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The Significance of Promoting the Implementation of Medical Device Vigilance

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Abstract

The necessity of constructing a medical device vigilance system is proposed in the context of the implementation of the pilot work of medical device vigilance in China. This paper analyzes the significance of the implementation of medical device vigilance in China based on China's medical device regulatory system, drawing on the experience of medical device adverse event monitoring and combining pre-market and post-market risk management. Thus, it is concluded that the introduction of medical device vigilance system is of great significance to promote the supervision of the whole life cycle of devices in China.

Keywords

Medical Device; Device Vigilance; Adverse Events; Risk Management.

1. Introduction

In recent years, the expansion of China's economic scale and the improvement of the living standard of the population has contributed to the growing demand for health, leading to the rapid development of the medical equipment industry in various cities and towns. The Measures for the Management of Adverse Event Monitoring and Re-evaluation of Medical Devices released in 2018 and the revised Regulations for the Supervision and Administration of Medical Devices in 2021 highlight the china's continued focus on the issue of patient safety in the use of devices. The introduction of these regulations shows that the state has strengthened its regulatory efforts in the medical device industry to ensure the safety of patients using devices. Therefore, it is necessary to build a perfect regulatory system for medical devices [1].

The term vigilance first appeared in the medical industry in the context of drugs, based on the 2019 version of the Drug Administration Law of the People's Republic of China, the State Drug Administration promulgated the Good Pharmacovigilance Practice (GVP) on May 13, 2021, which, as the first document related to vigilance to be introduced in China, is of great significance to the advancement of drug safety and has a far-reaching impact[2]. Pharmacovigilance (PV) is the scientific activity of discovering, evaluating, recognizing and preventing adverse drug reactions or any other drug-related problems, and the monitoring of adverse drug reactions (ADR) is the basis for the construction of pharmacovigilance system[3].Similarly, in the field of medical device regulation, medical device vigilance is the need for the development of high quality monitoring of medical device adverse events, and vigilance work is a new stage reached by the development of adverse event monitoring work. It not only expands the vision of monitoring work, improves the initiative of monitoring, but also provides a stronger guarantee for timely identification and control of medical device product risks.

From the overall view of Fig. 1 since 2015, the number of medical device adverse event reports has significantly improved, in 2022, the national medical device adverse event monitoring information system received more than 690,000 medical device adverse event reports, the

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average number of reports per million population was 493, the number of registered users of the adverse event monitoring information system has continued to improve, and the county-level coverage of adverse event reporting has reached 100%[4]. This phenomenon also indicates that China's adverse event monitoring is effective. The development of China's medical device adverse event work, from the beginning of the pilot work to the current standardized monitoring, from the increase in the number of reports to report the quality of the report to improve the content of the monitoring from the collection of pure reports, individual case evaluation to early warning analysis and management, risk identification and control, indicating that China's medical device regulatory work in the continuous innovation. By continuously improving the regulatory mechanism and strengthening the monitoring capability, we are able to detect and handle medical device adverse events in a more timely manner and effectively protect the rights and safety of patients[5].

