

Potential and future of medical ICT from the viewpoint of medical information system management

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Abstract

Almost 30 years have past since the first installation of computer systems into Japanese hospitals. At the beginning they were simply used for calculating charges. With increasing medical specialization, it has become difficult for one doctor to perform all medical functions, especially for critical patients. In the current situation, quick and precise information sharing between the many medical staff members of a large-scale hospital is important. In order to attain this, information and communication technology (ICT) is increasingly being applied to medicine. Also, the extraction of biomedical signals and automated analysis of the extracted signal are typical applications of ICT. However, because many of the doctors and nurses who use ICT cannot, in many cases, understand the technology, communication with ICT engineers can be quite difficult. Herein, medical applications of ICT and its problems along with some commercial problems related to the introduction of ICT to Japanese medicine are presented.

Keywords:

ICT, medical information system, medical devices

Introduction, Expansion of medical information systems

Hospital information system (HIS) in Japan

In the 30 years since their first installation, computer systems have come to be used in most medical sections of Japanese hospitals. The architecture of the systems has evolved from independent computers to server/client systems connected through a network. Also, the function of the systems has developed to include diagnostic assistance, confirming the treatment regimen prescribed by a doctor, acquisition and transmission of "living body" information, and the sharing of information.

The beginning as a "medical accounting system"

The main purpose at the time of the first installation of computers into Japanese hospitals was the calculation and collection of medical treatment fees. This is commonly called a "medical accounting system". In Japan, the health care system

has the patient pay part of the cost of treatment (at present 30 %), with the balance coming from premiums paid to the national health care system. This system was established in 1961. The medical costs consist of three types: the fees of doctors, hospital costs, and the cost of medical materials used. The fee for each is defined by the government and is computed for every procedure carried-out in a hospital. However, it is quite complicated in practice to understand and follow the regulations. A hospital calculates a bill and charges the balance to a government fund every month. On-line billing to the fund began from 2008. However, there are problems with the security of the communications and the recording of data on the receiving side. Much work will be necessary to establish a system that functions well.

Evolution and development of order entry systems

Soon after medical accounting system use became wide spread, a system for doctors was developed. The uses of this "order entry system" include the input of medical directions ("order") by doctors, the transmission of orders to the appropriate section, and the sharing of directions with the co-medical staff. Only "directions" are input into the order entry system; the implementation is not recorded. This is because the record was indicated on the patient chart. Recently, the functions of the system have improved, and cooperation between systems has been enabled. In the current Japanese large-scale hospital, each support section, such as the pharmacy, clinical laboratory, and radiology section, has introduced their own system, in addition to the medical accounting system and the order entry system. These systems are connected through a network and are useful for the load distribution of a computer.

Electronic patient record system in Japan

After the government began requiring that records be input into the system, the "electronic patient record system (EPR system)" appeared. Installation of the EPR is not progressing well in Japan. The Ministry of Health, Labour and Welfare of Japan (MHLW) aimed to "finish the installation of EPR in 60% of all hospitals with 600 or more beds in the 2008 fiscal year", but this goal was not achieved. Unlike US doctors, Japanese doctors do not employ medical clerks; therefore, they must write medical records by themselves. Most Japanese

