PLANNING AND FINANCING A PET CENTER

The planning and financing of a PET center is an extensive, time-intensive process that entails the consideration of many factors, including budgeting, reimbursement and other financing strategies, facility design, vendor selection, staffing requirements, and licensing. The following are discussions of the experiences of four PET centers, in the United States—the centers at Bowman Gray School of Medicine, Winston-Salem, North Carolina, the University of California, Los Angeles, at the University of Tennessee Medical Center at Knoxville, and at Creighton University Medical Center, Omaha, Nebraska.

FOLLOWING BUDGETARY DISCUSSIONS AND the development of reimbursement strategies, many believe vendor selection comprises the next most difficult decision in establishing a PET facility. At Bowman Gray School of Medicine, however, basic operational and planning issues addressing facility design, ancillary equipment selection and personnel staffing were of equal importance.

Once the clinical versus research pro formas have been developed and the go-ahead has been given, questions that address the needs of the facility design are next to be answered. Sufficient space allocation is essential to provide for patient comfort and convenience, while permitting the efficient operation of the facility. 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.

Specific issues related to facility design include the following. The cyclotron room must be capable of supporting at least 120,000 lbs, a substantial weight that accounts not only for the cyclotron but also for the necessary ancillary shielding (either a polyethylene/cement/boron carbide "self" shield or a concrete "bunker"). It's worth pointing out that if the self-shield option is chosen, the purchase contract should address, among other specifications, maximum radiation levels at the surface of the shield. The sheer weight of the cyclotron and its shielding may, in some cases, restrict the placement of this equipment. Exhaust/ventilation requirements must also be taken into account in this room, and adequate bench-top and support space should be provided for the mechanical support of the cyclotron and targetry.

The radiochemistry/radiopharmacy area should be carefully designed to take into account the dual personality of the "hot" and "cold" functions of radiochemical/radiopharmaceutical production. Most facilities have chosen to separate these areas. Adequate bench space, atmospheric exhaust hoods (supported to hold up to 1,500 lbs lead), and laminar exhaust hoods should be included in the design of the pharmacy facility. A "weighty" issue for the pharmacy area is whether or not to purchase "hot" cells, and if they are purchased, to determine for what purpose they will be intended. Hot cells cost around $70,000 each, not including remote manipulators, which are typically $20,000–$25,000/arm (double this cost for a pair for an individual hot cell). Thus, the total cost per hot cell equipped with manipulators is approximately $110,000–$120,000 each. In some institutions, hot cells are integral components inside which all handling of radioactive materials occurs beginning with the handling of the raw radionuclide up to the preparation of the final dose form and its dispensing in a syringe. In others, hot cells are not so extensively utilized. Regardless, hot cells should be appropriately modified by the manufacturer to permit the placement of a radionuclide dose calibrator ionization chamber in the floor of the hot cell and the readout for the dose calibrator in a remote location.

Associated with the issue of hot cells and their utilization is the method of radiochemical synthesis and the question of whether computer-assisted robotics or automated chemical synthesis modules will be purchased and utilized for the preparation of routinely employed radiopharmaceuticals. Neither method is inexpensive—robotic systems cost approximately $100,000, and radiochemical synthesis modules for fluorine-18 (^{18}F) products are around $55,000 each. Costs for these two methods are comparable since most experienced PET users suggest that start-up facilities purchase two automated synthesis modules (total cost around $110,000). The acquisition of either method requires some type of dedicated shielding. Computer-assisted robotics favor placement into hot cells, while either hot cells or a specialized type of lead cave or cabinetry can suffice for the automated modules. Costs and space requirements for so-called smaller "mini-hot cells," which are currently quoted at $15,000 each, are certainly less than those for hot cells. With the mini-hot cells, specialized ventilation and heat dissipation requirements must be taken into account. With either choice, it is necessary to install shielded conduit lines in order that the cyclotron-produced radionuclide may be transferred into the radiochemical synthesis facility.

