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Practice and Prospect of Group Standard for Innovation and Transformation of Medical Equipment

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Abstract: The importance of group standards is becoming increasingly evident. These standards are developed and released by groups following their own established procedures, intended for voluntary adoption by group members or the public. In the field of medical equipment innovation and transformation, group standards play a crucial role in multiple aspects. They provide unified technical specifications and operational procedures, clearly defining quality requirements and evaluation criteria at each stage, which helps reduce the randomness in R&D and enhances the efficiency of transformation. They also facilitate communication and collaboration among industry, academia, research, and application sectors, enabling scientific research institutions, medical facilities, and enterprises to share resources and complement each other's strengths within a common standard framework, thus accelerating the transition of innovative outcomes from the laboratory to the market. By establishing group standards, the healthy development of the industry can be guided, market order can be standardized, and the overall quality and international competitiveness of China's medical equipment products can be enhanced, promoting China's transition from a major player to a leader in medical equipment manufacturing. Through an in-depth exploration of the practical applications and development trends of group standards in the innovation and transformation of medical equipment, researchers can better understand the intrinsic connections and mechanisms between group standards and the innovation and transformation of medical equipment, providing new perspectives and theoretical foundations for future research, and enriching the theoretical framework in this field.

Keywords: Medical equipment innovation and transformation group standard; Medical device; Prospect

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1. Introduction

Medical equipment, as a vital material foundation for healthcare, directly impacts the quality and efficiency of medical services and is closely tied to public health. Globally, the medical equipment industry is undergoing rapid transformation and development [1]. With the continuous advancement of technology, such as artificial

intelligence, big data, and the Internet of Things (IoT), these emerging technologies are deeply integrated with medical equipment, presenting unprecedented opportunities for innovation. From early simple devices like stethoscopes and thermometers to today's advanced medical imaging equipment and intelligent surgical robots, the variety and functionality of medical equipment have significantly expanded, playing a crucial role in disease diagnosis, treatment, and rehabilitation [2].

Innovation and transformation are the core drivers of the continuous development of the medical equipment industry. Only by continuously converting scientific research into practical medical equipment can people meet the growing clinical needs and enhance the quality of medical services. However, the process of innovation and transformation in medical equipment faces numerous challenges [3]. Research and development involve the interdisciplinary fields of medicine, engineering, and materials science, which are highly technical. The entire transformation cycle, from laboratory research to clinical trials and market promotion, is long and costly. Additionally, it must comply with stringent regulatory oversight and navigate a complex market environment. According to relevant studies, the rate of converting scientific research into practical applications in China's medical equipment sector still needs improvement. Many innovative technologies and products have not been effectively converted into practical productivity, which, to some extent, hinders the development of China's medical equipment industry [4].

2. Challenges faced by group standards for innovation and transformation of medical equipment

2.1. Technical challenges

The innovation and transformation of medical equipment group standards face many severe challenges at the technical level, which profoundly affect the formulation and implementation of group standards and restrict the development of the medical equipment industry [5].

The rapid speed of medical equipment technology development brings new challenges to group standards. With the rapid development of artificial intelligence, big data, Internet of Things, and 3D printing technologies, a series of new medical devices can work better and provide richer performance. For example, using AI technology can quickly analyze huge amounts of medical images and give doctors correct diagnostic suggestions, which can greatly improve the efficiency and accuracy of diagnosis. Using 3D printing technology can customize some special medical devices according to the characteristics of the disease for patients [6]. However, the appearance of this kind of new technology makes it difficult for existing group standards to keep up with the pace of technological innovation; that is, in the process of standard setting (which involves scientific research and draft writing, solicitation of opinions, review, etc.), after consuming time, the emergence of the next generation of products may already be completed by technological updates, so there will be a phenomenon of delayed technology or even lagging behind. If timely and effective standards cannot be formed at the stage of medical equipment innovation and transformation, it will inevitably affect the efficiency and quality of innovation and transformation, resulting in phenomena such as product quality not being stable and technical connection problems. By the time the standards are finalized, new technological advancements may have already occurred, causing the standards to lag behind the latest developments [7]. This lack of timely and effective standards during the innovation and transformation of medical equipment can lead to issues such as product quality instability and poor technical compatibility, thereby affecting the efficiency and quality of

innovation and transformation.

