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Core Curriculum

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)*

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INTRODUCTION

The SCAI Expert Consensus Statement: 2012 Best Practices in the Cardiac Catheterization Laboratory provides standards for preprocedure, intraprocedure, and postprocedure evaluation and management, and served as a patient-centered approach to safety and quality in the cardiac catheterization laboratory (CCL) [1]. It was noted that the CCL is a setting in which elective, urgent, and emergent percutaneous procedures are performed, and that high throughput and increasing patient complexity demand optimal periprocedural communication, clinical management, documentation, and protocol. Regulations primarily targeted at open surgical suites have the potential to negatively impact the quality of care because they shift the focus to performance measures that are not necessarily relevant to the CCL. Accordingly, directives were tailored to the percutaneous setting in order to assure quality and optimal patient safety while maintaining efficiency.

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*The Canadian Association of Interventional Cardiology (CAIC) is approached by other guideline developers and asked to review and consider guidelines for endorsement. Guidelines developed by external organizations will be considered for affirmation of value. The CAIC may not agree with every recommendation in such a document, but overall considers the document to be of educational value to its members.

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This clinical expert consensus statement pertains to diagnostic and therapeutic coronary artery procedures. Given the variety of practice settings in which peripheral vascular procedures are being performed, and the more nascent field of structural heart interventions, which have their own expert consensus statements, a discussion of noncoronary artery procedures is beyond the scope of this document. The purpose of this document is not to represent all acceptable practices, but to provide a consensus opinion on "best practices" as goals for CCL implementation. This update of the 2012 best practices incorporates new standards in the field, and a section on CCL governance has been added. It is anticipated that regulatory bodies, accreditation organizations, hospitals and health systems, and CCL directors and hospital administrators will reference this document for process improvement and standardization. This document should not be used to determine coverage or reimbursement policies in the United States. There remains a dearth of objective evidence guiding many aspects of this document. When available, evidence-based data have been cited. Further research specifically on the CCL process and quality improvement is needed.

INSTITUTIONAL AND OPERATOR QUALIFICATIONS AND COMPONENTS OF AN OPTIMAL CCL PROCEDURAL TEAM

Provider/Institutional Competence and Documentation

All physicians must maintain procedure-specific credentialing and privileging by their institution, typically requiring American Board of Internal Medicine (ABIM), American Osteopathic Association (AOA), or evolving certification models such as that from the National Board of Physicians and Surgeons (NBPAS) [2]. Each CCL should have a procedure for recertification of privileges, required every 2 years by The Joint Commission (TJC). TJC requires the completion of ongoing professional practice evaluations (OPPE) more often than annually on all physicians. TJC also mandates completion of a focused professional practice evaluation (FPPE) for newly hired operators, established operators requesting permission to perform a new procedure, and established operators performing a procedure in case of a perceived problem [3]. Case volume should be documented by the CCL director on a biannual basis. In addition, procedural outcomes, including success rates and observed in-hospital complications, should be documented. Risk adjustment models are recommended to put these observed outcomes in perspective [4,5]. Participation in national or regional quality improvement registries, such as the National Cardiovascular Data Registry (NCDR) CathPCI registry, is necessary to meet NCDR quality standards [6]. In addition, physicians should participate in at least quarterly quality improvement, peer review, and/or morbidity and mortality (M&M) meetings to maintain privileges, as well as participate in procedural appropriateness evaluations. Technologists are strongly encouraged to obtain Registered Cardiovascular Invasive Specialist (RCIS) certification, and nursing staff ideally should have a minimum of one year of critical care experience. In addition, nursing, physician assistant, and technologist staff must comply with continuing education requirements for their state(s) or certifying bodies.

Clinical competence guidelines state that in order to maintain proficiency while keeping complications at a low level, a minimum volume of $\geq$200 PCIs/year be achieved by all institutions [2]. In addition, although the clinical competence guidelines acknowledge only a moderate correlation between operator percutaneous coronary interventions (PCI) volume and mortality, for each operator a minimum PCI volume of $\geq$50/year is recommended, averaged over 2 years.

The performance of primary percutaneous coronary intervention (PPCI, PCI in the setting of acute ST elevation myocardial infarction) requires an additional cognitive and technical skill set [2]; therefore, it is recommended that operators perform $\geq$11 PPCI/year and that institutions should perform $\geq$36 PPCI/year, when possible [2]. For institutions without on-site cardiac surgery, oversight to ensure the quality of procedures is paramount [2,7]. For such sites, operators should perform at least 50 PCIs/year, including $\geq$11 primary PCIs, and the institution should ideally recruit more experienced operators. Less experienced operators should have additional oversight, such as backup support. The CPORT-E Trial serves as a model for facilities performing PCI without on-site cardiac surgery [8]. Consistent with its design, such facilities should participate in national registries, routinely utilize risk-adjustment tools, have immediately available consultation with a tertiary care center, implement cross-training of personnel, and have a well-developed system for expeditious transfer for emergency coronary artery bypass graft (CABG).

Optimal Catheterization Laboratory Team

A multidisciplinary approach within the CCL is needed. The primary operators must be adequately trained and credentialed. They are usually assisted by a physician trainee and/or physician extenders (e.g., certified technologist, physician assistant, or nurse). Typically, 1–2 CCL staff are tableside, with an additional 2 CCL staff serving in "circulating" and "monitoring/

recording" roles. Tableside assistants must be trained in the setup of manifolds, automatic/power injectors, the use and preparation of wires, catheters, balloons, and other devices, as well as in radiation safety and sterile technique. Appropriate staffing to ensure an adequate nurse-to-patient ratio should be ensured. A nurse providing moderate sedation during the procedure must have no other responsibilities that would compromise continuous patient assessment. In cases where there is concern for using more than moderate sedation, an anesthesia provider should be present, and policies should be drafted that are consistent with hospital credentialing and state guidelines. Basic Life Support and Advanced Cardiovascular Life Support certification of all staff should be up to date.

