READY for PET

Practical Considerations in Starting a Cardiac PET Program

ASNC

American Society of Nuclear Cardiology

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OVERVIEW

Cardiac positron emission tomography (PET) myocardial perfusion imaging (MPI) has evolved into a powerful, versatile, and essential technology in the management of patients referred for evaluation of ischemia. PET MPI has many advantages, including high diagnostic accuracy, consistent high-quality images, low radiation exposure, short acquisition protocols, strong prognostic power, evaluation of true peak stress ejection fraction, and the ability to quantitate absolute myocardial blood flow (MBFR) and myocardial blood flow reserve (MBFR). The non-invasive quantification of myocardial blood flow (MBF) is one of the most important features of cardiac PET. This essential characteristic augments the scope of conventional MPI from detection of advanced flow limiting epicardial coronary artery disease (CAD) to include all levels of myocardial ischemia, including early-stage atherosclerosis, microvascular disease, and focal and balanced reduction in all three epicardial arteries. In addition, cardiac PET imaging with F-18-fluorodeoxyglucose (^{18}F-FDG) allows for assessment of viability, cardiac sarcoidosis, and device and valve infection.

Given these advantages, many practices are interested in developing a cardiovascular PET program but may be discouraged by the cost and reimbursement, potential issues with computed tomography (CT), and the planning required to implement a cardiac PET program. This monograph seeks to serve as a template for practices initiating a successful cardiac PET laboratory for MPI (***Table 1***). Topics covered include considerations in preplanning, equipment needs, setup and design, education of technologists, physicians and referring healthcare providers, business aspects, going live, and ongoing improvement.

PREPLANNING

As each laboratory is unique, taking an initial inventory of the current state, goals, and constraints of the proposed program and educating oneself on the modality are important to ensure the program is designed in a manner that will meet current and future needs of the practice (***Table 2***).

Checklist of Considerations	
☐ Pre-planning ☐ Data on current state ☐ Goals/vision for the program ☐ Constraints ☐ Delineate team ☐ Review PET guidelines ☐ Equipment ☐ Understand PET technology ☐ Acquiring a system (new vs. refurbished) ☐ Attenuation correction ☐ Tracers ☐ MBF software ☐ CT considerations ☐ Program setup ☐ Setting (hospital-based or outpatient) ☐ Room design ☐ Other space ☐ Staffing ☐ Scheduling ☐ Protocols ☐ Reporting program	☐ Business ☐ Volumes ☐ Costs ☐ Reimbursement principles ☐ Payors – Medicare vs. Private payors ☐ Downstream effects ☐ Developing a *pro forma* ☐ As you get started ☐ Technologist training ☐ Physician training ☐ Educating referring providers ☐ Myocardial blood flow measurement ☐ Training/education

Table 1. Checklist to assist in the planning process

The following are suggested for review in the preplanning stage:

- **Assess** current state by determining the existing volume of pharmacologic single photon emission computed tomography (SPECT) MPI studies in your lab, how many of these studies will convert to PET, and how much incremental new volume is anticipated.
- **Define** goals for the program and whether protocols will include performing MBF and/or coronary artery calcium (CAC) scoring along with PET MPI. Aside from the standard United States Food and Drug Administration (FDA)-approved PET perfusion tracers of N-13 ammonia (^{13}N-NH_3) and rubidium-82 chloride (^{82}Rb), consider whether the FDA-approved tracer ^{18}F-FDG will be used for viability, inflammation, and/or infection imaging. Consider whether novel ^{18}F perfusion imaging agents in development will be used in the future. Anticipate future volume and radiotracer needs for continued growth in the lab.
- **Determine** constraints, including budget, space, or vendor limitations. If considering PET/CT, limitations may include space or room design, cost, how to train technologists appropriately, and how to address non-cardiac findings. Know state-specific requirements; for example, some states do not allow nuclear medicine

technologists (NMT) to acquire diagnostic quality CTs, and gating for CAC scoring falls into this category.

