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Discussion on Medical Device Adverse Event Surveillance

Lei Liu

Lepu Medical Technology (Beijing) Co., Ltd., Beijing 100022, China

Abstract: With the continuous development of medical technology and the wide application of medical devices, the risk of medical device adverse events is gradually increasing. In order to ensure the safety and effectiveness of medical devices, timely detection and treatment of adverse events of medical devices, and to protect the safety and rights of patients, the state continuously strengthens the monitoring of adverse events of medical devices. This paper firstly introduces the domestic and foreign medical device adverse event related regulations, it introduces the form of medical device adverse event monitoring work in China, compares and analyzes the data of medical device adverse events in recent years, and puts forward some problems in medical device adverse event monitoring work, in order to continuously improve the control and management of the risk level of medical devices, and ensure the clinical use of medical devices and patient safety.

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

1. Introduction

Medical device adverse event refers to the marketed medical device in the normal use of the process occurred in a variety of events that lead to or may lead to human injury[1]. There are many factors for the occurrence of medical device adverse events, involving product design, material use and clinical process[2], medical device failure, user's physical reasons, there are errors in the product specification, etc., many reasons lead to the use of the period of adverse events may occur, the occurrence of adverse events not only damage to the patient's physical health and safety of life, but also may lead to the emergence of medical disputes. With the advancement of science and technology, new medical devices are emerging, how to effectively manage medical devices has become a new issue for the medical industry to face.

2. Medical Device Adverse Event Regulations

2.1. China

The development of China's medical device adverse event regulations started with the launch of the pilot work of medical device adverse event monitoring in 2002, and in 2008, the Administrative Measures for Monitoring and Re-evaluation of Adverse Events of Medical Devices (for Trial Implementation) was enacted, and after revision, the Administrative Measures for Monitoring and Re-evaluation of Adverse Events of Medical Devices was enacted in 2019[3]. The Medical Device Adverse Event Surveillance Information System pushes adverse event information to the registrant, who evaluates the reports received. For the first registration of Class II and Class III medical device products in accordance with the requirements of regular completion of the periodic risk evaluation report submitted to the adverse event monitoring information system; for Class I medical devices and the continuation of registration of the product, the registrant is required to complete the next continuation of the registration of the periodic risk evaluation report, to be retained for future reference; for innovative medical devices, the requirements of the first registration cycle, every six months, to submit the analysis and evaluation of the adverse event report. State Drug Administration and the State Council administrative department of health to determine the key monitoring varieties list, through key monitoring, to strengthen the risk of post-market medical devices active monitoring research.

2.2. European Union

In 2001, the Guidelines for Medical Device Vigilance Systems were issued and revised in 2007 to emphasize medical device adverse event reporting and evaluation efforts as well as field safety corrective actions. In 2017, the EU issued the MDR medical device regulation, which requires manufacturers to collect and analyze quality and safety information throughout the life cycle of medical devices, as well as to collect any adverse events other than known medical device adverse events that result in, or are likely to result in, patient deaths / serious injuries, and to report them to the competent authorities, notified bodies, or authorized representatives, through the European Medical Devices Database (Eudamed). Pay particular attention to unknown risks and changes in risk-benefit ratios and, based on the findings, determine the need for precautionary measures and, if necessary, organize risk evaluations. The EU requires manufacturers of Class I medical devices to prepare periodic post-market surveillance reports; manufacturers of Class IIa, IIb and III medical devices to collect safety information under the post-market surveillance program and complete periodic safety update reports [4].