Maintenance of Qualifications

ABIM or AOA certification in interventional cardiology is required for operators who completed fellowship training after 1993 and is strongly recommended for all operators. After the first certification, ongoing recertification is also strongly recommended. NBPAS certification, an alternative to the ABIM recertification process, is also available. Utilization of national benchmarking and self-assessment tools such as the NCDR registries, hospital or CCL quality data, and patient satisfaction data is highly encouraged. Continuing Medical Education (CME) $\geq$30 hr in invasive or interventional cardiology over 2 years, or consistent with state regulations should be completed by all physicians. Physician and CCL staff membership in professional societies such as Society for Cardiovascular Angiography & Interventions (SCAI) and the American College of Cardiology (ACC) is highly encouraged. CCL staff should obtain, at a minimum, the continuing education units (CEUs) as required by the respective state.

PREPROCEDURE BEST PRACTICES

Documentation: Procedure Indications and History and Physical (H&P) Examination

Procedural indications should be well documented and reconciled with published appropriate use criteria (AUC); key variables (e.g., anginal class and medication use) must be documented to confirm appropriateness [9,10]. A number of on-line calculators are available to assist in this process [11]. Supporting data, such as a pre-procedure electrocardiogram (ECG), prior cardiac procedures or surgeries, echocardiography, coronary computed tomography (CT) angiography, and/or stress testing results (with characterization of findings as "low-risk," "intermediate-risk," or "high-risk" rather than "abnormal") should be described [9]. For procedures with "rarely appropriate" ratings, additional documentation should be included to explain why the procedure is appropriate for the particular patient.

All patients must have an H&P examination prior to the procedure, performed by either a physician or an advanced practice professional (APP) (e.g., physician assistant or nurse practitioner). For emergent procedures, a targeted history and limited physical examination are reasonable, with more complete information added following the procedure. For outpatient procedures, a timed and dated H&P within 30 days (sooner if dictated by local hospital policy) is acceptable, with a focused update by the attending physician within 24 hr prior to the procedure. This update should reflect any changes in history, physical examination findings, test results, or medications. For inpatients, an H&P should be performed within 24 hr of admission or registration. At a minimum, this H&P should include the history of the present illness along with Canadian Cardiovascular Society angina and New York Heart Association heart failure classes, documentation of relevant medications, including those received within the last 48 hr, relevant comorbidities, and a review of systems, focusing on the systems encountered during cardiac catheterization (i.e., renal, gastrointestinal, peripheral vascular, neurological and pulmonary). Any history of contrast reaction or other allergies should be documented, including the specific reaction. Potential issues related to antiplatelet or anticoagulant therapy, such as a concomitant requirement for long-term oral anticoagulation, and barriers to long-term dual antiplatelet therapy (DAPT) adherence should be noted. The history should note any prior airway or moderate sedation issues.

The physical examination should be focused on the cardiopulmonary and vascular system and document peripheral pulses [12,13]. In addition, because the patient may undergo sedation, appropriate evaluation should be performed of the patient's ability to tolerate sedation, and at what level. Orthopedic, neurologic, or other conditions that might impact the performance of the procedure (e.g., an inability to remain supine) should be noted. Ideally, risk scores and calculators (www.ScaiPCIRiskApp.org) for predicting complications (e.g., mortality, bleeding, contrast-induced nephropathy [CIN]), and methods employed to reduce risk should be documented [11,14,15].

Informed Consent Process and Documentation

Informed consent (IC) is a legal process that ensures a patient is familiar with all the risks, benefits, and alternatives of a procedure. To be valid, the patient must be competent and voluntarily provide consent;

otherwise, a person with power of attorney may act as a surrogate. IC is necessary before every procedure and is consistent with the ethical principles of patient autonomy [16]. The hospital must have a written policy on IC that describes the process used to obtain consent, including documentation and surrogate decision-maker issues, as well as circumstances that would allow for exceptions to obtaining IC, such as emergent ST-Elevation Myocardial Infarction (STEMI) in an unconscious patient.

Ideally, the IC process should be performed in a neutral environment. According to the 2012 ACC/SCAI Expert Consensus Document on Cardiac Catheterization Standards Update, "the written informed consent may be obtained by trained secondary operators or physician extenders, but the major concerns should be reiterated when the primary operator discusses the procedure with the patient" [17]. The IC should be in the patient's native language, using terms that allow a layperson to understand what the procedure entails; the risks, benefits, and alternatives to the procedure proposed, including no invasive treatment; and potential outcomes and complications that may occur during and after the procedure [18,19]. Potential treatments that may result from the findings of a diagnostic procedure (e.g., ad hoc PCIs and their attendant risks) should be reviewed, as well as issues surrounding dual antiplatelet therapy (DAPT) and restenosis. Ideally, the IC process should be witnessed by a third party, preferably by the patient's family or a staff member independent of the CCL, and subsequently entered into the medical record. The consent must be obtained within 30 days (sooner, if indicated by hospital policy), and must be reaffirmed on the day of the procedure. Specific mention should be made of do not resuscitate (DNR) status and that it has been revoked for the duration of the procedure and a minimum of 24 hr following the procedure, with the interventional cardiologist involved in any decision to reinstate DNR. Recently, tools have been developed to enhance the informed consent process with the use of electronic decision-making aids [19,20].

Sedation, Anesthesia, and Analgesia Evaluation

Moderate sedation/analgesia is frequently provided during procedures to minimize patient discomfort and anxiety, and is usually ordered by the performing physician. The need for moderate sedation can be individualized by the treating physician, and anxiolysis or pain control alone may suffice for coronary artery procedures. The American Society of Anesthesiologists (ASA) has defined a continuum of depth of anesthesia and has established guidelines in this area for the training and credentialing of physicians [21]. Physicians in the CCL should be credentialed by their hospital for providing moderate sedation/analgesia, typically referred to as "conscious sedation". Monitoring of the level of sedation, pulmonary ventilation, and oxygenation should be performed during the procedure and documented by the staff. ASA and Mallampati classification as part of pre-sedation assessment and updated within 24 hr of the procedure is required in some hospitals, although there is no evidence to support this process in the CCL. Patients traditionally fast prior to a procedure, for at least 2 hr after ingestion of clear liquids or at least 6 hr after ingestion of a meal, although some institutions no longer require *nil per os* (NPO) status given the lack of supportive evidence [22]. These instructions can be waived for emergency procedures, perhaps at some increased risk of aspiration.

