



Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: Cardiac Catheterization Services.

Cardiac Catheterization Services

Ascension Michigan supports the continued regulation of cardiac catheterization, and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan

Beaumont

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Cardiac Catheterization Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2020. Beaumont Health supports the continued regulation of Cardiac Catheterization Services Open Heart Surgery Services. These standards received a major overhaul in 2017-2018, including updated procedure types and weights, and procedures to follow if physician procedure volume is below minimum requirements. No additional changes to these standards are recommended at this time.

Sincerely,

A handwritten signature in blue ink that reads "Patrick O'Donovan". The signature is written in a cursive style and is contained within a light blue rectangular box.

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 8, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Cardiac Catheterization services:

Henry Ford Health System (HFHS) appreciates the work the Standard Advisory Committee did in 2017 and 2018 and continues to support the regulation of Cardiac Catheterization. This includes language allowing pacemaker and ICD implantation to be done exclusively in hospitals with Cardiac Catheterization service approval.

HFHS does not believe there are any necessary changes to the standards as they are currently written.

Respectfully,

A handwritten signature in cursive script, appearing to read "Barbara Bressack".

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

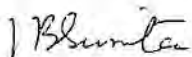
MidMichigan Health appreciates the opportunity to offer comments on the Certificate of Need review standards for cardiac catheterization services. MidMichigan Health would like consideration of the current delivery requirements for cardiac catheterization services. Specifically, MidMichigan is requesting that the minimum volume/procedure equivalent requirements be reviewed in order to maintain adequate cardiac catheterization services for our patients.

The existence of a relationship between volume/procedure equivalents and outcomes is controversial, and 300 procedure equivalents is an arbitrary number. While we recognize a minimum number of procedures are required to maintain adequate skills and proficiency for staff and physicians within the laboratory, we also know doing more does not guarantee excellence. Our interest is to ensure that the quality of the program itself, including physicians and staff, are how these programs are evaluated; based on appropriate outcome measures.

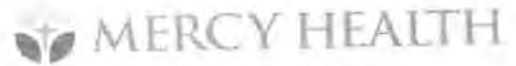
In addition to ensuring quality programs and services based on outcome measures, we would also propose increased exceptions for more rural programs where travel would cause increased risk for the patient. This will ensure adequate access to quality services is maintained for all of our patients, even in the rural areas.

Thank you for the opportunity to share our comments on the Certificate of Need review standards for cardiac catheterization services. MidMichigan Health appreciates the Commission's consideration of our comments.

Respectfully submitted,



Sunita Vadakath, MD
Vice President Service Lines
MidMichigan Health



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Cardiac Catheterization Services Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Cardiac Catheterization Services. Trinity Health Michigan supports continued CON regulation of Cardiac Catheterization Services.

Trinity Health Michigan believes the changes made in 2016 to the Certificate of Need Review Standards for Cardiac Catheterization Services appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. Specifically, Trinity Health supports the 2016 clarification that Cardiac Catheterizations, including the implantation of cardiovascular devices, should be limited to hospitals to ensure CON-approved facilities have sufficient volume to ensure adequate staff experience. Research has consistently demonstrated a strong link between facility case volume, operator case volume and the quality of patient outcomes. We believe that limiting cardiac catheterization procedures and laboratories to hospitals ensures the highest quality of care and we do not believe this limitation to hospitals limits access to care.

In keeping the CON standards aligned with standards of care, Trinity Health would support a review of what we believe to be discrepancies between current professional guidelines and the CON standards. Specifically, in January 2019, the Society of Cardiovascular Angiography and Intervention and American Academy of Neurology (AAN) issued a consensus statement that supports the performance of PFO closure in facilities without open heart surgery. The SCAI/AAN consensus statement is included with this letter. The septal closure device companies' FDA approved instructions for use (IFU) similarly do not mandate on-site open heart surgery. Our request is limited to PFO closures where current guidelines clearly support the performance of these procedures in facilities without open heart surgery. We do support the continued CON requirement of on-site open heart surgery to perform other structural heart procedures such as transcatheter aortic valve replacement (TAVR), MitraClip and Watchman appendage occlusion.

Additionally, Trinity Health would support a review of current professional guidelines and the CON standards to evaluate the ability of elective PCI programs to perform left-sided cardiac ablations in the cases where patients have low risk Atrial Fibrillation, left-sided Premature Ventricular Contraction/Ventricular Tachycardia in the absence of severe heart failure, left sided Atrial Tachycardia, and Supraventricular Tachycardia Associated with Wolff-Parkinson-White Syndrome. While such procedures were previously

limited to advanced tertiary care institutions, the Heart Rhythm Society's (HRS) Expert Consensus Statement on Electrophysiology Laboratory Standards acknowledges that a range of facilities, such as elective PCI program, have the level of resources and support to perform these complex procedures. The HRS consensus statement is included with this letter.

Because these issues are clinically complex, we would encourage the CON Commission to establish a Standards Advisory Committee comprised of clinical experts to review the current CON Review Standards and to recommend changes necessary to more clearly align the CON Review Standards with the guidelines established by SCAI, AAN and HRS and others. Trinity Health would appreciate the Commission's consideration for participation in any established Standards Advisory Committee regarding these issues.

We appreciate the CON Commission's consideration of our comments.


A handwritten signature in black ink, appearing to read "Kelly C. Smith". The signature is stylized with a large initial "K" and a long horizontal stroke at the end.

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan

CLINICAL DECISION MAKING

SCAI expert consensus statement on operator and institutional requirements for PFO closure for secondary prevention of paradoxical embolic stroke

The American Academy of Neurology affirms the value of this statement as an educational tool for neurologists.

Eric Horlick MD, FSCAI (Chair)¹ | Clifford J. Kavinsky MD, PhD, MSCAI (Co-Chair)² |
Zahid Amin MD, MSCAI³ | Konstantinos Dean Boudoulas MD, FSCAI⁴ |
John D. Carroll MD, MSCAI⁵ | Ziyad M. Hijazi MD, MSCAI^{6,7} | Dana Leifer MD, FAAN⁸ |
Helmi L. Lutsep MD, FAAN⁹ | John F. Rhodes MD, FSCAI¹⁰  |
Jonathan M. Tobis MD, MSCAI¹¹

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Abstract

Until recently, evidence to support Patent Foramen Ovale (PFO) closure for secondary prevention of recurrent stroke has been controversial. Publication of high-quality evidence from randomized clinical trials and the subsequent FDA approval of two devices for percutaneous PFO closure is expected to increase the volume of PFO closure procedures not only in the United States but worldwide. As this technology is disseminated broadly to the public, ensuring the safe and efficacious performance of PFO closure is essential to mitigate risk and avoid unnecessary procedures. This document, prepared by a multi-disciplinary writing group convened by the Society for Cardiovascular Angiography and Interventions and including representatives from the American Academy of Neurology, makes recommendations for institutional infrastructure and individual skills necessary to initiate and maintain an active PFO/stroke program, with emphasis on shared decision making and patient-centered care.

KEYWORDS

ASD/PDA/PFO, comparative effectiveness/patient centered outcomes research, closure, evidence-based medicine, structural heart disease intervention

1 | PREAMBLE

Cryptogenic stroke in young to middle-aged individuals represents a significant problem in terms of disability and societal costs. The FDA

approval of the Amplatzer Patent Foramen Ovale (PFO) Occluder in October 2016, and the Gore Cardioform device in March 2018, represents an important nonpharmacologic treatment to reduce the risk of recurrent stroke. These approvals cap an almost two-decade journey in

the United States in which several devices have been used off-label, some under a humanitarian device exemption (HDE) and others as part of randomized clinical trials. Since PFO closure using FDA approved devices with clearly stated indications for use are now available in general clinical practice, it is essential that physician stakeholders ensure the safe promulgation of this technology and establish criteria for the performance of these procedures that will be used in granting initial and ongoing privileges. These criteria are offered to support The Joint Commission mandate that medical staff privileges be granted based on professional criteria specified in the medical staff bylaws to ensure safe and effective patient-centered care. As an extension of this concept, the Society for Cardiovascular Angiography and Interventions (SCAI) and representatives from the American Academy of Neurology (AAN) agreed to provide recommendations to institutions and interested physicians for the establishment and maintenance of PFO closure programs. Since PFO closure is considered a nascent technology the recommendations contained herein initially rely on expert consensus and the lessons learned from clinical trials. As experience with PFO closure grows, these recommendations will be revised and updated based on expanded expertise and published data. However, the recent FDA approval of two percutaneous PFO occluder devices underscores the need to make initial recommendations now to provide a starting point for future modifications. The recommendations that follow were reviewed by the entire writing committee, with a majority required in order to be incorporated.

In accordance with SCAI policies on relationships with industry and other entities (RWI), relevant author disclosures are included in Supporting Information Table S1. To avoid actual, potential, or perceived conflicts of interest because of industry relationships or other personal conflicts, members of the writing committee and the peer reviewers of this document were asked to disclose all present or prior (within 12 months before the initiation of this clinical document) potential conflicts. The writing committee includes a majority of members without relevant RWI. Authors with relevant RWI were not permitted to draft or vote on content or recommendations pertaining to their RWI. RWI were reviewed during conference calls and updated as changes occurred. The work of the writing committee was supported exclusively by SCAI without commercial support. Writing committee members donated their time for the preparation of this document. Conference calls of the writing committee were closed and attended only by committee members and society staff. The respective executive boards of the two professional societies provided final review and approval of the document.

SCAI and AAN hope that adherence to the recommendations in this document will ensure safe and effective PFO closure technology dissemination for prevention of recurrent PFO mediated stroke in the United States and other countries to reduce the risk of recurrent ischemic stroke in patients with stroke due to a presumed paradoxical embolism.

2 | INTRODUCTION

Stroke is the fifth most common cause of death and the leading cause of preventable disability in the United States. There are approximately 795,000 strokes that occur each year of which 87% are considered

ischemic.¹ The societal cost in terms of healthcare, medications and missed work days is estimated to be in excess of \$34 billion dollars. Cryptogenic stroke, defined as brain infarction that is not attributed to definite large vessel atherosclerosis, small artery disease, or embolism from cardiac abnormalities despite extensive vascular, serologic, and cardiac evaluation, represents from 10–40% of ischemic strokes.¹ PFO is present in 25% of the general population and generally thought to be a benign persistence of a remnant of the fetal circulation.² Paradoxical embolism, defined as a systemic thrombotic embolism of venous or right atrial origin is presumed to pass through a right-to-left cardiac shunt, usually a PFO, but rarely a pulmonary arterio-venous malformation or other right to left shunt, and is thought to be the etiologic mechanism in some patients with cryptogenic stroke. Such patients tend to be younger and have a paucity of traditional stroke risk factors.

Cryptogenic stroke patients have traditionally been treated with a variety of oral anti-platelet agents and anticoagulants alone or in combination to reduce the risk of recurrent stroke. Despite this, there is a lingering 4.5% risk of recurrent stroke over 4 years of follow-up in an updated meta-analysis of randomized trials.³ Such events in young patients can lead to devastating lifelong consequences and long term disability. Optimal medical therapy to prevent recurrent stroke in this patient population has not been studied in a randomized clinical trial. Since oral anti-coagulants have not been proven to confer additional protection over anti-platelet therapy but have been associated with increased bleeding complications the AAN has recommended anti-platelet therapy for these patients.⁴

There has been interest in seeking an alternative, nonpharmacologic therapy that may, more effectively, reduce recurrent stroke risk in these patients without adverse consequences. Several approaches to PFO closure have evolved over the years including surgical suturing and endovascular closure most often using devices with a double disc design and a connecting waist. The appositional forces applied by the two discs on either side of the septum exert pressure on the septum primum and septum secundum closing the PFO.

The evolution of approval for device-mediated PFO closure has spanned two decades. Prior to 2006, PFO closure in the United States was only permitted under an FDA humanitarian device exemption (HDE). In 2006, the number of patients exceeded the regulatory mandated limit of 4,000 patients and the HDE was voluntarily withdrawn. Over the ensuing years randomized controlled trials (RCTs) were initiated using several different devices. Early trials were hampered by poor device design, poor enrollment, off label PFO closure, selection bias, and excessively liberal enrollment criteria. Initial PFO closure device designs were hampered by high residual shunt rates and thrombosis. As a result, the early RCTs for PFO closure versus medical therapy did not meet the primary endpoints. Despite this a patient-level meta-analysis of the early trials demonstrated superiority of PFO device closure over medical therapy.⁵ Four contemporary RCTs of PFO closure using more advanced device designs and more stringent enrollment criteria have recently been completed and published.^{6–9} Each of these trials has consistently shown a statistically significant advantage of PFO device closure over medical therapy in preventing recurrent ischemic events in young to middle aged patients with unexplained stroke and a PFO. Interestingly, the most recently published of the RCTs, the DEFENSE-PFO trial, from South Korea studied only patients with large shunts or atrial septal aneurysms

TABLE 1 Contemporary randomized trials on percutaneous Closure of patent foramen Ovale

Trial name	Year published	PFO device used	Control arm(s)	N	Mean follow-up (years)	Primary endpoint	Results		Conclusions	
							Closure	Control		
CLOSURE I	2012	STARFlex (NMT medical)	Aspirin and/or warfarin (INR 2-3)	909	2	Composite of stroke/TIA, all-cause mortality, death from neurologic causes	5.5%	6.8%	HR 0.78 95% CI 0.45-1.35 p = 0.37	Closure is not superior to medical therapy
PC trial	2013	Amplatzer PFO Occluder (Abbott structural)	Antiplatelet therapy or oral anticoagulation	414	4.1	Composite of death, nonfatal stroke, TIA, or peripheral embolism	3.4%	5.2%	HR 0.63 95% CI 0.24-1.72 p = 0.34	Closure is superior to medical therapy
RESPECT	2013	Amplatzer PFO Occluder (Abbott structural)	Aspirin or warfarin or Clopidogrel, or aspirin with extended release dipyridamole	980	2.6	Composite of recurrent nonfatal ischemic stroke, fatal ischemic stroke, or early death after randomization	Intention-to-treat: 0.66 events per 100 pts/year As-treated 0.39 events per 100 pts/year	Intention-to-treat: 1.38 events per 100 patients/year As treated 1.45 events per 100 patients/year	HR 0.49 95% CI 0.22-1.11 p = 0.08 HR, 0.27 95% CI 0.10-0.75 p = 0.007	No significant benefit for closure (intention-to-treat-analysis) Closure is superior to medical therapy (as-treated analysis)
RESPECT (long-term follow-up)	2017	Amplatzer PFO Occluder (Abbott structural)	Aspirin or warfarin or Clopidogrel, or aspirin with extended release dipyridamole	980	5.9 ^a	Composite of recurrent nonfatal ischemic stroke, fatal ischemic stroke, or early death after randomization	Intention-to-treat: 0.58 events per 100 pts/year New stroke of unknown mechanism: 0.31 events per 100 pts/year	Intention-to-treat: 1.07 events per 100 pts/year New stroke of unknown mechanism: 0.86 events per 100 pts/year	HR 0.55 95% CI 0.31-1.0 p = 0.046 HR 0.38 95% C, 0.18-0.79 p = 0.007	Closure is superior to medical therapy on extended follow-up in intention-to-treat analysis
CLOSE	2017	Any CE marked PFO device	(1) Antiplatelet arm: Aspirin or Clopidogrel or aspirin with extended release dipyridamole (2) Oral anticoagulant arm: Vitamin K antagonists or NOACs	663	5.3	Recurrent fatal or nonfatal stroke	Closure vs. antiplatelet therapy: 0 Closure vs. antiplatelet therapy: 4.9% 5-year estimate Anticoagulant vs. antiplatelet therapy: 1.5% vs. 3.8%, respectively, 5-year estimate	Closure vs. antiplatelet therapy: 4.9% 5-year estimate Anticoagulant vs. antiplatelet therapy: 1.5% vs. 3.8%, respectively, 5-year estimate	Closure vs. antiplatelet therapy: HR 0.03 95% CI 0-0.26 p < 0.001 Anticoagulant vs. antiplatelet therapy: HR 0.43 95% CI 0.1-1.5 p = 0.17	Closure is superior to antiplatelet in patients with ASA or PFO with large shunt Anticoagulant is equivalent to antiplatelet therapy
REDUCE	2017	Helex Septal Occluder and Cardioform Septal Occluder (W.L. Gore and Associates)	Aspirin or Clopidogrel or aspirin with dipyridamole	664	3.2 ^a	(1) recurrent stroke (2) new brain infarct inclusive of silent brain infarct (SBI)	Ischemic stroke: 0.39 strokes per 100 patient years ^b New brain infarct: 5.7%	Ischemic stroke: 1.71 strokes per 100 patient years New brain infarct: 11.3%	HR 0.23 95% CI 0.09-0.62 p = 0.002 RR 0.51 95% CI 0.29-0.91 p = 0.04	Closure is superior to antiplatelet therapy

(Continues)

TABLE 1 (Continued)

Trial name	Year published	PFO device used	Control arm(s)	N	Mean follow-up (years)	Primary endpoint	Results			
							Closure	Control	p value	Conclusions
DEFENSE-PFO	2018	Amplatzer PFO Occluder (Abbott structural)	Aspirin or aspirin and Clopidogrel, or aspirin and Cilostazol, or warfarin	120	2.8 ^a	Stroke, vascular death or TIMI-defined major bleeding	Ischemic stroke: 0	Ischemic stroke: 10.5%	$p = 0.023$	Closure in patients with high risk PFO characterized in lower rate of ischemic stroke versus medical therapy
							2 year event rate 0	2 year event rate 12.9%	Log-rank $p = 0.013$	
							New ischemic lesion on MRI: 8.8%	New ischemic lesion on MRI: 18.4%	$p = 0.24$	

N: Number of patients.

CLOSURE I: Evaluation of the STARFlex[®] Septal Closure System in Patients with a Stroke and/or Transient Ischemic Attack Due to Presumed Paradoxical Embolism through a Patent Foramen Ovale.

PC: Percutaneous closure of patent foramen ovale using the AMPLATZER[®] PFO occluder with medical treatment in patients with cryptogenic embolism.

RESPECT: Randomized evaluation of recurrent stroke comparing PFO closure to established current standard of care treatment.

CLOSE: Closure of patent foramen ovale or anticoagulants versus antiplatelet therapy to prevent stroke recurrence.

REDUCE: GORE[®] HELEX[®] Septal Occluder/GORE[®] CARDIOFORM septal occluder and antiplatelet medical management for reduction of recurrent stroke or imaging-confirmed TIA in patients with patent foramen ovale (PFO).

INR: International normalized ratio.

TIA: Transient ischemic attack.

PFO: Patent foramen ovale.

ASA: Atrial septal aneurysm.

HR: Hazard ratio.

RR: Relative risk.

CI: Confidence interval.

Pts: Patients.

Yr: Year.

NOACs: Novel oral anticoagulants.

TIMI: Thrombolysis in myocardial infarction.

^a Median follow-up reported.

^b New brain infarction defined as clinical ischemic stroke or silent brain infarction.

was prematurely terminated after publication of the other recent RCTs due to safety concerns.¹¹ There have now been six RCTs completed comparing PFO closure to best medical therapy (Table 1) and a meta-analysis of these trials encompassing 3,440 patients with a mean follow-up of 4 years demonstrated a recurrent stroke rate of 2% for PFO closure versus 4.5% for medical therapy.⁵

The landmark study, *Randomized Evaluation of Recurrent Stroke Comparing PFO Closure to Established Current Standard of Care Treatment (RESPECT)* trial compared medical therapy with one or more antiplatelet medications or warfarin alone with PFO closure using the Amplatzer PFO Occluder (Abbott Structural) in 980 patients with cryptogenic stroke who were initially reported in 2013 after 25 primary end-points had occurred.¹⁰ The primary efficacy endpoint was nonfatal ischemic stroke, fatal ischemic stroke or early death after randomization. With a mean follow-up of 2.6 years, the intention-to-treat cohort did not reach significance, although both the prespecified per-protocol and the as-treated analyses suggested superiority of closure over medical therapy. In May 2016 the FDA convened an expert advisory panel to review longer term follow-up results from RESPECT and the panel voted in favor of approval.¹¹ The FDA also requested supplemental long-term analysis of the RESPECT patient cohort before finalizing device approval in October 2016 (Approval announcement). Long-term follow-up with a mean of 5.9 years now demonstrated a significant reduction in recurrent ischemic stroke in the closure arm as compared to medical therapy (18 vs. 29 had events HR, 0.55; 95% CI, 0.305–1.0; $p = 0.046$). The reduction in new stroke of unknown mechanism was significant in the closure arm and superior to medical therapy (10 vs. 23 had events, HR, 0.38; 95% CI, 0.18–0.79; $p = 0.007$). Based upon extended follow-up results of the RESPECT trial, the FDA approved the Amplatzer PFO Occluder for use as the first device for PFO closure in the United States to reduce the risk of recurrent ischemic stroke in patients, predominantly between the ages of 18 and 60 years, who have had a cryptogenic stroke due to a presumed paradoxical embolism, as determined by a neurologist and a cardiologist following an evaluation to exclude known causes of ischemic stroke.¹² More recently, on March 30, 2018, the FDA approved a second device, the Gore Cardioform™ Septal Occluder for PFO Closure, based on the results of the REDUCE trial.⁸ The REDUCE trial randomized 664 patients with cryptogenic stroke to PFO closure versus treatment with antiplatelet therapy. At a median follow-up of 3.2 years of follow-up the study demonstrated a significant reduction in the rate of ischemic stroke (1.4 vs. 5.4% HR, 0.23; 95% [CI], 0.09 to 0.62; $p = 0.002$) and the incidence of a composite of new brain infarction on MRI and clinical events (5.7 vs. 11.3% relative risk, 0.51; 95% CI, 0.29 to 0.91; $p = 0.04$) favoring device closure.

Percutaneous PFO closure techniques have the potential to have a major, positive impact on treatment of patients with paradoxical embolic stroke and fulfill an important unmet clinical need. PFO occlusion techniques are relatively safe when carried out by experienced operators. This expert consensus document statement outlines our proposed institutional and operator requirements to assist with the implementation of credentialing standards and help providers to participate responsibly, safely, and effectively in this new and important clinical field. The safe application of PFO closure requires specific cognitive and technical skillsets and respect for the potential for

serious procedure and device-related complications of these interventions. Procedural specialists performing PFO closure will come from a variety of backgrounds, including interventional, structural, and pediatric cardiology. It is expected that physicians will operate in the context of a multidisciplinary team (MDT) to optimize patient selection and clinical benefit. A PFO closure program should be institutional in nature, with assessments and therapy delivered across multiple disciplines. Patient centered care defined by the Institute of Medicine as "health care that establishes a partnership among practitioners, patients, and their families to ensure that decisions respect patients' wants, needs, and preferences and that patients have the education and support to make decisions and participate in their own care". Patient-centered care will be a guiding principle in the implementation of these novel interventional therapies. Physicians participating in PFO closure programs must work together in the context of a larger system of health that includes stakeholders from multiple disciplines. The notion of MDTs was first validated in the surgical arena and has gained traction more recently with the evolution of percutaneous valve therapies.¹³ It is therefore expected that recurrent stroke prevention in the cryptogenic stroke patient population will be a collaborative effort of physician and nonphysician experts that may include vascular neurologists, interventional cardiologists, hematologists, imaging experts, primary care providers, and others.

3 | BACKGROUND

Historically, societal guideline documents regarding management of patients with cryptogenic stroke and a PFO have not supported device closure except in highly restricted patient subsets such as patients with deep vein thrombosis.¹⁴ This was the result of a lack of RCT data supporting this procedure related to poorly designed early trials, which included patients with TIA, and using devices with high rates of device associated thrombus, atrial fibrillation, and residual shunt.¹⁵ Recently published contemporary RCTs comparing device closure of PFO to best medical therapy using contemporary devices with longer follow-up demonstrate the superiority of PFO closure over medical therapy in this patient population. Based on the totality of evidence from RCT data, the FDA has now approved two devices for PFO closure for patients with paradoxical embolic stroke. While there are a variety of devices for PFO closure available in other countries through their regulatory pathways, the Amplatzer PFO Occluder and the Gore Cardioform device are currently the only devices approved in the US for this indication. We can anticipate that PFO closure in the management of patients with unexplained stroke will assume a greater role as the guideline documents regarding management of these patients are revised. This has already begun as evidenced by the recently published Canadian Stroke Best Practice Recommendations stating that PFO closure is suitable for patients in alignment with the FDA labeling with level of evidence A.¹⁶ As the penetration of percutaneous PFO closure increases, physicians have a fiduciary responsibility to ensure the safe and effective application of these technologies. Therefore, it is essential that stakeholders have a thorough understanding of the cognitive and technical skillsets surrounding PFO closure.

As this procedure spreads into the wider public domain, training of new proceduralists needs to be carried out in a controlled, systematic fashion to ensure optimal results with respect to efficacy and safety. A PFO closure program must be established in the context of a larger stroke program that includes all stakeholders such as cardiologists, stroke neurologists, hematologists, and imaging specialists. In addition, there are specific cognitive and technical skillsets essential for proceduralists to master when performing PFO closure. Physicians performing PFO closure should have knowledge of principles surrounding ischemic stroke, including:

1. Etiologies of ischemic stroke.
2. Clinical syndromes that mimic stroke.
3. Stroke phenotype classification systems such as ASCOD.¹⁷
4. Stroke risk scoring systems including (CHA2DS2-VASC) and risk of paradoxical embolus (RoPE) scores.^{18,19}
5. Interpretation of invasive and noninvasive stroke neuroimaging results.
6. RCTs comparing PFO closure to medical therapy.
7. Medical therapies for prevention of recurrent stroke including anti-platelet and anti-coagulants
8. Diagnostic evaluation of patients with ischemic stroke
9. Cardiac imaging techniques in patients with ischemic stroke potentially related to a cardiac source of embolism including transthoracic, transesophageal, intracardiac, and contrast echocardiography and transcranial Doppler (TCD).²⁰
10. Indications and contraindications for PFO closure.
11. Knowledge and understanding of shared decision making and working in the context of a MDT.²¹

Proceduralists planning on developing a PFO closure program must understand ischemic stroke in terms of how it presents clinically, predisposing risk factors, and how recurrent stroke is prevented using traditional pharmacologic therapy. The proper application of adjunctive diagnostic testing in stroke patients is important. Certain stroke syndromes are more likely to be cardio-embolic. Appropriate use and interpretation of noninvasive brain imaging modalities including CT, MRI, and ultrasound is vital for establishing the cause of stroke and screening patients for possible PFO closure. Multiple cortical strokes in different vascular distributions of different ages are more likely to be embolic than a lacunar stroke. These differences must be recognized since their treatments to prevent recurrent events are different. This highlights the importance of close collaboration between cardiovascular specialists and stroke neurologists for any patient presenting with a possible unexplained ischemic stroke and being considered for PFO closure. Establishing the diagnosis of unexplained, or cryptogenic stroke, implies that an exhaustive search for secondary causes has been carried out and should focus on excluding all forms of congenital and acquired cardiovascular disease. Searching for disorders of coagulation is also important in select patients and may involve hematologists as part of the MDT. Detection of occult atrial fibrillation using long-term monitoring (see below) is also essential due to the strong association of nonvalvular atrial fibrillation and ischemic stroke in certain patient subsets. Scoring systems have been validated which predict the probability that an unexplained stroke was due to a PFO-

mediated paradoxical embolism and relies on young age, absence of traditional stroke risk factors and infarct location on neuroimaging to establish attributable risk.¹⁹ Such scoring systems may be useful in assessing the likelihood that a stroke was caused by a PFO and in assessing the risk-benefit ratio of PFO closure.

Evaluation of patients with suspected cryptogenic stroke should include echocardiography, either transthoracic and/or transesophageal.²² A nuanced understanding of image interpretation of these modalities as well as intra-cardiac echocardiography is required for proper patient selection as well as procedural guidance (Table 2). Echocardiography should include echo contrast, usually in the form of agitated saline microbubbles. Transesophageal echocardiography (TEE) provides more detailed morphological data on the interatrial septum with regards to tunnel length, thickness of the septum secundum, the presence of a Eustachian valve or Chari network, and the magnitude of the atrial shunt, all of which is essential for procedural planning.^{23,24} The presence of a large sized-PFO associated with a large shunt or an atrial septal aneurysm is important to recognize and increases the risk of recurrent stroke.²⁵ TCD can also aid in detecting CNS-directed PFO-mediated shunting.²⁶

Proper patient selection for PFO closure is critical in order to treat the patients who will benefit the most and avoid unnecessary procedures. The risk/benefit ratio of performing PFO closure should be weighed carefully especially in patients with a low RoPE, for example, those with a RoPE score of less than 7.²⁷ The RoPE score was derived from a large database of patients with cryptogenic stroke and PFO and incorporates six variables (hypertension, diabetes, history of stroke, smoking, cortical infarct on imaging, and age) to assist in determining the likelihood that a stroke is related to paradoxical embolism.²⁸ The RoPE score should not be used in isolation since it does not take into consideration a recent history of DVT, stroke shortly after straining, or echocardiographic features suggestive of a PFO favorable for transmitting emboli (i.e., large size, atrial septal aneurysm). The FDA approval of both PFO Occluders clearly mandates that patients be evaluated by both a cardiologist and a neurologist prior to consideration of PFO closure. The "Heart-Brain Team" fosters shared decision making between the patient and a MDT of providers, promotes proper patient selection, serves to select only appropriate candidates for PFO closure while mitigating unnecessary risks.²⁹

4 | PROCEDURAL AND OPERATOR REQUIREMENTS

Proceduralists performing PFO closure will come from a variety of different backgrounds including interventional cardiology, structural heart disease (SHD), and pediatric interventional cardiology. Regardless of background all operators must possess the same technical skillsets that would include:

1. Use of various imaging modalities for procedural guidance including fluoroscopy, TEE and/or intracardiac echocardiography (ICE)
2. Manipulation of intracardiac catheters, wires and sheaths, and balloons in the left and right atrium and pulmonary veins
3. Techniques for vascular access management

4. Use of all forms of endovascular retrieval devices including snares and forceps
5. Ability to recognize and treat complications including percutaneous pericardiocentesis

Experience with specific percutaneous procedures requiring access to the left atrium is helpful in forming a foundation of technical expertise for PFO closure. These would include:

- Closure of secundum atrial septal defect
- Left atrial appendage (LAA) occlusion
- Techniques for transseptal puncture
- Closure of prosthetic mitral paravalvular leaks
- Mitral valve repair using techniques involving transseptal puncture
- Balloon mitral valvuloplasty
- Left ventricular assist device placement when such devices involve a transseptal approach (i.e., Tandem Heart)
- Pulmonary vein interventions
- Balloon atrial septosomy or septoplasty

4.1 | Imaging guidance

Operators performing PFO closure should have a mastery of imaging modalities used for procedural guidance. These modalities include fluoroscopy, angiography, TEE interpretation, and/or ICE. Operators should also be familiar with the anatomy of the atrial septum and its surrounding structures including the aorta, the vena cava, and adjacent valve structures. Fluoroscopic landmarks provide invaluable information to understand the precise location of wires, sheaths catheters, and devices which are not always visible on echocardiographic imaging. Integrating fluoroscopic and echocardiographic data is important for successful PFO closure. Fluoroscopy, either single or biplane, should be used for visualization of the relational anatomy in the posterior anterior or left anterior oblique views (with or without cranial angulation) to define the atrio-septal plane.

Imaging for PFO device closure typically requires TEE or ICE guidance (Table 2). The implanter needs to understand echocardiographic imaging interpretation to inform proper device selection. Skill in echocardiographic guidance for PFO closure aids in identifying anatomic variants which would make PFO closure more difficult and guides proper positioning of the closure device. Wide tunnels, Long tunnel length, the presence of an ASA, eustachian valves, Chiari network, thick septum secundum and pacemaker leads can lead to difficulties when performing PFO closure and be associated with inadequate disc apposition, residual shunts or device embolization. The writing committee strongly recommends that proceduralists rely on procedural TEE or ICE guidance for imaging of the interatrial septum in multiple planes. TEE provides excellent image quality of the entire IAS (interatrial septum), as well as adjacent cardiac and extra-cardiac structures. TEE can effectively image left atrial and LAA thrombi, prominent Eustachian valves and Chiari networks. With the echocardiographer as the main TEE operator, the proceduralist is freed from additional tasks during device closure. However, TEE may require general

anesthesia (GA) which exposes the patient to risks of GA, esophageal trauma, and patient discomfort. Relying on TEE for PFO closure requires the presence of an additional physician to manipulate the TEE probe and acquire necessary images. Alternatively, ICE imaging quality has been shown to be comparable to TEE and allows for a better visualization of the septal rims prior to closure.^{23,30} ICE also obviates the need for GA. In addition, the operator has complete control over image acquisition, eliminating the need for an additional physician for the procedure. The choice of imaging modalities used for PFO closure will differ among sites and depend on local factors including the availability of technologies, local expertise, and patient-specific factors. The preprocedural echocardiographic imaging is essential to the initial diagnosis and characterization of the PFO, assessment of additional potential causes of paradoxical embolism, and clarifying the image guidance needs of the PFO closure procedure. While some very experienced proceduralists may be able to perform PFO closure using fluoroscopy and angiography alone, it is recommended for less experienced proceduralists to incorporate some form of ultrasound guidance.³¹ Even for experienced proceduralists the addition of soft tissue imaging is essential for many anatomic variants.