The innovation and transformation of medical equipment involve the integration of multiple disciplines, where technical languages and ways of thinking differ across disciplines, posing challenges for communication and coordination in the development of group standards. Medical equipment technology innovation transformation is an integration project of multiple disciplines, but because technical languages and ideas are different between each discipline, it becomes an obstacle to inter-disciplinary communication and coordination when formulating group standards. Medical equipment R&D involves various disciplines such as medicine, engineering, materials science, and electronic information technology. In the field of medicine, it mainly discusses how to solve clinical needs and treatment results; engineers emphasize product design, manufacturing processes, and performance; material science aims to find new materials that meet the special requirements of medical equipment; electronic information technology focuses on providing related technical support for the intelligence and informatization of medical equipment. When formulating group standards, it should take into account the needs and technical characteristics of each professional subject and strive to achieve smooth cooperation and coordination among them. Due to the differences in professional terms, technical standards, and research methods, it is easy to cause misunderstandings and deviations during interprofessional communication and coordination. During the standard-setting process for intelligent medical devices, medical experts and engineering technicians may have different opinions on functional requirements and performance indicators of intelligent medical devices. That is, medical experts tend to focus more on its effect in diagnosing and treating diseases, while engineering technicians focus more on its technological realization and stability [8]. Therefore, disagreements and disputes often occur during the process of setting group standards, making it more complicated [8].

As shown in **Figure 1**, the average time spent on each stage of the group standard development process is relatively long, further exacerbating the issue of standards lagging behind technological advancements [9].

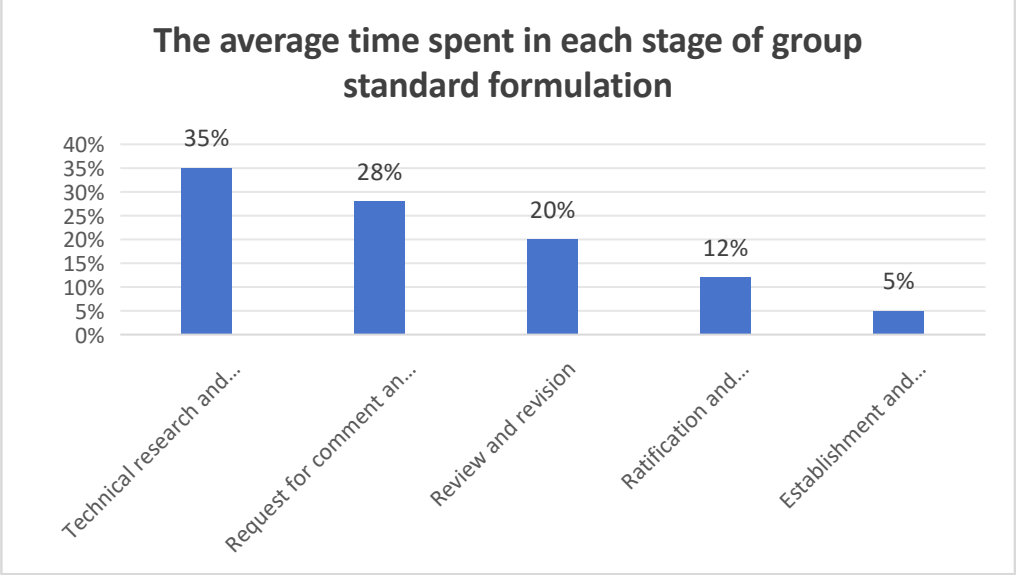

Figure 1. The average time spent in each stage of group standard formulation. Source of data: The data is derived from the analysis of the development cycle of 182 medical-related group standards in the "China Group Standardization Development Report (2023)."

2.2. Talent challenges

Talent shortage: It is one of the main factors restricting the process of innovation transformation and the group standard construction of medical equipment. It restricts the innovative ability, quickness, and effective construction and implementation of group standards in aspects of the medical equipment industry [10].

