Hitachi's Clinical PET Screening Support Service

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OVERVIEW: PET (positron emission tomography) imaging is an advanced and highly accurate diagnostic tool for detecting dementia of the Alzheimer's type, malignant tumors, and heart disease. Especially in the case of malignant tumors, PET is very effective at detecting minute cancers only several millimeters in diameter in a single whole body scan, and is expected to see extensive use not only for regular periodic physical exams but also for detecting the recurrence and metastasis of tumors. There has been a stepped-up interest on the part of hospitals and clinics to acquire PET imaging systems since April 2002 when the national health insurance coverage was extended to cover malignant tumors. Yet the decision to install a PET system is not made lightly, first because PET imaging facilities are costly and second because considerable technical expertise is required to operate the equipment. This situation led Hitachi to develop a comprehensive clinical PET screening support service that assists hospitals with financing to procure PET equipment, provides engineering support in areas of radiation and cyclotron technology based on years of experience in dealing with nuclear technologies, and operational and maintenance support once the system is up and running.

INTRODUCTION

MEDICINE has seen a fundamental shift in emphasis from treatment of illness in the 20th century to a preventative medicine approach in the 21st century. Rather than treating the victim of a traffic accident after the accident has occurred, the new approach is to try and prevent the accident from occurring in the first place. By encouraging the middle-aged and elderly to get regular health screenings—blood tests to detect early onset of adult diseases, stomach X-rays, ultrasounds, head MRIs (magnetic resonance imaging), X-ray CTs (computed tomography), etc.—this is effective for suggesting changes to prevent "life-style" type diseases, and also for early detection of heart disease, dementia, and malignant tumors. If this preventative approach is successful in getting people to make life-style changes and detecting early onset of adult type diseases, then this should help hold down overall medical costs. The problem is that making the latest MRI and X-ray CT equipment available for adult health screening is quite costly, and thus represents a major financial burden at this time when demand is growing to hold medical costs down.

In contrast to MRI and X-ray CT that reveal anatomical information, PET (positron emission tomography) is an imaging technique designed to measure functional attributes within the cell (metabolic activity associated with glucose and amino acids, activity associated with levels of blood flow and oxygen consumption, etc.), and has already proven to be enormously useful for clinical diagnostics[1)]. Yet PET imaging facilities are also quite costly for the initial investment in hardware such as the accelerator and PET camera and also for ongoing engineering involved in the handling of radiation technology.

This article describes a clinical PET screening support service offered by Hitachi, Ltd. that helps hospitals and clinics acquire PET imaging capabilities by providing engineering and financial support in addition to the equipment itself (see Fig. 1).

EFFECTIVENESS OF PET AND BARRIERS TO DEPLOYMENT

Effectiveness of Clinical PET

PET equipment (the PET camera) captures an image by detecting gamma rays (photons) that are emitted during radioactive decay of RIs (radioisotopes) that are administered to the patient in the form of a

