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Publication Date

2018-09-27

Peer reviewed

CORE CURRICULUM

A quality framework for the role of invasive, non-interventional cardiologists in the present-day cardiac catheterization laboratory: A multidisciplinary SCAI/HFSA expert consensus statement

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Abstract

The present-day cardiac catheterization laboratory (CCL) is home to varied practitioners who perform both diagnostic, interventional, and complex invasive procedures. Invasive, non-interventional cardiologists are performing a significant proportion of the work as the CCL environment has evolved. This not only includes those who perform diagnostic-only cardiac catheterization but also heart failure specialists who may be involved in hemodynamic assessment and in mechanical circulatory support and pulmonary hypertension specialists and transplant cardiologists. As such, the training background of those who work in the CCL is varied. While most quality metrics in the CCL are directed towards evaluation of patients who undergo traditional interventional procedures, there has not been a focus upon providing these invasive, noninterventional cardiologists, hospital/CCL administrators, and CCL directors a platform for quality metrics. This document focuses on benchmarking quality for the invasive, noninterventional practice, providing this physician community with guidance towards a patient-centered approach to care, and offering tools to the invasive, noninterventionalists to help their professional growth. This consensus statement aims to establish a foundation upon which the invasive, noninterventional cardiologists can thrive in the CCL environment and work collaboratively with their interventional colleagues while ensuring that the highest quality of care is being delivered to all patients.

KEYWORDS

cardiac catheterization laboratory, invasive, non-interventional, quality

1 | INTRODUCTION

The breadth of practice of invasive cardiology has grown considerably in recent years. In the era prior to percutaneous coronary intervention (PCI), the cardiac catheterization laboratory (CCL) was primarily a place for hemodynamic examination and coronary angiography. As PCI gained importance in the CCL, the focus turned towards interventional procedures; as such, there has been a focus upon developing quality metrics and necessary guidance for interventional cardiologists. However, the CCL continues to be a place where many practitioners perform invasive, diagnostic procedures; but, not interventional procedures. These physicians are an important part of the CCL team and perform diagnostic procedures such as coronary angiography and hemodynamic evaluations. While most quality metrics in the CCL are directed towards evaluation of patients who undergo interventional procedures, there has not been a focus upon providing these invasive, noninterventional cardiologists, hospital/CCL administrators, and CCL directors a platform for: (1) benchmarking quality for the invasive, noninterventional practice, (2) providing this physician community with guidance towards a patient-centered approach to care, and (3) offering tools to the invasive, noninterventionalists to help their professional growth. This consensus statement aims to establish a foundation upon which the invasive, noninterventional cardiologists can thrive in the CCL environment and work collaboratively with their interventional colleagues while ensuring that the highest quality of care is being delivered to all patients.

2 | SCOPE OF DOCUMENT

There is clearly a niche in the CCL for proceduralists who evaluate the cardiovascular system through the use of invasive means, but who are not “interventional” cardiologists. Specifically, these “invasive cardiologists” do not perform therapeutic interventional procedures including coronary, peripheral vascular, or structural. There is now considerable overlap between what is purely a diagnostic, and what is considered a therapeutic modality in the CCL. This is particularly

evident for those procedures where the diagnostic modality requires instrumentation of the cardiovascular circulation and/or placing a device [e.g., fractional flow reserve (FFR) measurement or intravascular ultrasound (IVUS) imaging]. The scope of this document is to provide guidance and support for invasive noninterventional cardiologists performing these procedures and provide a framework for how this might be done in a collaborative and safe way with back-up from interventional cardiologists when necessary. There are three main types of invasive noninterventional cardiologists that this document addresses: (1) general cardiologists, (2) heart failure/pulmonary hypertension specialists, and (3) interventionalists who no longer perform interventions but continue to perform invasive diagnostic procedures. Table 1 outlines the major areas of concern and why this document is important and offers proposed solutions. The document also serves as an important guide for hospital/CCL administrators and CCL directors to develop a patient-centered framework around quality assurance for procedures performed by these subsets of cardiologists. The writing committee felt that including trained structural or peripheral specialists/proceduralists who do not perform coronary interventions is beyond the scope of this document. This document reveals areas where this writing committee feels there could be additional clarity regarding training and maintenance of certification standards for various procedures performed in the CCL.

2.1 | General cardiologists

As a part of training in general cardiology, all cardiologists are expected to understand the use of, integrate the findings from, and, in most cases, perform, and interpret diagnostic cardiac catheterizations in patients with coronary, valvular, and pericardial disease.^{1,2} The writing committee recognizes that the training and completion of a general cardiology fellowship should be adequate to allow for safe and successful performance of a wide range of invasive diagnostic procedures, as well as certain therapeutic procedures (e.g., pericardiocentesis, temporary pacemaker placement).² Some cardiologists, trained in diagnostic procedures in the CCL, may continue to perform those procedures when needed as part of their general cardiology practice. While recognizing that at times additional

TABLE 1 Scope of this document with summary of areas addressed and proposed solutions