4.2 | Venous access and manipulation of sheaths and catheters into the left atrium

Current PFO devices require a medium to large bore outer diameter sheath or delivery system (8Fr–12Fr). Fundamental aspects of obtaining vascular access using large venous sheaths, achieving hemostasis at the end of the procedure, working with long wires and sheaths, and closed loop hemodynamic monitoring systems would be expected to be part of the foundational knowledge base of the PFO proceduralist. It is the usual practice for stroke related PFO device closure to perform sheath exchanges over a stiff 0.035" guidewire positioned in the left upper pulmonary vein. Physicians must also be familiar with advancement of PFO delivery systems safely into the left atrium as well as a nuanced understanding of device size selection accounting for all the anatomic issues described above. Meticulous attention must be given to safe catheter techniques to avoid emboli (air or thrombus). Once catheters and delivery sheaths are in the left atrium, operators need to understand the relationship between the sheath and the left atrial roof, LAA, pulmonary veins and posterior wall at all times, since these are thin walled structures prone to perforation that would lead to pericardial effusion and tamponade.³²

4.3 | Management and best practice recommendations to avoid/manage adverse events

Physicians must be familiar with potential adverse events that can arise related to the procedure and the techniques required to promptly treat them. Physicians must have knowledge of the different types of sheaths, catheters, snares or forceps that can be used for device retrieval in case of device embolization. It is important to know the limitations of transcatheter device retrieval, especially if the device is caught in chordae or subvalvar apparatus of the mitral or tricuspid valves. Further, physicians must be well trained in managing vascular access and performing pericardiocentesis. As was seen with percutaneous ASD closure, the success

TABLE 2 Stroke-related PFO closure peri-procedural imaging modality knowledge

Image modality	Indication	PFO shunt	Advantages	Disadvantages
Transthoracic echocardiography	Assess left ventricular function and screen for valvular disease	Positive for right to left shunt at the atrial level when contrast enters the left atrium within the first three cardiac cycles. Trace <5 bubbles -moderate: 6–20 particles Severe: >20 particles	Easily available preliminary evaluation for sources of emboli and left to right shunting In most cases, allows for a better Valsalva maneuver with agitated saline contrast	Limited anatomic assessment of intraatrial septum Inability to resolve the nature of a septal defect Often limited by technical factors such as body habitus
Transesophageal echocardiography With contrast (microbubbles)	Morphological characterization of interatrial septum, atrial structures Evaluation of ascending aorta Anatomical details of PFO indicated for intervention	Positive for right to left shunt at the atrial level when contrast enters the left atrium within the first 3 cardiac cycles. Trace ≤ 5 bubbles Moderate 6–20 particles Severe: >20 particles	Gold standard for visualization of the foramen ovale and associated anatomy.	More invasive as a technique and usually requires general anesthesia if used procedurally Can result in local pharyngeal and esophageal trauma Not universally possible in all patients (previous esophageal surgery, dysphagia, musculoskeletal problems with neck, esophageal varices)
Intra cardiac echocardiography	Intra procedural assessment of intraatrial septum and device position	Positive for right to left shunt at the atrial level when contrast enters the left atrium within the first three cardiac cycles. Trace ≤ 5 bubbles Moderate: 6–20 particles Severe: >20 particles	Excellent resolution of septum and intracardiac structures Obviates the need for intraprocedural TEE and general anesthesia Provides a critical skill that can be translated to other procedures	Requires the presence of a dedicated physician operator Requires another venous access Cost of the probe Can be difficult to use if there is no access to the heart from the IVC (chronic thromboembolic disease with collateralized IVC, Azygous continuation of inferior vena cava)
Transcranial Doppler (TCD)	Diagnosing right-to-left shunts at rest and after a Valsalva maneuver	Presence of right to left shunt but not location of the shunt. Mild–moderate Spencer grade I, II Moderate–severe Spencer grade III–V ⁵⁰	Highly sensitive for identifying presence of a right-to-left shunt, determination of shunt magnitude, and predictor of post device residual shunting during follow-up	Not useful intraprocedurally for anatomic evaluation Baseline positivity in patients with no anatomic shunt

rate of PFO closure improves with increasing experience, leading to reduced procedural complications such as air-embolization, stroke, atrial arrhythmias, LAA perforation and high radiation dose.^{33,34}

Among the most serious adverse events associated with PFO device closure include device malposition and device embolization. The proceduralist should be skilled in retrieval techniques including the use of various forms of biotomes and snares. A strong understanding of the above imaging modalities will improve recognition of device malposition. Embolization events can be categorized by location as either intracardiac or intravascular. Current experience in device retrieval suggest that intracardiac location should be approached with extreme caution due to risk of perforation or valve injury. Most intravascular embolization events occur to the descending aorta and can be removed early and some limited reports suggesting mid-term follow-up removal using a snare technique and covered stent angioplasty if deemed necessary after removal. The most concerning serious adverse event involves cardiovascular perforation, pericardial effusion, and tamponade. This can occur acutely (early), during the midterm (weeks) or occasionally late following implant due to erosion.³² Erosion has been reported with the Amplatzer PFO device at a rate of 0.018%, no erosions have been reported with the Gore device. It is critical, particularly in the acute presentation, that operators recognize early signs of an effusion so that it can be managed quickly and safely. Continuous hemodynamic monitoring during an implant is essential. There are multiple modalities that can allow a rapid determination of a new effusion, including fluoroscopy (decreased excursion of the left side of the cardiac silhouette in the LAO projection often precedes hemodynamic changes), echo imaging, and hemodynamic monitoring.³⁵ The implanting physician must be well trained in the basic principles and equipment required to safely access and drain the pericardial space. The patient must be monitored for other adverse events including procedure-related stroke, air embolus, and device thrombus, all of which are mitigated by sophisticated handling of the sheath delivery system and the anticoagulation status of the patient during the procedure. Sudden ST segment elevation, which is usually transient, can signify air introduced into the left atrium that has embolized into the more anterior right coronary artery. Air embolism can result in severe bradycardia, cardiac arrest, and stroke. The implanting team should continuously monitor ultrasound images for the presence of thrombus on the PFO device or sheath/delivery system during the case. Having access to an interventional stroke team is advisable to minimize embolic stroke severity should a stroke occur during or after the procedure. Postprocedure patients should be monitored in a suitable recovery area until they have recovered from the effects of anesthesia. Unexplained hypotension or instability should prompt immediate echocardiography to assess for device embolization, tamponade or other mechanical complication. A new pericardial effusion postprocedure should be monitored and determined to be stable prior to discharge.

There should be a structured program for postdischarge follow-up and evaluation by a cardiovascular specialist. That evaluation will likely include an ECG, an echocardiogram as well as a clinical visit. Further ambulatory ECG monitoring should be carried out if atrial arrhythmias are suspected post device closure.

It is important to be knowledgeable of the long-term medical therapy required postprocedure including anti-platelet therapy, anti-

coagulation therapy, when indicated, and endocarditis prophylaxis. In addition, appropriate timing of clinical follow-up and serial echocardiography imaging should be established according to the device's approved labeling. A physician must also be aware of the symptoms and signs of potential long-term adverse events including late device erosion, infection, endocarditis, nickel allergy, atrial fibrillation, and others.

4.4 | Operator-specific requirements

Currently, no data are published on the average number of procedures performed by various individual operators. Furthermore, there are no data in the literature to indicate the total number of stroke-related PFO closure procedures required to achieve proficiency as a procedural specialist. There is published survey data garnered from experts in the field suggesting initial procedure volumes of 7–50 cases to achieve a basic level of proficiency.^{36–38} Such data will be important to collect going forward. Given the limitations of the available data regarding PFO specific device closure, the writing committee arrived at consensus recommendations for operator requirements for stroke-related PFO device closure which includes >50 life-time structural or congenital catheter based interventions which includes a minimum of 25 procedures involving atrial septal interventions or 12 specific to PFO closure (Table 3). Qualifying life-time procedures would include those listed above and in Table 3. As mentioned earlier, each device has unique characteristics that necessitate a consistent, organized training approach provided by the manufacturer that complies with FDA requirements. Before undergoing formal training for a specific device or technique, there are skillsets fundamental to transcatheter PFO device closure in which all operators must demonstrate a high level of training, competence, and continued experience. Therefore, our recommendations are purely based on current guidelines regarding secundum ASD device closure requirements and consensus opinion of the writing group.³⁹ This is similar to other documents addressing operators and institutional requirements for interventional catheterization procedures.^{40–43} Recommendation categories include the experienced operator and the novice operator. On an ongoing basis, an experienced operator should perform >30 procedures that involve atrial septal interventions or > 15 PFO device closures over a 2 years period (Table 3).

4.5 | Additional requirements for the novice operator

The writing group supports the standards of the 2007 multi-society guidance document³⁶ suggesting that an interventional cardiologist with no experience in PFO device closure should have a physician proctor or mentor during interventional training, for the initial 10 cases and have a physician proctor present for 3–5 cases for each new device system used. Novice operators should also attend an FDA recommended mandatory peer-to-peer training course. Such courses should include:

- Patient selection process and establishment of neurological relationship.
- Clinical baseline assessment and category of stroke determination.

TABLE 3 PFO closure requirements—Procedural specialist and medical facility

Procedural specialist ^a	<p><i>Initial qualification</i></p> <ul style="list-style-type: none"> • Clinical knowledge-base that includes a comprehensive understanding of stroke-related PFO closure and appropriate treatment strategies for this unique patient population. • Suitable training on the PFO closure device(s) approved by the FDA. • Understanding of atrial anatomy and imaging • >50 life-time structural/congenital^b catheter interventions with either a minimum of 25 involving septal interventions^c or 12 specific to PFO device placement. • Experience with catheter-based management of potential complications, including pericardiocentesis, recognition of device malposition, and embolized device retrieval. <p><i>Novice operators</i></p> <ul style="list-style-type: none"> • Mandatory peer-to-peer training course. • Physician proctor or mentor during interventional training--10 cases total. • Physician proctor present for 3–5 cases for each new device system. <p><i>Ongoing</i></p> <ul style="list-style-type: none"> • Over a 2-year period, >30 procedures that involve septal interventions^c or >15 specific to PFO device placement. • Process for identifying whether additional training is required on the basis of technological or clinical changes.
Medical facility	<ul style="list-style-type: none"> • >100 structural/congenital^b catheter interventions in the 2 years leading to PFO program initiation. • Yearly and thereafter, 50 structural/congenital^b interventions, at least 25 of which involved septal interventions^c and/or 12 specific to PFO device placement. • Continuous intraprocedure availability of a physician (interventional cardiologist, imaging cardiologist, or cardiac anesthesiologist certified in echocardiography and with experience in guiding structural/congenital heart interventions) with experience at transesophageal echocardiography or intracardiac echocardiography in structural/congenital heart disease. • Multidisciplinary team that includes necessary staff and expertise for preoperative evaluation, performing the PFO closure procedure, and acute and long-term postprocedure follow-up • Ready access to an active cardiothoracic surgery program with cardiac surgeons and perfusionists. • Cardiac catheterization laboratory, or hybrid room with hemodynamic monitoring and high-resolution imaging.
Data collection and quality	<ul style="list-style-type: none"> • Internal collection of data on all cases with a structure process for analysis of the program with quality assessment and quality improvement process. Data should include patient characteristics, indication for procedure, procedure performance, and up to 30 day outcomes. • Submission of all cases to a national or multicenter registry (if and when available) for benchmarking. • Institutional multi-stakeholder process for evaluation of patient selection, outcomes, and quality of care

^a Procedures for stroke-related PFO device closure are typically performed either by interventional adult or pediatric cardiologists. This document uses the term “procedural specialist” to apply to members of any subspecialty who perform stroke-related PFO closure procedures. In some cases, a physician team will be composed of two operators; therefore, the procedural volume criteria and ongoing proficiency requirements apply to at least one member of the team.

^b Structural/congenital procedures include cardiac catheterization procedures for cardiovascular structure or congenital heart defect interventions.

^c Septal interventions included transseptal puncture, PFO and ASD placement, mitral valve interventions, mitral paravalvar leak closure, LAA occluder placement, pulmonary vein interventions, and other trans atrial procedures.

- Transcatheter stroke-related PFO device closure procedural technique.
- Anticipated potential serious adverse events and their management.
- Perform three simulated PFO device placement scenario cases (if available.)
- Perform first 2–3 PFO device placement cases under the supervision of a proctor and at the end of these cases, the trainee should be certified by the proctor to perform PFO closure procedures independently.

4.5.1 | Patient selection

A successful PFO program must have a rigorous process for selection in order to offer the procedure to only the patients with unexplained stroke who will benefit the most in order to mitigate risk and avoid unnecessary procedures. As mandated by the FDA, patient selection should involve close collaboration between the PFO proceduralist and a neurologist (preferably a stroke neurologist). Discussions with the patient regarding the risks and benefits of the procedure should be carried out in the spirit of patient centered care. Patient selection should adhere closely to the FDA labeling which coincides with the inclusion criteria for the major RCTs. The contemporary randomized trials of PFO closure only included patients with documented stroke

60 years of age or less and this is the subset of patients primarily included in the FDA labeling. Patients with transient ischemic attack (TIA) were not included. Operationally, stroke is defined as an acute neurologic deficit, presumably due to ischemia, that either resulted in clinical symptoms lasting 24 hr or longer, or symptoms lasting less than 24 hr but associated with a new, neuro-anatomically relevant, cerebral infarction on noninvasive imaging. Prior to considering PFO closure, a careful evaluation should be done to rule out other causes of stroke including hypercoagulable states, atherosclerotic lesions, small vessel disease other cardioembolic sources and arterial dissection which would obviate the need for PFO closure. It is also important to exclude atrial fibrillation due to its association with cardioembolic stroke. A period of extended cardiac monitoring should be performed for approximately 4 weeks in patients over the age of 40 with a presumed cryptogenic stroke prior to considering PFO closure.^{44,45} A shorter period of monitoring of 1–2 weeks may be appropriate for patients under 40 unless there are superimposed atrial fibrillation risk factors such as hypertension, hyperthyroidism, valvular disorders or alcohol use. Unmasking a significant burden of occult atrial fibrillation or flutter would suggest an etiologic association and mandate guideline-directed chronic anticoagulation as opposed to PFO closure. The RoPE score can also be helpful in determining the probability that a given stroke event was PFO mediated and is based

on age, cortical location of stroke and an absence of traditional stroke risk factors.¹⁹ Other factors such as a history of deep vein thrombosis, recent travel, pulmonary embolus, or Valsalva maneuver prior to the stroke event tend to add to the likelihood of a PFO-mediated stroke and needs to be explored.⁴⁶

5 | INSTITUTIONAL REQUIREMENTS AND COLLABORATIVE CARE MODELS

PFO closure should not be carried out by a single individual in isolation but rather as an institutionally supported program for the comprehensive evaluation and treatment of all forms of stroke. The medical facility should have an established SHD and/or Adult Congenital Heart Disease (ACHD) Program, as well as physical space and ancillary services to execute the procedure effectively and safely. Specifically, the writing committee considered the following aspects to be key institutional requirements:

5.1 | Institutional requirements

The institutional requirements to embark on a stroke-related PFO closure program are summarized in Table 3. Specifically, the institution should have performed >100 structural/congenital catheter-based interventions in the year leading to program initiation. On an ongoing annual basis, the institution should perform at least 50 structural/congenital procedures at least 25 of which involve atrial septal interventions and/or 12 specific to PFO device closure. There should be ready access to an active cardiothoracic surgical program. While it is preferred that this program exist on-site, rapid transfer to a nearby facility which offers cardiothoracic surgery may be acceptable in some carefully considered circumstances.

5.2 | Procedural area

1. Stroke-related PFO closures should be performed in the interventional cardiac catheterization laboratory or hybrid OR with continuous hemodynamic monitoring.
2. Fixed single plane or biplane radiographic imaging systems with fluoroscopy, offering catheterization laboratory-quality imaging are required.
3. The capability to acquire and record cineangiograms.
4. A mobile C-Arm for fluoroscopic imaging is currently not considered acceptable.
5. The room should have adequate dimensions to accommodate, in the event of urgent or concomitant situations, standard echocardiographic and anesthesia equipment, in addition to the regular cardiac catheterization radiographic imaging system.
6. The interventional cardiac catheterization laboratory or hybrid suite should be stocked with equipment for safe procedures and for handling adverse events such as device stabilization or retrieval and managing pericardial effusions. This equipment includes a variety of endovascular sheaths, diagnostic catheters, transseptal kits, wires, various vascular snare types and sizes, bioprtomes, vascular occluders, and pericardiocentesis equipment.

5.3 | Imaging specific requirements

1. Preprocedural and procedural Imaging:
 - An echocardiography laboratory with the full array of on-site transthoracic echocardiography (TTE) and TEE capabilities with sonographers and physician echocardiographers experienced in atrial anatomy and/or congenital heart disease as well as placement of TEE probes.
 - Intracardiac echocardiography (ICE) is an alternative to TEE but not required.
 - Either a TEE or ICE capable console and probe should be available in the procedure room.
 - Three-dimensional echocardiography capability is helpful but not required.
 - Appropriate staff should be present during the procedure, which may include a noninvasive cardiologist or cardiac anesthesiologist familiar with the procedural steps and subtleties of invasive echocardiography and TEE probe placement.
 - If a general anesthetic is used, an appropriately staffed area to recover patients safely
2. Radiologic imaging
 - Neuro CT capabilities.
 - Neuro MRI capabilities.
3. Cardiovascular catheterization laboratory equipped with a fixed X-ray system with fluoroscopy offering high-resolution imaging, hemodynamic recording, and archiving capabilities.

6 | SHARED DECISION MAKING AND THE MDT

The benefits of a patient-centered, MDT evaluation for SHD procedures has convincingly been demonstrated and mandated for transcatheter aortic valve replacement, percutaneous mitral valve repair, and LAA closure. It is the opinion of the writing committee that an analogous concept be extended to programs engaged in PFO closure for prevention of recurrent ischemic stroke and that it be embedded in centers which have stroke and structural/congenital heart disease programs. The FDA-approved indications for use for the currently approved PFO occluder devices clearly mandate that patients be evaluated by both a cardiologist and a neurologist to determine that the patient had a cryptogenic stroke due to a presumed paradoxical embolism and that other known causes of ischemic stroke have been excluded. This *Heart-Brain* MDT fosters a shared decision making process between the patient and a MDT of stakeholders which ensures appropriate patient selection and follow-up care. The outpatient setting is where most patients are seen and evaluated. A MDT of a cardiologist and a neurologist jointly seeing the patient is efficient, allows the team to learn from one another, and eliminates the possibility of patients receiving contradictory recommendations.^{47,48} The composition of the MDT will vary from site to site but will include an interventional cardiologist skilled in PFO closure and other structural/congenital heart disease catheter-based procedures who may function as the leader. A stroke neurologist with expertise in the diagnosis and management of stroke syndromes particularly in the younger age groups is

also critical. It is understood that many patients being considered for PFO closure will be referred from the community after evaluation by a local neurologist. In cases of diagnostic uncertainty, the stroke neurologist will provide a second opinion regarding the appropriateness of PFO closure. Neurologists participating in assessment of patients with PFO should have a minimum of 8 hr of continuing medical education per year in keeping with the recommendations of the Brain attack coalition for neurologists participating in care of stroke patients at primary stroke centers.⁴⁹ In addition to the stroke neurologist, a noninvasive cardiologist with expertise in imaging and a neurovascular radiologist would also be required as essential components of the MDT. Other physician and nonphysician personnel are required for a successful PFO closure program and may include nurses, mid-level providers, cardiac anesthesiologists, coordinators, and hematologists. It is expected that the MDT will meet on a regular basis to discuss the best approach for each patient. The MDT will also discuss issues related to quality metrics, complications, and future opportunities for quality improvement and education. The composition of the implanting team will also vary from center to center. In some institutions, physician teams, consisting of a primary operator along with an assistant or co-operator, may jointly perform the procedure to offer the greatest expertise and to optimize procedural success and safety. In other highly experienced centers, a single procedural specialist may be adequate for PFO device closure procedures. Specific components and services required for a successful PFO closure program will include:

6.1 | Stroke neurologist

- A neurologist with expertise in stroke, preferably a neurologist with subspecialty certification in vascular neurology.
- The stroke neurologist will serve as both a primary consultant and as a second opinion, when necessary, for patients referred for PFO closure.
- The stroke neurologist should have:
 - Expert level understanding of the differential diagnosis of transient or permanent central neurologic dysfunction.
 - Expert level skills in the investigation of stroke syndromes in the young.
 - Detailed understanding of neuroimaging and its role in determining stroke etiology.
 - Expertise in the management of medical therapy in the treatment of stroke.

6.2 | Structural and/or adult congenital interventional cardiologist

- Board certified or board eligible
 - Adult interventional cardiologist
 - Pediatric cardiologist with expertise (including advanced training) in interventional cardiology
- Consultative and cognitive skills to assess completeness and adequacy of investigations for stroke in the young

- Cognitive and technical skillsets as described in the sections above
- Procedural volumes in accordance with consensus recommendations (Table 3).

6.3 | Hematologist

- The institution where PFO closure is carried out should have access to a hematologist with experience in coagulation disorders

6.4 | Noninvasive imaging physicians

- Neuroradiologists skilled in the interpretation of invasive angiography and noninvasive MRI and CT imaging should be readily available

The institution where PFO closure is carried out should have a board certified/board eligible cardiologist with expertise in echocardiography with skillsets necessary to:
- Carryout and interpret transthoracic and transesophageal echocardiograms as well as use of contrast echo
- Evaluate atrial level defects and anatomic variations along the spectrum of congenital heart disease
- Assess device placement and stability and residual shunts

6.5 | Anesthesia

- An anesthesiologist should be available if necessary at the time of PFO closure
- The anesthesiologist should be able to support a procedure with conscious sedation or GA
- If TEE is being used for imaging an anesthesiologist should be on site and available as dictated by local policies

6.6 | Cardiac surgery

- A cardiac surgeon, anesthesiologist, perfusionist, and cardiothoracic operating room staff should be available for surgical backup. Cardiac surgery operating rooms should be available in the rare event of a severe adverse event requiring surgical intervention.

6.7 | Ancillary services

- After undergoing PFO closure, patients can be managed in a post-anesthesia care unit or telemetry unit. Personnel experienced in managing patients undergoing complex cardiac procedures must be present.
- An outpatient clinic should be present and staffed by members of the MDT who engage in patient follow-up and gather data for quality assessment.

7 | TRAINING MODELS

Effective and efficient acquisition of the technical skills for transcatheter device PFO closure is variable. These skills are dependent on prior experience with complex structural and/or congenital heart

procedures in general, and across the atrial septum in particular, as well as a detailed understanding of the associated imaging techniques. The writing committee recommends an educational program that will provide the background necessary for proceduralists as well as imaging specialists to develop skills for a successful, consistent, and safe technology delivery. Education may be in the form of a formal didactic course focused on basic principles of the field of PFO device technology. Training should also consist of hands-on experience with procedure equipment, viewing live cases performed by experienced physicians in an interactive format, and the use of simulation. Finally, proctors who are experienced in PFO device closure with a specific device should be available to monitor the initial implants performed by the procedural specialist.

7.1 | Technical skill development

During the run-in phase of technology dissemination, interventional physicians who took part in the pivotal trials will likely serve as teachers and proctors. Training should entail a review of clinical issues surrounding PFO related stroke and adverse event risks of the procedure, the relevant atrial anatomy, and imaging of the atrial septum, as well as the delivery system and the devices available under FDA approval. Training should also highlight techniques to maximize the likelihood of successful device placement while minimizing the risk of periprocedural adverse events by acknowledging potential pitfalls and techniques to avoid them. Bailout techniques including retrieval of embolized devices should be included.

The process should include manipulation of the delivery system into the left atrium and device placement using simulations and three-dimensional models for appropriate tactile learning. While theoretical knowledge is requisite when establishing a program, practical experience is desired. Until new physician specialists become proficient, proctoring by physicians or clinical specialists with extensive experience should be considered. Over time, implantation techniques will likely change as the field evolves and new devices emerge. Therefore, continuing medical education will be necessary. Simulation-based education has been shown to be an effective method for learning and for safe implementation of new technology, and the development of simulators for PFO device closure techniques will likely become an integral part of a comprehensive training program.

8 | QUALITY OF CARE ASSESSMENT

A rigorous approach to the assessment of the quality of care is becoming commonplace in medicine and should be applied to the care of patients undergoing PFO closure.⁵⁰ This assessment should include not only the procedure itself, but also the pre- and post-procedure evaluation and care (Table 4).

8.1 | National Registry

Professional societies have a responsibility to consider how to collect and analyze data to enable setting national standards so that individual sites and physicians can evaluate their program's performance

with national benchmarks. Presently, no system exists for the evaluation of the quality of programs offering patients an evaluation and treatment that may include a PFO closure procedure. There is no national coverage decision mandating a national registry that would include data from all patients undergoing PFO closure. The National Cardiovascular Data Registry (NCDR) IMPACT Registry⁵¹ captures some data elements relevant for this procedure but does not capture many pre-, intra-, and post-procedure data elements relevant to the care of patients who have suffered a cryptogenic stroke after a comprehensive evaluation, have had their PFO characterized by anatomic and physiologic criteria, and have undergone a PFO closure. In addition, there is currently no neurology professional society registry for cryptogenic stroke in the United States. Tracking procedural outcomes and long term follow-up data is of particular importance with regard to patients undergoing PFO closure since such patients tend to be younger (mean age in the RESPECT and REDUCE device cohorts were 48 and 45) and looking forward to many more years of quality life. It is the hope of the writing committee that a registry is formed to track immediate and long term outcomes of patients undergoing PFO closure. This registry should consider standardized follow-up, such as is done with the TVT registry. There are industry-sponsored ongoing FDA mandated postapproval studies that will follow patients out to 5 years. However, even 5-year follow-up may not be adequate for these young patients with many years of life ahead of them.

8.2 | Establishing and maintenance certification criteria

Presently, the focus of quality of care assessment in the area of PFO closure is on local site performance, that is, hospitals offering services to evaluate and treat patients who are being considered for PFO closure to prevent recurrent ischemic strokes. This document proposes a quality assessment program for individual sites. Quality measurements are essential for quality assessment and quality improvement processes but are also potentially used in pay-for-performance programs, public reporting, and site performance rankings.

As a template for a site's quality assessment program it is important to consider:

1. A framework for quality measurements.
2. Specific aspects of care of patients undergoing PFO closure that would be germane to assessment of quality of care.
3. A proposed quality assessment process that is practical for use by individual sites.

Accepted and relevant frameworks for the assessment of quality of care are useful for application to a newly approved therapy such as PFO closure. The Donabedian triad of structure, process, and outcomes measures of quality of care is one reasonable framework⁵².

The *structure measures of quality* include the requirement of operators and institutions to have the skills, experience, on-going procedure volume, and facilities that are fundamental to delivering the multidisciplinary initial evaluation and the performance of PFO closure. These operator and institutional requirements have been previously covered in this document.

TABLE 4 Proposed quality assessment measures

Metric	Target performance
Operator and institutional requirements met	100%
Percentage of patients who were seen by both a cardiologist and neurologist prior to PFO closure	100%
Procedure-related major adverse outcomes:	
<ul style="list-style-type: none"> • Mortality • Intraprocedure stroke • Air embolism • Device embolization • Major vascular complications • Major bleeding complications • Atrial fibrillation, transient or sustained, if treatment required, and if oral anticoagulation initiated • Myocardial infarction • Pericardial effusion with and without tamponade • Emergency surgery 	<p><1% or below the 10th percentile if registry benchmarking data becomes available</p> <p><5%</p>
Postprocedure major adverse outcome	
<ul style="list-style-type: none"> • Stroke • Mortality • Deep vein thrombosis or pulmonary embolism if occurring within 6 months of the procedure • Atrial fibrillation, atrial flutter, ventricular tachyarrhythmias, or complete heart block requiring pharmacologic therapy or cardioversion • Thrombus on device detected • Pericardial effusion with and without tamponade • Device erosion • Device explantation • Residual moderate or severe shunting if persistent after 6–12 months 	<1% or below the 10th percentile if registry benchmarking data becomes available
Discharge with dual antiplatelet therapy or anticoagulant and aspirin	100%
<ul style="list-style-type: none"> • Provide rationale for deviation in individual patients 	
Freedom from recurrent ischemic stroke at 1 year	100%

The *process measures of quality* defined as best practices and standardized processes that are accepted and incorporated into programs, have not been identified in any professional society expert consensus statements regarding PFO closure.

- The multidisciplinary approach to patient evaluation involving those with both cardiology and neurology expertise is a process measure of quality that can be assessed at the site level. It is expected that all potential PFO closure patients will receive evaluation by a MDT consisting of a cardiologist and neurologist.
- Other process measures used in other areas of medicine are appropriate use criteria (AUC) that categorize different patient scenarios with the assignment of levels of appropriateness of a treatment based on the current understanding of procedure outcomes plus the potential patient benefits and risks. The new terms “appropriate care,” “may be appropriate care,” and “rarely appropriate care,” are assigned in this AUC process. Currently AUC do not exist for patients with cryptogenic stroke and PFO but such an effort can be considered for the future.
- Another process measure of quality is the use of shared decision-making and the development of educational material for patients and families. Best practices may include directing patients and family to an objective, noncommercial website for education. Decision aids could also be developed to assist decision-making for patients facing the decision of whether or not to undergo PFO closure. These educational and decision-aids are not currently available but should be considered for future efforts by professional societies, individual site, and other stakeholders.

The *outcome measures of quality* are of critical importance since they address the quality domain of safety. From the clinical trials in PFO closure there are data on rates of complications that may serve as the first set of standards. The frequency of adverse events related to the procedure or the closure device should be very low. Individual serious adverse events in the RESPECT and REDUCE trials were very low, often <1%. One-year assessment of outcomes is important but has been challenging for centers due to many patients who are often not followed by the site performing the procedure but by referring clinicians who may or may not be part of the same medical system and, as a consequence, the medical records may not be readily available. Therefore, the outcome measures recommended in this first document of operator and institutional requirements will focus predominantly on 30-day outcomes.

Outcome measures, especially those related to complications, ideally should be adjusted to patient characteristics that are separate determinants of outcomes from that due to the quality of procedure performance. Bleeding and vascular complications are typically risk-adjusted. Given the lack of a comprehensive national registry gathering data on all patients undergoing PFO closure it is currently not feasible to have the large database necessary to develop, validate, and report risk adjusted outcomes for PFO closure. Therefore, absolute rates of complications will need to be reported as a quality metric for PFO closure.

The proposed assessment of quality of care at the site level is outlined in Table 4. This can serve as a blueprint for PFO closure programs to gather the appropriate data and review their findings on a regular basis. Through this process of quality assessment, it is key that the following steps be taken after data collection: (1) identification of

problematic areas, (2) analysis of potential causes of these problems, (3) identification and implementation of opportunities for improvement involving specific action items, and (4) re-evaluation of outcomes after an improvement process has been implemented.

In addition to Table 4, a program should have a running assessment of patient characteristics that were evaluated, the reasons that PFO closure was not recommended, and overview statistics of those who underwent PFO closure in terms of patient and procedure characteristics.

9 | LONG-TERM FOLLOW-UP

Although participation in a registry is currently not mandatory for use of the currently approved devices, it is important for individual institutions to have aggregate and operator-specific quality analysis processes. Within institutions, a regular quality analysis process reviewing key metrics, including number of implants, complications, and outcomes, should be a standard part of any stroke-related PFO program.

After PFO device closure procedures, results from continued follow-up and the post approval studies, along with an analysis of national databases, would be beneficial for measuring initial and long-term clinical outcomes. However, individual institutions should have protocols in place for follow-up that include echocardiographic and other imaging data that identify the presence and severity of persistent leaks; medication use (particularly anticoagulants); and clinical outcomes, including bleeding, neurologic events, and device complications. Clinicians and institutions performing PFO closure procedures should consider by what means they gather longer-term data on their patients. This process needs to be individualized to the health care system, the individual PFO closure program, the ability to capture long-term data from the electronic medical record, and the ability of the program to have patients return for follow-up. Follow-up is particularly important given the enhanced clinical benefits of PFO closure found in the long term follow-up in the recent RCTs.⁶⁻⁸

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SUPPORTING INFORMATION

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

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Heart Rhythm Society Expert Consensus Statement on Electrophysiology Laboratory Standards: Process, Protocols, Equipment, Personnel, and Safety



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TABLE OF CONTENTS

1. Introduction	e9
2. Evolution of the EP Laboratory	e10
3. Laboratory Environment	e10

4. Laboratory Design	e12
5. Laboratory Equipment	e17
6. Laboratory Staffing	e21
7. Laboratory Personnel Credentialing	e26
8. Procedural Issues	e29
9. Pediatric and Adult Congenital Heart Disease	e35
10. Quality	e37
11. Occupational Health Concerns	e39
12. Ethical Concerns	e43

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KEYWORDS Cardiac electrophysiology laboratory; Laboratory equipment; Cardiac electrophysiology laboratory staffing; Cardiac electrophysiology staff credentialing; Quality assurance; Occupational safety

ABBREVIATIONS **CIED** = cardiovascular implantable electronic device; **CT** = computed tomography; **EP** = electrophysiology; **FDA** = U.S. Food and Drug Administration; **ICD** = implantable cardioverter-defibrillator; **MRI** = magnetic resonance imaging; **QA** = quality assurance; **QI** = quality improvement; **RF** = radiofrequency; **VT** = ventricular tachycardia (Heart Rhythm 2014;11:e9-e51)

Developed in collaboration with and endorsed by the American College of Cardiology (ACC), the American Heart Association (AHA), and the Pediatric and Congenital Electrophysiology Society (PACES). Endorsed by European Heart Rhythm Society (EHRA), and Sociedad Latinoamericana de Estimulacion Cardiaca y Electrofisiologia (SOLAECE)-Latin American Society of Cardiac Pacing and Electrophysiology. EHRA endorses the recommendations of the expert consensus statement, with the exception of those statements specifically addressing US regulations. **Address correspondence:** David E. Haines, MD. E-mail address: dhaines@beaumont.edu.

