PETITION TO STATE HEALTH COORDINATION COUNCIL REGARDING A POLICY FOR DEDICATED CARDIAC PET FOR OPEN HEART SURGERY PROVIDERS.

March 5, 2025

Petitioner

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Statement of Requested Adjustment

Mission Hospital respectfully requests a change in the 2026 State Medical Facilities Plan ("SMFP") to allow providers of Open-Heart Surgery ("OHS") to a acquire a dedicated cardiac Positron Emission Therapy ("PET") scanner irrespective of the need calculated by the Standard Methodology in the SMFP. The proposed policy requires that the applicant be an existing or approved provider of OHS and that the proposed PET Scanner be dedicated to the provision of cardiac PET imaging.

Policy TE-5: Plan Exemption for Dedicated Cardiac PET for Open Heart Surgery Providers

1. It is a licensed North Carolina acute care hospital or hospital campus that has the following characteristics:
    a. has licensed acute care beds;
    b. provides emergency care coverage 24 hours a day, seven days a week;
    c. has Certificate of Need approval or other authorization (grandfathered) to provide Open Heart Surgery as recognized in Chapter 7B of this plan.

2. The proposed dedicated Cardiac PET scanner and associated equipment will perform at least 1,040 PET procedures during the third full operating year.

3. The proposed dedicated Cardiac PET scanner will be located:
    a. on the main campus of the hospital as defined in G.S. § 131E-176(14n); or
    b. on an acute care hospital campus that operates under the main hospital's license.

4. The proposed Cardiac PET scanner and associated equipment will be dedicated to providing cardiac PET procedures and will serve non-cardiac patients in an emergency situation such as temporary downtime for other PET scanners owned or operated by the applicant.

The performance standards in 10A NCAC 14C.3703 are not applicable.

Reason for Proposed Adjustment

Addressing the Diagnostic Deficit: Capacity is Needed for both Cardiac and Oncology PET Imaging

According to 2022 data from the Centers for Disease Control and Prevention ("CDC"), heart disease remains the leading cause of death in North Carolina, signaling the urgency for OHS providers to have access to advanced diagnostic tools like cardiac PET. With heart disease taking a significant toll on the North Carolina population, early and precise detection is essential for effective diagnosis and treatment planning. PET imaging, renowned for its superior accuracy in assessing myocardial perfusion and viability, and the diagnosis and follow up for cardiac sarcoidosis is rapidly becoming the standard of care in cardiology. Ensuring that OHS providers can integrate cardiac PET into their diagnostic capabilities allows for more accurate diagnoses and better-informed surgical and treatment decisions, ultimately improving patient outcomes.

Additionally, PET is widely utilized in oncology diagnostics and treatment planning, as cancer is the second leading cause of death in North Carolina, based on 2022 CDC data. Given the dual reliance on PET technology for cardiology and oncology, larger high-acuity providers that offer both service lines must have sufficient PET imaging capacity to adequately support both specialties without limiting access to either. However, in many (if not most) of these facilities, like Mission Hospital, PET scanner utilization is largely dominated by oncology services, leaving limited availability for cardiology applications. This imbalance restricts the ability of the cardiology service line from utilizing PET imaging for cardiac patients, limits access to advanced diagnostic care for cardiac patients and hinders advancement of cardiology programs. As a result, cardiology providers face delays in critical assessment, which impacts timely treatment decisions. To address this issue and to ensure heart disease patients receive the highest standard of care, a policy must be implemented to allow OHS providers to access a dedicated cardiac PET scanner.

North Carolina faces an increasing demand for PET imaging, driven by its critical role in both cardiology and oncology. The rising prevalence of these conditions requires expanded PET capacity, yet the existing methodology fails to account for the distinct and growing need for cardiac PET. Many (if not most) facilities, including Mission Hospital, struggle to balance PET scanner use between oncology and cardiology patients. Given the high volume of oncology PET scans, cardiac imaging often gets deprioritized, delaying crucial diagnosis and treatment plans for cardiac patients. Without a dedicated cardiac PET scanner, tertiary heart programs cannot fully integrate this gold-standard imaging modality into patient care. This imbalance restricts timely access to advanced cardiac diagnostics and hinders the development of cardiology programs.

Cardiac PET is not just a diagnostic tool—it is an essential component of modern cardiovascular care. It provides unparalleled accuracy in detecting coronary artery disease, assessing myocardial viability, and diagnosing conditions like cardiac sarcoidosis. Ensuring OHS providers have direct access to dedicated cardiac PET scanners will lead to more timely diagnoses, improved surgical planning, and ultimately, better patient outcomes. However, the current need methodology for PET/CT in Chapter 15F of the SMFP does not differentiate between PET applications. This means that tertiary heart programs requiring cardiac PET access can be denied approval in favor of oncology-focused providers, creating a gap that must be addressed.

By allowing OHS providers to acquire dedicated cardiac PET scanners, Policy TE-5 ensures that facilities treating the most complex cardiovascular cases have the tools they need to provide state-of-the-art care.

This policy would directly address the diagnostic deficit, ensuring that North Carolina residents receive timely, accurate, and potentially life-saving cardiac assessments.

The Advancing Role of PET in Cardiac Imaging

For over 25 years, PET has significantly advanced the understanding of cardiac physiology and pathophysiology. Research, including a comprehensive review from the University of Michigan Health System published in Academic Radiology (April 2003. Vol. 15:4. pp. 4-1-4451), highlights PET's superiority over perfusion imaging, CT angiography ("CTA"), and MR angiography ("MRA"). Some of the main uses for cardiac PET imaging include:

- Screening for cardiovascular disease in symptomatic individuals or those with risk factors like family history or high cholesterol.
- Monitoring heart condition and treatment efficacy in patients diagnosed with coronary artery disease ("CAD").
- Evaluating previously detected blockages to determine candidacy for coronary stents or bypass surgery.
- Assessing tissue damage and scarring post-heart attack to identify optimal treatment.

Additionally, cardiac PET imaging is increasingly important for diagnosing and managing cardiac sarcoidosis, a manifestation of systemic sarcoid disease that significantly impacts morbidity and mortality. The prevalence of clinically evident cardiac involvement is approximately five percent, though this may be an underestimation given the difficulties of diagnosing cardiac sarcoidosis.[1] Despite challenges in diagnosing cardiac sarcoidosis, PET imaging is now recognized as an excellent tool for early diagnosis, prognostication, and patient follow up.

As research continues to expand the clinical applications of PET for cardiac imaging, it will be used more and more frequently in diagnosing chronic heart conditions. Mission Hospital is already seeing a frequent need for access to this modality for its cardiac patients. However, the anticipated rise in clinical applications and demand for existing cardiac applications will further necessitate additional access to cardiac PET services in North Carolina.

PET vs. SPECT: Advanced Cardiac Imaging with Superior Diagnostic Capabilities

PET scanners are increasingly becoming the gold standard in cardiac imaging, particularly for Myocardial Perfusion Imaging ("MPI") and viability assessment. Historically, Single Photon Emission Computed Tomography ("SPECT") has been the dominant modality for nuclear cardiology. See **Attachment A** for an article from the American College of Cardiology discussing the advantages of PET versus SPECT. However, PET is rapidly gaining traction due to its superior image quality, higher diagnostic accuracy, and improved spatial resolution. These advancements are particularly crucial for patients with heart failure or severe CAD, where precise imaging plays a vital role in guiding treatment decisions. Additionally, image quality and diagnostic certainty with PET are relatively unaffected by patient gender, body size, or body shape, further enhancing its clinical value.