- **Designate** a physician and a technologist champion who will lead outreach, process, and guide others in setting up the laboratory, and maintain quality once initiated. An inter-disciplinary team involving nurses, scheduling, pre-authorization, coding and billing personnel, and radiation safety are important. A PET physicist is an invaluable member of the team and can facilitate technology, tracer, and protocol decisions.
- **Review** the American Society of Nuclear Cardiology (ASNC) PET imaging guidelines, information statements, practice parameters, reporting guidelines, and MBF documents. (See bibliography.) Remaining aware of relevant PET Current Procedural Terminology (CPT) codes and regional variations in reimbursement is important.
- **Establish** if you will be performing CAC scoring or cardiac inflammation and infection imaging as a PET/CT scanner will be required. Determining responsibility for the interpretation of the non-cardiac portion of the CT images can be challenging. This may be performed by the interpreting physician or as an over-read by a radiologist, and the legal ramifications of each should be discussed. It must also be determined whether CAC scoring will be performed, and if so, in which patient population. The addition of MBFR significantly improves the diagnostic and prognostic ability of MPI and is the most significant benefit of PET. Quantification of MBFR should be a consideration for every new cardiac PET laboratory.

Question	Consideration
Who?	• Types of patients • Referral sources • Volume of current pharm SPECT shifting to pharm PET • Incremental volume of new studies
What?	• Protocols to perform • Myocardial perfusion imaging • Flow quantification • Coronary artery calcium • Viability • Sarcoid/infection
Where?	• Review existing space, design, shielding • Any possibility for new space or redesign
Why?	• What is the primary goal in moving to PET?
How?	• Existing vs new camera • Camera dedicated to cardiac studies or shared time

Table 2. Factors to consider when setting up a PET lab

EQUIPMENT

Critical consideration needs to be given when choosing camera technology, software, and tracers to ensure quality imaging and accurate MBF quantification with cardiac PET.

- **Acquiring a PET camera**
  - Options for a cardiac PET camera include a camera dedicated to cardiac imaging, shared with radiology or nuclear medicine, or if in a situation with a smaller volume of patients, mobile imaging.
  - Most systems (new or refurbished, line-source, or CT attenuation correction [AC-AC) currently available produce good quality images of perfusion, electrocardiogram (ECG)-gating for left ventricular (LV) function and wall motion, and dynamic imaging for MBF. Camera differences exist with regards to efficiency, reader preference, and types of advanced technology.
  - Cameras can be purchased as new equipment or refurbished.
    - New cameras are ideal and offer high quality, the latest technology, and efficiency, but are more expensive. Purchase or lease options are available. Sharing a camera with other imaging departments may allow leveraging into more advanced technology at the onset.
    - Refurbished cameras are less expensive, frequently older, more often employ line-source AC, and may have limited availability and support. Given the lower expense, this may be a good initial option for some labs. If considering a refurbished camera, it is important to research the system to ensure proper technology for PET MPI and MBF assessment. If planning to include inflammation/infection imaging or if a camera will be shared with other imaging groups, CT-based technology is advised.
  - Turnkey services can be used to facilitate program setup, provide equipment, and mitigate financial risk. Mobile- and fixed-site options are available and may include training programs. It is recommended to work closely with the service to ensure it is reputable and has compatible priorities, and to ensure quality.
  - Processing packages should be reviewed for reconstruction options (e.g., iterative reconstruction, time-of-flight), mis-registration correction, display, and quantification of MBF.
- **Attenuation correction: CT or line-source**
  - All cardiac PET studies require AC. Two approaches are available:
    - CT-AC: This newer technology is preferred as it offers potential for concurrent CAC scoring, but is prone to CT-related artifact. A minimum of 4 slices is required for CT-AC, and a minimum of 8 to 16 slices (preferably with ECG gating) is needed to assess CAC. Purchase of a PET/CT should include discussion of responsibility for interpretation of non-cardiac findings on the CT images.
    - Line-source AC: This is prevalent on older cameras, avoids CT artifacts, but requires a longer imaging protocol.
- **Cardiac PET tracers**
  - FDA-approved and reimbursable PET perfusion tracers are $^{13}N\text{-}NH_3$ and ^{82}Rb.
    - ^{82}Rb is the perfusion tracer most commonly used and is be supplied via an on-site infusion system and generator, or for smaller study volume

