen the government's risk management of medical devices and safeguard the rights and interests of the public life and health.Methods: Evidence - based analysis was used.By analyzing the definition of medical device, risk and risk management, five particularities of medical device risk management are revealed.Based on the theory of risk management, this paper systematically studies the current regulatory system of medical device management in China, analyzes the regulatory policies of all links before and after the marketing of medical device products in China, and clarifies the requirements of current medical device regulations on product risk control.Results: our country has prelim established in product market approval, post-marketing surveillance and vigilance, as well as supervision of production enterprises as the core of the medical device regulatory system, has established the national, provincial, municipal and county level 4 medical instrument law enforcement and team, has built a strong, professional operation of independent technical support system, medical device adverse event monitoring and reporting system have been established,The overall prevention of medical device risks is orderly.Compared with developed regions in the world, China's market risk management laws and regulations of medical devices have been basically in line with international standards, but the post-market risk management laws and regulations are generally weak, with nine problems.Conclusion: the overall risk management regulations after the medical apparatus and instruments listed in China is weak, there are still many problems, need through the public policies and regulations means for medical instrument, which can identify risk measure, processing and evaluation, rules and regulations, and gradually perfect the risk management to risk management throughout the development of the medical apparatus and instruments, production, sales and put into use after the whole process.

Methods this paper analyzes the procurement management requirements in the supervision and cleaning of medicinal materials in military hospitals and finds out the

problems existing in the procurement and daily management of medical equipment and medical consumables by comparing the inspection standards and detailed rules.Results;It is proposed to strictly implement the Articles of Association of Medical Device Committee and clarify the functional departments and personnel division of labor.Strengthen the life cycle management of medical equipment, clarify the work flow;Strengthening the planning of purchasing medical consumables and realizing the in for supervising the use of medical consumables can effectively improve the level of purchasing and using medical devices in military hospitals.Conclusions;It is an effective means to strengthen the procurement and supervision level of medical devices in military hospitals to continuously implement the standards and detailed rules for supervision and cleaning of medicinal materials procurement.The purchase of medical equipment is the bottom guarantee of medical treatment, teaching, and scientific research.With the rapid development of medical technology and the diversified choice of patients for disease treatment, the traditional procurement method has been unable to meet the needs of modern medicine, while the new procurement method of medical devices still faces many safety and supervision problems.This paper briefly introduces several main forms of current medical device procurement and the problems of procurement management, according to the relevant laws and regulations, from the perspective of responsibility supervision, quality supervision, price monitoring, and so on, analyzes the procurement problems and provides countermeasures, to provide a reference for today's reasonable and effective procurement of medical devices.Medical equipment is an important material basis for the diagnosis and treatment of patients in hospitals, which is very important. Therefore, the procurement management of medical equipment also occupies a very important position.With the development of medical technology, coupled with the improvement of patients' requirements for medical services, and the continuous increase of various devices, the traditional procurement methods are no longer applicable, so many hospitals begin to use new medical device procurement methods, but there are still many problems in the process of medical device procurement management.

For this reason, the author combined with the work experience and the actual situation put forward some countermeasures, to solve the problems of medical equipment procurement management to play a reference significance.Are high-risk medical devices implanted or used to support and sustain life or medical device products with potential danger to the human body, used in the secondary medical institutions for orthopedic steel plate, screw, artificial roll bones, artificial crystal, and disposable aseptic medical apparatus and instruments, such as

its quality fit and unfit quality directly related to patient safety.In the use process, we found that there are still many problems and hidden dangers in the procurement, storage, use, and other links of high-risk medical devices.

**Fault Tree Analysis**

Is primarily a fault tree analysis is used to analyse the harm of has been ruled by other methods, the method of the consequences of it from a set of don't want to start, in deductive way, determine the possible reasons of the top event or failure mode, and step by step down, until all the event cannot be down analysis, or unnecessarily again down analysis.

In the process of logical deduction, the events, reasons and the logical relationship between them are expressed in the way of pictures, which is the fault tree.

(Watson &Mesrns 1961)FTA is one of the tools for systematic reliability and safety analysis, which can be used to analyze various factors, including human interactions, and provide an estimate of the probability of failure through risk analysis.The graphical representation also makes it easier to understand the system characteristics and related factors.

In the product or system design stage, fault tree analysis can be used to help identify potential faults and improve the design.In the use and maintenance phases, fault tree can be used for fault diagnosis, help to correct the problems in use and improve the maintenance scheme.

Since FTA highly depends on the professional knowledge of the analysis team members, a multi-professional team should be formed before the fault tree analysis, including experts from engineering, clinical, quality, manufacturing, service, regulations and other professional fields. Independence and diversity are the basis for the effectiveness of the analysis conclusions of the group.

FTA analysis includes qualitative analysis and quantitative analysis.The main purpose of qualitative analysis is to find the causes and combinations of causes that lead to the occurrence of undesirable events related to the system, that is, to find all the failure modes that lead to the occurrence of the top events.

The main purpose of quantitative score is to find the probability of the occurrence of the top event when all the probabilities of the bottom events are given.(see Figure 2.2).