Topic	Areas of Concern	Proposed Solutions
Scope of practice for general cardiologist or heart failure or interventional cardiologists who no longer perform PCI	<ul style="list-style-type: none"> Heterogeneous spectrum of training and competency in various procedures (i.e., pericardiocentesis, endomyocardial biopsy, FFR, IVUS) with inconsistent oversight in varying practice settings Procedures may be performed without formal interventional training with variable ability to address procedural complications (i.e., coronary dissection) 	<ul style="list-style-type: none"> Frequent, ongoing assessment of operator volume, quality of angiographic images and procedural data collection/analysis, acute procedural success, intra-procedural complication rates, and patient outcomes in each institution in order to maintain privileges for the operator and to maintain a high standard of procedural quality and patient care Quality assurance meetings to review complications and case volume to provide ongoing feedback and educational opportunities for both invasive noninterventionalists and interventionalists Completion of appropriate training to perform specified procedures and the ability to treat potential related life-threatening complications

TABLE 2 Selected knowledge elements for placing hemodynamic support or monitoring devices

<ul style="list-style-type: none"> Understanding appropriate indications for use of MCS devices <ul style="list-style-type: none"> Multidisciplinary “Heart Team” is strongly encouraged to help evaluate goals of care
<ul style="list-style-type: none"> Ability to properly assess and interpret invasive hemodynamic data
<ul style="list-style-type: none"> Technical Competencies (Some competencies apply to only specific MCS devices) <ul style="list-style-type: none"> Femoral vascular access <ul style="list-style-type: none"> Large bore sheaths Trans-septal techniques <ul style="list-style-type: none"> Placement of large intravascular catheters Use of vascular access closure techniques
<ul style="list-style-type: none"> Understanding of contraindications to MCS devices
<ul style="list-style-type: none"> Ability to treat potential related life-threatening complications

invasive coronary evaluation may be requested as part of a diagnostic catheterization, the writing committee does not support general cardiologists performing procedures, like FFR and IVUS that require instrumentation of the coronary arteries with guide wires or devices—a position consistent with current COCATS and ACGME standards. This is largely because of the recognition that while these procedures are generally safe, complications can occur, and are best treated by those specifically trained in coronary interventional procedures.

2.2 | Congestive heart failure/cardiac transplantation/pulmonary hypertension specialists

A critical facet of the evaluation and management of patients with acutely decompensated systolic heart failure or cardiogenic shock or pulmonary hypertension is a thorough hemodynamic assessment including right and/or left heart catheterization and/or endomyocardial biopsy in post-transplant patients. Depending on the clinical circumstance, evaluation of the coronary anatomy, patency of bypass grafts, or assessment of valvular lesions may be necessary. There is an increasing role for acute mechanical circulatory support (MCS) for the stabilization and management of these critically ill patients.^{3,4} Available MCS devices include the intra-aortic balloon pump, various percutaneous ventricular assist devices, which support left and/or right ventricular cardiac output, and veno-arterial extracorporeal membrane oxygenation (e.g., ECMO) support.⁵ Additional procedures include elective placement of permanent invasive hemodynamic monitoring devices (e.g., CardioMEMS™).⁶ Whenever practitioners do these procedures, she/he should at least be knowledgeable of the technical issues listed in Table 2 that may pertain to particular devices even if they do not have personal technical know-how. Some of the competencies listed in Table 2 pertain to only specific devices.

Each device has a unique set of cognitive and technical skills required for proficiency. The writing committee acknowledges that training and procedural requirements are often defined by the institution including recommendations forwarded to the local hospital credentialing committees by the CCL director and often by industry with explicit training programs and proctorship. Furthermore, the writing committee acknowledges the current reality that there are individual practitioners who are performing these procedures without having

completed an advanced heart failure/transplant or interventional fellowship training; current training standards are not specific enough to address these issues. While these individuals may be “grandfathered” and continue their practice by their local institutions, the writing committee strongly recommends that clear future standards and ongoing quality assessment be developed to guide noninterventional cardiologists performing these procedures.

In addition, some transplant cardiologists may perform coronary angiography for their post-transplant patients. There are nuances to these cases due to the rotation of the heart when transplantation occurs and often concomitant renal dysfunction, which demands parsimony with contrast administration. Advanced imaging techniques like IVUS and optical coherence tomography (OCT) may require additional training and oversight since they involve placement/manipulation of intracoronary guide wires/devices. The writing committee recommends that clear training standards be defined for practitioners wanting to perform these procedures if they have not completed a formal interventional training.

2.3 | Interventional cardiologists who no longer perform therapeutic interventional procedures

This third group includes cardiologists who have been trained in interventional cardiology, but who have retired those specific skill sets and are now performing only diagnostic and invasive procedures. They have technical knowledge and experience with PCI and this background may be helpful, but may become outdated over time without focused continuing medical education (CME) and maintenance of proficiency. Additionally, these cardiologists may still be performing intracoronary diagnostic procedures such as IVUS, FFR, coronary flow reserve, or OCT, historically judged to be within the proficiency domain of interventional cardiology.

