Medical Image Information Solution and Laboratory Test Information Solution for Improvement of Diagnostic Accuracy

● Yasuharu Ogino ● Fumio Fukushige ● Kohei Murao

A wave of medical record computerization is sweeping through the medical field, starting with individual hospitals and extending to regional cooperation. Medical records include images obtained by computed tomography (CT) and magnetic resonance imaging (MRI) and numerical measurements of specimens such as blood and urine. Systems for managing image and numerical information have become widespread as departmental business systems, and they are now evolving into decision-making support systems and systems for improving diagnostic accuracy. This is because they transmit and process exponentially increasing amounts of image information for each patient and because they provide easy access to the electronic medical records. In this paper, we introduce Fujitsu's solutions related to medical images and laboratory tests and describe our activities for making systems better able to support improvements in diagnostic accuracy.

1. Introduction

Medical treatment information that provides the grounds for diagnosis in clinical sites includes results obtained by imaging equipment such as computed tomography (CT) and magnetic resonance imaging (MRI), and laboratory test results obtained by using devices to analyze specimens such as blood and urine. These examination results are important for identifying clinical diseases. The diagnostic imaging department reads information concerning diseases from images generated by medical equipment, as its main work. The volume of image data generated on a daily basis has become massive (1000 or more images per examination) along with the advancement of medical equipment. This in turn means institutions need to be able to accurately identify pathological changes from the enormous amount of image data, and this is placing an increased burden on doctors.

Against this background, there have been demands for systems to reduce the burden of interpreting images, help doctors and technologists accurately interpret images and help improve diagnostic accuracy at the same time in recent years.

Among such attempts are studies on computer-aided diagnosis and some of them have reached the practical application phase. Fujitsu provides a medical image information solution that helps doctors and technologists in their diagnostic imaging operations, and a laboratory test information solution that helps laboratory technicians in their operations of laboratory testing. We call these solutions collectively as central clinical departmental solutions. Fujitsu is also developing an intra-departmental examination solution that manages the results of examinations conducted in clinical departments or wards other than the central clinical departments.

This paper describes these solutions by explaining their present status and activities for

improving diagnostic accuracy.

2. Medical image information solution

The medical image information solution provided by Fujitsu starts with the acceptance of examination orders in linkage with an electronic medical record system. It is composed of a system that assists radiology technologists who carry out the actual imaging, a system that stores, sends and displays images, and a system for inputting and viewing reports so that they can be fed back to electronic medical records. These systems are incorporated into a package as HOPE/DrABLE-EX, and it is being widely used by medical institutions.

Images generated in a hospital include plain X-rays (CR), tomographic scans such as CT and MRI, video sequences such as angiography and ultrasonography, and endoscopic images. HOPE/DrABLE-EX can take an overall perspective of various examinations conducted on one patient (**Figure 1**). It is also capable of studying the way a lesion changes by arranging the results of similar examinations in chronological order, and thus assisting doctors engaged in diagnostic imaging.

Radiographical images were conventionally studied on film, but studying them on a monitor has now become the mainstream along with the computerization of imaging equipment and diffusion of electronic medical record systems. The medical image information solution uses no film, eliminates the need for developers, and also makes significant environmental contributions by reducing the space required to store film and reducing waste.

2.1 Higher accuracy with image quality assurance

The age of filmless imaging has arrived. Consequently, images taken by a radiology technologist become more quickly available for studying on a PC in the consultation room with the doctor who requested the examination. On the other side of the coin, there has been a problem in which the low-quality images are sent to the doctor on rare occasions because they are not adequately verified with regards to whether the image content matches the purpose