[1] Skali, Hicham et al. "18F-FDG PET/CT for the assessment of myocardial sarcoidosis." Current cardiology reports vol. 15,4 (2013): 352.

One of the key advantages of PET over SPECT lies in its efficiency. PET imaging requires significantly shorter scan times, with images typically captured in about five (5) minutes compared to SPECT's 15-25 minutes. This reduced duration is especially beneficial for ill patients or those who struggle to remain still during imaging. Additionally, a complete rest/stress study with PET can be performed under 35 minutes, whereas SPECT often requires several hours. The shorter scan times and faster rest/stress studies allow for more procedures to be completed with a given timeframe, improving efficiency and throughput for the facility.

PET also provides significantly lower radiation exposure than SPECT, reducing levels by up to 85%. With radiation levels far lower than those known to pose risk of adverse effects, PET is particularly beneficial for patients with chronic CAD who undergo frequent radiation-associated diagnostic and therapeutic procedures throughout their lives, further enhancing its safety profile for those requiring ongoing imaging.

Another major advantage of PET is its ability to measure myocardial blood flow directly. SPECT relies on comparing blood flow between different areas of the heart; however, this approach may miss blockages effecting multiple arteries (multivessel CAD), especially in certain stress testing scenarios where reduced blood flow in all areas may go undetected/undiagnosed. PET, by contrast, delivers a more complete picture of coronary circulation by quantifying actual blood flow to the heart. This capability enables physicians to detect or rule out significant blockage more accurately, ensure precise stress test results, and make more effective and cost-efficient treatment decisions.

Beyond its strengths in MPI, PET also offers versatility for broader diagnostic applications including coronary artery calcium scoring, thoracic and abdominal aortic studies, left atrial imaging prior to atrial fibrillation ablation procedures, identification of cardiac sarcoidosis, and evolution of device infections. These additional uses further enhance PET's value as an indispensable tool in modern cardiology.

As PET continues to outperform SPECT in imaging quality, diagnostic accuracy, and efficiency, its role in advancing cardiovascular care becomes increasingly evident. This emphasizes the critical need for OHS providers to have access to dedicated cardiac PET scanners, ensuring they can fully leverage this advanced technology to improve patient outcomes and enhance diagnostic capabilities.

Obesity and the Need for Advanced Cardiac Imaging in North Carolina

Obesity is a significant health concern in North Carolina, affecting nearly half of the state's residents. A 2024 study conducted by NORC at the University of Chicago found that approximately 45% of North Carolina have a body mass index (BMI) over 30, classifying them as obese.[2] This growing prevalence of obesity further highlights the urgent need for advance cardiac imaging, as obesity is a major risk factor for cardiovascular disease and complicates both diagnosis and treatment.

Obesity contributes to several conditions that increase the risk of cardiovascular issues, including:

- **High Blood Pressure (Hypertension)**: Excess fat tissue requires more oxygen and nutrients, increasing the workload on the heart. This leads to high blood pressure, which strains the arteries and raises the risk of heart attacks.

[2] https://abc11.com/american-heart-month-new-data-north-carolina-obesity/14468346/?utm_source=chatgpt.com

- **Inflammation and Blood Clotting**: Visceral fat, fat around internal organs, triggers chronic inflammation, damaging blood vessels and promoting clot formation, increasing the risk of heart attacks.
- **Heart Struture and Function Changes**: Obesity can cause structural changes to the heart, such as left ventricular hypertrophy (thickening of the heart muscle), which makes it harder for the heart to pump blood efficiently.

Given the increasing burden of obesity-related cardiovascular disease, cardiac tertiary care providers (such OHS) must have sufficient access to cardiac PET imaging, which offers significant advantage for diagnosing and managing heart disease in patients with larger body sizes.

According to a joint position statement from the American Society of Nuclear Cardiology and Society of Nuclear Medicine ("ASNC/SNMMI"), published in the *Journal of Nuclear Cardiology* (2016. Vol. 20. pp. 916-94), PET/CT is a valuable, non-invasive cardiac imaging test that aligns CMS goals of delivering effective, safe, efficient, patient-centered, equitable, and timely care. PET/CT stands out due to its high diagnostic accuracy, low radiation exposure, short test duration, and ability to accommodate patients of varying characteristics and conditions such as high-risk patients, or those with large body habitus.

Also, according to ASNC/SNMMI, PET/CT has outperformed other noninvasive approaches in the detection of multilevel coronary artery disease. Unlike other imaging modalities, PET/CT maintains high-quality images that are unaffected by body shape or size. Its short test duration also makes it particularly beneficial for acutely ill patients, ensuring quicker and more accurate diagnosis and treatment.

As obesity rates continue to rise in North Carolina, expanding access to advanced cardiac imaging technologies like cardiac PET is essential for improving cardiovascular outcomes and providing equitable care to all patients.

Cardiac PET Necessity for Open Heart Surgery Providers

Cardiac PET is becoming an essential tool for OHS providers, playing a crucial role in guiding surgical decision-making. One of its primary functions is preoperative risk stratification and surgical planning. By evaluating heart muscle functions and blood flow, cardiac PET helps doctors assess the degree of ischemia and potential for future heart events, such as heart attacks. This information is vital in determining the most appropriate course of action for patients. For instance, Cardiac PET can aide in deciding whether revascularization, such as Coronary Artery Bypass Grafting ("CABG"), would be beneficial, or whether a heart transplant might be a more suitable option for the patient.[3]

Additionally, cardiac PET is instrumental in determining the optimal placement of a graft when revascularization is needed by measuring myocardial blood flow ("MBF") and detecting perfusion defects. This also provides clarity on whether the CAD is obstructive or non-obstructive. This insight allows

[3] Arjomandi Rad A, Tserioti E, Magouliotis DE, Vardanyan R, Samiotis IV, Skoularigis J, Ariff B, Xanthopoulos A, Triposkiadis F, Casula R, Athanasiou T. Assessment of Myocardial Viability in Ischemic Cardiomyopathy With Reduced Left Ventricular Function Undergoing Coronary Artery Bypass Grafting. Clin Cardiol. 2024 Jul;47(7):e24307. doi: 10.1002/clc.24307. PMID: 38953367; PMCID: PMC11217808.

surgeons to assess the severity of coronary artery blockage, especially when multiple arteries are involved, and decide on the most effective surgical intervention.[4]

The use of cardiac PET also helps to avoid unnecessary surgeries. By differentiating between hibernating (MBF - reduced blood flow) and non-viable myocardium (MBF – no blood flow), cardiac PET can prevent unnecessary bypass procedures, ensuring that only patients who will truly benefit from surgery undergo invasive interventions. Moreover, cardiac PET enhances outcomes in high-risk patients by predicting post-surgical recovery. It helps identify patients who are more likely to regain heart function after revascularization, allowing for better-target intervention and improved recovery rates.[5]

The integration of cardiac PET into a heart surgery program not only strengthens the program's overall capabilities but also makes the facility more attractive to potential referrals and patients. With the ability to offer more accurate diagnosis and better surgical outcomes, facilities that utilize Cardiac PET will be better positioned to expand their programs and remain at the forefront of cardiovascular care.