situations by mobile imaging. Given its short physical half-life of 75 seconds, timing of imaging is critical for both perfusion and MBF.
    - ^{13}N-NH_3 is an alternative perfusion tracer if a cyclotron is on site or nearby (<20 to 30 minutes) with unit-dose availability. There is an option to install a dedicated mini-cyclotron on site for this tracer.
    - Factors to consider in choosing a perfusion tracer include production method, half-life, speed of protocol, whether it will permit exercise, cost, and local availability.
  - ^{18}F-FDG is currently used for viability and sarcoid/infection imaging. Its longer physical half-life allows unit-dose delivery but requires additional shielding in patient areas.
  - Novel ^{18}F agents for perfusion are in development and offer the potential for exercise, unit-dose delivery, and other clinical applications.
  - Tracers have different shielding considerations, receiving and hot-lab requirements, and staff protection needs.
- **Software for quantification of MBF**
  - MBF measurements should be a consideration for every new or existing cardiac PET laboratory.
  - There are multiple software programs for MBF. It is important to understand which MBF model your software provides, how to assess flow software and compatibility with your tracer and camera, and how to ensure quality control for accurate flow quantification.

PROGRAM SETUP

It is important to review set-up considerations, including room design, staffing, scheduling, and reporting.

- **A cardiac PET imaging room should be designed to optimize safety and workflow.** This should include consideration of the following:
  - Weight and shielding requirements of the room, as well as shielding requirements of the waiting area to accommodate these scenarios:
    - Perfusion only with ^{82}Rb or ^{13}N-NH_3 (less shielding);
    - Perfusion and ^{18}F imaging (more shielding); and
    - CT imaging (more weight and shielding).
  - Power and heating, ventilation, air conditioning (HVAC) requirements for air vs. liquid-cooling system.
  - Location and proximity to the hot lab and stress lab to optimize nursing and physician supervision. Consider location of the camera if being shared with other imaging groups.
  - Patient and equipment positioning in the room should optimize viewing of the patient, ECG, vitals, and infusion system from the control room. This helps to ensure close patient observation while minimizing staff radiation exposure.
  - Time required for construction and build out needs to be calculated.
  - Consider designated ^{18}F-FDG uptake rooms with higher shielding to minimize radiation exposure to other patients.

- **Staffing and patient scheduling**
  - It is recommended to have at least one nurse and one NMT.
  - High-volume labs may want additional team members to facilitate processing, enable efficiency, and extend hours.
  - NMTs may need additional training in CT if PET/CT is used. Local regulations should be reviewed.
  - It is recommended to start with a low volume of patients to provide adequate time to adjust to PET imaging, and then increase to one patient per hour for ^{82}Rb. Line-source AC and ^{13}N-NH_3 require more imaging time.
  - Weight-based dosing can help standardize image quality across various patient sizes.
  - If a hospital-based program, consider 2 to 3 inpatient/emergency room slots for add-ons depending on local practice and in-patient mix.
- **Other**
  - Reporting program will need to accommodate PET documentation of tracers, activity, and MBF. Reports may also include CAC scoring and CT over-read data (highly variable). If viability, infection, and inflammation are under consideration, additional reporting requirements will be necessary.
  - Recommend in-house or consulting physicist to review safety considerations, tracer, and camera setting and quality control and for accurate MBF.

BUSINESS

The primary motivator in advocating for PET MPI should be quality and patient-centered imaging, however, fiscal considerations are an important and practical component of successful cardiovascular service lines. Budgetary review should include volumes (historical and projected), cost of equipment and build-out, reimbursement, and downstream effects. Unique considerations related to regional practice style, organizational structure, referral patterns, and growth potential should be examined. As the business considerations of initiating a successful cardiac PET program have significant geographic variation, a single templated *pro forma* or business plan is challenging to formulate. Development of a program-specific business *pro forma* and financial models are useful to illustrate the financial benefits and growth potential of a cardiac PET program.

- **Costs to consider:**
  - Fixed costs required up front include the camera purchase, hardware, software, room construction, and shielding for new systems.
  - Ongoing costs include the tracer and related expenses, including lease of infusion system, saline, IV lines, equipment maintenance and upgrades.
  - Staffing costs should include at least one full-time NMT and stress-lab nurse, with allotment for additional coverage for vacation or unexpected absences. Less staffing may be required if equipment is shared. Consider additional costs If CT will be overread by a radiologist.
- **Overall reimbursement considerations:**
  - Average reimbursement for PET is 1.5 to 2.5 times greater than SPECT per study, but varies geographically.

- Private payors vary in reimbursement as well as preauthorization eligibility requirements (e.g., body weight, etc.).
- CPT codes are separate for line-source AC cardiac PET and CT-AC cardiac PET. CT-AC reimbursement is higher than line-source AC reimbursement.
- Educate yourself on CPT codes for PET and average reimbursement rates. The latest information can be found on the ASNC website under Advocacy, Reimbursement, and Coding Procedures: *https://www.asnc.org/paymentcharts*.