Patient Preparation within 48 hr and Immediate Preprocedure Checklist (Table I) T1

Medications. Patient medications should be reviewed with attention to those that could impact the conduct or outcome of the procedure. The use of antiplatelet agents should be reviewed, and physicians may wish to begin aspirin or P2Y12-receptor-inhibitors in advance of procedures where coronary intervention is possible or likely. For patients who may receive a stent, potential issues with long-term DAPT should be reviewed. Anticoagulant therapy with vitamin K antagonists (e.g., warfarin) or Target-Specific Oral Anticoagulants (TSOACs) presents a particularly important preprocedural consideration. Whether to continue or discontinue anticoagulation in such cases should be individualized. There is recent support for radial access procedures regardless of anticoagulation status [23]. The indication for anticoagulation and the risk of thromboembolic events should be taken into account, as this will impact the decision for either bridging with unfractionated heparin or low molecular weight heparin (LMWH) or performing the procedure on anticoagulation; algorithms for bridging are available [24]. For patients on chronic warfarin therapy in whom anticoagulation can be held, the international normalized ratio (INR) should be obtained $<$24 hr prior to the procedure, with the goal INR of $<$1.8 for femoral procedures. There has been increasing attention to the use of bleeding avoidance strategies [25], and approaches such as radial artery access may offer increased safety when the INR is elevated; however, because successful radial access cannot always be assured in advance, and because an elevated INR can complicate the PCI, efforts should still be made to reduce the INR when

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TABLE I. Pre-Procedure Check List for Cardiac Catheterization

Patient name	MRN	Procedure date	
Planned Procedure:	Diagnostic Cardiac Catheterization (L, R, simultaneous)		
(circle all that apply)	Coronary angiography		
	Left ventriculography		
	Intravascular Imaging/Hemodynamic Assessment (IVUS, OCT, FFR)		
	Possible PCI		
	Planned PCI		
	Other		
History and Physical Examination:			
Elective Outpatient Procedures: H&P documented within 30 days?		Yes	No
Inpatient Procedures: H&P documented within 24 hours of admission?		Yes	No
History of prior PCI or CABG: Yes No If yes, report/s obtained?		Yes	No
Stress test/LVSF assessment: Yes No If yes, report/s obtained?		Yes	No
Candidacy for DES:			
1. Major surgery in the past month or next year?		Yes	No
2. Is there any clinically overt or suspected bleeding?		Yes	No
3. Is patient on chronic anticoagulation (e.g., warfarin, TSOAC)?		Yes	No
4. Is there history of/anticipated medication non-adherence?		Yes	No
Allergies:			
1. Contrast: Yes No If yes, was the patient pretreated?		Yes	No
2. Aspirin: Yes No If yes, was the patient desensitized?		Yes	No
3. Heparin (HIT) Yes No If yes, consider alternative anti-thrombotic agents (DTI)			
4. Latex Yes No If yes, remove all latex products from procedural use			
Medications:			
1. Did patient take aspirin within the past 24 hr?		Yes	No
2. Did patient take clopidogrel, prasugrel, or ticagrelor within the past 24 hr?		Yes	No
3. Did patient take metformin within the past 24 hr?		Yes	No
4. Did patient take sildenafil (or other PDE5 inhibitor) within the past 24 hr?		Yes	No
5. Did patient receive LMWH within the past 12 hr?		Yes	No
If yes for LMWH, time of last dose _____			
6. Did patient take anticoagulants		Yes	No
If yes, which agent _____ and when was last dose _____			
Informed Consent:			
Was informed consent obtained within 30 days?		Yes	No
Is there a healthcare proxy?		Yes	No
Is the patient DNR or DNI?		Yes	No
If Yes, was it revoked for procedure?		Yes	No
Sedation, Anesthesia and Analgesia:			
Are ASA and Mallampati Class documented?		Yes	No
Is there any contraindication to sedation present?		Yes	No
Risk scores applied?		Yes	No
Bleeding		Yes	No
CIN		Yes	No
Mortality		Yes	No
Laboratories and Studies:			
CBC and renal profile within 30 days (outpatient) or 24 hr (inpatient)?		Yes	No
Hgb _____			
eGFR _____			
Was ECG performed within 24 hr?		Yes	No
PT/INR performed within 24 hr (for patients on warfarin)?		Yes	No
INR $\leq$ 1.8?		Yes	No
Urine/serum hcg in woman of childbearing age?		Yes	No
Does the patient require preprocedure hydration?		Yes	No
Preferred vascular access:		R L TR TF	
Same Day Discharge candidate?		Yes	No

possible. Vitamin K administration and/or the administration of Fresh Frozen Plasma (FFP) may be considered when the INR cannot be corrected and the benefits of doing so outweigh the risks. For patients on TSOACs, the timing for discontinuation of therapy in advance of the procedure is impacted by renal function, but it is generally 1–2 days prior to the procedure [24,26].

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Medication review and adjustment is also important for patients with diabetes, and insulin dosing should be adjusted to account for the time that the patient will be NPO. Metformin should be held on the day of the procedure and for 48 hr afterward [17,27].

Labs and other studies. Patients scheduled for outpatient procedures should have a complete blood count (CBC) and renal profile within 30 days. When clinically indicated, CBC and a renal profile are recommended within 24 to 48 hr. Significant anemia should be addressed prior to the procedure, especially when PCI and associated anti-platelet therapy are being considered. Routine measurement of the PT/INR is not necessary for all patients, but should be obtained for those with severe anemia or liver disease. A baseline ECG should be obtained. A chest x-ray is not required unless vascular congestion or other pulmonary pathology is evident on physical examination. Women of childbearing age should have beta-HCG levels checked within 2 weeks of the procedure [17]. For patients who have had prior catheterization or coronary/peripheral bypass surgery, every effort should be made to review procedural reports and prior cardiovascular angiograms to help guide the operator during the procedure.

Chronic kidney disease (CKD). Patients with baseline renal insufficiency (eGFR <60 mL/min/1.73 m^2) and/or elevated risk scores are at increased risk of developing contrast-induced neuropathy (CIN). As noted in the 2011 ACCF/AHA/SCAI PCI Guidelines, the only strategies consistently shown to reduce the risk of CIN are hydration and minimizing the contrast dose [28,29]. Preprocedure intravenous (IV) hydration with normal saline should be provided in patients deemed hypovolemic. Administration of N-acetyl cysteine does not offer a significant benefit, and is no longer recommended [28–30]. In addition, the total contrast dose should be monitored, and risk scores can be helpful in identifying a suggested limit [15,31]. One tool uses the ratio of contrast volume to creatinine clearance (CrCl), with a ratio of contrast volume/CrCl >3.7 as predictive of renal injury [31,32].