The Standard Methodology Does Not Recognize the Demand for Cardiac PET Services

The current need methodology for PET/CT in Chapter 15F of the SMFP bases need for an additional PET/CT Scanner on a capacity of 80% of 3,000 scans, or a threshold of 2,400. Thus, the methodology is driven by the current utilization of existing providers and does not contemplate future demand or any growth factor that would include the demand for PET services that are not currently provided, like cardiac PET.

Moreover, the capacity threshold is applied to the reported PET/CT volume of existing providers, which does not consider the type of scans performed. There is no current mechanism to determine if any existing providers of PET/CT are using equipment for both oncologic and cardiac imaging or only for oncology imaging. There is also no mechanism to know how many cardiac scans have been provided if an existing provider is offering cardiac PET.

Finally, any need that is generated may be awarded to an applicant that does not propose to offer cardiac PET services and does not have the patient base or clinical/staff expertise to offer this service. Thus, a tertiary cardiac provider, such as an OHS provider that treats the highest acuity cardiac patients, may not be awarded a CON based on a need determination. Thus, any Agency approval may not recognize or address the need for cardiac PET capacity to provide this unique service under the current methodology for PET/CT.

As discussed in detail below, cardiac PET is the standard of care for certain cardiology and cardiac surgery patients. To offer this service, tertiary cardiac providers in North Carolina need access to sufficient PET/CT capacity regardless of the need determination, which is largely driven by oncology scan volume.

[4] Al-Mallah MH, Nayfeh M, Alrifai M. The role of cardiac PET in diagnosis and prognosis of patients with ischemia with no obstructive coronary arteries (INOCA). Am Heart J Plus. 2024 May 18;43:100399. doi: 10.1016/j.ahjo.2024.100399. PMID: 38828445; PMCID: PMC11141139.

[5] Panza, J, Chrzanowski, L, Bonow, R. Myocardial Viability Assessment Before Surgical Revascularization in Ischemic Cardiomyopathy: JACC Review Topic of the Week. JACC. 2021 Sep, 78 (10) 1068–1077. https://doi.org/10.1016/j.jacc.2021.07.004

Providers Who Would Benefit from This Policy

Mission exemplifies a tertiary cardiac provider and existing OHS program that would benefit from this policy. Mission also has a highly utilized oncology PET/CT scanner in its cancer center. Based on volume and location, this scanner does not have the capacity to develop a cardiac PET program. Mission Hospital estimates that it has sufficient demand within its cardiac surgery/cardiology program to generate over 1,040 cardiac PET scans.

Mission Hospital generated a need for an additional PET/CT unit in the 2021 and 2023 SMFPs. In response, Mission applied in both 2021 and 2023 for a second PET/CT scanner that would allow sufficient capacity to develop a cardiac PET program and to locate this second PET unit in its Heart Center. Mission Hospital projected well over 1,000 cardiac scans for its proposed second PET scanner, which could not be accommodated on its current PET unit operating at 83.57% capacity in the 2021 SMFP and 93.6% of capacity in the 2023 SMFP. In each instance, the Agency approved a provider that proposed primarily, oncology PET services.[6] Thus, Mission Hospital cannot develop a cardiac PET program despite the fact that it has consistently been among the top two providers (by volume) of OHS in the state for over ten years. See **Table 2** below.

Another example is Moses Cone Hospital ("Moses Cone"), who applied for the HSA II need in the 2023 SMFP. Focusing on the need for cardiac PET and proposing to locate its new PET unit in its Heart and Vascular Center (Project ID# G-12425-23). Moses Cone projected well over 1,000 cardiac scans to be performed on its proposed PET scanner, which certainly could not be accommodated on its exiting scanner operating at over 90% of capacity in 2023. In this competitive review, Novant Health Forsyth Medical Center was awarded the CON (Project ID# G-12432-23). The need for additional PET/CT capacity at Novant Health Forsyth Medical Center is not in dispute; however, Moses CON was prevented from being able to develop at cardiac-focused PET service to support its tertiary cardiac and OHS services based on limited need in the SMPF driven heavily by historical oncology scan volume.

Furthermore, a similar situation is currently under review in HSA III under the 2024 SMFP need determination. Two OHS applicants, Atrium Health Pineville (Project ID# F-12550-24) and Novant Health Presbyterian Medical Center (Project ID# F-12557-24), have applied for the one additional PET scanner identified through the PET/CT need methodology. Ultimately, only one of the OHS applicants will be approved. See **Table 2**. Atrium Health Pineville does not currently have access to a PET scanner and Novant Health Presbyterian Medical Center per the 2025 SMFP is operating near the 80% threshold. In either instance an OHS provider will be disapproved effecting access to cardiac PET for their tertiary cardiac patients.

<u>OHS Programs' Cardiac PET Offerings</u>

There is no publicly reported data to determine which hospitals in North Carolina are offering cardiac PET. The data reported on PET/CT services in the Agency's Licensure Renewal Applications ("LRAs") does not distinguish the volume by provider of non-oncology scans or the provision of cardiac PET scans, as shown in the excerpt of LRA below.

[6] In 2021, the needed PET/CT was awarded to Messino Cancer care, an oncology physician practice. In 2023, the needed PET/CT was awarded to AdventHealth Hendersonville, which lacks both a cardiac catheterization program and an OHS program.

g. Positron Emission Tomography (PET). Campus – *if multiple sites*: _____

	Number of Units	Number of Procedures*		
		Inpatient	Outpatient	Total
Dedicated Fixed PET Scanner				
Mobile PET Scanner				
PET pursuant to Policy AC-3				
Other PET Scanners used for Human Research only				

* PET **procedure** means a single discrete study of one patient involving one or more PET scans. PET **scan** means an image-scanning sequence derived from a single administration of a PET radiopharmaceutical, equated with a single injection of the tracer. One or more PET scans comprise a PET procedure. **The number of PET procedures in this table should match the number of patients reported on the PET Patient Origin Table on page 31.**

For questions, please contact Healthcare Planning and Certificate of Need at 919-855-3873.

CON Project ID numbers for all non-grandfathered fixed PET scanners on this campus: _____

_____

Based on a review of hospital websites, it is clear that some OHS providers are offering cardiac PET. For other providers, it is fairly clear that they are only providing oncology scans. Mission Hospital suggests that the LRA be amended to request information on whether providers are offering cardiac PET and if so, how many annual scans. Given the current LRA format, it is unclear whether an OHS provider is offering cardiac PET and/or if they have sufficient capacity to meet demand for both oncology and cardiac PET.

Mission Hospital's research from provider websites and calling existing OHS providers suggests the following status of cardiac PET for existing OHS providers as shown in **Table 1**.

There are two OHS providers that do not offer fixed or mobile PET/CT services at all:

- Atrium Health Pineville, and
- Duke Regional Hospital

In addition, Mission Hospital's research shows that three other OHS providers do not offer cardiac PET including:

- Atrium Health Cabarrus
- First Health Moore Regional
- High Point Regional Medical Center

The proposed new policy would allow these providers to seek a CON for a cardiac PET program to support their OHS program.