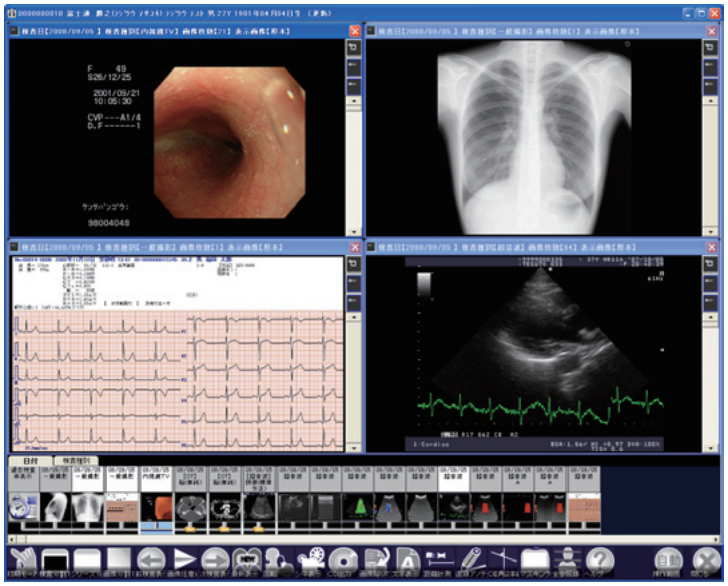


Figure 1
Example of screen shown in HOPE/DrABLE-EX.

of the examination order. This problem becomes more serious when an electronic medical record system is introduced, and may lead to a risk of distributing inappropriate images across the hospital without them being verified by the radiological department.

In order to assure image quality before the information is released within a hospital, the notion of the need to inspect images has been spreading as the electronic medical records and filmless imaging are widely used. An image quality assurance system has been gradually coming closer to the phase where it will be practically applied. Results of a survey on actual medical sites have shown the percentage of images judged inappropriate by image inspection before distribution was approximately 1% of all examinations. The cases in which distribution is judged inappropriate include:

1) Imaging of the wrong parts of the body
2) Wrong orientation
3) Confusion between left and right limbs, etc.
4) Confusion between front and side
5) Inappropriate image quality (brightness, contrast, blurs)
6) Other (wrong order of images in a set, omission of plates for identification between left and right, etc.)

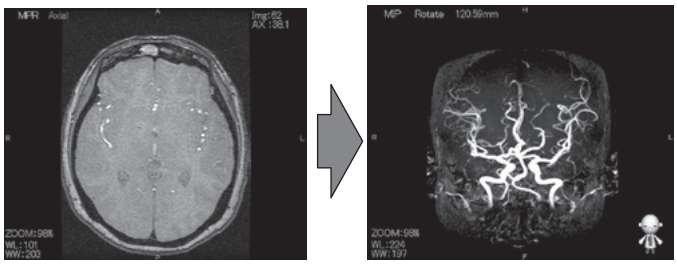
In reality, facilities that carry out image quality assurance assign staff exclusively in charge of image inspection. As described above, however, inappropriate imaging occurs in only 1% of all examinations. So assigning staff exclusively for image inspection may impose a burden on hospital management. Under the circumstances, as an advanced attempt, Fujitsu has been trying to use image pattern matching technology to automatically detect any mismatches between the details of the examination request (parts of the body and orientation to be imaged) and the images actually obtained. Results of a trial conducted in actual medical sites have shown that the pattern matching technology judged correctly at least 95% of the images of the chest and abdomen, which account for a large portion of all images.[1)] If the coverage of regions to be identified is further expanded and the accuracy is improved in the future, only images that have been identified as potentially having problems will need to be inspected, and this will likely eliminate the need for staff exclusively in charge of image inspection.

We intend to continue to improve the function and performance of this image quality assurance system and help to ensure the quality of distributed images so that accurate diagnosis can be performed.