Allergies. Allergies to latex, contrast, heparin (and heparin-induced thrombocytopenia), aspirin, narcotics, and other medications should be documented. Several regimens have been used to prevent contrast allergy, although none have been subject to randomized controlled trials. Each CCL should have a protocol for preventing contrast reactions. One regimen is prednisone 50 mg orally at 13, 7, and 1 hr prior to the procedure, or alternatively prednisone 60 mg orally the night before and the morning of the procedure. 50 mg of diphenhydramine orally is given 1 hr before the procedure in both regimens [29,33]. Many CCLs administer H2 blockers, although there are minimal data to support this approach. Minimal data are available for patients with contrast allergy undergoing emergency PCI, but one regimen is 60 mg Methylprednisolone intravenously prior to the procedure [34,35]. Shellfish allergy is not a predictor of contrast reactions and does not require pretreatment.

INTRA-PROCEDURE BEST PRACTICES

Patient Preparation in the Procedure Room

Upon arrival to the procedure room, a nurse, technologist, APP, physician extender, or physician should review the preprocedure checklist (Table I). If a checklist review was not performed, a thorough review of the medical record, including documentation of NPO status and duration, access site concerns, allergies, results of blood tests, recent medications (such as heparin and other anticoagulants), advance directives, IC, and living wills must occur. NCDR-related (or equivalent) preprocedural information should be reviewed by the attending physician or designee and clarified with personnel responsible for entering that information into the electronic health record. All of these items must be documented in the medical record prior to the procedure or as part of the checklist mentioned above. Noninvasive hemodynamic and oximetric monitoring of patient vital signs should be routine. Defibrillation pads should be attached to all STEMI patients. Access related risks should be considered with the goal of choosing the optimal access site to reduce complications. CCL staff should ensure that at least one working IV is in place prior to the start of the procedure.

Sedation, Anesthesia, and Analgesia Administration and Documentation

All patients should have documentation of their suitability to receive moderate sedation according to five classes categorized by the ASA guidelines [36]. Moderate sedation should be considered for all patients [37]. Nasal cannula should be considered for all patients in whom conscious sedation is utilized. A nurse, or provider with equivalent credentials, should be present during sedation administration to monitor for side effects, hemodynamic instability, and changes in respiration and/or oxygenation. A combination of opioids, such as fentanyl 25–50 mcg, and benzodiazepines, such as midazolam 0.5–2 mg, are most frequently utilized, but dosage should be carefully considered based on age, body size, and comorbidities. Reversal agents should be readily accessible. Naloxone 0.001 mg/kg IV can be utilized and titrated to reverse narcotic analgesics, and re-bolus may be required, given its short duration of action. Flumazenil, a pure

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benzodiazepine antagonist, can be given 0.2 mg IV every 2–5 minutes to a maximum of 1 mg. All drugs must be recorded in a procedure log or electronic record and signed by the attending physician, and such records should be easily accessible, particularly when the patient leaves the CCL.

Infection Control in the Catheterization Laboratory

Infectious complications resulting from cardiac catheterization are exceedingly rare; however, best practices for sterile technique are essential. Electric clippers should be used to prepare the femoral access site. A variety of antimicrobial agents are available, and chlorhexidine-based preparations are most commonly used due to their demonstrated efficacy. Patient drapes that adhere to skin around the access site without loosening during the procedure are important. Physicians may use Chlorhexidine/ethyl alcohol solutions, such as 3M Avagard, an FDA-approved surgical hand antiseptic, which can be used for the first scrub of the day and all subsequent scrubs. However, a traditional surgical scrub with water and soap is an alternative. Although their efficacy remains unproven, it is reasonable but not mandatory for hats and masks to be worn for every procedure. Antibiotic prophylaxis is not indicated for routine coronary procedures, but is often used before permanent implantations other than coronary stents and, at some institutions, before vascular closure device (VCD) placement in high-risk subsets, such as diabetics or immunocompromised persons (38).

Radiation Exposure

All CCL procedures should be performed with the goal of keeping radiation doses as low as reasonably achievable (ALARA) [39,40]. All personnel in the room should wear personal protective equipment, including lead aprons and thyroid shields as well as radiation badges. For team members closest to the radiation source, leaded glasses should be used. Radiation exposure to the staff should be carefully monitored and posted in a central area. Reducing imaging frame rates (15 fps or 7.5 fps), using "fluoro store" when possible, masking, and keeping the flat panel detector close to the patient are recognized methods, among others, of reducing radiation exposure. Using multiple angles for imaging reduces the radiation exposure to any one site on the patient's body, and keeping the image intensifier farther away from the operator can minimize physician exposure. A complete description of strategies to reduce radiation exposure to patients and operators is beyond the scope of this article [39].

CCLs should record total radiation doses in Grays (Gy) in real time, and inform the operator and referring physician when thresholds indicative of potential radiation damage are reached [39]. For exposures greater than 5 Gy, patients should be educated regarding potential skin changes (e.g., erythema). For >10 Gy exposure, a qualified medical physicist should promptly calculate peak skin dose with skin examined at 2–4 weeks. TJC considers exposures over 15 Gy a sentinel event for which hospital risk management and regulatory agencies should be contacted within 24 hr. Suspected tissue injury should be referred to a specialist, with a biopsy performed if required.

Angiographic Contrast Administration

Nonionic, low-osmolar contrast (e.g., iohexol, iopamidol, ioversol) should be utilized for the majority of cases. While iso-osmolar contrast agents (e.g., iodixanol) could be considered for patients with chronic kidney disease, recent data suggest this approach may have no benefit. Total contrast administered to the patient must be monitored in real time and limited as clinically possible. A maximum contrast volume of 3.7 x eGFR can be used as an upper limit of acceptable contrast dose during a single procedure to help limit the risk of CIN [32]. CCL staff should inform physicians when these limits have been reached.