Table 1
Open Heart Surgery Providers – Status of Cardiac PET Services

Providers	Open Heart Surgery	Offer Cardiac PET imaging?
Carolinas Medical Center	Yes	Yes
Cone Health	Yes	Yes
University of North Carolina Hospitals	Yes	Yes
Duke University Hospital	Yes	Yes
Atrium Health Wake Forest Baptist	Yes	Yes
Novant Health New Hanover Regional Medical Center	Yes	Yes
WakeMed Hospital / Wake PET Services^	Yes	Yes
ECU Health Medical Center*	Yes	Yes
Southeastern Regional Medical Center	Yes	Yes
Novant Health Presbyterian Medical Center	Yes	Yes
Novant Health Forsyth Medical Center**	Yes	Yes
Rex Hospital	Yes	Yes
Frye Regional Medical Center/ Catawba Valley Medical Center^^	Yes	Yes
CarolinaEast Medical Center	Yes	Yes
Cape Fear Valley Medical Center	Yes	Yes
CaroMont Regional Medical Center	Yes	Yes
Mission Hospital	**Yes**	No
Atrium Health Cabarrus	Yes	No
High Point Regional Health	Yes	No
FirstHealth Moore Regional Hospital/ First Imaging of the Carolinas#	Yes	No
Atrium Health Pineville	Yes	PET not available
Duke Regional Hospital	Yes	PET not available

Source: Facilities websites

**CON issued to convert fixed PET to mobile PET December 13, 2022. CON Project ID: Q-012223-22*

***CON issued for second PET March 29, 2024. CON Project ID: G-012432-23*

^OHS program based on WakeMed Hospital (H0199).

^^Frye Regional Medical Center is an OHS provider; Catawba Valley Medical Center is not.

#OHS program based on First Health Moore Regional Hospital (H0100). PET based at affiliate First Imaging of the Carolinas.

Comparison of OHS Programs and PET/CT Volume and Capacity

Table 2 provides an analysis of OHS programs in the state and their capacity of PET/CT services. In addition to Mission Hospital, there are four other OHS providers with PET programs operating at over 80% of capacity. These include Carolinas Medical Center, Cone Health, UNC Hospitals, and Duke University Hospital. Rex Hospital is also operating just below 80% capacity and Novant Presbyterian Medical Center is operating at 75.8% capacity. Although 75.8% does not meet the PET need threshold under the SMFP methodology, it leaves little to no available capacity to support both an oncology and cardiac PET program.

As noted, there are two OHS providers that do not offer fixed or mobile PET/CT services:

- Atrium Health Pineville, and
- Duke Regional Hospital

While both facilities might benefit from a cardiac PET program, they have affiliate hospitals within the same HSA that offer PET programs. However, as shown in **Table 2**, Duke Regional Hospital's affiliate, Duke University Hospital, is operating at 82.7% of its PET capacity. Similarly, Atrium Health Pineville can refer to Carolina's Medical Center, which is operating at 94.8% of capacity. The high utilization of these affiliates may limit access to cardiac PET.

Table 2
Analysis of OHS Providers and PET Utilization/Capacity

			PET Services (2025 SMFP)			OHS Volume (2025 SMFP)	
Licenses #	**Providers**	**Open Heart Surgery**	**Planning Inventory**	**2022-2023 Procedures**	**PET Utilization**	**2022**	**2023**
H0042	Atrium Health Pineville	Yes	**Not Available**			270	344
H0233	Duke Regional Hospital	Yes	**Not Available**			97	91
H0036	**Mission Hospital**	**Yes**	**1**	**2,862**	**95.4%**	1,099	1,254
H0071	Carolinas Medical Center	Yes	2	5,686	94.8%	777	803
H0159	Cone Health	Yes	1	2,750	91.7%	601	546
H0157	University of North Carolina Hospitals	Yes	2	5,375	89.6%	351	339
H0015	Duke University Hospital	Yes	3	7,442	82.7%	1,259	1,286
H0065	Rex Hospital	Yes	2	4,772	79.5%	520	490
H0010	Novant Health Presbyterian Medical Center	Yes	1	2,275	75.8%	360	450
H0011	Atrium Health Wake Forest Baptist	Yes	2	4,248	70.8%	840	925
H0100	FirstHealth Moore Regional Hospital/ First Imaging of the Carolinas#	No	1	2,091	69.7%	234	228
H0221	Novant Health New Hanover Regional Medical Center	Yes	2	4,130	68.8%	433	466
H0104	ECU Health Medical Center*	Yes	2	3,849	64.2%	805	865
H0199	WakeMed Hospital / Wake PET Services^	Yes	1	1,660	55.3%	487	519
H0053/ H0223	Frye Regional Medical Center/ Catawba Valley Medical Center^^	Yes	1	1,649	55.0%	177	207
H0201	CarolinaEast Medical Center	Yes	1	1,576	52.5%	222	255
H0209	Novant Health Forsyth Medical Center **	Yes	2	2,907	48.5%	436	500
H0031	Atrium Health Cabarrus	Yes	1	1,417	47.2%	195	337
H0213	Cape Fear Valley Medical Center	Yes	1	1,352	45.1%	124	139
H0105	CaroMont Regional Medical Center	Yes	1	1,282	42.7%	268	283
H0064	Southeastern Regional Medical Center	Yes	1	1,169	39.0%	53	43
H0052	High Point Regional Health	Yes	1	583	19.4%	19	30

Source: 2025 SMFP

**CON issued to convert fixed PET to mobile PET December 13, 2022. CON Project ID: Q-012223-22*

***CON issued for second PET March 29, 2024. CON Project ID: G-012432-23*

^OHS program based on WakeMed Hospital (H0199). PET based at affiliate 210 PET Imaging in Cary , NC.

^^Frye Regional Medical Center is an OHS provider; Catawba Valley Medical Center is not.

#OHS program based on First Health Moore Regional Hospital (H0100). PET based at affiliate First Imaging of the Carolinas.

Need for PET/CT Under the Methodology

There is need in the 2025 SMFP for additional PET/CT services in HSAs I, II, III, and IV as shown below and in **Table 3**. The following highly utilized OHS providers and OHS providers without cardiac PET will have the opportunity to apply for PET in 2025.

- Mission Hospital – HSA I
- Cone Health – HSA II
- Carolina Medical Center – HSA III
- Novant Health Presbyterian Medical Center – HSA III
- Atrium Health Pineville – HSA III
- UNC Medical Center - HSA IV
- Duke University Hospital – HSA IV
- Rex Hospital – HSA IV
- Duke Regional Hospital – HSA - IV

Like Mission Hospital, these providers can apply for PET/CT based - at least - partly on demand for cardiac PET scans and the need for a cardiac PET program. However, there is no guarantee that the Agency will approve any of these providers.

Additionally, the current SMFP PET need methodology limitations affect HSAs with multiple OHS providers. For example, HSA IV has a need for two (2) PET/CT units but there are four (4) OHS providers with PET/CT programs that are either highly utilized or do not have PET/CT access at all. Not all providers can be approved. In fact, there are seven (7) total applicants that have just applied for this need determination for the March 1, 2025 review including OHS providers Duke University Hospital, UNC Medical Center, WakeMed Raleigh, as well as multiple other hospitals and freestanding providers. There is no guarantee that a highly utilized OHS provider will be approved for more capacity to support cardiac PET, particularly when the Agency gives credit to new providers under the "competition" comparative factor.