Innovation transformation of medical equipment and its group standard construction needs compound talents with possession of medical technique as well as standardization, but such kind of talents are few at present. The involved content scope between medical equipment field is wide, not only require comprehensive strength to be mastered, but also belong to multi-discipline techniques (such as medicine, engineering, materials), which limits high-efficiency cooperation among society according to industry, academy, research and application, then it restricts the promoting and popularizing degree of the group standards while the medical equipment innovating and transforming [11]. Professionals must have a solid foundation in their field and possess interdisciplinary, comprehensive qualities. Standardization work has its unique requirements, necessitating familiarity with the processes, methods, and norms of standard setting, as well as strong communication and coordination skills and effective written expression. They must accurately understand industry needs and develop scientific, reasonable, and practical standards. Cultivating such versatile professionals, who are proficient in both medical equipment technology and standardization, is challenging. Universities and vocational education institutions lag behind in setting up relevant majors and talent cultivation models, making it difficult to meet the market's urgent demand for such talents [12].

In the process of medical equipment innovation and transformation, the collaboration among enterprises, research institutions, and medical facilities is becoming increasingly close. This requires individuals with cross-disciplinary knowledge and communication skills to facilitate collaboration among all parties. In medical-engineering projects, it is essential for professionals to understand the distinct ways of thinking and technical languages in both medicine and engineering, building a bridge for effective communication between the two fields to ensure the smooth progress of the project [13]. However, such cross-disciplinary talents are still scarce. Due to the significant differences in professional knowledge and working environments across different fields, professionals face numerous challenges and difficulties in developing across disciplines, leading to a limited number of individuals who can play a coordinating role in the innovation and transformation of medical equipment. This affects the efficiency and effectiveness of cooperation among industry, academia, research, and application, thereby hindering the promotion and application of group standards in the innovation and transformation of medical equipment [14].

2.3. Market-level challenges

Firstly, from the perspective of the market, there are many serious challenges in the promotion and application of medical equipment innovation and transformation group standards, which affect the effective performance of group standards in the development of the medical equipment industry. There is fierce competition between companies in the field of medical equipment, so it is difficult to promote and apply group standards. Under such circumstances, some enterprises constantly produce and sell new products and services to seize more market shares, resulting in a severe situation of product homogenization in the market [15]. These enterprises may chase short-term benefits instead of emphasizing the importance of group standards, so they may use inferior production processes and technology under the guise of reducing costs and increasing price competitiveness.

This has caused inconsistent product quality in different manufacturers' medical devices, which affects the effectiveness and credibility of medical equipment innovation and transformation group standards. It also reduces the possibility of enterprises adopting these group standards widely, making the medical equipment innovation and transformation group standards unfeasible to promote effectively among most manufacturers. Therefore, at present, some problems still exist in promoting and applying group standards in the highly competitive medical equipment market environment.

Secondly, the issue of intellectual property protection has a huge impact on the development of medical equipment innovation and transformation group standards. The achievement of medical equipment innovation usually requires consuming much human, material, financial, and technological strength, etc., and the problem of protecting medical equipment patents has always been an important focus. At the same time, in view of the current weak protection situation of intellectual property rights in the field of medical equipment in the country, various types of infringement events often occur. For example, when companies produce and sell medical devices, some illegal operators will use other companies' patent techniques and technical secrets without authorization; In addition, imitation design and counterfeiting of product appearance by some people have seriously violated the legal interests of innovative companies [16]. When the legitimate and normal business activities of innovative enterprises suffer heavy damage, people generally think that this is not only a violation of laws and regulations, but also an unreasonable infringement of social morality and corporate ethics. Under such circumstances, medical equipment innovation enterprises may not dare to innovate again after being damaged, and therefore they will definitely not pay attention to the group standards during subsequent product production and manufacturing processes, thus failing to effectively achieve the purpose of improving the core competitiveness of domestic related enterprises and cultivating key brand in the specific field of medical equipment through innovation and transformation group standards.

Thirdly, some low-level product producers or suppliers in the medical equipment innovation chain do not strictly follow the group standards of raw materials, parts, etc., for production and manufacturing, because of the purpose of occupying more of the relatively mature mid-low-end medical equipment market space, in order to gain more profit or cost advantages in the competition of price. Such behaviors make some products that comply with the standard lose the stable growth space in the mid-low-end medical equipment market and increase the safety hazard risks of patients using such products [17].

2.4. Challenges at the level of cooperation

Firstly, the difficulty of the cooperation level restricts the realization and development of group standards in the process of medical equipment innovation transformation. The first problem to be solved is the medical engineering collaborative innovation discipline obstacle.