Fault tree analysis includes the following basic steps:

(1) Determine adverse effects (damage to patients, bystanders and operators)

(2) Identification of hazard sources (damage sources of equipment)

(3) Identify relevant conditions and events

(4) Related conditions and events and identified hazards

(5) Identify related conditions and events at the next level

(6) Connect the related conditions and events of the next level with those of the upper level

(7)Repeat/continue

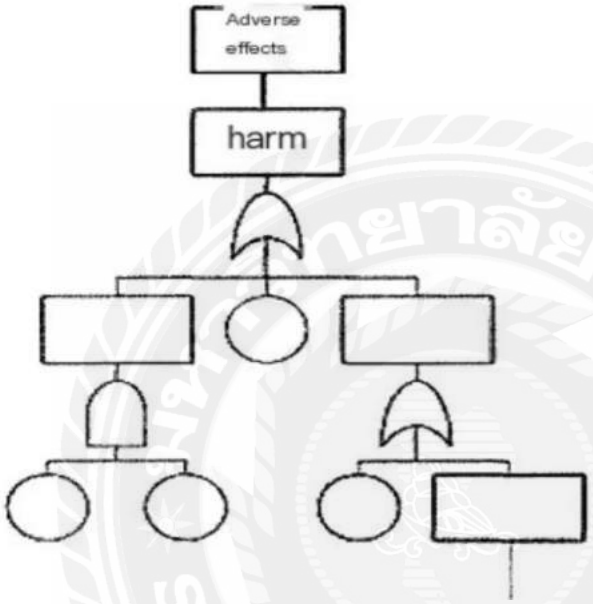


Fig 2.2

FTA analysis results are represented by graphs in the form of fault mode tree.Fault tree analysis uses special symbols (see figure 2.3) that help to graphically represent the relationship between hazards and events or conditions. At each level of the tree, the combination of failure modes is represented by logical symbols (and gates, or gates, etc.).

The failure modes determined in the tree may be those events that cause top events.

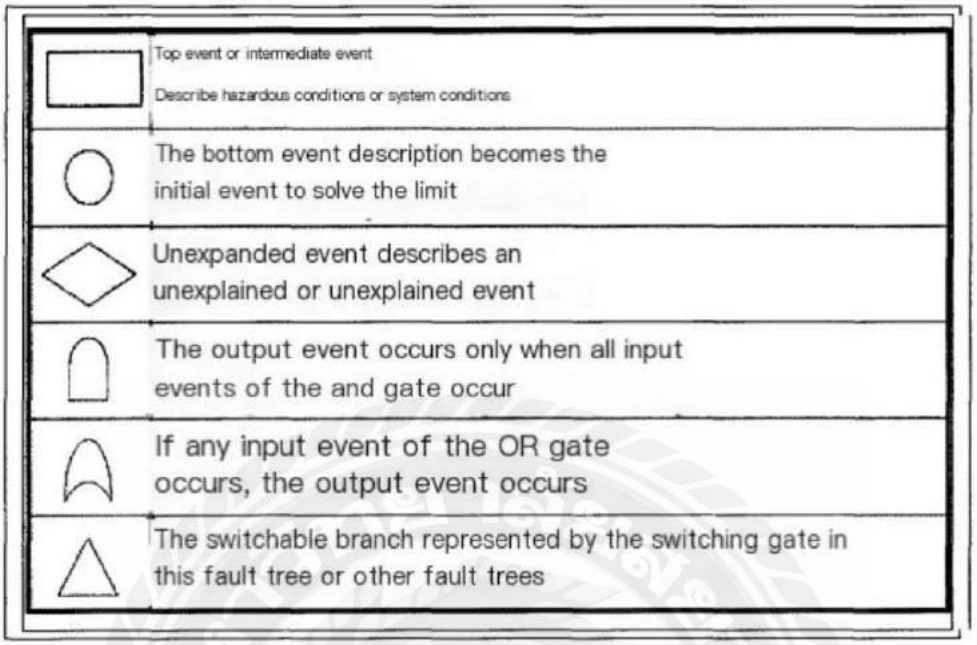


Fig 2.3

An effective risk management process requires the application of appropriate tools.

There are few practical tools for medical device risk management and related research methods lack of combination with practice.

At present, the lack of in-depth analysis on medical risks and prevention in the application of medical devices in China is a relatively general analysis, and there is no in-depth report on systematic application of analysis methods.FAT is a very useful graph of event relationships that should be further studied in combination with other tools.

To sum up, it is very important to strengthen risk management for hospitals. Medical device risk management is the key link of hospital risk management, and strengthening medical device risk management is of great significance to promote the healthy development of China's medical device industry.

# CHAPTER 3 RESEARCH METHODS

## 3.1 Research methods

This paper adopts the mixed research method Spot investigation, this article QuYang hospital of Shanghai in Shanghai QuYang hospital long-term work in the medical device adverse event risk management management and clinical engineering and technical personnel for the in-depth interviews to get firsthand material and through the application in Shanghai medical instrument risk management seminar to communicate with experts, in order to understand the latest development of relevant subject. Finally, the risk management status of medical device adverse events in Shanghai Quyang Hospital was obtained by collecting and processing non-numerical data from the questionnaire.

Through the questionnaire survey of the current situation of risk management of medical device adverse events in Shanghai Quyang Hospital, the field questionnaire was carried out with the current situation of Risk management of Medical device Adverse Events in Hospitals written by Professor Wang Bo from clinical Medicine Department of Affiliated Hospital of Fujian Medical University, and the data of medical device risk management in Shanghai Quyang Hospital were obtained.

For further QuYang hospital adverse medical device adverse event in Shanghai a thorough investigation into the present situation and problems of risk management, we will use the fujian major medical hospital clinical medical department professor webber's "about hospital medical device adverse event risk management present situation investigation questionnaire, the Shanghai QuYang hospital adverse medical device event risk management work pattern investigation.

The design of this questionnaire strictly follows the basic principles of questionnaire design, clarifying the purpose and requirements of the survey, ensuring that respondents can fully cooperate with the survey and provide accurate and effective survey information

In the early stage of adopting the questionnaire, I consulted a large number of various literatures and conducted a lot of on-site investigation.