Similarly, in HSA III, there are five (5) OHS providers including Atrium Health Pineville without a PET unit and highly utilized Carolinas Medical Center, yet the 2025 SMFP identifies a need of only one PET/CT unit. Like HSA IV, multiple other applicants may apply including freestanding PET providers and other non-OHS providers limiting the opportunity to ensure that cardiac PET is available to OHS providers for their complex cardiac patients.

In both examples above, multiple providers could benefit from a PET/CT unit to support a cardiac PET program. However, not all applicants can be approved. In fact, a new provider not currently providing PET/CT services could be approved instead. As a result, even with the identified need in the 2025 SMFP, multiple tertiary cardiac providers may continue operating at high capacity or without a PET/CT program – limiting their ability to support a cardiac PET program, which is now considered the standard of care for imaging related to certain cardiac diagnoses identified previously.

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Table 3
2025 Need for PET/CT in HSAs for OHS Programs

Licenses #	Providers	Open Heart Surgery	PET Services (2025 SMFP)			PET Need in the 2025 SMFP for HSA
			Planning Inventory	2022-2023 Procedures	PET Utilization	
H0036	**Mission Hospital**	**Yes**	**1**	**2,862**	**95.4%**	**HSA I - Yes**
H0053/ H0223	Frye Regional Medical Center/ Catawba Valley Medical Center^^	Yes	1	1,649	55.0%	HSA I - Yes
H0159	Cone Health	Yes	1	2,750	91.7%	HSA II - Yes
H0011	Atrium Health Wake Forest Baptist	Yes	2	4,248	70.8%	HSA II - Yes
H0209	Novant Health Forsyth Medical Center**	Yes	2	2,907	48.5%	HSA II - Yes
H0052	High Point Regional Health	Yes	1	583	19.4%	HSA II - Yes
H0071	Carolinas Medical Center	Yes	2	5,686	94.8%	HSA III - Yes
H0010	Novant Health Presbyterian Medical Center	Yes	1	2,275	75.8%	HSA III - Yes
H0031	Atrium Health Cabarrus	Yes	1	1,417	47.2%	HSA III - Yes
H0105	CaroMont Regional Medical Center	Yes	1	1,282	42.7%	HSA III - Yes
H0042	Atrium Health Pineville	Yes	**Not Available**			HSA III - Yes
H0157	University of North Carolina Hospitals	Yes	2	5,375	89.6%	HSA IV - Yes
H0015	Duke University Hospital	Yes	3	7,442	82.7%	HSA IV - Yes
H0065	Rex Hospital	Yes	2	4,772	79.5%	HSA IV - Yes
H0199	WakeMed Hospital / Wake PET Services^	Yes	1	1,660	55.3%	HSA IV - Yes
H0233	Duke Regional Hospital	Yes	**Not Available**			HSA IV - Yes
H0221	Novant Health New Hanover Regional Medical Center	Yes	2	4,130	68.8%	HSA V - No
H0213	Cape Fear Valley Medical Center	Yes	1	1,352	45.1%	HSA V - No
H0064	Southeastern Regional Medical Center	Yes	1	1,169	39.0%	HSA V - No
H0100	FirstHealth Moore Regional Hospital/ First Imaging of the Carolinas#	Yes	1	2,091	69.7%	HSA V - No
H0201	CarolinaEast Medical Center	Yes	1	1,576	52.5%	HAS VI - No
H0104	ECU Health Medical Center*	Yes	2	3,849	64.2%	HSA VI - No

Source: 2025 SMFP

**CON issued to convert fixed PET to mobile PET December 13, 2022. CON Project ID: Q-012223-22*

***CON issued for second PET March 29, 2024. CON Project ID: G-012432-23*

^OHS program based on WakeMed Hospital (H0199). PET based at affiliate 210 PET Imaging in Cary , NC.

^^Frye Regional Medical Center is an OHS provider; Catawba Valley Medical Center is not.

#OHS program based on First Health Moore Regional Hospital (H0100). PET based at affiliate First Imaging of the Carolinas.

Part 2 of the PET/CT Need Methodology

The 2025 SMFP identifies a need in HSA III based on Part 2 of the PET/CT need methodology ("Part 2").

Part 2 is designed to ensure that a hospital serving as a major cancer treatment facility has access to fixed PET/CT equipment, implicitly recognizing that PET/CT is the standard of care for a major oncology center.

This is important for two reasons.

First, it recognizes that offering PET/CT is the standard of care for a major oncology treatment program. Likewise, cardiac PET should be recognized as the standard of care for tertiary cardiac providers of open-heart surgery. The proposed Policy TE-5 would formalize this recognition.

Second, Part 2 does not limit approval to the provider that generated it. In fact, the 2025 SMFP does not specify which provider in HSA III triggered the need under Part 2. However, based on utilization data (Chapter 15.C) for linear accelerators, Atrium Health Pineville is likely the major cancer treatment center without a fixed PET/CT program that meets the requirements under Part 2.

Yet, because the need determined by Part 2 is classified as general need in the 2025 SMFP, any provider can apply and be approved in a competitive or non-competitive review cycle. As a result, Atrium Health Pineville is not guaranteed approval to remedy its SMFP identified need for PET/CT services to support its oncology program (or its tertiary cardiac program), effectively undermining the purpose of Part 2 by failing to ensure that the provider generating the need actually receives the PET/CT approval necessary to meet its patient care demands. In contrast, the proposed Policy TE-5 would ensure that OHS programs requiring access to PET/CT are able to acquire this critical tool.

Statement of Adverse effect on Providers and Consumers If the Adjustment is Not Made

Failure to implement the policy necessary for the Plan Exemption of dedicated Cardiac PET/CT services will have significant negative consequences for OHS providers and their patients.

Adverse Effects on OHS Providers

First, failure to implement the proposed policy will reduce diagnostic precision by OHS providers lacking this technology, forcing clinicians to rely on less accurate modalities such as SPECT and stress echocardiography. These alternatives lack the advanced imaging capabilities of cardiac PET, leading to compromised diagnostic accuracy. Without the precise viability assessments that cardiac PET offers, surgical planning becomes less reliable, increasing the risk of complications and failed interventions. This heightened surgical risk can result in unnecessary or ineffective revascularization procedures, exposing patients to avoidable dangers. Moreover, the lack of accurate imaging will likely lead to higher readmission rates due to missed diagnoses and suboptimal surgical decisions.

Providers will face a competitive disadvantage compared to facilities with the equipment and capacity to offer cardiac PET, potentially impacting their reputation and patient volume. Additionally, inadequate imaging contributes to increases in healthcare costs by necessitating longer hospital stays, more ICU admissions, and higher overall expenses due to insufficient surgical planning.

Adverse Effects on Cardiac Patients

Cardiac patients will also face significant adverse effects if cardiac PET services are not made available. The absence of this advanced imaging technology increases the risk of misdiagnosis or delayed treatment. Cardiac PET is the standard of care providing superior capabilities to identify critical information often missed by other imaging modalities.