3 | TRAINING STANDARDS AND MAINTENANCE OF PROFICIENCY

COCATS 4 Task Force 10 is the most recent document for cardiology fellowship training in cardiac catheterization and provides the foundation for the criteria and standards needed for a trainee during cardiology fellowship.²

TABLE 3 Areas of concern and proposed solutions for issues related to training and maintenance of proficiency

Topic	Areas of Concern	Proposed Solutions
Maintenance of proficiency	<ul style="list-style-type: none"> Lack of consensus of optimal caseload to maintain procedural skill competency after training Varying patient volume per operator without oversight of competency may result in more procedural complications and suboptimal patient care 	<ul style="list-style-type: none"> Routine assessment of appropriate use, performance and interpretation for each procedure should be monitored Implementation of quality assurance program Assurance of quality of diagnostic angiograms Mandated participation in educational forums (i.e., M&M conference, relevant CME)

3.1 | COCATS 4 task force 10 and training standards

As defined by COCATS 4 Task Force 10, there are three incremental levels of proficiency in cardiac catheterization.² It is important to note that regardless of the level of training achieved, the trainee needs to show proficiency in patient care and procedural skills, medical knowledge, systems-based practice, practice-based learning and improvement, professionalism, and interpersonal and communication skills.⁷

With level I training, invasive procedures should be limited to cardiac care unit procedures with venous and arterial access and to right heart catheterizations.² To practice as an invasive, non-interventional cardiologist after cardiology fellowship, level II training must be completed.² Completion of level III training qualifies the cardiologist to perform PCI, however additional training is needed to perform peripheral, carotid, and/or structural heart interventions (i.e., valves, congenital heart) and insertion of MCS devices.^{2,8} With regard to cardiologists who have been credentialed and who have been performing these procedures without completing a formal training program, the writing committee agrees that they can continue to perform these procedures as long as they have demonstrated a track record of high quality and low complication rates, and oversight mechanisms are in place for quality assurance. The writing committee recognizes that the COCATS 4 Task Force requirements do not encompass all procedures performed by all types of cardiologists; therefore, there may be some individual and institutional variation. Ultimately, it is the responsibility of every institution's CCL Director and the credentialing committee to develop a plan to evaluate and determine competency based on prior training, case volume, procedural performance, and interpretation of results while always functioning within the published training standard requirements.

3.2 | Maintenance of procedural proficiency

There is a lack of consensus on the caseload needed to maintain procedural skill competency after completion of training.⁹ Data suggest that operator and hospital volumes both play a role in PCI outcomes, although there are no data on the volume-outcome relationship for diagnostic cardiac catheterization (a lower risk procedure) or other

invasive non-PCI procedures.^{10,11} The writing committee proposes that the CCL director with a quality oversight committee (QOC) should determine competency of the proceduralist by performing routine assessment of appropriate use, performance, and interpretation for each procedure, and an assessment by a quality assurance program, outlined later in this document. Routine participation in educational forums including morbidity and mortality (M&M) conference, and relevant CME should be required. These measures will allow the acquisition and maintenance of knowledge and continued competency in performing the related procedures.

There has been an increase in utilization of devices today for the management of heart failure such as biventricular (BiV) pacemakers, implantable cardioverter defibrillators (ICD), implantable hemodynamic monitoring systems, MCS, IVUS for the assessment of coronary arteries postcardiac transplantation, and others.¹² For these reasons, interventional heart failure (IHF) is an emerging field focused on device-based approaches for the treatment of advanced heart failure. Guidance regarding the scope of this field and the training required is recently being introduced and will have significant implications in the CCL.^{13,14} While delving into the details of the IHF pathway are beyond the scope of this document, this training requires an additional year of advanced heart failure training. Trainees who complete IHF training are generally board-eligible to take the advanced heart failure/transplant medicine Board Examination. The IHF training pathway focuses on invasive approaches for patients with advanced heart failure.¹⁵ For operators interested in electrophysiology procedures, the curriculum requirements for training on BiV and ICD devices must be completed and should comply with COCATS 4 Task Force 11 (Training in Arrhythmia Diagnosis and Management, Cardiac Pacing, and Electrophysiology).¹⁶

The writing committee recognizes that there is evolution in the various training pathways and requirements for physicians to perform certain procedures in the CCL environment. For instance, heart failure specialists who have received training outside of formal fellowship training programs might be performing FFR, IVUS, or insertion of acute MCS devices at certain institutions. As such, it is imperative for the CCL Director, in collaboration with both the Medical and Surgical

TABLE 4 Areas of concern and proposed solutions for issues related quality oversight

Topic	Areas of Concern	Proposed Solutions
Quality Oversight	<ul style="list-style-type: none"> Institution-dependent on degree of involvement of QOC in quality improvement efforts in CCL 	<ul style="list-style-type: none"> Adhere to standards as listed in SCAI or other professional society position papers All physicians who perform invasive procedures should undergo periodic review of randomly selected patient cases in regards to pre-, post-procedural planning, and clinical decision making All adverse events and procedural complications should be reviewed by QOC and/or a M&M conference

Directors of the Advanced Heart Failure/Transplant program, to formalize a plan based on the local institutional environment to determine and continuously examine competency so that only physicians with the proper training, knowledge, and experience are performing these procedures. Table 3 outlines the areas of concern and proposed solutions for issues related to training and maintenance of proficiency; however, as stated earlier, the writing committee recommends that appropriate professional societies establish the training standards for these procedures when performed by cardiologists who have not completed a formal interventional training.

4 | QUALITY OVERSIGHT

As stated in earlier SCAI position papers, it is imperative that CCL implement a continuous quality improvement (CQI) program to monitor process and performance within the CCL.¹⁷ The CCL Director, working in concert with an established QOC, typically oversees the CQI program. The composition of the oversight committee is left to the discretion of individual institutions, but usually includes the Director of the CCL, physician(s) who work within the CCL, nursing and/or ancillary medical personnel affiliated with the CCL, and an administrator. The QOC should be composed of individuals that represent the spectrum of the entire CCL including diagnostic-only physicians, interventional cardiologists, and invasive heart failure/pulmonary hypertension specialists. The primary goal of the QOC is to ensure patient safety in the CCL by comparing site-specific data to benchmark metrics, identifying deficiencies, and establishing an appropriate framework for continuous process improvement and remediation of deficiencies.^{18,19} Table 4 summarizes the main goals of this section of the document.