Universal Protocol and "Time out" Procedure

All team members should understand the intended procedure and the sequence of that procedure. This should be performed during a dedicated "Time Out" protocol, performed before vascular access or moderate sedation is initiated, when all members of the team are present. Patient identification should be confirmed with unanimous agreement on the procedure to be performed. Since the goal is to access the heart and its associated vasculature, "wrong site" procedures are generally not a concern (access to the coronary arteries can be gained via radial, brachial, and femoral arteries) and therefore site marking is not indicated [41,42]. Table II provides a sample "Time Out" checklist. If team members rotate out, then it is their responsibility to brief their replacement, who must introduce themselves to the team and announce their role, whereupon a repeat "Time Out" should be completed. T2

Universal infection precaution protocols for the staff should be followed in each case rather than on a case-by-case basis. All solutions on the table must be labeled in real-time (not prelabeled), including syringes specifically used for lidocaine and other agents (e.g., iodinated contrast). Preprinted labels of common medications should be incorporated into drape kits, and sheets of

TABLE II. Sample "Time Out" Preprocedure Checklist

All members of the procedural team must be present for the "Time Out"
Time Out must take place immediately before vascular access is obtained
The physician taking ultimate responsibility for the procedure should lead the Time Out and ensure each of the following items is announced:
1. Patient's name and medical record number
2. Procedure to be performed (e.g., left heart catheterization, coronary angiography, right heart catheterization)
3. Confirm that the equipment needed is available or alternatives are available including intended stent type for PCI or cath-possible patients
4. Patient's allergies and premedication if appropriate (e.g., heparin-induced thrombocytopenia, contrast allergy)
5. Special laboratory or medical conditions (e.g., INR, GFR)
6. Confirm IC signed, witnessed and present

blank labels and felt-tip markers must also be available as part of the sterile field. For ad-hoc coronary interventions, a "Pre-PCI Timeout" should be strongly considered, during which there is consideration of (1) appropriate use classification; (2) radiation exposure and contrast use; (3) issues regarding dual-antiplatelet therapy; (4) adequate pre-treatment with aspirin, P2Y12-receptor inhibitors, and statins; and (5) baseline hemodynamics. A pre-PCI timeout assumes more importance if another operator is performing the PCI. Finally, appropriate documentation of the physician's verbal orders needs to be carried out by the recording technologist or nurse and these orders confirmed by the performing physician at the close of the case with a signature.

Procedural Data Recording

All elements of the procedure should be recorded into an electronic record that documents the procedure and events that took place. The record should contain the patient's vital signs during the procedure, the access site, the time and dosage of medication administration, what catheters were used and when, all hemodynamic measurements, the target lesion and equipment that were delivered to the body, the names of the CCL staff, and whether a closure device was used at the end of the procedure. This record should be immediately available to the staff in the post procedure area.

For patients who receive heparin, an Activated Clotting Time (ACT) must be checked to document adequate anticoagulation. It is reasonable to target ACT >200 in the presence of intravenous anti-platelet therapy, >250 in the presence of adequate oral anti-platelet therapy, and potentially >300 in the absence of both. This should be repeated every 15–20 min for patients on heparin, but only an initial acceptable ACT is required for patients receiving bivalirudin. Results and timing of such testing should be recorded in the procedure log.

NCDR-specific information (or equivalent) is critical for maintenance of quality standards in the CCL. Accordingly, methods to facilitate the transfer of information collected in the CCL during procedures should be established among physicians and CCL staff. Prior to closure of the case, the physician should be responsible for reviewing all the pre- and intra-procedural data entered for NCDR purposes to ensure accuracy and completeness.

POSTPROCEDURE BEST PRACTICES

Physician to Patient Communication

The physician should discuss the findings, interventions performed, and complications directly with the patient and family. The post procedure management plan should also be addressed. Discussions with patients should be delayed until cognitive impairment due to sedation has resolved.

Procedure Report

A procedure report, whether electronic or handwritten, should be generated immediately postprocedure and included in the patient's chart prior to transferring to the next level of care. If a procedure report cannot be placed in the medical record immediately after the procedure, then a brief progress note should be entered with sufficient information for the immediate postprocedure care, including the name of the operator, indication and type of procedure, findings, estimated blood loss, specimens removed if appropriate, complications, post-procedure diagnosis, and recommendations. In this instance, a procedure report should be completed within 24 hr of the procedure and include essential elements mandated by TJC for operative procedures, as well as comprehensive documentation of indications for PCI that provide all the information needed to determine appropriateness. Since terminology is critical for a quality procedure report, we recommend that key data elements and definitions from the 2013 ACCF/AHA Key Data Elements and Definitions for Measuring the Clinical Management and Outcomes of Patients with Acute Coronary Syndromes and Coronary Artery Disease be adopted [43]. For a comprehensive procedure report specific to commonly performed procedures in the CCL, we recommend including the additional information outlined in Table III. The writing committee concurs with the ACC/AHA/SCAI 2014 Health Policy Statement on Structured Reporting for T3

TABLE III. Recommended Elements of the Procedure Report

Element	Notes
Patient demographics	Age, gender, risk factors, medications
Primary operator and CCL team members	Primary and assisting physicians, fellows, nurses, technologists, anesthesiologists
Procedures performed	Right/Left heart catheterization, PCI
Indications	Clinical presentation, symptoms, exam findings, prior studies
Access site	Femoral, radial, brachial
Equipment	Sheaths, catheters, wires
Drugs and doses	Cardiac medications and sedation
Contrast data	Type and amount used
Radiation exposure	Dose
Complications	Clear description of complications, otherwise report "none"
Hemodynamics	Computer generated measurements must be verified by the operator. Initial and end aortic pressure, left ventricular systolic and end-diastolic pressure, valve gradients and areas, right sided chamber pressures, cardiac output, and shunt data
Left ventriculogram	Ejection fraction, wall motion abnormalities, valvular abnormalities
Coronary angiography	Detailed anatomy, lesions, variants, size of vessels, collaterals
Interventional procedures	Procedure description including equipment, results and complications, TIMI flow pre- and post-PCI
IVUS, OCT	Indication, artery segment evaluated, measurements performed, morphology and changes in management
FFR	Indication, documentation of vasodilator used and route, location of lesion evaluated, results, interpretation
Method of hemostasis	If VCD, comment on whether or not device was successful
Summary of findings, diagnosis, and follow-up	Management plan, admission or observation status, follow-up
Communication	Report that results and complications were discussed with the patient and/or family, receiving team, consultants, and referring provider

*Adapted with modifications from the Accreditation of Cardiovascular Excellence Cath/PCI Standards 2015. Online at http://www.cvexcel.org. IVUS, intravascular ultrasound; OCT, optical coherence tomography; FFR, fractional flow reserve.

the CCL, which states that a structured report is the optimal format for generating procedure reports [44].

