Inspection and Supervision of Imported Medical Equipment

Chenman Cao *

Technology Center of Anhui Entry-Exit Inspection and Quarantine Bureau Anhui, 230022 China

*caochenman3866@yeah.net

Abstract

With the continuous development of modern medical cause, it is important to rely on advanced medical equipment for diagnosis and treatment. Now our country has entered an age of aging population. With the improvement of people's living standards, coupled with the continuous advancement of the new medical reform, the continuous expansion of foreign exchanges and the gradual increase of imported medical equipment. In recent years, the import of medical equipment has gradually increased. The import of medical equipment has promoted the development of economy and medical cause. Using modern information means, integrating resources, ensuring the smooth flow of information, and other seven countermeasures, providing reference for improving the supervision laws and regulations on imported medical equipment and effectively supervising imported medical equipment, and establishing a fair, just, scientific, democratic, efficient and transparent The government regulatory agencies to achieve scientific and efficient supervision, promote the healthy development of China's medical equipment independent industry, and lay the foundation for improving the country's overall medical capacity and medical care.

Keywords

Medical equipment; Inspection and supervision.

1. Introduction

Now our country has entered an age of population aging. Up to now, the proportion of the elderly over 60 in our country has reached 12 % of the total population [1]. As the elderly need long-term medical care and people's demand for health care is increasing, on the other hand, with the improvement of people's living standards and the continuous advancement of new medical reform, foreign exchanges are expanding and imported medical devices are gradually increasing [2]. In our country, imported medical equipment, like imported medicines, is a special commodity related to people's health and even life safety [3]. With the rapid development of economy, people's requirements for life and health are constantly raised, the demand for health examination is constantly increasing, the requirements for disease diagnosis are constantly accurate, the requirements for disease treatment are constantly free of side effects, medical personnel operate in secret and medical equipment in developed countries is superior to domestic medical equipment, which provides better convenience for the development of imported medical equipment in China [4]. In recent years, many large and medium-sized hospitals have been importing some international advanced medical equipment, and the number of imports is on the rise [5]. Therefore, the inspection and supervision of imported medical equipment is very important to protect the interests of the people and protect the rights and interests of consumers.

The medical industry is a high-tech, high-difficult, high-risk industry. Any clinical activity carries more or less risks. There are objective accidents. These risks are increasing due to defects in medical equipment [6]. Main features of medical equipment risks: 1. High risk level. 2. The risk is complex

and uncertain, and its uncertainty is manifested in all aspects of production, storage, transportation and use [7]. 3. Once the risk of medical equipment occurs, it may cause damage to the organ function of the patient, or even death, and bring many adverse effects and consequences to the life and work of the patient and his family [8]. In China, the number of imported medical equipment is large, the quantity is large, the scope is wide, the technical content is high, the inspection standards are not unified, and the laws and regulations on supervision and management are imperfect, which leads to the negative impact of the imported medical equipment market, resulting in the same function of production in China. There is no sales market for products at home and abroad [9]. This leads to the hard work of the supervision and management of imported medical equipment, which brings huge safety risks to people's health and life, and also affects the development of China's independent industry of medical equipment and even the economic development of our country to a certain extent [10]. According to the development of China's economy, in the coming decades or even hundreds of years, China will still be in a state of importing medical equipment from abroad [11]. In this case, it is an urgent task for us to analyze the problems existing in the supervision of imported medical equipment and how to effectively and effectively use the government's market supervision function to manage and use imported medical equipment [12].