2.2 From tomographic to 3D images, from subjective to quantitative evaluation

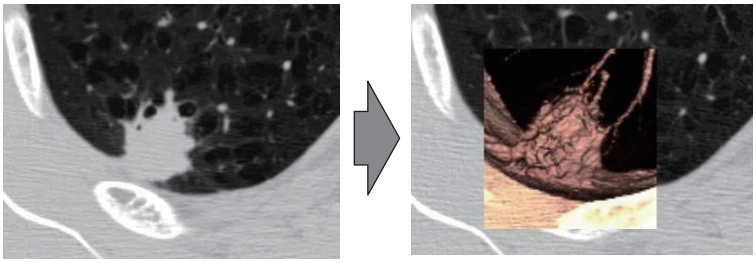
As mentioned in the Introduction, large volumes of tomographic images are output from CT and MRI machines on a daily basis. These tomographic images have allowed diseases such as cancer to be detected in the early stages and made it possible to accurately locate the disease sites and identify their states. For doctors who examine these images, however, interpreting large amounts of them is laborious no matter how experienced they are, and oversight due to fatigue tends to occur. In addition, the decreasing thickness of slices has made it difficult to gain a three-dimensional understanding of the entire states of diseases. Accordingly, there is a need to handle them collectively rather than as individual tomographic images.

To solve these problems, HOPE/DrABLE-EX is equipped with display functions such as SUM that can display images with a desired thickness added to them, and MIP, which projects the maximum value in the thickness. As shown in **Figure 2**, in an MRI image of cerebral blood vessels, the paths of the vessels are not clear in the tomographic image but the MIP image of the entire head clearly shows how the vessels run, and this is useful for identifying an arterial cancer. In addition to these, there is also an original function called ROI VR, which gives a



(a) MRI image (b) MIP representation

Figure 2
One-slice image from MRI of head and MIP representation of whole head.



(a) CT image (b) ROI VR representation

Figure 3
Example of ROI VR for lung nodule.

volume rendering (VR) representation only of the region of interest (ROI) specified on a tomographic image. For example, this function allows the form of a lump that may grow into a lung cancer, or nodule, to be immediately identified, and the way it is related to the surrounding blood vessels to be grasped on a tomographic image of the inside of a lung (**Figure 3**). These 3D image display functions are popular among both department doctors and image interpreters. They do not require an exclusive 3D image display unit, but can be easily used with a viewer generally used for medical care. They are useful for giving explanations to patients in doctors' offices or wards. For patients, the functions allow them to check the locations and progress of their diseases, making doctors' treatment policies easier to understand, and they feel reassured as they receive medical treatment.

HOPE/DrABLE-EX also has a function capable of measuring the volume of small lesions such as lung nodules or liver cancers. Conventionally, the maximum diameter of an abnormal part such as a nodule was measured on one tomographic image, and this was not an adequate way to accurately measure the volume of a lesion with a three-dimensionally flat or complicated shape. As thinner tomographic images have become available and the image processing functions of HOPE/DrABLE-EX have been enhanced in recent years, quantitative processing, such as determining the volume of a lesion and the average or distribution of concentration, has become possible.

2.3 Diagnostic imaging in medical examinations

Among all cancers, lung cancer in particular claims the lives of many people, and many facilities offer lung cancer CT examinations in an attempt to give early treatment to cancers that can be cured by early identification with

CT equipment. Accordingly, to share and certify the technology and knowledge for imaging and image interpretation, an incorporated nonprofit organization called the Japan Accreditation Council for Lung Cancer CT Screening was founded. Radiology technologists now have a new role of informing radiologists or doctors of abnormal parts such as nodules. Fujitsu provides a testing system for certifying the skill of radiologists in identifying abnormal parts. At the test site, about 100 attendees access CT images at the same time and mark the locations that they think are abnormal. The answers can be immediately graded and analyzed after the test. In this way, Fujitsu engages in activities that contribute to educating radiology technologists for improved diagnostic accuracy.

In medical examinations, identifying chronological changes of nodules provides important information for doctors' diagnoses. Fujitsu has incorporated a program that calculates the nodule doubling time (number of days it takes for the volume to double) from the volume measurement made possible with 3D image analysis into the prototype system, and subjected it to clinical evaluation. In the clinical evaluation conducted so far, it has been reported that for low-density nodules, which doctors find difficult to judge, the doubling time can be used as a reference when judging whether they are benign or malignant.[2), 3)]

In this way, we intend to further enhance the functions of HOPE/DrABLE-EX in response to the needs that change over time and thus help improve diagnostic accuracy.