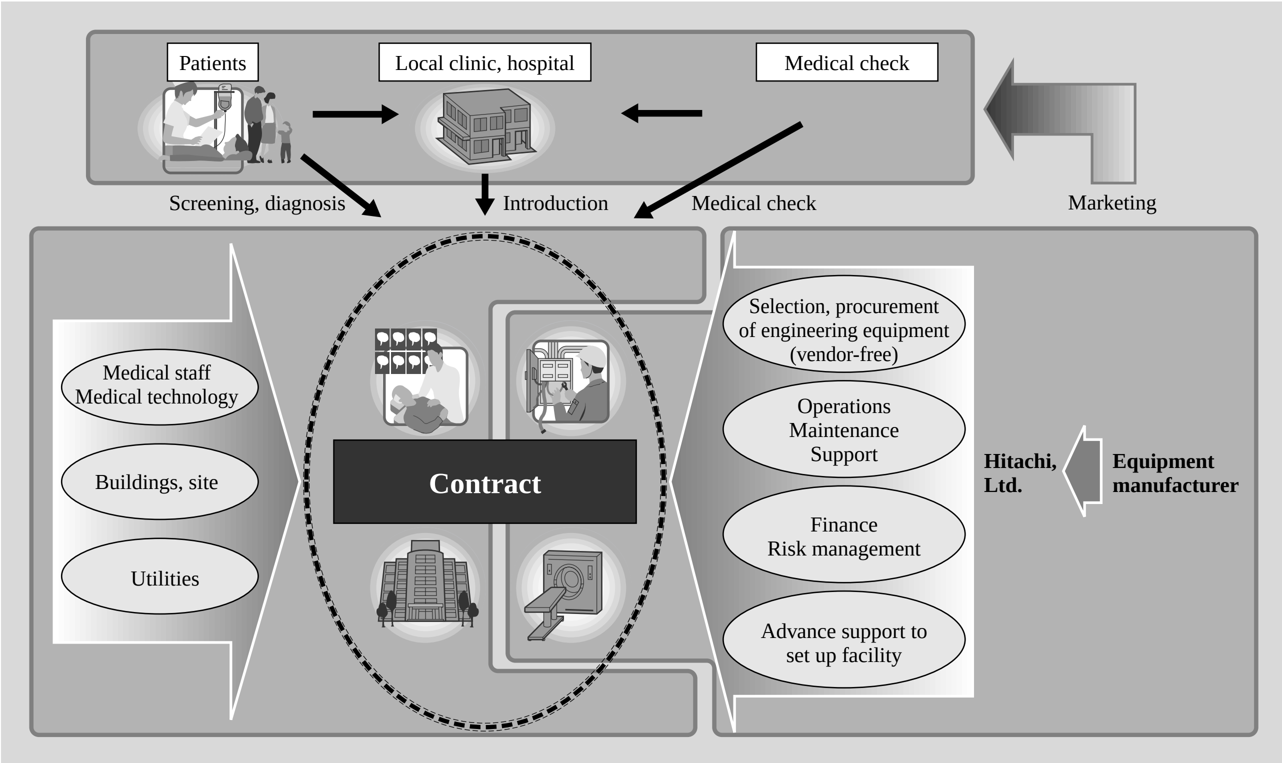

Fig. 1—Idealized Image of Clinical PET Screening Support Service.
In order to help hospitals acquire advanced PET imaging systems, Hitachi, Ltd. has established a clinical PET screening support service that provides a full range of support capabilities including assistance in arranging financing, engineering, and the operation and maintenance of equipment.

radiotracer which reveals their line of origin and movement through the body. Because PET uses positron emitting radionuclides in organic molecules such as glucose and amino acids, images are created of physiological functions in the body. The glucose analog FDG (fluoro-deoxy-glucose) derived from grape sugar is particularly useful for cancer screenings, because it is absorbed into cancer cells about eight to ten times more compared to normal cells. Indeed, Dr. Kanji Torizuka, professor emeritus of Kyoto University, has reported that PET yields improved sensitivity and spatial resolution compared to other conventional scanning methods, and gives a very high success rate ranging from 85% to 96% in diagnosing a long list of medical conditions including malignant lymphomas, malignant melanomas, and tumors in the lungs, mammary glands, pancreas, livers, colon and rectum, and head and neck[1)]. PET systems also have whole body scanning capability, are non-invasive and cause little discomfort to patients, and reveal very readily if a cancer has metastasized. PET imaging thus provides detailed diagnostic information before and after surgery, and also provides an excellent procedure for cancer and other health screening exams.

PET imaging facilities began to appear in Europe and in the U.S. about ten years ago, and now many private hospitals in Japan are scrambling to procure PET equipment since the national health insurance was extended in April 2002 to cover 12 conditions involving malignant tumors.

Barriers to More Widespread Use of PET Screening

Essentially there are two requirements that must be met before PET screenings can become more widely available to the general public:
(1) the individual cost for the procedure must be minimized by making sure that PET screenings are covered by insurance, and
(2) steps must be taken so that many hospitals and clinics can acquire the PET imaging equipment.