In order to better maintain the market economy, we should determine the weight of various management in the system according to the actual situation of our country and the types of problems. It is our economic goal to implement effective supervision over imported medical equipment and promote the development of China's medical equipment industry [13]. So the use of government functions of economic management for medical equipment manufacturing enterprises in China to provide favorable development space, to some extent, the use of system or regulations increase imports into the door of our country, the independent research and development of medical equipment in our country exports abroad, the promotion of the competitiveness of the medical equipment production and management enterprises in China [14]. Therefore, using public management government market supervision means to study the problems existing in the supervision of imported medical equipment and to explore effective countermeasures has a very far-reaching and realistic significance [15]. For the supervision of medical equipment, there are corresponding regulatory systems at home and abroad. The typical ones are the US FDA, the EU MDD Directive, and the Chinese SFDA. However, the three have many similarities and differences in the way medical equipment is regulated [16]. In 2007, some scholars proposed the application of risk management in the inspection of imported food, which can be used to refer to the inspection and supervision of imported medical equipment [17]. In 2014, some scholars put forward the current situation and suggestions of medical device testing institutions in China [18]. In 2016, some scholars put forward the medical device testing process in medical institutions, through software solutions [19].

2. Materials And Methods

In the United States, " medical equipment" refers to instruments, equipment, appliances, devices, implants, extracorporeal reagents or other similar or related items used in the following ranges, including any parts or accessories thereof. Published on official national formulary or U.S. pharmacopoeia, or their supplementary volumes. For the diagnosis of diseases or other conditions in humans or animals, for the intended purpose of monitoring, alleviating, treating or preventing diseases. The intended purpose is to influence the tissues or functions of human beings or animals, but this purpose is not obtained by chemical reaction between human beings and animals or by metabolic means [20]. In the EU, medical equipment refers to any instrument, equipment, apparatus, materials and other objects, whether used alone or in combination, including the corresponding necessary software; Its effect on human body surface or body is not obtained by pharmacological, immunological or metabolic means, but it may be assisted by these means, including the diagnosis, prevention, monitoring, treatment and relief of diseases. Diagnosis, monitoring, treatment, mitigation

and compensation of injury or disability. The study, substitution, and regulation of anatomical or physiological processes. Pregnancy control [21]. In China, "medical equipment refers to instruments, equipment, utensils, materials or other items used alone or in combination with human body, including the required software [22]. Its use in human body surface and in vivo is not pharmacological, immune Learning or metabolic means are available but may have these means to participate and play a certain auxiliary role [23]. Its use is to achieve the following intended purposes: (1) prevention, diagnosis, treatment, monitoring, and mitigation of diseases; Diagnosis, treatment, monitoring, mitigation, compensation for injury or disability; (3) Research, substitution, and regulation of anatomical or physiological processes; (4) Pregnancy control. [24] Definition of imported medical devices in China: Imported goods are Refers to goods purchased from other countries and regions. Its import flow chart is shown in Figure 1.

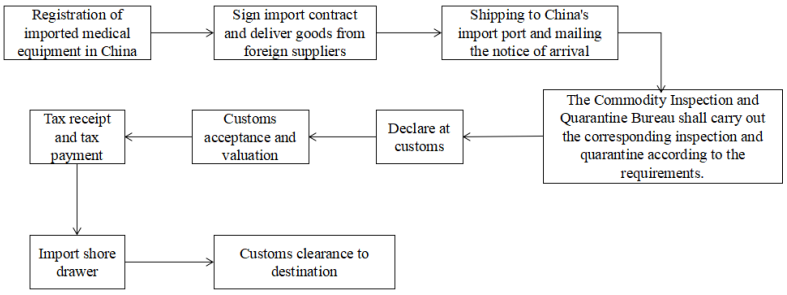

Figure 1 Medical equipment import flow chart

At present, with the rapid development of modern information technology, medical equipment is becoming more and more intelligent, complex and diversified. Many key equipment is running normally on the surface, but the background log has produced warning information, prompting maintenance, inspection, maintenance and other information. If this kind of information is ignored and not handled in time, more serious consequences are likely to occur after a certain period of time. The existing inspection mode is to check and maintain the equipment after it fails. This mode has certain passivity. The equipment of the hospital is limited, and the modern diagnosis and treatment mode highly depends on the inspection results of the medical equipment, so once the equipment has problems, its consequences can be imagined. At present, most active medical devices are monitored in real time, forming a log form with a large amount of data to reflect various data and parameters of device status. Test of medical equipment management, using the Apriori algorithm is based on the equipment run log, from a mass of clutter data to find out the inherent law of hidden in it, to extract the state features of different classifying its possible running state and forecast its trend, and to improve the Apriori algorithm to adapt to the needs of actual medical equipment inspection regulation.