The assessment of individual physician performance is a responsibility of the QOC. Historically, the quality assurance (QA) evaluation of an individual operator has included a periodic review of randomly selected interventional cases, and a detailed appraisal of all procedures associated with a M&M endpoint. The standards for assessing physician competence in PCI have been established, and the same general framework should be applied to assessing the competency of invasive, noninterventional physicians performing procedures within the CCL.^{17,20}

All physicians performing diagnostic coronary angiography, irrespective of interventional credentials, should undergo a periodic review of randomly selected diagnostic catheterization procedures. This review should include variables ranging from preprocedural planning to postprocedural clinical decision-making. Such a review should be performed quarterly.^{17,20} The assessment of each case begins with preprocedural variables such as appropriate indication and consent for the procedure, proper adjustment of medications (i.e., anticoagulants, metformin), proper medical therapy prior to procedure (antiplatelet, antianginal, and statins), choice of vascular access, and hydration for prevention of renal insufficiency when appropriate.²¹ The procedural technique, hemodynamic data, and images should be reviewed to ensure that a high quality study was performed while maximizing patient safety. Finally, the review should assess whether the diagnostic images were interpreted correctly, and determine if appropriate clinical decisions were made based on the data acquired at the time of the procedure.

In addition to random review of diagnostic procedures for QA purposes, all diagnostic angiographic procedures with a post-procedure complication should be reviewed by the QOC. These events include, but are not limited to, death, myocardial infarction, stroke, or transient ischemic attack (TIA), coronary dissection or perforation, coronary embolism (air or thrombus), ventricular arrhythmias, anaphylaxis, access site complications (i.e., retroperitoneal hematoma, pseudoaneurysm formation), and over-sedation requiring reversal agents.²⁰ In particular, the QOC should evaluate whether the complication was avoidable, recognized promptly, treated appropriately and whether an interventional cardiologist (or surgical subspecialty) was consulted or should have been consulted. Such information is critical for appropriate process improvement to assure the highest level of patient safety. In addition, if procedural technique results in the use of excessive contrast administration or radiation exposure, the QOC should review these cases to determine if these issues could have been avoided. To better facilitate cross-discipline discussion of QA measures, it is reasonable to include a noninterventional physician or IHF specialist on the QOC. When any invasive, noninterventional physician performs intracoronary procedures, the writing committee recommends that an interventional cardiologist should be readily

TABLE 5 Important areas of concern and proposed solutions related to preprocedural care of patients

Topic	Areas of Concern	Proposed Solutions
Preprocedural patient care issues	<ul style="list-style-type: none"> • Appropriate communication with interventional cardiologist during ad hoc PCI regarding contraindications to long-term DAPT or optimal antiplatelet regimen • Lack of communication in discussion of indications for PCI may lead to inappropriate interventions or with inappropriate stent type • CCL flow may be detrimentally affected with a "two operator" case if involved interventionalist has other ongoing cases • Miscommunication and/or inadequate informed consent to patients/families about disposition and interventional strategies 	<ul style="list-style-type: none"> • Documentation of AUC criteria for indication for coronary angiography (i.e., severity of angina, stress testing findings, medical regimen, etc.) as well as for PCI if indicated on diagnostic and interventional report • Appropriate notification and assignment of case to interventionalist in the event of procedural complications, or consideration of ad hoc PCI before with discussion of clinical details of case with any pharmacologic contraindications, anatomical concerns, and discussion of stent choice (i.e., drug eluting stent versus bare metal stent versus bioresorbable vascular scaffold) • Appropriate informed consent given to patient before procedure regarding all foreseeable interventional strategies if ad hoc PCI is anticipated • Interventionalist to meet with patient if at all possible before the case

TABLE 6 Preprocedural evaluation for invasive noninterventionalists

• Adequate Joint Commission-required documentation within 24 hr of procedure availability
• Documentation of AUC classification for diagnostic catheterization and intervention
◦ Specific documentation of Canadian Cardiovascular Society/CCS symptom class
◦ Specific documentation of antianginal medications
◦ Specific documentation of risk (low/intermediate/high) of noninvasive testing
• Assurance that Oral anticoagulants (Vitamin K antagonists and novel anticoagulants), phosphodiesterase 5 inhibitors, and metformin (for those with reduced GFR) have not been administered within the prespecified time prior to the procedure, unless clinical reasons dictate otherwise
• Knowledge of parenteral heparin (unfractionated or low-molecular weight) last dosage
• Assurance that ASA/P2Y12 receptor inhibitors/statins administered and timing
• Knowledge of patient specific absolute/relative contraindications to prolonged DAPT that might influence choice of stent (bare metal stent vs. drug eluting stent vs. bioresorbable vascular scaffold)
• Knowledge of pharmacokinetics of P2Y12 receptor inhibitors and contraindications for prasugrel (prior TIA/CVA), ticagrelor (prior CNS hemorrhage, liver disease)
• Not administering systemic anticoagulation with either heparin or direct thrombin inhibitors until interventionalist has reviewed the case and agreed to proceed with ad hoc PCI unless required for IVUS or FFR procedures
• Preprocedural assessment of PCI risk (contrast induced nephropathy, bleeding, mortality) and anticipated AUC (absent the final element of intraprocedural angiographic data) for PCI/revascularization
• Direct communication between the interventionalist and noninvasive physician regarding all the items to mitigate errors of commission

available, ideally on site, to assist with any potential coronary complications.