Collaborative innovation between medical institutions and industry is a key driver for the innovation and transformation of medical equipment. However, it currently faces numerous challenges. There is a lack of long-term and stable mechanisms for cooperation among medical institutions, research institutions, and enterprises. In practice, cooperation teams are often formed on a temporary basis for specific projects, and the partnership ends once the project concludes, making it difficult to establish a long-term and stable cooperation model [18]. This short-term cooperation model results in a lack of deep communication and collaboration among all parties, hindering the full utilization of their respective strengths and the accumulation and inheritance of knowledge

and technology. In some medical equipment R&D projects, medical institutions only propose clinical needs at the initial stage of the project, with minimal subsequent involvement. Research institutions and enterprises lack clinical feedback during the R&D process, leading to a disconnect between the R&D outcomes and actual clinical needs, which affects the effectiveness of innovation transformation.

The unreasonable distribution of benefits is a significant factor hindering the collaborative innovation between medical professionals and engineers. In the process of innovating and transforming medical equipment, issues related to the distribution of interests, such as intellectual property rights and the benefits from scientific research achievements, arise. Because the mechanism of interest distribution is not scientific and reasonable, it is easy to disagree and conflict among all parties. On the one hand, research institutes and enterprises think that they have made great efforts in technology development and product transformation, so they should receive a large proportion of the benefits; on the other hand, medical institutions think that they have brought clinical needs and applications, so they should receive a huge part of the benefits. The problem of dividing the interests between the two sides may cause the breakdown of the cooperative relationship, which affects the smooth progress of innovation transformation. In a certain medical equipment R&D project, due to the failure to agree on the ownership of intellectual property rights and the sharing of benefits, the cooperating parties are in a deadlock, and the project progresses slowly, which seriously affects the transformation and application of innovative results. At the same time, there are also some obstacles to be solved in terms of interdisciplinary collaboration in the whole process of group standard construction in the process of medical equipment innovation transformation, because medical equipment innovation involves various disciplines such as medicine, engineering, materials, computer, etc., with significant barriers between disciplines. Different research methods, thinking modes, and professional terminologies make it difficult for members of different disciplines to communicate and share information. When discussing device design, medical experts pay more attention to clinical effect and safety, while engineering technicians focus on its technical implementation and performance indicators, which may cause a balance of design plans between clinical needs and technical feasibility, affecting the quality of products and competitiveness in the market. At the same time, when facing interdisciplinary project team building and management, the challenge of cross-disciplinary composition makes it difficult for members of the team from different academic background and professional categories to adapt to each other's working habits and value concepts, which poses challenges to team collaboration and management, and leads to the low efficiency of decision-making by members' opinion reaching consensus. During the execution of the project, the inability to coordinate and manage effectively causes the uncoordinated work advancement status and unreasonable task allocation of project participants, which hinders the normal project progress. A multi-disciplinary medical equipment innovation project was delayed, and the cost of multiple iterations and repeated trials was high due to poor team management, causing different members to be in charge of their own specialties without a sense of being one family, and repeated rework.

At the cooperation level, it is essential to establish a long-term and stable working mechanism of medical engineering innovative cooperation, define the rights and obligations of all parties, enhance interaction and connection, and promote each other's learning and technology exchange. A fair and reasonable profit distribution mechanism should be established, taking into account the contributions and investments of all parties, to ensure that the distribution is fair and reasonable, thereby stimulating the enthusiasm for cooperation among all parties. To overcome the barriers to interdisciplinary collaboration, efforts should be made to strengthen the training of interdisciplinary talents, improving the cross-disciplinary communication and

collaboration skills of team members. An effective team collaboration and management mechanism should also be established, with clear team goals and task assignments, enhancing internal coordination and communication within the team, and improving the team's work efficiency and innovation capabilities.

3. Development prospect of group standards for innovation and transformation of medical equipment

3.1. Trend of technological innovation and standard integration

In the era of rapid development of science and technology, the field of medical equipment is undergoing profound changes. Technological innovation presents diversified, intelligent, and integrated development directions, which also put forward new requirements and challenges for the innovation and transformation of group standards of medical equipment, and promote the deep integration of group standards and technological innovation.