3. Laboratory test information solution

Fujitsu's laboratory test information solution consists of a laboratory test system that assists with general, hematological, biochemical and other tests; a bacteriological test system that supports microbiological tests; an accuracy management system that manages the control serum results; a laboratory operation assistance system that assists with subsequent use of data; a test history system that provides the test results to outside parties; and an infectious disease management system for managing infectious diseases.

The operations of a laboratory mainly include, after the acceptance of test requests from doctors, collection of specimens (blood, urine, etc.) from patients, acceptance of specimens, preparation for and execution of tests, confirmation of test results and reporting the results to the doctors. Unlike the medical image information solution, test objects are specimens (blood, urine, etc.).

Laboratories are required to promptly offer reliable and accurate test results to attending doctors in the course of the operations mentioned above.

3.1 Fujitsu's laboratory test information system

After personal computers started to become widespread around 1995, multiple laboratory test information systems emerged in the respective regions within the Fujitsu Group. This posed a major challenge because it was hard to promptly respond to environmental and technological changes. HOPE/LAINS-GX, the package currently offered, has integrated the existing multiple laboratory test systems to offer uniform services and support all over Japan. With this integration as the start, we have managed to incorporate requirement specifications of over 20 hospitals and link information with electronic medical records, which could only be done by Fujitsu as an electronic medical record vendor.

3.2 Prompt provision of reliable and accurate results

Analysis equipment for measuring specimens is indispensable to laboratories of today, and accuracy management refers to the process of ensuring the analysis equipment

produce accurate data. It includes management of analysis equipment with a control serum (external accuracy management) and management of the results of patient specimen measurement (internal accuracy management), and they are described below.

1) External accuracy management

Control serum with known measurement results is used for measurements and the results are saved. Then, based on those results, statistical techniques are used to manage the accuracy of the data.

2) Internal accuracy management

Internal accuracy management means confirming whether the results of patient specimen measurements are correct (checking for any mix-up of specimens or mechanical error in analysis). It includes techniques such as checking the upper and lower limit of measurement results, comparing them with the values obtained in previous measurements, and conducting delta checks and inter-item checks.

However, these mechanical accuracy management methods alone are not enough to confirm that patient specimens are accurately measured. Factors such as the conditions of the patients as their blood samples were obtained must be taken into account, and the types of patients' diseases and drugs taken also tend to affect the results of measurement. For example, diabetics often have high blood sugar and glycohemoglobin levels, and if they take warfarin then a PIVKA 2 test may result in false positive.[4)]

The types of diseases or conditions of medication alone are not enough to grasp the conditions inside the body. For elements that cannot be handled by the algorithms currently implemented in computers, clinical technologists' judgment based on many years of experience is also important.

Accordingly, HOPE/LAINS-GX conducts computer checks (upper/lower limit check, previous value check, delta check, etc.) to generate warnings when there are any questionable measurement results. It then displays disease information and medication information in real time from electronic medical records together with the measurement results, and sends the result to technologists who judge it for approval. In this way, computer checks and clinical technologists' judgment supplement each other, and this has made it possible to offer more accurate examination results to attending doctors and assist them in their diagnosis.

An international standard ISO 15189[5)] has been established for the provision of reliable, accurate and high-quality examination results. Obtaining this ISO 15189 certification is an effective way to publicly show the reliability and capability of a laboratory. HOPE/LAIN-GX conforms to the requirements of ISO 15189, and we believe it will be useful for customers (laboratories) intending to obtain ISO 15189.

ISO 15189

ISO 15189 is an international standard based on ISOI/IEC 17025 and ISO 9001, and is intended especially for medical laboratories.

It is officially referred to as ISO 15189:2007 Medical laboratories—Particular requirements for quality and competence.

ISO 15189 includes all the requirements that must be met by a medical laboratory that intends to demonstrate that it is:

- operating its quality management systems,
- technically competent and
- capable of producing technically adequate results.

As with ISO/IEC 17025, ISO 15189 is mainly composed of the following two sets of requirements:

Quality management system requirements

These are requirements concerning sound management.

