Cost Analysis and Effectiveness of PET and PET/CT

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Positron emission tomography (PET) has been used for almost 37 years to quantify normal physiology and metabolism, to characterize disease, and to evaluate the changes resulting from disease processes. The data that have been developed from these research applications have led to the clinical applications. Clinical PET is one of the many uses of PET, including clinical care, and it is reimbursed by insurance companies. Clinical PET became a reality only after widespread reimbursement became available for the procedure. Rapid growth in the utilization of PET is directly related to changes in radiopharmaceutical regulation and reimbursement. In the Food and Drug Administration (FDA) Modernization and Accountability Act passed by Congress in 1997, it was stated that PET radiopharmaceuticals have the equivalence of FDA approval until a new process for regulating PET radiopharmaceuticals is developed. In 1998, the Health Care Financing Administration (HCFA) began covering fluorodeoxyglucose (FDG) PET for the evaluation of solitary pulmonary nodules, initial staging of lung cancer, detection of recurrent colorectal cancer with rising carcinoembryonic antigens, staging of lymphoma, and detection of recurrent malignant melanoma. The HCFA-approved indications were paid using G codes, and hospital outpatients have been reimbursed using the Ambulatory Payment Classification (APC). The PET imaging devices, both dedicated and hybrid systems, have also been covered [1]. The growing recognition of the cost effectiveness of FDG PET in cancer management has made oncology the focus for most clinical PET studies [2].

The coverage or payment for the treatment of breast cancer and Alzheimer's disease as well as myocardial viability has been recently approved. The revenue generated by PET is now a substantial portion of the total nuclear medicine department income. With the expanded coverage by Medicare of PET in oncology and cardiology, the trend of clinical PET applications seems to be toward continued growth [3]. However, the survival of PET centers may be affected by the potential decrement in reimbursement and by competition for patients from nearby PET centers. The short age of human resources may be another challenge in the future, and the reimbursement for tracers other than ^{18}F and ^{82}Rb may be necessary for further growth in clinical PET.

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PET Facility

To ensure a financially successful PET center, whether hospital based or in a private practice, several steps should be followed in the initial planning and developing of the facility. A mission statement should be created to define the type of facility and its goals, which can be clinically based or research oriented, or a combination of both. The decision-making process for purchasing a PET scanner is very complicated, entailing choice of equipment, potential clinical use in the service area, physician knowledge, and FDG availability. The equipment options are dedicated PET scanners with or without a cyclotron, a coincidence camera-based PET, and a mobile PET service. There are multiple camera options with varied capabilities and differences in purchasing and operating costs. The least costly venture with the lowest financial risk is either a mobile PET service or a dual-head coincidence camera for both FDG and general nuclear imaging. The most costly and financially risky venture is a dedicated PET scanner with a cyclotron, which costs as much as $5 million. The operating cost of the cyclotron increases the operating cost of the facility by as much as one half million dollars per year. The physical location of the facility should meet federal, state, and city requirements.

The purchase of the equipment should include having the vendor as a continuous resource because the vendor's support is critical for a new technology. The following programs also should be included: initial and ongoing technician training, preceptorship and over-read programs for physicians, assistance of reimbursement, and a marketing program (speakers, materials, and a resource library). Minimum space planning should include estimations for the cyclotron room (500 sq. ft.), the heat exchanger room (150 sq. ft.), the hot/cold pharmacy laboratory (800 sq. ft.), the clinical laboratory (450 sq. ft.), the imaging suite (400 sq. ft.), the equipment control areas (100 sq. ft.), the patient preparation rooms (125 sq. ft.), and specialized support areas [4]. The cyclotron room must be capable of supporting at least 120,000 lbs for cyclotron and ancillary shielding. Adequate bench space, atmospheric exhaust hoods to hold up to 1,500 lbs, and laminar exhaust hoods should be included in the design of the pharmacy facility. Hot cells are priced at approximately $70,000 each, and remote manipulators are usually priced at $25,000 per arm. The cost of computer-assisted robotic systems for radiochemical synthesis is approximately $100,000, and the cost of automated synthesis modules for ^{18}F products are approximately $55,000 each. Specific equipment includes high-pressure liquid chromatography ($75,000), gas chromatography ($25,000), radionuclide dose calibrators, flammable safety storage cabinets, incubation ovens, and glassware. In the clinical laboratory, a glucose analyzer, a blood gas analyzer, microfuges, and a sampling device are needed for assaying blood samples. Patient preparation rooms should be configured conveniently with the imaging suite, and should be of adequate size with a nurse call system as well as a sound- and light-controlled environment.