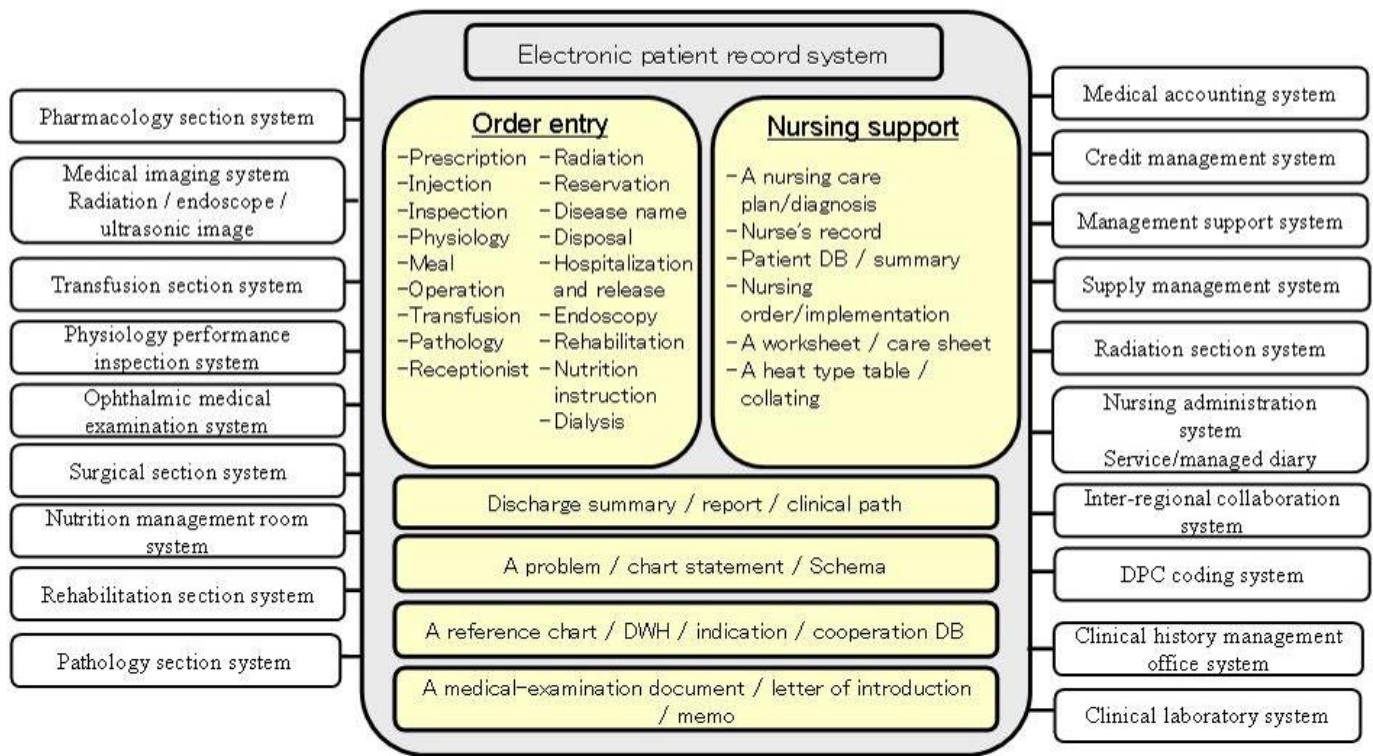


Fig. 1 An example of the functional architecture of an HIS in a Japanese national university hospital

doctors are not skilled typists, which has complicated introduction of the EPR system.

EPR is often described as paperless record keeping, with the directions and records of medical treatment by doctors and nurses input and recorded directly in a computer, with no paper intervention. Some large-scale hospitals, including some University hospitals, have installed EPR. An example of HIS with EPR in a university hospital is shown in Fig. 1.

Medical information systems other than HIS

Clinical medicine has progressed greatly. With this progress, great differences have arisen between the cost and equipment required for illnesses that can be managed with easy medical treatment and other illnesses that need advanced medical treatment. Thus, MHLW is currently promoting a system called "medical cooperation". In this system, two or more hospitals cooperate in the treatment of a patient with a critical disease, and the sharing of patient information is critical. Through communication and the sharing of databases, mutual cooperation can be achieved with reference to patient information. A system with such a function is called a "Local medicine cooperation system". There is also an example in which EPR and medical examination information are shared regionally. However, because a patient's medical data is sensitive personal information, it is subject to strict privacy protection.

In recent years, the treatment of "in-home patients" (medical treatment is required but hospitalization is unnecessary) and preventive care for healthy persons have been topics of interest. The sharing of information by caregivers and the elderly people they care for is of great importance. Insurance information for each patient is also important for a hospital. Information concerning the financial support and assistance that a

patient has received is very important for a hospital in terms of fee calculation. However, the establishment of an I.D. card system and database for the health insurance system that can handle the necessary information has not progressed well.

ICT and Medical information systems

Wireless voice/data communication and the systems used in hospitals

Electromagnetic waves and their compatibility with medical devices

Because wireless apparatus use in a hospital requires the use of electromagnetic waves, there has been some anxiety about their introduction, such as fear that they may cause a malfunction of medical devices (electromagnetic interference, EMI). However, it has become clear that the relation between the output and the distance from it is the main factor related to the danger of EMI. Therefore, safe installation of wireless communication is currently an important topic of discussion [2, 3].

Patient monitor network

In hospitals that use many patient monitors for the observation of critical patients, a data transmission network that gathers information has been constructed. For the transmission network, a wireless communication system in the 420 MHz band has long been used, even though HIS have developed greatly.