The Apriori algorithm is an algorithm for quickly mining association rules. The algorithm idea is a set that can be divided into two operations, one is the merge operation, which is used to generate the minimum support. The items in the item set are first sorted alphabetically, and then the operation is performed, and the set of candidate sets is generated as K.

$$K_i = \frac{t * sqrt(Ne) + \alpha}{L + \beta}, \tag{1}$$

Secondly, the filtering operation is performed, the filtering rule is established, and the infrequent itemsets in the set are filtered out, and the rest are frequent itemsets. Its filtering operation is:

$$S(\tau, f) = \int_{-\infty}^{+\infty} h(t)\omega(\tau - t)e^{-i2\pi ft}\, dt \tag{2}$$

Among them, the filtered infrequent set and the remaining frequent sets are:

$$G_a(s) = \frac{K_a}{1 + T_a s} \tag{3}$$

$$G_r(s) = \frac{K_r}{1+T_r s} \tag{4}$$

The above formulas are scanned and counted to obtain the subset item Gg (s) as the candidate item set:

$$G_g(s) = \frac{K_g}{1+T_{d0} s} \tag{5}$$

The function Cost (Pi) is used to calculate the support of the itemset:

$$Cost(P_i) = \sum_{e \in P_i} C(e)\,, \tag{6}$$

Candidate sets are generated by merging operations:

$$V = \bigcup_{a_i \in A}^{m} V(a_i) \tag{7}$$

Finally, the inappropriate candidate sets are deleted through the multi-consideration operation again, and the following results can be obtained:

$$S = (U, A, V, g) \tag{8}$$

Where, the deleted inappropriate candidate set is shown as follows:

$$c_{\max} = c\left(j_n, m\right) \tag{9}$$

Through the above operations, prior knowledge can be used to obtain:

$$cell_{ps-1} = \arg\max_{n}\left(\sum_{m=1}^{M} P_{f-n_m}\right) \tag{10}$$

In the process of medical equipment inspection and supervision, an event log database is established for the operation log of medical equipment. Through analysis, it is found that there are certain rules in the event log database. By using these rules to optimize Apriori algorithm, it makes the optimized algorithm no longer need how long to scan database and merge operations to generate frequent itemsets, improves the processing efficiency, makes the optimized Apriori algorithm more suitable for medical equipment inspection and supervision system, and can quickly mine useful rules. Figure 2 shows the relationship between the running time of Apriori algorithm and Apriori optimization algorithm and the number of Items. It can be seen from Fig. 2 that the calculation time of the Apriori optimization algorithm and the Apriori algorithm increases as the number of records increases. However, the growth of the Apriori optimization algorithm is small and tends to be flat, while the Apriori algorithm increases rapidly with the increase in the number of frequent items.