Access Site Management and Closure Devices

Manual compression, compression devices, and VCDs are all options in cases of femoral access. Femoral angiography is recommended after access to identify any immediate procedure-related complications and the sheath location, particularly prior to anticoagulation for PCI and prior to VCD placement [45,46]. For patients who have received heparin, sheath removal and manual compression can occur when the ACT is <180 sec. ACT is generally not useful with LMWH. For bivalirudin, sheath removal and manual compression can occur at 2 hr post cessation of infusion in patients with normal renal function. In patients with a creatinine clearance <30 mL/min or those on dialysis, ACT should be checked and sheaths removed once the value is <180 sec. Sheaths can be safely removed 8 to 12 hr after the last dose of acute coronary syndrome therapeutic LMWH. After manual compression, ambulation is restricted for 2–6 hr following the procedure, depending on the ease of initial access, sheath size, and any early signs of bleeding [47,48]. If VCDs are utilized, ambulation is restricted for 1–4 hr postprocedure [49,50]. Generally, studies show that while use of VCD is noninferior to manual compression with respect to access site complications, and infection rate may be higher, the time to hemostasis and earlier ambulation are potential advantages [45,51]. Resterilization of the access site, the use of new gloves, and the use of antibiotics prior to VCD insertion may reduce infection risk in high-risk subsets.

Hemostasis by manual compression for the radial access site is usually obtained with wristband compression devices. Sheaths are removed immediately after the procedure, regardless of anticoagulation status. The "patent hemostasis" technique should be used, performed by placing a pulse oximeter on the corresponding index finger and compressing the ulnar artery while lowering the hemostatic wristband compression pressure to the point where the plethysmographic waveform returns without pulsatile bleeding at the radial access site [52–54]. There are no ambulation restrictions with radial access, but patients should avoid weight-bearing or other activity of the arm for 2–4 hr after sheath removal. Further information is available in a separate expert consensus statement on transradial best practices from the SCAI transradial working group [52].

Appropriate Monitoring and Length of Stay

Patients should be monitored on telemetry in a recovery or other unit specializing in the care of patients

receiving cardiac procedures. Vital signs should be monitored every 15 min for the first 2 hr post procedure by personnel trained in recovery from moderate/conscious sedation and access site management. Telemetry is continued throughout the hospital stay, unless specified otherwise by the attending physician. Length of stay for diagnostic catheterization ranges from 2–6 hr, depending on the access site used and the nursing assessment of patient ambulation and well-being. The length of stay for PCI is dependent on access site complications, patient comorbidities, and need for further procedures, therapy, or testing [55]. Selected patients after elective PCI can be considered for same-day discharge [56] if the appropriate monitoring time has been completed (usually 6–8 hr) and the discharge aligns with patient preference and physician approval.

Discharge Instructions and Patient Information

At the time of discharge, the duration of DAPT should be discussed and need for adherence stressed. If a patient received a stent, a card with the device information should be provided. Limitations of physical activity, driving, along with instructions for the follow-up appointment and further tests should be discussed and included with discharge instructions. Patients at increased risk for CIN should have serum creatinine checked within 3–5 days. All patients, especially those having same-day discharge post-PCI, should be contacted by a CCL team member within 24–48 hr of the procedure to ensure that no complications have occurred, medication adherence is reinforced, and to answer any questions the patient or caregiver may have.

Medication Reconciliation

Medication reconciliation is necessary before discharge to update all medications, including those deleted or added during the hospitalization, and must be clearly documented on the discharge instructions, which are sent immediately to the referring physician. The expected duration of DAPT should be based on current guidelines and documented as part of medication reconciliation. Particular attention should be given to patients requiring "triple therapy" (antiplatelets/anticoagulants), and duration of each medication should be explicitly stated. Due to increased bleeding risk, triple therapy should be maintained for the least amount of time possible. Patients previously on a TSOAC can restart the next day. Patients previously on warfarin should restart their standard regimen immediately, and arrange for follow-up PT/INR within 1 week of discharge. LMWH as a bridge to therapeutic warfarin is not routinely recommended (due to the potential for bleeding) except in cases of mechanical prosthetic valves, recent deep venous thrombosis or pulmonary embolism, and other causes for extreme risk of thrombosis [57]. Metformin should be held for 48 hr [58]. Proton-pump inhibitors should be prescribed for patients with prior history of gastrointestinal bleeding who are discharged on DAPT, and should be considered for all patients on triple therapy [29].

Appropriate Attending to Referring Physician Handoff

Although an invasive cardiologist performs the procedure, noninvasive cardiologists, internists/hospitalists, and nursing personnel can subsequently assume patient care. Formal handoffs (nurse-to-nurse and physician-to-physician) should be conducted and the operator should ensure that the formal procedure note is available to the team assuming care and is sent to all referring physicians.

Appropriate Follow-up Evaluation

The patient should have a follow-up visit with a provider (physician or physician extender) who is competent in the management of post-procedure care within 4 weeks of discharge. For patients with baseline renal insufficiency, anemia, or procedural complications, follow-up should be earlier, with indicated studies performed prior to or during the visit. A documented evaluation of the access site must be performed. The patient's medical therapy should be assessed for effectiveness, side effects, compliance, and conformity with guidelines. Additional outpatient care should address lifestyle modifications, including cardiac rehabilitation and smoking cessation, and reinforce the plan for long-term follow-up based on procedural results [29]. All patients following PCI should be referred to cardiac rehabilitation [29].