Detailed consultation with experts in Shanghai QuYang hospital and medical equipment

management personnel and hospital staff, please they respectively according to their working experience and management from the perspective of professional Angle to evaluate objective problem questionnaire survey, one out of the question in the questionnaire research, the subjectivity of the emotional biases and personal likes and dislikes, and avoid inducing respondents to answer the question.The obtained data have authenticity and reliability

The questionnaire is divided into two parts, with a total of 18 questions, summarized as follows:

The first part consists of five questions, namely the basic information of the interviewees, including age, gender, working time, education background, title and so on.Through literature survey and expert interview, the related factors that may affect medical risk in Shanghai Quyang Hospital were estimated.Respondents thought that the publicity and training of medical staff in risk management, the education level of medical staff, the title of medical staff, the length of working hours of medical staff, and other factors in Quyang Hospital in Shanghai would affect the cognitive degree of risk management.

The second part consists of 12 questions：

According to the respondents' cognition of the medical risk management of Shanghai Quyang Hospital, pre-job training, risk management, management organization, risk management process and system construction of the hospital adverse medical device event risk management rules and regulations were discussed.The establishment of risk management network information system should deal with the current situation of the internal medical device adverse event risk management in Shanghai Quyang Hospital.This part of the questionnaire fully considers the rationality and correctness of the questionnaire questions, and the research questions proposed in the above aspects try to closely focus on the development of the risk management of medical device adverse events in Shanghai Quyang Hospital.

Considering the high cultural literacy of the interviewees, most of them had limited time to answer questions due to their busy work.

Therefore, the answers to the questionnaire are closed answers.Respondents do not need to fill in the text when answering a survey question, but simply tick the box that suits their situation among the restricted answers.This is more likely to be accepted by respondents.

In this study, we personally sent questionnaires to the respondents, who filled in the questionnaires themselves, and then the researchers collected the questionnaires.A total of 200 questionnaires were sent out, 198 were recovered, 195 were valid with recovery rate of 99% and 98.5%.

The valid questionnaires collected included 26 clinical departments, 12 medical technology departments and 6 administrative departments.The questionnaire survey went smoothly.The medical staff filled in various answers and the statistical results were clear, ruling out the possibility of one-sided or exaggerated results.After collecting the questionnaire, the data were analyzed statistically.

## 3.2 Literature review Methods

The theoretical literature related to quality management has been researched, and a lot of research has been done by scholars from home and abroad on total quality management theory, DMAIC analysis, data quality theory and quality cost theory. It is of great significance to the conclusion of this paper.

## 3.3 Case study Methods

After outlining the quality problems of medical devices in Shanghai Quyang Hospital, the study summarises how the theories are applied to medical devices in Shanghai Quyang Hospital, such as applying the new technology of Industry 4. 0 for DMAIC improvement, applying data quality to optimise internal data management, applying total quality management and quality cost theory to improve quality costs and clarify quality responsibilities, etc. This is a summary of the quality management strategy of Shanghai Quyang Hospital in the era of new products for medical devices 4.0.

# CHAPTER 4 DATA ANALYSIS

## 4.1 Data Presentation

1) Gender distribution:

In this study, 75 male respondents, accounting for 38.5%

120 females, accounting for 61.5%

2) Age distribution:

Among the respondents in this study, 20 are over 50 years old, accounting for 10.3%;

68 persons aged between 40 and 50, accounting for 34.9%;

56 persons aged 30 to 40, accounting for 28.7%;

48 persons aged between 20 and 30 years old, accounting for 24.6%(see Figure 3.1).

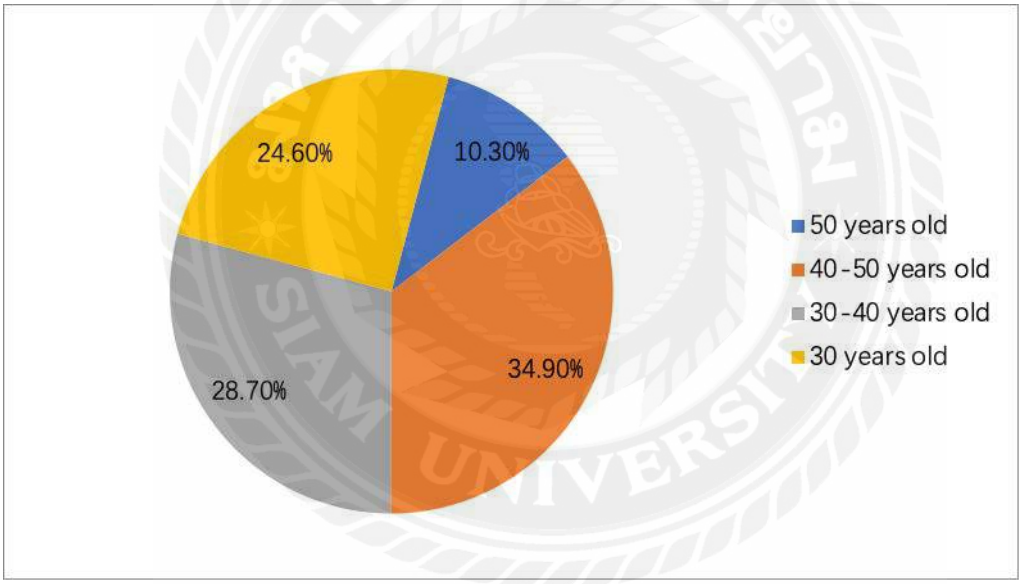


Fig. 3.1 Age distribution of respondents

3) Distribution of cultural process:

Among the respondents in this study, 73 have doctoral degrees, accounting for 45.9%;

66 students with master's degree, accounting for 41.5%;

52 undergraduates, accounting for 32.7%;

4 persons with a junior college degree or below, accounting for 2.5% (see Figure 3.2).