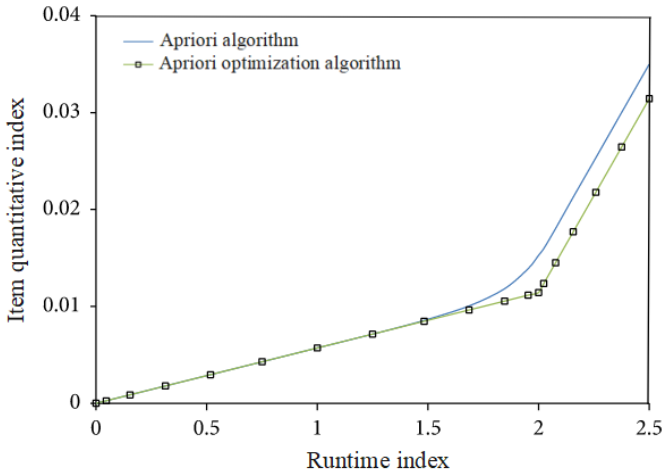

Figure 2 Comparison of the two algorithms

There is no denying that some aspects of our current inspection and supervision system are still backward compared with the management systems in Europe and the United States. At a meeting organized by the inspection and quarantine bureau in Beijing to discuss relevant technical regulations and standards with experts from the European Union and the United States, an EU expert once said that China's current regulatory system is similar to that of Europe a decade ago. This sentence is actually quite thought-provoking. Can we say that our current inspection and supervision system is at least ten years behind that of developed countries? Looks like we have a long way to go. History also gives this generation of prosecutors a responsibility to narrow that gap through their own efforts.

Some medical equipment imported by medical institutions, especially some second-hand medical equipment, have many quality problems. They are not submitted for inspection when they arrive, until the equipment fails to operate normally, and they think of the commodity inspection, which brings difficulties to the claim work. Caused a loss. In response to this situation, the Inspection and Quarantine Bureau has actively taken measures to increase supervision, publicize the commodity inspection regulations, enhance the legal awareness of medical units, and apply drugs to the symptoms. First, we will seize some typical cases, such as penalizing some of the escaping cases in accordance with the commodity inspection regulations, and notifying those cases that are not promptly submitted for inspection and delaying the claims in the district medical system. Due to proper measures, many medical units have realized the importance of commodity inspection, knowing the law and obeying the law, and promptly submitting imported medical equipment after arrival, and the number of cases of escape has been significantly reduced. Take the initiative to contact the medical unit and sign the contract. The quality of contract signing is the key to the quality of imported equipment and the timely and effective claim. Because some medical units are not familiar with international trade practices, coupled with poor information, lack of experience and lack of self-protection consciousness, when signing contracts, they often pay attention to price only, ignoring key terms such as quality, inspection, claims and so on. Give full play to the role of social and technological forces, contact a number of national accredited laboratories (testing centers), establish a group of experts, play the role of technical leverage, improve the scientific nature of inspection and supervision work. In addition, we should give full play to the expertise of inspection and quarantine, consult well before signing the contract, and play a good role as a consultant in business negotiations. Improve the image of inspection and quarantine institutions through various services.

3. Results

In the process of our country to build a well-off society in an all-round way, as the scale of import and export food, especially food imports further rapid growth of the scale, its quality and safety problems and also increasingly prominent, the potential risks, improper regulation and respond to public health, national image of our country and economic ecology, social security caused great negative impact. As the competent department of import food safety supervision, inspection and quarantine departments need to have a more accurate, comprehensive and timely grasp of the situation of imported food at various ports, and make use of information means to assist daily management, so as to realize effective inspection and supervision of imported food by scientifically and effectively utilizing limited testing resources. For the import entity, the inspection and quarantine bureau may file the enterprise qualification documents, and the import entity shall designate a special person to organize the inspection and acceptance of the goods. The import entity shall coordinate and assist the inspection and quarantine personnel to complete the inspection and supervision work, and shall be responsible for the feedback and report of the sales and use of the goods to the inspection personnel and the communication of relevant laws and regulations on inspection and quarantine. According to the management level and integrity of the importing units of medical devices, the risk level and quality status of the imported medical devices and the import scale, the importing units of medical devices shall be classified into one importing unit, two importing units and three importing units. For

enterprises with good reputation and high integrity, the Inspection and Quarantine Bureau can also help them establish a system of receiving and inspecting arrivals, which highlights the safety, hygiene and environmental protection of arrivals, and improves the effectiveness of inspection and supervision. The archives of imported medical equipment in China can be found in Table 1.

