Changes in the environment for healthcare services

According to the data of World Health Organization (WHO), the average life expectancy of the world’s children born in 2012 was six years longer than that of the children born in 1990. Global mortality due to infection decreased from 40% in 2000 to 32% in 2012. On the other hand, diseases such as ischemic heart disease, stroke, cancer, and chronic obstructive lung disease cause more than half (56%) of the world’s deaths. While heart disease is the leading cause of death (30%), deaths from lung cancer and diabetes are also increasing (1) (2).

In the developed countries, in addition to the conventional lifestyle diseases, aging-related diseases are expected to increase, raising the total number of cases. In developing countries, owing to changes in the way of life caused by economic growth, lifestyle diseases associated with factors such as excessive calorie intake are expected to increase. In order to raise social productivity and minimize the total healthcare costs, penetration of healthcare services for healthy adults and elderly people should be promoted, and preventive diagnosis should be enhanced as a measure to reduce the number of potential cases and to replace the conventional healthcare services that are only aimed at affected people.

Efforts to conduct clinical research

Diagnostic imaging systems, including diagnostic X-ray equipment, computed tomography (CT) systems, magnetic resonance imaging (MRI) systems, and diagnostic ultrasound systems, are mainly used for morphological diagnosis based on images. However, in view of the progress of diagnostic imaging systems, research and development of new scan protocols, and advances in technologies for image analysis and image processing, it is now possible to obtain not only morphological information but also various types of functional information from image data. The latter includes the blood flow for perfusion of the brain, a tumor such as a cancer tumor, the myocardium, etc.; the blood volume retained in each tissue; and the left ventricular ejection fraction. Diagnostic imaging systems are now increasingly used for functional diagnosis as well as morphological diagnosis (see pages 7–32 and pages 39–55 of this issue). An example of its activities addressing this trend is the research and development of new techniques using Aquilion ONE, a 320-slice CT system pioneered by Toshiba Medical Systems Corporation (TMSC). Aquilion ONE boasts a wide axial scan range of 160 mm, making it possible to scan the whole organ, such as the brain and heart, in a single rotation. In addition, with advanced image reconstruction techniques and a detector, images can be acquired with less exposure.
dose. The introduction of Aquilion ONE has triggered research and development of new methods for functional diagnosis, such as measurement of the blood flow in an organ or tumor, and evaluation of the motion of lung fields with breathing and the movement of joints. With the development of morphological and functional diagnoses, some diagnostic imaging systems have been actively used for treatment planning and preoperative evaluation in addition to diagnosis, which has created expectations for a certain level of effects they may have on the improvement of workflow and reduction of medical costs in healthcare institutions.

In the research and development of new diagnostic systems, component technologies, clinical application software for functional diagnosis, and scan protocols for such applications, manufacturers can conduct research and development of a new technology, but cannot check its clinical efficacy or whether it will improve clinical workflow. This necessitates joint research with medical institutions.

When we conduct joint research, there are cases where clinical evaluation of a technology developed by us is mainly performed, and cases where we and medical institutions work together from the research and development of a technology through to its clinical evaluation. These joint clinical studies are important in order to develop new technology that is useful for clinical practice.

In recent years, there has been a worldwide trend toward the suppression of medical costs and stricter check of clinical usefulness. In U.S.A. for example, to apply for the approval of new equipment or a new technology, data showing clinical usefulness of the equipment/technology must be submitted. In view of changes in disease trends and in the needs for diagnostic equipment, verification through joint clinical study is becoming increasingly important, as well as the research and development of new technology (see pages 33–38).

**Efforts to reduce medical costs**

Rising medical costs due to population aging are becoming a concern in each country. In Japan, the world's most rapidly aging nation, medical costs in the social security expenditure exceeded 37 trillion yen in fiscal year 2014. Ministry of Health, Labour and Welfare has forecast that medical costs will reach 54 trillion yen in 2025(3), or 8.9% of the nation's gross domestic product (GDP). There are concerns that medical reforms, especially reduction of medical treatment fees, may make it more difficult to maintain sound hospital management. In U.S.A., the future increase in medical costs attributable to implementation of "Obamacare" (comprehensive healthcare insurance reform bill enacted in 2010) has become a great concern, a factor that may impose pressure on the management of each medical institution. It is imperative for medical institutions to further reduce their costs by improving the overall efficiency of their services and optimizing the utilization of their facilities. Medical tourism, for people who seek less expensive treatment overseas, is an aspect of this trend toward low-cost healthcare services.

In the planning and development of new products, we have been making efforts to simplify examination workflow in order to improve the efficiency of medical care and reduce costs. Specifically, we introduced the latest clinical applications for cardiac CT so that a series of conventional examinations that require multiple imaging systems can be completed in a single examination. This has achieved shorter examination time and lower examination costs (see pages 12–16). In addition, a new technique called non-contrast magnetic resonance angiography (MRA) pioneered by us has helped reduce the costs for contrast media, and contributed to the improvement of overall examination efficiency by eliminating the process for contrast medium injection. We are also actively promoting product designs that can minimize the cost throughout the product lifetime, from purchase to move-in, usage and disposal (see pages 28–32).

**Utilization of ICT**

Utilization of ICT is rapidly expanding, boosting the healthcare ICT market in Japan (including medical equipment and systems) to more than one trillion yen in 2013(4). It is expected that the worldwide healthcare ICT market will reach 66 billion dollars in 2020.

