Contemporary nuclear cardiology practice: The Cleveland Clinic approach

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Received Aug 20, 2018; accepted Aug 20, 2018

doi:10.1007/s12350-018-1423-4

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Since the first nuclear cardiology studies were performed in the mid-1970s, clinical practice has evolved from a boutique operation performed at academic and tertiary medical centers to widespread use in community hospitals and outpatient offices. During my cardiology fellowship training, every weekday morning we met with Dr. Wackers and Zaret at 8 am sharp to read the prior day's studies. The day before a technologist had used a tri-lens Polaroid camera attached to a funnel which was placed over a workstation screen to make hardcopy of the 3-view planar Thallium-201 images at 3 different black and white intensities. First pass studies were processed by technologists and curves generated and printed. We sat in a circle and the hard copy was passed from fellow to fellow and eventually given to Wackers or Zaret who would daven over the images and proclaim the undisputed findings that were handwritten

on sheets which eventually made their way to patients chart and the requesting clinicians. When Dr. Iskandrian offered me a job in Philadelphia, he was doing mostly first pass studies and TI-201 and reading technologist prepared hard copy print. When I started my first job in 1983 at the Seattle Veterans Administration Hospital, Drs. Ritchie, Caldwell, and I would meet for lunch every Tuesday to read a weeks' worth of studies using a similar approach. A report eventually went out. Small volume. No computers. Technologists made decisions. No quality review. No hurry.

We have aged and nuclear cardiology has grown and matured. It has adapted to economic pressures, the development and implementation of Appropriate Use Criteria and the pending shift from volume to value. Despite the rapid volume increases and eventual slow decline, it continues to provide diagnostic and management value in the care of cardiac patients. In order to provide value in this new inpatient and outpatient environment, nuclear cardiology needs to standardize and implement operational efficiencies and meet and exceed patient and referring physician needs. This new approach, which some have labelled industrialization or assembly line production of nuclear cardiology services, is a far cry from the early days when I was starting out. Some may take offence to this approach and claim that the art/humanity is being taken out of the field. Unfortunately, this is the reality which we must address to remain of value and relevant.

At the Cleveland Clinic, nuclear cardiology practice has evolved and adapted into an efficient and high volume practice in order to accommodate the acquisition of hospitals, creation of outpatient family health centers and the purchase and incorporation of cardiology office practices. Although it would be flattering to take credit for proactively designing the program, the reality is that it was created and improvised as new situations arose and it took multiple iterations to get it to its current state.

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J Nucl Cardiol 2018;25:1491–7.

1071-3581/\$34.00

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The current state is not permanent and we continue to improvise and be flexible. Clearly this is a move away from performing 3 to 4 individualized studies per day, 3 to 4 days a week in an office or community hospital setting. Even though we perform a high volume of studies in complex, unique patients getting top of the line clinical and surgical management, it is not the setting to create a fabled academic career. Management of complex cases needs to be individualize and not always part of protocols. We are too overworked to get the necessary data or the time to make sense of it all.

The scope of the Cleveland Clinic program will first be defined and this will be followed by specifically addressing how we have handled the 8 areas listed in Table 1 that are the critical components to make such a program function successfully. This is not an infomercial for the Cleveland Clinic. We are not a good fit for all healthcare situations. We have economic and profit tradeoffs that are not efficient or cost effective, but put in place and subsidized to accommodate and support unique patient populations seen in the Cleveland Clinic practice setting.

SCOPE OF THE PROGRAM

At the Cleveland Clinic, nuclear cardiology is a joint operation between Nuclear Medicine, which is part of Radiology within the Imaging Institute, and the Cardiology Imaging Section within Cardiovascular Medicine which is part of the Heart and Vascular Institute. Nuclear Medicine services are provided at 27 different sites within 100 miles of Cleveland, using 44 gamma cameras and 7 PET/CT systems. All the cameras are shared and available for nuclear cardiology, PET and general nuclear medicine. Nuclear cardiology service is provided at 20 of the facility types listed in Table 1. In 2017, we performed nuclear cardiology studies in just over 17,500 patients. SPECT was used in 92% and 8% were PET studies. Fewer than 300 ERNA studies were performed and there are a growing number of Tc-99m Pyrophosphate studies for evaluation of amyloid.

Over a 12-year period Nuclear Medicine/Nuclear Cardiology has adding 8 new hospital sites, opened 6 family health centers, took over service at 3 acquired cardiology practices and placed a SPECT camera at an outpatient radiology imaging center. Outpatient studies can be scheduled at any of our facilities based on availability or patient convenience.