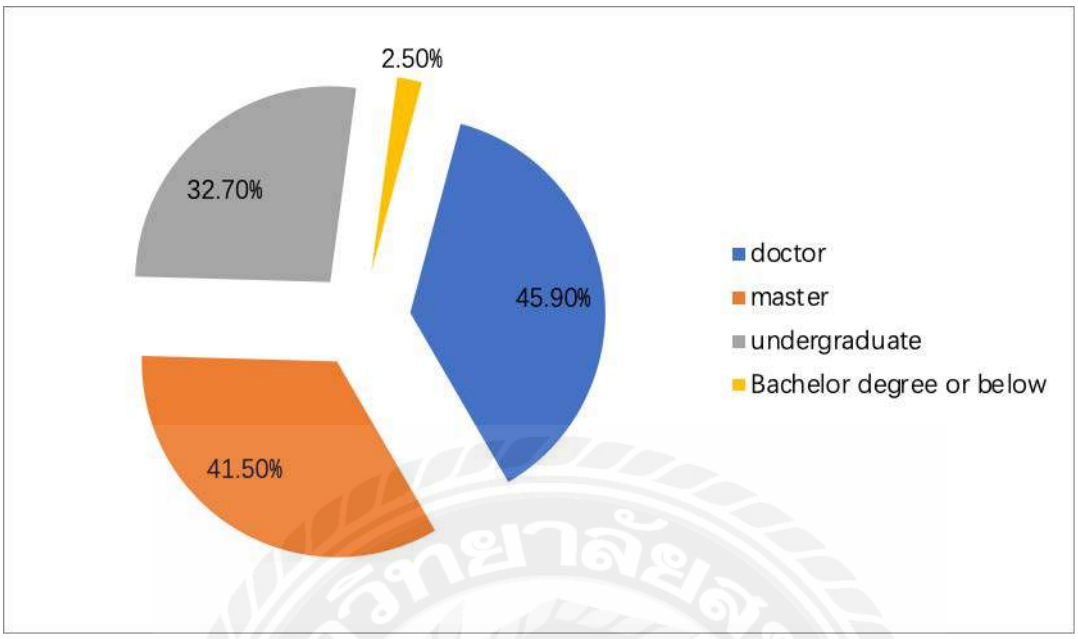


Fig. 3.2 Distribution of educational level of respondents

4) Distribution of professional titles:

Among the respondents in this study, 28 persons are high, accounting for 17.6%;

34 deputy high officials, accounting for 21.4%;

Intermediate 52, accounting for 32.7%;

81 junior or below, accounting for 50.9% (see Figure 3.3).

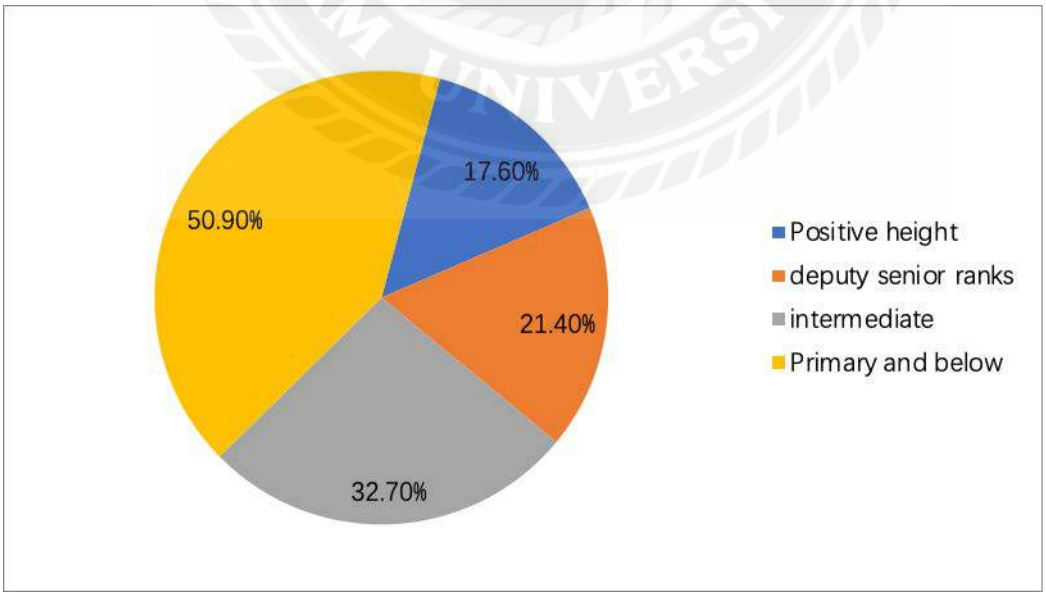


Fig. 3.3 Title distribution of respondents

5) Distribution of Working Years:

In this study, 19 people, accounting for 11.9%, have worked for more than 30 years;

63 persons with 20-30 years' experience, accounting for 39.6%;

54 people with 10 to 20 years, accounting for 34%;

59 persons with 10 years or less, accounting for 37.1% (see Figure 4).