The first requirement involves broadening the range of conditions covered by the national insurance, and this falls largely under the purview of the government. The second requirement means not only acquisition of the costly hardware itself—accelertor, RI production

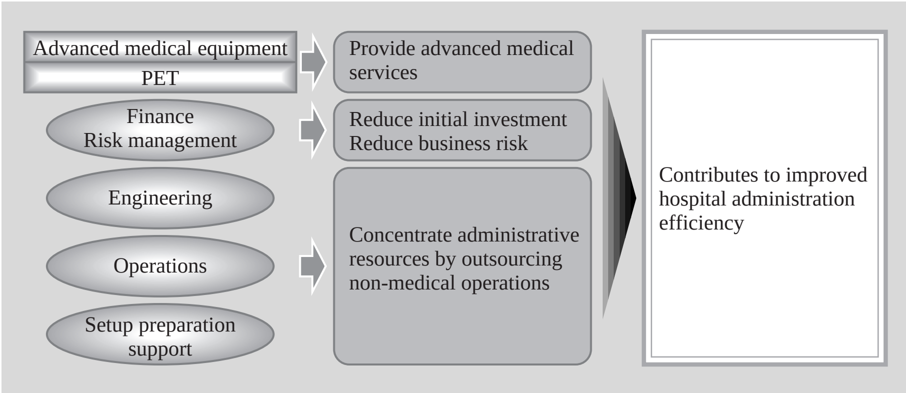

Fig. 2—Advantages of PET Service Contract Approach for Hospitals.
Core administrative capabilities are strengthened by outsourcing the initial startup investment and non-medical operations.

equipment, RI testing equipment, PET cameras, etc.—but also extensive radiation shielding, air conditioning, drainage systems, and other special modifications of the building to accommodate PET systems, and this involves substantial investment. And there are other requirements including acquisition of approvals and authorizations regarding the RIs, designing and implementing adequate shielding for buildings that house PET equipment, and engineering tasks to manage the production of RIs and safety. In addition to the equipment, it is clear that the successful deployment of a PET imaging facility also requires substantial financial strength as well as engineering capacity. Given this situation, Hitachi combined its financial clout with its radiation-related engineering skills accumulated through long years of work on nuclear technologies, and began offering the clinical PET screening support service to assist hospitals in designing and deploying PET imaging systems.

COMPONENTS OF CLINICAL PET SCREENING SUPPORT SERVICE

Basic Concept

The basic concept of the clinical PET screening support service is for Hitachi as a private company to enter into a partnership agreement with a hospital as a medical institution, then for each party to contribute their respective core competencies and technical expertise to the joint enterprise. For its part, the hospital assumes responsibility for medical technologies and medical staff, for buildings and land, and for utilities. Meanwhile, Hitachi contributes the engineering required to design, select, and procure PET equipment, various advance support to set up the facility, operations and maintenance services for the accelerator and equipment to produce radiotracers after the facility is up and running, and financial advice and assistance.

Fig. 2 shows the advantages of this kind of approach for hospitals. First, the initial investment to deploy the PET imaging system is reduced, and the business risk is reduced even more. Second, the overhead for engineering tasks and other non-medical operations and support is also greatly reduced. This permits the hospital administration to concentrate their resources, which should contribute to substantial improvement in administrative efficiency.

Process Leading up to Contractual Agreement

Before a hospital and Hitachi enter into a final partnership agreement, a business plan feasibility study is carried out between the hospital and Hitachi. While the content varies somewhat depending on the specific installation, the feasibility study generally involves joint examination of

(1) the PET implementation plan,
(2) engineering,
(3) planned operating expenses and revenues,
(4) marketing,
(5) risk management, and
(6) other considerations.

Terms and conditions are spelled as the two sides discuss each item, and it is only after both sides reach agreement that the contract becomes official. Before the contract is signed, a careful assessment is done of all the potential risk factors—the management policy of the hospital, geographical location, estimated number of patients, relationships with other hospitals in the area, etc.—and finally a comprehensive decision is reached. Then, based on the division of tasks established by the contract, the hospital and Hitachi work hand in hand to construct and operate a safe and efficient PET imaging facility that provides enormous health benefits to patients and to the local community.

Fig. 3—Exterior of Tokyo Women's Medical University Ambulatory Care Center.
Opened in 2003, the state-of-the-art Ambulatory Care Center can accommodate up to 5,000 patients on an outpatient basis per day. The PET scanning equipment is installed in the basement.

Fig. 4—Radiation Exposure Distribution in PET Facility Caused by Radiation from Patients.
Amount of radiation exposure in the facility from the patients was simulated and evaluated.