Nurse-call system

A "nurse call system" is a system by which inpatients can contact a nurse. In Japanese hospitals, there is a pushbutton-type call terminal for every bed that allows communication be-

tween the inpatient who operated the terminal and a nurse. Although previously calls were able to be received only at the nurse station, the function has changed so that a nurse can talk with a patient directly from anywhere by use of an in-house Personal Handy-Phone system (PHS). PHS is a totally digital mobile communications system developed in Japan [1]. Because the output of a PHS terminal is as weak as 80 mW at the maximum, almost no influence on medical devices can be found.

A PHS terminal can be used as an HIS terminal to check the medicines of a patient at the time of intravenous drip or to display the warnings that medical devices and monitors automatically send to a PHS screen, making the working environment of nurses safer and more efficient. A Personal Digital Assistant (PDA) can be used for these purposes, but a PDA cannot yet be used for voice communication.

Wireless data communication for HIS

As a hospital becomes larger, HIS and the network required also become larger. However, because the construction costs of HIS cannot be covered completely by medical treatment fees, hospitals have installed wireless LAN to reduce the number of terminals and to improve labor efficiency. Wireless LAN introduction brings about an environment in which entry and reference to data without location or time limits is possible ("ubiquitous" environment). Communication was historically limited because fixed terminals could previously only be installed in the staff room of a hospital, but it has become possible to immediately share the information generated in the sickroom by the introduction of wireless LAN, with great benefits to the patient and medical staff.

IC tags (RF-ID tag) are also gaining attention as a location system. To date, the main purposes of IC tags have been to determine the location of patients who need immediate attention because of poriomania or a sudden condition change and for the prevention of the theft of expensive medical devices.

Cooperation between hospitals

As mentioned above, networks for advancing medical specialization and new system introduction will be highly promoted in the future. However, where information is collected and who manages it remains problematic. In Japan, there are people who resist government and public office collection and management of information concerning medical and other personal information. Also, because Japanese clinics and hospitals are organized as independent entities, other organizations will resist them holding a local resident's information. Although it is possible that an independent organization might be allowed to hold the information, it is a difficult problem that must be solved, along with problems such as funding and management authority.

Databases for medical studies

Medical-examination progress and therapeutic results are important data for measuring the progress of medicine. The results are collected in a database and used in university hospitals for the development of new medical treatments. A variety

of data of not only medical practice but also test results and photo/X-ray images, etc. require careful storage.

In-home patient management (health observation) system

In order to monitor the health condition of citizens who have not been hospitalized or gone to a hospital regularly (those who are not "patients"), many technologies for extracting and transmitting "living body" information are being considered for introduction. These technologies can be used for the prevention of illness, miscarriage, and solitary death, etc., by monitoring the condition of a pregnant mother and her embryos or for monitoring elderly people (especially those living alone). Although it is unfortunate, many of these technologies remain in the experimental stage.

Successful ICT Application vs. Things that cannot be done with ICT

Products that apply ICT to medicine

Team medicine

Japanese medical doctors have traditionally been responsible for general medical practice. However, with the advance of medicine, the need for specialists has increased. The development of advanced medical devices has also created a need for specialists other than doctors. Thus, the construction of teams that include doctors and so called "co-medical" staff, such as nurses, pharmacists, and clinical laboratory technologists, who are involved in medical practice under a doctor's direction, are vital to the smooth operation of a hospital. This kind of system is called "team medicine". In order to carry out "team medicine", a doctor's directions must reach the co-medical staff quickly and accurately.

Cooperation between hospitals

As already stated, "medical cooperation", in which one patient is managed in two or more hospitals, is being emphasized in Japan. For example, the critical stage is managed in a large hospital and rehabilitation is done at another hospital. When two or more hospitals cooperate to treat one patient, the sharing of patient information in a timely and accurate way is indispensable. Applying ICT to medicine has made possible the quick and accurate sharing of patient data, including examination data and radiological pictures.

The gathering of patient information

Each hospital historically stored patient information individually. However, through the cooperation of hospitals, information services are being developed that, for example, collect information on infectious disease incidence and local cancer registries etc.. The National Institute of Infectious Diseases is doing a trial of infectious disease surveillance for the purpose of preventing new types of influenza and for the quick detection of bioterrorism. The Japanese government is promoting a "cancer registry enterprise." The purpose is to investigate cancer according to area and to calculate the results of every

treatment procedure for "cancer", which is the primary cause of death in Japan. This will be able to be done only after the development of communication technologies and organizational concepts, such as how best to express information and unification of communication protocols.