Facilities and Equipment

When new family health center facilities are designed, we equip with large field of view SPECT systems to provide general nuclear medicine and nuclear cardiology services that optimizes efficiency. At one site

with 7 cardiologists, we have installed a dedicated small field of view cardiac SPECT system. Equipment utilization is monitored and when the nuclear cardiology slots are not being filled, we limit service to fewer days or slots/day. At one site, we stopped doing nuclear cardiology all together. When existing hospitals or cardiology practices are acquired, we cannot immediately replace older existing gamma cameras. For hospitals, we have a replacement plan aimed at having at least 1 large field of view SPECT/CT system at each site. SPECT/CT is available at 6 of 10 hospitals, but due to demands from general nuclear medicine, use is restricted primarily in cardiac patients with large BMI. SPECT/CT is not available at Family Health Centers or cardiology offices. Given the need to perform both general nuclear medicine and nuclear cardiology and high cost, we have not purchased CZT systems for any of our sites.

Radiopharmaceuticals

SPECT At the Main campus, where volumes are high, we have an on-site Radiopharmacy receiving Tc-99m generators and purchasing bulk perfusion tracer kits for in-house radiolabeling. All other sites order unit doses from local commercial radiopharmacies.

PET Cardiac PET using Rb-82 is offered only at the Main Campus. Approximately 75% of cardiac PET studies are performed in combination with F-18 FDG for assessment of myocardial viability and a growing number of cardiac sarcoid evaluations. Even though we have an onsite cyclotron which operates as a joint commercial venture for F-18 FDG production, we continue to use Rb-82 which offers greater flexibility. When Rb-82 generators were not available, we used N-13 ammonia and found that logistics were difficult, operational efficiency decreased and there was significant interference with commercial FDG production. N-13 ammonia is produced only for patients with anomalous coronary arteries or myocardial bridges where dynamic exercise is required.

Since F-18 FDG is used so often, perfusion PET studies are performed on one PET/CT unit, with the Rb-82 generator in the room, and the F-18 FDG studies on a similar unit which also does whole body F-18 FDG oncology studies. Although we have 7 PET/CT systems that could potentially be used for cardiac PET studies, the high cost of Rb-82 generators and the high volume of F-18 FDG oncology studies on these units has restricted use to a single site. If a unit dose F-18 radiolabeled perfusion tracer were available, we would consider using it at our other PET/CT sites. Cardiologists at outside hospitals have requested and we performed viability assessment using PET F-18 FDG

Table 1. Components of Cleveland Clinic nuclear cardiology service

Facility types and equipment at 20 sites performing nuclear cardiology

Main campus-SPECT systems, SPECT/CT and PET/CT

9 Regional Hospitals-multiple SPECT systems, 6 SPECT/CT, 1 PET/CT and mobile PET/CT

6 Family Health Centers: 1 or 2 SPECT systems also used for general nuclear medicine

3 Cardiology practices with small field of view dedicated SPECT systems

Outpatient Radiology Imaging Center-1 SPECT system

Radiopharmaceuticals

Main campus

Central Radiopharmacy receiving Tc generators and formulating kits

Rb-82 generator

Onsite cyclotron for Commercial F-18 FDG and rare N-13 ammonia

All other sites get unit doses from local commercial Radiopharmacies

Radiation safety-across system under Quality & Patient Safety Institute

Information Technology-all sites

EPIC

Radiology Information System

PACs

Staffing

Physicians-4 nuclear medicine and 19 cardiology readers

Technologists

59 total in system covering PET, general nuclear medicine and cardiology

Cross coverage throughout system

PRN technologists for vacation, emergency and maternity leave

Ancillary staff: Radiopharmacist, medical physicist, dedicated IT staff

Standardization, interpretation and reporting

Identical online protocols across system with mandatory yearly review

Interpretation

All studies stored and available on RIS and PACs

Standardized report templates with pulldown menus

Semiquantitative scoring

Reports

Limit free text

Attempt normal/abnormal binary interpretation

Attempt mandatory risk assessment based on scoring and EF

Conclusions at top of report

Goes immediately to EHR and billing upon verification

Communication

Between sites

Telephone, cell phone, text messaging, paging, technologist notes in RIS

Referring clinicians

Pager

Mobile phones

Quality

All Laboratories individually Accreditation by ACR

Physician's Board certified, reading minimum case number and participate in continuous quality improvement meetings

EHR decision support system for appropriate use criteria

Monitor report turnaround time-90% of studies reported in < 1 h after completion

Peer review 2%-3% of all reports

and Tc-99m SPECT perfusion. However, due to issues with image quality associated with differences in tracer properties and matrix acquisition size, we only do viability assessment at Main Campus.