The ancillary equipment list for the radiochemical/radiopharmaceutical production areas is relatively long and costly. Specific equipment (and approximate costs and/or number of units) include high-pressure liquid chromatography units ($75,000+ for at least two dedicated units), gas chromatography ($25,000), radionuclide dose calibrators (one to three systems with remote ionization chambers), flammables safety storage cabinets, incubation ovens, and glassware. For the laboratory without these facilities, start-up costs can be considerable. Additionally, in the clinical laboratory, where

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blood samples are processed, assayed, and stored, dedicated equipment includes a glucose analyzer, a blood gas analyzer, microfuges, and a sampling device. A synchronous clock system with time displays in all clinical areas is a very worthwhile purchase that will ensure precision and uniformity during the recording of radiopharmaceutical administrations, the collecting of blood samples, or the timing of various imaging events. Radiation safety equipment for the entire facility may include, in addition to the hot cells and/or mini-hot cells, several hundred interlocking lead bricks, syringe and vial shields for high-energy gamma-emitting radionuclides, a neutron monitor, area gamma monitors, radiation alarms, general purpose probes and monitors, and an air exhaust (stack) monitoring and recording system. Additional clinical support equipment includes a defibrillator and other emergency crash cart components. A cardiac exercise cycle and an electrocardiograph machine will also be required for facilities performing cardiac imaging.

Basic questions that need to be answered relative to the imaging suite include the manner of dose delivery from the hot pharmacy area (pneumatics versus shielded hand cart). If a pneumatic tube system is desired, careful consideration must be given to the path of the tube system (avoid passage over and/or through the imaging suite), the placement and shielding of the receiver unit, and the noise associated with its use. Gas conduit lines should be placed into the facility during construction and shielded, where appropriate. Special ventilation considerations are necessary whenever gas-type radionuclides are used. Additionally, a radioactive gas delivery system should be included in the equipment purchase. Sufficient counter-top workspace, "hot" waste storage areas, a radionuclide dose calibrator, and a shielded, exhausted area for conversion of oxygen-15 (^{15}O) gas into ^{15}O water should be taken into account. Counter-top space should be strengthened to support up to 1,000 lbs of lead. Some type of head mobilization technique, such as a molded thermal plastic mask, should also be included and space should be made available for a heated water bath for the mask.

Patient preparation rooms should be configured conveniently with the imaging suite and should be of adequate size to contain an exercise device, patient stretcher or reclining-type chair, and other patient support materials. A nurse call system is mandatory, and the additional costs for an intercom and video monitoring unit may be worthwhile. At least two preparation rooms per imaging suite are desirable in order that one patient may be prepped for a study while another occupies the scanner, thus ensuring optimal scanner utilization. If a sound and light controlled environment is desirable for neurologic stimulus studies, at least one prep room should be lightproof and soundproof.

The purchase of at least one additional computer workstation for image processing, and the inclusion of a cable trough for the installation of fiber optic lines associated with ethernet applications is also recommended. All things considered, PET will surely represent the largest single undertaking by any imaging department. Careful evaluation of each PET component by those specialty areas—health physics, radiochemistry, radiopharmacy, nursing—and continuing intradepartmental communication technology will be necessary to ensure successful design and operation. Finally, when preparing to execute a purchase agreement, purchasers should develop a stringent, yet realistic, performance criteria for instrumentation. In particular, such agreements should address every major point of operation for the cyclotron, the radiochemical synthesis equipment, and the scanner. A thorough "up-front" discussion of operational parameters and a subsequent precisely written agreement regarding performance characteristics will significantly aid in preventing any future discrepancies between expectations and reality. Among those areas to be addressed are:

1. Cyclotron performance including specific yields and values for each radionuclide, the corresponding descriptive irradiation parameters, and the manner of actual testing;
2. radiochemical synthesis yields (robotics or automated chemical modules);
3. radionuclide delivery rates (at the scanner) for those gas-type radionuclides, with specifications addressing both "flow-type" and bolus delivery;
4. radionuclide dose calibrator performance criteria;
5. training for PET center personnel;
6. maintenance contract agreements (labor and parts);
7. scanner performance criteria;
8. source code and service documentation; and
9. hardware and software upgrade.

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THE UNIVERSITY OF CALIFORNIA, LOS Angeles (UCLA) PET program has been in existence since the 1970s, and it now includes four tomographs (two whole-body units, a head unit, and an animal unit) and two cyclotrons. This program has been expanded with the addition of molecular and cellular biology, immunology, and communication sciences to the previously existing chemistry/biochemistry, physical sciences, biomathematics, neuroscience, and cardiovascular sciences programs. The fundamental nature of this program was recognized by the recent consolidation of all these activities into a new institute at UCLA, the Crump Institute for Biological Imaging. In addition, we have recently established a Clinical PET Center within