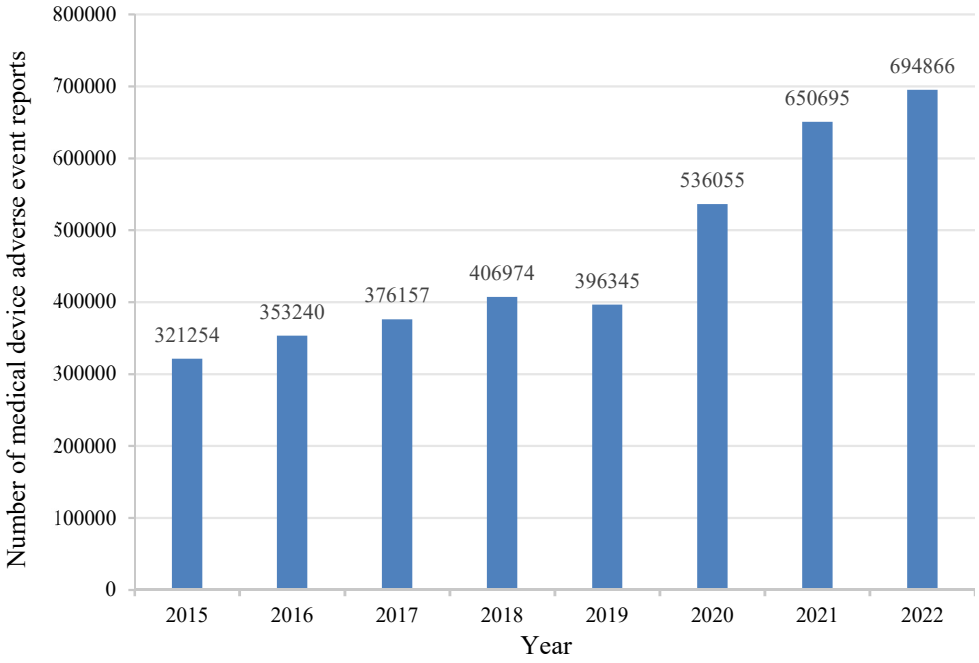

Fig. 1 Number of national medical device adverse event reports, 2015-2022

2. Vigilance Related Regulatory Developments

In the field of medical devices in the country's regulatory system of laws and regulations continue to improve the situation, drawing on the experience of the "pharmacovigilance quality management standard", the State Drug Administration put forward a "medical device vigilance" new ideas[6]. The concept of "vigilance" refers to the establishment of a series of vigilance mechanisms and measures in the field of medical device regulation, in order to raise awareness of and attach importance to the safety of medical devices, to anticipate and identify potential risks, and to take appropriate measures to control and manage them. In the newly revised Regulations for the Supervision and Administration of Medical Devices also emphasizes the need to strengthen the supervision of the whole life cycle of medical devices in the whole process[7].

With economic development and communication between countries, the regulatory aspects of devices have been gradually improved in order to provide the public with a safe environment for the use of devices. The EU published the Guidelines on a medical device vigilance system (MEDDEV2.12-1 Rev 5) back in 2001, which are based on the Medical Devices Directive (MDD, 93/42/EEC), and in the new EU (2017/745) Medical Device Regulation (MDR) the concept of

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medical device vigilance is clarified[8,9]. Although the U.S. Food and Drug Administration (FDA) has not clarified the meaning of vigilance, the requirements for medical device vigilance are reflected in the MDR report, The Safe Medical Devices Act, the Medical Device Active Reporting System (MedWatch) and the Adverse Event Reporting System (FAERS)[10].

The development of medical device vigilance not only improves the lack of regulations, but also strengthens the international exchange and cooperation, China actively participates in the international regulatory work, based on the national conditions of research, the introduction of international advanced vigilance standards, norms and so on, to realize the internationalization of medical device vigilance work.

3. The Heart of Medical Device Vigilance

3.1. The Need for a Medical Device Vigilance System

The establishment of a medical device vigilance system is the basis for carrying out device vigilance activities, with reference to the "Pharmacovigilance Quality Management Standard" registrants should establish a medical device vigilance system[11], incorporate the organization, people, systems and resources related to vigilance activities into the quality management system, and effectively prevent risks by operating the system to reduce the uncertainty of risks and further identify the possibility of product improvement. The newly revised Regulations emphasize the need to pay attention to the risk of the whole life cycle of the device, and the medical device alert system carries out risk identification through early warning to help enterprises identify potential risks in a timely manner. Incorporating device vigilance into the quality management system and keeping and managing documents and records in accordance with the requirements of the quality management system is conducive to the healthy development of the entire medical device industry.

3.2. Medical Device Risk Management

Medical device risk management is a top priority in device vigilance activities. The basic process of pharmaceutical risk management, i.e., monitoring, identifying, evaluating and controlling risks, is defined in the Code of Practice for Quality Management in Pharmacovigilance[12]. Risk control for devices can refer to the same idea, first of all, risk monitoring to collect similar devices related to adverse reactions; risk identification is from the collected information to find out the risk points that may jeopardize the health of the patient; risk evaluation for each identified hazardous situation, the development of risk acceptability guidelines, combined with the probability of occurrence of injuries and the severity of the incident, to determine whether the risk is acceptable; risk control is The risk control is to take measures to minimize the risk and to ensure that the benefit always outweighs the risk[13].