Technical requirements

These are requirements concerning the technical competence according to the types of clinical tests undertaken by medical laboratories.

4. Intra-departmental examination solution

So far, we have described medical image information and laboratory test information solutions implemented by central clinical facilities in a hospital. From the perspective of examinations in a hospital, however, the entire examination results cannot be managed without incorporating the results of examinations conducted by all the departments other than central clinical departments. Examinations that take place outside the central clinical departments include echography by the obstetrics department; endoscopy by the ear, nose and throat department; and arterial blood gas measurement in the ICU. To address this need, Fujitsu plans to provide an intra-departmental examination solution for managing the results of examinations conducted in clinical departments and wards.

Intra-departmental examinations are called "*Jikakensa*" in Japanese meaning that the examination is conducted without any orders from another department. In most cases, the actual examinations are conducted by doctors of the respective departments. For that reason, they never issue examination orders to themselves and they store the examination results on paper to use for medical care. As computerization of medical records progresses, examination results that are recorded on paper may lead to data being omitted when converted to electronic medical records, leading to a possible failure to incorporate the results of the examinations. It may not cause any problem with regards to consultations held on the day, but if the results of examinations conducted in the department are unavailable during the observation of the patient's conditions or for visits to other clinical departments, medical care may be hindered.

In addition, medical fees for examinations conducted cannot be claimed without taking the trouble to make accounting entries, and this tends to cause potential claimants to forgo claiming. Conversely, claiming without entering examination records in electronic medical records may lead to human errors about claiming of medical fees. Furthermore, when a patient undergoes medical examinations at more than one hospital, the patient's personal healthcare records become unavailable for reference.

To solve these problems, the intra-departmental examination solution is indispensable to hospitals.

5. Conclusion

In this paper, we have focused on a medical image information solution that assists with diagnostic imaging operations, a laboratory test information solution that helps laboratory test operations, and an intra-departmental examination solution for supporting examination operations other than the above that are generated in clinical departments and wards. Furthermore, we described the solutions currently provided by Fujitsu and its activities in line with changing customer needs.

The range of examinations that any one patient may undergo in medical institutions can be diverse. Among them, biological and specimen test results are part of valuable medical treatment information essential as personal medical care information. Fujitsu values each and every patient's medical treatment information generated in one medical institution, and intends to provide the results of examinations conducted by multiple facilities in the context of regional cooperation. Going further, we are committed to continuing to offer solutions that provide accurate examination results anytime and anywhere in a human-centric society.

References

1) H. Imao et al.: Auto Image-checking system for X-ray Radiology by image processing—For reducing radiologic technologists' workload. (in Japanese), Proceedings of the Joint Conference on Medical Informatics, No. 28 (Suppl.), 2008, pp. 1173–1174.
2) S. Niizuma et al.: Judgment of Progress of

Pulmonary Adenocarcinoma Noguchi Type C by Measurement of Doubling Time of Solid Region. (in Japanese), The Japanese Society of CT Screening Scientific Meeting, February 13, 2010, OR6-5.
3) S. Oda et al.: Computer-Aided Volumetry of Pulmonary Nodules Exhibiting Ground-Glass Opacity at MDCT. *American Journal of Roentgenology (AJR)*, Vol. 194, pp. 398–406 (2010).
4) T. Shibata: Cases of Variations in Laboratory Test Values due to Administration of Drugs—Variations in test values as drug side effects may result from direct action and indirect reaction through living body. (in Japanese), *IMIC*, Vol. 24, No. 3. pp. 34–45 (2003).
5) Japan Accreditation Board: ISO/IEC 17025 and ISO 15189. *http://www.jab.or.jp/eas/02.html*

Yasuharu Ogino
Fujitsu Ltd.
Mr. Ogino is engaged in development of a central clinical facility package for medical institutions.

Fumio Fukushige
Fujitsu Ltd.
Mr. Fukushige is engaged in development of a laboratory test department package for medical institutions.

Kohei Murao
Fujitsu Ltd.
Mr. Murao is engaged in development of a medical imaging system package for medical institutions.