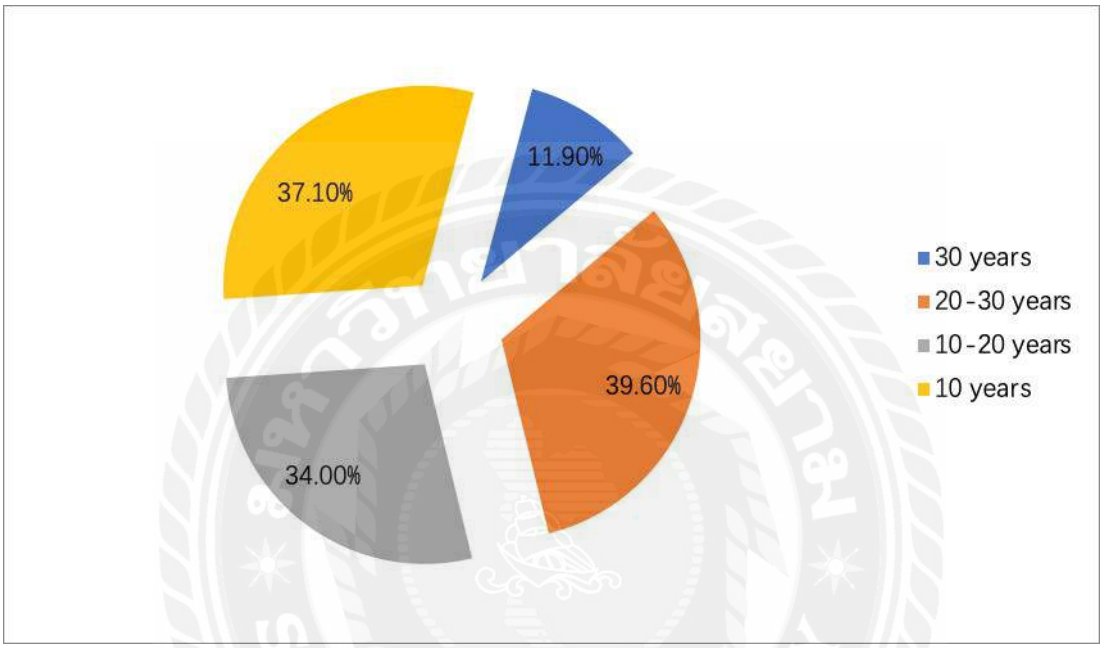


Fig. 3.4 Distribution of working years of respondents

## 4.2 Data analysis of cognitive ability of risk management in medical institutions

The answers to the second part of the question are assigned to three options: A, B, and C, which are recorded as 3, 2, and 1, respectively. The respondents who choose the answer option with a higher score indicate that they have A higher cognition of the risk management work involved in the project and vice versa.

There are 74 respondents, accounting for 37.9% of the total number, whose total score is higher than 24, which is considered as passing.

After classifying the subjects, it can be known that the risk management of adverse

medical device events in Shanghai Quyang Hospital is not optimistic.

The above statistical results can, to a certain extent, illustrate the risk management of adverse medical device events carried out by the respondents.

Among them, the statistical results of three subjects showed that the number of people who passed the exam did not exceed 1/5 of the total number of people, which attracted the attention of the author:

(2-1) In the investigation of the risk management organization setup in Shanghai Quyang Hospital, only 34 respondents, accounting for 17.4% of the total, scored 3 points (i.e., "a risk management organization was established to be especially responsible for the risk events of medical devices").

It can be seen that Shanghai Quyang Hospital does not have a clear risk management organization, that is, there is no specific and clear regulation of "who should do the risk management of adverse medical device events".

(3-2) investigates the development and implementation of risk management working methods and procedures in Shanghai Quyang Hospital. Among them, only 27 medical staff understand the risk management working procedures in Shanghai Quyang Hospital and can strictly implement them, accounting for 13.8% of the total number.

It can be seen that Shanghai Quyang Hospital failed to develop a clear risk management method and process to guide medical personnel to "what to do" when they encounter adverse events of medical devices, which seriously affected the effective implementation of risk management of adverse events of medical devices by medical personnel in their work.

(5-1) Only 30 people, accounting for 15.4% of the total, scored 3 points (i.e., "establishing risk management module and timely reporting") in the project of investigating the risk management network information system of adverse medical device events in Shanghai Quyang Hospital.

It can be seen that because Shanghai Quyang Hospital failed to build a complete risk management information network system, it could not instruct medical staff to "how to do" to

complete the risk management work when encountering adverse events of medical devices.

According to the above investigation and analysis results, the medical institutions of Shanghai Quyang Hospital have performed well in the publicity and training of the risk management of adverse medical device events, and have gained a certain understanding of the risk management methods of adverse medical device events.

However, because the risk management work has not yet developed a sound risk management process and management system when the risk comes, often appear management disconnection coordination ability is not enough, resulting in the rapid and effective handling of risk.

## 4.3 Risk management rules and regulations are not perfect

In 1996, the State Council promulgated the Regulations on the Supervision and Administration of Medical Devices, which endues the State Food and Drug Administration (SFDA) with the power of the supervision and administration of medical devices.

In December 2002, SFDA launched the pilot monitoring of adverse medical device events and carried out the investigation and drafting of the Administrative Measures for the Monitoring and Reevaluation of Adverse Medical Device Events. In December 2008, SFDA officially issued the Administrative Measures for the Monitoring and Reevaluation of Adverse Medical Device Events.

It can be seen that the relevant rules and regulations on the risk management of adverse medical device events in medical institutions in China are still in the exploratory stage, with insufficient working experience and many imperfections. The supporting rules, regulations, and regulations in medical institutions are not perfect enough.

It is far from effective guidance for risk identification, risk assessment, risk control, and other aspects in the risk management of adverse medical device events, which seriously affects the enthusiasm of Shanghai Quyang Hospital to carry out the risk management of adverse medical device events.

## 4.4 Unsound risk management organization

Because the risk management of adverse medical device events started late in China, and the risk management is a preventive work, the management process is complicated, but it is difficult to bring direct economic benefits.