The application of artificial intelligence (AI) and big data technology in medical equipment will become more profound and extensive. AI algorithms can swiftly analyze and process vast amounts of medical data, enabling early and precise disease diagnosis, the development of personalized treatment plans, and the intelligent maintenance of medical devices. In the field of medical imaging, AI technology can help doctors more accurately identify lesions in images, thereby improving the accuracy and efficiency of diagnoses. After integrating and mining different data, including patients' genetic information, clinical symptoms, and treatment experience, big data can achieve precision medicine by providing customized treatment suggestions for patients.

IoT technology and telemedicine technology will have a wide development prospect. The medical instrument is linked by IoT technology to collect and transmit the patient's physiognomic data in real-time. Doctors complete the diagnosis, treatment, and follow-up work of patients through online consultation platforms based on telemedicine technology; thus, the problem of time and space is solved, and people's access to medical care has been significantly improved. In particular, it makes great contributions to people living in remote areas and medical institutions at the grassroots level. Telemedicine technology enables these regions' patients to enjoy excellent medical service resources. At the same time, the novel application of biomaterials and 3D printing technology brings some surprises to the innovation of medical equipment. New kinds of biomaterials can increase the biomedical compatibility, stability, and practicability of medical devices. For example, some degradable biomaterials can be applied to medical equipment to avoid repeated operations when patients are implanted with the device again. At the same time, medical devices such as artificial limbs and implants made by 3D printing can be customized according to the specific circumstances of each patient, which can meet the personalized needs of patients more effectively, provide better medical treatment effects, and improve the quality of life of patients.

Therefore, people should further build the dynamic update mechanism of group standards, give full play to the monitoring and analysis role of technological innovation and market demand, revise and perfect the group standards in time, make timely supplements or changes according to the situation, so that the group standards can always keep up with the times. At the same time, encourage enterprises, scientific research institutes, medical institutions, and other units to take the lead in establishing group standards and updating them to promote the integrated development between technological innovation and group standards; strengthen international exchanges and cooperation, organize relevant personnel and professional experts to participate

actively in the formulation of related group standards and revision of international standards, study advanced foreign experiences and technologies, coordinate and solve problems existing in the implementation process, compare Chinese medicine equipment technological innovation and transformation group standards with corresponding international standards in time, make the two standards conform, thus improving the competitive ability of China's medical equipment product and occupying an important position in the international field, while taking full advantage of the country's medical equipment advantages and good achievements in technology innovation during standardization activity. Through participation in international standardization activities, China can integrate its achievements and advantages in medical equipment technology innovation into international standards, thereby increasing its influence and voice in the international medical equipment sector.

3.2. Talent training and team building strategy

The development of talent cultivation and team building is crucial for advancing the innovation, transformation, and standardization of medical equipment. To address the current issues of talent shortages, an unbalanced talent structure, and low team collaboration efficiency, it is essential to develop practical strategies to cultivate a high-quality, professional workforce and build highly collaborative, innovative teams.

In terms of talent cultivation goals and positioning, it is essential to clearly define the training of versatile talents who are proficient in medical equipment technology and familiar with standardization work, as well as collaborative innovation talents with cross-disciplinary knowledge and communication skills. Universities and vocational education institutions should optimize their professional settings and curriculum systems based on these goals. In terms of professional settings, they can offer majors or directions such as medical equipment standardization and medical-engineering integration innovation, providing students with systematic professional knowledge learning. In the construction of the curriculum system, emphasis should be placed on the setting of interdisciplinary courses, integrating knowledge from medicine, engineering, and standardization organically. Courses such as medical fundamentals, principles and design of medical devices, principles and methods of standardization, and medical-engineering collaboration practice should be offered, enabling students to acquire solid professional knowledge and develop interdisciplinary thinking and problem-solving skills.

In terms of practical skills training and internship mechanisms, it is essential to enhance practical teaching components to improve students' practical operational skills and problem-solving abilities. Universities and vocational education institutions should increase investment in practical teaching, building comprehensive laboratories and training bases equipped with advanced medical equipment and experimental devices, thus providing students with a conducive practical environment. The proportion of experimental courses should be increased to deepen students' understanding and mastery of theoretical knowledge through practical experience. Establishing internship partnerships with medical equipment companies and healthcare institutions can provide students with a wealth of internship opportunities. Through internships, students can gain insights into the industry's actual needs and development trends, apply their knowledge to real-world work, accumulate practical experience, and enhance their employability.