Table 1 Archives of imported medical equipment

Number	Content
1	Purchase contract, lease or gift agreement
2	Copy of the supplier or the donor's unit, medical device production and operation qualification certificate
3	A copy of the qualification certificate for the registration of medical equipment and equipment products
4	Product certification
5	Product manual (Imported medical equipment and equipment should request the Chinese manual of the product), product samples, use and maintenance manuals, circuit diagrams and other relevant information
6	Metrological verification certificate (for measuring instruments)
7	Medical device testing report
8	A copy of the customs inspection certificate of the imported medical equipment and equipment
9	Purchase acceptance, use, maintenance and other records
10	List of main medical equipment information: equipment name, specification model, production date, registration number (or date of manufacture), manufacturer, date of activation, quantity, unit price, production batch number, date of activation (or factory number), supplier, license Certificate number, purchase certificate, supply enterprise license, business license, product registration certificate, commodity inspection certificate, contract, gift agreement, salesperson power of attorney, purchase demonstration, inspection status, manual, certificate, warranty card, date of inspection , random data, inspection report, acceptance and installation, commissioning, installation engineer, remarks, maintenance, maintenance, operation, etc.

In view of the uncertainty and universality of medical equipment risk, it is necessary to carry out dynamic risk analysis for imported medical equipment. The determination of product risk at each stage needs to be integrated with the monitoring and inspection data of the previous year. At the same time, according to the requirements of risk management, we should rely on the technological strength of the enterprise and the scientific and technological strength of the testing center to improve the whole risk analysis and management system. From Figure 3, the import of medical equipment in China is increasing year by year. Figure 4 shows the supervision status of imported medical equipment in the jurisdiction.

Imported medical equipment as a new industry involving a variety of disciplines such as sound, light, electricity, magnetism, mechanics, bioengineering, tissue engineering, etc., with a very high technical content, from simple tongue depressors to the structure of products consisting of tens of thousands of parts The characteristics of technology and variety are ever-changing. These characteristics determine that the supervisors must have relatively high theoretical quality. They also need people with strong professional skills or interdisciplinary professional skills to effectively control the quality of various imported medical equipment. , performance implementation supervision and inspection. There are two main aspects in the issue of regulatory power: First, the number of supervisors is insufficient, the overall professional quality is not high, and the technical level is limited. Second, technical support is insufficient. Medical equipment industry is a high-tech, difficult and dangerous industry, so quality

inspection is an important means to ensure the healthy development of medical equipment industry. See Table 2 and Table 3 for details. Table 2 and Table 3 are respectively converted into Figure 5 and Figure 6 for detailed description. It can be seen that most regulatory units lack training of counterpart professionals and professional systems, and there is a shortage of full-time medical device supervisors at the grass-roots level. At the same time, the stability of medical device supervisors is poor and their mobility is arbitrary. All these conditions lead to the lack of necessary medical device common sense and professional knowledge of the existing medical device administrative supervision personnel, forcing the supervision work to stay on the surface rather than go deep into the internal, which brings great difficulty to the supervision work.