1. Introduction

The modern electrophysiology (EP) laboratory is a complex environment providing an array of interventions for the diagnosis and treatment of heart rhythm disorders and is a result of many transformations over the last three decades. The EP field has witnessed rapid expansion in the number of therapeutic procedures treating a wide range of arrhythmias and in the new technologies available to perform these procedures. Because of the increasing complexity of equipment and procedures and an ever-expanding knowledge base, it was concluded that the field would benefit from a consensus document that would define the critical components and processes of a modern EP laboratory. To this end, the Heart Rhythm Society (HRS) convened a multidisciplinary team to review EP laboratory design, ergonomics, personnel, equipment, occupational hazards, and patient

safety, as well as clinical and ethical issues related to diagnostic and therapeutic EP procedures. The goal is to provide physicians, administrators, and regulatory personnel with the recommended requirements for building, staffing, and running a modern EP laboratory to optimize patient outcomes, minimize patient risk, and provide a safe and positive environment for physicians and staff.

The writing committee was formed by the Scientific and Clinical Documents Committee of the HRS, with approval by the President of the HRS and the HRS Executive Committee. The composition of the committee was meant to represent the range of stakeholders in the EP laboratory. The choice of the writing committee members was in accordance with the HRS Relationships With Industry policy.¹ All members of the writing committee were required to fully disclose all potential conflicts of interest (see [Appendix 1](#)).

Relatively little published literature addresses the EP laboratory environment, staffing, and processes. Therefore, many of the statements in this document are the product of expert consensus by the writing committee and reviewers. For cases in which there were divergent opinions on a statement, a vote among writing committee members was taken, and if a two-third majority supported the statement, it was adopted in the document. The sections pertaining to pediatric and adult congenital heart disease were reviewed and approved by the Pediatric and Congenital Electrophysiology Society (PACES), a nonprofit organization dedicated to the treatment of arrhythmia disorders in children and individuals with congenital heart disease (CHD). The final document was approved by the Board of Trustees of the HRS. This document is directed to all health care professionals who design, manage, and/or work in the EP laboratory environment.

2. Evolution of the EP Laboratory

The field of clinical cardiac electrophysiology (CCEP) has grown from its origin as a field of clinical research for

3. Laboratory Environment

Laboratory Environment Recommendations

- Highly complex procedures or procedures on patients with certain conditions and comorbidities that are associated with higher procedural risk should not be performed in a freestanding laboratory (i.e., an EP laboratory that is not physically attached to a hospital).
- Emergency cardiovascular surgical support should be immediately available in case of life-threatening bleeding complications from the extraction of chronic device leads and complex mapping/ablation procedures, particularly those requiring pericardial access.
- High-risk procedures in critically ill patients, such as ablation of ventricular tachycardia in patients requiring extracorporeal hemodynamic support, can only be safely performed in institutions offering comprehensive programs with active engagement from electrophysiologists, surgeons, intensivists, and anesthesiologists.

3.1. Procedure Room Options

There are multiple options and practice settings for performing EP and implantable device procedures. Medical centers may adopt one or more of the following laboratory operations for their practice. The choice among the following options involves a trade-off between increasing capability for procedure complexity and increasing construction and operating costs.

arrhythmogenesis to its present-day incarnation as an important specialty offering advanced therapies for a wide variety of disorders. Clinical EP laboratories emerged in the late 1960s, and by the early 1970s, formal fellowships had been established and EP laboratories were taking shape. First-generation EP laboratories often shared space with cardiac catheterization laboratories and were typically subordinate to coronary angiographic and hemodynamic procedures. When a space was dedicated for electrophysiological testing, it was often small, and fluoroscopy was delivered with portable C-arm units. These laboratories were sufficient for diagnostic EP studies and electropharmacological testing. Second-generation EP laboratories developed in the 1980s with the introduction of catheter ablation and cardiac implantable electronic devices (CIEDs) to the electrophysiologist's armamentarium. Pacemaker implantation was shifting from the domain of surgery to that of cardiac EP. With increasingly complex procedures being performed in EP laboratories, more space was allocated to new dedicated laboratories and fluoroscopy equipment began to be upgraded to systems commensurate with those used in cardiac catheterization laboratories.

The third generation of interventional cardiac EP has been driven by the success of catheter ablation and advanced device therapy. The precise anatomy and physiology of a wide variety of arrhythmias has been elucidated through the development of advanced mapping systems and improvements in ablation catheter technologies. Modern device therapy incorporates multimodal multisite pacing, sophisticated therapies for tachyarrhythmias, and advanced diagnostics. With the increasing complexity of EP procedures and equipment has come increasing sophistication of laboratory processes and greater demands on laboratory personnel. The cost and complexity of the modern EP laboratory now demands that standards are developed to ensure a high level of care.

3.1.1. Dedicated EP Laboratory

In a dedicated EP laboratory, the staff space and procedure room space are separate from the cardiac catheterization laboratory and/or radiology laboratory, although the staff space and procedure room space often exist within a common area. The preparatory and recovery rooms are often shared with other subspecialties. Procedures that can be performed in this

laboratory setting include diagnostic EP studies, ablation procedures, use of cardiac implantable devices, implantable device extractions, use of temporary pacemakers, three-dimensional (3D) mapping, intracardiac echocardiography (ICE), and use of robotics. The advantages of using a dedicated EP laboratory include greater availability of more highly trained allied personnel, room equipment dedicated to only EP procedures, and decreased overall equipment costs per room.

3.1.2. Shared EP and Catheterization Laboratory

A shared procedural laboratory program is usually in association with a cardiac catheterization laboratory program, but can also be shared with an interventional radiology program. A shared room allows for two or more practices to share common equipment that includes fluoroscopic equipment, recording systems, emergency equipment, and anesthesia equipment, as well as the space. This is helpful in circumstances of low overall volumes when sharing a room allows for flexibility in patient care while controlling costs and space requirements.

3.1.3. Device-Only Laboratory

These types of procedure rooms have been created at large-volume institutions that can support a procedure room dedicated only to CIED surgery. The procedures performed in this type of room include the use of pacemakers and defibrillators that are single chamber, dual chamber, or biventricular in operation. Other procedures can include the use of temporary pacemakers, the use of implantable loop recorders, and lead and device extractions. Device and lead extractions may also be performed in a surgical operating room (OR) on the basis of the patient's condition or on the standard agreed on by the institution. Advanced mapping and EP recording systems are not required, and the costs of equipping this type of laboratory are lower, which is the key advantage of this type of room. Device-only laboratories are appropriate for high-volume centers that already have one or more fully outfitted EP laboratories.

3.1.4. Advanced Mapping, Ablation, and Combined Hybrid Laboratories

These procedure rooms are designed to the rigorous standards of ORs (positive airflow, medical gas availability, surgical lighting, and substerile scrub area) but have high-quality fixed fluoroscopy and a full complement of EP and/or cardiac catheterization equipment. These rooms are ideal for procedures that may be combined with open or minimally invasive cardiac surgery and for lead extraction procedures. When not being used for hybrid surgical procedures, these laboratories can function either as fully functional ORs or as fully functional EP/catheterization suites. Procedures that can be performed include complex ablation procedures that involve EP and surgical components, left atrial appendage occlusion or clipping, epicardial lead placement, and minimally invasive valve replacement.

3.1.5. Special Procedure Rooms

Some organizations incorporate special noninvasive rooms into their practice to accommodate patient care that does not require fluoroscopy or other specialty equipment. These rooms are often

used to perform minor procedures such as cardioversions, tilt table studies, and noninvasive programmed stimulation defibrillation threshold testing. Autonomic testing with head-up tilt table testing requires a procedure table that has the capability for 70° head-up tilt, an electrocardiogram (ECG) monitor, noninvasive blood pressure monitor, supplemental oxygen, and basic supplies. Equipping these rooms is much less expensive than equipping a full procedural laboratory and can help improve patient flow and volume through a busy EP department.

3.1.6. Pediatric EP Laboratory

The room and equipment standards for pediatric EP procedures are similar to those for adult EP procedures, except for the availability of pediatric resuscitation equipment and drug doses as well as a wider inventory of smaller catheters. Pediatric and congenital EP patients can require a combined procedure of EP and the need for cardiac catheterization, including angiography and possible intervention. Thus, it is optimal (although not a necessity) for a pediatric/congenital EP laboratory to meet all the standards of a pediatric catheterization laboratory. Pediatric EP procedures in young children should be performed in pediatric hospitals or hospitals that have a pediatric cardiology and EP service.

3.2. Freestanding Cardiac EP Laboratory

An EP laboratory that is not physically attached to a hospital is considered a freestanding laboratory. Freestanding EP laboratories can be privately owned, and when owned by physicians, there may be concerns about conflicts of interest (as discussed in [Section 12](#)). This arrangement presents challenges that stem from the separation of the laboratory from vital hospital services. In the event of a life-threatening complication, such as pericardial tamponade² or endovascular tear during lead extractions,³ an emergency response from certain hospital-based services such as cardiothoracic surgery can become necessary, and even possibly lifesaving. Performing EP procedures in freestanding EP laboratories on patients with clinical conditions that confer increased risk are relatively contraindicated. These include preexisting advanced heart failure and severe left ventricular dysfunction⁴; recent myocardial infarction, recent stroke, chronic kidney disease, severe chronic obstructive pulmonary disease, pulmonary hypertension, and severe/morbid obesity⁵; and severe valvular dysfunction or prosthetic heart valve, CHD (including atrial septal defect repair), active oral anticoagulation, advanced age, and pediatric age. Procedures that necessitate lesion creation close to coronary arteries, such as aortic cusp ablation⁶ and epicardial ablation,⁷ carry a higher risk of intraprocedural myocardial infarction and should not be performed outside a hospital. As part of the consent process, patients should be informed that the procedure is being performed without on-site surgical backup. In order to ensure the safety of a patient undergoing a procedure in a freestanding EP laboratory, a functional and tested system must be in place to quickly transfer patients to a hospital with immediate surgical support in case of an unanticipated complication. The receiving program should be familiar with complications unique to the EP laboratory. There must be a standing agreement between the laboratory and the receiving hospital so that there is no unnecessary delay in the transfer process.

3.3. Hospital and EP Laboratory

The hospital environment plays an important role in shaping the structure and function of the EP laboratory. A “closed EP laboratory” is commonly present in academic institutions and limits physician practice to faculty members of the particular institution or university. In contrast, “open EP laboratories” allow credentialing and the participation of multiple physician groups, including those who do not hold faculty level appointments. Such laboratory structuring is common in community and private institutions and is also present in some academic settings. Whether an EP laboratory is open or closed is determined by the institution’s leadership on the basis of economic, historical, political, and geographical factors that are often beyond physician control. An inherent difficulty in the open EP laboratory format lies in procedure scheduling for multiple physicians; a centralized scheduling structure that can arrange scheduling while organizing and prioritizing procedures on the basis of urgency and acuity is important to avoid conflicts and optimize patient care.

The complexity and degree of invasiveness of EP procedures is dependent on the level of support provided by the hospital or other health care organization in terms of personnel, facilities, and equipment. Anesthesia support is desirable for the safe performance of potentially lengthy and complex procedures. The role of anesthesia services in the EP laboratory is detailed in [Section 6](#). Surgery backup must be immediately present for lead extraction procedures in which a lead to be removed is older than 1 year (or require tools other than a standard stylet to be removed if younger than 1 year from implantation)⁸, and mapping/ablation procedures require pericardial access. Complex ablation procedures, such as atrial fibrillation and ventricular tachycardia (VT) ablation, should be performed only in hospitals equipped and prepared to manage these types of emergencies, with access to emergency surgical support when required. Finally, high-risk procedures in critically ill patients, such as ablation of VT in patients requiring hemodynamic support with extracorporeal membrane

oxygenation, can only be safely performed in institutions offering comprehensive programs with active engagement from electrophysiologists, surgeons, and anesthesiologists. Although such collaborations were limited to advanced tertiary care institutions in the past, the increasing availability of institutional resources and support has expanded the range of facilities in which complex procedures are performed to include private institutions.

3.4. Regulatory Standards Related to EP Laboratories

Federal guidelines for the construction and retrofitting of health care facilities have been influenced by recent catastrophic events, such as the Northridge earthquake of 1994, Hurricane Katrina in 2005, and the F5 tornado that made a direct hit on a hospital in Joplin, MO, in 2011. In the mid-1990s, three formerly competing code writing agencies united to form the International Code Council. Their mission was to develop a national construction code that, among other entities, would regulate the construction of health care facilities to mitigate the risk of damage due to seismic, wind, and flood dangers. Known as the International Building Code, one of its versions has been adopted by every state. In addition, the Federal Emergency Management Agency, a branch of the Department of Homeland Security, published revised guidelines for improving hospital safety in earthquakes, floods, and high winds.

The primary legislative avenues for controlling the dissemination of expensive health care services are Certificate of Need (CON) laws. As of 2009, 39 states still have a CON process, law, or set of requirements. In most cases, the approval of CON is based on the actual or projected volume of services provided in the procedural laboratories. As procedural volumes for percutaneous coronary arterial interventions have diminished at most tertiary referral hospitals, many hospitals have shifted some coronary interventional laboratory CONs to EP laboratories. Once an EP laboratory is established, the primary government body overseeing its operations, policies, and procedures is the Joint Commission (TJC).

4. Laboratory Design

Laboratory Design Recommendations

- The *Guidelines for Design and Construction of Hospitals and Health Care Facilities* published by the American Institute of Architects and the Facility Guidelines Institute provide space and functionality standards for EP laboratories with a goal to improve work flow in the EP environment. (Specific recommendations not derived from this document are based on the consensus opinion of the writing committee.)
- The minimal procedural area of a complete EP laboratory (not including control room space) is 350 sq ft of clear floor area.
- Current electrical system regulations for health care facilities should follow Article 517 of the *National Electrical Code (NEC) Handbook*.
- An uninterruptible power supply for all computer equipment is required.
- The air flow/heating, ventilation, and air conditioning design should comply with the *Guidelines for Environmental Infection Control in Health-Care Facilities Recommendations* of the Centers for Disease Control and Prevention and the Healthcare Infection Control Practices Advisory Committee document.
- Lighting should include an overhead light on an articulating arm, 2 × 2 ft lighting squares to flood the main procedure area, and a dedicated workspace light for the nursing/anesthesia area.
- The ideal sound/communication system is an always-on, full-duplex, two-way intercom system.
- Network cabling and hardware should have a minimum capability of support for gigabit Ethernet speed.
- Electronic storage of EP data should be Health Insurance Portability and Accountability Act (HIPAA) compliant. Data should be maintained for at least the minimum duration as determined by each state.

The American Institute of Architects and the Facility Guidelines Institute regularly publish the *Guidelines for Design and Construction of Hospitals and Health Care Facilities*.⁹ This document is recognized by federal and state authorities, and recently this document has included EP laboratories. It provides defined standards in terms of the space and functionality of EP laboratories with a goal to specifically improve work flow in the EP environment, acknowledging that the EP laboratory requires more space than an angiographic/interventional laboratory for supporting equipment and supplies. Traditionally, however, the construction of an EP laboratory had no specific guidelines because of its special applications. The typical layout is generally derived from a cardiac catheterization laboratory,⁹ which is not ideal for the performance of the full range of EP procedures. The limitations of direct adaptation of an angiography suite design to the practice of cardiac EP include space constraints relative to the special equipment used in EP procedures, the necessity to work on either side of the patient table, and the requirement to access the patient's upper chest for device implantation. EP laboratory plans should take into account not only the available space within the procedure room but also its location relative to pertinent services such as the patient prep area, recovery area, OR, intensive care unit, the ward, and specialized resources such as an adjacent magnetic resonance imaging (MRI) suite that might permit real-time MRI imaging during procedures in the future. The rationale is to consider the proximity of all needed services in the overall design during the planning stage so that enhanced patient flow can be achieved. The aim of the planning committee should be to build a consensus on a minimum set of specifications that will meet the needs of the clinicians and support staff, and enable them to provide optimal patient care, while maintaining occupational safety for the staff.

4.1. Space Requirements

The EP laboratory needs as much space as is practical to ensure the freedom of movement of the operator and staff, to accommodate all equipment used, and to facilitate movement of staff in emergency situations. The recommended procedural area of a complete EP laboratory (not including control room space) is 500 sq ft or greater of clear floor area, although 350 sq ft is the absolute minimum requirement. There should be a minimum of 8 ft of clear space between the wall and the edges of each side of the patient table when it is positioned at the isocenter. Enough clearance at the head of the bed should be allocated for anesthesia equipment on either side and sterile access to jugular vein entry sites, if employed, while allowing for free range of movement of the fluoroscopy C-arm. The ceiling height is dependent on the requirements of the X-ray/fluoroscopic equipment⁹ (Figure 1). Preexisting laboratories that are being renovated where it is impossible to expand the gross area because of building and location constraints should follow federal and state code requirements, but due caution should be taken to meet suggested recommendations.

4.2. Room Layout

The fluoroscopic equipment plays a major role in determining the amount of ideal space in the procedural area and

could serve as the reference point. Equipment can be either mounted on the floor or suspended from the ceiling. The latter configuration allows for the floor to be optimally cleaned; however, because of the amount of equipment that would need to be suspended from the ceiling (monitors, surgical lights, X-ray barriers, equipment racks, and anesthesia gas supply), a floor-mounted configuration may be more practical in some laboratories. It is best if X-ray generators and tanks are located in a space separate from the procedure and control rooms. The size and portability of the fluoroscopy unit is important in planning room size, especially when cabinetry and other fixtures are planned for installation on the walls within the procedural area. Installation of cabinetry at the head of the bed is discouraged because it further limits space to allow free movement of the X-ray arm, anesthesia supply cart, and life support equipment. Cabinetry for supplies frequently used during cases should be positioned on the side walls for easy access. The room should be wide enough to accommodate the cabinet and open door swing without impinging on the sterile field and traffic flow through the laboratory.

Most peripheral equipment such as recording systems, stimulators, and radiofrequency (RF) generators are made from multiple components, some of which need to be in a control room and others in the laboratory itself. It is strongly recommended that none of the modules sit on the floor. This can reduce sterility and cleanliness as well as put the equipment at risk of being damaged by fluids. A ceiling-mounted boom removes all equipment from the floor and reduces damage to cables by allowing them to remain connected at all times. By placing the recording system amplifier, the RF generator, the mapping system amplifier, the stimulator amplifier and router, and other peripheral equipment together on a ceiling-mounted equipment boom, all cabling will be permanently placed and connected, reducing cable wear. The removal of rolling equipment carts from the room improves staff access to the patient. Removing cables and equipment from the floor reduces the tripping hazard to the staff and risk of equipment damage. Because additional portable EP equipment is often employed during a procedure, it is necessary to have ample power outlets installed to accommodate such needs.

Anesthesia gases are best supplied via a ceiling-mounted anesthesia boom, which should include two oxygen lines, one nitrous oxide line, one medical air line, two vacuum lines, and one waste anesthetic gas disposal line.¹⁰ It should be equipped with at least one slide clamp for vacuum canister placement, which should allow the canisters to be located within 4 in. of the floor for ease of removal when full. The anesthesia boom should have a minimum of six electrical outlets, at least some of which should be on emergency (red plug) circuits in case of general power outage during a procedure. A mounted light controlled independently from the room lighting for charting in a dark room is a useful option. Video can be routed from the anesthesia boom to display data from an anesthesia cart to monitors placed around the room.

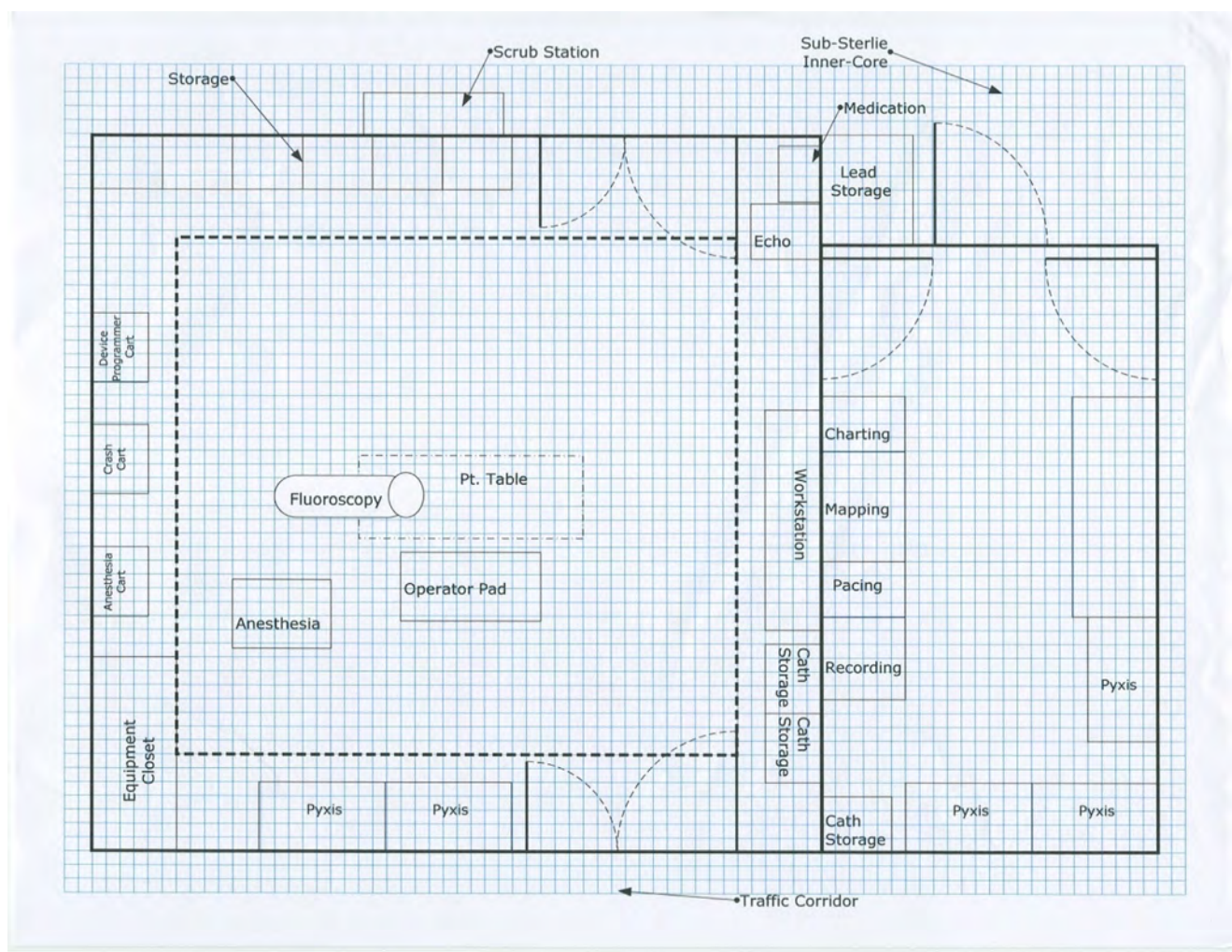


Figure 1 Space requirements. The sample layout of EP laboratory with adjacent control room area. Note the availability of enough free space at the head of bed area allowing freedom of movement of fluoroscopy arm and anesthesia equipment. EP = electrophysiology.

4.3. Hybrid Laboratory

The hybrid laboratory has all the requirements of a full EP laboratory but has added features that allow it to serve as a fully functional operating suite. These laboratories are often larger and have the fluoroscopy equipment on a track so that it can be entirely removed from the surgical field. It is typically located within or contiguous to the other ORs and has a full substerile scrub and supply area. The use of a hybrid laboratory for EP procedures is evolving. Hybrid laboratories in which EP procedures are performed need to be outfitted with the appropriate EP-specific equipment, including EP recording systems, mapping systems, and programmed stimulators. Procedures that might benefit from performance in this setting would include those where surgical intervention or extracorporeal hemodynamic support might be required, such as lead extractions, VT ablation procedures in patients with structural heart disease, and hybrid atrial fibrillation ablation procedures.

4.4. Control Room

Although some EP laboratories house all the monitoring and stimulating equipment in the procedure room, it may be

preferable to have a contiguous control room with an interposed leaded wall and large viewing window so that members of the team (apart from the primary operator, the circulating nurse, and the anesthesia professional) can work without exposure to ionizing radiation. The control rooms can be shared among two or more laboratories. A separate control room demands a full duplex intercom system so that there is no barrier to communication. The space required for a control room is not inclusive of the procedural area measurements. Adequate ventilation should be supplied to account for excess heat production from the electronics. The counters should be at least 30 in. deep so that the monitors can be 20 in. away from the user. At least 160 in. of desk space is suggested for a laboratory with a single-plane fluoroscopy system and 180 in. of desk space for a biplane fluoroscopy system to allow for fluoroscopy monitors, a mapping system, a recording system, and a stimulator. An additional 45 in. of desk space is suggested for a two-monitor reading station or a single-monitor workstation (Figure 2). The participation of an ergonomics expert in the planning should be considered as a measure to comply with Occupational Safety and Health Administration standards.

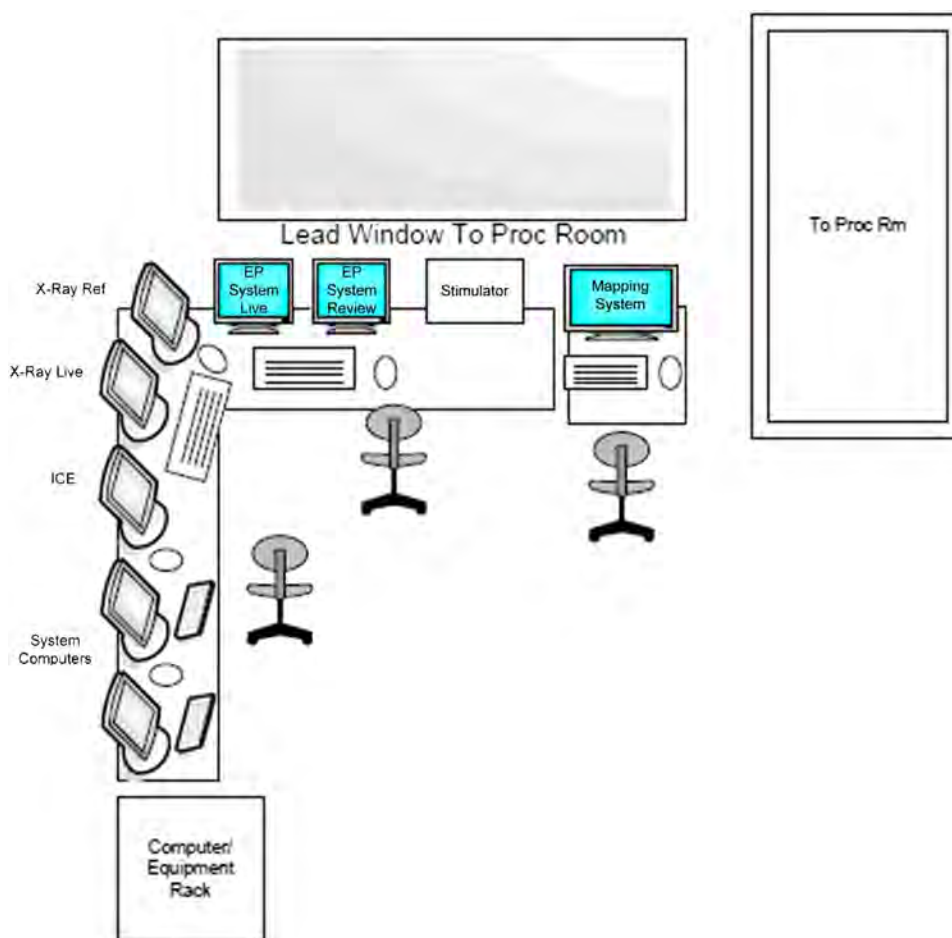


Figure 2 Control room. Example of a simplified layout of the control room and EP equipment. Recommended counter measurements should be applied as mentioned in the text. EP = electrophysiology; ICE = intracardiac echocardiography.

4.5. Traffic Flow

The ideal design for an EP suite should be similar to that of an OR, including a substerile entrance with scrub sinks (dedicated or common). Patient transport from the prep area to the EP laboratory and vice versa should be limited to a common egress that connects to hallways leading to the hospital wards and other areas. If the EP laboratories are placed in existing space that does not allow for OR-quality substerile entrances and hallways, every effort should be made to prevent through traffic flow past the entrance to the EP laboratories where sterile procedures are being performed.

4.6. Conduits and Cabling

EP suites require special consideration from electrical design engineers because there are multiple high load and electrically sensitive pieces of equipment in this wet environment. Conduits used as wireways should follow the specifications of Articles 376, 378, and 392 of the *NEC Handbook*.¹¹ The EP laboratory setup primarily involves the data and power cabling layout that connects equipment between the control room and the procedural area, and the following requirements should suffice, considering the few cables that need to be run in these enclosures. For rooms that are not equipped

with ceiling-mounted equipment booms, the conduits should be at least two runs of 4-in.-diameter tubes that connect the procedure room to the control room through the floor, dedicated solely to EP equipment cabling (separate from X-ray equipment and power receptacle requirements). This conduit should be conductive and bonded to equipotential grounding. Floor openings or ports should be concealed by an enclosure that should be fluid tight with protective grommets that will prevent cable insulation damage. The length/reach is dependent on the location of each cable termination linking the equipment, as specified by the EP representative who oversees the room project and design. For rooms equipped with ceiling-mounted equipment booms, cabling runs through ceiling trays connecting the control room to the procedure room boom. The trays can be used in conjunction with other equipment that terminates at the equipment boom as long as there is enough separation between power lines and data transmission lines to prevent electromagnetic interference (EMI) induced by adjacent power lines running in parallel. Open trays are preferable for ease of access above the ceiling and should be conductive and bonded to equipotential grounding. The length/reach is dependent on the location of each cable termination linking the equipment, as specified by the EP representative who

oversees the room project and design. Backup temporary cabling should be available in case of failure of conduit cabling during a case.

4.7. Electrical System/Noise Immunity

Current regulations for health care facilities should follow Article 517 of the *NEC Handbook*. Because the EP procedure room is classified as a “wet procedure location,” the installation of an isolated power system with line isolation monitoring is required, which provides a layer of protection from the hazards of electric shock with the added benefit of line noise isolation because of its design.⁹ In addition, all computer equipment directly related to the ongoing monitoring and treatment of a patient must have an uninterruptible power supply (UPS). The UPS may be integrated into the power for the entire suite, or individual UPS may be placed in line for each central processing unit. The main purpose of the UPS is to prevent the EP system, mapping system, or other critical imaging or monitoring system from going through a hard shutdown and full reboot procedure in case of a transient power outage or surge. Other important electrical components of the laboratory, such as the imaging train, should be connected to emergency backup power so that cases can be completed even if line power is lost. Power lines and data lines should be run separately and isolated from each other in different conduits to prevent EMI from power line wiring induced through data line wiring that could affect optimal performance of the EP equipment. If open cable trays are used above the ceiling, careful consideration should be given to the placement of power lines and other fixtures that can be sources of EMI. Although power lines used on these runs do not necessarily involve enough energy to induce heating, it is still a good rule to follow the specifications of Article 300.20 of the *NEC Handbook* as a reference.¹¹ Adequate spacing of EP laboratory equipment in the procedural area should be followed. Interface cables between the patient and the equipment (e.g., ECG cables and intracardiac catheter cables) should not dangle by the X-ray tube and should be kept neatly arranged by the side of the patient to provide easy access for troubleshooting purposes during the procedure.

4.8. Air Flow/Heating, Ventilation, and Air Conditioning

Air flow should be of OR quality. The design should comply with the *Guidelines for Environmental Infection Control in Health-Care Facilities Recommendations* from the Centers for Disease Control and Prevention and Sections 5 and 6 of the Healthcare Infection Control Practices Advisory Committee document.¹⁰ Emphasis should be placed on the use of in-line filters or mechanical smoke evacuation systems to prevent airborne infective and toxic particles from the plume produced by electrocautery and similar equipment. The temperature control should support effective configuration for temperatures as low as 60°F. This allows comfort for practitioners who are wearing sterile gowns, hats, and masks on top of lead aprons during long procedures. Patient comfort should also be

addressed, particularly as they are fully draped and may be only lightly sedated.

4.9. Lighting

The patient table should be flanked by large lighting squares or the equivalent to flood the main procedure area with light. Appropriate grounding is required to prevent EMI from these lights. The lighting squares should be tied to an X-ray pedal switch that can be turned on and off at will by the X-ray operator. Additional spotlights that are dimmable from a distant wall switch are also recommended for procedures that require a darker environment to optimize glare reduction and visualization of display systems in front of the operator. There should be at least one overhead OR light of surgical quality mounted on an articulating arm, strategically placed to be accessible for use on the left shoulder, right shoulder, or abdomen at either side of the patient. There should be sufficient range of motion to be able to focus light intensity at a steeper angle toward and into the implant pocket. Two lights are optimal for reducing shadows. The preferred OR light is mounted on a boom that extends from the ceiling and has free range of movement to focus the beam at the angles and distance optimal to adequately light the surgical field and device implant pockets. Anesthesia and/or nursing should have a light over their workspace that is independent of the room lighting on either side of the patient table, which should be oblique at a distance from the X-ray C-arm.⁹

4.10. Sound Systems/Communications Equipment

For laboratory designs that employ a separate control room, there may be difficulties with the use of communication systems that link the operator in the procedure room to the control room staff. Because critical processes such as timing of ablation onset and offset require close coordination between the bedside and the control room, the importance of good two-way communication for patient safety and quality of care cannot be overstated. The ideal equipment is capable of a always-on, two-way system because of the constant and instantaneous need to communicate. The ideal system is an always-on, full-duplex, two-way intercom system, with a toggle to silence unnecessary chatter from the control room. This requires electronic noise cancellation to prevent acoustical feedback and has variable effectiveness depending on room acoustics. A simpler solution is a one-way push-to-talk intercom, but this does not allow spontaneous back-and-forth communication. The use of wireless headsets is a favorable solution, which broadcasts spoken words directly to the headphone users, with simultaneous talk paths open as needed. Whatever system is selected should be high fidelity, spectrum friendly, and encrypted to prevent eavesdropping and potential HIPAA violations, making it a more expensive solution.