Radiation Safety

We have developed and monitor a radiation safety program that is implemented throughout the system and includes hospitals, outpatient facilities and office practice sites. The Quality & Patient Safety Institute in the Cleveland Clinic system has oversight and monitors our operation. Ohio is an agreement state and our practice has been reviewed multiple times and all sites within our system are compliant with both Ohio State and Federal regulations.

Information Technology

This is the critical component to have the system work properly. When these systems are down, we cannot read the studies. Identical hardware and software infrastructure is present at each site so that EPIC, Radiology Information System (RIS) and Picture Archiving and Communication System (PACS) systems can be installed to allow operation remotely from a central location. Each site is equipped with workstations and software so that studies can also be interpreted locally. This redundancy allows central reads when nuclear cardiologists are not available or during emergencies. We are able to operate these sites with just a single reader but continue to operate when they are not available. We have 2 full time IT staff in nuclear medicine that operate, monitor, and trouble shoot any problems that arise at the outside or central sites. In many ways, IT is the critical rate limiting step for operations at 20 different sites.

Staffing

Physicians This is an area where we have had to make the most compromise in operations and efficiency in order to handle “unique” situations arising from acquisitions and practice settings. All readers must meet board certification requirements and minimum yearly numbers as detailed later. At our central location, we have 2 full time readers who have minimal or no other clinical commitments on the days when they read nuclear cardiology. One reader supervises the stress lab, protocols studies, reads the stress ECGs, teaches fellows and reads cases performed at the Main Campus immediately upon completion.

At 4 of our Family Health Centers, we have 5 cardiologists interpreting studies. At the acquired

cardiology office practices, 4 qualified cardiologists continue to interpret studies performed on site. One hospital has 2 cardiologists interpreting inpatient and outpatient studies. At these predominately outpatient sites where referrals usually come from within the practice, studies are batched and read at the end of the day. These 11 readers have lower yearly volumes but still meet the minimum case number requirements.

Technologists We have 1 technologists dedicated to supporting the administrative needs of the 26 sites away from Main Campus. When new hospitals or outpatient sites are added, new technologists are brought to Main Campus for training and explanation of protocols, radiation safety, camera and workstation-specific software, RIS and PACs. For new sites, the dedicated technologist initially spends 5 days or longer on-site to address compatibility issues, application questions and camera-specific issues.

We have 59 technologists in the system with the majority staying at a single location on a regular basis. A limited number of technologists are cross trained on other site's equipment allowing us to operate at all times with often a single technologist at most sites with cross coverage provided from our pool for vacation and sick time. As a result, we seldom close down operations or cancel cases due to not having technologist coverage. We also have PRN technologists familiar with operations to staff during high volumes or emergencies.

Ancillary Staff We have a full time medical physicist and radiochemists based at the main campus who are involved in laboratory accreditation, equipment testing and operation of the onsite Radiopharmacy at main campus. We have 2 IT specialists as part of our operation and they interact directly with the Imaging Institute and Cleveland Clinic IT systems.

Standardization, Interpretation, and Reporting

Standardization. With so many sites, we have a wide variety of camera manufacturers, year of production, software vendors and versions and DICOM writing capabilities. In order to standardize the acquisition, processing and transmissions to a central site for interpretation and archiving, our physicist, technologists and IT staff identify, test and workout all the many small details required to have all sites consistently create high-quality images that can be reviewed locally or remotely for interpretation. Each site usually requires custom software creation and often hardware and software upgrades. Once this process is implemented, it is constantly monitored. When problems with acquisition, image transmission or display on physician interpretation workstations are identified, they are reported and

immediately reviewed and corrected by IT staff. Rapid response is required as clinical decisions are dependent on same day study interpretation. Raw and processed image files from all sites are achieved in a central PACs system and can be retrieved by all workstations for review.

Once these complex and time consuming details have been worked out, all 20 of our nuclear cardiology sites use the same dosing, acquisition, processing and display protocols that are available online. These protocols are reviewed, modified and signed off by interpreting physicians yearly.