CATHETERIZATION LABORATORY GOVERNANCE

Role of CCL Director, Manager, and Hospital Administration

Management of the CCL presents unique challenges due to the volume and complexity of patients treated, the multidisciplinary (e.g., anesthesia, surgery) coordination required, the use of advanced and continuously evolving technologies, and the resultant magnitude of resources required. All CCLs should have a physician director and a nonphysician manager, working in collaboration with all the other team members, including hospital administration. Hospital administration is critical to providing the requisite resources for the CCL to perform its duties. These include not only staffing and

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TABLE IV. Responsibilities of CCL Physician Director

Administrative
Co-lead CCL administration meetings
With CCL manager, resolve personnel problems
Attend CCL staff meetings and serve as liaison between CCL personnel and physicians
Lead administrative meetings of CCL physicians
Resolve CCL issues among CCL physicians
Coordinate CCL physician call schedule
Co-lead (with CCL manager) CCL Quality Committee meetings, including reporting data on NCDR outcomes, M&M conferences, adverse event reports, root cause analyses, Department of Health inspections, TJC surveys
Assist CCL manager to prepare for Department of Health and TJC surveys
With CCL manager and administration, assist in cost effectiveness and efficiency strategies
Quality Improvement
Oversee QI data collection and reporting processes for NCDR PCI Registry, review Quarterly reports from NCDR and communicate with CCL physicians, perform annual review of individual physician data
Quality review of non-registry procedures (e.g., atrial septal defect closures)
Arrange for random case reviews and monitor results of reviews
Ensure review of adverse events either by M&M conference or CCL Quality Committee
Coordinate/oversee CCL M&M conference, report minutes to appropriate hospital committees
Co-chair (with CCL manager) CCL Quality Committee responsible for all other aspects of CCL quality, including door to balloon initiatives
Set criteria for privileging for CCL procedures
Review physician performance as necessary for bi-annual re-credentialing for procedures
Academic Responsibilities
Oversee (with program director) fellows' CCL rotation, provide evaluations
Oversee research in the CCL
Oversee acquisition and launch of new technologies and programs

TJC = The Joint Commission.
CCL = Cardiac Cath Lab.

capital needs but also the personnel required for collection, maintenance, submission, and retrieval of accurate quality data.

The director should be a licensed, board-certified interventional cardiologist, ideally with a minimum of 5 years' experience. Likewise, the manager should be an APP, either a registered cardiovascular technologist or nurse, with a minimum of 5 years' CCL experience, who also has administrative expertise to participate in institutional and CCL decision making. The director role requires dedicated administrative time. Larger labs will require more administrative time, but even small labs require a fixed amount of administrative time. A minimum of 10% of time (e.g., $1/2$ day per week) is necessary. This should be compensated by the institution at a level commensurate with the physician's income derived from clinical activities, and consistent with fair market value.

The director is responsible for setting the example and expectations for all other physicians and is responsible for developing policies, establishing criteria for granting and renewing privileges, reviewing physician performance, and overseeing nursing and technical supervisors. Additionally, the director should partner with the manager on quality improvement, fiscal administration, patient throughput, team training, provision of debrief and feedback after adverse events, delegation of authority, and facilitating education and mentorship to all team members (Table IV).

Management of Industry Presence

Industry influence at the point of care may raise a number of ethical issues [59]. Even small gifts may influence physician behavior [60]. Industry representatives in the CCL have been shown to influence use of products [61], and this effect may be variable among physicians, with some physicians influenced more than others [62]. While some have defended the role of industry in education and training [63,64], many institutions set strict limits on the presence of industry. Organizations representing industry have established codes of ethics to define appropriate interactions between industry and physicians [65,66]. General principles regarding industry representatives or clinical specialists in the CCL include the following:

1. Their role in individual CCLs should be consistent with policies set by the hospital and/or director.
2. They should not have "hands-on" equipment in the CCL, except for defined educational purposes or device preparation.
3. They should always provide information and advice that is in the best interests of the patient, regardless of other considerations.
4. Their presence in the CCL is reasonable when it is helpful to the physician in providing patient care. Hospital policies should not prohibit these interactions.

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TABLE V. Topics for CCL Emergency Drills

Drill topic	Elements to include in the drill
Vascular Complications	Anticoagulation reversal protocol
	Paging protocol for immediate assistance from interventional cardiology, surgery or interventional radiology
	Protocol for emergency non-contrast computed tomography when retroperitoneal hemorrhage is suspected and not responsive to supportive measures
	Protocol for emergency computed tomographic angiography to identify bleeding site when appropriate
	Protocol for immediate invasive angiography to balloon tamponade or stent bleeding vessel when available
Acute stroke	Protocol for calling stroke alert and activating stroke team (including a neurologist, neurological interventionalist, and access to emergent neuroimaging)
	Protocol for emergent transfer to institutions for higher level care when appropriate
Emergency Pacing	Protocol for emergency transcutaneous and transvenous pacing
Ventricular Fibrillation/ Cardiac Arrest	Protocol for emergency defibrillation
	Protocol for obtaining immediate anesthesia care and intubation in the CCL
	Protocol for initiation of standard or mechanical cardiopulmonary resuscitation (e.g., Lukas device)
Coronary perforation	Protocol for immediate location of supply of covered stents
	Protocol for placement of covered stent (including 2nd access site, larger guide catheter, etc.
	Protocol for obtaining emergency echocardiography
	Protocol for emergency pericardiocentesis
Contrast Reaction	Protocol for emergency treatment of anaphylactic/anaphylactoid reaction including IV fluids, IV steroids, and epinephrine (1:10,000 (1ml=0.1 mg) IV every minute until pulse restored)
	Protocol for obtaining immediate anesthesia care and intubation in the CCL
Tamponade	Protocol for emergency pericardiocentesis
Sudden cardiogenic shock	Protocol for alerting cardiac surgery as needed for emergency CABG or ECMO
	Protocol for obtaining immediate anesthesia care and intubation in the CCL
	Protocol for emergency IABP or percutaneous left ventricular assist device (eg. Impella)

5. Their presence in the CCL without specific purpose, (e.g., to "observe"), is of uncertain appropriateness and may reasonably be prohibited.

Incorporation of Guidelines, New Data, and New Procedures

The CCL is a dynamic environment shaped by ever-changing technologies, guidelines, and clinical data. As such, the entire CCL team, led by the director, should review and at least annually update CCL policies and processes, and provide appropriate education and training to operators and staff around any changes. Protocols should define the roles of all relevant personnel. When appropriate, related process and/or outcome metrics should be reviewed for continuous quality improvement as well.