4.11. Data Network

Procedural charting and operative reports should be part of the institution's electronic medical record. The network

cabling and hardware should have a minimum capability of support for gigabit Ethernet speed.⁹ The data demands of imaging systems, including 3D electroanatomic mapping systems, are great and require larger storage repositories in comparison with the compressed images of major imaging equipment such as ultrasound and X-ray radiograph systems. There is an increased use of imaging created by computed tomography (CT) and MRI, which are 3D in nature, necessitating high transfer speeds between the picture archiving and communication system (PACS) and the EP laboratory environment. Collaboration with the information technology (IT) department and its infrastructure within the institution is necessary in this venture. EP systems gather information in digitized format for patient records and review at a later time. It will be important for industry to develop a better and unified standard for storing and retrieving cardiac electrogram information. Waveform information in EP is constructively different from image information and needs to be handled in a different manner. The complexity involved in translating the files without losing the ability to utilize the tool sets needed during review, and to scroll through the whole EP study, is a challenge. The Digital Imaging and Communications in Medicine standard is a

more robust model to follow and should be the preferred method, when feasible.¹²

For current equipment standards and needs, the recommendation is to involve the IT department in the safekeeping of digital records of patient information. Storing information in an enterprise-wide network repository managed by the health care IT staff within the institution is recommended, as they are adequately equipped to comply with policies governing hospital data. Data storage must be HIPAA compliant¹³ and must be maintained according to the laws of each individual state—typically 5–7 years for adults and 5–7 years past the age of maturity for pediatric patients. Practically, the duration of data storage should be longer than the minimum requirement, because old invasive study data are often important in the management of patients decades later. Electronic storage of all EP laboratory information could require 5–10 terabytes of space annually; therefore, the IT department must anticipate commitment of these resources for this process. Regardless of the equipment's capability to store to the network, the IT department should be involved as long as they comply with the EP equipment manufactureres' recommendations.

5. Laboratory Equipment

Laboratory Equipment Recommendations

- Both single-plane and biplane fluoroscopic systems are suitable for the modern EP laboratory.
- A basic EP laboratory should be equipped with a monitoring system that includes 12-lead surface ECG and 24 intracardiac electrogram channels; advanced laboratories (e.g., those performing complex ablation procedures) require EP systems with 64–128-channel capabilities.
- A biphasic external defibrillator is required in each EP laboratory, with a backup defibrillator immediately accessible.
- An anesthesia cart that contains endotracheal intubation equipment, as well as sedative, paralytic, and anesthetic agents, should be readily accessible for all EP procedures.
- Emergency trays should be immediately available for pericardiocentesis, thoracentesis, and thoracotomy.
- Programmable electrical stimulators must provide reliable, accurate, and effective electrical stimulation.
- It is recommended that all EP laboratory personnel using the ablation systems are able to demonstrate familiarity and proficiency with the setup, operation, and characteristics of all ablation system(s) employed at their site.
- Advanced mapping systems should be available for complex ablation procedures.
- ICE may be useful as an adjunctive imaging modality during complex procedures.
- Transthoracic echocardiography and transesophageal echocardiography should be readily available for emergency use and for adjunctive imaging in selected cases.
- Integrated data display systems provide flexibility and efficiency in data display; it is advisable to have separate backup monitors in case of failure.

5.1. Procedure Table

Patient safety and comfort are the most important considerations for the modern EP laboratory table. The ability to support a heavy patient is one of the most important features of the modern EP procedure table, with tables capable of supporting more than 200 kg being commercially available. The length and width of the table are also important considerations. Although standard table lengths are usually sufficient to accommodate most patients, there is growing need for the

increased width provided by bariatric surgical tables. Motorized tables with adjustable height and a tilting capacity of up to 20° have become standard. Tilting into the Trendelenburg position may be helpful in cases of difficult subclavian venous access or internal jugular venous access in ablation and device procedures. Reverse Trendelenburg positioning can be helpful for patients unable to lie flat because of musculoskeletal or respiratory difficulties. Table rotation up to 180° facilitates patient transport but more importantly provides better access to

the table head in cases of emergency. This feature, as well as the ability to tilt sideways, may also be helpful for maximizing surgical exposure in hybrid OR laboratories. Given the need to perform both right- and left-sided procedures, having rails on both sides of the table is particularly useful for mounting equipment and tableside controls. Finally, given the length of some EP procedures, in which patients may lay supine for several hours, a comfortable and supportive EP table pad is important. Foam material is commonly used in EP table pads, but other materials are also available.

5.2. Radiographic Equipment

Although fluoroscopy remains the mainstay of EP procedures, it is imperative to reduce ionizing radiation exposure to patients, operators, and staff as best possible. Specific issues related to radiation and limiting exposure are detailed in Section 11. The complexity of procedures performed in the laboratory is the primary determinant of the specific fluoroscopy features needed. Both single- and biplane fluoroscopic systems are suitable for the modern EP laboratory, and the choice of the system is dictated by the specific needs of the laboratory. In basic EP laboratories designed primarily for device implantation, a single-plane system is usually sufficient. Biplane systems are often preferred in more advanced laboratories where ablation is performed, as these biplane systems can be converted to single-plane units for device insertion; however, the advent of 3D mapping technology has diminished operator reliance on biplane fluoroscopy.

The introduction of digital imaging has been the most important recent change in fluoroscopic imaging. Digital flat panel detectors permit reduction in radiation and provide excellent image quality with a physically smaller and thinner detector. These systems allow greater temporal resolution and contrast ratio with less image distortion and veiling glare and allow the acquisition of high-quality still images. The latter feature is particularly useful for procedures depending on the imaging of vascular structures such as coronary arteries, the coronary sinus, and its branches. Floor- and ceiling-mounted units are available depending on the exact specifications and setup of the laboratory space. Some digital fluoroscopic systems offer advanced imaging capabilities, which may be useful in EP procedures including rotational angiography, rotational CT imaging, and multimodality integration of 3D magnetic resonance and CT images. These features are generally more suited for advanced laboratories performing complex ablation procedures. Three-dimensional reconstructed images from CT, MRI, and rotational fluoroscopy can guide ablation planning, catheter navigation, and catheter ablation.¹⁴ The pattern of myocardial scarring defined by delayed enhancement MRI scanning can influence the method of access (endocardial vs. epicardial), catheter type, and type of mapping technology.¹⁵ In the setting of atrial fibrillation ablation, a preprocedural 3D image can be helpful in cases of unusual atrial or pulmonary vein anatomy. Creation of a 3D map during the procedure using a mapping system can obviate the need for a preprocedural 3D image.

5.3. EP Systems

An EP system refers to the hardware and software programs that allow clinicians to record, display, store, and review data acquired during EP procedures. The monitoring system includes a computer workstation with both local and bedside high-resolution color display monitors, a recorder, amplifiers and filters for signal acquisition and processing, a printer, and device interface cables. The workstation contains an integrated computer that uses data processing software with amplifiers and adjustable filters to process and display electrogram signals and waveforms. At a minimum, the system should contain 12-lead surface ECG and 24 intracardiac electrogram channels, which is sufficient for the basic EP laboratory. Advanced laboratories performing complex ablation procedures require EP systems with 64–128-channel capabilities to simultaneously record signals from different multipolar catheters and display hemodynamic data from arterial and/or left atrial pressure transducers. Useful features for EP systems include a triggered sweep, template matching, and capability to save fluoroscopic images. These data are displayed on color monitors that include both real-time and review screens for visualization and analysis of electrogram signals during mapping and ablation. The number of available channels displayed on color monitors is configurable and differs among the various EP systems. Storage capabilities are often included in EP systems with various hard disk capacities and digital media for archival purposes and retrieval of data. Ideally, data should be stored in a central repository and be available to any workstation over the network. Integration and interfacing with RF-generating devices, fluoroscopy, mapping, and ablation systems are also important components of the system. Finally, the systems should be capable of communicating with institutional information systems and electronic medical records.

5.4. Resuscitation Equipment

Resuscitation equipment is mandatory, given the potential for induction of malignant arrhythmias. A biphasic external defibrillator is required in each EP laboratory, with a backup defibrillator immediately accessible. Routine preventative maintenance of external defibrillators should be performed, according to U.S. Food and Drug Administration (FDA) guidelines and manufacturer recommendations.¹⁶ A crash cart containing standard advanced cardiac life support (ACLS) medications must be available to assist with the management of tachy- and bradyarrhythmias. Standard ACLS medications should be available, including, but not limited to, epinephrine, atropine, dopamine, vasopressin, adenosine, amiodarone, and lidocaine, in addition to magnesium sulfate, calcium chloride, potassium chloride, and sodium bicarbonate. Sedative reversal agents should also be available, including flumazenil and naloxone. It is essential that the laboratory be stocked with appropriate long needles, guide wires, and catheters for emergency pericardiocentesis and that all operators and staff are familiar with the use of this equipment.

Given the increasing complexity of EP procedures and the potential need for general anesthesia, an anesthesia cart that

contains endotracheal intubation equipment as well as sedative, paralytic, and anesthetic agents is highly recommended. This includes a resuscitator bag and mask, a non-rebreather mask, suction equipment, and arterial blood gas kits. Such a cart should also contain a separate monitoring system for ECG and hemodynamics, including a pressure transducer and end-tidal carbon dioxide monitor, and should be available even in cases not staffed by an anesthesiologist. Finally, all modern EP laboratories should possess high-flow oxygen and vacuum for suctioning as detailed in [Section 9](#).

5.5. Stimulators

Programmable electrical stimulators are the mainstay of EP studies and must provide reliable, accurate, and effective electrical stimulation. Modern programmable electrical stimulators have multiple output channels, usually ranging from two to four channels. It is important for these channels to be independent and isolated and to accurately provide stimuli of adjustable amplitude and pulse duration. Burst pacing and delivery of one or more premature extrastimuli are standard features of all stimulators. In addition, some modern stimulators are fully automated and have the capacity of delivering several types of preprogrammed stimulation protocols to assess physiological parameters such as thresholds, sinus node recovery times, refractory periods, and Wenckebach periods.

5.6. Ablation Systems

In order to perform catheter ablation of cardiac arrhythmias, an ablation system is required in the EP laboratory. Ablation systems generally consist of a generator, cables, and catheters for the delivery of energy and may or may not include a ground patch, depending on the energy source. The ablation systems should interface with EP monitoring and electroanatomic mapping systems. Energy sources can be in the form of RF ablation, cryoablation, ultrasound ablation, microwave ablation, and laser ablation. RF and cryotherapy sources are the most widely clinically utilized, and a discussion of the other sources is beyond the scope of this document.

RF ablation as a therapeutic modality is the most commonly used and has been proven to be highly effective and safe for the treatment of a wide array of arrhythmias.¹⁷ Irrigated RF energy ablation systems require an irrigation pump to infuse saline in either a closed- or an open-irrigated tip catheter. Cryoablation systems consist of a cryocatheter, a refrigeration console with nitrous oxide, a coaxial tube for the delivery of nitrous oxide, and an electrical cable. During cryoablation, heat is removed from the tissue by using a refrigerant (nitrous oxide) in a closed-irrigated tip catheter. Cryoablation can be delivered at a single site (catheter based) or over a larger tissue area (balloon device). The selection of ablation modality depends on operator preference, patient size,¹⁸ and ablation target. RF energy remains the most established modality for ablation. Cooled RF technologies are generally employed where deep and/or transmural lesions are required, such as with VT ablation. Either irrigated RF energy or the cryothermic balloon ablation

system is commonly used for atrial fibrillation ablation procedures, depending on operator preference.

It is desirable for an EP laboratory to have more than one type of ablation system, but the selection of an ablation system and energy type is entirely discretionary. Different catheters have different handling characteristics, and different ablation systems have different strengths and weaknesses. It is recommended that all EP laboratory personnel using the ablation systems are able to demonstrate familiarity and proficiency with the setup, operation, and characteristics of all ablation system(s) employed at their site.

5.7. Mapping Systems

Three-dimensional electroanatomic mapping systems are commonly used in the EP laboratory for the acquisition of accurate and reproducible electrical and anatomic information and display in 3D. Reconstruction of complex cardiac geometry with direct nonfluoroscopic catheter visualization is combined with endocardial electrogram data to create a 3D map of the cardiac chamber. Advanced signal processing can present acquired electrophysiological data in a variety of formats to direct the operator to optimal ablation targets. In addition, standard fluoroscopy, CT, MRI, and intracardiac ultrasound images can be integrated with electroanatomic mapping systems to link electrogram information with anatomical structures. This allows nonfluoroscopic catheter localization, reducing radiation exposure during catheter ablation procedures.¹⁹ Mapping systems consist of a workstation computer, local and bedside monitors, fiber-optic media converter with a fiber-optic cable, an amplifier, diagnostic and ablative catheters, and a patient interface unit that provides the central connection of the computer system to catheters, cables, and the amplifier. The system can interface with recording systems and integrate with ultrasound, fluoroscopy, and CT/MRI systems. The system consists of a workstation computer, local and bedside monitors, an amplifier, fiber-optic media converter with a fiber-optic cable, and a multielectrode array catheter.

5.8. ICE Systems

ICE is often useful as an adjunctive imaging modality during complex procedures. It has the potential to improve both the safety and the efficacy of a procedure. Dynamic visualization of intracardiac structures, catheters, and other procedural devices is possible using ICE. The ability to use this modality in real time is an advantage that improves the work flow of the procedure compared with using other pre- or postprocedural augmentative imaging modalities. Using ICE to directly visualize and confirm the proper position of the transeptal needle on the atrial septum can minimize procedural complications, such as cardiac perforation. Pulmonary vein stenosis can be avoided by using ICE to confirm an ostial position of the lasso catheter during pulmonary vein isolation.²⁰ Early detection of complications, such as pericardial effusion or intracardiac thrombus formation, can lead to earlier and more effective interventions.²¹ Fluoroscopic

exposure and its associated risks can be minimized when navigation of catheters and procedural devices are guided by using ICE.²² The success of a procedure can depend on the recognition and successful navigation of challenging anatomy that can be detectable through ICE, such as a prominent Eustachian ridge during atrial flutter ablation, a crista terminalis ectopic tachycardia focus, or a ventricular arrhythmia involving the papillary muscles or aortic cusps.²³ Contact of the ablation catheter with tissue can be verified before the delivery of ablative energy, and ablative effects on the tissue can be monitored by assessing morphological changes, including tissue swelling and increased tissue echogenicity. Presently, two different types of ICE systems are available: systems using a linear phased array transducer that produces a 90° image longitudinal to the catheter and systems that use a rotational transducer to display a 360° image perpendicular to the catheter. Each system has relative advantages and disadvantages, and their selection is based on operator preference. Some ultrasound catheters can work with 3D electroanatomic mapping systems and can import 2D ultrasound images to augment 3D electroanatomic mapping.²⁴

Despite the potential value of ICE, reviewed in detail above, it is important to recognize that clinical trials are not available to demonstrate that the use of ICE improves the outcomes or safety of ablation procedures. Although some operators and centers depend heavily on ICE, many others use it only in selective situations. ICE substantially increases procedure costs, requires an additional site for vascular access, and requires extensive training in order to accurately interpret the images.²⁵

5.9. Robotic Navigation Systems

Catheter movement can be performed using robotic navigation systems, allowing for reproducible complex catheter manipulation, improved tissue contact and stability, and the potential for more efficient and efficacious lesion formation. Because of the automated nature of catheter navigation using 3D anatomic mapping systems, fluoroscopic exposure may be reduced, especially for the primary operator, who typically performs the ablation procedure seated in the control room. This may also translate into less orthopedic strain from the use of lead aprons.

Two distinctly different types of robotic navigation systems are currently available. Robotic arm systems use steerable sheaths to direct catheter movement. These systems can use a full array of conventional catheters, including irrigated ablation catheters. The rigidity of the sheath and the lack of tactile feedback increase the risk of cardiac perforation and pericardial tamponade.²⁶ Pressure sensor technology is used to assess appropriate tissue contact and to avoid perforation, but can be confounded by indirect forces and tortuous catheter positions. A simpler robotic approach to control the catheter movement involves the use of a robotic arm to remotely manipulate a steerable ablation catheter exactly as an operator would manipulate the catheter directly.²⁷ Although the operator sacrifices the tactile feel of catheter manipulation

with this system, it allows the operator to move to a radiation-free space and to perform the ablation from a seated position.

Magnetic systems use two large banks of external magnets to manipulate a magnetized catheter. These magnets can be either solid magnets that are physically moved or electromagnets using electromagnetic field manipulation. Specialized ablation catheters for these systems are available, including open-irrigated tip catheters. Because the body of the catheter has no rigidity and the catheters are directed solely by a limited low-intensity magnetic field, the risk of cardiac perforation is virtually eliminated.²⁸ The constant magnetic force holds the catheter in contact with tissue, even during cardiac and respiratory motion, translating to potentially more precise and efficacious lesions.²⁹ The use of robotic navigation systems takes the primary operator away from the patient's side during the procedure; thus, subtle changes in clinical status that are usually noticed in close proximity to the patient or the tactile sensation of a steam pop may no longer be detectable. Hence, close monitoring by an anesthesiologist and the nursing staff is of paramount importance when robotic navigation is being used.

5.10. Integrated Data Display Systems

As the breadth of technologies in the modern EP laboratory has grown, so too has the challenge of displaying information in a meaningful and useful way. The model using a fixed number of separate monitors, each displaying a single signal, is not well suited for laboratories using multiple systems and performing complex procedures. Modern advanced laboratories have increasingly taken advantage of integrated data display systems (IDDSs). These IDDSs replace the multiple fixed monitors with a single large screen that displays multiple signals, thereby allowing the physician and laboratory staff to display as many images as required in whatever layout they choose. Not only do IDDSs enhance flexibility, they also diminish the physical requirements for monitoring, thereby liberating space within the EP laboratory. The drawback of IDDSs is the addition of another layer between the operator and the source systems that may be susceptible to image distortion or complete failure that would affect all signals. Thus, it is necessary to have separate backup monitors for critical functions in case of failure. Lastly, IDDSs should have a simple, intuitive user interface; otherwise, any benefit they provide would be outweighed by issues relating to the complexity of use.

5.11. Telemedicine Applications

Telemedicine has grown in many areas of medicine over the past decade, and EP is no exception. In fact, EP is better suited than most specialties to leverage this growing trend, thanks in part to the integration of many laboratory systems into a single interface and to advances in remote catheter navigation systems. Remote diagnostics are already a reality because of the growth of several networks that link various laboratories and facilities together. Physicians from a number of institutions can broadcast live and prerecorded procedures and perform real-time consultations with other participating

facilities. Remote surgery has been demonstrated using the current generation of remote catheter navigation technologies and has been further bolstered by the addition of newer laboratory integration systems. While the requirements for remote surgery are similar to those of remote diagnostics,

there should be much less tolerance for latency and system responsiveness as well as enhanced fail-safe measures and the ability for local override. Significant gaps in state, federal, and international regulations will need to be addressed before telemedicine can reach its full potential in this field.

6. Laboratory Staffing

Laboratory Staffing Recommendations

- Medical staff credentialing committees should be familiar with the training and credentialing standards for specialists in cardiac arrhythmias.
- Staff physicians must have prerequisite training and appropriate credentialing reflecting expertise in the management and treatment of cardiac arrhythmias.
- Because of the complexity of the EP procedures, patient safety and positive outcomes are critically dependent on the skill levels of the staff. Additional staff is needed as the complexity of the case increases and more equipment is required.
- It is desirable that anesthesia services be an integral part of clinical practice in the EP laboratory.
- Advanced practice nurses (APNs) and physician assistants (PAs) should be used in areas where they will have a maximum impact on patient care and where they can assume roles and responsibilities unique to their training and certification.
- At least one registered nurse should be present for every invasive procedure in the EP laboratory.
- Industry representatives should function according to clear policies under the direction of the laboratory manager, staff, or physician.

6.1. Physicians

6.1.1. Qualifications

Staff physicians must have prerequisite training and appropriate credentialing reflecting expertise in the management and treatment of cardiac arrhythmias. Training requirements and guidelines for pacemaker/ICD selection, implantation, and follow-up as well as catheter ablation procedures have been addressed by the American Heart Association (AHA), American College of Cardiology (ACC), and HRS^{30–34} and are addressed in [Section 7](#).

Physicians performing procedures in the EP laboratory often supervise the administration of intravenous sedatives given by the nursing personnel in the laboratory. Therefore, all physicians in the laboratory should demonstrate proficiency in sedation pharmacology, patient monitoring, and airway management. There should be a credentialing process in the institution that establishes a standard for conscious sedation management.

6.1.2. EP Laboratory Medical Director

The EP laboratory medical director must be an expert in CCEP and satisfy the above requirements, in addition to carrying out important administrative duties that include physician leadership, patient care clinical leadership, quality of care, and education. As a physician leader, the medical director is responsible for providing overall medical direction and supervision within the EP laboratory. The roles and responsibilities of the other EP staff physicians must be specifically outlined by the director so that there are clear measures by which the EP staff physicians are evaluated. Ensuring staff members are appropriately credentialed and that they are maintaining cognitive and procedural

competency is important for maintaining up-to-date health care provider standards. The laboratory director should work with the institution's leadership to establish specific training- and volume-based credentialing and recredentialing criteria based on published clinical care guidelines (when available). Those criteria should be understood and adhered to by all.

The medical director must develop and implement quality measures that result in fewer complications, reduced cost, and successful patient outcomes. Working closely with administrative staff to develop policies, procedures, and practice guidelines impacts accountability measures used by accreditation authorities, including TJC and the National Committee for Quality Assurance. Additional responsibilities may include planning or coordinating ongoing educational opportunities for all EP personnel, championing the EP service line, identifying budgetary savings and efficiencies, participating in or initiating purchasing of capital items that keep the service line current, and assisting as requested with the development and review of EP-related policies and procedures. Policies should be compatible with other areas with which the EP service interacts, such as the prep and recovery areas, anesthesia, surgery, and the cardiac catheterization laboratory.

6.1.3. Faculty/Teaching Attending Physician

Faculty physicians typically work in a teaching hospital or affiliate institution. They must satisfy the same qualifications as above, in addition to those set forth by the Accreditation Council for Graduate Medical Education (ACGME). These requirements are quite rigorous, and failure to adhere to requirements may result in the program being placed on probation or loss of accreditation.

6.1.4. EP Laboratory Attending Physician

Although certain components of the procedure can be delegated to a trainee or other secondary operator, the laboratory's attending physician of record is ultimately responsible for all activities within the laboratory and for patient welfare. It is important for the staff physician to recognize that patient safety and successful outcomes depend greatly on effective communication in the EP laboratory. This communication should include preoperative discussions with all members of the team before the case is underway regarding specific patient needs. The physician should review the diagnosis, indications for the procedure, anticipated equipment needed, and potential findings of the procedure. The patient should have a clear understanding of what to expect post-procedure in order to minimize anxiety. After the procedure, clear communication of the procedure findings, postprocedure orders, and recommendations should be exchanged with the treatment team, including physicians, APNs, PAs, and nurses.

6.1.5. Secondary Operators

Secondary operators are those physicians assisting with a procedure who might or might not participate in certain aspects of EP procedures and who might bill separately for an area of expertise not provided by the primary physician in the laboratory (Table 1). Their role is planned and limited to nonemergency procedures. The patient should be informed before the procedure of any secondary operators expected to be assisting with the case.

6.1.6. Cardiovascular Trainee (Fellow)

The role of the fellow can be variable and dependent on the attending physician present in the laboratory. There are specific requirements that each fellow in training must satisfy

in order to successfully complete his or her training and be eligible for the American Board of Internal Medicine (ABIM) certification examination (or American Board of Osteopathic Medicine for those individuals following the osteopathic route). The fellow should begin under the direct supervision of a key clinical faculty member from the training program. With ongoing evaluation and feedback, the fellow is given graduating responsibility. Varying levels of supervision are appropriate depending on skill level and level of training. It is appropriate for fellows to perform components of the procedure without direct supervision (such as vascular access, catheter placement, device pocket incisions, and pocket closures), but the attending physician must be available to intervene promptly if any issues arise.

6.2. Anesthesiology

It is desirable that anesthesia services be an integral part of clinical practice in the EP laboratory. An anesthesia group composed of anesthesiologists and certified registered nurse anesthetists (CRNAs) can provide a high level of perioperative/periprocedural care to patients undergoing EP procedures. Having anesthesia services readily available for the EP service is advantageous. The anesthesia service can provide important educational assistance to nonanesthesia staff administering conscious sedation, such as training on the use of various sedation agents, and the use of special monitoring techniques such as capnography. Patients undergoing EP procedures present special challenges related to sedation. It is imperative that sedation/anesthesia personnel function collaboratively with the electrophysiologist in the management of these patients during procedures. Procedural issues relating to anesthesia management are discussed further in Section 8.

Table 1 Secondary Operators in the Cardiac EP Laboratory

Secondary operator	Role/duties
Cardiac electrophysiologist	<ul style="list-style-type: none"> Operates the EP/mapping system and assists with cardiac stimulation and mapping while the primary operator is manipulating the catheter Manipulates the mapping/ablation catheter while the primary operator is operating the EP/mapping system
Interventional cardiologist	<ul style="list-style-type: none"> Performs angiography for defining coronary anatomy in epicardial ablation procedures Performs aortography to define location of coronary ostia in LVOT/cusp ablation procedures Assists with transseptal puncture and left atrial access Places intra-aortic balloon pump or other support devices
Interventional radiologist or interventional cardiologist	<ul style="list-style-type: none"> Performs angioplasty of venous vessels
Noninterventional cardiologist	<ul style="list-style-type: none"> Performs transesophageal echocardiography Assists with intracardiac echocardiography
Cardiothoracic surgeon	<ul style="list-style-type: none"> Operates epicardial pacemaker or epicardial ICD systems Assists with hybrid atrial fibrillation procedures Assists with epicardial access via pericardial window Assists with lead extraction backup Assists with extracorporeal membrane oxygenation for VT storm and hemodynamically unstable VT ablation
Anesthesiologist	<ul style="list-style-type: none"> Supports cases by providing conscious sedation or general anesthesia

EP = electrophysiology, LVOT = left ventricular outflow tract; VT = ventricular tachycardia.

6.3. Allied Professional Personnel

To ensure optimal safety and efficacy of interventional EP, it is important to emphasize the necessity of a multidisciplinary team approach. In this respect, the term *allied professionals* has been employed. Allied professionals are defined as all nonphysician members of the health care team involved with the care of the patient in the EP laboratory. This includes, but is not limited to, registered nurses (RNs), EP technologists, radiological technologists, certified nurse practitioners (NPs), PAs, CRNAs, patient prep and recovery staff, and OR staff. Other key personnel that are important for the safe and efficient function of the laboratory include quality assurance (QA) staff; information technologists; biomedical engineers; scheduling coordinators; purchasing, inventory, and supply personnel; and housekeeping. Based on evidence-based practice and best practice patterns, it is important to acknowledge that there is limited published research regarding the roles and responsibilities inherent in EP. Recommendations as to how these positions may be filled by any one of the several categories of personnel are discussed below.

6.3.1. Advanced Practice Nurses and Physician Assistants

APNs and PAs can play major roles and serve many functions in the EP laboratory, as determined by the director of the laboratory. They should be placed in those areas where they will have maximum impact on patient care and assume roles and responsibilities unique to their training and certification. APNs are often placed in clinic settings where they may evaluate and treat arrhythmia or device-related issues. They can make rounds on inpatients, make assessments, develop plans for care, write histories and physical exams, and admit and discharge patients. They can perform pre- and postprocedural evaluations and follow-up. Particularly in nonacademic institutions or practices, an APN or PA may function as the most experienced or skilled nonphysician practitioner in the laboratory setting and thus function as a first assistant for many technical aspects of the procedure. Each institution should have established policies defining the role of the APN and/or PA in the care of hospital patients.

6.3.2. Registered Nurses

An RN should be present for every invasive procedure in the EP laboratory. The nurse must be familiar with the overall function of the laboratory as well as coordinate with the physician operator and the other team members. The nurse (either RN or CRNA) is the primary individual responsible for the direct observation, sedation, and nursing care of the patient during the EP procedure and must be prepared to respond to any emergency. The number and type of nursing personnel required in the EP laboratory will vary depending on the type of procedure, equipment used, and additional support staff assigned to the procedure.³⁵ EP procedures are complex by their nature, and it is essential that the nursing staff participating in such procedures provide safe, evidence-based care.

In institutions where nurses are responsible for the administration of intraprocedural sedation, they are to follow institutional training and guidelines for the care of the patient.

When a nurse is administering deep sedation, his or her focus should be only on monitoring patient status, vital signs, oxygenation, and level of sedation. However, during moderate or light sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation/anesthesia and vital signs have stabilized, provided that adequate monitoring of the patient's level of sedation is maintained.³⁶ The nurse can also manage point-of-care testing for activated clotting times (ACTs), oxygen saturation, and blood gas measurements. In most states, only RNs may administer medications and blood products. The nurse optimizes patient safety by adhering to policies, protocols, and procedures, such as completing the "active time-out" preprocedure and ensuring that the proper airway assessments are completed before the administration of sedation. Keeping a record or charting during the procedure is generally the responsibility of nurses. In addition, training on the use of stimulators, infusers, and ablation generators is recommended so that nurses are able to function in multiple roles. Overall, nurses are coordinators of all patient care in the laboratory and they oversee the care other allied professional-EP personnel are providing.

6.3.3. Technologists

Because of the extremely complex and technical aspects of many EP procedures, there should be at least one additional person involved in the more complex procedures, in addition to the nurse who provides direct patient care. Depending on the complexity of the procedure, there may need to be more than one additional person. In this arena, specific training, experience, and certifications may determine which team member occupies each role. For example, a nurse and a technologist may be equally capable of performing a certain duty or responsibility but economics, staffing availability, and the simultaneous performance of multiple duties can dictate who does each job in the laboratory. Because of the multiplicity of roles, it is useful for members of the EP team to be cross-trained and be able to function in multiple roles and situations. There is a wide array of additional equipment that requires training to operate. This includes, but is not limited to, lasers, energy source generators, electroanatomic mapping systems, robotic and magnetic catheter navigation systems, echocardiography (transesophageal and intracardiac), and CT and MRI imaging.

In many laboratories, it is the technologist or nurse who monitors and operates the recording system. This activity requires a thorough understanding and knowledge of the electrophysiological properties of the heart as well as pacing protocols and ablation. The operator must be able to troubleshoot pacing problems and remain calm and functional in emergency situations. All technologists must have basic cardiac life support certification, and ACLS certification is preferred. In the pediatric laboratory, pediatric cardiac life support certification is required. As with the nurse, the technologist should have the ability to review, understand, and synthesize into practice new knowledge and practices.

EP technologists perform as essential team members. They may be a first assistant, which requires in-depth knowledge of

percutaneous procedures, catheters, sterile technique, energy generators, and integrated noninvasive imaging. They should be trained in the use, maintenance, and troubleshooting of all the equipment. EP technologists should be skilled in sterile technique, passing sterile supplies, and obtaining and performing point-of-care testing on blood samples. They are often the person who assists on device implant cases and lead extractions—roles that require fastidious adherence to sterile technique and an in-depth understanding of the implant process along with its risks and goals. A technologist or nurse may serve as the first assistant for an invasive case. The circulator is typically a nurse, but this role can be filled by a technologist, depending on the staffing mix in the laboratory, the scope of practice in this job description, and the institutional requirements.

At least one department member should be a certified radiological technologist or equivalent technologist with expertise in the operation of fluoroscopic equipment as well as expertise in radiographic and angiographic imaging principles and techniques. Requirements for the participation of a radiological technologist in fluoroscopic procedures vary from state to state. In conjunction with a qualified medical physicist, the radiological technologist should monitor radiation safety techniques for patients and laboratory personnel. In many states, the Nuclear Regulatory Commission has specific regulations for who may operate ionizing radiation equipment and under what circumstances. It is imperative that these regulations are understood and followed in the laboratory for the protection of patients and staff.

6.3.4. *Industry Employed Allied Professionals*

Device programmers, mapping and recording systems, and some ablation systems may sometimes be operated by industry representatives. Industry representatives must function according to clear policies under the direction of the laboratory manager, staff, or physician. They are often required to provide the institution with evidence of appropriate immunizations, competency documentation, and endorsement from their company before being allowed in the laboratory. They are generally allowed to have patient contact only under direct staff supervision.²⁵

During device implants or other device-related procedures, a clinical industry representative may be present under the direct supervision of the attending physician. They may bring device equipment to the laboratory, provide intra-procedural programming and testing, and may even be asked to participate in data collection related to device registries. A member of the EP laboratory staff, however, should be assigned the ultimate responsibility for the accurate and complete submission of data to national device registries. These industry representatives are often excellent sources of information and education for the regular EP laboratory staff.

