Research on Risk Management and Quality Control of Medical Devices Based on Humanized Concept

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Keywords: Humanization concept, medical equipment, risk management, quality control

Abstract: As a special product, the safety and effectiveness of medical devices are closely related to people's health and even life. The risk of medical devices also includes damage to social property and environment. Therefore, based on the concept of humanization, the author studies the risk management and quality control of medical devices. Introduce the humanization criteria in medical devices and explore the design of medical device products based on the concept of humanity. Research shows that through the particularity of medical products and the analysis of needs and appeals of different users, it is clarified that user research and psychoanalysis are important foundations for humanized design. This research can provide reference for medical device quality management and risk control in large comprehensive hospitals in China.

1. Introduction

As a special product, medical devices are closely related to people's health and even life [1]. As a special or large-scale use or inspection tool, medical devices must ensure the safe, efficient and comfortable operation of medical personnel, and the patients should be physically and psychologically relieved of pain and relaxation during treatment [2]. On the other hand, under the premise of not affecting its function of use, in the design process, from the perceptual and psychological needs of human beings, the color and shape of medical device products are designed with full consideration of people's aesthetic and emotional needs [3]. Thereby balancing people's emotions. However, the risks of medical devices are very common, and there are risks before they are introduced, or in fault conditions and under normal conditions, and even after they are disposed of [4]. The risk control and risk management level of medical devices determine the level of medical care, and medical personnel should fully consider the safety and effectiveness of medical devices during the use of medical devices [5]. The market of medical devices in our country is large and the competition is fierce. The quality and added value of products can be improved by design. Pearl River Hospital affiliated to Southern Medical University applies the concept of humanized management to the evaluation system of medical quality, and encourages all medical staff to participate in [6]. As a manufacturer of medical devices, it is incumbent upon the manufacturer to ensure the delivery of qualified medical devices through sound quality management. Risk management of medical devices is one of the important methods to ensure the quality and safety of medical devices.

Humanized design of medical device products is the premise and foundation of good design. Medical devices as a tool are the extension of human limbs, sensory organs and thinking organs [7]. The risk of medical devices not only may cause injury to human body or even death, but also damage to social property and environment. There are many kinds of medical devices, which are widely used, and the products and technologies are constantly updated [8]. On the one hand, it is based on ergonomics to establish a harmonious relationship between the human body and medical devices, so as to better protect people's health, make it easier for people to accept medical devices and improve work efficiency [9]. In order to control and manage risks, it is necessary to recognize risks and control the risks of medical equipment within acceptable limits. Especially under the system of inversion of burden of proof in medical malpractice, the safety and effectiveness of equipment are particularly important. In the development of medical technology, the safety risks in

  DOI: 10.25236/icebfm.2019.138

the use of medical devices have attracted great attention of the medical community [10]. Therefore, strengthening design innovation and research in this field has certain significance and effect. However, due to the wide variety of medical devices, how to use risk management techniques to effectively carry out risk management activities for different products. As a result, the damage of the medical device to the patient, the user and other related personnel and the surrounding environment is ultimately reduced to an acceptable level. This is still the subject of urgent research and research by medical device manufacturers and regulators.

2. Exploring the design of medical devices based on the concept of humanization

2.1. Humanization guidelines in medical device design

Medical device design has its basic principles, such as the safety of product technology assurance, the comfort of product operation, the processability and economics of product processing. Governments around the world attach great importance to the management of medical device risks. Many countries have implemented medical device risk management standards as mandatory requirements through regulations and other measures. Medical device design not only requires high technology, high quality, but also requires high emotional and humanized, in line with human physiological and psychological needs, that is, the humanization and emotional criteria of design. The difference between medical devices and other products is that they need to meet the requirements of the user (health care personnel) for the comfort, safety and clarity of the product. When we pay more and more attention to medical risks, risk control management can not only be regarded as a means to effectively reduce risks and meet the requirements of patients and national laws and regulations. It is also a necessary guarantee for hospitals to achieve their own strategic objectives within the scope of safety. Optimizing the management of medical devices is an important means to measure the quality of hospital medical treatment and ensure the safety of patients'lives. Medical device design has its basic criteria, such as technical performance, safety, economy, operation comfort and so on. It refers to the premise that the design meets the use function of the product, should focus on people's emotional and psychological needs, meet people's aesthetic needs in the form, color and texture of the product, and coordinate and balance people's emotions.

According to the severity of possible injury, it is divided into five levels, each of which represents a detailed description of the situation as shown in Table 1:

Table 1 Severity Qualitative Grading List

Standard item	Identifier	System value	Possible description
Negligible	S1	1	Inconvenience or temporary discomfort
Slight	S2	2	Inconvenience or temporary discomfort
Serious	S3	3	Cause injury or injury requiring occupational medical intervention
Critical	S4	4	Creation that causes permanent damage or life-threatening damage 伤
Catastrophic	S5	5	Causing death

2.2. Strengthen user usability and demand research

The humanized design of medical devices should be carried out so as to realize the reasonable distribution of people's feelings and product functions, and ensure the high efficiency, safety and comfort of products. User usability research can not be separated from ergonomics. Medical device design not only requires high performance, but also requires a higher degree of humanization due to

the particularity of users. Humanized management is based on respecting and giving full play to human potential. It focuses on people's life and work habits, so as to make management closer to human nature, so as to achieve the purpose of improving people's work potential and work efficiency reasonably and effectively. For example, for a medical equipment, hospital managers (purchasers) consider the performance, color and shape, size and mobility of the product due to the factors of efficiency and hospital environment. As a medical device manufacturer, it is necessary to comprehensively and effectively carry out risk management activities for medical devices, both from the perspective of ensuring product quality and from the perspective of regulatory compliance. In the design process, we must adhere to the basic principles of ergonomics. Starting from the psychological needs of human beings, the design of medical devices fully reflects the characteristics of human beings, thus achieving a harmonious relationship between humans and medical devices. Promote the greatest role of medical devices to better protect human health.