One of the expectations concerning introduction of ICT is that it could reduce medical costs by improving the efficiency of medical care. In U.S.A., the Health Information Technology for Economic and Clinical Health (HITECH) Act was signed into law in 2009. This Act uses an index called meaningful use (MU) to define the functional requirements needed to improve healthcare efficiency, thus promoting the effective use of ICT. The Act also imposes strict penalties in cases where the specified MU cannot be accomplished after a certain period of time. In view of these trends, some customers started activities to utilize ICT to create new value. For example, American College of Radiology (ACR) started an activity called Imaging 3.0 in its efforts to realize efficient healthcare services. The activity involves utilization of ICT to assist the user to select the optimum type of examination and the optimum technique for evaluation of each disease.

With ICT being widely used in medical equipment and systems, the importance of cybersecurity is gaining attention. Although cybersecurity is generally discussed from the viewpoint of privacy, it is increasingly discussed from the viewpoint of patient safety in terms of medical equipment and systems. Under these social
circumstances, Food and Drug Administration (FDA) in U.S.A. issued guidance on cybersecurity in 2014, and a number of discussions on new regulations and international standards are underway in other countries (see Column). From early on, considering the importance of cybersecurity, the TMSC Group has been actively promoting measures to strengthen cybersecurity of its products. Ahead of other manufacturers, it obtained the Authorization to Operate (ATO) that complies with Department of Defense Information Assurance Certification and Accreditation Process (DIACAP), which is one of the requirements needed for delivery of information equipment to facilities under the control of Department of Defence (DoD) (Figure 1). Maintaining a certain level of cybersecurity functionality not only ensures the delivery of safe and secure medical equipment and systems, but also could promote further circulation and greater utilization of medical data (see pages 45–50).

Utilization of data

Many attempts have been made to utilize medical data in various fields. In Japan, Council of Competitiveness-Nippon led “Next-generation medical system project” in 2011. In the final report of the project, “supporting diagnosis and treatment through utilization of medical information” was identified as one of the factors contributing to the realization of healthcare innovation. The proposal includes “accelerating the commercialization of systems for supporting decision-making by general physicians” and “enhancing personalization of diagnosis and treatment through utilization of extensive medical information”. In 2014, we concluded a joint research contract with Johns Hopkins University in U.S.A., and started research on technologies for supporting tumor treatment planning through the utilization of clinical big data.

In this research, we are aiming to develop a system for supporting decision-making by physicians. The system analyzes various types of data generated by CT systems, radiation therapy systems and radiotherapy planning systems, to discover new clinical knowledge. Then, the physician can utilize the knowledge to provide personalized treatment (Figure 2). By applying the outcomes of the research, diagnostic and treatment support solutions, which can be utilized not just in radiation therapy but in many other fields such as heavy particle radiotherapy, could be developed.

By using safe and secure ICT to merge the hardware (diagnostic imaging systems), data (patient data and the data on equipment characteristics), and people (knowledge and experience), we aim to provide solutions that benefit society.

Environmental considerations

Today, there are concerns over the impact of business on the global environment, and environmental consid-

**Column Product safety and cybersecurity**

Traditionally, a risk-based approach has been adopted to ensure the safety of medical equipment. However, it came to be recognized that there was a limit to the product safety that could be achieved through activities based on product standards and product process standards, and that recognition sparked a discussion on the necessity of standards dedicated to product safety. IEC 80001-1 (International Electrotechnical Commission standard 80001-1), a standard issued in 2010 dedicated to product safety, specifies that risk management should be performed mainly by the user with the assistance of hardware manufacturers and software vendors. In this standard, cybersecurity is recognized as an important item to which risk management should be applied. A technical report on cybersecurity has been issued as part of the IEC 80001 series, and more reports will be added in the future.

In line with these international activities, various organizations are promoting establishment of guidelines on cybersecurity.

In order to quickly and properly implement a wide range of cybersecurity measures, it is important to judge specific requirements to be applied to products based on comprehensive evaluation of the highly abstract requirements of these international standards and organizational guidance.

![Figure. Standards and guidances on cybersecurity.](image-url)
operations should also be reflected in medical equipment without compromising the pursuit of improved clinical performance to achieve better diagnosis and treatment. Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulation (on the control of chemicals) and Directive on Eco-Design of Energy-related Products (ErP Directive) of European Union (EU) have already been applied to medical devices. In 2014, medical devices were designated as a subject of the EU's Directive on the Restriction of the use of certain Hazardous Substances in electrical equipment (RoHS Directive). Following the EU’s environmental regulations, other countries are also proceeding with environmental legislation. However, the primary goal of medical equipment is to provide new clinical value. In an effort to balance this goal with environmental impacts, industrial groups in Japan, U.S.A. and Europe, mainly diagnostic imaging systems manufacturers, are collaborating. They are actively exchanging opinions with European Commission (EC) and governments of other countries, aiming to achieve a balance between economic efficiency and environmental sustainability.

As one of our environmental initiatives, we are striving to reduce environmental impacts by controlling the amounts of hazardous chemical substances contained in our products. We are also actively promoting introduction of environmentally friendly designs into the product development process, in order to focus on downsizing and energy saving (see pages 28–32). For example, in the product development phase, energy consumption and resource utilization at each phase of the product life cycle (material procurement, manufacturing, trans-

**Figure 1. Cybersecurity measures based on DIACAP.**
Effective and efficient cybersecurity measures can be implemented from multiple points of view.

**Figure 2. Configuration of tumor treatment planning support technology utilizing big data.**
New knowledge is discovered through data mining using feature quantities extracted from image data and non-image data, and the knowledge is utilized for decision-making to realize the optimum diagnosis and treatment.
Transportation, use by hospital, recycle as pre-owned equipment or parts, and disposal) are evaluated to minimize the environmental impact of the product (Figure 3). In Japan, U.S.A. and Europe, we are also promoting effective use of resources through the refurbishment and resale of our products that have been used.

References