They may assist in the provision of formal training and education on device-related issues.²⁵

6.3.5. *Staffing Patterns*

To ensure optimal safety and efficacy of interventional EP, it is important to emphasize the necessity of a multidisciplinary team approach. EP procedures are complex and include diagnostic, interventional, and therapeutic measures and should be performed by experienced personnel. Because of the complexity of the EP procedures, patient safety and positive outcomes are highly dependent on the skill levels of the staff (Table 2). Therefore, personnel dedicated to EP laboratory procedures are recommended. Additional personnel are needed as the complexity of the case increases, and more equipment is required. The staffing mix may be influenced by regulations, regional practice patterns, type of institution (academic vs. nonacademic), credentialing bodies, and economics. Cross-training of staff within the EP department maximizes staffing flexibility and is strongly recommended.

6.4. **Administrator/Manager**

The role of the EP department administrator is typically held by someone with broad knowledge of the field of EP. Depending on the size and volume of the laboratory, the administrator may have no clinical obligations or may serve as the head nurse of the laboratory. The responsibilities can include, but are not limited to, the following: strategic planning in association with the medical director, managing operational issues, capital planning, budgeting, hiring, planning orientations and training programs for allied professionals, and other general administration duties. A nurse or a cardiovascular technologist, preferably with some business training or experience, is best suited for this role. In shared or combined cardiac catheterization laboratories and EP laboratories, there may be a common administrator overseeing both areas.

In many departments, the manager is a nurse. The responsibilities of a nurse manager include an overall understanding of the day-to-day operations of the laboratory, management of pre- and postprocedural care areas, and direct participation in the observation and care of patients undergoing EP procedures. Additional areas of responsibility include application of institutional guidelines for patient monitoring, medication administration, procedural sedation, and patient safety. Staff competencies and proficiency in performing tasks required before, during, and after the procedure must be developed, updated, and reviewed on a regular basis. The nurse manager will collaborate with anesthesia, pharmacy, biomedical engineering, purchasing, equipment vendors, and housekeeping to coordinate the operation of the EP laboratory.

Table 2 Staffing Recommendations for Electrophysiology Procedures

Type of procedure	Recommended personnel (<i>Alternatives/additional ad hoc personnel</i>)	Pediatric laboratory staffing personnel (<i>Alternatives/additional ad hoc personnel</i>)
Basic EP study	1 EP credentialed MD performing the procedure (<i>Fellow, NP, PA, and technician performing under the supervision of an MD responsible for the procedure [as approved by the institution]</i>) 1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation* (<i>1 nurse or 1 cardiovascular technologist/radiology technologist*</i>)	1 EP credentialed MD performing the procedure 1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation 1 Nurse 1 cardiovascular technologist/radiology technologist
Tilt table tests	1 nurse, NP, or PA MD must be on the premises, readily available, and aware that testing is occurring (<i>1 tilt table technician</i>)	1 nurse, NP, or PA Pediatric cardiologist must be on the premises, readily available, and aware that testing is occurring (<i>1 tilt table technician</i>)
Cardioversions	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation
Noninvasive programmed stimulation	1 MD performing/supervising the procedure (<i>1 nurse or technologist circulating and documenting</i>)	1 MD performing/supervising the procedure 1 nurse monitoring and recovering the patient
Defibrillation threshold testing	1 EP credentialed MD performing the procedure (<i>Secondary MD operators may be desirable to perform certain parts of the procedure</i>) (<i>Fellow, NP, PA, and technician performing under the supervision of an MD responsible for the procedure [as approved by the institution]</i>)	1 specialist in pediatric EP performing the procedure (<i>Many laboratories have a working standard of a secondary MD operator for all cases</i>) (<i>Fellows or other students assisting or observing</i>)
Ablation procedures	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation (<i>1 nurse giving medications, and patient care during the procedure may do charting</i>) (<i>Physician extenders such as an NP or PA</i>) 1 technologist or nurse running the recording system, stimulator, and ablation system; may be a radiation technologist (<i>Vendor representative running the mapping system</i>) (<i>Vendor representative or hospital technologist assisting with echocardiography</i>) (<i>Vendor representatives assisting with the operation of other specialized equipment, such as lasers, cryoablation generators, and intracardiac echo machines</i>)	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation 1 nurse giving medications, and patient care during the procedure, may do charting (<i>Physician extenders such as an NP or PA</i>) 1 technologist or nurse running the recording system, stimulator, and ablation system; may be a radiation technologist (<i>Vendor representative running the mapping system</i>) (<i>Vendor representative or hospital technologist assisting with echocardiography</i>) (<i>Vendor representatives assisting with the operation of other specialized equipment, such as lasers, cryoablation generators, and intracardiac echo machines</i>)
Device implant procedure	1 EP or device-credentialed MD performing the procedure (<i>Fellow, NP, PA, and technician performing under the supervision of an MD responsible for the procedure [as approved by the institution]</i>) 1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation* (<i>1 nurse or technologist circulating*</i>) (<i>1 technologist or nurse may be a surgical assistant</i>) (<i>Vendor representative from the device manufacturer</i>) (<i>Vendor representative assisting with the operation of other specialized equipment, such as lasers and other extraction equipment</i>)	1 specialist in pediatric EP performing the procedure (<i>Secondary operator, including physician extenders</i>) (<i>Fellows or other students assisting or observing</i>) 1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation 1 nurse circulating 1 technologist or nurse may be a surgical assistant (<i>Vendor representative from the device manufacturer</i>) (<i>Vendor representative assisting with the operation of other specialized equipment, such as lasers and other extraction equipment</i>)
Lead extraction procedure	1 EP or device-credentialed MD performing the procedure (<i>Secondary operator including physician extenders</i>)	1 MD specialist in pediatric EP performing the procedure) (<i>Secondary operator, including physician extenders</i>)

Table 2 (continued)

Type of procedure	Recommended personnel (<i>Alternatives/additional ad hoc personnel</i>)	Pediatric laboratory staffing personnel (<i>Alternatives/additional ad hoc personnel</i>)
	(Fellow, NP, PA, and technician performing under the supervision of an MD responsible for the procedure [as approved by the institution])	(Fellows or other students assisting or observing)
	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist, or 1 nurse trained and credentialed in procedural sedation	1 CRNA administering anesthesia under the supervision of an MD anesthesiologist
	1 CV surgeon to be immediately available (may be required to be in the room for the critical part of the procedure)	1 congenital CV surgeon in the operating room at the time of extraction and immediately available periprocedure
	1 nurse circulating (1 <i>technologist or nurse scrubbing</i>)	1 CV surgery fellow on call for surgical assistance 1 perfusionist 1 nurse 1 cardiovascular technologist/radiology technologist
	(May require a second scrub person for the surgical procedure)	1 CV OR scrub nurse 1 CV OR circulating nurse
	(An operator to monitor a TEE that may be in place. This function is sometimes performed by the anesthesiologist)	(An operator to monitor a TEE that may be in place. This function is sometimes performed by the anesthesiologist)
	(Vendor representative from the device manufacturer)	(Vendor representative from the device manufacturer)
	(Vendor representative assisting with the operation of other specialized equipment, such as lasers and other extraction equipment)	(Vendor representative assisting with the operation of other specialized equipment, such as lasers and other extraction equipment)

CRNA = certified registered nurse anesthetist; CV = cardiovascular; EP = electrophysiology; MD = physician; NP = nurse practitioner; PA = physician assistant; TEE = transesophageal echocardiography.

*In procedures performed with deep sedation/analgesia, the CRNA or nurse administering sedation/anesthesia should have no responsibilities other than monitoring the patient. A second nurse or technologist must be available to circulate and document. However, in procedures performed with moderate or light sedation, this individual may assist with minor, interruptible tasks once the patient's level of sedation/analgesia and vital signs have stabilized, provided that adequate monitoring for the patient's level of sedation is maintained.⁵²

7. Laboratory Personnel Credentialing

Laboratory Personnel Credentialing Recommendations

- All clinicians working in the EP laboratory have a responsibility to achieve and maintain the recommended credentials and continue medical education to optimize patient care.
- It is recommended that any non-CCEP-certified physician who wants privileges for implantable cardioverter-defibrillator implantation should complete formal training in this field as defined by the COCATS criteria, achieve certification of Competency in Cardiac Rhythm Device Therapy for the Physician (CCDS) from the International Board of Heart Rhythm Examiners (IBHRE), and maintain an adequate volume of device implants to meet hospital-based credentialing criteria.
- For the benefit of patients, it is paramount that physicians be held to a high performance standard and that remediation, withholding recertification, or revocation of privileges occurs if criteria are not met.

7.1. Attending Physicians

7.1.1. Credentialing

A range of procedures is performed in cardiac EP suites. Procedures that fall within the domain of physicians trained and ABIM certified in cardiovascular diseases include performance of electrical cardioversions and placement of temporary pacemaker wires. Invasive cardiac EP procedures in adults, including diagnostic electrophysiological testing and catheter ablation, should be restricted to physicians who are ABIM certified in CCEP.³¹ All CCEP board-certified physicians have completed at least 1 year of

comprehensive subspecialty training in CCEP at an ACGME-approved training program³⁰ or had substantial experience and a career focus in CCEP if they trained in an era before the development of formal CCEP training programs. The majority of programs encourage a second year non-ACGME advanced fellowship. The 2013 guidelines for advanced training in pediatric and congenital EP represent procedural requirements for those completing training.³⁷ The clinical competence statement on invasive electrophysiology studies, catheter ablation, and cardioversion,³⁴ supplemented by expert consensus statements on

transvenous lead extraction,⁸ catheter and surgical ablation of atrial fibrillation,³⁸ and catheter ablation of ventricular arrhythmias,³⁹ provides guidelines for appropriate training in CCEP. This document is scheduled to be updated in the near future. As training standards evolve, these minimum requirements will be updated regularly. A successful passage of the ABIM CCEP board examination is required to receive the Certificate of Added Qualification in CCEP. A similar but alternate pathway is available for doctors of osteopathy through the American Board of Osteopathic Medicine. Physicians for whom these pathways are unavailable because of international training or pathway choices and who are actively involved in the clinical management of EP patients may choose to certify through the IBHRE with the Certification Examination for Competency in Cardiac Electrophysiology. Physicians performing complex catheter ablation procedures, such as atrial fibrillation/complex atrial tachycardia ablation and VT ablation, should treat at least 25 cases of each with an experienced mentor before becoming independent. Alternatively, they should perform these procedures during their CCEP training program, as recommended by the 2012 HRS/EHRA/ECAS expert consensus statement on catheter and surgical ablation of atrial fibrillation³⁸ and the 2009 EHRA/HRS expert consensus on catheter ablation of ventricular arrhythmias.³⁹

A number of training pathways can lead to the practice of implanting CIEDs. Although physicians who are board certified in CCEP have met minimum training standards for CIED implantation, some cardiovascular diseases (CVD) board-certified physicians and some American Board of Surgery-certified cardiac, thoracic, and general surgeons also devote a substantial portion of their practice to the prescription, implantation, and follow-up of CIEDs. The criteria established by the ABIM program requirements²⁸ and the Recommendations for Training in Adult Cardiovascular Medicine Core Cardiology Training document³³ strongly recommend that any non-CCEP-certified physician who wants privileges for ICD implantation in adults completes formal training in this field. Achieving CCDS from the IBHRE for CIED prescription, implantation, and follow-up is strongly recommended.

Credentialing is ultimately the responsibility of the credentialing committee of the individual hospital, who should be familiar with the training and credentialing standards for specialists in cardiac arrhythmias. Although most major centers already follow the guidelines above, some centers allow less qualified practitioners to perform these EP laboratory procedures. Unfortunately, hospital credentialing committees have substantial conflicts of interest that could lead to granting privileges to physicians without appropriate board certification and experience, as refusal of these credentials usually results in a loss of patients and revenues to competing institutions. Ultimately, the patient pays the price when inappropriate credentials are allowed.

7.1.2. Evaluation and Recredentialing

All EP laboratory physicians should be subject to periodic peer review and recredentialing. Important components in the recredentialing process should include a review of ABIM board certification and IBHRE CCDS status, case volume, patient outcomes, peer evaluation, and continuing medical education (CME). The specific criteria for recredentialing are determined by each individual hospital, but should generally parallel the following recommendations: ABIM CCEP board certification and IBHRE certification are limited to 10 years; to stay current for CCEP, the physician must complete a series of CME and/or practice improvement activities⁹; recertification examination for CCEP and CCDS are each required at 10-year intervals; to ensure that cognitive and technical skills are maintained, the physician's clinical competence must be evaluated and documented on a regular basis; it is the responsibility of the medical staff credentialing committee to ensure that physicians perform the necessary number of evaluations and procedures needed to maintain their expertise³¹ and also that they participate in regular CME activities. The EP laboratory should have a robust QA process (see Section 9), and physician outcomes should be compared with national benchmarks derived from the literature or databases such as the National Cardiovascular Data Registry (NCDR) on a regular basis; regular 360° evaluations, including evaluations from physician coworkers, fellows, nursing staff, technical staff, and patients, should be considered as part of the recredentialing review process.

For the benefit of patients, it is paramount that physicians be held to a high performance standard and that remediation, withholding recredentialing, or revocation of privileges occurs if criteria are not met. The physician leaders must be committed to working aggressively to maintain the highest standards of patient care in their laboratories.⁴⁰

7.1.3. Pediatric Training and Credentialing

PACES, working in conjunction with HRS, has developed guidelines for advanced training in EP focused on pediatric patients and patients of any age with CHD. The original guidelines, endorsed by the HRS and published in 2005, required at least 12 months of specialized training, and were followed by a 2008 document focused on the implantation of pacemakers and defibrillators in these populations.^{41,42} There are currently no third-tier board examinations for diplomates of the pediatric cardiology subboard of the American Board of Pediatrics. However, pediatric electrophysiologists are eligible to take the IBHRE examination for physicians with special competency in EP, as that examination includes a pediatric module. PACES has recently written a competency statement for training in this field.⁴³ That competency statement strongly recommended that all graduating fellows and active pediatric EP clinicians take the IBHRE EP examination.

7.1.4. Adult Congenital Heart Disease Training and Credentialing

The field of adult congenital heart disease (ACHD) is an important and expanding clinical domain that is typically staffed by clinicians who are competent in both pediatrics and internal medicine. Cardiologists providing invasive EP care for this unique patient population can enter the field from either specialty, but a portion of their formal training must be focused on the complex anatomy and unique EP of ACHD. Further recommendations on the expertise necessary to care for this patient group can be found in a recent consensus statement supported by AHA/ACC/HRS.⁴⁴ A board certification process for ACHD is being developed and is scheduled for implementation by 2015.

7.2. Nurses

7.2.1. Training and Credentialing

Nursing licensure, credentialing, recredentialing, continuing education, and laboratory training are affected by the requirements of multiple agencies, including federal and state governments, the health care organization, and Occupational Safety and Health Administration.

The standards of professional practice for nurses employed in the EP laboratory environment have been defined.³³ All EP nurses should have a critical care or a strong cardiology background, ACLS certification, and, in the pediatric EP laboratory, pediatric ACLS. An extensive knowledge of cardiac anatomy and physiology, electrocardiography, pharmacology, and training in sterile technique is also required. Nurses need to have a thorough understanding of catheter-based interventions and surgical procedures, cardioversion, arrhythmia discrimination, and emergency treatment of life-threatening arrhythmias and complications/emergencies. Familiarity with fluoroscopic, electroanatomic, and echocardiographic imaging is a required skill set. Annual or biannual competencies required for nurses working in heart rhythm service operations should include basic life support, ACLS, infection control, emergency and TJC preparedness, training in conscious sedation, charting, and patient safety. Demonstration of competency in radiation safety, sterile technique, external defibrillator operation, unit-specific nursing protocols, ACT operation, and temporary pacemaker operation should also be mandatory. Depending on the roles and responsibilities assumed by RNs, competencies may be needed in the EP recording system and programmed stimulator operation, ablation, generator operation, mobile laboratory operations, sheath insertion/removal, operation of vascular ultrasound, 3D mapping operation, and ICE operation.

Certification offered by the (IBHRE is an integral part of heart rhythm education, training expectations, and requirements. In addition to the standard certification requirements for being an RN, the IBHRE offers two certification examinations for allied professionals designed to demonstrate a mastery of knowledge in cardiac rhythm management.

7.2.2. Evaluation and Recredentialing

Continuing education requirements are highly variable by state and nurse specialty. Nurses need to review requirements for the state in which they are practicing to ensure proper compliance and maintenance of certification, as requirements can range from no required continuing education to as many as 30 hours every 2 years.⁴⁵ The Certification Examination for Competency in Cardiac Rhythm Device Therapy and the Certification Examination for Competency in Cardiac Electrophysiology are required at 10-year intervals.

7.3. Advanced Practice Nurses

7.3.1. Training and Credentialing

The APN (usually a NP) is educated through a certified graduate level NP program, meets the requirements of the state credentialing bodies, and practices according to the American Nurses Association consensus model.⁴⁶ An NP is trained to perform preprocedural evaluation, order and interpret diagnostic tests, and conduct postprocedural follow-up. After on-the-job training, NPs may assist in diagnostic EP studies, catheter ablation procedures, and device implants but cannot serve as a primary operator. NPs working in heart rhythm services should be certified in basic and advanced cardiac life support and have knowledge of radiation safety, sterile technique, external defibrillator operation, ICE operation, and temporary pacemaker operation. Among laboratories represented by writing committee members, NPs (or PAs) are involved in pre- and postprocedural care in more than 75% of the centers but only 19% of the centers employ these individuals for assistance in the procedural laboratory.

7.3.2. Evaluation and Recredentialing

There are no uniform recredentialing criteria for NPs in the EP laboratory. NPs are expected to maintain certification and licensure as per certification and state guidelines. The institution should establish volume criteria for the maintenance of procedural competencies.

7.4. Technologists

7.4.1. Training and Credentialing

Individuals with a variety of backgrounds and qualifications can work in an EP laboratory as a cardiovascular technologist or technician. There is no professional regulatory body for cardiac technologists, although efforts are underway in some regions to achieve this goal. Most technologists have postsecondary education (university degree or college diploma) with extensive on-the-job training. Industry-sponsored courses often provide supplemental education specific to technologies used in the EP laboratory environment. Some cardiovascular technologist programs offer EP as a component within a cardiovascular technology program; there are also certificate programs available at some accredited colleges.⁴⁷ Cardiovascular technologists can be credentialed as a registered cardiovascular invasive specialist, registered cardiology technologist, registered cardiopulmonary technologist, or registered cardiac electrophysiology specialist through an accredited association such as

Cardiovascular Credentialing International.⁴⁶ Advanced EP specialty certification is achieved through the IBHRE.

7.4.2. Evaluation and Recredentialing

Satisfactory institutional performance appraisals (e.g., through 360° assessments of skills, competency, professional development, decision making, and leadership) are recommended. The individual should treat a sufficient volume of cases to maintain competency. If the technologist is IBHRE certified, then the maintenance of certification through continuing education or certification examination is required.

7.5. Physician Assistants

7.5.1. Training and Credentialing

The PA is an advanced practice professional who is trained through a graduate level university program to perform many tasks, including preprocedural evaluation (history and physical examination and diagnostic tests) and postprocedural follow-up under the direct supervision of the physician.^{48,49}

After on-the-job training, PAs may assist in diagnostic EP studies, 3D mapping, catheter ablation procedures, and device implants, but cannot serve as a primary operator. Institutional internal certification, minimum volume of annual cases to maintain competency in invasive EP, performance appraisal, and maintenance of continuing

education should be a requirement for a PA practicing in the clinical EP laboratory.

7.5.2. Evaluation and Recredentialing

There are no uniform recredentialing criteria for PAs. They should perform a minimum number of procedures as determined by the EP laboratory director and EP laboratory manager and demonstrate current competence on the basis of the results of ongoing professional practice evaluation and outcomes.

7.6. Industry Employed Allied Professionals

Industry Employed Allied Professionals (IEAPs) are hired employees of a medical device company who may serve as assistants in the EP laboratory. The HRS published a statement on the clinical role of IEAPs in 2008. IEAPs should provide technical assistance only on the manufacturer-specific products they represent, and they must work under the direct supervision of the responsible physician.²⁵ Although IEAPs may contribute substantially to patient care in some settings, overreliance on their service may lead to a lack of continuity of care, suboptimal patient education and counseling, and issues with liability and accountability. Among laboratories represented by writing committee members, approximately 90% of the laboratories use IEAP support in most or all device implant cases, and two thirds of the laboratories use IEAP support in most or all 3D mapping cases.

8. Procedural Issues

Procedural Recommendations

- Preparation for EP procedures requires a preprocedural history and physical examination by a physician, NP, or PA.
- As many management strategies for arrhythmias require chronic and/or periprocedural anticoagulation, careful evaluation, assessment, and planning are needed.
- In patients undergoing pacemaker or defibrillator lead extraction, or who require pericardial access for epicardial ablation or left atrial ablation ligation, additional preparation may be required on a case-by-case basis, such as typing and crossmatching of blood products in select patients and immediate availability of thoracic surgical backup.
- In most diagnostic and ablation cases, rhythm active drugs (including β -blockers and calcium-channel blockers) are discontinued five half-lives before the procedure to allow the target arrhythmia to be induced, mapped, and ablated.
- A complete description of the procedure, including the anticipated success rates and possible complications, is best delivered in the outpatient setting before the EP procedure.
- A "time-out" must be performed immediately before the initiation of the procedure when all key personnel are present.
- Health care facilities should insist that clinicians administering or supervising the administration of moderate sedation meet the requirements of the American Society of Anesthesiologists.
- Anticoagulation is necessary for all left heart procedures with heparin (activated clotting time ≥ 250 –350 seconds) or with bivalirudin in patients allergic to heparin.
- It is important to achieve the lowest possible noise signal with all recording systems.
- All physicians and staff are required to be familiar with identifying all potential procedural complications and to understand their role in managing them.
- The decision for patient discharge takes into account procedural detail, patient age and health status, potential for complications (such as blood loss), and the ability of the patient (or caregivers) to evaluate signs of concern.
- The procedure report should include, at minimum, all the following: the primary and secondary operators, the indication for the procedure, names and doses of any medications administered, catheter/pacing/ICD lead model and serial numbers, insertion sites and intracardiac destinations, findings and procedure performed, complications encountered, and fluoroscopic exposure (fluoroscopy time, radiation dose, and the dose-area product) by an Advanced Cardiac Life Support (ACLS)/Pediatric Advanced Life Support (PALS)-certified nurse.

8.1. Patient Preparation

8.1.1. History, Physical Examination, and Laboratory Examination

Preparation for EP procedures requires a careful preprocedural history and physical examination by a physician, NP, or PA to confirm the reason for the procedure that day and identify all comorbidities that could adversely impact procedure outcome. A thorough medication history, including allergies, must be gathered. The patient needs to be evaluated for factors that will impact anesthesia management (adequacy of airway, history of anesthesia experiences, obstructive sleep apnea, and physical indicators for difficult intubation). All adult patients should have recent (usually within 2 weeks) laboratory work, including electrolytes, blood urea nitrogen, creatinine, complete blood count, and, if taking anticoagulants, prothrombin time. All women of childbearing potential, including girls older than 12 years, should have serum or urine pregnancy testing within 2 weeks before the procedure. The need for a preprocedure laboratory exam in healthy children undergoing elective electrophysiological testing is not clear and is not common practice.

8.1.2. Patients Receiving Oral Anticoagulants or Antiplatelet Medications

As many management strategies for arrhythmias require chronic and/or periprocedural anticoagulation, careful evaluation, assessment, and planning are needed. Among the considerations are the agent used, thromboembolic risk, bleeding risk, comorbidities, laboratory values, and availability of reversal agents or blood products such as fresh frozen plasma. Consideration should be given to performing additional preprocedural transesophageal echocardiograms or the use of intracardiac ultrasound to reduce the risk of complications. In patients undergoing pacemaker or defibrillator lead extraction or who require pericardial access for epicardial ablation or left atrial ablation ligation, additional preparations may be required, including typing and cross-matching of blood products, availability of thoracic surgical backup and/or OR, and, in some cases, intraprocedural transesophageal echocardiogram.

8.1.3. Patients Receiving Antiarrhythmic Drugs

Many patients are taking one or more medications to control the heart rate and/or rhythm at the time of an EP procedure. In most cases, rhythm active drugs (including β -blockers and calcium-channel blockers) are discontinued five half-lives before the procedure to allow the target arrhythmia to be induced, mapped, and ablated. In patients undergoing anatomically based ablation, withholding these drugs may not be necessary.

8.1.4. Patient Education and Consent

For most patients, the EP laboratory is an unfamiliar and intimidating environment, one in which an equally unfamiliar procedure is about to be performed. A complete description of the anticipated events is best delivered in the outpatient setting before the procedure day. Education as to

the planned agenda, the other participants (nurses, technologists, EP doctors, and anesthesiologists/anesthesiologists), and the nature of some of the equipment in the laboratory is important to ease the patient's anxiety and aid in their cooperation during the procedure. Many of the technical terms used to describe the procedure are foreign to the patient; the staff must take care to use lay language in their descriptions, to evaluate the patient's ability to learn and preference how to learn, and to assess the patient's comprehension. This role is usually filled by an RN familiar with the procedure. The requisite process for informed consent is detailed in [Section 12](#). Critical components include ensuring patient understanding, full disclosure of the risks and alternatives to the planned procedure, and the opportunity for the patients to ask questions and fully discuss their concerns. The patient education and consent process must be completed before the administration of any sedative or anxiolytic agents. In the case of pediatric patients or adult patients with cognitive impairment, education must be given and consent requested of the patient and the legal guardian.

8.1.5. Time-Out

A time-out must be performed immediately before the initiation of the procedure when all key personnel are present. All members of the team are to cease their activities while one member recites two patient identifiers (i.e., name, date of birth, and medical record number), the type and laterality of the procedure, the name of the operator, and any known allergies. All members of the team must agree on all points before the procedure can commence.⁵⁰

8.2. Procedural Issues—EP Catheter Procedures

8.2.1. Sedative agents, Relaxants, and Anesthesia

The goal of analgesia and anesthesia in the EP laboratory should be to provide a safe, nontraumatic experience for the patient. The administration of anesthesia varies among case types and among institutions, from anxiolysis or moderate procedural sedation by an Advanced Cardiac Life Support (ACLS)/Pediatric Advanced Life Support (PALS)-certified nurse under the supervision of the cardiac electrophysiologist^{51,52} to monitored anesthesia care or general anesthesia administered by an anesthesiologist or CRNA under the supervision of the anesthesiologist. The health care institution must require those administering or supervising moderate sedation who are not anesthesiologists to meet the requirements of the American Society of Anesthesiologists to obtain privileges.⁵³ Credentialing for this privilege must be periodically renewed. If intravenous procedural sedation will be used, the physician must establish an American Society of Anesthesiologists classification and Mallampati score for the patient before the procedure.³⁶ It is necessary to have these assessments done before the procedure so that, if necessary, alternate plans for sedation may be arranged to optimize patient safety and minimize procedural delays. Medications typically employed include etomidate, propofol, ketamine, fentanyl, midazolam, methohexital, and inhalational agents. Individual

states regulate what medications can be administered by nonanesthesiologists. As the provision of sedation is a continuum and the depth of sedation may vary, best practice is that all patients receiving moderate or deep sedation be evaluated by continual observation of qualitative clinical signs, pulse oximetry, noninvasive blood pressure monitoring, heart rate and rhythm, and monitoring for the presence of exhaled carbon dioxide to ensure the adequacy of ventilation unless precluded or invalidated by the nature of the patient, procedure, or equipment.⁵¹ Monitoring equipment should be in working order and have appropriate audible alarms. In pediatric cases, factors to be considered for the choice of sedation or general anesthesia include young age, preexisting medical conditions, presence of CHD, airway issues, physician or family choice, and the length and complexity of the procedure. The 2002 NASPE Position Statement on Pediatric Ablation delineated the types of anesthesia (conscious sedation, moderate sedation, and general anesthesia), and these remain applicable.⁵⁴

Regardless of whether the administration of sedative agents is under the control of the electrophysiologist or another caregiver, the electrophysiologist must have a working knowledge of the effects of the agents used and how they might impact the electrical aspects of the procedure (such as arrhythmia inducibility and effects on blood pressure) or interact with other medications that may be given. Deep sedation or general anesthesia can minimize patient discomfort, can benefit the EP procedure by preventing patient movement, and is necessary during defibrillation threshold testing. An immobile patient facilitates accurate and precise 3D mapping and reduces risk during transseptal puncture, pericardial access, or ablation in close proximity to critical structures. Note that in cases where the assessment of phrenic nerve function is important for a favorable case outcome (such as placement of a coronary vein branch pacing lead or ablation within the right superior pulmonary vein), paralytic dosing should be reduced or eliminated. Improved safety, efficacy, and procedure times have been shown with the use of general anesthesia with certain procedures such as atrial fibrillation ablation.⁵⁵ Using high-frequency ventilation can further minimize respiration-related cardiac movement during ablation.⁵⁶

Although adequate sedation should be administered to ensure patient comfort because certain arrhythmias such as atrial tachycardias and outflow tract VTs can be dependent on adrenergic tone, excessive sedation can result in the inability to induce the clinical arrhythmia. In cases in which an adrenergic-dependent arrhythmia is suspected, sedation must be minimized until the clinical arrhythmia is induced and mapped. Deep sedation is usually administered while performing ablation to prevent patient movement. When assessing the end point in these cases, care must be used to differentiate the effect of sedation from the actual elimination of the arrhythmia.

8.2.2. Sterile Preparation of the Access Site and Vascular Access

Although the risk of infection is extremely low with EP catheter procedures,⁵⁷ appropriate sterile techniques should

be maintained. This includes sterile preparation of all access sites, such as the groin and neck. If there is the potential for pericardial access, the subxiphoid region, and possibly the parasternal and apical regions, should also be prepped and draped. In cases with a higher risk of cardiac tamponade, sterile preparation of the subxiphoid region can be considered at the onset of the procedure.

8.2.3. Diagnostic Catheter Selection

Catheters with a smaller French size and fewer electrodes are more flexible, exert lower axial force, and may carry a lower risk of perforation,⁵⁸ but should perhaps be avoided because of difficulty maintaining stable catheter position. Catheters with more electrodes can facilitate rapid recognition of arrhythmia activation patterns and are particularly beneficial at sites such as the coronary sinus. Smaller electrodes and narrower interelectrode spacing detect a more local activation signal and can provide more precise activation mapping, but may be less maneuverable. Activation confined to a small structure or circuit, such as the His bundle or an accessory pathway, however, may be difficult to localize with narrow electrode spacing. The field of signal detection can be increased either by changing to a catheter with wider electrode spacing or by reconfiguring the electrode pairing. With this wider field of view, anatomical localization is decreased. Some diagnostic catheters are designed with electrodes in a specialized spatial configuration, such as circular/ring, basket, or star-shaped catheters. These catheters can enable rapid deciphering of an activation pattern even with a paucity of arrhythmia. The number of catheters and recording sites should be adequate to achieve the desired end points of the procedure, but not so many that vascular damage or obstruction or intracardiac entanglement could occur.

8.2.4. Anticoagulation

Anticoagulation is necessary for all left heart procedures with heparin or bivalirudin in patients allergic to heparin.^{38,39} Even in patients with therapeutic international normalized ratio on warfarin, heparin must be administered for left heart procedures, though typically in lower doses than in patients not taking warfarin. For right heart procedures, there is no evidence favoring routine use of anticoagulation; in cases where there is concern that the patient is at an increased risk for thromboembolic complications (prolonged procedure, known or discovered patent foramen ovale), some centers administer heparin for anticoagulation.

8.2.5. Selection of Ablation Catheters

Selection of the mode and catheter for catheter ablation is operator dependent. Catheter factors such as torque delivery, axial stiffness, steerability, and introducer diameter affect device selection. Ablation modes, including RF, cooled RF, laser, and cryotherapy all have their strengths and weaknesses. The goal is to achieve a therapeutic ablation by identifying the ablation target, maneuvering to that site, and then destroying enough tissue to prevent arrhythmia

initiation/propagation while minimizing the risk of collateral injury. The use of open-irrigated tip catheter ablation may result in the infusion of 2–3 L of volume during the case, which can precipitate heart failure in susceptible patients.⁵⁹ Multielectrode or “single-shot” ablation systems are being developed for the treatment of complex substrates such as atrial fibrillation. Experience with many of these technologies is limited. A preferred device for these applications may emerge in the future as our experience increases. Selecting the appropriate ablation catheter is a process that involves a correct interpretation of the arrhythmia mechanism, a firm understanding of the advantages and disadvantages of the different catheters and energy sources, and the need for the responsible use of resources.⁶⁰

8.2.6. Optimizing Signal Recording

Bipolar intracardiac recordings are standard in most laboratories because they theoretically detect only near-field signals, unlike unipolar recordings that incorporate both near and far-field components.^{61,62} Far-field signals can still be detected in bipolar recordings but are typically a lower amplitude and frequency. Unipolar recordings can be helpful in mapping sites of focal activation, such as ventricular insertion sites of accessory pathways in preexcitation syndromes and idiopathic outflow tract ventricular arrhythmias, in which deep sharp QS configurations signify a site from which activation emanates (i.e., site of the earliest ventricular activation). The unipolar signal can help clarify the content of the bipolar electrogram (near vs. far-field), the timing of actual local depolarization (intrinsic deflection of the unipolar signal), and the relative proximity of the tip vs. the ring electrode to the ablation target.