Interpretation. RIS Each reader has access to the RIS system that shows patients scheduled for that day and when the studies have been completed and all processed images are available. This system is linked to scheduling, sending reports to EPIC, and submitting completed reports for billing. For readers covering multiple sites, often as many as 8 hospitals, the list is prioritized for interpretation by location and time of completion. Inpatients and ED patients are given priority and listed first followed by elective outpatient studies. For outpatients, if there were ischemic endpoints during stress or there is suspicion that a study will be high risk, these studies are given high priority and moved up on the list. This smart list prioritization allows earlier decisions on patients awaiting discharge, surgery, ED decisions or suspected of being high risk as a result of stress.

Clinical data. Each physician reader has access to EPIC to review outpatient visits, hospital inpatient and ED notes and prior diagnostic testing. Since some referring physicians are not part of the Cleveland Clinic staff and do not make EPIC entries, we have a standardized basic clinical questioner that is completed on every patient at each site. This information as well as radiotracer dose, time of injection, the use of attenuation correction and dose of pharmacologic stress agent is entered by technologists into the online report template. The sheets are also scanned and available in the RIS system. The results of exercise or pharmacologic stress are entered by the exercise staff into the report template.

Physician review and interpretation. When the interpreting physician opens the completed study, images launch on one monitor in a standardized third-party nuclear cardiology program and the report template with the entered data from the questioner and exercise results opens in a second monitor.

The images have been processed by the technologist at the site of acquisition, but the physician can check and modify the orientation, identify the mitral valve plane and define limits to exclude liver or GI activity if present. With these corrections, the images are reprocessed. Ejection fraction and transient ischemic dilation ratios can be

reviewed and adjusted as needed. Rotating projection images are reviewed for quality assessment. Static and gated images are aligned between rest and stress and compared. When available, attenuation corrected images can be compared to non-corrected images. The processed images are compared to gender matched normal files and 17-segment scoring generated. These scores are adjusted by the reader. The reviewed and modified final volumes, EF, 17-segment scoring and TID are exported to the report program. At each step of the process, the reader enters into the report template indications, study quality observations and the final interpretation.

Although the extent of physician intervention varies between readers, the majority of interpreters actively process their own images. As part of our Continuous Quality Improvement program for nuclear cardiology, we have in person and video online quarterly staff meetings for all readers where studies are reviewed and discussed to achieve consensus as much as possible on quality and interpretation. Echocardiography and cardiac CT and MR readers have a similar program. Participation in a minimum of 3 meetings is required for continued privileges in nuclear cardiology.

Reporting All of our reports use separate templates for cardiac SPECT, PET, amyloid and sarcoid PET studies. These templates have pull down menu options for each variable required. These have been modified overtime through consensus amongst readers and mandated changes in report requirements.

Every attempt is made to avoid ambiguous and unclear final nuclear cardiology reports. The use of report templates and placing limits on free text is an attempt to force the readers to reach a normal or abnormal binary interpretation. In rare cases due to technical issues, studies can be called uninterpretable. Unfortunately, we still allow the use of free text fields in most pull down menu options and free text can be added to the conclusion.

The following type of interpretation is not acceptable: “Fixed rest and stress inferior wall perfusion defect with normal motion on gated study. Inferior wall infarction cannot be excluded and further testing is recommended.” If attenuation correction is not available, we encourage every reader to look in EPIC to see if there is a history of infarction. Does the ECG have inferior q-waves? Is wall motion normal on a recent echocardiogram? Is there a prior SPECT or PET study? Has the patient had a left heart catheterization? Searching for this information is difficult and takes time but with the electronic health record and features like Care Everywhere that searches records from other hospitals it is available. It just take time and effort.

We have modified our reports and put the conclusion at the top of the report as this is the first and usually

the only item most referring healthcare providers' review. This saves them from having to scroll to the bottom. If the referring healthcare provider needs to be contacted to report abnormal findings, this is documented in the report with a date and time stamp. Once the report is verified, it goes immediately into EPIC and is sent for billing.

Communication. Site communication between technologists and readers during study protocoling and acquisition is critical for quality. Equally as important and often more difficult is the interpreting nuclear cardiologists reaching referring clinicians.

For the technologist at the Family Health Centers and cardiology offices, the readers maybe on site and can be immediately reached. When the reader is at a remote location, technologists have several options when needing to reach a reader with questions. There is a posted hardcopy and online schedule at each site listing the reading physician on a given day. Technologist can contact them on a land line, paging, an internal RIS text messaging system, via technologist's notes in RIS and more frequently via mobile phones. The Cleveland Clinic has issued and posts mobile phone numbers for all healthcare providers and there is an option to use the phone in place of a pager. By these measures, technologist can get answers on protocols, have images reviewed before patient leaves the area or any other issues that may arise. The reader does not supervise the stress portion of the studies at remote sites so questions of patient safety or complications are handled at the site. If the studies need to be reprocessed or reacquired, the reader calls the sites directly or uses the text messaging system to make a request.