Shanghai Quyang Hospital is often worried that the medical device risk events will expose the problems existing in the internal work, which will affect the social image and economic benefits of Shanghai Quyang Hospital. It has a lot of concerns about the risk management work such as the reporting of adverse events and ignores the importance of the medical device adverse event risk management work.

To set up a clear risk management organization and take full charge of the risk management of Shanghai Quyang Hospital is an essential condition for the smooth development of the risk management of adverse medical device events in Shanghai Quyang Hospital.But the survey questionnaire statistical results show that the weak awareness of risk management seriously affected the Shanghai QuYang hospital management's recognition of the importance of risk management level, since there is no set up a sound risk management organization, leading to failure to explicitly specify the specialist is responsible for Shanghai QuYang hospital medical device adverse events within the risk management work by the "who's going to do" problems.

## 4.5 Risk management method process is not clear

The survey results show that Shanghai Quyang Hospital has not yet established a perfect risk management method and process for adverse medical device events in line with China's national conditions, and is seriously lacking in execution.

Although Shanghai Quyang Hospital has barely established a set of risk management process mechanisms in theory and written form, it is difficult to strictly implement the established management process in practical work and calmly deal with the impending adverse events of medical devices.

In the absence of a clear risk management workflow, risk management work is often difficult to be implemented because of no rules to follow, no supervision, and no specific workflow guidance in actual management work.

## 4.6 The risk management information system is imperfect

Shanghai QuYang risk of hospital medical equipment management work has the characteristics of complexity, sudden, progressive, perfect medical device adverse event risk management system can timely transfer between medical staff and worker risk management information, through risk analysis, risk evaluation, risk control and so on effective measures,

Real-time monitoring of adverse events of medical devices in Shanghai Quyang Hospital, effectively avoiding the recurrence of similar adverse events of medical devices.

However, the construction of a medical device adverse event risk management network information system in Shanghai Quyang Hospital is still not perfect, which is far from keeping pace with the development speed of Shanghai Quyang Hospital.

In addition, the risk management ability of Shanghai Quyang Hospital is generally not strong, and the management is weak in establishing the risk management system of adverse medical device events. They only blindly pursue to expand the medical scale and increase economic benefits, and seldom consider the potential risks of the hospital in the rapid growth of economic benefits.

In addition, due to the lack of publicity, the risk management awareness of clinical medical staff is even weaker. After the occurrence of adverse events of medical devices, they worry about damaging the image and economic interests of the department and then conceal the information, which seriously affects the development of risk management work.

Not at the first time after the occurrence of medical devices adverse events through the computer network system, timely report to the related management department directly lead to the risk management in the face of medical risk events response is slow, cannot find problems in time, the delay of risk analysis, evaluation, and control, such as management, management of risk management is unable to clear the objective facts,

The decision-making work is difficult. Because the risk management department cannot

timely take corresponding improvement measures after the occurrence of adverse events of medical devices and feedback them to the clinic, and guide the medical personnel to reasonably avoid risks, the frequent occurrence of medical device risk events often results in a vicious circle.

# CHAPTER 5 FINDING AND CONCLUSION

## 5.1 Findings

With the continuous improvement of the overall medical level in China, a new doctor-patient relationship is gradually forming. Faced with the continuous improvement of patients' self-protection consciousness, all hospitals are facing unprecedented responsibilities and risks.

Adverse medical device event risk management is an important part of medical risk management. It is of great significance to implement adverse medical device event risk management in Shanghai Quyang Hospital.

Through draw lessons from foreign advanced management theory and experience, introduce enterprise risk management theory in the management of medical apparatus and instruments, this article from the perspective of the medical institution, enterprise risk management theory, and process was established in Shanghai QuYang hospital internal matching, suitable for China's national conditions of medical device adverse event risk management system,

Can effectively identify, analyze, evaluate and control the occurrence of medical device risk events, able to carry out effective scientific management of medical device products in Shanghai Quyang Hospital.

Will ever deal with medical devices adverse events consumed by a large amount of manpower and material resources and financial resources for the preventive risk management work, promote the development of Shanghai QuYang hospital itself, is conducive to protect the patient's life safety and body health, improve the economic efficiency of Shanghai QuYang hospital at the same time, and enhance the social benefit of the hospital.

## 5.2 Conclusion and Recommendations

### 5.2.1 Strengthen the construction of risk management rules and regulations

EN 1441:1997 is the first standard that puts forward the application requirements of risk management for medical devices in the world.

The International Organization for Standardization (ISO) ISO/TC 210 working group and the International Electrotechnical Commission IEC/SC 62A working group jointly updated the standard, issued ISO14971-1:1998 standard (" Medical devices - risk management - Part 1 Application of risk analysis ").

After 2000, it was revised and released in 2000 edition and 2007 edition successively, which has become the recognized standard of international medical device risk management activities.

China in 2000 equivalent to the conversion of ISO 14971-1:1998, issued YY/ T0316-2000 "medical devices a risk management: the first part of risk analysis on the application of medical devices".

In 2003, the same conversion ISO14971:2000, issued YY/T0316-2003 "Medical Devices -- Application of Risk Management to Medical Devices".

In April 2008, the State Food and Drug Administration issued YY/T0316-2008 "Medical Devices -- Application of Risk Management to Medical Devices".

This standard is equivalent to IS014971:2007, replacing YY/ T0316-2003, and will be implemented from June 1, 2009.

In May 2008, the State Food and Drug Administration and the Ministry of Health jointly promulgated the Administrative Measures for the Monitoring and Reevaluation of Adverse Medical Device Events (Trial).