Without it, patients may undergo unnecessary open-heart surgeries, such as CABG, performed on individuals with non-viable myocardium due to inadequate imaging. This not only subjects patients to avoidable surgical risks but also fails to deliver any meaningful benefit.[7]

Furthermore, the absence of cardiac PET services reduces early detection capabilities, as other imaging modalities lack the advanced diagnostic precision of PET/CT scans. This limitation can lead to disease progression or inappropriate treatment plans, increasing the likelihood of higher morbidity and mortality rates.

Inadequate assessment of ischemia or myocardial viability heightens the risk of heart failure progression, arrythmias, and sudden cardiac death. Lastly, the lack of advanced imaging limits access to specialized advanced therapies. Eligible candidates for advanced intervention like cardiac transplantation may be overlooked, as inadequate imaging prevents accurate patient selection for these lifesaving treatments.

Alternatives Considered and Found Not Feasible

Alternative: Rely on Standard Methodology

Relying on the SMFP to produce a documented need for PET/CT services is an unreliable approach, as it would not guarantee that the PET/CT scanner will be granted to a facility that has the ability or intention to utilize the PET/CT scanner for cardiology. PET/CT scans are widely used in oncology for diagnostic and treatment planning, making the allocation of PET/CT resources highly competitive. Even if a need for additional PET/CT scanner is identified, there is no guarantee that the need determination will favor an OHS provider or be allocated to a facility with an established tertiary cardiac program. This uncertainty jeopardizes timely access to cardiac PET services for both providers and patients, potentially delaying critical advancement in cardiac care. Moreover, waiting for the standard methodology is not an effective alternative, as it does not ensure that an approved provider will generate sufficient utilization to generate a need determination for additional cardiac PET units in an HSA. It could be years before additional need arises.

[7] Allman KC, Shaw LJ, Hachamovitch R, Udelson JE. Myocardial viability testing and impact of revascularization on prognosis in patients with coronary artery disease and left ventricular dysfunction: a meta-analysis. J Am Coll Cardiol. 2002 Apr 3;39(7):1151-8. doi: 10.1016/s0735-1097(02)01726-6. PMID: 11923039.

Alternative: Adjust PET/CT Need Methodology for Cardiac PET

A potential adjustment to the SMFP need methodology could involve adding a Part 3, similar to Part 2, that specifically identifies the OHS providers. The identified provider would need to be hospital-based and would generate a need for an additional PET/CT scanner.

However, this approach would likely be subjected to the same limitations as the other parts of the methodology, which restrict the number of units the need methodology could generate (see Chapter 15F, Methodology Step 7). Additionally, its general need classification would allow any provider to apply, with no guarantee that the awarded provider will offer cardiac PET. This would fail to directly address the need for cardiac PET at tertiary cardiac providers, thereby limiting North Carolina residents' access to the standard of care for cardiac imaging.

Best Alternative: Petition the SHCC for a Policy TE-5: Plan Exemption for Dedicated Cardiac PET/CT for OHS Providers

The most effective alternative is to petition the SHCC for Policy TE-5, which would create a plan exemption allowing OHS providers to acquire a PET/CT scanner dedicated to cardiac services. This policy would enable OHS providers to secure cardiac PET services by demonstrating demand, regardless of identified need in the SMFP.

Policy TE-5 ensures that OHS facilities with sufficient demand for cardiac PET will have access to the services and ensures that the equipment is dedicated to cardiac services. The dedicated cardiac PET maybe used to serve non-cardiac patients in emergency situations – temporary downtime for other PET/CT scanners. This policy will address the growing unmet need for cardiac PET services as technology advances, without disrupting the availability of PET/CT scanner for oncology and other services.

Evidence of No Unnecessary Duplication of Services

There are currently no PET/CT scanners strictly dedicated to cardiac imaging. Existing PET/CT Scanner are multi-purpose, serving a wide range of diagnostic needs including oncology, cardiology, and neurology. The proposed policy would not result in unnecessary duplication of services but would instead allow OHS providers to acquire a PET/CT scanner solely for cardiac services. Approving this policy will ensure that the growing demand for specialized cardiac imaging is met without compromising the availability of PET/CT resources for other medical specialties.

Evidence of Consistency with the North Carolina Medical Facilities Plan

The petition aligns with the SMFP's Basic Principles regarding safety, quality, access, and values as outlined below.

Safety and Quality

PET scanning has become a standard component of comprehensive cardiology services due to its superior detection capabilities compared to other imaging modalities. To support this advancement, adopting a policy that allows OHS providers to obtain a fixed, dedicated cardiac PET scanner will ensure that these

scanners are used specifically for cardiac purposes. This targeted approach enables OHS providers to deliver advanced, high-quality, and comprehensive cardiac imaging.

In tertiary facilities like Mission Hospital, where PET/CT scanners are heavily utilized for oncology, there is limited capacity to fully support cardiology services. By addressing this unmet need for cardiac PET scans, the SHCC can ensure the patients in North Carolina have access to state-of-the-art cardiology care. This will promote timely, accurate cardiac imaging, while reducing risk associated with delayed or missed diagnoses.

Access

Adopting a policy that accommodates OHS providers who do not have a PET/CT scanner – or whose existing PET/CT scanners are at capacity – and who have sufficient demand for cardiac imaging will address the basic principle of access. North Carolina has twenty-two (22) OHS providers and nine (9) of these providers (about 40%) could benefit from this policy. Specifically, there are seven (7) OHS providers that have at least one PET/CT Scanner operated at over 75% capacity, while the remaining two (2) OHS providers do not have a PET/CT scanner. See **Table 2** above.

Furthermore, all the facilities that generated facility deficits for PET/CT services in the 2025 SMFP were OHS providers, indicating that the demand for PET/CT services in North Carolina is driven by limited access and capacity, including for cardiac PET imaging. See **Table 4**.

Table 4
2025 SMFP Dedicated Fixed PET Scanner Need Determination

Service Area	Provided that Generated the Deficit	Open Heart Surgery	Planning Inventory	PET Utilization	Facility Deficit	Need Determination
HSA I	Mission Hospital	Yes	1	95.4%	1	1
HSA II	Cone Health	Yes	1	91.7%	1	1
HSA III	Carolinas Medical Center	Yes	2	94.8%	1	1*
HSA IV	Duke University Hospital	Yes	3	82.7%	2	2
	University of North Carolina Hospital	Yes	2	89.6%		

Source: 2025 SMFP Table 15-F-1 and Table 15F-4

**Need determination generated pursuant to Part 2 of the Application Methodology.*

In these service areas, there is no guarantee that the need determination will be awarded to an existing provider or an OHS provider. In addition, there are multiple OHS providers for which cardiac PET capacity may be limited. For example, Mission Hospital generated the need determination for an additional general fixed PET/CT scanner in HSA I in the 2021 and 2023 SMFPs. Although Mission Hospital has applied for additional PET/CT scanners when a need was identified, the equipment has consistently been awarded to new providers focusing primarily on oncology PET/CT services.[8] This has left the need for cardiac imaging among HSA I residents – beyond just Mission Hospital's cardiac patients – unmet. Thus, the oncology-based need determination will not necessarily meet the needs of tertiary cardiac providers.

Notably, HSA V did not generate a need in the 2025 SMFP; however, all PET/CT providers (or their affiliates) in this area are also OHS providers. Under the current methodology none of these providers would have an opportunity to add capacity to ensure access to cardiac PET services.