Cost Considerations

Providing the highest value care is a major element of healthcare reform. Components of high-value care include appropriateness, reducing complications, and the judicious use of resources. Cost reduction efforts may target CCL operating costs and/or costs of care outside the CCL. For example, lower stent prices will reduce expenses in the CCL, whereas drug-eluting stents may reduce costs outside the CCL; reducing procedural complications will reduce both in-lab and out-of-lab costs [67,68]. Specific recommendations include the following:

1. CCL physicians should collaborate with managers to reduce in-lab expenses through negotiating lower prices, assisting in volume-related discounts and supply-chain management, and reduction of turnover times and overtime pay.
2. When two products differ in cost but not efficacy, it is reasonable for physicians to preferentially use the most cost-effective. Cost-reduction efforts should not compromise patient care, but physicians should be aware of the cost consequences of their decisions. Tracking physician-specific cost data (e.g., cost per case) may be useful, but should be adjusted for case complexity.
3. Physicians should participate on hospital technology-assessment committees to coordinate access to and acquisition of equipment [69].
4. Physicians should be aware of evolving strategies to reduce out-of-lab costs and use them when appropriate [70]. For example, radial artery access may offer cost savings in addition to its clinical benefits, and heparin may be as safe and effective as bivalirudin in certain subsets [71].

Quality Assurance: Registry Participation, Case Review, and M&M Conference

Every CCL must have a quality assurance (QA) program, which includes appropriate quality registries, and at least quarterly, scheduled QA/case review and/or M&M conferences. Quality registries may be regional or national and should allow for anonymous

TABLE VI. Key Techniques for Enhancing Patient Satisfaction in the CCL

Preprocedure
Prompt easy scheduling for outpatients
Minimize or eliminate NPO period before procedure (some institutions allow clear liquids until 2 hr before procedure, or no longer require NPO)
All outpatient suite and CCL personnel introduce themselves by name
Update patients when delays are anticipated
Emphasize comfort and privacy, including of family members
Respect confidentiality
Intraprocedure
Careful attention to adequate sedation and pain control during the procedure
Time out with introduction of all team members to the patient
Postprocedure
Full explanation of results of procedure to patients and when appropriate family
Prompt food and drink when tolerated after procedure
Discuss follow-up plans, provide instructions for emergency help after discharge, and provide appointment before discharge
Follow-up call to answer questions and identify post-procedural problems

benchmarking of process and outcome metrics against other operators and institutions. Procedure-based registries are available for PCI (e.g., NCDR CathPCI, http://cvquality.acc.org/NCDR-Home/Registries.aspx). Outpatient registries (e.g., NCDR PINNACLE) may provide additional pre- and post-procedure data and allow for linkage of follow up with procedural data. Hospitals should provide dedicated, trained personnel to perform chart abstraction, data entry, registry query, and report generation/distribution. Registries should be utilized to monitor operator and institutional volumes and outcomes as well as procedural appropriateness [10]. It is important that when comparing outcomes (e.g., bleeding, CIN, mortality) across operators/institutions that these rates be risk-adjusted [72–74].

Diagnostic and interventional cases should be randomly selected and peer reviewed for all operators. Ideally, peer review should be blinded and, when possible, performed by physicians external to the hospital/program. Cases should be reviewed for their appropriateness and for any complications. However, AUC ratings should not be used to judge all cases since there are times when patient preference or clinical judgment calls for a procedure. In such circumstances, clear documentation is necessary. While the current AUC criteria are a useful framework, not all indications have been rated and there is still much to be learned about how they impact quality of care and outcomes.

All major CCL and in-hospital complications should be reviewed at a regularly scheduled M&M conference, held at least quarterly [75]. Cases requiring review may be identified using procedural registries such as those cited above, assuming that data are entered in a timely fashion. CCL M&M should be distinct from Clinical Cardiology M&M as the former may emphasize technical aspects of the procedure. Presentation of more serious events (e.g., death) should take precedence over less serious (e.g., vascular complications) events, and review should occur as soon as feasible after an adverse event has occurred, especially when a preventable cause is suspected. A formal phase of care (preprocedure, intraprocedure, postprocedure) analysis in which various aspects of care at each stage are critically analyzed and where consensus is reached over preventability of the complication is recommended [76].

The aim of random case review and M&M is process and outcome improvement; thus, it is critical that the environment remain non-punitive. Ideally, physicians, physician trainees, APPs, nursing, and technical staff should be required to attend. A statement of confidentiality should appear on any material distributed in print or electronically. Applicable state and federal laws should also be cited and unauthorized disclosure or duplication should be prohibited.

Each CCL should have a Quality Committee that includes the director, manager, and representatives of other stakeholders. This committee is responsible for reviewing complications not discussed in M&M conferences and other metrics of CCL quality, such as completion of time-outs, quality assurance checks of equipment, door to balloon times, and others as required by the hospital, state department of health, and TJC [77].

CCL Emergency Preparedness Protocols

Though rare, serious complications do occur in the CCL and these can have devastating consequences if not handled in a timely manner. Select complications for which specific protocols should be developed are listed in Table V. Drills should be performed at routine intervals in the CCL to practice response to these complications. T5

Patient Experience Optimization

Patient experience and satisfaction may impact clinical outcome. All hospitals participate in a patient

survey process that measures patients' perspectives of their hospital care, known as Hospital Consumer Assessment of Healthcare Providers and Systems, (HCAHPS, http://www.hcahpsonline.org). HCAHPS is designed and regulated by the Centers for Medicare and Medicaid Services (CMS), endorsed by the National Quality Forum, and results are publicly available on the website, hospitalcompare.hhs.gov. However, these surveys do not directly measure patient satisfaction with CCL services. CCL physicians interested in assessing the CCL patient experience would need to develop and administer a unique survey for this purpose.

CCL team members as well as those involved in scheduling and postprocedure care all have the ability to impact the overall patient experience and, thus, overall outcome. Some techniques for enhancing T6 patient satisfaction are listed in Table VI [78].

CONCLUSIONS

From the patient, physician, physician extender, and hospital perspective, these "best practices" further the goal to help assure the consistent delivery of high quality care in the cardiac catheterization laboratory. These measures are critical to patient safety, laboratory efficiency, and patient and referring physician satisfaction. Health care systems should provide resources through adequate staffing, equipment, and information technology, inclusive of physician extenders where appropriate, to assure the performance of these practices and their ongoing review.

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