The accurate interpretation of potential ablation target sites involves correctly differentiating local from distant activation as well as from electrical noise. Noise troubleshooting is a complex issue and involves many variables. It is necessary to be familiar with the basics of signal acquisition provided in [Appendix 1](#) to correct noise issues. An inadequate signal-to-noise ratio will result in physiological signals being obscured by ambient noise with loss of critical information. At the onset of the procedure, steps should be taken to ensure that the signal quality is optimized for successful mapping. This should include the following: (1) choosing the appropriate electrode spacing, (2) setting the high-pass filter high enough to exclude low-frequency artifacts, such as respiratory drift, (3) setting the low-pass filter low enough to exclude high-frequency noise artifacts, (4) turning on the notch filter that excludes the 50–60-Hz bandwidth typical of electrical interference, and (5) gaining the signal appropriately to visualize low-amplitude signals of interest while minimizing the magnification of noise artifacts. It should be noted that using the notch filter on bipolar intracardiac signals can introduce ringing to sharp simple signals, making them appear fractionated. This is a particular concern when targeting fractionated potentials in cases of VT and atrial fibrillation. If the laboratory and equipment are

properly grounded and the electricity in the laboratory is conditioned, there should be no 50–60 Hz noise on the intracardiac signals. Lower gain recording should be employed if the electrogram signals exceed the recording range of the amplifier. Efforts should be made, working with the facility’s biomedical engineering personnel, to achieve the lowest noise signals possible. Steps toward this goal include appropriate equipment grounding and shielding of cables, scheduled maintenance of connecting cables with replacement if contact plugs lose continuity, maintaining the shortest distance traveled by all electrical cables, ensuring that cables are off the floor and removed from potential hazards such as wheeled carts and cleaning solutions, and maintaining separation between high-voltage lines, such as power cables, and low-voltage lines used for transmitting the patient’s electrical signals.

8.3. Acute EP Catheter Procedural Complications

Dealing with complications in the EP laboratory has several components: avoidance, recognition, and response. To the extent possible, complications should be avoided by adhering to standard techniques and practices. When a complication occurs, the outcome for the patient hinges on how quickly a problem is recognized and appropriately evaluated as well as how quickly and appropriately the response to the incident rectifies the situation. Even the most careful and skilled operator will have occasional unavoidable complications ([Table 3](#))^{63–68}.

8.4. Procedural Issues—CIED Implantation

8.4.1. The OR Environment

One of the most important risks in device implantation procedures is infection. The device implantation laboratory should be regarded as an OR, with the same attention to sterile technique. Hats, masks, and shoe covers should be worn in the procedure room when the sterile field is exposed. Efforts should be made to restrict traffic in and out of the procedure rooms and minimize the number of personnel in the room. Studies have demonstrated that microbial counts increase significantly in unoccupied ORs when the door is left open to the hallway.⁶⁹ After explanation of a device from an infected pocket, the room should undergo cleaning according to standard procedures employed in the OR for contaminated cases.

8.4.2. Antibiotic Prophylaxis

The use of preoperative antibiotics has been conclusively proven to reduce CIED infection.⁷⁰ Administration of an antibiotic, usually a first-generation cephalosporin, 1 hour before implantation is required. In light of the prevalence of the colonization with methicillin-resistant strains of *Staphylococcus*, some operators choose vancomycin in patients at higher risk of infection, although data are lacking to support this practice. Vancomycin is a suitable choice for patients with penicillin allergies. If vancomycin is selected, it should be administered within 2 hours of the procedure.⁷¹

Table 3 Procedural Complications

Complication	Prevention	Diagnosis	Treatment
EP catheter procedural complications			
Pericardial effusion/ tamponade	Avoid excess catheter force	Fluoroscopy of cardiac border, ⁶³ 2D echocardiography	Reversal of anticoagulation, urgent pericardiocentesis
AV nodal block	Monitor for accelerated junctional rhythm, VA block, AV block during overdrive atrial pacing	ECG	Pacemaker
Phrenic nerve palsy	Phrenic nerve mapping, phrenic nerve pacing during RSPV, SVC, and LAA ablation ^{64–66}	Fluoroscopy, chest radiography	Conservative therapy
Stroke	Anticoagulation (ACT > 300 or 350 s in the LA), avoid char formation	Neurological exam, MRI scan (DWI and FLAIR imaging)	Conservative therapy, Merci thrombectomy
Coronary artery injury	Avoid excess power delivery in the CS, coronary angiography before epicardial ablation, coronary ostia visualization by angiography and ICE before ablation in the aortic root	ECG	Percutaneous intervention
Access site complications (hematoma, AV fistula, pseudoaneurysm)	Site selection, excellent technique, vascular ultrasound to guide puncture, ⁶⁷ micropuncture	Physical exam, ultrasound	Manual pressure, bed rest
Radiation burn	Minimize radiation exposure	Physical exam (presentation typically 2–8 wk postprocedure, but can be > 40 wk)	Avoid repeat exposure
CIED implant procedural complications			
Pneumothorax	Extrathoracic vascular access (axillary or cephalic vein)	Chest radiography	100% oxygen rebreather, chest tube
Lead dislodgement	Test lead for acute fixation (“tug test”)	ECG, device interrogation, chest radiography	Reoperation and repositioning
Pericardial effusion/ tamponade	Avoid excess forward pressure during lead placement	Fluoroscopy of the cardiac border, ⁶³ 2D echocardiography	Urgent pericardiocentesis
Pocket hematoma	Avoid heparin and clopidogrel	Exam	Conservative therapy, pressure wrap, reoperation for pocket evacuation
Infection	Preoperative antibiotics, prevent hematoma, ⁶⁷ score or excise chronic pocket fibrosis	Exam, wound culture, blood culture	Antibiotics, extraction of the entire system (unless superficial)
Air embolism	Use introducer sheaths with hemostatic valves	Fluoroscopy	100% oxygen rebreather
Postprocedural complications			
Hematoma	Avoid heparin and clopidogrel	Exam	Conservative therapy
Infection	Good wound care	Exam, wound culture, blood culture	Antibiotics, extraction of entire system (unless superficial)
Late pericardial effusion/ tamponade	None	2D echocardiography	Pericardiocentesis
Phrenic nerve palsy	Phrenic nerve mapping, phrenic nerve pacing during RSPV, SVC, and LAA ablation ^{64–66}	Loss of diaphragmatic motion on fluoroscopy, elevated hemidiaphragm	Conservative therapy
Stroke	Postprocedure anticoagulation ⁶⁸	Neurological exam, MRI scan (DWI and FLAIR imaging)	Conservative therapy, consider Merci thrombectomy
Myocardial infarction	Appropriate anticoagulation	ECG, biomarkers	Medical therapy, percutaneous intervention
Atrial-esophageal fistula	Limit power, time, temperature, pressure during posterior wall ablation, monitor esophageal temperature	Fever, malaise, leukocytosis, systemic embolism, CT or MRI findings	Surgery
New arrhythmias	Avoid creation of gaps in linear ablation	ECG, ambulatory monitor	Antiarrhythmic drugs, repeat catheter ablation

Table 3 (continued)

Complication	Prevention	Diagnosis	Treatment
Radiation burn	Minimize radiation exposure	Physical exam (presentation typically 2–8 wk postprocedure, but can be > 40 wk)	Avoid repeat exposure

2D = two-dimensional; ACT = activated clotting time; AV = atrioventricular; CS = coronary sinus; CT = computed tomography; DWI = diffusion weighted imaging; ECG = electrocardiogram; EP = electrophysiology; FLAIR = fluid-attenuated inversion recovery; ICE = intracardiac echocardiography; LA = left atrium; LAA = left atrial appendage; MRI = magnetic resonance imaging; RSPV = right superior pulmonary vein; SVC = superior vena cava; VA = ventricular atrial.

8.4.3. Sterile Technique

The instruments and components used in the device implant laboratory must be opened in a clean air environment. By doing so, bacterial contamination of these instruments and components will be kept to a minimum. All personnel in the room must wear a cap and mask at all times, and all who are in contact with the sterile field must perform a complete surgical scrub and must be gowned and gloved.

8.4.4. Sterile Preparation of the Surgical Site

The operative site(s) should be prepared with an antiseptic agent. Although these agents eliminate the immediate bacterial count on the skin surface at the operative site, hair follicles may prevent complete sterilization of the skin. Hair clipping close to the skin in the prep room, rather than shaving, is recommended because bacteria on the skin surface begin to recolonize within 30 minutes in the presence of hair follicles despite complete sterilization.⁷² Some centers instruct patients to use preprocedural home cleansing kits. Site preparation with alcohol-based solutions should be allowed to dry completely before draping. The combination of evaporating alcohol, supplemental oxygen, and electrocautery poses a significant fire risk in the surgical field.

8.4.5. Concomitant Groin Access During Implant Procedures

In some cases, additional femoral venous access for the placement of a temporary pacing catheter may be warranted (e.g., lead extraction and pacemaker-dependent patients with an inadequate escape rhythm who are undergoing generator change).⁸ Large-bore venous sheaths are useful for rapid volume resuscitation in the event of vascular tears during lead extraction, and arterial access facilitates beat-to-beat monitoring of blood pressure.

8.5. Acute CIED Implant Procedural Complications (Table 4)

Complications associated with acute CIED implantation are often technique related. Attention to detail will minimize the risk of difficulties related to the implant procedure.

8.6. Postprocedural Issues

8.6.1. Vascular Hemostasis

Venous sheaths may be removed at the end of the procedure if no anticoagulant has been administered, with pressure held for 10–20 minutes. If heparin has been administered, waiting

until the ACT is more than 175 seconds (<250 seconds if the patient is receiving therapeutic warfarin) before sheaths are removed decreases the likelihood of bleeding and hematoma formation. Reversal of heparin effect with

Table 4 Definitions and Terminology Used in Clinical Fluoroscopy

Roentgen (R) is the unit of radiation exposure in air. The total charge produced in air per unit mass by ionizing radiation is easily measurable with survey instruments.
Gray (Gy) is the International System of Units (SI) of absorbed radiation dose of ionizing radiation, which has replaced the term <i>radiation absorbed dose</i> (in rad). One gray is the absorption of 1 J of ionizing radiation by 1 kg of matter (equivalent to 100 rad), and it assesses the potential biological risk to that tissue. The U. S. unit for absorbed dose is rad. 1 Gy = 100 rad.
Equivalent dose Sievert (Sv) is a measure of equivalent dose, and is also an SI unit. It takes into account the different probability of effects that occur when the same amount of absorbed dose is delivered by different types of radiation (protons vs. X-rays). It is equal to the absorbed dose in Gy multiplied by the radiation weighting factor, W_R , and other modifying factors. The W_R is 1 for X-rays. The equivalent dose can be used to assess radiation risk if the person's whole body is uniformly irradiated. For partial body exposure, such as cardiac electrophysiology, additional correction is necessary to assess the radiation risk.
Effective dose is used to assess the risk when only a part of the body absorbs energy from radiation. Since some organs in the body are more sensitive to radiation effects than others, the equivalent dose is multiplied by the appropriate tissue weighting factors. This terminology is used to assess the risk of radiation-induced cancer and hereditary effects. For example, the effective dose for a typical chest X-ray radiograph is 0.0001 Sv (0.1 mSv). The U.S. unit for sievert (Sv) is rem. 1 Sv = 100 rem.
As low as reasonably achievable (ALARA) standard is a system for limiting the amount of radiation a person receives. Radiation exposure should be justified on the basis of the assumption that there is no threshold below which ionizing radiation is free from harmful biological effects and that shielding from radiation exposure is needed, no matter how low the dose.
Kerma is an acronym for kinetic energy released in the material. Kerma is measured in Gy.
Kerma-area product (P_{KA}) is the integral of air kerma (absorbed dose to air) across the entire X-ray beam emitted from the X-ray tube. P_{KA} is a surrogate measurement for the entire amount of energy delivered to the patient by the beam. P_{KA} is measured in $Gy \cdot cm^2$. Another term for this is the dose-area product (in $Gy \cdot cm^2$).
Reference air kerma ($K_{a,r}$) is the kerma-area product at a specific point in space relative to the fluoroscopic gantry (the interventional reference point) during a procedure. It is measured in Gy.
Peak skin dose is the highest dose of radiation exposure on any portion of a patient's skin during a procedure.

protamine is employed in many laboratories to more rapidly reverse heparin effect and allow almost immediate sheath removal, although one must be prepared to treat uncommon but sometimes severe protamine reactions.⁶⁴ Vascular closure devices are uncommonly used in EP,^{64,65} but are an appropriate choice for arterial closure. After atrial fibrillation ablation, the reestablishment of therapeutic anticoagulation soon after sheath removal is desirable to lessen periprocedural stroke risk but there is no consensus on the optimal regimen or timing.

8.6.2. Postanesthesia Recovery

When mild anesthesia is used, vital signs and oxygen saturation should be monitored continuously until the patient is conscious and communicative. Access sites, cardiac rhythm, and neurological state should be assessed every 15 minutes during the first hour and then periodically thereafter. Late complications, such as access site hematomas and hemodynamically significant pericardial effusion, can develop after the patient leaves the postprocedural recovery area. If a patient received midazolam during the procedure and a dose of its antidote (Romazicon/flumazenil) was administered, the patient must be monitored for a rebound effect of midazolam. If general anesthesia was used, patients usually recover in a postanesthesia care unit.

8.6.3. Postprocedural Complications

Procedural complications that can arise after the patient leaves the laboratory area (or even after hospital discharge) are listed in [Table 4](#). A process for tracking postprocedural complications should be in place as part of the laboratory's QA process (see [Section 9](#)).

8.6.4. Medication

Postprocedure anticoagulation is recommended in patients who are at high risk of stroke on the basis of evaluation tools such as CHADS₂ or CHA₂DS₂-VASc scores. In many laboratories, chronic warfarin therapy is not interrupted

during either device implantation or ablation procedures in patients who are taking it for stroke prevention in the setting of atrial fibrillation or mechanical heart valves; the procedure is safe, with the international normalized ratio ranging from 2.0 to 3.5.^{35,64}

In patients with insulin-dependent diabetes, the morning insulin dose is typically halved on the day of the procedure and glucose is periodically monitored during the procedure and the patient is treated accordingly.

8.7. Hospital Discharge

The setting for EP procedures may be outpatient, 23-hour observation, or inpatient. The decision for discharge takes into account procedural detail, patient age, and health status, the potential for complications (such as blood loss), and the ability of the patient (or caregivers) to evaluate signs of concern.⁶⁷ This is a medical decision and should be determined irrespective of reimbursement issues.

8.8. Reporting Procedural Results

The procedure report should include, at a minimum, the following: the primary and secondary operators; the indication for the procedure; names and doses of any medications administered; intake, output, and estimated blood loss; catheter/pacing/ICD lead model numbers, serial numbers, insertion sites, and intracardiac destinations; findings and procedure performed; complications encountered; and fluoroscopic exposure (minutes; mGy; dose-area product). Patients who receive excessive radiation exposure during a procedure (typically >3000 mGy, but requirements vary by state) must be notified and followed up for evidence of skin damage. Ideally, this information is stored in a database for QA purposes. Recordings made during the procedure (electrograms and fluoroscopic and mapping system images) should be archived on digital media (ideally on a network, or alternatively on a CD or DVD) for future reference, if needed.⁶⁴

9. Pediatric and Adult Congenital Heart Disease

Pediatric and Adult Congenital Heart Disease Recommendations

- Pediatric EP procedures on small and young children should be performed in centers where there is pediatric surgical backup.
- Procedures on adult patients with CHD can be performed in pediatric or adult facilities by physicians who have expertise in the area of CHD and the potential arrhythmia substrates of patients with CHD.
- There are special considerations for performing pediatric EP procedures, including unusual arrhythmia mechanisms, small patient size, and the effect on future patient growth.

9.1. Patient Factors Different From Adults

Issues that pertain to EP laboratory standards and practice for pediatric EP and patients with pediatric and adult CHD with rhythm abnormalities differ from those pertaining to adults

and are not confined to issues of patient and cardiac size compared with the adult patient. The decision-making process for interventions has implications for patient quality of life and development. Success, failure, and procedural factors related to intervention therefore span many decades. A significant

factor in treating cases involving young patients in the EP laboratory is the need for age-appropriate supportive care.

9.1.1. Arrhythmia Substrate, Patient Size, and Future Patient Growth

Arrhythmia mechanisms in young patients vary by age⁷² and influence decision making. Patient size can dictate the use of and expertise with smaller ablation catheter sizes or the use of esophageal pacing if vascular access is limited, such as is the case in neonates. Knowledge of ablation lesion formation and potential expansion in an immature myocardium is critical to the care of pediatric patients.⁷³ Children and young adults will experience decades of device-related issues compared with the typical adult patient. These issues should affect decision making in terms of timing and location of cardiac EP devices, accounting for growth, potential need for multiple extractions and replacements, and issues of venous occlusion. For patients with CHD, these factors are complex and affect the decision to intervene. Surgical interventions for all forms of CHD have resulted in improved survival rates,⁷² and the details of these surgical interventions are critical in the analysis of rhythm substrates in the EP laboratory. More complex pediatric CHD survivors comprise an increasing percentage of the adult CHD population.⁷² It is recommended that procedures in pediatrics and patients with CHD be performed by (1) pediatric cardiologists, (2) a collaboration of adult and pediatric cardiologists, or (3) an adult cardiologist with established interest and expertise in adult CHD.

9.2. Indications for EP Procedures in Pediatric Patients and Patients With CHD

The indications for catheter ablation in the pediatric population derived from an understanding of the natural history of arrhythmias in young patients, likely rates of procedural success and complications, and the risk of recurrence and have been reviewed in prior publications.^{54,74} The guidelines for the assessment of the asymptomatic young patient with Wolff-Parkinson-White syndrome are published as a joint PACES/HRS statement.⁷⁵ In the pediatric population, the presence of CHD affects the expected results of ablation and recommendations for intervention. The guidelines for the implantation of cardiac rhythm devices in young patients and patients with CHD were last updated in 2008.⁷⁶ Epicardial pacing is used for those in whom transvenous pacing is contraindicated, such as prosthetic tricuspid valves, right-to-left intracardiac shunts, and small patient size, or for those undergoing concomitant heart surgery. The majority of ICDs are implanted via the transvenous route, but this may not be possible in some individuals because of anatomical constraints. Because ICD leads are larger and prone to fibrosis, patient size limitations for transvenous systems are considerable. Although established in adults, the indications for cardiac resynchronization therapy in children are less certain and are based on retrospective reviews, rather than randomized trials.^{77,78}

9.3. Patient Safety Concerns

Because younger patients may have a longer life span after EP procedures than do adults, the lifetime risks of malignancy and birth defects (stochastic risks) are higher. Adult patients with CHD incur increased radiation exposure resulting from the electroanatomic complexity of cases and the need for multiple procedures. Strategies for radiation dose reduction as detailed in Section 11 should be aggressively implemented. The most significant complications in small children include pericardial effusion, pneumothorax, atrioventricular block, and death.^{79,80} Animal and clinical studies have shown the potential expansion of scar tissue with maturation⁷⁰ and the risk of late coronary artery injury⁷⁹ potentially related to ablation location. The risk of atrioventricular block is increased by small patient size and septal pathways, presumably because of the smaller anatomical dimensions of structures. Smaller tip catheters, lowered RF energy, shorter lesion duration, and the use of apnea and pacing techniques may diminish risk.⁸¹ Cryoablation is perceived as being safer, but may have a higher recurrence rate compared with RF lesions.⁸² It is recommended that EP laboratories conducting procedures on pediatric patients have cryoablation capability.

9.4. Procedural Issues

9.4.1. Inpatient vs. Outpatient Setting

The procedure setting for invasive EP studies and ablation for pediatric and congenital EP patients may be outpatient or inpatient. The decision for discharge takes into account procedural detail, patient size, potential for complications, and the ability of the parents to evaluate signs of concern. The protocol for EP device placement or revision is mostly less than 1 day of observation, but generator changes in older patients may not require more than 6 hours. Young patients with new devices are monitored overnight to administer peri-procedural antibiotics, evaluate for pneumothorax or hemothorax, evaluate the device parameters, check lead location, and manage pain.

9.4.2. Sedation, Anesthesia, and Medications

The goal of sedation in the pediatric and congenital EP laboratory should be to provide a safe, nontraumatic experience for the patient by considering young age, preexisting conditions, presence of CHD, airway issues, family choice, and complexity of the procedure. The 2002 NASPE Position Statement on Pediatric Ablation delineated the types of anesthesia (e.g., conscious sedation, moderate sedation, and general anesthesia), and these remain applicable.⁵⁴ Personnel responsible for sedation, anesthesia, and administration of medications must be experienced with pediatric and congenital EP patients, and PALS and ACLS certification should be maintained. All physicians performing EP procedures should be knowledgeable regarding sedation, monitoring, and airway management. Allied health professionals (e.g., nurses, APNs, and PAs) can be involved with sedation of a patient, if directly supervised by a physician.

9.4.3. Facilities

The room and equipment standards for pediatric EP procedures are similar to those for adult EP procedures (see Sections 4 and 5) but must have a cardiac defibrillator specifically for use with children, a code cart meeting pediatric needs, and age-appropriate anesthesia equipment. Pediatric and congenital EP patients may require a combined procedure of EP and hemodynamic catheterization, including angiography and possible intervention. Thus, it is desirable that a pediatric/CHD EP laboratory meet the same standards as a pediatric catheterization laboratory.

9.5. Lab Staffing

General recommendations for EP laboratory staffing are detailed in Section 6 and Table 2. Pediatric and congenital EP guidelines recommend that the facility and laboratory staff should be appropriate for the patient population and pediatric and CHD interventional and surgical experts be urgently available during laboratory procedures.⁴² All members of the team should be trained in PALS (when treating a child/infant) and ACLS (if treating an adult).

9.5.1. Physicians

Training and board certification pathways employed by physicians who perform EP procedures on pediatric and congenital EP patients include the pediatrics and internal medicine pathways (see Sections 6 and 7).

9.5.2. EP Laboratory Personnel

Recommended staffing for pediatric cases is detailed in Table 3. While laboratory staff roles are similar to those outlined in Section 6 for pediatric cases, these staff should have expertise in performing cardiac procedures in pediatric and congenital EP patients.

9.6. Emergency Supportive Care and Surgical/Intensive Care Unit Backup

Pediatric EP procedures should be performed (earlier than the teenage years) in centers where there is pediatric cardiovascular surgical availability. For procedures performed on patients in their teenage years or procedures on adult patients with CHD that are performed in adult or mixed pediatric and adult institutions, a CV surgical plan should be formalized to accommodate on-site emergencies (notably, cardiac perforation) and a rapid transfer made to a pediatric cardiovascular center should the anatomy of the patient require this expertise.

9.7. Postprocedural Care

The postprocedural care can be performed in a separate periprocedural area, the general cardiology floor, or the intensive care unit. Continuous telemetry should be available for the evaluation of heart rhythm. The environment for postprocedural care should be appropriate for patient age and development. The nursing and physician staff should be experienced in the care of pediatric and congenital EP patients.

10. Quality

Quality Recommendations

- A process for tracking postprocedural complications should be in place as part of the laboratory's QA process.
- An essential component of a successful EP laboratory is to have an internal QA/quality improvement (QI) process in place, in addition to public reporting requirements.
- Components of the QA/QI process should include national requirements for tracking (e.g., device implants), minimum acceptable complication rates (e.g., infections), and compliance with national registries, including the NCDR ICD Registry.
- It is the responsibility of each institution to ensure that staff credentialing, maintenance of certification, and necessary continuing medical education requirements are met.
- Procedure outcomes, including success rates and complications, should be documented and recorded. Data acquired from the EP laboratory QA process should be used to benchmark the complication rates and outcomes of both individual practitioners and the overall EP laboratory.
- Physicians should participate in regularly scheduled QI and/or peer review meetings to maintain privileges and evaluate procedural appropriateness.
- A quarterly EP laboratory morbidity and mortality conference should be mandatory, with attendance documented.
- A QA process for the equipment should be established that provides a mechanism to demonstrate optimal function and operation of the equipment and that offers staff training in equipment maintenance, setup, and operation.
- Given the often poorly defined relationship between case volumes and outcomes, a more appropriate measure is to ensure that all major complications are reviewed by the QA committee and handled as described in the previous section.

10.1. The QA/QI Process

High-quality, consistent care delivery in a busy cardiac EP laboratory requires standard protocols for procedures, communication channels, and documentation. An essential component of a successful EP laboratory is to have an

internal QA/QI process in place, in addition to public reporting requirements. This requires a commitment from facility administrators to provide adequate staffing, including a committee chair, staff coordinator, and funding for collecting and managing data. The goal of the program should be to motivate and encourage physicians and staff to

participate and to take initiative in the QA/QI process and overall success of the laboratory. It is acknowledged that there is little published data on the QA/QI process in the EP laboratory and that expert consensus is the primary basis for our recommendations. Further research and development of quality metrics specific to the practice of cardiac EP is ongoing.

To begin the QA/QI process, its components should be identified. These components include national requirements for tracking (e.g., device implants), minimum acceptable complication rates (e.g., infections), and compliance with national registries, including the NCDR ICD Registry. A QA/QI program must ensure that key data are collected prospectively and systematically. When the QA/QI team is identifying potential quality metrics, either strong scientific evidence or expert consensus must support the metric. The metric must measure areas important to patient care, and it is best if it covers an aspect of practice where there is a gap in patient care. The data must be available in a usable format for future analysis. These data allow the laboratory to benchmark its performance and provides a reference by which appropriate changes can be made.

Provider qualifications are typically well established by national guidelines and certification bodies. It is the responsibility of each institution to ensure staff credentialing, maintenance of certification, and necessary CME requirements are met (see [Section 7](#)). Practitioners should be expected to adhere to published practice guidelines unless the reason for deviation is documented. Clinical situations not directly addressed by the guidelines inevitably arise and require judgment and skill to address. Periodic peer review of cases that fall outside the guidelines is recommended to ensure appropriate delivery of care. The guidelines evolve and, by definition, require a consensus of data before they can be written and revised. The writing group recognizes and encourages the development of new clinical pathways and tools. This development is best achieved through research protocols that adequately capture patient demographic characteristics, procedure characteristics, and outcomes. The research consent process ensures that patients are aware that the treatment being offered is beyond the current recommendations of the practice guidelines.

Procedure outcomes, including success rates and complications (and ideally including 30-day outcomes), should be documented and recorded. The writing group recognizes that success for some procedures requires clinical follow-up (particularly atrial fibrillation and VT ablation procedures). In these instances, an acute end point for the procedure should be specified (e.g., pulmonary vein isolation, noninducibility for VT, or creation of a planned RF ablation lesion set based on the results of an endocardial voltage scar map) and documentation should indicate if the end point was achieved. An assessment of freedom from arrhythmia recurrence after 1 year of follow-up should be performed. Risk-adjusted models are not well developed by which the relative frequency of complications and successful outcomes among different patient populations can be interpreted and physician results compared. Therefore, the interpretation of success rates and complication rates

requires judgment by peers. Physicians should participate in regularly scheduled QI and/or peer review meetings to maintain privileges and evaluate procedural appropriateness. A quarterly EP laboratory morbidity and mortality conference (stand-alone or as a component of another conference) should be mandatory, with attendance documented.

The modern cardiac EP laboratory depends on many complex hemodynamic and physiological recording systems, advanced imaging systems, advanced mapping systems, and multiple ablation systems. Rigorous processes must be established to ensure that (1) a QA process for equipment is established; (2) equipment is tested and demonstrated to be functioning appropriately, both on a routine basis and immediately before a case in which the specific item will be used; verification of equipment function should be included in the time-out procedure; (3) EP laboratory staff are appropriately trained in the maintenance, setup, and operation of the equipment; and/or (4) representatives from the vendor are available, qualified, and cleared by administration and occupational health to participate in the operation of the equipment before, during, and after the procedures. Competencies in clinical skills, ACLS, PALS (when appropriate), sterile technique, radiation safety, and fire safety should be assessed on a regular basis.

The EP laboratory requires processes be in place to ensure proper communication within the EP laboratory and with other hospital services. Within the laboratory, protocols for emergency situations (such as tamponade or ventricular fibrillation refractory to defibrillation) can make the difference between an organized, streamlined, successful resuscitation effort and a chaotic effort during which leadership is absent, team members duplicate some activities and neglect others, and ultimately a tragic but potentially avoidable outcome occurs. Beyond the boundaries of the EP laboratory, communication between the EP team and other health care professionals is essential, particularly during handoffs from one care team to another and at the time of patient discharge. It is the role of the QA/QI committee to oversee that excellent communication processes are developed, maintained, and adhered to by the staff.

10.2. Clinical Outcomes and Complications

Data acquired from the EP laboratory QA process should be used to benchmark the complication rates and outcomes of both individual practitioners and the overall EP laboratory. For practitioners with complication rates above the benchmark, an objective unbiased peer review of the relevant cases is critical to determining whether a deviation in the standard of care occurred. Because event rates are low and risk-adjusted models are not well developed for the EP laboratory, peer review is particularly important. Practitioners should not be penalized for accepting higher risk and/or more challenging cases. However, if reckless behavior or inadequate skills or knowledge is deemed to be present and a deviation in care occurs, verbal and written communication by the chair of QA is imperative. This communication should include a clear plan for corrective action and documentation of potential future actions if corrective action is not successful.

10.3. Case Volumes

A link between operator case volume, skills, and outcomes has been documented in some but not all areas of cardiac EP, yet controversy and conflicting data remain. Specific case volumes for training are outlined by the ABIM²⁹ (Table 3), and for clinical competency they are available in the HRS clinical competency statements.^{8,17,33,38,39,42} Given the often poorly defined relationship between case volumes and outcomes, a more appropriate measure is to ensure that all major complications (see Table 3) are reviewed by the QA committee and handled as described in the previous section.

10.4. Database

A prospective plan to acquire data in an accessible and functional database is an essential building block for any QA/QI process. Without objective, reliable data to measure outcomes, no meaningful effort at QI can be undertaken. Minimum data that should be recorded in a searchable aggregate form include patient demographic characteristics, relevant history of present illness, medications, CIED product information data, and data on outcome and complications from any invasive procedures. Patients with CIED should be identifiable by the device that has been implanted to permit rapid identification of patients who may have received defective hardware in the event of a recall or other notification from the manufacturer or FDA.

11. Occupational Health Concerns

Occupational Health Concern Recommendations

- Fluoroscopy equipment should report three parameters: fluoroscopy time; radiation dose (air kerma, in Gy), a measure of deterministic injury potential; and the dose-area product (in $\text{cGy} \cdot \text{cm}^2$), a measure of stochastic injury potential. A minimum of 0.5-mm lead-equivalent protective apron, thyroid shield, and eye protection should be used by EP laboratory personnel.
- All lead should be tested at 6-month intervals to check for cracks or leaks.
- Risks of acquisition of infectious diseases by health care workers can be minimized by adherence to current infection control guidelines.

11.1. Radiation Safety

The field of cardiac EP is greatly dependent on fluoroscopic imaging for the placement of catheters and device leads into the heart. This results in significant radiation exposure to the patient, the operator, and the laboratory staff. While this exposure cannot be eliminated in most cases, attention to fluoroscopic technique can minimize radiation dose. Competencies in radiation safety should be completed yearly by the EP laboratory staff. Some states mandate fluoroscopy licenses be obtained by all personnel using fluoroscopy and renewed periodically, including physicians and radiation technologists.

11.1.1. Terms for Understanding Radiation Exposure in the Cardiac EP Laboratory

Nonionizing radiation, such as microwave or infrared radiation, can cause heating but not molecular damage to cells. Ionizing radiation, such as β , γ , and X radiation, strips

electrons from atoms and causes molecular injury to DNA. Ionizing radiation has great potential for damage to tissue, including burns and malignancy. Understanding the basic definitions and terminology used to describe ionizing radiation is helpful when trying to understand the potential effects on the human body (see Table 4).⁸⁶

10.5. Pediatric and Adult Congenital Heart Disease

The field of medical informatics is on the verge of exponential growth. Registries such as the ACC/NCDR ICD Registry have identified specific data fields that should be captured for participation in the registry and compliance with payer mandates.⁸³ Beyond these basic requirements, recommendations for more detailed database fields are included in clinical guidance documents for the management of patients with atrial fibrillation and for the management of patients with VT.^{38,39} These standard data elements provide an opportunity for EP laboratories invested in research to aggregate and/or compare their data with that of other laboratories working in the same field.

To date, QA efforts in pediatric and congenital EP have centered on the creation of large EP procedural registries.^{84,85} In late 2010, a PACES taskforce began to develop and implement a self-sustaining multicenter QI registry known as MAP-IT. Presently, the MAP-IT taskforce is creating a registry of patient-centered late outcome measures of catheter ablation procedures. For the first time, an empirical and data-derived method of risk/complexity adjustment for pediatric and CHD EP procedures, known as the COMPASS score, has been developed. The future of QA efforts for procedure-based subspecialties will require the benchmarking and reporting of risk-adjusted “patient-centered” outcome measures. Widespread implementation of the MAP-IT initiative within PACES should satisfy this need.

11.1.2. *Biological Risks From Radiation Exposure*

Radiation effects are described by their deterministic and stochastic effects.⁸⁷ Deterministic effects are harmful tissue reactions that are determined by an absorbed threshold dose. Radiation-induced skin burns are an example of deterministic effects.⁸⁸ Stochastic effects include malignancy and heritable effects and are not determined directly by the dose, but a higher dose increases the probability of an adverse outcome. Human tissue radiosensitivity varies directly with

the rate of cellular proliferation and number of future divisions and indirectly with the degree of morphological and functional differentiation. The most sensitive tissues include the bone marrow, spermatocytes, and intestinal crypt cells.⁸⁷ Local skin injury is the most commonly encountered deterministic effect in cardiovascular medicine, with changes noted at doses above 2 Gy. Findings often do not appear until weeks after exposure.