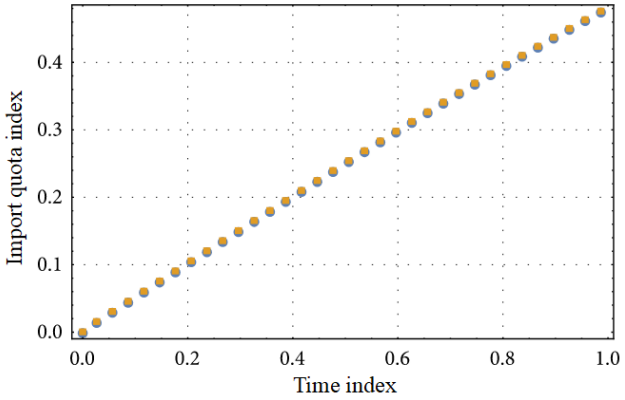

Figure 3 Increase in imported medical equipment

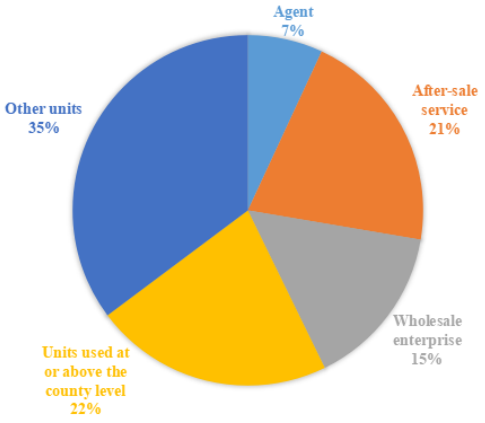

Figure 4 Distribution of regulatory objects

Table 2 Education status of supervisory institutions

Total people	Graduate student	Undergraduate	Junior College	Secondary specialized school	High school
48	9	25	7	4	3

Table 3 Distribution of educational qualifications in regulatory units

Total people	Pharmacy	Law	Medical Instrument Major	Medicine related	Other
48	8	13	3	10	14

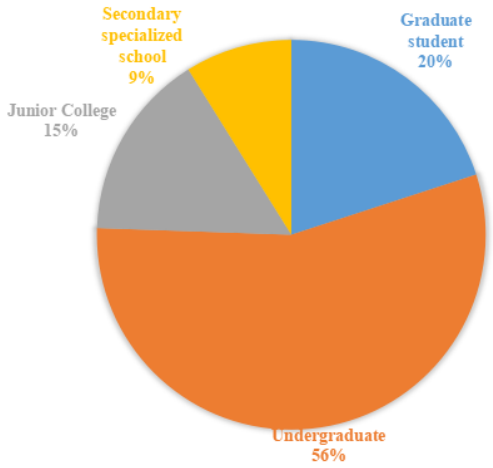

Figure 5 Status of education in the supervision unit

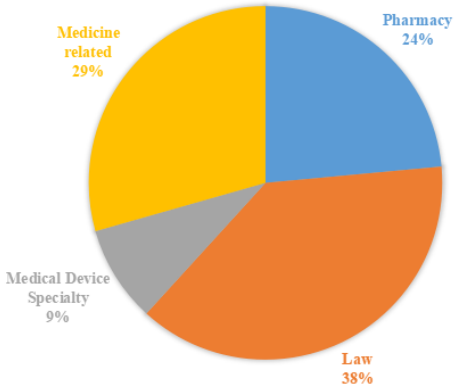

Figure 6 Distribution of academic qualifications of the supervisory unit

Table 4 lists the predicted values, actual values, and errors obtained by the Apriori optimization algorithm in tabular form.

Table 4 Forecast error table

CT exam	Preliminary diagnosis	Predictive value	Error
1	187	211	3
2	206	253	3
3	154	131	1

In the work of inspection and supervision, on-site evaluation and instrument testing can be used as the basis. Only with the ability of instrument testing, can we strengthen our technical checkpoint role. Under the condition that trade and tariff barriers are gradually weakening, technical barriers have become the main legitimate means of protecting national industries in our country, and inspection and quarantine institutions are the main institutions to implement technical barriers and safeguard the rights and interests of consumers in our country, which will inevitably be impacted in many ways. In order to fulfill this duty, it is very important to have a high level of inspection and supervision ability. In our daily work, especially at the critical moment of making decisions or solving problems and contradictions, we often have the reasons for judgment, the basis for decision-making and the basis for law enforcement only when we master accurate data through detection. For all regulatory work, it is relative to the integrity of domestic and foreign production, trade and use enterprises, which is also the basis of European and American supervision of similar products inspection. At present, the adverse

event reporting system implemented in European and American countries is based on the consciousness of enterprises.