Introduce talents and encourage mechanisms. Actively introduce first-class talents in the fields of medical equipment technology and standards from home and abroad as well as some excellent talents in the company system itself, improve the benefits and incentives of their salaries and treatment; construct a relatively perfect

employment (work) atmosphere and career development channel to attract high-quality talents, play the advantages of talent in enterprises to the fullest, create conditions for the retention of professional talents needed by the cause and those with room for development. Officials should also accelerate the construction of their own stock of talents, set up talent training projects, improve various talent incentive measures, focus on motivating scientific and technological workers' enthusiasm for creating new achievements in the field of medical instruments, actively promoting the transformation and promotion of scientific research results, stimulating the creation ability and innovation awareness of group standards, doing more important work, creating good conditions, fully mobilizing enthusiasm, and giving certain material rewards such as Science and Technology Innovation Award and Standard Contribution Award to people who make significant achievements in technology or formulating standards.

3.3. Market expansion and international cooperation prospects

The third one is to promote group standards in depth on the domestic market for the deep development of medical equipment innovation and transformation, and make general and specific plans.

Actively participate in the formulation of international standards, making China's voice and influence more colorful and powerful in the competition of the international medical equipment market. With the rapid development of China's medical equipment industry, China's technological innovation ability and product quality level have significantly improved, and it has reached a certain level to formulate related industry standards. Actively participate in related standard organizations such as ISO and IEC, so that domestic experts in various aspects such as medical equipment and standards can attend foreign expert meetings to draft and revise related medical device industry standards, input more innovative ideas from the country, incorporate Chinese techniques and advantages, typical cases and practical experience into related medical engineering products, and contribute solutions and suggestions on the content and structure of the standard in different ways to fully consider China's strength. When proposing artificial intelligence standards for the first time during the process of forming health standards, let the proposed international standards reflect China's research results in this direction, China's own practices in this regard should play an important guiding role when proposing related artificial intelligence standard technologies, so as to gain more say in foreign standardization work in the field of medical devices, help Chinese companies achieve a prominent international position in foreign standardization in the artificial intelligence direction of medical devices by introducing China's development trends in terms of technology, application, product research, etc., promoting the export rate and utilization efficiency of China's products at home and abroad, increase its representation in relevant national standard formation negotiations with a greater proportion of domestic experts in the artificial intelligence healthcare industry than before, improve the ability of the domestic medical device industry represented by Chinese companies to lead or control global standards formation to some extent, and also help promote China's medical device industry to make full use of its strong scientific achievements in medicine, advanced research in many new branches and other factors and the relatively comprehensive existing domestic theoretical research foundations to better exert itself on the medical standards formation stage platform among the world's leading developed countries under the conditions where the era's economy is developing along a path mainly dominated by economic trade liberalization trends, so that more advanced domestic research ideas can be reflected in the development direction of human life in all directions and professional industries around the globe through

foreign standard organizations formed for discussion, thereby enhancing its power in guiding future major directions of similar standard-related matters at multiple stages and in numerous fields [19].

3.4. Improvement of policy support and guarantee mechanism

Policies supported, more policy support for the group of medical equipment innovation and transformation to transform into form a group of standards; improving the guarantee mechanism is key. The improvement in depth of relevant policies such as finance: Establish a special fund, subsidy and reward the related enterprises or research institutes are actively engaged in the formation and practice of the group of standards with special funds, reward according to the enterprise's group standard leading in the field situation and other situations, important and influential on the group issued standards, encourage the leader issued group standard issued by the enterprise, encourages the enterprise to play an active role in developing the group standard, transforming existing products based on forming the group of standards, reducing the innovative cost for research and development expense subsidies to purchase the equipment of the enterprise for producing medical equipment conforming to the group standard, reduced pressure from the aspects of value-added tax and corporation income tax of enterprise innovating conversion equipment, accelerated depreciation amount in conformity with the law with purchasing the equipment (to conduct the research produced medical equipment), meets with the group standard. Enterprises purchasing equipment for research and production of medical equipment that meets group standards should be allowed to accelerate depreciation, enhancing the efficiency of capital utilization [20].