Although most CCL that perform PCI have QA processes in place, they often focus exclusively on PCI performance measures, and do not include a review of cases by invasive, noninterventional cardiologists performing diagnostic procedures in the CCL. Invasive noninterventional physicians should be included in the QOC and undergo similar QA review, in parallel with their interventional peers. Likewise, any adverse events occurring during diagnostic catheterization should be reviewed using the same M&M process applied to adverse PCI outcomes. A full description of an effective M&M process is described in the 2016 SCAI Cath Lab Best Practices Document.¹⁷ The QA process, when implemented effectively, affords an excellent opportunity to allow for ongoing physician education on topics related to diagnostic cardiac catheterization, endomyocardial biopsy, hemodynamic support devices, and new techniques.

5 | PATIENT CARE RELATED TOPICS

5.1 | Preprocedural patient-care issues

There are several preprocedural patient care issues that must be recognized when there is an interaction between an invasive noninterventional and an interventionalist, outlined in Table 5.

It is the responsibility of the invasive noninterventional to adequately document symptoms, specific antianginal medications, and other pharmacotherapy of all patients being brought to the CCL for diagnostic procedures. The invasive noninterventional physician should estimate and document the risk/benefit ratio of proceeding with the invasive evaluation and potential interventional procedure based on comorbidities and functional testing. The nuances of these points and other important preprocedural considerations are provided in Table 6. The SCAI PCI risk calculator and SCAI AUC (for both diagnostic catheterization and coronary revascularization) applications are instrumental in decision-making in the ad hoc setting, and are

available on the SCAI website at www.scai.org for download. These tools should be used to standardize the approach.

5.1.1 | Cath lab operations and efficiency

While it may be more efficient for large CCLs with multiple rooms to have cases with a low likelihood of PCI or diagnostic only cases (e.g., right heart catheterizations) triaged to a specific operator, there is potential for schedule disruption and inefficiency involving “two operator” cases, especially in smaller CCLs. This may contribute to variable costs for the institution and introduce delays for patients and paradoxically decrease capacity.

The invasive noninterventional proceduralist needs to assure that the selected interventionalist has the appropriate skill set for the specific task at hand, particularly in complex cases, and strongly consider deferring an ad hoc procedure until a staged later date or possibly later the same day if that is not the case.²² It is important to minimize the duration and consider the potential consequences of sheath dwell time in such “off the table, same day PCI” cases. Systemic anticoagulation should be administered and in-dwelling sheaths should have pressure lines connected to them in order to minimize complications due to prolonged duration of sheath dwell times. The writing committee recommends that a second interim “time-out”/verbal sign-out between the two involved operators at the time of interventional procedure is critical to maintaining overall CCL quality and patient safety. This is consistent with the The Joint Commission requirement of a formal time-out prior to any procedure.¹⁷ Triaging unassigned patients with a high likelihood of PCI to an interventional operator rather than a noninterventional operator may improve patient flow by minimizing the number of “off the table, same day PCI” cases.

5.1.2 | Process for informed consent and effective communication with patient and family

Informed consent is a critically important issue in cases involving two operators and should follow the principles outlined in the SCAI Code of Ethics (<http://www.scai.org/codeofethics/default.aspx>). Ideally, the designated potential interventional physician should meet with the

TABLE 7 Considerations and proposed solutions related to vascular access

Topic	Areas of Concern	Proposed Solutions
Vascular access	<ul style="list-style-type: none"> • Unfamiliarity with newer vascular access techniques (i.e., radial, brachial) and vascular closure devices • Vascular access for ad hoc PCI may differ from initial vascular access depending on interventional operator preference (i.e., interventionalist prefers femoral access) 	<ul style="list-style-type: none"> • Discussion of case with assigned interventionalist including vascular access preferences • Vascular access techniques and closure devices should be subject of bidirectional feedback between noninterventionalist/interventionalists and at QOC • Educational training sessions and mandated proctoring by industry/experienced operators in the CCL should occur to ensure appropriate training in newer access techniques and closure devices.

patient and family members prior to the procedure. When this is not possible, the invasive noninterventionalist is obligated to include in the consent process that another individual with interventional training may be involved in their care and discuss the relevant issues regarding PCI. The writing committee emphasizes the fact that ad hoc PCI is not a fait accompli, and that several situations may preclude this in the general interest of patient safety and shared decision making.^{17,22}

5.2 | Procedural patient-care issues

Specific issues may arise in the care of patients by invasive noninterventionalists (Table 7). Vascular access and closure remain fundamental aspects of the cardiac catheterization procedure. Working in the contemporary CCL requires familiarity with radial access, large bore vascular access, and an array of vascular closure devices.²³⁻²⁵

Ideally, the invasive noninterventional and the interventional operator should discuss the case to decide the route of vascular access. Radial or femoral access may influence decisions regarding the type and intensity of anticoagulation.^{26,27} The writing committee recommends that invasive, noninterventionalists develop proficiency with transradial access while also maintaining proficiency with transfemoral approaches. The CCL Director should develop a mentoring program to facilitate proficiency with both transradial and transfemoral access and closure techniques for all operators.