Communicating with the healthcare provider ordering studies is always difficult and multiplied in complexity when reading from many sites with providers who may not be part of the Cleveland Clinic Staff. If they are staff we use offices, EPCI, paging numbers, email and the best is the mobile phone number. Reaching non-Staff healthcare providers is even more difficult. Hospital records are frequently incomplete or missing. Resorting to a search engine is often the best way to get contact information.

Unfortunately, we sometimes reach them only to find out they are off service and another physician is managing the patient. Or they are on vacation. Or they are in the operating room. Catheterization laboratory. Anywhere. This is the most difficult, time consuming and frustrating part of the process. Through experience, once a frequent user of nuclear cardiology, staff or non-staff is reached, every attempt is made to get a mobile phone number and keeping it updated and available. This means that sometimes you reach someone on

vacation in Mexico but at least you get a better phone number for the covering physician.

Quality. With so many operating variables, it is critical to have measures in place to guarantee study quality. These are listing in item 8 of Table 1.

Laboratory Accreditation All of our laboratories and the cameras are accredited by the American College of Radiology every 3 years. Our medical physicist and a technologist do all the equipment testing that is required for accreditation and continuously monitor scheduled quality performance measures from each site. If the on-site technologist or readers identify issues, the technologist or physicist deal with them immediately

Physician Credentialing All readers are board certified by the Certification Board of Nuclear Cardiology, the American Board of Nuclear Medicine or the American Board of Radiology. They are required to read a minimum of 300 nuclear cardiology cases yearly. In addition, attendance or online review of 3 Continuous Quality Improvement sessions yearly is mandatory. There is great variability in the number of cases read yearly by individual readers. Readers at Main Campus and those reading from outside hospitals have higher numbers than individuals at family health centers or office practices. It would be more efficient to limit the number of readers, but due to individual job satisfaction needs, billing concerns and existing arrangements, we continue with 23 readers.

Decision Support System We are in the process of implementing across all nuclear cardiology and nuclear medicine sites in our system the ACR Select program that uses the American College of Cardiology Appropriate Use Criteria for nuclear cardiology. This system is very complex and it is being customized for our specific practice setting and is currently in use as part of EPIC ordering. More work will be required on this system prior to full implementation in 2020.

Report Turn Around Time For each patient, our RIS system records a time stamp from each camera when study acquisition is complete. A separate time stamp is recorded when a study is verified in the reporting system and sent to EPIC and available by the clinical services. A quality measure for nuclear medicine is that 90% of all studies are reported within 6 hours of completion. There are individual requirements for inpatients and ED patients that are much shorter. In nuclear cardiology for the entire system and all patients, 80% of studies are verified and available in EPIC within 1 hour of completion. There is considerable variability between physicians. Readers at hospitals achieve very short completion times. Readers at Family Practice Centers and cardiology office, who batch studies to the end of the day, having longer times. These parameters are monitored quarterly.

Peer Review As part of the Nuclear Medicine peer review process, we have a separate independent blinded read of 2-3% of all studies performed. Since nuclear cardiology is part of this process the total percentage of studies reviewed is less. We are in the process of separately identifying nuclear cardiology cases and instituting separate peer review to achieve 2-3% for nuclear cardiology studies.

SO... WHERE DO WE GO?

Since I trained in Nuclear Cardiology, there have been tremendous changes in radiotracers, cameras, computers, and the demands placed on studies. We were small and could meet the clinical demands. With growth, there has been increasing demand on appropriateness of studies, documentation of quality and value, efficiency and cost effectiveness. These demands can be met by small operations but larger systems maybe a

better option. How we operate at the Cleveland Clinic has evolved to meet operational needs and was not prospectively designed. Does our system work flawlessly? No. Is it free of departmental turf issues? No. Can it work in any environment? No. Is it modular with easy addition of new units? Yes. Can it handle increased volume? Yes. Given the continued efforts and improvement in the identified problem areas and the ability to readily implement the infrastructure in hospital and outpatient settings, there are many positives to consolidation of nuclear cardiology services.

Industrial nuclear cardiology is not all bad. I wonder what Zaret, Wackers, Iskandrian, Ritchie, and Caldwell would think of this approach? Would they buy into the Cleveland Clinic approach or prefer the boutique practice of Nuclear Cardiology? Could they handle the high volume? Would they want to?