In order to further simplify the inspection and quarantine procedures, improve work efficiency, and standardize the inspection and supervision of imported medical devices, the Inspection and Quarantine Bureau can use the low-risk, long-term stable, low-value class I and parts based on risk analysis management. Class II imported medical devices, the inspection and inspection department can directly or indirectly determine whether the relevant requirements are met, and allow the receiving and the consignee to carry out preliminary inspection and acceptance, and send the inspection results to the inspection and inspection department on schedule. If problems are found, the inspection and quarantine agencies at the place of delivery shall send inspection personnel to conduct inspections.

It is the duty of inspection and quarantine personnel to strengthen the inspection and supervision of imported medical devices, ensure the health and safety of the people, protect the environment, prevent fraudulent ACTS and safeguard national security. By means of conformity assessment mode, inspectors are liberated from daily sensory testing and put into risk information collection and analysis and adverse event monitoring and treatment to obtain the maximum benefits. Based on long-term supervision experience, we believe that the following basic aspects should be considered in deepening the reform of inspection mode: improving the legal system, providing evidence for law enforcement and providing evidences for services. We will actively explore new models of inspection and regulation. Optimize the environment, strengthen cooperation, service enterprises, establish image. There are many departments and institutions involved in the inspection and supervision of imported medical devices. On the whole, we should constantly strengthen capacity building, innovate regulatory means, simplify procedures, constantly optimize the inspection and supervision environment, and enhance the effectiveness of law enforcement and supervision.

The inspection and quarantine institutions should take the initiative to continuously strengthen ties with enterprises, strengthen cooperation, achieve close cooperation, supervision and place, and form synergy, not only let the role of imported medical devices be played, but also ensure health and safety, and create inspection and supervision of imported medical devices. Good environment. It is necessary to fully publicize the work objectives, make full use of typical cases, educate and improve the attention of all sectors of society through various channels, give full play to the comprehensive strength of society, and do a good job in the inspection and supervision of imported medical devices. And actively strive for the support of local governments, and introduce relevant supporting measures.

4. Conclusion

The inspection and supervision of imported medical devices is a difficult problem. In order to safeguard the public interests of the society and the legitimate rights and interests of all parties involved in import and export trade, and ensure the quality and safety of imported medical devices, it is necessary to further improve the inspection and supervision system and mode of imported medical devices. It requires the full cooperation of various departments, the full assistance of local governments and the implementation of inspection and supervision staff according to law. The duty of the post and the consciousness of customs service need the cooperation of the importing units and the conscientious fulfillment of their obligations. Based on the analysis of the problems existing in imported medical equipment, this paper proposes an Apriori optimization algorithm for mining association rules in medical equipment health management. Through experimental verification, Apriori optimization algorithm can dig out association rules of device condition. These association rules indicate the relationship between device operation parameters and device state, and provide good decision support for medical device managers to better manage equipment.

References

[1] Hamdi N, Oweis R, Zraiq H A, et al. An Intelligent Healthcare Management System: A New Approach in Work-order Prioritization for Medical Equipment Maintenance Requests[J]. Journal of Medical Systems, 2012, 36(2):557-567.

[2] Pardeshi G. Medical equipment in government health facilities: Missed opportunities[J]. Indian Journal of Medical Sciences, 2005, 59(1):13-9.

[3] Kwang-Soo L, Hyuk-Jun K. Analyzing the geographic distribution of major medical equipment with smart geographic system[J]. Journal of Supercomputing, 2015, 71(6):1996-2019.

[4] Gagliardi J. Medical Equipment Management[J]. Biomedical Instrumentation & Technology, 2013, 48(4):302-303.

[5] Faizulaev B N, Oraevskii K S, Porfir'Ev I N, et al. Testing of Domestic and Imported Medical Devices for Interference Stability Requirements[J]. Biomedical Engineering, 2001, 35(3):129-130.

[6] Anuja S, Goyal R. Current status of the regulation for medical devices[J]. Indian Journal of Pharmaceutical Sciences, 2008, 70(6):695-700.