- **Medicare facts to consider:**
  - Medicare Part A is bundled reimbursement and will apply to hospital-based imaging centers that are currently using this as their billing.
  - Medicare Part B is "multi-segment" reimbursement and will apply to most outpatient centers, although some outpatient practices associated with hospitals bill using Part A. Part B reimbursement typically involves billing each element separately.
- **Private payor considerations:**
  - Pre-authorization requires good documentation of indication for testing, inability to exercise, prior equivocal testing, and/or body habitus concerns. Eligibility requirements for PET vary by payor.
  - Consider developing a peer-to-peer review team that is familiar with indications for PET to assist referring physicians with authorization. Have a templated letter to facilitate denials.
  - Engaging your payors, reviewing contracts, and negotiating with them before you begin a cardiac PET program is very important. Payors often need education on cardiac PET.
- **Development of business models and a *pro forma*** is helpful to illustrate the benefits and growth potential of a cardiac PET program:
  - Pitch the **P**s: **P**atient-centered, **P**ower of flow reserve, **P**romote value, **P**otential for future growth, and **P**roductivity.
  - Most *pro formas* utilize Medicare reimbursement as the basis of anticipated reimbursement and potential profitability.
  - Adjustable mock *pro forma* for ^{82}Rb is available on the ASNC website and depicted in ***Table 3***. Visit *https://www.asnc.org/pet* to use the adjustable *pro forma* calculator.
  - Delineate areas of downstream improvement (e.g., shorter hospital length of stay, increased patient throughput, lower catheterization-to-percutaneous coronary intervention ratios, and higher patient satisfaction) and areas of future growth.
  - For labs using ^{82}Rb, 4 patients per day is required to "break even" based on the average reimbursement rates and cost of an ^{82}Rb generator combined with other fixed costs.
  - Third-party turnkey options are available to conduct independent practice analysis and determine local reimbursement scenarios.

Year	Patients per Day	Patients per Year	Total Revenue	Expenses	Net Revenue	Loss PHARM SPECT Cases	Adjusted Income
1	4	1008	V	W	X	0.4Y*	Z
2	4	1008	V	W	X	Y	0.8Z**
3	5	1260	1.23V	W	X	Y	2.6Z
4	6	1512	1.5V	W	X	Y	4.42Z
5	6	1512	1.5V	W	X	Y	4.42Z

Notes: Demonstrates incremental growth from 4 patients a day to 6 patients per day over a 5-year period and the projected increased revenue over years 3 through 5 using ^{82}Rb. This considers a loss of revenue from some loss of SPECT cases to PET and assumes average Northeast Medicare reimbursement. Access calculator at: *https://www.asnc.org/pet*.

*0.4Y accounts for loss of prior reimbursement/revenue from pharm SPECT patients converted to PET, this number can be expected to remain constant.
**Slight decrease in net income in year two is due to expiration of typical 1-year warranty and expense of yearly service contact.

Table 3. Cost effectiveness of a PET program over a five-year period

CLINICIAN EDUCATION AND TRAINING

Introduction of cardiac PET into a cardiology practice requires education of several groups, including technologists, interpreting physicians, members of the cardiology practice who will be referring patients or receiving data, and the outside community. Ensuring that all individuals are properly educated on the diagnostic information cardiac PET can provide and, in particular, the role and interpretation of MBF data, will assure success of the program.

- **Technologists** should begin training prior to program initiation and should include on-site training that includes the following:
  - Specifics of PET and CT camera technology and system. PET requires accurate AC and transmission-emission alignment, which may be new for the practice and may require more specific certification. Regular quality control for the PET camera and troubleshooting is needed.
  - Tracer education, infusion system training, and daily quality-control protocols are usually provided by the isotope vendor.
  - Strict adherence to time-dependent protocols is critical to acquiring perfusion and MBF accurately. Accurate MBF quantification requires that the full duration of blood pool and myocardial phase blood flow are obtained during the dynamic acquisition. This is even more important during stress imaging where dynamic imaging should be obtained at maximum and sustained hyperemia.
  - Knowledge of the differences in processing from SPECT, including iterative reconstruction, transmission-emission alignment, and motion correction for