In June 2011, the Medical Device Department and Drug Evaluation Center of the State Food and Drug Administration issued the Guidelines for the Monitoring of Adverse Medical Device Events (Trial), which is closely related to the risk management of adverse medical device events. Since then, the monitoring of adverse medical device risk management events has been supported by regulations and documents.

Medical institutions may, according to the medical device adverse event monitoring and evaluation measures for the administration of medical device adverse event risk management in the specific provisions of the latest policy system, speeding up construction is suitable for the medical device adverse events in our hospital risk management rules and regulations, clear responsibilities, risk management personnel to develop a perfect risk management system and implementation process,

We will comprehensively improve the level and quality of medical services and enhance the value of risk management.

**5.2.2 Set up the risk management organization**

The risk management of adverse medical device events in domestic medical institutions is in the initial stage, and the regulations, standards, and management systems of risk management are not perfect. It often takes a process for the relevant managers to understand the importance of the risk management of adverse medical device events.

Widely and deeply carrying out the publicity and training of the knowledge of risk management of adverse medical device events can improve the risk cognition ability of medical personnel and gradually enhance the awareness of risk management.

Medical institutions related management should realize the importance of medical device adverse event risk management work, set up including head director, head of the medical department, clinical medical engineering department supervisor, mainly using medical equipment department, the director of the personnel, perfect risk management organization, from the macro to determine the range of risk management, risk management procedures, Carry out the regular assessment to effectively supervise the risk management work and ensure the effective implementation of a series of risk management measures.

### 5.2.3 Develop risk management workflow

Formulated with risk management organization and perfect the medical device adverse event matching the risk management process, can improve the risk management consciousness of medical personnel, medical risk events in the work can accurately identify the adverse events of medical equipment, and through the risk management of network information system, timely report to the information. After summarizing the data, medical device adverse event risk management personnel will conduct systematic risk analysis, risk assessment, and other professional processing work, and finally draw conclusions and feedback to the leadership to provide a basis for risk management decision-making work.

Set up scientific rigorous risk identification, risk assessment, and risk control management process, can effectively improve the performance of medical device adverse event risk management, reasonable to avoid risk factors existing in the medical equipment in use process, guarantee the medical quality, to protect patient safety, medical staff and patients to provide a safe, harmonious medical environment, It is an important goal of risk management in medical institutions.

### 5.2.4 Establish a risk management information system

Accurate collection and timely feedback of risk information play an important role in the risk identification, evaluation, and treatment of adverse medical device events in Shanghai Quyang Hospital.

Therefore, Shanghai Quyang Hospital should take the digital information network management system as an auxiliary means to establish a complete medical device adverse event risk management information system in Shanghai Quyang Hospital.

Arrange responsible medical device risk information monitoring personnel to complete the collection of risk information. At the same time, statistical analysis software is used to conduct targeted scientific analysis on the collected information, providing the basis for risk control and risk management evaluation of adverse medical device events risk management, and comprehensively improving the scientific and effectiveness of risk assessment and analysis of risk management work.

Perfect medical device adverse events, therefore, the risk management information system, can make the risk of adverse events of medical equipment management information

report promptly, the effective collection, scientific analysis, and comprehensive utilization, strengthen medical devices adverse events from the overall risk management level, thus to ensure the safety of the patients using medical apparatus and instruments. To sum up, it is far from possible to comprehensively improve the overall level of ADR risk management in Shanghai Quyang Hospital only by relying on the unilateral efforts of Shanghai Quyang Hospital. It is suggested that the government regulatory authorities should systematize the specific requirements and implementation process of the risk management laws and regulations based on the actual situation in China, and strengthen the effective monitoring of the use of medical devices in Shanghai Quyang Hospital.

In addition, medical device manufacturers should also master the industry standards, strengthen the awareness of risk management, and implement the concept and management methods of risk management into the actual production process.

Only government regulators and Shanghai QuYang hospital medical device manufacturing enterprise work together to build a set of the scientific and standardized mode of medical device adverse event risk management process, through standardized management and effective supervision, to maximize control of the potential risks of medical equipment, to prevent the occurrence of adverse events, from the largest extent, ensure the life safety of patients.

This paper is mainly a qualitative study based on literature and case analysis. Since scale questionnaire is not adopted, quantitative analysis and empirical hypothesis research are not carried out, which may be limited in research issues. In future studies, scale questionnaire can better cover research issues.

# REFERENCES


Dai, S. B., Cui, L., & Sun, Z. G. (2019). Application effect of risk management in hospital medical device management and its impact on management quality. *China Medical Equipment*, *16*(1), 131-134.

Dai, X. & Zhang, X. M. (2019). Application of risk management in the management of foreign medical devices. *Electronic Journal of Clinical Medicine Literature*, *6*(55), 181.

Du, J., Li, Q., Shi, L., & Li, C. (2019). Analysis of problems in risk management of medical devices in use and Discussion on Optimization Measures. *Friends of Health*, (9), 175.

Duan, Z. H. (2019). Risk management and quality control of medical devices. *China Health Industry*, *16*(25), 48-49.

Han, Y., Yang, X. H., & Dong, H. (2019). The impact of risk management on the quality of medical device management. *Electronic Journal of Integrated Chinese and Western Medicine on Cardiovascular Disease*, *7*(35), 205-205.

Li, J. & Zhuang, Z. (2019). Enlightenment of medical device industry risk management on government risk management. *China Medical Device Information*, (19), 1-5.

Lin, X. (2019). The role of strengthening medical equipment risk management in improving medical quality. *Science and Technology Innovation Guide*, *16*(36), 176-177.