Problems that cannot solved even with ICT

The responsibility of the medical doctor

Although biomedical data can be precisely gathered with ICT and artificial intelligence systems show great promise for diagnosis, the ultimate responsibility for diagnosis and treatment will continue to fall to the doctor. In the case of diagnosis, designing a treatment protocol, and insuring that the treatment regimen is followed, the doctor will continue to have the responsibility for interpreting the information, advice, and warnings that a computer or diagnosis apparatus provides. ICT technology cannot act as a doctor: It should be devoted to activities that support the doctor.

Differences in doctor evaluation of the data from medical devices used in home medical care

At present, when the patient or his /her families operate a medical device that provides biomedical information, the interpretation of the results often differs between doctors. This is because there is no guarantee that the medical device was used correctly. Moreover, especially when a measurement instrument is used incorrectly, measurement precision may fall. However, the Japanese government is continuing to promote home medical care for the purpose of reducing health care costs. If home medical care is to progress, it will be important to solve this problem of differences in precision. Development of medical devices that can consistently give information of the same quality even if when operated by a non-specialist, including children or aged persons, is desirable.

Barriers to the introduction of ICT into medical devices in Japan

The production and introduction of new biomedical signal acquisition technology (an aspect of ICT) for commercial medical devices can be expected to take a very long time in Japan. This is because the approval of the MHLW (recognition based on the Pharmaceutical Affairs Law) is required before devices used for clinical practice can be sold in Japan, whether for examination or treatment. When a medical device needs to be embedded or attached to a human body, it must be approved by MHLW. A company is obliged to submit the results of animal experiments and their plans and the results of clinical trials.

In Japan, an independent administrative agency the Pharmaceuticals and Medical Devices Agency (PMDA) does an approval review of all drugs and medical devices. However, because most applications are for drugs, far too many of the judges are pharmacists. The screening skill of the people responsible for medical devices is insufficient. Moreover, because PMDA is an independent administrative agency, it is dependant on its own funding, resulting in a charge of 1.2

million to 2 million yen (12 thousand to 20 thousand US dollars) per hour for consultation. In addition, it is necessary to prepare a huge amount of explanatory material. Thus, in order to put a new technology in practical use in a medical setting, great expense and much administrative time and effort are needed. In order to develop a medical device that attaches to a human body or that is embed, a company can expect to spend 200 million to 300 million yen (2 million to 3 million US dollars) over a period of four to five years.

Moreover, there is no funding support system for medical device development or for the planning of clinical trials in Japan. Although there is some financial support for venture businesses, there is no financial support system for small and medium-sized enterprises that develop new medical technologies. This is in contrast with the much shorter time required by PMDA for the approval of medical devices that have been approved in foreign countries, which makes the introduction of foreign devices much less expensive and quicker than domestically produced devices. This creates a huge barrier to the development of medical devices in Japan.

ICT itself is not directly concerned with medical practice. Therefore, in almost all cases, the approval of the MHLW is technically unnecessary. However, approval may be required when it is placed in medical devices, even if the new/replacing/additional function to be added to the device does not have a medical function (for example, when adding only a communication function). If PMDA judges this addition as a reconstruction of the device, full approval will be again needed.

Medical staff expectations of ICT engineers

In Japan, education about computers and communications systems is not done in most medical school courses for the training of doctors and nurses. Therefore, there is a tendency for people who work in hospitals to look at ICT merely a tool, and this trend can be expected to continue for many years. A "mediator", who knows the job specifications of each medical specialty and who can explain state of the art technology to the medical staff is indispensable to a hospital. Mediators are required both in the hospital and on the development / sale side.

Japanese doctors and nurses are not necessarily resistant to the use of new technologies, such as telemedicine systems. For example, if a financial support system were made available by the government, hospitals would support telemedicine for use in remote medical examinations. Telemedicine would benefit hospitals that are short of doctors [4]. However, it is important to take care when installing such systems in a medical setting to insure that efficient communication takes place that promotes and protects the health and lives of the patients.

When an engineering person implements research or developments that are useful for medicine and the general welfare, it is important to give concrete explanations concerning "when it can be realized" and "how it will be useful and for what."

Also, it is important to show the usefulness from a business standpoint, such as "how it can reduce labor costs" and "how it will lead to patient acquisition", etc. It is my hope that this research will lead to safer, more effective introduction of new technologies into a broad range of medical settings.

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