Drawing on the valuable experience gained in medical device adverse event surveillance to fully assess whether the same problems will be encountered in the implementation of device vigilance efforts. Build device alert system should be closely integrated with the medical device adverse event monitoring system, medical device alert is an extension of the medical device adverse event monitoring work. At present, the data analysis of adverse events mainly comes from the production enterprises, operating companies and users through the adverse event system of active reporting, reporting ratio there is an obvious imbalance in the phenomenon, most of the report still comes from the use of the unit, the production enterprises for the active reporting of the information collected there are still some concerns[14]. Although the amount of data and information collected is increasing year by year through the tireless efforts of all parties, continued efforts are needed to obtain more information on the safety of products and to promote the continuous improvement of products. The United States, the European Union, and other countries use social media to obtain product-related safety information. Although

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there are drawbacks such as the content and form of the reported data being uncontrolled, the advantages of social media's large number of users, which is conducive to obtaining more data on individual cases, should not be ignored. Therefore, China should make full use of the emerging information system in the era of big data, fully analyze the advantages and disadvantages, and explore the establishment of a management mechanism for layered sharing of data between the alert system and the adverse event system that is suitable for China's national conditions, so as to gradually complete the conversion from the adverse event monitoring system to the medical device alert system[15]. The use of big data can strengthen the collection of risk information and the establishment of vigilance system, providing a more scientific and accurate basis for the safety management of medical devices.

4. The Role of Medical Device Vigilance

The pre-market and post-market regulatory systems for medical devices are separate, and the pre-market regulatory requirements for devices are reflected in the Code for Quality Management of Clinical Trials of Medical Devices[16], while the post-market requirements are reflected in the Measures for the Management of Adverse Events Monitoring and Re-evaluation of Medical Devices. The introduction of the alert system builds a bridge between the pre-market and post-market regulation of devices, and more intuitively shows the concept of the full-life-cycle management of devices. Although this system is not yet universally implemented, the pilot work has achieved outstanding results, and it is believed that the medical device regulatory system will be improved through continuous efforts.

The establishment of the medical device alert system promotes the further improvement of the device regulatory system, which will help to realize the scientific supervision of medical devices, strengthen the adverse event monitoring and risk control of post-marketing medical devices, accurately prevent and control the risk of the whole life cycle of the products, boost the product innovation and industrial upgrading, and provide the people with a wider range of more practical and safer medical device products to effectively safeguard public health[17].

5. The Significance of Medical Device Vigilance

The implementation of medical device alert work is of great significance for building a system of device alert system, standardizing device alert activities, guiding manufacturers to establish a quality system for device alert, improving the management level of device alert, providing the public with more practical and safe medical devices, and safeguarding the health of patients.

The introduction of the device vigilance system provides a basis for enterprises to establish a device vigilance system, and enterprises can establish a system to carry out their work in accordance with the requirements based on their own actual situation and with reference to international experience. The introduction of the system also provides an important basis for drug regulatory authorities to check whether enterprises fulfill their legal responsibilities according to the requirements. The regulatory authority promotes the implementation of the alert system, promotes the implementation of the system in enterprises through a combination of training, publicity and inspection, and mobilizes the enthusiasm of enterprises to collect risk information in order to achieve the purpose of safeguarding the safety of public use of devices[18].

6. Reflections on the Construction of the Apparatus Vigilance System in China

The application of new materials, the development of new technologies and the continuous declaration of new products in the market have led to the gradual emergence of risks in medical

device products. With the convergence of international regulatory concepts and the deepening of regulatory internationalization, the monitoring and evaluation of adverse events is facing a new opportunity to transform into medical device vigilance, which is conducive to strengthening the management of devices, expanding the scope of vigilance information collection, improving the ability of risk response level, and enhancing the effectiveness of monitoring. Strengthening the awareness of risk management of registrants through regulatory training, supervision and inspection[19]. Through the establishment of monitoring sentinel sites to carry out post-marketing real-world data collection; with the help of professionals in various fields of society, such as universities, scientific research institutions, hospitals and excellent personnel, to improve the scientific accuracy of data analysis, in order to find out the problems in the design, manufacture or use of the device, so as to improve the ability of risk identification and control[20]. Accelerating the construction of the medical device vigilance system and promoting the scientific and standardized operation of the medical device vigilance system is indispensable.

7. Summary

In the global environment of constant attention to vigilance, China's device vigilance is the sublimation of adverse event monitoring. Under the current regulatory system, establishing a medical device warning system and thinking about how to mobilize all participants to actively carry out risk identification, monitoring and control are issues that need to be considered carefully. The introduction of the medical device vigilance system will undoubtedly bring the field of device regulation in China to a higher level, which is of great significance and far-reaching impact on promoting the regulation of the whole life cycle of devices in China. The work in the field of instrument vigilance in China still has a long way to go.

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