Liu, F. (2020). Discussion on monitoring and risk control management methods of adverse events of medical devices in hospitals. *China Equipment Engineering*, *447*(11), 181-182.

Liu, H. P. (2017). Thinking on risk management of medical device adverse events. *China Medical Device Information*, (23), 133-135.

Liu, H. Y. (2019). Practice and discussion of risk management in hospital medical device management. *China Medical Device Information*, *25*(9), 164-165.

Sun, G. M. (2019). R & D and risk management of medical devices under total quality management. *Digital Users*, 25(32), 64, 66.

Sun, J. M. (2019). On the application of risk management in medical device management. *Journal of Science and Technology Economy*, *27*(8), 253.

Sun, Y., Li, X., Lou, X. D., & Chen, Z. G. (2020). Analysis of new characteristics of medical device risk management development -- Interpretation and discussion of the new version of the ISO14971 standard. *China Medical Device Information*, *26*(5), 13-18.

Wang, S., Tian, L., & Wang, M. Q. (2019). Study on risk management and quality control strategy of medical devices. *Shanxi Medical Journal*, 48(6), 731-732.

Wang, T., Zhao, L. L., & He, D. (2019). Application of risk assessment management in medical device disinfection and supply center. *China Clinical Nursing*, *11*(3), 265-267.

Wu, W. (2018). Risk management problems and Countermeasures of medical devices in use. *Diet Health*, *5*(47), 281-282.

You, Y. M. (2020). Application effect of risk management in quality control of medical devices in the operating room. *Medical Equipment*, *33*(4), 37-38.

Yuan, X. (2020). Discussion on adverse event monitoring and risk management of medical devices in hospitals. *China Hospital Building and Equipment*, 21(9), 99-100.

Zhai, X. L. (2020). Construction of medical device safety management system in a modern

hospital. *Cooperative Economy and Technology*, (8), 142-143.
Zhao, L. N. (2020). Analysis on the application of risk management in hospital medical device inspection management. *China Medical Device Information*, *26*(4), 188-190.

# Appendix

Questionnaire on the current status of medical device adverse event risk management in Shanghai Quyang Hospital

Part I: Basic information of the respondents. Including respondents' age, gender, years of practice, education, title, etc.

(1) Your gender:

A, Female B, Male

(2) Your age:

A, Over 50 years old B, 40~50 years old C, 30~40 years old D, Under 30 years old

(3) Your education level:

A, Doctoral B, Master's C, Bachelor's D, Specialist and below

(4) How long have you been working in your current profession?

A, More than 30 years B, 20-30 years C, 10-20 years D, Less than 10 years

(5) Your title:

A, Senior B, Deputy Senior C, Intermediate D, Junior and below

Part II: Respondents' awareness of medical risk management in our hospital. This includes the establishment of rules and regulations on medical device adverse event risk management in medical institutions, education and pre-service training on risk management knowledge, establishment of risk management institutions and systems, research and funding on risk management topics, and establishment of risk management network information systems.

(1-1) Has your medical institution established a medical device adverse event risk management system?

A, The system is well established B, The system is well established C, No system is established

(1-2) Has your department established a risk management system that is applicable to the work content of your department and provides guidance on the management of medical device adverse event risks in healthcare services?

A, Very applicable B, Fairly applicable C, Very inapplicable

(2-1) Does your medical institution have a risk management organisation consisting of a risk management leadership team and an expert panel dedicated to assessing complex medical device risk events?

A, There is a risk management organisation dedicated to medical device risk events

B, A risk management organisation is in place but not specifically responsible for assessing medical device risk events

C, No risk management organisation in place

(2-2) Does your department have a dedicated medical device adverse event risk management staff responsible for the risk management of medical device adverse events?

A, A medical device adverse event risk management liaison officer is responsible for the risk management of medical device adverse events

B, Medical device adverse event risk management focal points are available but are not responsible for the risk management of medical device adverse events

C, No Medical Device Adverse Event Risk Management Liaison Officer

(2-3) Are you able to accurately determine and report medical device adverse events when they occur in your work?

A, Most of them can be accurately judged and reported

B, A few can accurately determine and report

C, You are able to report it after inaccurate judgment

(3-1) Does your medical institution provide pre-service training to its staff or trainees on medical device adverse event risk management and require them to have a certain level of risk management expertise?

A, Regular and frequent training B, Occasional training C, No training at all

(3-2) Has your healthcare organisation developed a medical device adverse event risk management process and are you able to deal with medical device adverse events effectively in accordance with the process developed when you encounter them at work?

A, A management process is in place and I can handle it effectively

B, I have developed a management process but I cannot handle it effectively

C, No management process is in place

(3-4) When you encounter medical device adverse events in your daily medical work, have you ever concealed them for fear of affecting your personal or departmental financial interests or departmental image?

A, Never concealed the incident B, Occasionally concealed the incident C, Often concealed the incident

(4-1) Does your medical institution organize academic seminars and research on medical device adverse event risk management?

A, Regularly B, Occasionally C, Not at all

(4-2) Does your medical institution have a special management fund for medical device adverse event risk management?

A, Regularly funded B, Funded but not regularly funded C, Not funded

(5-1) Has your medical institution established a medical device adverse event risk management module in its HIS network system so that risk information can be reported to the relevant management department in a timely and convenient manner?

A, Risk management module is in place and can be reported in a timely manner

B, Risk management module is in place but medical device risk information is rarely reported through this module

C, No risk management module is in place

(5-2) Is there someone in your department responsible for regularly reporting medical device adverse events through the risk management information network system?

A, Staffed and regularly reported B, Staffed but not regularly reported C, Not staffed and responsible for reporting