Strengthening the protection of intellectual property rights is also a crucial aspect of improving the safeguard mechanisms. Enhance the legal framework for intellectual property, and increase the protection of intellectual property rights for innovations in medical equipment. Clarify the ownership and distribution of intellectual property rights for these innovations, encourage innovation entities to actively apply for patents, trademarks, and other intellectual property rights, and crack down on infringement to raise the cost of such acts. Establish a rapid response mechanism for intellectual property rights to shorten the time required for rights protection and reduce costs, thereby creating a favorable environment for the innovation and commercialization of medical equipment.

Strengthen the construction of the intellectual property service system to offer comprehensive services, including consultation, agency, and evaluation, for enterprises. Establish an intellectual property information platform to timely release information on intellectual property in the medical equipment sector, providing a reference for enterprise innovation and standard setting. Encouraging knowledge property service institute provides intellectual property. Special service promoting medical equipment helps the enterprise better manage and use knowledge property. Promote the transfer application medical equipment and innovative achievements. As shown in **Figure 2**, China's contribution to international standards for major medical equipment remains relatively low, and active participation in the formulation of international standards is a key path to enhancing its voice.

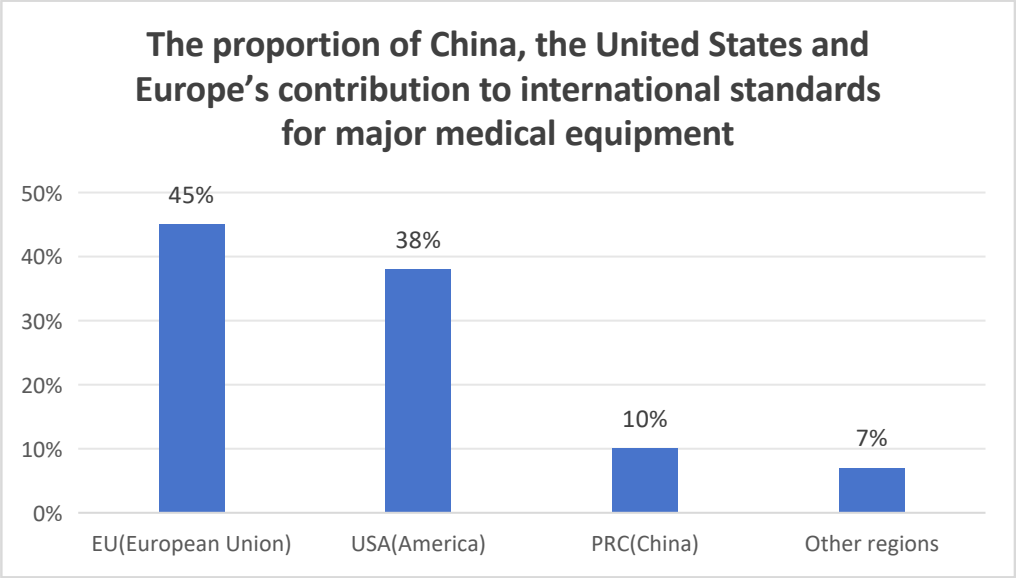

Figure 2. The proportion of China, the United States, and Europe's contribution to international standards for major medical equipment. Data source description: Contribution ratio is calculated by analyzing indicators such as standard proposals, working group conveners, and editorial staff numbers from ISO and IEC technical committees related to medical devices. The data is compiled from ISO Annual Reports, IEC Annual Reports, and analyses conducted by Tsinghua University's Standardization Research Base.

4. Conclusion

In summary, this paper makes a theoretical exploration of group standards in medical equipment innovation transformation, studies case analysis, the current situation, and difficulties. Through researching the related standards of group standards in the field of transformation of medical equipment innovation process — when introducing new products from the technical research index to the standardization of the clinical department trial process during the production process — inspecting product quality, setting evaluation requirements, the whole innovation activity is carried out according to regulations. So it not only improved efficiency and quality in transforming innovation results, promoted different parties such as medical units, scientific research institutions, enterprises with cooperative innovation to conform to the internal process between them, but also easy to coordinate between organizations; convenient for external cooperation among various departments, and accelerated the transition of innovation achievements from laboratory to clinics. In addition, the introduction of group standards provides a good foundation for supervisory authorities to regulate the order of the medical instruments market, which can effectively protect the interests of consumers and promote the orderly development of the medical instruments industry.

Disclosure statement

The author declares no conflict of interest.

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