In the setting of proposed ad hoc PCI, AUC criteria should be determined and documented in both the noninterventionalist's and interventionalist's procedure note to ensure consistency as recommended in the 2016 SCAI Expert Consensus Statement on Best Practices and previously published statements on ad hoc PCI and other diagnostic procedures.¹⁷ Depending on the specifics of any particular case, the interventionalist and noninterventionalist should have a discussion about what angiographic views are required and they should review the angiograms prior to PCI.

5.3 | Post-PCI and postprocedural care

5.3.1 | Physician-to-patient and physician-to-physician communication

Once the interventional procedure has been completed, the writing committee agrees that the interventionalist should discuss the details of the imaging or physiological assessment (e.g., IVUS, FFR), interventions, and complications directly with the patient and family as well as with the referring invasive cardiologist. Postprocedure management including medications, observation for relevant complications, appropriate education, and transitions of care should be clearly established between the interventionalist and the invasive noninterventional cardiologist and explained to patient and family. The interventionalist should clearly convey instructions regarding access site management, timing of ambulation, and return to normal activities to the patient and family. Standardizing institutional practice and development of order sets may assist in decreasing postprocedural related complications. The key considerations and approach to solutions are detailed in Table 8.

5.3.2 | Procedure report

A preliminary procedure report should be generated immediately postprocedure and included in the patient's chart prior to transferring patient to the next level of care. The final report should be completed within 24 hr and should include the names of all operators, specifying which operator performed which part of the procedure, and include all essential elements mandated by The Joint Commission. An alternative is to have each operator submit a report specifying their findings and results for the procedure that they performed. The details of a comprehensive procedure report specific to commonly performed procedures in the CCL can be found in the 2016 Best Practices in the CCL document.¹⁷

TABLE 8 Important areas of concern and proposed solutions related to postprocedural care of patients

Topic	Areas of concern	Proposed solutions
Post-PCI/procedural care issues	<ul style="list-style-type: none"> • Lack of effective communication between invasive noninterventionalist and interventionalist may result in inadequate observation duration, postprocedural issues to evaluate for as outpatient (i.e., vascular access sites, periprocedural bleeding, compliance and choice of DAPT/triple therapy), leading to potentially worse patient outcomes • Lack of communication to family about disposition may also result in inability to recognize postprocedural complications, limitations of physical activity, follow up, and medication compliance 	<ul style="list-style-type: none"> • Closed loop communication between invasive noninterventionalist and interventionalist regarding procedural findings, postprocedure plan of care should always occur • Communication with patient and patient's family about findings, outpatient follow-up, return precautions, and medication compliance • Completion of both procedure reports within 24 hr as per 2016 Best Practices in the SCAI CCL document

5.3.3 | Appropriate monitoring and length of stay

The interventional cardiologist should discuss with the invasive noninterventionalist cardiologist the duration of observation, the length of stay after PCI and the appropriateness of same-day discharge, which will depend on access site complications, patient comorbidities, and the need for further management.²⁸ The chart should clearly delineate the primary physician or advanced practice provider charged with caring for the patient during the observation and/or hospitalization period and which provider will be providing discharge and follow-up instructions.

5.3.4 | Discharge instructions

The interventional cardiologist should discuss and document the duration and type of dual antiplatelet therapy (DAPT) with the invasive noninterventionalist cardiologist and the patient.²⁹ The physician discharging the patient should perform medication reconciliation, stress the need of DAPT adherence, discuss the expected duration of DAPT or “triple therapy” (antiplatelets + anticoagulants) if needed.^{30,31} Patients previously on warfarin, LMWH or target-specific oral anticoagulants should receive specific instructions when to restart their regimen and when to obtain follow-up PT/INR. The discharging physician should also provide instructions to patients regarding limitations of physical activity, driving, and instructions for the follow-up appointment in addition to discussion regarding secondary prevention measures and referral to cardiac rehabilitation.

Recent evidence demonstrates that same-day discharge is safe in selected patients and is associated with significant cost savings, improved patient satisfaction, and increased bed availability.^{32–34} With respect to PCI patients who are observed overnight, an analysis of the NCDR CathPCI registry demonstrated that from 2009 to 2014, the proportion of outpatients not admitted to a hospital after PCI increased from 32.8% to 66.3%, with admitted patients being older, having more comorbidities, and having experienced post-PCI complications.³⁵ However, of the patients who were not admitted, those who were at high risk for predicted mortality increased significantly from 17.0% to 19.8% during the time period. In the situation where an interventional cardiologist is called to perform a PCI on a patient who underwent diagnostic angiography by an invasive noninterventionalist cardiologist, there is the potential for knowledge disparity between the two cardiologists regarding the patient's comorbidities and home social support. Communication is key to coordinating post-PCI disposition. Outpatient follow-up, medication reconciliation, appropriate secondary prevention measures, and referral to cardiac rehabilitation should also be coordinated post PCI.³⁶

5.3.5 | Appropriate attending to referring physician handoff

A formal handoff should be conducted between either the interventional cardiologist or invasive cardiologist and the physician who will be assuming patient care after discharge, if different from either of them. The final procedure note and discharge instructions, including updated medication list, should be available to the team assuming care and should be sent to all referring physicians. The patient should have a follow-up visit with either a referring provider, invasive cardiologist

or interventionalist performing PCI within 4 weeks of discharge. A CCL team member should contact all patients within 24–48 hr of the procedure to identify potential complications, ensure medication compliance and appropriate follow-up. When postprocedural complications are identified, there should be a mechanism in place for physicians to manage those complications.