[7] George B. Registration of medical devices.[J]. Perspectives in Clinical Research, 2010, 1(3):90-93.

[8] Bliznakov Z K J, Gueorgu K. Q-Pro: a quality control management system for medical equipment[J]. Journal of Medical Engineering & Technology, 2000, 24(3):117-122.

[9] Walther K A, Gr?Ter F, Dougan L, et al. China Delays Inspection Requirement for Imported Medical Devices[J]. Proceedings of the National Academy of Sciences of the United States of America, 2007, 104(19):7916-21

[10] Kogan I I, Petropavlovskii V V. Improving the supervision of measuring equipment in medical and prophylactic institutions[J]. Measurement Techniques, 1962, 5(3):255-256.

[11] Government C L &. Regulations on the Supervision and Management of Medical Equipment[J]. Chinese Law & Government, 2012, 45(2):79-88.

[12] Yue W. [Great significance of accelerating publishing medical equipment supervision and management regulations (amendment)][J]. Chinese Journal of Medical Instrumentation, 2013, 37(37):40-43.

[13] Pan Y, Lin W, Liu J. [Meet the challenge of the implementation of the EMC standard for medical electrical equipment].[J]. Zhongguo Yi Liao Qi Xie Za Zhi, 2011, 35(2):137-140.

[14] Sneed R C, Graves M, Green V. The physician's role in supervision of therapies and durable medical equipment for children with special health care needs in the educational system and early intervention programs[J]. Journal of the Mississippi State Medical Association, 2004, 45(7):195-200.

[15] Fønstelien, E, Nilsson F. Investigation of accidents by the Special Inspection for Electrical Electrical Medical Equipment[J]. Tidsskrift for Den Norske Lgeforening Tidsskrift for Praktisk Medicin Ny Rkke, 1989, 109(16):1801-3.

[16] Li W J, Quan J G. [Experience of preventive maintenance of medical equipment].[J]. Zhongguo Yi Liao Qi Xie Za Zhi, 2009, 33(2):147-149.

[17] Yin-Yu C, Xiao-Li L I, Chun C. Application of Risk Management in Inspection and Supervision of Imported Food[J]. Food Science, 2007, 28(8):589-592.

[18] Xiaofang Y, Xiaoliang L, Ruihong M, et al. The Current Situation and Suggestions on the Institutes for Medical Devices Test in China[J]. Chinese Journal of Medical Instrumentation, 2014, 38(1):57-60.

[19] Gurbeta L, A. Badnjević. Inspection process of medical devices in healthcare institutions: software solution[J]. Health & Technology, 2016, 7(1):1-9.

[20] Wang W. [Introduction of accompanying documents on the new EMC standard of medical electrical equipment].[J]. Zhongguo Yi Liao Qi Xie Za Zhi, 2013, 37(4):287-290.

[21] Chen L. The Risk Analysis and Strategy in Medical Equipment Inspection and Acceptance[J]. Zhongguo Yi Liao Qi Xie Za Zhi, 2011, 35(5):376-378.

[22] Niu S , Jiang S . [Study on IEC 60601-1-2: the standard of electromagnetic compatibility for medical electrical equipment][J]. Zhongguo yi liao qi xie za zhi = Chinese journal of medical instrumentation, 2011, 35(5):371-3, 391.

[23] Wang W. [Study on selection of the EMC test system of medical electrical equipment][J]. Zhongguo yi liao qi xie za zhi = Chinese journal of medical instrumentation, 2011, 35(6):449-452.

[24] Badnjevi? A , Cifrek M , Magjarevi? R , et al. [Series in Biomedical Engineering] Inspection of Medical Devices ‖ Inspection and Testing of Electroencephalographs, Electromyographs, and Evoked Response Equipment[J]. 2018, 10.1007/978-981-10-6650-4(Chapter 7):141-157.