2.3. United States

In 2001, the Guidelines for Medical Device Vigilance Systems were issued and revised in 2007 to emphasize medical device adverse event reporting and evaluation efforts as well as field safety corrective actions. FDA categorizes adverse event reports into two types: mandatory reports and voluntary reports. Mandatory reports are submitted by the manufacturer or importer and include reports of events in which a medical device caused or may have caused death or serious injury, and reports in which a medical device malfunction again caused or may have caused death or serious

injury. Voluntary reporting encourages patients, healthcare professionals and consumers to come forward and submit adverse event reports as described above[5]. FDA has clarified the exemption for reporting an adverse event that is analyzed by a person with the ability to perform a medical evaluation and who believes that a recurrence of the adverse event will not result in death/serious injury. Potential risks of medical devices can be identified through methods such as adverse event reports, corrective actions, recall information, pre-market data reviews, post-market data analyses, reports from other government agencies, or scientific literature. In order to monitor post-market medical devices, FDA discusses with the manufacturer, develops a monitoring plan, and supervises and guides its implementation. Manufacturers are required to submit transitional and summary reports to the FDA according to the timeline. When a team of FDA experts jointly review and approve, it indicates that the risk signal has been terminated or the post-market monitoring plan has been completed. If the assessment concludes that the medical device poses a serious risk of deception or unreasonableness, the FDA can make a request to disable it [4].

3. Medical Device Adverse Event Reporting Process

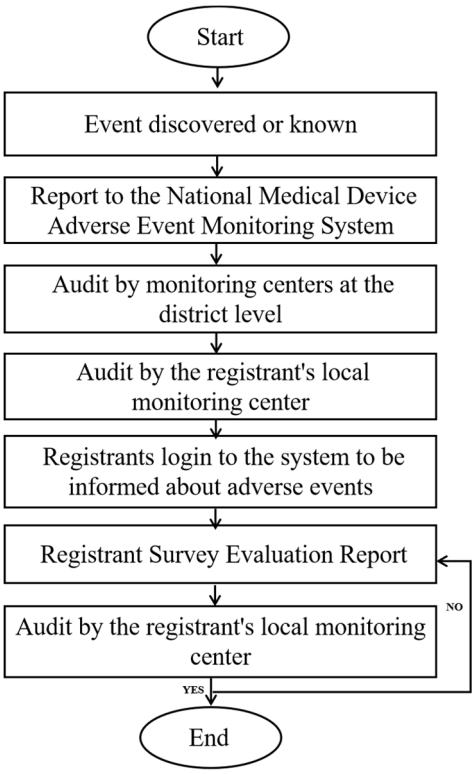

Fig 1. Adverse Event Reporting Process

Adverse event monitoring of medical devices serves as an important means of medical device risk management [6]. At present, the monitoring of post-marketing adverse events mainly relies on the National Medical Device Adverse Event Monitoring Information System, and the reporting process is shown in Figure 1.

4. Summary of Domestic Medical Device Data Analysis in Recent Years

The number of medical device adverse event reports as an important indicator for assessing the performance of adverse event monitoring work [7]. With the release of the Medical Device Adverse Event Monitoring and Re-evaluation Management Measures in 2019, the number of adverse event reports is on an overall upward trend, with the number of reports rising from 406974 in 2018 to 694866 in 2022. The average number of reports per million population is an important indicator of a country's ability to report medical device adverse events and provides a visual representation of adverse event efforts. Number of reports per million population from 305 in 2018 to 493 in 2022. The total number of users registered in the medical device adverse event monitoring information system in 2018 was 275715, of which 13854 were manufacturers, 143535 were operating enterprises and 118326 were using units. The total number of users registered in the national medical device adverse event monitoring information system in 2022 was 397561, of which 31648 were registrants, 234, operating enterprises and 234,836, and 131077 utilization units (Table1). The overall data show that as the depth and breadth of surveillance continues to expand, adverse event surveillance has been highly effective [8].

Adverse event reports received were analyzed, and in 2018, 138 reports were received where the degree of injury from the event was fatal; 68,807 reports were received where the degree of injury was serious; and 338,029 reports were received where the degree of injury was other. 153 adverse event reports of reported deaths in 2022, none of which found a clear correlation between the adverse event and the medical device involved; 45,012 reports of serious injuries; and 649,701 reports of other injuries (Fig. 2) [9].