6 | CONCLUSIONS

The CCL remains a dynamic place where physicians with varied backgrounds, training, and experience are treating patients. The writing committee fully supports the continued practice of these cardiologists who provide invaluable care in the CCL. (Supporting Information Table S1) This consensus statement establishes a framework of standards for invasive noninterventionalist cardiologists to maintain quality in the cath laboratory, improve interprovider communication, and ultimately improve the patients' experience and outcomes.

CONFLICT OF INTEREST

There are no relevant conflicts of interest pertaining to this document for any author.

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REFERENCES

- Halperin JL, Williams ES, Fuster V. COCATS 4 Introduction. *J Am Coll Cardiol*. 2015;65(17):1724–1733.
- King SB III, Babb JD, Bates ER, et al. COCATS 4 task force 10: Training in cardiac catheterization. *J Am Coll Cardiol*. 2015;65(17):1844–1853.
- Kolte D, Khera S, Aronow WS, et al. Trends in incidence, management, and outcomes of cardiogenic shock complicating ST-elevation myocardial infarction in the United States. *J Am Heart Assoc*. 2014;3(1):e000590.
- Wayangankar SA, Bangalore S, McCoy LA, et al. Temporal trends and outcomes of patients undergoing percutaneous coronary interventions for cardiogenic shock in the setting of acute myocardial infarction: A report from the CathPCI Registry. *JACC Cardiovasc Interv*. 2016;9(4):341–351.
- Morine KJ, Kapur NK. Percutaneous mechanical circulatory support for cardiogenic shock. *Curr Treat Options Cardiovasc Med*. 2016;18(1):6.
- Abraham WT, Adamson PB, Bourge RC, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: A randomised controlled trial. *Lancet*. 2011;377(9766):658–666.
- Williams ES, Halperin JL, Arrighi JA, et al. 2016 ACC lifelong learning competencies for general cardiologists: A report of the ACC competency management committee. *J Am Coll Cardiol*. 2016;67(22):2656–2695.
- Ruiz CE, Feldman TE, Hijazi ZM, et al. Interventional fellowship in structural and congenital heart disease for adults. *JACC Cardiovasc Interv*. 2010;3(9):e1–e15.
- Harold JG, Bass TA, Bashore TM, et al. ACCF/AHA/SCAI 2013 update of the clinical competence statement on coronary artery interventional procedures: A report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task

- Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). *J Am Coll Cardiol*. 2013;62(4):357-396.
10. Dehmer GJ, Weaver D, Roe MT, et al. A contemporary view of diagnostic cardiac catheterization and percutaneous coronary intervention in the United States: A report from the CathPCI Registry of the National Cardiovascular Data Registry, 2010 through June 2011. *J Am Coll Cardiol*. 2012;60(20):2017-2031.
 11. West R, Ellis G, Brooks N, Joint Audit Committee of the British Cardiac Society and Royal College of Physicians of London. Complications of diagnostic cardiac catheterisation: Results from a confidential inquiry into cardiac catheter complications. *Heart*. 2006;92(6):810-814.
 12. Abraham WT, Smith SA. Devices in the management of advanced, chronic heart failure. *Nat Rev Cardiol*. 2013;10(2):98-110.
 13. Jessup M, Drazner MH, Book W, et al. 2017 ACC/AHA/HFSA/ISHLT/ACP advanced training statement on advanced heart failure and transplant cardiology (Revision of the ACCF/AHA/ACP/HFSA/ISHLT 2010 clinical competence statement on management of patients with advanced heart failure and cardiac transplant): A Report of the ACC Competency Management Committee. *J Am Coll Cardiol*. 2017;69(24):2977-3001.
 14. Kapur NK, Dimas V, Sorajja P, et al. The interventional heart failure initiative: A mission statement for the next generation of invasive cardiologists. *Catheter Cardiovasc Interv*. 2015;86(2):353-355.
 15. Adamson PB, Abraham WT, Love C, Reynolds D. The evolving challenge of chronic heart failure management: A call for a new curriculum for training heart failure specialists. *J Am Coll Cardiol*. 2004;44:1354-1357, 1357.
 16. Calkins H, Awtry EH, Bunch TJ, Kaul S, Miller JM, Tedrow UB. COCATS 4 task force 11: Training in arrhythmia diagnosis and management, cardiac pacing, and electrophysiology. *J Am Coll Cardiol*. 2015;65(17):1854-1865.
 17. Naidu SS, Aronow HD, Box LC, et al. SCAI expert consensus statement: 2016 best practices in the cardiac catheterization laboratory: (Endorsed by the cardiological society of India, and sociedad Latino Americana de Cardiologia intervencionista; Affirmation of value by the Canadian Association of interventional cardiology-Association canadienne de cardiologie d'intervention). *Catheter Cardiovasc Interv*. 2016;88(3):407-423.
 18. Messenger JC, Ho KK, Young CH, et al. The National Cardiovascular Data Registry (NCDR) Data Quality Brief: The NCDR Data Quality Program in 2012. *J Am Coll Cardiol*. 2012;60(16):1484-1488.
 19. Moussa I, Hermann A, Messenger JC, et al. The NCDR CathPCI Registry: A US national perspective on care and outcomes for percutaneous coronary intervention. *Heart*. 2013;99(5):297-303.
 20. Writing Committee Members, Harold JG, Bass TA, et al. ACCF/AHA/SCAI 2013 Update of the Clinical Competence Statement on Coronary Artery Interventional Procedures: A Report of the American College of Cardiology Foundation/American Heart Association/American College of Physicians Task Force on Clinical Competence and Training (Writing Committee to Revise the 2007 Clinical Competence Statement on Cardiac Interventional Procedures). *Catheter Cardiovasc Interv*. 2013;82(2):E69-E111.
 21. Nijssen EC, Rennenberg RJ, Nelemans PJ, et al. Prophylactic hydration to protect renal function from intravascular iodinated contrast material in patients at high risk of contrast-induced nephropathy (AMACING): A prospective, randomised, phase 3, controlled, open-label, non-inferiority trial. *Lancet*. 2017;389(10076):1312-1322.
 22. Blankenship JC, Gigliotti OS, Feldman DN, et al. Ad hoc percutaneous coronary intervention: A consensus statement from the Society for Cardiovascular Angiography and Interventions. *Catheter Cardiovasc Interv*. 2013;81(5):748-758.
 23. Dauerman HL, Applegate RJ, Cohen DJ. Vascular closure devices: The second decade. *J Am Coll Cardiol*. 2007;50(17):1617-1626.
 24. Feldman DN, Swaminathan RV, Kaltenbach LA, et al. Adoption of radial access and comparison of outcomes to femoral access in percutaneous coronary intervention: An updated report from the national cardiovascular data registry (2007-2012). *Circulation*. 2013;127(23):2295-2306.
 25. Rao SV, Stone GW. Arterial access and arteriotomy site closure devices. *Nat Rev Cardiol*. 2016;13(11):641-650.
 26. Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): A randomised, parallel group, multicentre trial. *Lancet*. 2011;377(9775):1409-1420.
 27. Nathan S, Rao SV. Radial versus femoral access for percutaneous coronary intervention: Implications for vascular complications and bleeding. *Curr Cardiol Rep*. 2012;14(4):502-509.
 28. Seto AH, Shroff A, Abu-Fadel M, et al. Length of stay following percutaneous coronary intervention: An expert consensus document update from the society for cardiovascular angiography and interventions. *Catheter Cardiovasc Interv*. 2018;00:1-15.
 29. Levine GN, Bates ER, Bittl JA, et al. 2016 ACC/AHA Guideline focused update on duration of dual antiplatelet therapy in patients with coronary artery disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *J Am Coll Cardiol*. 2016;68(10):1082-1115.
 30. Dewilde WJ, Oirbans T, Verheugt FW, et al. Use of clopidogrel with or without aspirin in patients taking oral anticoagulant therapy and undergoing percutaneous coronary intervention: An open-label, randomised, controlled trial. *Lancet*. 2013;381(9872):1107-1115.
 31. Lip GY, Windecker S, Huber K, et al. Management of antithrombotic therapy in atrial fibrillation patients presenting with acute coronary syndrome and/or undergoing percutaneous coronary or valve interventions: A joint consensus document of the European Society of Cardiology Working Group on Thrombosis, European Heart Rhythm Association (EHRA), European Association of Percutaneous Cardiovascular Interventions (EAPCI) and European Association of Acute Cardiac Care (ACCA) endorsed by the Heart Rhythm Society (HRS) and Asia-Pacific Heart Rhythm Society (APHRS). *Eur Heart J*. 2014;35(45):3155-3179.
 32. Shroff A, Kupfer J, Gilchrist IC, et al. Same-day discharge after percutaneous coronary intervention: Current perspectives and strategies for implementation. *JAMA Cardiol*. 2016;1(2):216-223.
 33. Rao SV, Kaltenbach LA, Weintraub WS, et al. Prevalence and outcomes of same-day discharge after elective percutaneous coronary intervention among older patients. *JAMA*. 2011;306(13):1461-1467.
 34. Brayton KM, Patel VG, Stave C, de Lemos JA, Kumbhani DJ. Same-day discharge after percutaneous coronary intervention: A meta-analysis. *J Am Coll Cardiol*. 2013;62(4):275-285.
 35. Vora AN, Dai D, Gurm H, et al. Temporal trends in the risk profile of patients undergoing outpatient percutaneous coronary intervention: A report from the National Cardiovascular Data Registry's CathPCI Registry. *Circ Cardiovasc Interv*. 2016;9(3):e003070.
 36. Smith SC Jr, Benjamin EJ, Bonow RO, et al. AHA/ACCF secondary prevention and risk reduction therapy for patients with coronary and other atherosclerotic vascular disease: 2011 update: A guideline from the American Heart Association and American College of Cardiology Foundation endorsed by the World Heart Federation and the Preventive Cardiovascular Nurses Association. *J Am Coll Cardiol*. 2011;58(23):2432-2446.

SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

How to cite this article: Mulukutla SR, Babb JD, Baran DA, et al. A quality framework for the role of invasive, non-interventional cardiologists in the present-day cardiac catheterization laboratory: A multidisciplinary SCAI/HFSA expert consensus statement. *Catheter Cardiovasc Interv*. 2018;1-9. <https://doi.org/10.1002/ccd.27841>