ACTUAL IMPLEMENTATION OF CLINICAL PET SCREENING SUPPORT SERVICE

Nuclear Medicine and PET Laboratory at Tokyo Women's Medical University

The first clinical PET screening support service partnership agreement was between Hitachi and Tokyo Women's Medical University to establish the Nuclear Medicine and PET Laboratory, which opened its doors in May 2003. The facility encompasses PET camera rooms (three rooms), a procedure room, and a patient waiting room on the first basement level, and an accelerator, hot laboratory, and other facilities on the second basement level (see Fig. 3).

Naturally, the university's primary concern was that the facility be designed and constructed to ensure that their medical personnel including doctors, radiologists, and nurses were completely safe and only exposed to the absolute minimum of radiation during the course of their work at the PET facility. Simulations were therefore carried out to determine the radiation dose medical staff would receive from patients after radioisotopes were administered to the patients[2, 3]. Fig. 4 shows the calculated radiation exposure distribution. Based on these results, the shielding in the facility was designed to reduce the amount of staff radiation exposure to under 1 mSv per year, and the facility was completed with safety being the number one priority.

Fig. 5—PET Center at Utsunomiya Central Clinic.
The PET Center (on the left in the photo) was constructed next door to the Imaging Center on the outskirts on Utsunomiya City in Tochigi Prefecture.

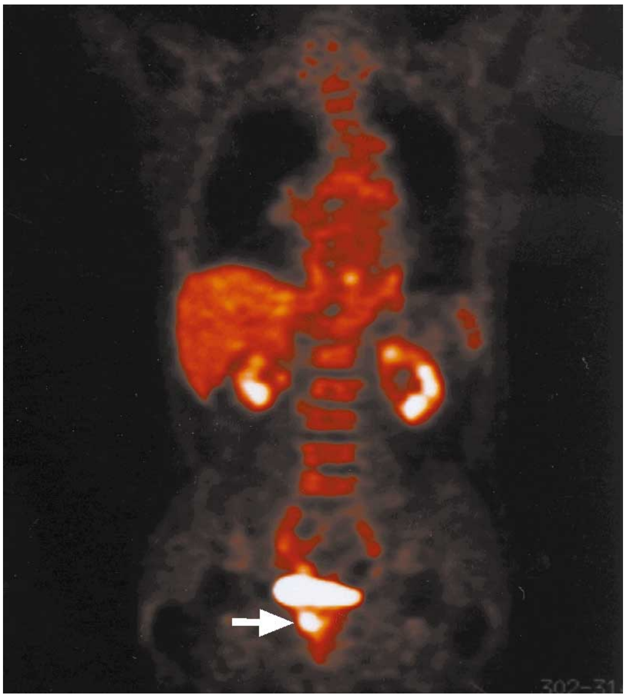

Photo: courtesy of the Utsunomiya Central Clinic

Fig. 6—PET Image.
The use of FDG permits whole body scanning capability. One can observe the high concentration of FDG in the exogenous area in the lower right bladder (indicated by the arrow) that in this case permits the doctor to make an accurate diagnosis of prostate cancer.

Utsunomiya Central Clinic PET Center

Utsunomiya Central Clinic saw further expansion with the opening of a new PET Center (see Fig. 5) in May 2003 alongside preexisting advanced high-magnetic-field MRI and X-ray CT imaging facilities. With this new PET imaging facility, Utsunomiya Central Clinic boasts the best and most advanced medical imaging facilities in the North Kanto region. Seeking as their basic policy to produce the highest resolution images with their new state-of-the-art imaging equipment and make the best, most accurate diagnosis, the entire staff is now working to define the optimum operating conditions including optimum doses of RIs administered to patients, imaging protocols, image reconfiguration, etc. This is illustrated in Fig. 6. Although prostate cancer has been notoriously difficult to detect using conventional methods due to the halation effect caused by a high concentration of FDG in the bladder, the condition is clearly identified using a PET image.

CONCLUSIONS

This article presented an overview of Hitachi's clinical PET screening support service that makes a significant contribution to better preventative health care through more accurate screening and diagnostic capabilities.

Since the RIs used in PET screenings are only able to mark bio-matter, its potential is limited to the number of bio-matter. Although today FDG which has proved so useful in cancer imaging predominates, we can anticipate the development of a diverse range of even more useful RIs in the future that will dramatically enhance our diagnostic capabilities.

Hitachi is committed to provide whatever support is needed in order for hospitals to acquire PET imaging equipment and extend the diagnostic benefits of this imaging technology to the general public.

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