Radiation exposure increases lifetime risk of fatal malignancy. The as low as reasonably achievable standard was derived from the Biological Effects of Ionizing Radiation VII Report.⁸⁹ This report makes the assumption that cancer risk increases proportionally with radiation exposure and that there is no radiation dose that is without risk. All personnel working in the laboratory must be aware of the as low as reasonably achievable standard. A skin threshold dose of 2 Sv should not be exceeded. Because the prevalence of fatal malignancies continues to increase over time after radiation exposure, children and young adults are more susceptible to these complications in their lifetimes. Adult patients with CHD incur increased radiation exposure resulting from the electroanatomic complexity of cases and the need for multiple procedures.

11.1.3. Measuring Radiation Exposure

A normalized X-ray dose at a specific kilovolt peak 1 m from the source, total fluoroscopic time, backscatter correction factor, and source-to-skin distance can be used to estimate radiation exposure.⁹⁰ A direct measurement of radiation doses at multiple sites can be performed with lithium fluoride thermoluminescent dosimeter sensors and optically stimulated luminescence. The highest exposure to patients has been observed with a median skin entrance dose of 7.26 rem (range 0.31-135.7 rem) at the ninth vertebral body. This dose is predicted to be associated with a lifetime excess risk of malignancy to the female breast, active bone marrow, and lung of greater than 700 cases per million undergoing routine catheter ablation. Operator exposure was highest at the left hand, waist, and left maxilla.⁹¹ Fluoroscopy equipment should report three parameters: fluoroscopy time; radiation dose (air kerma, in Gy), a measure of deterministic injury potential; and the dose-area product (in $\text{cGy} \cdot \text{cm}^2$), a measure of stochastic injury potential. Radiation exposure is a superior metric to fluoroscopy time; reliance on fluoroscopy time is discouraged. The United States Nuclear Regulatory Commission annual dose limits for radiation are 0.50 Sv for skin, arms, and legs; 0.15 Sv for eyes; and 0.05 Sv for the whole body. The fluoroscopy dose for each case should be recorded in the medical record and accessible to patients.

11.1.4. Minimizing Radiation Exposure to Patients

The predominant strategy for minimizing radiation exposure to patients is to minimize the radiation dose.^{86,92} The most effective approach is to minimize fluoroscopy pedal time. Operators should develop the habit of tapping the fluoroscopy pedal rather than standing on the pedal for a long period of time. If the eyes stray from the fluoroscopy screen, the foot should come off the pedal immediately. Decreasing

the fluoroscopy pulse rate will significantly reduce dose at the cost of temporal resolution of the image. Supplementation of fluoroscopic imaging with nonfluoroscopic electroanatomic guidance systems by using stored fluoroscopy loops rather than cine loops and using pulsed fluoroscopy will reduce the total procedural dose. As the X-ray tube gets closer to the patient, X-rays at the skin entry point increase and the risk of deterministic injury also increases; thus, the operator should position the table at a comfortable height with some distance between the tube and the patient. If the image intensifier is not positioned as close to the patient as possible, the image will be magnified but the radiation dose will be much higher. To magnify the image, use the appropriate magnification mode. Both geometric and electronic magnification increases dose to the patient. Doses may be limited effectively by collimation, limiting the field of view with shutters as much as possible. For example, reducing the diameter of the field of view by 29% will reduce the radiation dose by half. Steeply angulated projections should be avoided, and if used, the C-arm should be repositioned somewhat throughout the procedure to avoid delivering radiation to the identical skin entry site. Depending on which procedure is being performed, local shielding of the patient's thyroid and gonads can be employed.⁹³

Since the stochastic effects of radiation exposure are cumulative, the caregiver should be sensitive to the lifetime exposure of the patient to ionizing radiation. There has been active discussion among regulators on implementing a system for lifetime tracking of radiation exposure to patients, but the tools for this type of system are not available, and therefore it is not presently mandated.⁹⁴ It is important to emphasize that radiation exposure is dependent on the age and condition of the equipment. Thus, aggressive limitation of fluoroscopy pedal time is desirable, but those efforts may be futile if the dose rate is high because of a high frame rate or employment of an old imaging train. It is now an accepted standard that fluoroscopy dose, not only fluoroscopy time, is entered in the permanent medical record for each fluoroscopic procedure. Ideally, the peak skin dose, the reference air kerma, the kerma-area product, and the fluoroscopy time should be recorded for every case.⁹⁵ A review of fluoroscopy use by individual operators should be part of every laboratory's QA process.

11.1.5. Minimizing Occupational Radiation Exposure

The primary approaches used to reduce radiation exposure to the operator and laboratory staff are increasing distance from the source, scatter reduction, and dose limitation. Radiation dissipates in proportion to the square of the distance from the source, and so even a modest effort to move away from the tube will significantly reduce exposure. Radiation scatter occurs as radiation from the generator tube enters the patient and is partially reflected or refracted by body tissues. Scatter from the patient is the main source of radiation exposure to the patient outside the imaging field and to the operator. The operator and laboratory personnel must be protected from exposure to the scatter radiation with shielding. A minimum

of 0.5-mm lead-equivalent protective apron, thyroid shield, and eye protection should be used.

Proper table shielding can dramatically reduce the scatter radiation escaping into the environment. Scattered radiation exits the body at all angles but is greatest on the same side of the patient as the X-ray source because only 1%–5% of radiation completely penetrates the patient's body and exits on the other side.⁹¹ Therefore, proper undertable shielding is paramount. Shield extensions above the table rail and a contoured ceiling-mounted shield in contact with the patient's torso will substantially reduce operator exposure. Since radiation doses decrease with the square of the distance from the source, the operator should perform the procedure as far from the radiation tube as is practical. Barium-impregnated drapes can further reduce radiation scatter in the procedure field.⁹⁶ All recommendations described above for limiting total fluoroscopy dose will also reduce the operator and laboratory staff radiation exposure.

Radiation exposure to a pregnant EP laboratory worker is a special situation and should be resolved on a case-by-case basis. It is recommended that radiation exposure to the pregnant staff member, as measured by a waist dosimeter (under the lead apron), should not exceed 0.05 rem/mo, or 0.5 rem for the entire pregnancy.³⁵ Additional layers of lead can be worn over the abdomen to further protect the fetus.

11.1.6. Quality Management

The FDA regulates fluoroscopy equipment manufacturing and has dose limits for systems with automatic exposure control.⁹⁷ States regulate the safe use and operation of radiation-producing machines, such as fluoroscopic imaging systems. TJC's sentinel event is an unexpected occurrence involving death or serious injury. Prolonged fluoroscopy that exceeds doses of 1500 rad (15 Gy) to the skin is a reportable sentinel event and requires an institutional response. A qualified medical physicist should perform initial acceptance testing and annual testing to ensure optimal image quality and radiation dose. Unfortunately, assuming that fluoroscopic equipment is functioning properly, the most important factor in radiation exposure to patients and staff is operator knowledge and behavior. TJC recommended (but did not mandate) credentialing standards for fluoroscopists,⁹⁸ and the recommended curriculum was endorsed by HRS, American College of Cardiology Foundation, AHA, and the Society for Cardiovascular Angiography and Interventions (SCAI).⁸⁶ The training of EP physicians and staff in radiation physics, radiation biology, and technological developments in X-ray imaging systems and X-ray dose management is highly variable, and physician credentialing and recredentialing has no requirement regarding knowledge of radiation safety. It is therefore incumbent on the hospital leaders to establish high local standards and to track fluoroscopy use and behavior.

11.2. Occupational Health Risks of Wearing Lead

11.2.1. Lead Aprons

Lead-equivalent aprons required for radiation protection of staff are heavy and present a substantial physical burden to

the interventional cardiologist.⁹⁹ Historically, lead aprons were made using 0.5-mm lead-equivalent materials, with weight per unit area of these garments being 7 kg/m².⁹⁸ An increased risk of cervical spondylosis is a known consequence for cardiologists who wear protective garments while standing for long hours performing procedures.⁸⁷ Orthopedic problems and user fatigue associated with the continued use of heavy aprons contributed to the development of lower-weight lead-equivalent materials that are commonly used for protective garments today. Modern nonlead 0.5-mm lead-equivalent protective garments have a weight reduction of 30% or more than do traditional lead aprons.⁹⁸ That modern aprons are lighter might be expected to lessen, but not eliminate, orthopedic discomfort and injury. It is important to emphasize that all lead should be tested at 6-month intervals to check for cracks or leaks.

Along with weight, there are several other physical and ergonomic aspects of radiation protection garments that should be considered. To minimize discomfort, garments must fit correctly and should be tightened around the midsection to shift weight from the shoulders to the hips as much as possible. There are several garment designs that are customized for various uses. Many interventional cardiologists choose a two-piece garment consisting of a skirt and vest (including internal frame), both of which should be snugly tightened around the midsection. Such garments are frequently designed to "wraparound" the wearer and typically provide the fully specified lead-equivalent protection from radiation only in the front where the garment overlaps. A thyroid shield should always be used,¹⁰⁰ and leaded glasses should be worn to minimize the risk of developing cataracts.¹⁰¹

11.2.2. Alternatives to Wearing Lead

Tablesides alternatives to lead-equivalent garments include a floor-mounted radiation protection cabin and a ceiling- or gantry-mounted suspended radiation protection system.^{99,102,103} Both these systems are designed to remove the weight burden of radiation protection while allowing tablesides access in a sterile working environment. Because the weight of the shielding is not borne by the operator, thicker, heavier materials can be used. This results in a 16–78-fold decrease in radiation exposure to the operator.¹⁰³ The disadvantages of these systems are that they restrict the motion of the operator to some degree, and they increase the equipment that is present in an already crowded procedure laboratory environment.

Robotic manipulation of ablation catheters can be accomplished using external magnetic fields to guide magnetic tipped catheters or robotic armatures that actuate sheath and catheter movement remotely. These systems allow electrophysiologists to perform most of the procedure behind fixed radiation barriers, thereby eliminating exposure to scattered radiation for the operator (but not the patient or in-laboratory staff) and eliminating the need to wear protective lead.^{26,104,105} Although there is a learning curve associated with these

technologies, they appear to yield results equivalent to conventional manual catheter procedures. Recent developments in electroanatomic mapping and ICE have been used to perform catheter ablation of atrial fibrillation²² with minimal use of X-ray imaging. Future developments of these and other imaging technologies that do not use ionizing radiation may obviate the need for radiation protection garments in the EP laboratory of the future.

11.3. Laboratory Ergonomics

The physical stresses associated with working in the EP/interventional laboratory have been identified as a high prevalence of orthopedic problems, particularly those related to the spine, hips, knees, and ankles.^{102,106} The primary contributor to orthopedic problems is wearing personal radiation protection apparel. Other factors may be those related to ergonomic design, increasing complexity and duration of interventional procedures, falls, and lengthy careers. A Multi-Specialty Occupational Health Group has been formed to evaluate risks and hazards and advocate for efforts to reduce these hazards.¹⁰⁷ Table 5 provides a list of measures to be considered in laboratory design and procedural processes to reduce the incidence of ergonomic stresses on the EP laboratory physicians and staff.

11.4. Operator Safety During Cardiac EP in Patients With Communicable Diseases

Preventing the transmission of infectious agents to ensure the safety of the operator and other staff in the EP laboratory as much as possible involves, first and foremost, adherence to standardized uniformly applied universal precautions in every aspect of patient care. Risks of acquisition of infectious diseases by health care workers can be minimized by adherence to current infection control guidelines.¹⁰⁸

11.4.1. Individual Personal Precautions

Institutions have policies on required annual or biannual staff inoculations. These may include inoculations such as hepatitis B, influenza, pertussis, and rubeola (measles). Such inoculations can provide immunity from certain highly transmissible diseases, enabling staff to care for these patients without inordinate risk. For example, health care workers not immune to chicken pox should not be required to care for patients with chicken pox.¹⁰⁹ Because of the specialization of staff in the EP laboratory, it can be difficult to provide adequate staffing if multiple concessions have to be made for noncompliant staff. The interval for regular testing of staff for tuberculosis is defined by every institution. In special situations, staff may be fitted for N95 filter masks, which are particulate respirators that are used to prevent inhalation of small infectious airborne particles transmitted by patients with active tuberculosis. Institutional policies should be followed closely in these situations.

11.4.2. Standard Precautions

The major features of universal precautions and body substance isolation are incorporated in standard precautions

and are used universally to prevent transmission of highly contagious or virulent infectious agents that may be spread by air and/or contact. The basic principle is that all blood, body fluids, secretions, excretions (except sweat), nonintact skin, and mucous membranes may contain transmissible infectious agents. Since it is impossible to identify all sources of all infectious agents, the same precautions are applied to every patient at every encounter. Each institution has a detailed description of how standard precautions are implemented. The following text highlights certain aspects particularly pertinent to EP laboratory processes.

Hand hygiene is the single most important factor in controlling and preventing the transmission of germs. Additional protection is offered by the appropriate use of medical gloves; however, the unnecessary and inappropriate use of gloves results in a waste of resources and may increase the risk of germ transmission.¹¹⁰ Hands are washed each time after gloves are removed. Hand-washing supplies should be readily accessible in the EP laboratory and environments. Sterile gloves are indicated for any surgical procedure, invasive radiologic procedure, and procedures involving vascular access (central lines). Examination gloves are indicated in clinical situations where there is potential for touching blood, body fluids, secretions, excretions, and items visibly soiled by body fluids. Splash protection with masks and eye shields is recommended when working with arterial and venous catheterization. Gloves are not indicated (except for contact precautions) for tasks involving direct patient exposure, including taking blood pressure, pulse, and temperature; administering intramuscular and subcutaneous injections; bathing and dressing the patient; transporting the patient; and any vascular line manipulation in the absence of blood leakage, or with indirect patient exposure, including using the phone, writing in the chart, removing and replacing linen for the patient's bed, and placing noninvasive ventilation equipment and oxygen cannula.¹¹⁰

Safe injection practices, including the use of needleless injection systems and proper disposal of any sharps and other equipment used for invasive procedures, are paramount. Single-dose vials are preferable to multiple-dose vials, particularly if the vial will be used for multiple patients.

Transmission-based precautions are as described in each institution's infection control policies. *Contact precautions* require the use of gowns and gloves when there is any contact with the patient or the surrounding area. *Droplet precautions* are invoked when infectious respiratory droplets can travel directly from the patient's respiratory tract to the recipient, generally over short distances. This necessitates facial protection, such as surgical mask, eye protection, and/or face shield. Personal eyeglasses and contact lenses are not considered adequate eye protection.¹¹⁰ Historically, the area of defined risk has been a distance of 3 ft or more around the patient, although depending on the size of the droplets (smallpox and SARS are examples of small droplets), the infective area may be up to 6 ft from the patient. Droplets do not remain infectious over long periods of time and therefore do not require special air handling and ventilation. *Airborne*

infection isolation precautions prevent transmission of infectious agents that remain infectious over long distances when suspended in the air (e.g., rubeola virus [measles], varicella virus [chicken pox], *Mycobacterium tuberculosis*, and possibly SARS coronavirus). If at all possible, EP procedures should be deferred in these patients unless a negative airflow procedure room is available. If an EP procedure is unavoidable, a regular positive pressure procedure room with airflow similar to an OR and a portable high-efficiency particulate air filtration unit may be used.^{110,111} The patient should wear a surgical mask, and the staff should wear N95 filter masks. The procedure should be the last case of the day, and the room left empty until adequate air exchange has taken place to clear the room.

11.4.3. Laboratory Processes

Protocols and regulations as established by the institution for the disposal or processing of infectious material, drapes, and fluids should be followed. Care should be taken to avoid shaking drapes or linens, which can aerosolize contaminants. All sharps that are to be reprocessed should be placed in puncture-resistant containers, leak proof on all sides and bottom, and labeled with a biohazard label. Blood, suction material, or other contaminated liquids can be converted to a solid by the addition of a gel-forming substance to avoid risk of fluid leaking out of containers. “Clean” and “dirty” areas of the laboratory should be maintained during procedures. Personnel touching a contaminated patient/wound/area should try to avoid touching surrounding objects before removing gloves and washing hands. After procedures, all touched surfaces need to be cleaned with a hospital-approved disinfectant, leaving the surfaces wet for the amount of time as directed on the bottle. This cleaning includes monitoring cables, intravenous pumps, transfer equipment, and all nondisposable objects within 3–6 ft of a patient on droplet precautions and within 6 ft if the patient has been coughing.

12. Ethical Concerns

Laboratory Environment Recommendations

- Obtaining an informed consent is necessary for all procedures.

12.1. Informed Consent

Obtaining an informed consent is a process whereby communication between a patient and a physician results in the patient authorizing the medical procedure. This is an integral procedure that safeguards patient autonomy and provides the patient with information about the procedure that allows them to understand and agree to the procedure being recommended. This process is not only a legal requirement but also an ethical obligation.

To ensure appropriate communication, sufficient time should be allocated to this process. A physician, APN, or PA that is part of the EP team should obtain the informed

11.4.4. Catheter Reprocessing

Catheter reprocessing is being adopted by many EP laboratories nationwide, which is aimed at reducing the cost of expensive single-use device and to lessen the environmental impact from discarded supplies. With the passage and enactment of the Medical Device User Fee and Modernization Act of 2002, the reprocessing of single-use devices is now supported in federal law. Physicians and the entire EP team must come to an agreement on whether reprocessing is going to positively impact their clinical operation and patient care from the financial, legal, and/or ethical point of view. Ablation catheters are classified by the FDA as class III devices; therefore, they cannot be reprocessed at this time. There are a few third-party FDA-approved reprocessors used by many EP and catheterization laboratories. In choosing a vendor for reprocessing, each team should consider not only the price of the reprocessed catheters but also the particular vendor's turnaround time, catheter collection logistics, and reprocessing success rate.

11.4.5. Transportation

When a patient must be transported to other units or departments, the referring area should communicate the patient's isolation needs to the receiving area before transporting the patient. All precautions should be followed throughout the transport process. Gloves and other appropriate barriers should be worn by the patient and/or health care worker during all transfers. Protective equipment is then to be removed, the hands washed, and the patient is to be transported to or from the laboratory. Patients on droplet precautions must have their mouths and/or tracheostomy covered with a surgical mask. Transporting a patient on airborne precautions should be discouraged, but if absolutely necessary, consult with the infection control officer as to specific transportation methods.

consent, and it should be made clear if trainees, PAs, or APNs will be operators. The process must take place before premedication with sedation so that the patient is able to understand the discussion and communicate a decision. The discussion should take place out of the procedure room and be in a language that the patient adequately understands, with a qualified interpreter when needed. Common risks, even if not considered serious, should be discussed, as should serious risks that are potentially life-threatening, even if exceedingly rare. All aspects of the procedure that can be reasonably anticipated should be included in the discussion.

Informed consent in the majority of pediatric cases will be granted by the parent or guardian acting on the patient's behalf. Adult patients with CHD are similar to other adults except in cases of cognitive handicaps, as in some genetic syndromes. A minor should be invited to participate in the process, but the consent should be obtained from a legal guardian. Consent/assent forms for young patients older than 12 years are frequently used. Serum or urine pregnancy testing is generally applied for females older than 12 years within 2 weeks before the procedure.

The physician should be aware that they can have a substantial influence on their patient's decision. As an expert, the patient looks to the physician for guidance. It is an ethical obligation for the physician to present a rational argument for undergoing the procedure. In contrast, any form of coercion with the use of verbal or nonverbal threat or manipulation through the incomplete or nontruthful presentation of information is always unethical. Patients should be given ample opportunity to discuss their concerns about the procedure and to have their questions answered satisfactorily. If the patient is incapacitated, every effort should be made to seek out and obtain consent from an appropriate surrogate.

12.2. Ethics of Teaching in the EP Laboratory Setting

Teaching invasive procedural skills is a necessary part of maintaining the availability of widespread medical expertise to patients. The use of simulators can be a helpful adjunct to teaching invasive procedures but cannot replace the experience gained from actual patient procedures.¹¹² Although teaching is the charge of institutions with postgraduate training programs and affiliations with medical schools, the teaching of invasive procedures can occur in any type of institution.

It is the ethical duty of physicians to communicate to patients when and in what way trainees will be involved in their procedures. When asked before the procedure, the majority of patients consent to allowing trainees to practice their skills.¹¹³ Most teaching institutions have patients sign a form during the admission process that acknowledges their implicit consent to allow trainees to perform procedures under the supervision of senior physicians. Although this may be sufficient communication to patients for minor procedures such as venipuncture or acquisition of a surface ECG, in more invasive procedures it is mandatory that a separate discussion takes place during the informed consent process that clearly states the participation and the role of the trainee. Allowing a trainee to practice on a patient under general anesthesia without the patient's explicit consent does not respect the patient's autonomy and compromises the trainee's moral integrity. Trainees should be invited to participate in the procedure only as an integral part of their training, not for mere curiosity. It is the responsibility of the supervising physician to allow the trainee to participate in the capacity that they are capable. The trainee should not be left performing the procedure unsupervised.

12.3. Clinical Research Studies During Clinical Procedures

Without clinical research, promising potentially lifesaving technologies and therapies cannot be safely made available for patients. Our understanding of disease processes progresses because of ongoing research. Clinical research, however, exposes patients to some risk without proven direct benefit. As a researcher, the operator's primary responsibility is generating knowledge, whereas as a physician, the operator's primary responsibility is the well-being of the patient. When there is a conflict between these two roles, the role of the physician must override the role of the researcher.

Patients should be considered for a research protocol if they are looking for improved outcomes compared with those of current therapies. Recruitment of patients should be carried out in a manner that does not coerce participation. Similarly, the opportunity for participation in available investigation protocols should be presented to all patients fulfilling inclusion and exclusion criteria even if the attending physician does not believe that the patient is an ideal candidate. A necessary amount of time should be given to the informed consent process in sufficient advance of the procedure so that the patient is not unduly pressured into making a decision. When children or adult patients unable to provide an informed consent are being considered for a research protocol, it may be helpful to have an independent advocate ensure that parents or legally authorized representatives are making a rational decision exposing the subject to risk.

It is not enough to obtain a patient's consent to participate in a study. It is the ethical duty of an investigator to ensure that the research protocol does not place the participants at unreasonable risk that is disproportionate to the expected benefits of the research study. The protocol must have scientific merit with an adequate likelihood of success as well as an expectation of social benefit. All research protocols performed in the EP laboratory must be reviewed and approved by an independent group, such as an institutional review board, to ensure that the study is ethically acceptable. Results must be reported honestly, not only to honor the risk that research participants took but also to protect future recipients of the technology and therapies made available through research.

12.4. Physician-Industry Relations

Industry can partner with physicians to promote medical knowledge and improve patient care through examples such as supporting CME programs, physician training, and clinical research. Although physicians and industry may share a common goal of advancing medical care, the primary interest of the physician is the well-being of the patient whereas that of the industry is profitability. Any interaction with industry, therefore, has the potential to influence a physician's decision regarding a company's product or service and a physician must stay vigilant to avoid being biased by these interactions.¹

Any gift or amenity that is offered has the potential to exert influence.¹¹⁴ Institutions and physician groups may

define policies regarding the acceptance of industry gifts, but anyone approached by industry must be able to judge whether accepting the gift carries the danger of biasing a medical decision and compromising patient care. It is unethical to accept any gift that is predicated on using a particular product or service. It is imperative that the conflict of interest disclosures to employers, editors, professional organizations, and audiences be accurate and up to date. The conflict of interest policies of each physician's institution and professional organization must be followed. Physicians who are on product review and new product introduction committees for their hospital or professional organization and who have consulting or other relationships with industry must disclose those relationships and recuse themselves from product decisions in those cases.

Appendix 1

See Tables A1 and A2.

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Table A1 Writing Group Disclosure Table

Writing group	Consultant/ advisory board	Speakers' bureau/ honoraria	Research grant	Fellowship support	Board Mbs/stock options/partner	Others
Joseph G. Akar, MD, PhD, HRS	None	None	None	None	None	None
Janice L. Baker, MSN, CCRN, CEPS, FHRS	None	None	None	None	None	None
Salwa Beheiry, MSN, RN, BSN, CCRN, HRS	None	None	None	None	None	None
Douglas Beinborn, RN, MA, HRS	1: Mediasphere Medical, Abiomed	None	None	None	None	None
John F. Beshai, MD, FHRS	4: Lifewatch	None	None	None	1: American College of Cardiology	None
Neil Brysiewicz, BSBME, MS, HRS	None	None	None	None	None	None
Christine Chiu-Man, MS, CEPS, CCDS, FHRS	None	None	None	None	None	1: St. Jude Medical, Medtronic
Kathryn K. Collins, MD, FHRS	None	None	None	None	None	None
Matthew Dare, CEPS, HRS	1: Stereotaxis, Medtronic, Biosense Webster	None	None	None	None	None
Kenneth Fetterly, PhD	None	None	None	None	None	None
John D. Fischer, MD, FHRS	2: Medtronic	1: Sanofi-Aventis	1: Medtronic, Boston Scientific, St. Jude Medical, Biotronik, Sanofi-Aventis	2: Biotronik; 3: Medtronic, Boston Scientific, St. Jude Medical	None	None
David E. Haines MD, FHRS	None	None	None	None	None	Equity interest; 0: nContact Surgical
Richard Hongo, MD, FHRS	1: Medtronic, St. Jude Medical, Boston Scientific	1: Boston Scientific, Medtronic, St. Jude Medical, Sanofi-Aventis	None	None	None	None
Samuel Irefin, MD	None	None	None	None	None	None
John Lopez, BS, BSN, RN, HRS	None	None	None	None	None	1: St. Jude Medical, Boston Scientific, Medtronic, Biotronik, Biosense Webster
John M. Miller, MD, FHRS	1: Biotronik, Boston Scientific, Biosense Webster, Medtronic, Stereotaxis, St. Jude Medical, Topera	None	None	3: Medtronic; 4: Biosense Webster, Biotronik	None	None

Table A1 (continued)

Writing group	Consultant/ advisory board	Speakers' bureau/ honoraria	Research grant	Fellowship support	Board Mbs/stock options/partner	Others
James C. Perry, MD, FHRS	1: Medtronic, U.S. Department of Justice	None	2: Medtronic	None	None	None
David J. Slotwiner, MD, HRS	None	None	None	None	None	None
Gery F. Tomassoni, MD, FHRS, FACC	1: St. Jude Medical, Biosense Webster, Boston Scientific, Stereotaxis, Medtronic	1: Biosense Webster, Boston Scientific, Medtronic, Stereotaxis, Pfizer, Sanofi-Aventis; 2: St. Jude Medical	None	None	None	1: Stereotaxis
Esther Weiss, RN	None	None	None	None	None	None

0 = \$0; 1 = <\$10,000; 2 = >\$10,000 to <\$25,000; 3 = >\$25,000 to <\$50,000; 4 = >\$50,000 to <\$100,000; 5 = >\$100,000.

Table A2 Peer Reviewer Disclosure Table

Peer reviewer	Consultant/ advisory board	Speakers' bureau/ honoraria	Research grant	Fellowship support	Board Mbs/stock options/partner	Others
Alfred Buxton, MD, HRS	1: Medtronic, Boston Scientific, St. Jude Medical	None	0: Biosense Webster, Medtronic	0: Biosense Webster, Medtronic, Boston Scientific	None	None
Anne Dubin, MD, FHRS	None	None	None	2: Medtronic	None	None
Craig Swygman, CEPS, FHRS	1: St. Jude Medical	None	None	None	None	None
David Benditt, MD, FHRS, CCDS	0: Medtronic; 1: CardioNet; 2: St. Jude Medical; 3: CVRx	None	None	None	None	Equity interests; 0: Medtronic; 1: Advanced Circulatory Systems; 2: CardioNet; 3: St. Jude Medical
George Crossley III, MD, FHRS, CCDS	2: Medtronic, Boston Scientific	2: Sanofi-Aventis, Boston Scientific, Medtronic	2: Medtronic	None	None	None
James Tchong, MD	1: American Board of Internal Medicine, Philips Medical Systems; 3: American College of Cardiology	None	2: U.S. Food and Drug Administration, National Institutes of Health	None	None	Fiduciary role and salary position funding; 3: American College of Cardiology
Kenneth Ellenbogen, MD, FHRS	1: Boston Scientific Corp, CardioNet, American Heart Association, American College of Cardiology Foundation, Cameron Health, Biotronik; 2: Medtronic, North American Center for Continuing Medical Education; 3: St. Jude Medical	None	0: National Institutes of Health, Blue Ash Therapeutics; 2: Medtronic; 3: Biosense Webster, Boston Scientific	3: Biosense Webster, Boston Scientific, Medtronic	None	Royalty; 0: Wiley-Blackwell; 2: Elsevier
Marianne Beardsall, NP, FHRS, CCDS	1: Medtronic, St. Jude Medical	None	None	None	None	None
Michael Lloyd, MD, FHRS	1: St. Jude Medical, Biotectix Corporation	None	1: Boston Scientific, Medtronic	None	None	None
Noel Boyle, MD, PhD, FHRS	None	None	None	3: Medtronic, St. Jude Medical, Boston Scientific	None	None
Paul Wang, MD, FHRS, CCDS	1: Medtronic, Biosense Webster, Boston Scientific, St. Jude Medical	None	None	2: Medtronic, Boston Scientific, Biosense Webster, St. Jude Medical	None	Equity interests; 1: Vytronus

Table A2 (continued)

Peer reviewer	Consultant/ advisory board	Speakers' bureau/ honoraria	Research grant	Fellowship support	Board Mbs/stock options/partner	Others
Sumeet Chugh, MD, FHRS	None	None	5: National Institutes of Health	2: Boston Scientific, Medtronic	None	Salary; 5: National Institutes of Health
Susan Etheridge, MD, FHRS, CEPS	None	None	None	None	None	Officer, 0: American College of Cardiology
Timm-Michael Dickfeld, MD, PhD, FHRS	1: Biosense Webster	None	5: GE Healthcare, Biosense Webster	None	None	None
Ulrika Maria Birgersdotter-Green, MD, FHRS	0: Biotronik, St. Jude Medical, Medtronic	0: St. Jude Medical, Medtronic	2: St. Jude Medical, Medtronic	None	None	None

0 = \$0; 1 = <\$10,000; 2 = >\$10,000 to <\$25,000; 3 = >\$25,000 to <\$50,000; 4 = >\$50,000 to <\$100,000; 5 = >\$100,000.



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October 18, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Cardiac Catheterization Services - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Cardiac Catheterization services. The University of Michigan Health System (UMHS) supports the continued regulation of this service; however, UMHS would like to provide the following comments for consideration related to accessibility of care and provision of key cardiac services outside a licensed hospital.

1. Performance of key cardiac procedures in an Ambulatory surgical center:

Cardiac catheterization services are currently only permitted to be performed in licensed hospitals in the State of Michigan. The risk of complications from most contemporary cardiac catheterization procedures is low and is determined by the underlying medical condition of the patient. Elective cardiac catheterization procedures are currently performed as outpatient procedures and most patients are discharged home the same day. The safety of the procedures has been highlighted in multiple studies. In 2018, the Centers for Medicare & Medicaid Services' (CMS) final 2019 payment rule added multiple diagnostic cardiac procedures to the Medicare ASC payable list, specifically for vascular, electrophysiology, and diagnostic cardiac cath procedures. In addition, CMS is requesting public comment of whether elective PCI should be added to this list. In light of these national changes, UMHS is requesting that the CoN commission consider the following suggestions:

- a. Diagnostic cardiac catheterization services should be allowed to be performed in ambulatory surgical centers (ASCs).
- b. Determine if elective Percutaneous Coronary Intervention (PCI) procedures should be allowed to be performed in ambulatory surgical centers (ASCs).
- c. Pacemakers and implantable cardioverter defibrillator (ICD) implants should be allowed to be performed in ambulatory surgical centers (ASCs).

2. Determine if a hospital that provides Primary PCI without on-site OHS (Open Heart Surgery) should be allowed to perform Left sided cardiac ablation procedures.

UMHS would like the CON Commission to provide clarification and consider an amendment (s), if recommended, to Section 2 (x):

Section 2, (x) requires;

“Primary PCI service without on-site OHS” means performing primary PCI on an emergent basis in a hospital having a diagnostic cardiac catheterization service. A hospital that provides primary PCI without on-site OHS may also perform right-sided cardiac ablation procedures including right atrial flutter, AV reentry, AV node reentry, right atrial tachycardia, and AV node ablation.

An emerging body of literature supports similar safety of atrial fibrillation ablation in patients treated at centers with OHS versus those treated at centers without OHS.

UMHS suggests that with careful case selection, left sided ablations can be safely performed by highly experienced operators at centers without OHS.

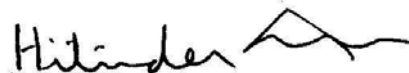
UMHS recommends that the CON Commission form a Standards Advisory Committee to further study the points made for possible inclusion into the CON Standards for Cardiac Catheterization Services.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,



T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
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Hitinder Gurm, MD
Professor of Internal Medicine
Associate Chief Clinical Officer
University of Michigan Medical School
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Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: Hospital Beds.

Hospital Beds

Ascension Michigan supports the continued regulation of Hospital Beds. Additionally, we request the Commission establish a Standard Advisory Committee or workgroup to review the requirements and provisions for limited access areas. We appreciate the Department's identification of some issues in the current provisions and although we understand they are working to present a solution to the Commission, we believe any potential solution should be vetted through a group of experts to ensure a complete understanding and no unintended consequences.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 18, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Hospital Bed Standards:

Henry Ford Health System (HFHS) supports the continued regulation of Hospital Beds. Additionally, HFHS recommends the standards be opened for review. Both national and local trends reflect a shift in care from inpatient to outpatient settings as healthcare systems prepare for seeing increasing complexity due to the aging population with chronic conditions and increased survivorship as well as, shifts in population centers. This shift in sites of care and systems of care calls for greater flexibility in the size, role and scope of hospitals to ensure the needs of our patients are met for cost, quality and access. HFHS asks a Standard Advisory Committee be established to evaluate flexibility in the licensed hospital definition to accommodate shifts in IP to OP settings and make appropriate recommendations to update the Hospital Bed standards.