Table 1. Comparison of data 2018-2022

Year	Total number of reports	Average number of reports per million population	Registered user		
			Registrant	Operating company	Utilization unit
2018	406974	305	13854	143535	118326
2019	396345	297	19662	178295	121029
2020	536055	402	27195	198833	124945
2021	650695	461	29436	219340	128296
2022	694866	493	31648	234836	131077

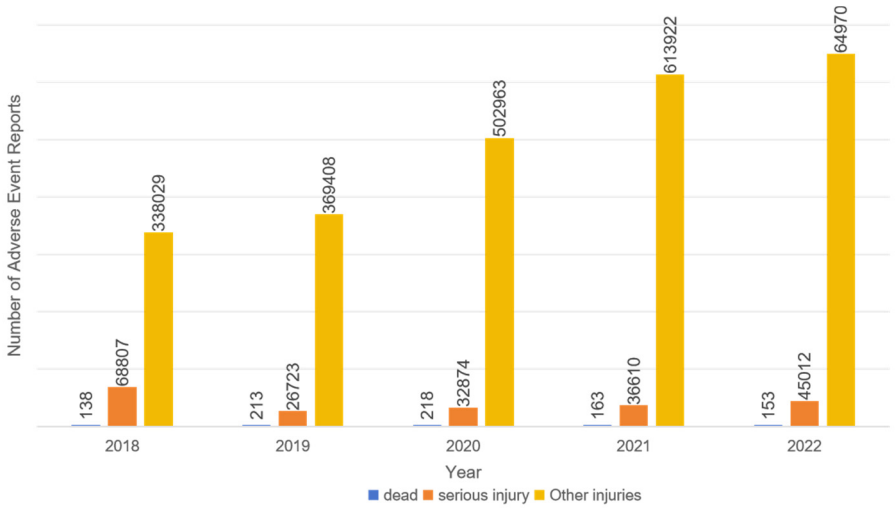

Fig 2. Analysis by degree of harm from the incident

In 2018, among the suspicious medical device adverse event reports received by the National Medical Device Adverse Event Monitoring Information System, 357,652 were reported by using units, accounting for 87.88% of the total number of reports; 10,827 were reported by registrants, accounting for 2.66% of the total number of reports; 38,340 were reported by operating enterprises, accounting for 9.42% of the total number of reports; and 155 were reported by other reports. 2022. 607,551 or 87.43% of the total number of reports were reported by user organizations; 16,100 or 2.32% of the total number of reports were reported by registrants; 70,877 or 10.20% of the total number of reports were reported by operating companies; and 338 reports were reported by other sources(Fig. 3). The ratio of user units to the total number of reports remains balanced and the number of reports has increased significantly. In terms of the percentage of reports, the source of reports still relies mainly on the reporting of user units, and it is necessary to continue to mobilize registrants and operating companies to report.

