

## **Interim evaluation report: Medical Safety Research Group**

### **1. Objectives**

With the rapid aging of the population, the predominant pattern of disease in Japan has changed from acute diseases such as infections to chronic diseases such as lifestyle-related diseases. Our universal health insurance coverage system is hailed by other countries as one of the key factors that has helped to make Japan the nation with the highest longevity and lowest infant mortality rate in the world. On the other hand, medical treatment fees are determined according to the actual treatment provided. Since there is now a growing likelihood that people will suffer chronic diseases, people have increased occasion to be diagnosed at medical institutions. This is placing a substantial burden on Japan's finances.

The government has implemented a variety of policies in its attempts to rectify the situation, one of which is the introduction of a bulk payment system whereby the government covers a fixed amount of medical treatment costs. This is an example of a reform intended to redesign the medical system from an economic perspective. Such efforts are expected to gather further momentum and, as a result, medical institutions will be motivated to embrace the reforms and provide ever more effective medical treatments both safely and efficiently.

As the first step toward resolving these problems, the Medical Safety Research Group was set up to prepare the basic information that would be a prerequisite to medical practice, and to build a foundation for implementing Evidence-Based Medicine (EBM). These are the Group's two missions.

Japan lags behind other countries in the field of clinical research to evaluate clinical efficacy and safety. Most medical treatments provided in Japan follow treatment guidelines derived from European and U.S. clinical data. These data show numerous differences from domestic data in terms of ethnic characteristics, frequency of disease occurrence, living environments and lifestyles, the metabolic enzyme activity of drugs, and other matters. Therefore, it has become increasingly necessary to gather basic medical information and to analyze clinical data specific to the Japanese population.

To solve these problems, the medical community is called on to establish an information system that systematizes and manages medical treatment information, to realize effective, efficient, and safe medical treatments. Generally speaking, most attempts to extract useful medical information from clinical data are carried out in the form of individual clinical research. If a method for sharing these individual medical treatment information pools among multiple physicians or among multiple hospitals

could be created and widely disseminated, it would ultimately contribute to realizing safer and more effective medical treatment in the most fundamental sense. The goal of this Research Group is to build and encourage the adoption of this system as science and technology for society.

## **2. Members**

To build an information system that systematizes medical treatment information, engineering specialists use information processing technologies. Medical professionals then investigate the means of using the findings thus obtained and examine how to apply them in actual clinical situations. Systematizing a series of these operations and sharing them on a nationwide basis are also engineering tasks. Members of the Medical Safety Research Group examine, from a legal perspective, how these systems influence society, and how they should be used. They then analyze the application of such systems as science and technology for society. Members of the Group will conduct comprehensive research linking medicine, engineering, and law based on the premise that they will not only develop the technologies for such systems but also encourage the general adoption of the systems as science and technology for society.

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## **3. Target Achievements**

The Medical Safety Research Group will build information systems equipped with the functions given below. The goals are (a) to raise the level of general medical care by systematizing basic medical treatment information management to provide safe medical treatment services and to realize efficient and effective treatments, and (b) to solve the economic problems associated with medical care.

- (1) Electronic management of medical treatment records (establishing a database of medical treatment information)
- (2) Analysis of medical treatment data, mainly through data mining
- (3) Real-time linkage and sharing of medical treatment information

An overview of each of these functions is given below.

- (1) Electronic management of medical treatment records (establishing a database of medical treatment information)

This system builds a database of various medical treatment information using the huge volumes of information obtained from daily diagnoses and treatments. A characteristic of this database is that it uses a data storage format that takes into account the elapse of time.

What specific advantages can be obtained by storing data in a chronological or sequential manner? The following are two such advantages.

- A patient's treatment information can be referred to chronologically.
- Both predictive and retrospective surveys can be easily conducted.

If a patient's medical treatment information can be shown in chronological format, such as on a chart, his or her treatment history can be evaluated visually. A display format that enables instantaneous judgment is extremely useful at medical treatment sites. Since the time required to learn a patient's treatment history could thus be reduced, such a format would also be an effective support tool when providing rapid treatment in emergency situations. By adopting a data storage format that takes the passage of time into consideration, it becomes possible to chronologically examine and analyze the data accumulated from daily medical treatment information. Clinical research requires the collection of a large number of new patients, huge amounts of money, and long-term follow-up. By using this system, however, physicians could browse the results of such research, and access similar information, always in real time.

- (2) Analysis of medical treatment data mainly through data mining

In this section, the function for extracting medical information based on the above-mentioned database will be discussed. The Research Group establishes an exhaustive data analysis method known as data mining, as well as an analytical system that displays data by extracting and processing them in ways suited to various purposes.

Data mining is a technology that has come into wide usage in recent years. By setting

simple evaluation criteria, it can be used to search efficiently, from among huge volumes of data, for a rule that meets set criteria. By means of exhaustive data analysis, data mining not only confirms empirically obtained medical information; it also can reveal previously unknown facts.

Meanwhile, the Group is also constructing an analytical system that is capable of extracting and processing data by simple condition-setting operations, and graphically displaying the search results. The characteristics of this analytical system are that it contains medical information obtained through data mining, extracts data pertaining to information that the searcher has some knowledge of from the start, and makes it possible to visually identify data trends. Graphic representations make it easy to see trends in data as well as differences between different groups. It is believed that the system will be a tremendous help in making clinical diagnoses. As can be seen, medical information extraction methods by means of data mining and analytic systems can make a significant contribution to establishing new diagnostic methods and to devising treatment guidelines. Moreover, if medical information can be shared by creating a database of diverse medical information that has been extracted (a database of diagnostic support information), this would greatly contribute to realizing even safer medical treatments.