The review is based on viewing risk management documents, and additional applicable documents can be added at individual stages. The review implementation phase and content requirements are shown in Table 2:

Table 2. List of risk management review implementation phases

Review implementation phase	Review content
Risk Analysis	Whether the characteristic determination is sufficient and whether the hazard determination is reasonable.
Risk Assessment	Whether the risk reduction requirement meets the acceptance criteria.
	Whether the risk control plan is complete, operational, and effective.
Risk control	Risk-benefit analysis is sufficient.
	Whether the new risks arising from risk control measures are fully considered.
Residual risk can be evaluated	Whether the acceptability evaluation of all remaining risks is sufficient and appropriate.
	The Risk Management Plan has been fully implemented.
Risk management report	The risk management results are in line with expectations.
	Information after production and production can be obtained smoothly.

3. Medical device product design based on humanized concept

At present, many medical institutions use medical equipment as the original import to publicize. In the design process, they are also accustomed to borrowing foreign medical equipment products, but they ignore the differences in ethnic and cultural differences between China and other countries. Therefore, the goal of risk control is to control the risk to an acceptable level. The development of the risk control plan is to analyze and identify feasible methods to reduce the risk. It can be seen that the design of medical devices needs to consider the needs and interests of patients, medical staff and hospital administrators. Due to ethnic and cultural differences, foreign products do not meet the physiological and psychological conditions of Chinese patients in terms of scale and cultural identity. The influencing factors include: the decoupling of departmental discipline planning and hospital strategy. The lack of evidence in demand demonstration results in the deviation of demand analysis results and the unused equipment and other adverse consequences. In the process of quality control, medical devices should be managed in stages. At the same time, the humanized design of medical devices should also consider the particularity and professionalism of users. Different users have different needs and demands for products. Understanding the evaluation as the ultimate goal ignores the development of employee's business ability, and lacks the link of communication and communication with employees after the evaluation, which is not conducive to the improvement of employee's skills, makes the continuous improvement of medical quality difficult, and reduces employee satisfaction.

With the continuous development of electronic technology, information technology and intelligent technology, medical devices are gradually becoming electronic, informative and intelligent. When designing the interface, the accuracy of the indicator, the consistency of information display and the flexibility of control should be carefully considered so that the operator can use it simply and efficiently. Therefore, the design of medical devices should strengthen the study of human usability and needs, reflecting the people-oriented design purpose. Equipment management departments should stand at the height of hospital strategic planning, study and judge the direction of clinical discipline development, and assess the annual performance of departments and the position of disciplines in China. And submitted to the hospital decision-making level "proposal equipment discipline development planning proposal" to predict and avoid risks in advance. The equipment management department should stand at the height of the hospital's strategic planning, study the direction of clinical discipline development, assess the annual performance of the department and the position of the discipline in the country, and submit the "Proposal for the Development of the Equipment for the Purchase of Equipment" to the decision-making level of the hospital, predicting and evading in advance. risk. Implement the vendor mutual audit strategy, use the competitive situation and technical advantages among the manufacturers in the procurement bidding, and conduct cross-evaluation between the manufacturers' configuration requirements and the vendor configuration standards. This makes it easier to use. At the same time, it uses rational shapes and lines to make the instrument reflect a high-tech sense. At the same time, the use of blue can effectively alleviate the patient's nervousness and relax, which is conducive to the medical process.

4. Conclusions

This article introduces the humanization criteria in medical devices and analyzes the issues that need attention when designing. The humanized scale design, humanized interaction design and humanized design are elaborated in detail, in order to provide reference for the design of medical device products based on humanized concept. The consequences of risk loss are taken as the positive focus of medical quality control, and the risk consequences can be measured. Finally, risk management mechanisms such as risk analysis, risk assessment, risk control, and risk management reporting are established according to the pre-judgment of the consequences of risk loss. The monitoring and maintenance of medical equipment is critical to improving the level of medical technology in hospitals. The hospital must fundamentally ensure the safety of medical devices in clinical use. To form a "low risk, high reliability, high efficiency and low cost" complete medical device life cycle quality and safety management and control system. Really embody the humanized design of medical devices, at the same time, it is conducive to enhancing the competitiveness and added value of products, and enhancing the share of medical devices in the high-end market in China. In a word, in order to implement risk management and quality control of medical devices in hospitals, we should design a comprehensive risk prevention and control plan based on the key elements of pre-demonstration and evaluation of medical devices, bidding strategy, safety criteria for later use, and medical engineering management.

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