Respectfully,

A handwritten signature in black ink, appearing to read "Barbara Bressack", with a long horizontal flourish extending to the right.

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Hospital Beds Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Hospital Beds. Trinity Health Michigan supports continued CON regulation of Hospital Beds.

Trinity Health Michigan supports the Certificate of Need Commission's September 2019 decision to review and revise the language and methodology related to Limited Access Areas to ensure the Standard reflects the intended use of the Limited Access Area provision. We believe the Limited Access Area language is appropriately addressed by the Certificate of Need Commission, and does not require a Standards Advisory Committee or a workgroup.

We support the changes made in 2016 related to inpatient rehabilitation beds and the comparative review standards. We believe the current Hospital Beds CON standards appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe the Certificate of Need Review Standards for Hospital Beds require any review or change in 2020 other than as related to the Limited Access Areas noted above.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

A handwritten signature in black ink, appearing to read "Kelly C. Smith" with a stylized flourish at the end.

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan



HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

T. Anthony Denton, MHA, JD
Senior Vice-President and Chief
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October 18, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Hospital Beds - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need Review Standards for Hospital Beds. The University of Michigan Health System supports the continued regulation of this covered service and does not believe any specific revisions to these standards are necessary at this time.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine

October 8, 2019

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S Grand Ave
Lansing, MI 48933

Dear Chairperson Falahee,

Alliance HNI, L.L.C. thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Magnetic Resonance Imaging (MRI) Services.

While MRI Services are not on the Commission's workplan for 2020, we ask that our comments be taken under consideration; and MRI is added for review and modification. Alliance HNI supports the continued CON regulation of this covered service; however, we would like to offer a suggestion for the commission to consider regarding these standards. Currently, MRI service providers operating an approved Mobile MRI Network are subject to minimum volume requirements of 5,500 adjusted procedures, as outlined in the project delivery requirements. Applicants agree to the project delivery requirements as a condition of CON approval on a date specific.

Subsequent to the approval, facts and circumstances change. Additional providers come into the market, technology improves, and population migrates. However, the project delivery requirements remain the same. Further, central service coordinators provide access to the host sites, but don't schedule patients or bill for the scans. Consequently, the central service coordinator will only ever have as much volume as the host sites generate.

This predicament is best evidenced by the most recent MRI service utilization list. Reviewing the mobile MRI data shows that of the 51 networks reporting data, only eight are meeting or exceeding minimum volume requirements. In order to take all of these factors into consideration, we ask the Commission to empanel a Standard Advisory Committee or workgroup to look at and consider lowering the project delivery requirements.

Thank you for this opportunity to share feedback and suggestions relative to the CON Review Standards of Magnetic Resonance Imaging (MRI) Services.

Regards,



Gregory Hedegore, CEO
Hospital Network Healthcare Services, LLC
Hospital Network Support Service, LLC
Hospital Network Ventures, LLC
President, Alliance HNI, LLC





Garden City Hospital

Compassion. Community. Quality.

October 18, 2019

Chairperson James Falahee
Department of Health and Human Services
Certificate of Need Policy Section
5th Floor South Grand Building, 333 S. Grand Ave.
Lansing, MI 48933

Dear Chair Falahee:

Garden City Hospital appreciates the opportunity to present testimony to the Certificate of Need (CON) Commission regarding Magnetic Resonance Imaging (MRI) Services.

We recognize that review of the MRI Standards is not on the Commission's work plan for 2020; and appreciate the Commission's time. However, we have concerns regarding the minimum volume requirements outlined in the project delivery requirements. As such, we would like to ask the Commission to review the MRI Standards next year.

Fixed MRI units are subject to a minimum volume requirement of 6,000 adjusted procedures every year. Taking into consideration multipliers set forth in the Standards, that equates to approximately 4,500 patients per year, or just over 12 patients per day (assuming a unit is operational 365 days per year).

Newly introduced CMS appropriate use criteria regarding diagnostic imaging that is expected to be fully implemented by January of 2021. Appropriate use criteria will require a consultation at the time a scan is ordered. It will also develop best practices in line with a national standard of care. The likely outcome will reduce the number of scans ordered rather than increase them. In fact, according to CMS statistics, the Garden City Hospital and Michigan utilization rate averages for MRI are approximately equal to the national average, which, by all accounts, we be reduced with the new appropriate use criteria. In addition, 12 patients per day can become an unattainable number when you take into account length of scan, patient prep time, missed appointments and equipment repairs.

In order to take the changing landscape into consideration, Garden City Hospital asks the Commission to form a Standard Advisory Committee (SAC) or workgroup to review the project delivery requirements and make recommended changes so that providers utilization thresholds are in line with industry practices.

We appreciate your consideration.

Sincerely,

Saju George
President & CEO



Improving the health of the people in our communities by
providing quality, compassionate care to everyone, every time

October 18, 2019

Mr. James B. Falahee, Jr., JD, Chairman
Certificate of Need Commission
Michigan Department of Health and Human Services
333 S. Grand Building, 5th Floor
Lansing, Michigan 48909

Re: CON Standards for MRI Services

Dear Chairman Falahee,

On behalf of Sparrow Health System, I am writing to provide comments on the Certificate of Need Review Standards for MRI Services. We understand that these standards are not scheduled for normal review by the Commission until 2021, however, we also understand that the Commission has the authority to review standards out of normal schedule when appropriate. We ask that you consider our comments as you review your 2020 workplan and if you see fit, add a review of these standards in 2020.

Sparrow Health System's mission includes an emphasis on providing access to critical health services in underserved areas in Michigan. In fulfilling this mission, we operate three Critical Access Hospitals (Sparrow Clinton, Sparrow Ionia and Sparrow Eaton).

Sparrow Carson Hospital operates 61 licensed acute care hospital beds and operates a Level IV Trauma Emergency Department. The hospital serves as a critical access point for healthcare services in the area, providing surgical services and diagnostic imaging services, including MRI. The hospital is located in Montcalm county, which was designated as a rural county until the 2010 census when the federal Department of Transportation reclassified it as a metropolitan county due to a change in traffic patterns in the County.

When the hospital originally obtained approval for fixed MRI service, the facility qualified for the rural adjustment factor of 1.4 and a minimum volume of 4,000. When the county designation changed to metropolitan, without any significant change to county population, patient population, or demographic of the county, the adjusted volume for the service was immediately reduced by the 40% factor. The facility now faces a situation where they cannot come into compliance with current CON project delivery requirements for volume, but feels they have a duty to the community to continue to provide access to this critical diagnostic tool.

We are reaching out to you to request the Commission review the minimum volume requirements for MRI services in 2020 and consider adding a provision to exempt facilities from the minimum volume if they are creating critical geographic access to this service, acknowledging the need for some MRI services to remain in operation, regardless of volume, if their closure would leave a void in the region.

Thank you for your time and consideration of this input. We would be happy to discuss this further and look forward to working with you on this change, hopefully in the coming year.

Respectfully,

A handwritten signature in black ink, appearing to read "W. Roeser". The signature is fluid and cursive, with a large initial "W" and a long, sweeping underline.

William Roeser, President of Sparrow Carson and Ionia Hospitals

cc: Brenda Rogers, Michigan Department of Health and Human Services



Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: Megavoltage Radiation Therapy Services/Units.

Megavoltage Radiation Therapy Services/Units

Ascension Michigan supports the continued regulation of MRT services and commends the work completed on these standards in the past year. We have no further recommended changes for CON Megavoltage Radiation Therapy Services/Units standards at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan

Beaumont

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: MRT Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2020. Beaumont Health supports the continued regulation of MRT Services. The Commission updated these Standards in 2019 based on the recommendations of a SAC. No further changes to these standards are recommended at this time.

Sincerely,

A handwritten signature in blue ink that reads "Patrick O'Donovan". The signature is written in a cursive style and is set against a light blue rectangular background.

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 8, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,


Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Megavoltage Radiation Therapy (MRT) Services:

Henry Ford Health System (HFHS) appreciates the work the Standard Advisory Committee did in 2018 and 2019 and continues to support the regulation of MRT. Additionally, we believe the changes in the MRT Standards effective September 12, 2019 are an appropriate reflection of how MRT care has advanced in the last several years, ensuring cost, quality and access are aligned to most effectively meet the needs of the communities we serve. HFHS does not believe there are any necessary changes to the standards as they are currently written.

Respectfully,

A handwritten signature in black ink, appearing to read "Barbara Bressack", written in a cursive style.

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202



SPECTRUM HEALTH
Spectrum Health
Lemmen Holton Cancer Center
145 Michigan St. NE Suite 5120
Grand Rapids, MI 49503

October 11, 2019

James Falahee, Chairperson
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Thank you for this opportunity to provide written testimony regarding the CON Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units.

The current MRT standards went into effect on September 12, 2019. Although we think it is possible that additional modifications could be warranted in the future, we would support gathering data under the new standards for a couple of years to see the full impact of the revisions before contemplating additional changes.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for MRT Services/Units Services. Spectrum Health appreciates the Commission's ongoing support for the safety and quality of care for Michigan's residents.

Sincerely,



Mary Kay VanDriel, FACHE



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Megavoltage Radiation Therapy (MRT) Scanner Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Megavoltage Radiation Therapy (MRT) Services/Units. Trinity Health Michigan supports continued CON regulation of MRT services.

Trinity Health Michigan believes the very recent changes made in 2019 to the Certificate of Need Review Standards for Megavoltage Radiation Therapy (MRT) appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. These changes were the result of a thoughtful Standards Advisory Committee process. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

A handwritten signature in black ink, appearing to read "Kelly C. Smith".

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan



HEALTH SYSTEM
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T. Anthony Denton, MHA, JD
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October 18, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Megavoltage Radiation Therapy Services/Units - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Megavoltage Radiation Therapy Services/Units (MRT). The University of Michigan Health System (UMHS) supports the continued regulation of this covered service; however, consistent with our attached testimony from 2016, we recommend changes to Section 3(4) to incorporate current and more relevant standards to support the delivery of health care to cancer patients who may benefit from High Megavoltage Radiation Therapy (HMRT), more commonly referred to as proton therapy.

In January, 2017 the CoN Commission voted to not open and consider any recommended revisions to Section 3(4) of the MRT Standards, as the approved applicants for proton therapy were still in the activation phase of their services. Today, both of the approved proton therapy facilities in Michigan are operational.

When the existing standards were drafted over a decade ago, radiotherapy was provided by more and smaller facilities. Only 5 providers had >30,000 ETVs, so 2/5 were required (40%) to have qualifying activity and form a collaborative. The consolidation that has occurred within our state has now led to an increase in the number of providers delivering over 30,000 ETVs, such that a third partner is required. Given that two of the existing parties already have proton facilities (ones that are far smaller than anticipated when policy was written and can treat only a small fraction of proton-eligible cases in the State), the regulations now pose an unreasonable barrier that does not meet the interests of the citizens of Michigan.

The current HMRT CoN Standards have been in effect for over 10 years and have not really been tested due to the onerous requirements of forming a collaborative with other qualified radiation oncology programs. A decade ago, the rationale of a collaborative was a thoughtful approach due to the exorbitant cost of a proton therapy facility. While still a significant investment today, the cost of proton therapy technology is a fraction of what it once was. The efficacy of this therapy is now well established, with evidence supporting superiority of this approach over others in numerous clinical situations. In addition to clear benefits in reducing toxicities and second radiation-induced cancers among children with cancer, many adults are now also expected to benefit. For example, studies have

shown a reduction in need for feeding tubes and improvements in survival and quality of life (by reducing permanent dry mouth) for patients with head and neck cancer. Impeding access to this technology for delivering radiation therapy at tertiary and quaternary medical centers is a disservice.

From a clinical perspective, UMHS provides MRT Services to the greatest number of patients in Michigan at a single site. In addition, UMHS is the home of C.S. Mott Children's Hospital, one of the premier children's hospitals in the world, but is unable to offer proton therapy due to the current standards. This is deeply concerning, as our pediatric patients who would benefit most from this life changing therapy must be referred outside our system and receive treatment from a different care team, unnecessarily complicating the coordination of care delivery and compromising the quality of care these vulnerable patients receive. In-state providers do not possess the clinical expertise or support system of a comprehensive children's hospital. Therefore, the only option for proton therapy at a comprehensive children's hospital for Michigan children with cancer and their already burdened families is to travel outside the State of Michigan.

From a research perspective, the University of Michigan is ranked #2 in research spending of all public universities in the United States and is home of the University of Michigan Rogel Cancer Center, an NCI designated Comprehensive Cancer Centers. Proton therapy is an evolving cancer treatment and not having this service readily available to Michigan Medicine patients is a detriment to new medical discoveries. We harness innovation by engaging disciplines that are not typically thought to be central to attacking the cancer problem, including faculty in fields such as engineering and mathematics, as well as through more traditional collaborations between faculty in medicine, public health, nursing and social work. Lack of access to this established technology for radiation treatment delivery impedes the development of critical research advances needed to serve the citizens of Michigan and beyond.

From an educational perspective, UMHS, in cooperation with the world-renowned U of M Medical School, are dedicated to training the next generation of oncologists and oncology researchers through residency and fellowship programs, graduate training programs and postdoctoral programs. Access to tools, such as proton therapy, is paramount in preparing skilled and innovative physicians and scientists of the future.

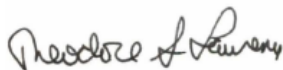
Speaking as a national and statewide leader in adult and pediatric cancer treatment, research and education, UMHS urges the CoN Commission to form a Standards Advisory Committee to develop and recommend new CoN Standards for the Initiation of an MRT Service with a HMRT Unit.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,



T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine



Theodore S. Lawrence, MD, PhD
Isadore Lampe Professor and Chair
Department of Radiation Oncology
University of Michigan Medical School
Michigan Medicine



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Senior Vice-President and Chief
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October 21, 2016

Marc Keshishian, M.D. - CON Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Megavoltage Radiation Therapy - Certificate of Need Standards Review

Dear Commissioner Keshishian:

This letter is provided as formal testimony pertaining to the Certificate of Need (CON) Review Standards for Megavoltage Radiation Therapy (MRT). The University of Michigan Health System (UMHS) supports the overall regulations for this service; however, our suggestion is that Section 3(4) needs to be replaced with more relevant and current standards to support delivery of health care to cancer patients who can benefit from high megavoltage radiation therapy, also referred to as particle therapy.

Section 3(4): "Initiate an MRT Service with a High MRT (HMRT) Unit", requires "the applicant to file a CON as a *collaborative*, consisting of at least 40% of all Michigan-based hospital MRT services with more than 30,000 Equivalent Treatment Visits (ETV) as reflected in the most current data available to the Department". Based on the 2014 Michigan CON Annual Survey data, five services in Michigan meet this definition: Genesys Hurley Cancer Institute, Karmanos Cancer Center, Lemmen Holton Cancer Pavilion, UMHS and William Beaumont Hospital – Royal Oak.

William Beaumont Hospital – Royal Oak¹ and Karmanos Cancer Center's parent company McLaren Health Care² received HMRT CON approval in July and August 2008, respectively, for single-provider proton therapy services prior to these specific "collaborative" CON Standards going into effect in November, 2008. As of the date of this letter, both of these providers are still working to activate their HMRT units.

Given concerns regarding cost, quality and access when Section 3 (4) was first initiated, requiring qualified providers to form a collaborative and work together in singular fashion was an important

and innovative approach to balance the provision of proton therapy with population size, need and cost.

The Particle Therapy Institute of Michigan (PTIM), was officially formed as a collaborative in September, 2008, consisting of Ascension, Henry Ford Health System, Karmanos Cancer Center, McLaren Health Care, St. Joseph Mercy and UMHS. McLaren Health Care and St. Joseph Mercy dropped out of the collaborative soon after the formation of PTIM. After numerous due diligence meetings over the course of several years a CON application was never filed under the CON Standards contained within Section 3(4). PTIM was officially dissolved in September, 2016.

The “collaborative” methodology to attain CON approval for HMRT was progressive and well thought out; however, it appears that the original intentions have not led to the practical aims as first envisioned, including creating this technological capacity to serve cancer patients who could benefit directly by having greater access to the technology in a State where there is significant provider consolidation and systems of care. We suggest that if the CON approval path to entry were more flexible, particle therapy services might become more readily available through individual organizational investment as costs have come down over time.

Cost containment was one of the primary drivers for the development of CON Standards, an important basis for requiring a collaborative for HMRT. Proton Therapy, a heavy particle accelerator covered under the definition of HMRT, requires a substantial capital investment. However, the costs for proton therapy facilities have been reduced over time, as more cost-effective alternatives have been introduced into the marketplace. In a 2009 article published in *The National Association for Proton Therapy*, the author talks about the \$144 million radiation therapy center being constructed at the University of Pennsylvania and describes it as the most complex and expensive medical machinery ever built³. In dramatic contrast, there was a 2015 article published in *The Wall Street Journal*, and that author talks about compact proton systems costing between \$25 million and \$30 million⁴, a clear shift to make the technology more cost-effective. To further reinforce this point, the project costs contained in both Beaumont’s and McLaren’s CON applications were amended down suggesting that the investment associated with this type of therapy modality has been reduced with the introduction of lower cost alternatives. Based on the amended project budgets of both CON applications, the cost of the Proton Therapy facilities in each was reduced by over \$100 million.

Quality and Safety goals are quite important as well. The National Association for Proton Therapy states that this therapy modality is the highest precision therapy for radiation treatment in use today. It delivers a higher effective radiation dose to the tumor site while sparing healthy tissues and organs when compared to other types of radiation therapy. This type of therapy also reduces the side effects of radiation treatment, particularly secondary cancers in pediatric populations⁵. Occurrence of treatment-related tissue damage and other side effects is reduced because of the precision of dose

delivery and the resulting limited amount of radiation delivered to healthy tissues adjacent to the tumor site⁶. M.D. Anderson Cancer Center indicates Proton Therapy appears to be a promising treatment for certain types of tumors where precision is of utmost importance⁷. Such tumors may include, but are not limited to: Brain, Head & Neck, Liver, Lung, Ocular and Pediatric.

Access to proton therapy is a challenge for the citizens of Michigan. Currently there is no access to proton therapy in the State of Michigan, requiring patients who need this treatment to travel out-of-state. Today, due to market consolidation, provider realignment and lower ETV numbers; the number of MRT services qualified to form a collaborative is half of what it was nine years ago. As previously stated there was an unsuccessful attempt to form a HMRT collaborative and it is unlikely a second attempt would yield any different results. Access to this life-changing therapy is being impeded by CON Standards that are not applicable to today's health care environment.

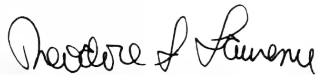
Speaking as the statewide leader in adult and pediatric cancer treatment⁸, UMHS urges the CON Commission to form a Workgroup or Standards Advisory Committee to develop new CON Standards for the Initiation of an MRT Service with a HMRT Unit.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,



T. Anthony Denton
Senior Vice President and Chief Operating Officer



Theodore S. Lawrence
Isadore Lampe Professor of Radiation Oncology
Chair, Department of Radiation Oncology

References

1. CON 08-0072, Add 1 MRT Unit for Proton Beam Therapy: Effective Date: 07/10/2008
2. CON 08-0089, Add 1 MRT Unit for Proton Beam Therapy: Effective Date: 08/11/2008
3. The National Association for Proton Therapy: The \$150 Million Zapper, David Whelan and Robert Lagerth: originally published in Forbes Magazine: March 16, 2009
4. The Wall Street Journal: Big Bets on Proton Therapy Face Uncertain Future, Melinda Beck: May 26, 2015
5. The National Association for Proton Therapy: Proton Therapy Fact Sheet, 2007 www.proton-therapy.org/facts.htm
6. The University of Texas M.D. Anderson Cancer Center: Clinical Benefits, 2008 www.mdanderson.org/care_centers/radiationonco/ptc/
7. The University of Texas M.D. Anderson Cancer Center: Clinical Benefits, 2008 www.mdanderson.org/care_centers/radiationonco/ptc/
8. US News & World Report – 2016 Best Hospitals Rankings: <http://health.usnews.com/best-hospitals/rankings/cancer>



Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: Open Heart Surgery Services.

Open Heart Surgery Services

Ascension Michigan supports the continued regulation of open heart surgery services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan

Beaumont

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Open Heart Surgery Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2020. Beaumont Health supports the continued regulation of Open Heart Surgery Services. No changes to these standards are recommended at this time.

Sincerely,

A handwritten signature in blue ink that reads "Patrick O'Donovan". The signature is written in a cursive style and is contained within a light blue rectangular box.

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 8, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Open Heart Surgery (OHS) services:

Henry Ford Health System (HFHS) supports the continued regulation of OHS services. HFHS does not have any proposed changes to the standards as currently written.

Respectfully,

A handwritten signature in black ink, appearing to read "Barbara Bressack", with a long horizontal flourish extending to the right.

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Open Heart Surgery Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Open Heart Surgery. Trinity Health Michigan supports continued CON regulation of Open Heart Surgery.

Trinity Health Michigan believes the changes made in 2018 to the Certificate of Need Review Standards for Open Heart Surgery appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

A handwritten signature in black ink that reads "Kelly C. Smith".

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan

October 10, 2019

Chairperson James Falahee
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S Grand Ave
Lansing, MI 48933

Dear Chairperson Falahee,

Alliance HNI, L.L.C thanks the CON Commission for the opportunity to provide written testimony on the CON Review Standards for Positron Emission Tomography (PET) Services.

The current PET standards require a list of supporting services to initiate a mobile PET host site. Oncology and Cardiology are the two primary health service lines associated with these supporting services. In the infancy of PET technology, it was unclear how this technology would be utilized. Many years later, the data shows that PET technology is focused almost exclusively on oncology patients. We estimate that 97% or greater of PET volume completed in Michigan has been for oncologic diagnosis as compared to the small amount of cardiac volume performed. With that said, currently the standards require a facility to have both service lines or a supporting letter from a facility within their service area to initiate services regardless of the focus of the services being provided.

Additionally, the PET imaging modality has been used safely for diagnostic purposes for many years. Other imaging modalities, such as MRI and CT, do not require support from other clinical service lines in order to be utilized safely for diagnostic purposes. Furthermore, most PET units operating in Michigan are combined with CT to bring both efficiency and clinical efficacy to patient exams.

This presents a challenge for applicants because the PET equipment requires additional contracting while the CT equipment does not. The situation is further complicated in planning areas where there is limited access to facilities that can meet the elements of the required oversight that may not even be applicable to the type of scans performed by the unit.

As a result, we recommend the Commission form either a SAC or a workgroup to discuss the oversight requirements in the standards and bring consistency to regulation of diagnostic imaging services.

Thank you for this opportunity to share feedback and suggestions.

Regards,



Gregory L Hedegore, CEO
Hospital Network Healthcare Services, LLC
Hospital Network Support Service, LLC
Hospital Network Ventures, LLC
President, Alliance HNI, LLC





Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: PET services.

Position Emission Tomography Scanners

Ascension Michigan supports the continued regulation of PET services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan

Beaumont

October 18, 2019

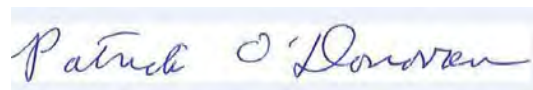
Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: PET Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2020. Beaumont Health supports the continued regulation of PET Services. One recommended change is that utilizing an interim replacement mobile PET unit due to repair of the existing mobile unit should not require a CON- perhaps just a LOI waiver or simple notification. This should apply to interim replacements for all CON covered equipment. This will reduce the potential for interruptions in service for equipment that already has CON approval.

Sincerely,

A handwritten signature in cursive script that reads "Patrick O'Donovan". The signature is written in dark ink on a light-colored background.

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 8, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Positron Emission Tomography (PET) Scanner Service Standards:

Henry Ford Health System (HFHS) supports the continued regulation of PET services. HFHS does not have any proposed changes to the standards as currently written.

Respectfully,

A handwritten signature in black ink, appearing to read "Barbara Bressack".

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Dear Certificate of Need Commission:

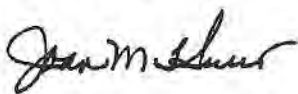
MidMichigan Health appreciates the opportunity to offer comments on the Certificate of Need review standards for Positron Emission Tomography (PET) scanner services. MidMichigan Health would like consideration of the current requirements to initiate a fixed PET scanner service. Specifically, MidMichigan is requesting that the minimum volume requirement be reviewed in order to better serve cancer patient populations.

We currently participate on a mobile PET route through Advanced PET Imaging Network (APIN), and due to the need and obligation to provide service in other regions we currently utilize the service two days per week. On these two days, we typically scan 10-12 patients per day, resulting in 734.25 PET equivalents. Therefore, utilizing a mobile route, we do not believe it will ever be possible to meet the 1,700 PET equivalents minimum volume requirement to initiate a fixed service.

Providers are frustrated with the limited availability of our PET service causing delays in service for cancer patients; which also causes increased anxiety and a delay in cancer staging and treatment for our patients. A fixed service would provide the best solution for better patient access, reducing the need for patients to unnecessarily travel and/or delay their care, and is also more financially feasible than alternative solutions of increasing mobile PET. Further, we do not believe this change would negatively impact the PET offerings of other locations given the geographic needs of this service. Patients would be better served if the current PET equivalent volume requirements could be adjusted to a more reasonable level enabling a fixed PET service.

Thank you for the opportunity to share our comments on the Certificate of Need review standards for PET scanner services. MidMichigan Health appreciates the Commission's consideration of our comments.

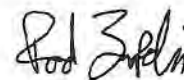
Respectfully submitted,



Joan Herbert, PharmD
Director, Oncology Service Line
MidMichigan Health



Melwyn Sequeira, MD
Chief, Oncology Service Line
MidMichigan Health



Rod Zapolski
Director, Imaging Services
MidMichigan Health



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Positron Emission Tomography (PET) Scanner Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Positron Emission Tomography (PET) Scanner Services. Trinity Health Michigan supports continued CON regulation of Positron Emission Tomography (PET) Scanner services.

Trinity Health Michigan believes the changes made in 2015 to the Certificate of Need Review Standards for PET Scanner services appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

A handwritten signature in black ink, appearing to read "Kelly C. Smith".

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan



HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

T. Anthony Denton, MHA, JD
Senior Vice-President and Chief
Operating Officer

University of Michigan Health System

300 N. Ingalls St, SPC 5474
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tadpole@med.umich.edu

October 18, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Positron Emission Tomography Services - Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need Review Standards for Positron Emission Tomography Services. The University of Michigan Health System supports the continued regulation of this covered service and does not believe any specific revisions to these standards are necessary at this time.

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine



Ascension

October 18, 2019

Chairman James Falahee, JD
Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 4th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Via E-Mail: MDHHS-ConWebTeam@michigan.gov

Dear Chairman Falahee,

On behalf of Ascension Michigan please accept this correspondence as written testimony regarding Ascension Michigan's recommendations on the following CON standards scheduled for review in 2020: Surgical Services.

Surgical Services

Ascension Michigan supports the continued regulation of surgical services and has no recommended changes at this time.

Thank you for the opportunity to provide written comments on the CON Review Standards being considered for review in 2020. We look forward to working with the Commission on these issues and any others in the coming year.

Sincerely,

Thomas "Tim" Stover
Interim Market Executive
Ascension Michigan

Alisha Cottrell
VP, Advocacy
Ascension Michigan

Beaumont

October 18, 2019

Certificate of Need Commission
c/o Michigan Department of Community Health
Certificate of Need Policy Section
South Grand Building
333 S. Grand Avenue
Lansing, MI 48933

Re: Surgical Services

Dear Certificate of Need Commission:

Thank you for the opportunity to provide comment on the CON Review Standards up for review in 2020. Beaumont Health supports the continued regulation of Surgical Services, and no changes to these standards are recommended at this time.

Sincerely,

A handwritten signature in blue ink that reads "Patrick O'Donovan". The signature is written in a cursive style and is contained within a light blue rectangular box.

Patrick O'Donovan
Director, Strategy & Business Development
947-522-1173



Henry Ford Health System
One Ford Place – Suite 4A
Detroit, MI 48202

October 8, 2019

Mr. James Falahee, JD
CON Commission Chairperson
South Grand Building, 4th Floor
333 S. Grand Avenue
Lansing MI 48933

Dear Commissioner Falahee,

Henry Ford Health System (HFHS) would like to offer comments on Certificate of Need review standards for Surgical Services:

Henry Ford Health System (HFHS) supports the continued regulation of Surgical Services. HFHS does not have any proposed changes to the standards as currently written.

Respectfully,

A handwritten signature in black ink, appearing to read "Barbara Bressack", written in a cursive style.

Barbara Bressack
Henry Ford Health System
Vice President, Strategy and Planning
One Ford Place, 4A
Detroit, MI 48202

October 14, 2019

James Falahee, Chairperson

Certificate of Need Commission
c/o Michigan Department of Health and Human Services
Certificate of Need Policy Section
South Grand Building, 5th Floor
333 S. Grand Ave
Lansing, Michigan 48933

Dear Chairperson Falahee,

Thank you for this opportunity to provide written testimony regarding the CON Review Standards for Surgical Services.

Spectrum Health supports continued regulation of surgical service and does not recommend any changes to the standards at this time.

Again, thank you for the opportunity to provide feedback on the CON Review Standards for Surgical Services. Spectrum Health appreciates the Commission's ongoing support for the safety and quality of care for Michigan's residents.

Sincerely,



John C. Shull
Vice President Surgical Services
Spectrum Health



October 1, 2019

James Falahee
Chair, CON Commission
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Public Comment for Surgical Service Certificate of Need Standards

Dear Chairman Falahee:

Trinity Health Michigan would like to thank the Certificate of Need Commission for the opportunity to comment on the Certificate of Need Review Standards for Surgical Services. Trinity Health Michigan supports continued CON regulation of Surgical services.

Trinity Health Michigan believes the current Certificate of Need Review Standards for Surgical services appropriately assure Michigan residents have access to safe, lowest cost, high quality care resources. As such, Trinity Health Michigan does not believe further revisions to these Certificate of Need Review Standards are necessary at this time.

We appreciate the CON Commission's consideration of our comments.

Respectfully,

A handwritten signature in black ink, appearing to read "Kelly C. Smith".

Kelly C. Smith
Chief Strategy Officer
Trinity Health – Michigan



HEALTH SYSTEM
UNIVERSITY OF MICHIGAN

T. Anthony Denton, MHA, JD
Senior Vice-President and Chief
Operating Officer

University of Michigan Health System

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October 18, 2019

James Falahee - CoN Commission Chairperson
Department of Health and Human Services - Certificate of Need Policy Section
5th Floor South Grand Building
333 S. Grand Ave.
Lansing, MI 48933

RE: Surgical Services- Certificate of Need Standards Review

Dear Commissioner Falahee:

This letter is provided as formal testimony pertaining to the Certificate of Need (CoN) Review Standards for Surgical Services. The University of Michigan Health System (UMHS) supports the continued regulation of this service; however, UMHS would like the CoN Commission to consider developing CON Standards that recognize the evolution and ongoing changes occurring in today's health care environment.

Health care delivery has evolved significantly since Michigan CoN was first enacted in 1972. Forty-seven years ago, "site specific" regulations were appropriate as most every, if not all, acute care hospitals in the state were independent. Over the past many years, there has been a paradigm shift as only a few hospitals today remain independent health care providers located only at one site. The vast majority have experienced organic growth or have joined together to create more efficient and geographically diverse "health system" organizations. As the consolidation that has occurred, there has also been a major shift toward delivering health care in outpatient settings in local communities to create networks of care, including ambulatory surgical procedures.

Surgical procedures that once required an inpatient admission are now routinely performed in a Freestanding Surgical Outpatient Facility (FSOF), with patients returning home just hours after surgery. While health care delivery has evolved and become more efficient since the 1970's, the CoN Standards that regulate this service for our State have not been modernized to align with these improvements as organizations seek to enhance patient care access across different settings.

Health systems today are geographically dispersed throughout multi-county service areas in Michigan. Allowing greater geographic planning flexibility to these organizations beyond the current 10-mile (metropolitan) or 20-mile (rural/micropolitan) relocation zones for the replacement of existing licensed Operating Rooms (OR) could be a significant step toward improving access.

Providing appropriate access to state-of-the-art health care in lower cost environment is a potential and beneficial outcome, consistent with principles of certificate-of-need regulations.

UMHS recognizes there may be challenges to defining what a “health system” is on a consistent basis to enable efficient administration term throughout the CoN Standards. A simple and logical definition would be sites that are operated under the same provider number or which have been formally integrated under a system consolidation. We don’t suggest we have the answer, but do propose that it may be time to determine a new framework to provide alignment to determine location of operating rooms within a system context rather than site-specific assessments which have been the norm.

UMHS recommends that the CON Commission form a Standards Advisory Committee or Workgroup to further study the points referenced in this letter and work toward developing new CoN Standards that recognizes today’s health system, allowing for more efficient and flexible deployment of licensed OR’s across a system to reflect the new normal of what is included in many health systems across our State. Finally, this may be a reasonable discussion to have for other covered services (e.g. MRI, CT).

Thank you for allowing the University of Michigan Health System to provide these comments for consideration.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "T. Anthony Denton". The signature is fluid and cursive, with the first name being the most prominent.

T. Anthony Denton, JD, MHA
Senior Vice-President and
Chief Operating Officer
University of Michigan Health System
Michigan Medicine