### (3) Real-time linkage and sharing of medical treatment information

A real-time medical treatment information linkage function is deemed necessary to boost the quantity and range data included in the medical treatment database mentioned above, and to share the medical information and new diagnostic methods obtained through data analysis. During periods such as immediately after a new drug has come into wide usage, for example, it would be difficult to extract, in a short period of time, medical information on adverse reactions, etc., associated with the new drug, unless medical treatment data were gathered and accumulated on a nationwide basis. It is therefore necessary to centrally manage the data accumulated at various medical institutions and to strengthen data-gathering capabilities. By rapidly disseminating acquired information throughout Japan, it should become possible to establish a set of standard diagnostic methods that can be used throughout Japan, thus also greatly enhancing the safety of medical care.

Today, thanks to the spread of the Internet and broadband services, it has become relatively easy to link various databases on a nationwide basis and facilitate exchange of data. Because of the special nature of the operations—the handling of medical care data—we must ensure watertight security appropriate to such operations. It is fully possible, nonetheless, to share medical treatment information on a nationwide basis.

The creation of a network of medical institutions throughout Japan is expected to enable the nationwide sharing of medical information obtained through the accumulation and analysis of vast amounts of medical treatment data, as well as of new diagnostic methods.

By establishing the Real-Time Clinical Navigator System (RCN System) equipped with the above functions, the Medical Safety Research Group aims to formulate treatment guidelines and implement the “one patient, one medical chart” system, and, as a result, hopes to promote the system such that it will contribute to realizing medical safety as research and technology for society.

#### **4. Status and Self-evaluation**

The Medical Safety Research Group has established the following as short-term goals for research and technology for society and medical safety to be achieved within five years: completion of the basic foundation for RCN System; the organization of tasks to be accomplished to expand the network on a nationwide scale and to apply it to other treatment departments; and the presentation of methods to solve these tasks. To expand this system to a wide range of medical institutions regardless of place or treatment department, we must clearly present incentives to assist its implementation. At the same time, we must plainly identify the tasks and challenges that are expected to arise when the system is introduced in medical treatment scenarios, and present specific ways to solve those challenges. Once the range of this system’s application has expanded throughout Japan, it will become possible to gather even more data, enabling us to maintain at a high level both the volume and the precision of the medical information extracted.

At the present stage, a basic structure has been more or less established for a medical treatment database in the cardiovascular sector. The construction of an infrastructure for gathering data is making steady progress. It has also become possible to extract medical information on a test basis, using medical treatment data from the Department of Cardiovascular Medicine in the University of Tokyo Hospital. Other activities are under way, including the development of functions to support diagnoses, and research into protocols for extracting medical information. The goal is to complete construction of the system’s foundation at this Department within one year. Future development tasks are to systematize and overcome technological challenges facing network expansion, and to apply the system to other medical treatment departments. These tasks will be discussed in detail below.

Data collection within individual medical treatment departments, the current practice, produces medical information that lacks credibility. The amount of information that can be obtained is also limited. Therefore, we wish to form, first of all, a network involving multiple medical treatment institutions and to then collaborate with them. Further, to make the system accessible to general users, the system must be equipped with user-friendly interface functions that allow simple operability. It will also be imperative to build security features (including software and communications) to prevent the leakage of personal information and unauthorized system intrusions. When these basic foundations for network linkage are built, we plan to conduct linkage tests with medical institutions located nearby within two years. Later, we will establish the necessary structure to extend the system to general medical institutions and to fine-tune the system. Our goal is to form a network linkage with ten medical institutions, mostly in Tokyo wards, within five years.

By linking the system on a nationwide basis in this manner, we can dramatically increase the volume and type of data collected. It would also become possible to collect data rapidly on rare patient cases. The result of all this would be the increased statistical reliability of medical information extracted from the system, and increases in the absolute amount of information that can be obtained. At the same time, it would become possible to share medical treatment data among multiple medical institutions. This means that, as long as medical institutions are connected by a network, physicians can quickly obtain comprehensive data on a patient, even on his or her initial visit. A patient's personal clinical background, such as history of past illnesses and laboratory test data, can be made available to a physician, enabling swift and effective diagnoses and treatments. As a result, patients could visit any hospital in Japan and receive adequate medical services without having to undergo redundant tests.

At the present stage, we are gathering patient data only from the Department of Cardiovascular Medicine in the University of Tokyo Hospital. In five years' time, however, we hope to present the results of our study on the appropriateness of applying the system to other medical treatment departments. For example, information on surgery and tests performed at the Department of Cardiovascular surgery is also important to the Department of Cardiovascular Medicine. If physicians can learn about the drugs that other departments prescribe, they can quickly obtain information on contraindications for drug combinations. Of course, building a system common to all medical treatment departments is difficult because of the differences in the nature of data gathered. However, we are studying the possibility of establishing a link, within five years, with the Department of Cardiovascular surgery (which sometimes handles the same clinical

data as the Department of Cardiovascular Medicine), the metabolic internal medicine department, and others.

Building on the linkage of multiple areas and with other medical treatment departments as described above, we aim to secure about 300 RCN System users (physicians) five years from now.