[8]In 2021, the needed PET/CT was awarded to Messino Cancer care, an oncology physician practice. In 2023, the needed PET/CT was awarded to AdventHealth Hendersonville, which lacks an OHS program.

Approval of this policy will improve access to cardiac PET services in North Carolina. The current limited number of general PET/CT scanners is unable to meet the demand for cardiology and other services. By adopting this policy, OHS providers who lack sufficient capacity – or do not have a PET/CT scanner at all – will be better positioned to offer essential cardiac imaging services.

Value

Implementing the proposed policy to allow dedicated cardiac PET services will provide significant value by reducing healthcare costs through early detection of heart disease and improving the accuracy of diagnosis and treatment planning. This approach helps minimize the need for unnecessary surgeries and reduces the associated adverse effects previously discussed, ultimately enhancing patient outcomes, and optimizing resource utilization.

In summary, the proposed policy to allow OHS providers to apply for dedicated cardiac PET scanners, regardless of general PET/CT need in the 2026 SMFP, will enhance safety, quality, access, and values, making it a necessary and beneficial adjustment for North Carolina.

Conclusion

In conclusion, adopting Policy TE-5 will address the critical gap in cardiac diagnostic services by allowing OHS providers to acquire dedicated cardiac PET scanners, ensuring timely, accurate, and advanced imaging for cardiac patients. This policy will enhance patient outcomes, improve surgical planning, and support the growing demand for specialized cardiac care without compromising PET/CT availability for other medical specialties.

Attachment A

American College of Cardiology Article

PET as an Essential Component of Every Modern-Day Clinical Nuclear Laboratory

Nov 09, 2016 | **Timothy M. Bateman, MD, FACC**

Expert Analysis

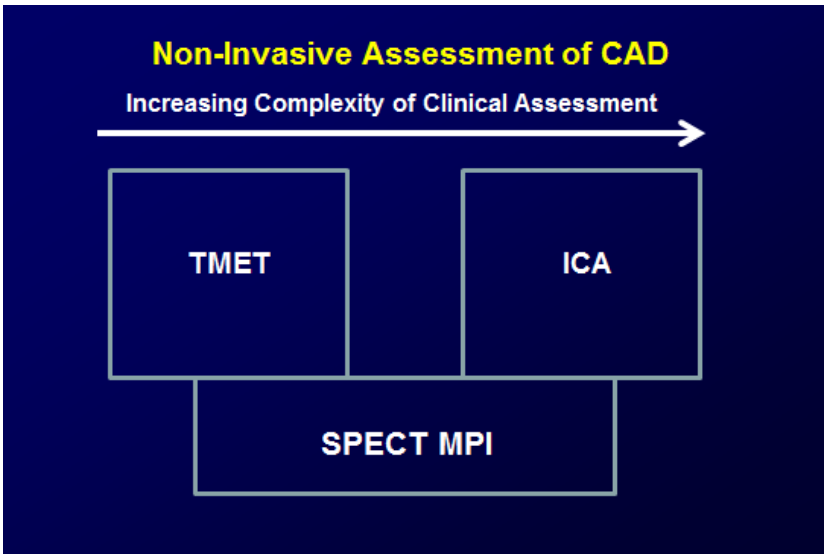
Note: *This is the* ***Pro*** *article of a two-part "Pro-Con" set.* ***Go to the Con article****.*

Background

Single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI) has been a mainstay of the noninvasive assessment of coronary artery disease (CAD) for more than 30 years. It has occupied a pivotal role between treadmill exercise and invasive coronary angiography (Figure 1), providing statistical improvements in diagnostic accuracy and helping to better identify patients needing a coronary intervention as opposed to medical therapy alone.[1] SPECT MPI is practiced widely in 2016 much as it was in the early 1990s. The Anger camera predominates despite limited count statistics; the protocols require radiation exposures no longer in favor; attenuation correction is rarely used; there have been no new tracers and none in late-phase development; and provision of the service is expensive due largely to through-put inefficiencies. In the current era, a nuclear cardiology service will be called upon to assess myocardial perfusion in a wide array of patients, from those with no known CAD but low-intermediate pretest probability, to the most complicated patients with long histories of CAD with, perhaps, prior revascularizations or infarctions, cardiomyopathies, co-existent valve diseases, and numerous comorbidities. Furthermore, nuclear cardiac imaging today is increasingly used for non-perfusion indications such as myocardial viability,[2]

device infections,[3] endocarditis,[4,5] and cardiac sarcoidosis.[6] I will argue here that SPECT will continue to be an important tool; however, providers will need to upgrade their SPECT scanners and will use them for a smaller percent of myocardial perfusion referrals. Furthermore, absence of cardiac positron emission tomography (PET) will impede a program's obligations for training tomorrow's nuclear specialists and will adversely affect the needs of heart failure and electrophysiology specialists.

Figure 1: The "old paradigm" in which SPECT MPI is viewed as an ideal test for a broad array of patients regardless of clinical complexity, ability to exercise, or physical characteristics. (TMET = treadmill exercise test; ICA = invasive coronary angiography)



Strengths of PET/Computed Tomography for MPI

The advantages of PET for MPI are many (Table 1). Higher diagnostic accuracy has been shown in several meta-analyses.[7-9] Image quality is consistently high and superior to SPECT when performed in the same patients. PET images are count-rich and reliably corrected for tissue attenuation and scatter, so that image quality and interpretive certainty are relatively unaffected by patient gender, body size, or body shape. Scan acquisition times are in the range of 5 minutes versus 15–25 minutes for SPECT. The shorter acquisition times are ideal for acutely ill patients and those who find it difficult to lay still. A full rest/stress study using rubidium-82 can be completed in less than 35 minutes, compared to several hours for a rest/stress SPECT.[10,11] Radiation exposures are in the range of 2 mSv for a rest/stress PET MPI, about 15% of typical SPECT exposures and far below any levels known to connote risk for adverse effects.[12,13] The lower radiation is important because many patients with chronic CAD undergo a large number of radiation-associated diagnostic and therapeutic procedures during the course of their lifetime battle with CAD. Finally, most PET scanners include a computed tomography (CT) component. For MPI studies, the CT is usually set at low tube

current and voltage settings because the scans are used primarily for attenuation correction. These CT scans expose patients to only about 0.2 mSv of radiation but are adequate to visualize presence of coronary calcium and accurately estimate its Agatston score[14] while also permitting recognition of pericardial and pleural effusions, thoracic aortic aneurysms, chamber sizes, valvular calcifications, and pulmonary pathologies. Studies such as those of Dorbala et al.[15,16] have demonstrated independent and incremental improvements in risk stratification when PET-derived indices are considered in addition to myocardial perfusion patterns.