Feasibility Study

To prepare a feasibility study of the PET operation, information should be gathered about the number of prospective referring physicians, the physicians' clinical awareness of PET, the reimbursement by third party carriers, the competition in the service area, and the commercial availability of FDG. The list of physicians to be interviewed include medical, surgical, and radiation oncologists; neurologists and neurosurgeons; and cardiologists and radiologists. Patient demographics are important if non-reimbursed procedures will constitute a significant portion of the work. Before interviewing the physicians, a matrix should be prepared that lists the local and national insurance carriers and their PET policy by covered clinical indications. After the interviews are completed, the potential number of requested scans can be estimated, and the potential financial success of the project may be computed. Total revenue (number of scans × $2,000 per scan) minus bad debt (25% of revenue) yields

the net revenue. Expenses include costs of equipment leasing, facility (utilities and insurance, maintenance, radiopharmaceuticals, and supplies), and staffing (technicians, a secretary, and their benefits). There are three options for purchasing equipment: direct purchase, direct financed lease/bank debt, and operating lease. Most manufacturers have capital finance companies that can assist in the financing of the equipment. To review the ability to collect fees for the studies completed, a review must be undertaken of existing practices by the payers (Medicare and private insurers), to gather information related to covered indications, preauthorization, precertification, and payment for services.

Financial Decision and Marketing

The most common business structure is for the hospital or private practice to purchase the equipment. In a fee-for-service contract, the hospital enters into an agreement with a company, usually a mobile provider. The hospital is responsible for the purchase of the radiopharmaceuticals and related supplies. The joint venture structure has been very effective in the PET market for both scanners and cyclotrons. The FDG vendors develop a distribution network to provide other sites with FDG by either ground or air transport. The price of FDG is approximately $800 per 10 mCi and is often negotiable. Projected financial stability both on a cash and accrual basis should be maintained. There should be enough funds to carry the PET center during the start-up phase and during difficult periods for collecting accounts receivable. The marketing plan is as critical as the financial analysis. Education is the key to developing a successful marketing program. A series of grand rounds or lectures for a broad overview of PET and its clinical uses should be set up. A general brochure and scientific articles on PET as well as information for the patients also should be sent to the physicians.

Computed tomography (CT) and PET are clinically useful in the staging of non–small-cell lung cancer because it reduces unnecessary surgeries [5]. It also has been shown to be economical, with a savings of $1,154 per patient [5]. It saves significantly more by not pursuing biopsy in patients with positive CT and PET results. Significant additional savings would result if PET was used to rule out surgical candidates based on the detection of distant metastases. Compared with optimized Ga-67 single photon emission computed tomography, FDG PET achieves a higher detection rate and more accurate staging in patients with high-risk melanoma and can also detect synchronous or metachronous primary malignancies more sensitively [6]. This incremental information can alter management in approximately 10% of patients at only marginally higher cost, providing a cost-effective alternative. The entire community, including the general population, insurance providers, and the administration of the hospital, in addition to physicians, needs to be educated on all aspects of PET. The newest and fastest growing source for consumers is the Internet. A public relations company places articles about PET, such as features and patient stories, in newspapers, magazines, and on television and radio.

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PET centers may be set up and operated in many different ways. Various configurations of equipment, staffing, and supplies may be combined to develop a fully functioning PET program.

The cost of developing a comprehensive PET center ranges from $5 million to $7 million as an investment for the equipment and facilities, with projected operating expenses ranging from $2 million to $2.5 million per year [7]. The cyclotron could serve the needs of multiple PET scanners in a region, and dual-use coincidence or hybrid scanners to image positron-emitting radiopharmaceuticals and traditional nuclear compounds cost less than dedicated PET scanners. Sharing operating resources between PET and other services in the hospital, developing below-market leasing rates, and securing endowment funds to cover part of the operating costs are some of many ways to reduce costs. Developing

the clinical demand for more than one scanner is another way to expand revenues. The impact of the concept of radiopharmaceutical distribution is best depicted by the difference in radiopharmaceutical cost per patient.

Medicare coverage has been expanded to broadly include the use of PET in almost all cancer types. Cost analyses are important tools used by business leaders and administrators, and cost studies provide data that are useful in pricing services and benchmarking operations. Given that reimbursement levels in the public sector are fixed, it is critical to understand the net margin per study at a level of demand. Business risk is generally thought to be a function of several factors, including operating leverage (fixed or variable costs), revenue diversification, competition, and market potential. These risks are quantified somewhat by the analysis of diagnostic sensitivity.

The cost effectiveness of the diagnostic strategy must take into account not only the monetary costs of the diagnostic tests, but also the downstream effects that the test has on both the cost of medical management and the patient's clinical outcome with or without the test. Clinical utility or effectiveness is defined in terms of patient life expectancy, and the cost is defined in terms of dollars of medical expenditure. Optimization of cost effectiveness as defined by these terms is chosen to ensure an algorithm in which the costs are minimized without any decrease in patient life expectancy. The potential cost effectiveness of using FDG PET in the management of non–small-cell lung cancer through rigorous decision tree analysis has been reported [5]. It has been shown that a CT + PET strategy is more economical and has a marginal increase in patient life expectancy as compared with the conventional strategy of staging patients with CT alone. PET/CT usually enhances the diagnostic specificity rather than sensitivity compared with PET alone.

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