Research on Adverse Event Monitoring and Risk Management of Medical Devices Based on BS Model

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Abstract: In order to improve the quantity and quality of reporting adverse events of medical devices, deal with the occurrence of adverse events in time, prevent the occurrence of adverse events, and ensure the safety of the use of medical devices. Based on BS model, the author studies the monitoring and risk management of adverse events of medical devices. Through the research on the status quo of monitoring the adverse events of medical devices in China, the problems existing in the monitoring work at the current stage are analyzed. At the same time, the main measures that can be taken after the risk management of medical devices are listed, and a brief review of the relevant work in this field in China is carried out. And outlook. The research results show that China's related work in this field has just started, and there is still a lack of systematization, and the regulations and technical systems are in need of improvement.

1. Introduction

The medical device industry is developing rapidly. The sales volume of the domestic medical device market has increased from 17.9 billion yuan in 2001 to 443.5 billion yuan in 2017. The number and types of medical devices are increasing day by day [1]. Of course, medical devices, like drugs, are inherently risky and may cause unacceptable adverse events in the human body during use [2]. With the development of China's social economy, the improvement of people's quality of life, and the public's concern for life and health, people's use of medical devices is not limited to satisfying the general diagnosis and treatment function [3]. Rather, it puts higher demands on the safety and effectiveness of its use. In 2005, the World Health Organization (WHO) pointed out that the medical device industry would become the fastest growing industry, and predicted that its global market value would exceed $400 billion in 2010 [4]. Therefore, adverse event monitoring of medical devices, as an important technical support and way for post-marketing safety supervision of medical devices, has become a key research direction of risk management of medical devices [5]. Like pharmaceuticals, any approved medical device is only a risk-acceptable product. In recent years, the focus of international supervision on medical devices has shifted from pre-market approval to post-market supervision. At present, China is gradually establishing and improving the legal and technical system of adverse events monitoring of medical devices.

Medical equipment is an important tool for diagnosis and treatment of diseases, which plays an irreplaceable role in modern medical treatment. The development of science and technology drives practitioners to apply more new technologies to the field of medical devices to meet the clinical needs [6]. As a product of modern science and technology, medical devices have been widely used in the prevention, diagnosis, treatment and rehabilitation of diseases and other fields. It brings people the expected use, but also has a certain potential risk. The implementation of adverse event monitoring and risk management system for post-marketing medical devices is one of the important means to ensure their safe and effective use [7]. At the same time, the total number of medical device adverse events reported has increased by nearly 10% year by year, and the issue of medical device safety has become an important issue affecting people's life safety and quality of life [8]. However, most people only see the positive side of medical devices, but lack of awareness of their potential risks and clinical application quality issues [9]. Medical devices are special commodities where risks and benefits coexist, although safety demonstrations and assessments are carried out before market access [10]. However, due to the congenital deficiency of pre-market research and

the complexity of the clinical application environment, adverse events will still occur during the actual use of medical devices. This is an objective fact that cannot be reversed. It is the responsibility and goal of the drug supervision and management department to ensure the safety and effectiveness of medical devices. The monitoring of adverse events and risk management of listed medical devices is the basic means to achieve this goal.

2. Medical device adverse event monitoring concept

2.1. Definition of medical device adverse events

Medical device adverse events are any undesired adverse events caused or likely to result from the approval of a marketed, quality medical device. The World Health Organization (WHO) definition of epidemiology is the study of the distribution and determinants of health-related events in specific populations and applies to the control of these events. The dynamic development of the situation requires that the prevention of medical device risks is not a once-in-a-lifetime process, but a process of advancing with the times. It can be said that the establishment of risk prevention mechanism is the product of multiple parties playing each other, then the change of mechanism can be regarded as a dynamic game process. With the establishment and development of medical device adverse event monitoring agencies in various countries, the global medical device risk management model has taken shape. When the risk is assessed as unacceptable, measures should be taken to reduce or control the risk. After the control is completed, the residual risk of hazard or damage should be evaluated repeatedly, and the assessment and necessary control should be repeated continuously until all risks are acceptable. In many countries, regulations mainly require reporting of deaths or serious injuries caused or likely to result from medical devices. Therefore, injury epidemiology refers to the use of epidemiological principles and methods to describe the frequency and distribution of injury, and to analyze the causes and risk factors of injury. It is a branch of epidemiology that puts forward intervention and prevention measures and evaluates their effects.

For the adverse events that have occurred, the degree of the adverse events is evaluated according to the pre-listing risk and post-listing risk. Table 1 lists the severity of the risks and their corresponding scores.