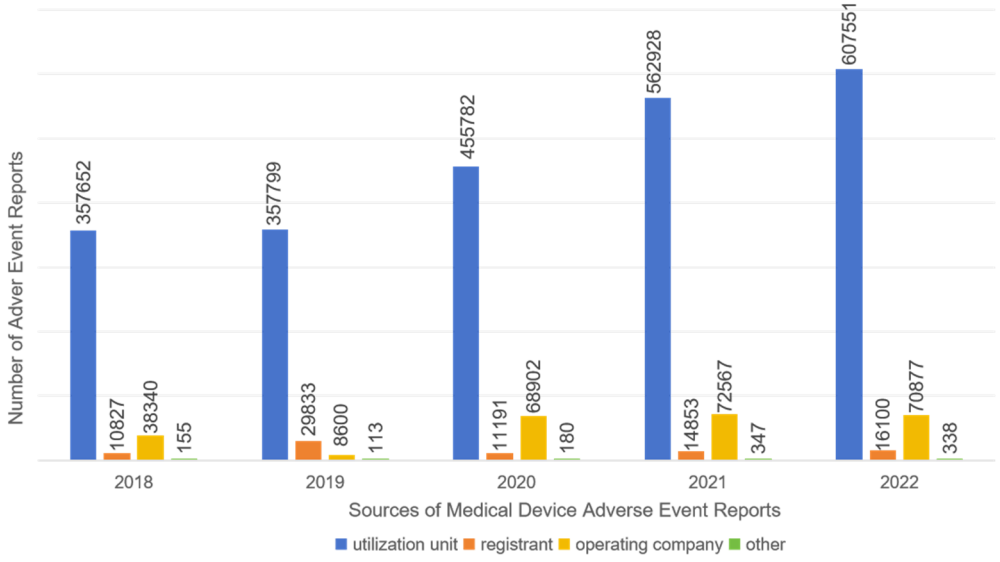

Fig 3. Sources of Medical Device Adverse Event Reports

5. Problems with Adverse Event Monitoring

Through continuous efforts adverse event monitoring work has achieved certain results, but there are still some shortcomings, we need to face up to the existing problems, and continuous improvement.

Adverse events were not reported in a timely manner and there were misreporting and false alarms[10].In many medical structures, due to more work, poor execution, for the occurrence of adverse events are not reported in a timely manner within the specified time, resulting in the extension of the reporting time, for the accuracy of the information can not be guaranteed, which is not conducive to the feedback of the later production companies to investigate, resulting in the investigation of the survey has not been effective, but also may have missed the best opportunity to investigate.

Lack of specialized knowledge and enhancement of professional competence [11]. In some user units, due to the division of labor, the reporting person may not be directly involved in the use of the device by the relevant medical staff, and may not be able to accurately describe the use of the device, and the choice of device terminology is not sufficiently accurate. Healthcare workers are not clear about the medical device adverse event monitoring system and reporting mechanism due to a lack of business knowledge, resulting in the inability to report relevant content and information in a timely manner when adverse events occur. If the staff is not professional enough, even if they make a report, they may not specify the problem, which has a certain impact on the overall work efficiency.

Monitoring is not focused[12]. In recent years, the state has continuously issued relevant regulations to carry out key monitoring of adverse events of medical devices, the relevant staff do not understand the performance and principles of medical devices, unable to carry out specific monitoring and risk assessment work, put part of the effort on the management of the number of adverse events, for the quality of the reported medical device quality requirements are negligent in the management of medical devices in the future use of the process of retaining the safety of hidden dangers.

Low ideological awareness[13]. We have raised the level of importance attached to medical devices, issued various documents on strengthening the regulation of medical devices, and enhanced the training for enterprises, as well as the frequency of daily supervision and audits. This is for medical device manufacturers and business enterprises, the implementation of the policy has attracted a certain amount of attention. However, the enterprises are still more concerned about how to improve economic efficiency, worried about the medical device adverse event report will affect the image of the enterprise or product ideological concerns[14]. For the discovery of adverse events and will not take the initiative to report, will be taken into account, so that the long-term development is not conducive to the discovery of product risk points, is not conducive to the improvement of the device, is not conducive to the benign development of medical devices.

Enhance the knowledge of the corresponding groups on adverse event monitoring, attach importance to medical device adverse event monitoring, and consider the long-term benefits of medical device adverse event monitoring and control management[15]. Construct the medical device adverse event monitoring system and system, create a reasonable, positive, scientific monitoring environment. Enhance publicity and education, popularize the business knowledge, not only for the relevant medical personnel adverse events related policies to carry out publicity, education, training, but also for the use of medical devices and the principle of the relevant knowledge to carry out targeted training, improve the business capacity, reduce the use of the process of adverse events occurring[16].

6. Summary

The use of medical devices is a double-edged sword, improving the level of diagnosis and treatment, but also accompanied by the occurrence of medical risks. By monitoring medical device adverse events, discovering risks and reporting them in a timely manner, we can take timely measures to intervene when patients experience uncomfortable symptoms, reduce the occurrence of adverse events, and ensure the safety and health of patients. Therefore, the quality of medical devices should be grasped from the root, the importance of adverse event monitoring should be raised from the consciousness, and the medical devices should be strictly controlled from the management process, so that problems can be detected in time, the probability of adverse events can be lowered, and medical risks can be prevented, so as to ensure that the work of the medical institutions can be carried out in an orderly manner, and to avoid the occurrence of the risky accidents of medical safety.

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