dynamic imaging.
    - Importance of patient counseling and preparation to prevent motion and mis-registration.
    - Artifact recognition specific to PET, including mis-registration and motion as well as CT-related artifact.
    - Technical differences between SPECT and PET are outlined in ***Table 4***.
- **Physicians** should be educated on differences in interpretation between SPECT and PET, including the following:
    - Normal variants, e.g., apical thinning on both ^{82}Rb and ^{13}N-NH_3 studies and decreased lateral wall perfusion on ^{13}N-NH_3 studies.
    - High-risk features of PET, which may include lack of EF reserve/augmentation, transient ischemic dilation (TID) cut-off, high CAC, and low MBFR.
    - Training on CAC and potentially the non-cardiac portions of chest CT.
    - Training on MBF quality control, motion correction, interpretation, and reporting.
    - Artifact recognition, including mis-registration and motion artifacts.
    - Differences between SPECT and PET study interpretation are outlined in ***Table 4***.
- **Referring healthcare providers** should be educated on the following:
    - Indications for cardiac PET and its value versus other imaging modalities.
    - How PET may affect downstream procedures, including referral to catheterization.
    - The clinical and prognostic significance of MBF and MBFR. This is particularly important when perfusion is normal or mildly abnormal and MBF is abnormal.
    - Non-responsiveness, which may occur with pharmacologic stress secondary to caffeine intake or vasodilator non-responsiveness.
    - Benefits of low radiation exposure and short imaging protocol to improve patient safety and lab efficiency.
- **MBF measurement requires specialized training and education for NMTs and interpreting physicians.** Educational materials are readily available and include ASNC information statements, imaging guidelines, flow-reporting guidelines, web-based cases, and hands on workshops.
    - MBF reporting is best initiated a few months after beginning a cardiac PET program, depending on the volume of studies and training of the team, and after ensuring correlation with cardiac catheterization.
    - Protocols require special attention to timing of radiotracer injection to ensure stress imaging at maximum hyperemia and to quantify total tracer activity for accurate assessment of MBF.
    - Vendor specific training for MBF software is important for NMTs and physicians.
    - Physician specific training should include the following:
        - Confirmation of good quality time-activity-curves and reliable data.
        - Knowledge of clinical factors that may alter rest, stress, and MBFR values.

- Understanding of the diagnostic and prognostic value of MBFR and how it relates to down-stream testing/intervention.
- Importance of integrated assessment of clinical history, ECG, perfusion, function, CAC, and MBFR to provide robust risk assessment.
- Education on how to interpret and report results of MBFR in a manner that referring physicians will understand (especially for non-cardiologist referring providers).

- **Ongoing evaluation in the cardiac PET laboratory should include:**
  - Continuous quality control of protocols and processing.
  - Ensure all new staff are educated on cardiac PET, including ongoing education of referring providers new to the technology. Referring physicians will want and need to understand how best to integrate the information into clinical decision making.
  - Consistency in lab interpretation and reporting.
  - Ongoing evaluation of payor and preauthorization issues.
  - Consider PET/cardiac catheterization correlation to ensure quality and accuracy of MBF for regional defects and to partner more closely with your interventional colleagues.
  - Demonstrate your value from a business perspective fiscally and in consideration of downstream resource use that impacts patient care.

	SPECT	PET
Timing of protocols	Independent	Dependent
Timing of stress perfusion	30–60 min	
Stress ejection fraction (EF)	Post-stress, resting EF, obtained ~45 min after stress	True peak stress EF obtained at peak hyperemia
Quantification of myocardial blood flow	In development	Mainstream
Acquisition time	Long	Short
Image quality	Low-moderate resolution	High resolution
Processing	Filtered back projection and iterative reconstruction	Iterative reconstruction
Primary cause of artifacts	Attenuation, GI artifact	Motion, mis-registration
Attenuation correction	Not performed routinely	Performed on every study
Motion correction	Available	Unavailable

Table 4. Differences between SPECT and PET

CONCLUSION

Cardiac PET has robust diagnostic and prognostic utility and improves patient safety and throughput of the nuclear cardiology laboratory. Following the framework above, including educating oneself on the technology, tracers, and benefits of cardiac PET, along with a vision for the lab that includes current and future needs, will empower one with the knowledge needed to set up a successful, high-quality and fiscally responsible cardiac PET program that improves patient care.

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