Table 1: Advantages of PET/CT Compared With Traditional SPECT for MPI

1. Higher diagnostic accuracy with pharmacologic stress
2. Consistent high image quality, independent of patient characteristics
3. Short acquisition times, reduced study times
4. Lower radiation exposure
5. Myocardial blood flow quantification
6. Improved risk stratification versus spatially relative MPI

A Unique Capability of PET MPI Compared With SPECT

A major limitation of SPECT is its dependency on differential perfusion of vascular territories in order to recognize functionally significant CAD. This so-called spatially relative interpretation of data opens the potential to under-detection of multivessel CAD. Especially with vasodilator stress, balanced flow reduction can go completely undiagnosed. PET is currently the only modality that permits routine quantification of myocardial blood flow, providing a patient-centric assessment of perfusion. Because myocardial blood flow is dependent on the functional integrity of the epicardial coronary arteries as well as the microvasculature, this measurement adds incrementally to perfusion defect analysis for risk stratification. In daily practice, myocardial blood flow quantification assures adequacy of vasodilator stress, improves recognition of multivessel CAD, rules out multivessel CAD, and in many instances results in different and more cost-effective management than would have occurred if this only depended on perfusion defect detection.[17-23]

The Expanding Applications of PET/CT for Cardiac Patients

In most cardiology programs, a PET/CT camera finds diverse uses beyond MPI. For example, even a relatively low-end device such as a PET/16-slice CT will be used for

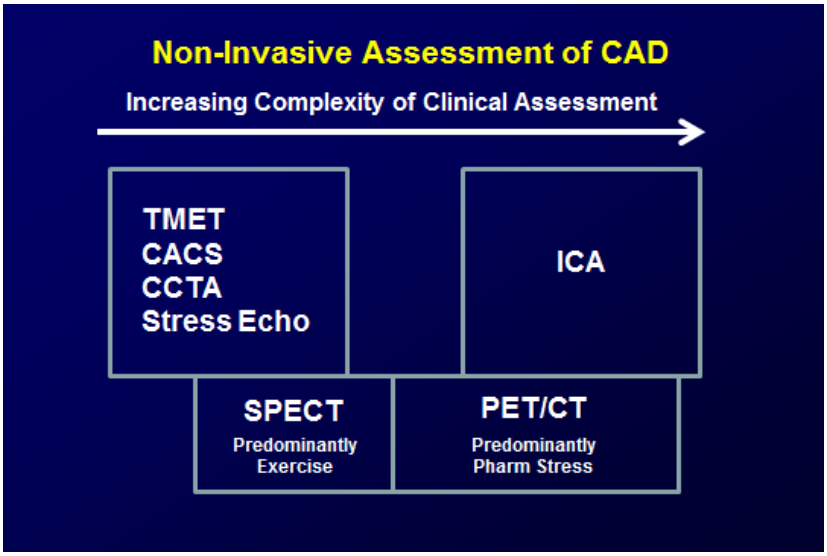
coronary artery calcium scoring, thoracic and abdominal aortic studies, run-off studies, left atrial imaging prior to atrial fibrillation ablation procedures, identification of cardiac sarcoidosis, and work-up of device infections. On a daily basis in our practice, PET/CT is used 5.5 times as often as a SPECT camera in the same testing unit.

A Modern-Day Clinical Cardiology Nuclear Laboratory

Design of a modern-day clinical nuclear laboratory needs to consider the diversity of patients needing nuclear cardiovascular imaging procedures. The paradigm of one camera and one protocol for all MPI needs has passed (Figure 1). An ideal laboratory today (Figure 2) will have a cardiac-dedicated SPECT camera for low-intermediate CAD-likelihood patients who need an MPI but can exercise. Such a device might be a solid-state camera with high sensitivity and high resolution, such that micro-dosages of tracer can be used. The same laboratory will have a PET/CT for more complicated patients as described above, predominantly those requiring vasodilator stress. Because of the high efficiency of the PET/CT, numerous other imaging applications will be possible each day. Some might argue that a SPECT camera in a cardiology department and a PET/CT in a radiology/nuclear medicine department could accomplish the same end-point as a revised nuclear cardiology laboratory that included both SPECT and a PET/CT. However, this would require duplication of stress-testing facilities and stress-test clinical teams and would impede ability of the imaging teams making on-the-fly decisions about best test after actually seeing the referred patient. An example might be recognizing on presentation that a patient admitted from the emergency department overnight had a caffeinated beverage 8 hours earlier and is unable to exercise. Only a PET study with blood flow quantification would be able to determine if a normal scan can be trusted or if the patient's A2a receptors did not respond to vasodilation stress. An alternative model is to have the PET/CT situated within the stress-test area that includes SPECT. The PET/CT can easily be assigned throughout the day, via either block scheduling or interspersed with cardiac indications, for oncologic or central nervous system studies.

Figure 2: The "new paradigm" in which newer SPECT protocols (solid-state cameras, advanced software options, stress-only imaging) optimized for low-intermediate risk patients share MPI referrals with PET/CT reserved for higher-risk, higher-complexity patients.

Economic Considerations



Imaging technology is expensive to purchase and maintain, and provision of PET radionuclides adds additional cost. However, PET/CT has a much greater potential than SPECT to add value and reduce the costs of care. Its rapid acquisition times and ability to complete studies in 30–35 minutes makes it ideal for improving the efficiency of diagnosing inpatients and those in chest pain units, facilitating timely discharges or same-day coronary angiograms depending on the findings. The costs are largely fixed, such that costs do not rise in proportion to volume as with SPECT. The radionuclide most commonly used, rubidium-82, is onsite and immediately available, as opposed to the technetium-99m-based SPECT tracers that from time of order may take an hour or more to arrive onsite. Greater diagnostic certainty by virtue of several markers not available from SPECT such as peak stress versus rest global and regional function, coronary calcium presence and extent, attenuation correction, scatter compensation, and blood flow quantification can all expedite correct diagnoses, limit unnecessary downstream testing, and provide an opportunity to inform both patients and referring physicians in a far more comprehensive way about the state of myocardial perfusion. As indicated, opportunities for shared usage are enabled by the rapid acquisition protocols; SPECT imaging takes longer and the rest/stress protocols are longer, making economically feasible sharing of a camera more challenging.

With all the Advantages, Why do Some Cardiology Programs Still not Have Access to Cardiac PET?

Few nuclear cardiologists today would argue that cardiac SPECT alone is sufficient to address the radionuclide imaging needs of a contemporary cardiology practice. In time, virtually all sizeable programs will need to have access to cardiac PET imaging. The impediments are financial, educational, and political. The economic barrier to entry is high for small practices but not so for larger programs, for which the high utilization for diverse purposes makes it more attractive than SPECT. Providers (technologists, physicians, and nurses) do need opportunities for both education and training because PET tracers and instrumentation differ significantly

from SPECT. PET scanners are widely available in the United States. In some settings, a PET scanner can and should be shared for oncologic and cardiac imaging. In others, the scanner might be dedicated for cardiac imaging. In my opinion, a cardiology program in an advanced center that does not have access to cardiac PET is most likely laboring under political constraints concerning inter-specialty cooperation that is standing in the way of best patient care. The reader is encouraged to browse two recent joint publications[10,11] of the American Society of Nuclear Cardiology and the Society of Nuclear Medicine and Molecular Imaging to understand the professional societal viewpoint on the role of PET in the contemporary care of cardiac patients.

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Keywords: *Constriction, Pathologic, Coronary Angiography, Coronary Artery Disease, Echocardiography, Electrocardiography, Electrons, Magnetic Resonance Imaging, Myocardial Perfusion Imaging, Physical Exertion, Positron-Emission Tomography, Rubidium, Sarcoidosis, Tomography, Emission-Computed, Single-Photon, Tomography, X-Ray Computed*

Last Updated August 2019