Table1. Risk severity and its score

Score	1	2	3	4	5
Classification of instruments	I	/	II	/	III
Damage risk	Suspicious	Slight	Moderate	Serious injury	Death
Duration of use	Short	Secondary	Long	Very long	Effective term
Usage frequency	Very low	Low	Secondary	High	Very high
Adverse Events in the History of Similar Instruments Damage degree	Suspicious	Slight	Moderate	Serious injury	Death
Credit Indicators of Adverse Events in Enterprises	A	B	C	D	E

2.2. Causes of medical device adverse events

The causes of adverse events of medical devices and the limitations of methods are unavoidable. Like other epidemiology, the direct cause of human injury events; third, hazard media are the media connecting medical device system and human body system, which play a decisive role in the nature and degree of adverse events of medical devices. In our country, there are few large-scale enterprises in the medical device industry, and most of the products are concentrated on low-end

products, which are at a disadvantage in high-end products. And the production concentration is low, the strength is dispersed, and the flagship enterprise group has not yet formed. The homogeneity and scale of products are serious. The first step is risk analysis, which determines the adverse events that have occurred or potential risks and reduces the uncertainty of potential risks. The second step is a risk assessment to assess the severity of the risk or the severity of the potential risk. The third step is risk control. Through the grading supervision of adverse events, timely and effective treatment of adverse events has occurred to prevent potential adverse events. These “acceptable” risks gradually become “unacceptable” as the performance of the device itself declines and the environment and people change. Or because the limitations of people's cognition before the listing are considered "acceptable", which ultimately leads to adverse events.

The probability of occurrence of risk is divided into impossible, almost non-occurring, rare, likely and frequent. According to the severity and probability of occurrence, the risk matrix is established as shown in Table 2.

Table 2 Medical device product risk matrix

Severity	Impossible	Hardly happening	Rarely	May occur	occur frequently
No	Ignorable	Ignorable	Ignorable	Ignorable	Ignorable
Green alert	Low	Low	Low	Secondary	Secondary
Yellow alert	Low	Low	Secondary	Secondary	High
Red alert	Low	Secondary	Secondary	High	High

3. Monitoring and optimization of adverse events of medical devices from the perspective of dynamic game theory

Although there are nearly 10,000 medical device manufacturers in China, the total industrial output value of this industry only accounts for 2% of the world market share. Therefore, among the four interactive factors of "host", "imposer", "hazard medium" and "hazard situation", because "hazard medium" is characteristic, related and decisive, this paper takes it as the classification standard of adverse events of medical devices. If the content of product labels or instructions is not accurate, specific and comprehensive due to cognitive or technical constraints, it will not play a role in guiding the correct use, or even mislead patients or operators, resulting in adverse events. The risk analysis of medical devices by manufacturers focuses on R&D risk, technology risk, production risk, management risk and policy risk. The risk analysis of the use unit focuses on quality risk, human risk, occasional risk and application environmental risk. The human-machine engineering view holds that in the process of human-computer interaction, people always have weaknesses and cause usage errors. Optimizing human-computer interaction can reduce the occurrence of usage errors. The GHTF Working Group is committed to the coordination of post-marketing surveillance and vigilance systems for medical devices and seeks to establish a unified global adversary alert system. Of course, these three strategies are not exclusive, and regulators often adopt a hybrid strategy.

It can be seen that whether it is the risk analysis of the production enterprise or the use unit, its main focus is on research and development, production or use management. As with the inherent risks of the device, the use error is not fully discovered before the device is released, and cannot be completely eliminated after listing, and can only be reduced as much as possible. In dynamic game theory, the pursuit of maximization of interests by various stakeholders is the basic assumption of its research. The monitoring of adverse events is mainly aimed at the risks in the actual application of the equipment stage. And the use of most instruments must be completed by the actual operation of a professional doctor, in which there is a strong information asymmetry between doctors and patients. When studying the classification of medical devices, this paper refers to the concept of matter and energy as “energy”. Therefore, the criterion is "harmful medium". The results of pre-market evaluation research are only used to judge whether it can be formally applied to the human body, compared with the life cycle and scope of use of the whole product. The risk analysis of

adverse events for regulatory authorities should be more inclined to the outcome risk analysis of the occurrence or potential adverse events of medical devices, and the impact of the occurrence or potential adverse events should be assessed. In practical use, adverse events of instruments may also be affected by other factors such as environment, doctor's diagnosis, biological experiments and so on. In addition, the combined use and poor compatibility of devices are other factors that may lead to adverse events.

4. Conclusions

This paper explores a new mode of adverse event monitoring of medical devices, and uses risk management method to carry out risk analysis, risk assessment and risk control of adverse events, so as to achieve the classification of adverse events. In the recall process, the recall laws, regulations and characteristics of medical devices in China are analyzed in detail, and the working process and content of the recall are determined. The reporting system of adverse events of medical devices provides an effective guarantee for timely discovery of new and serious adverse events, avoidance of repetition of the same events, and protection of public safety of equipment. It is the key point for the supervision department to carry out the safety supervision of medical devices. China's product quality law stipulates that a recall system may be implemented for some products with quality problems, but there is no clear legal provision for special products such as medical devices. The monitoring of medical device adverse events is beneficial to the country and the people, and has a long way to go. Because this study may still have problems such as “Is the medium manifestation of the hazard medium comprehensive and accurate?” and “Is the application practical and effective?”, it requires more in-depth verification and research. In order to achieve the purpose of "promoting practice with theory and correcting or supplementing theory with practice." To achieve automatic grading of adverse events, reduce the workload of administrative supervision departments, improve the efficiency of adverse event monitoring, and ensure the safety of medical device users and patients.

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