Executive Summary

Analysis for healthcare safety management system

Min-Jeong Kim[1], Sukyeong Kim[1], Jeong-Su Park[1], Hajin Tchoe[1], Jinjoo Park, Yeeshin Choo

[1] National Evidence-based Healthcare Collaborating Agency

▢ Background

Human lives are always exposed to various kinds of risks and it is practically impossible to live a life without risks. The apposite concept of "risk" would be "safety" which means protection from undesirable things of physical, social, spiritual, financial, political, emotional, occupational, psychological and educational dimension. A more practical definition of "safety" is that activity or exposure is sustained at the level of acceptable risk, which indicates to minimize controllable risks not to remove all the risks.

Healthcare system is a national or social system to describe every activities primarilly relating to health. Healthcare safety is sustained through the approaches of setting the acceptable risk levels scientifically and controlling the risks via various systems and activities. These risk management includes activities to prevent risks might occur due to all kinds of error and mistake. In healthcare field, it has started to establish the systems to review and set the acceptable risk level and to control the risk for health technologies such as pharmaceuticals, medical devices and procedures. On the other hand, the approach to safety matters regarding error and mistake which might occur in the process of implementation of health technologies has been started relatively late, which is currently regarded as "patient safety".

▢ Objective

This study aimed to investigate and analyze comprehensive healthcare safety management systems as well as their associated institutions and activities in developed countries. The goal is to suggest a direction for policy development by extracting management systems that must be either established or improved in order to enhance safety in domestic healthcare industries. The following provides the details of the research.

First, this study defined the concept and range of healthcare safety and categorizes healthcare safety management systems into more detailed levels based on state activities.

Second, this study investigated overseas cases of more sub-divided healthcare activities and areas that could or could not take preventative measures using the current knowledge and technologies.

Third, domestic safety management systems and their status were investigated to compare and review the analysis of the overseas cases to propose safety management activities for domestic implementation or improvement.

▢ Methods

The relevant institutions' websites and publications were investigated to analyze and summarize the data regarding overseas and domestic medical technology licensing, those institutions that evaluate medical technologies, and their reporting systems. The researchers also solicited advice from experts in Korea and other countries to aid in understanding and analyzing in detail the current status of domestic and overseas healthcare safety management systems.

▢ Results

“Healthcare safety” analyzes, evaluates, and assesses the danger of healthcare

technology causing harm or harmful incidents and indicates comprehensive safety measures including patient safety to prevent or fix errors and harm experience by patients. Therefore, in order to achieve healthcare safety, the danger presented by the healthcare technology itself evaluated. In other words, medical technologies are implemented when the benefit exceeds the risk. However, we must continue monitoring, analyzing, and evaluating the risks of medical technologies even after these are implemented in the market, because we cannot fully understand the danger of such technology with current technology or knowledge. Additionally, more safety management activities are required in order to prevent and fix medical errors or harm related to healthcare.

In this research, "healthcare technology" is used to investigate the country's safety management system. In accordance with the Health and Medical Service Technology Promotion Act, only the medicines, medical supplies, and medical devices permitted in Article 2 Section 1 A (medical, dental, acupunctural, and medical engineering technologies), Section 2 (regulated by pharmaceutical law sin Article 2 Section 4 and Section 7), and Section 3(regulated by medical device laws in Article 2 Section 1) were used.

Risks or harm related to healthcare safety can be divided into preventable harmful incidents associated with errors and unpreventable harmful incidents not associated with errors. When this is connected to the aforementioned concept of healthcare safety, unpreventable harmful incidents are safety issues related to risks posed by healthcare technology itself while preventable harmful incidents are safety issues related to patients. Therefore, as shown in Table 1, the healthcare safety management system is divided in this research into 1) the safety management system addressing risks posed by medical technology itself and 2) the management system addressing safety issues related to medical technology implementation,.

First, the safety management system addressing risks posed by medical

technology itself was divided into three management systems for licensing medical technologies, evaluating medical technologies (new and existing), and collecting and analyzing safety information by monitoring risks. The lower management system implemented the general management system, and the targeted medical technology could be divided into medicines, medical devices, and medical treatments.

When products created in the same way as medicines or medical devices are introduced into the market, the regulatory institutions determine product licensing after evaluating benefits against acceptable risks. Many countries accommodate restrictions for this level of safety management system; most do not have separate steps for licensing medical treatments as mentioned previously.

Evaluating medical technologies determines insurance benefits and price and is used to set a relative value; safety evaluation is meaningful when appraising existing technology. Risks related to medicines or medical devices are evaluated during the approval process when implementing new technologies. The safety of the technologies already implemented in the market is managed by consistently monitoring evaluations such as those gathered through post-market surveillance. There are no separate licensing steps required for medical treatments even when these treatments are new. The medical technology evaluation process functions as a gatekeeper; since medical treatments can have different chances of risk depending on the education and experience of the operator is, the qualification management of the professional is very important.

Monitoring the risks of medicines and medical devices consists of a variety of actions. Regulatory institutions collect and analyze the safety information, change the item labels, and cancel item approvals based on analysis using post-market surveillance and the adverse event reporting system (divided into mandatory and voluntary reporting systems). The risks associated with medical treatments are monitored as quality management for high-risk

surgeries using clinical indexes. This is understood to involve institutions that pay for insurance benefits, such as CMS in the United States, who monitor these risks to fundamentally manage the insurance financing.

Second, the management system for safety issues that occur during medical technology implementation can be divided into actions to prevent risks, to collect and analyze safety information, and to react and respond to risk issues.

As a preventative measure, standard guidelines and programs for quality assurance within medical institutions must be established at the national level, and professionals must be educated and trained consistently so that compliance can be monitored.

It is important to broadly collect, analyze, and respond to safety information in order to prevent any harm or similar incidents caused by medical errors. To this end, developed countries construct and manage patient safety reporting systems to collect safety information, analyze that information to educate the public, and provide analysis results in various forms such as literature and newsletters.

Most incidents are dealt with through criminal and civil litigation.

▢ Conclusions

Safety management systems for the risks associated with medical technology itself are relatively wellconstructed for medicines or medical devices; the risk monitoring system is especially wellestablished compared to medical treatments. A voluntary side-effect reporting system to collect and manage the safety information regarding medicines and medical devices is not legally required, but it actively supports data collection at the national level as it is a basic system collecting safety information from the actual medical field. It was found that the amount of information collected was

gradually increasing, contributing to safety information reports and establishing a culture for reporting sideeffects. In contrast, medical treatments do not have pre-approval systems such as item approvals. Therefore, medical technology evaluation works as a gatekeeper for medical technology management, and safety evaluation is very important when implementing new technologies. In addition, safety management must be enhanced systematically since the implemented medical technologies, such as high-risk surgeries, do not have well-constructed monitoring or reporting systems. It is necessary to monitor and understand the status using the main clinical indicators even after the new medical technologies are approved if these technologies require surgical procedures and additional education and training for professionals.

In December 2014, procedures were followed to enact regulations for a safety management system regarding safety issues during medical technology implementation. This legislation is intended to construct and manage a patient safety reporting and learning system at the national level. Previous studies on patient safety insisted on enacting patient safety laws and providing a patient safety reporting system. The patient safety reporting system would be mandatory for deaths or any other serious incidents; it can be voluntary for minor incidents or errors. As shown in many state-level incidents in the United States or United Kingdom, support from the national government is required in order to clearly define mandatory reports and activate voluntary reports. It is necessary to construct a detailed system in which patients or their legal guardians who directly receive medical services and experience side effects can file reports. In addition, safety information collected through the reporting system must be analyzed consistently to understand the incidents' status (not necessarily their cause), to study incidents that occur repeatedly, and to see whether responsive actions can be taken at the national level. Constructing a response system that provides medical service providers and consumers

with information about the analysis of the incidents and preventative measures is one of the most crucial missions of legislating patient safety laws.

Key words

healthcare safety, safety management, preventability, unpreventability, healthcare technology, patient safety