

Electrophysiology Continues to Thrive in Labs with Off-Site Surgical Backup: Key Steps to Bring These Services to Your Lab

By James Burns

Electrophysiology services (e.g., therapeutic and diagnostic cases, as well as device implantations) have continued to grow in cardiology programs without on-site open-heart surgery programs across the country. Much like its cardiology “cousin”, angioplasty, electrophysiology was once thought to be so specialized — and dangerous — that it could only be safely offered with the security of a cardiac surgery suite and surgeon that was on site and immediately available. However, as with interventional cardiology, years of technical advances, improvements in techniques and processes, and data showing minimal risk, have allowed programs to begin to offer many of these services in labs located in facilities that do not have, or plan to have, open-heart surgical services.

While improvements in device implantations and ablation/mapping techniques have significantly advanced arrhythmia treatment, decreased conduction-related morbidities, and improved overall patient outcomes, there remains a significant amount of infrastructure investment that a program needs to make in order to be successful in offering electrophysiology without on-site open-heart surgery.

First and foremost, hospital leadership needs to understand what is permitted under local laws. Not all states, or State Departments of Health, are the same. Some states limit catheter-based services or prohibit ICD implantation without on-site open-heart surgery, and some require formal application. Understanding what each state permits in terms of electrophysiology services (ablation, mapping, and device implantation), with and without on-site open-heart surgery, does require some investigative skills as there is no standard approach. Some states approve EP when PCI is permitted without cardiac surgery, some do not. And, conversely, some states don't have any electrophysiology requirements, even when a certificate of need is required for any expansion into open heart surgery or PCI.

Once these laws and regulations have been explored, the next question should be: is there a physician who wants to be a “Program Champion” and begin performing these procedures at your facility? Every program needs a strong leader, and an EP program with off-site open-heart surgery is no exception. In addition to being dedicated to the overall program and facility, the Program Champion (or perhaps, *de facto* Medical Director) should be qualified to lead the program. Ideally, he or she should have successfully completed an ACGME- or AOA-accredited

fellowship in clinical cardiac electrophysiology, have at least one year of recent lab experience, and be proficient with the current Heart Rhythm Society (HRS) guidelines.

This Program Champion/Medical Director will need the right tools to help govern the program, especially if there are varying professional opinions of what is safe and appropriate in a lab with off-site surgical backup. State regulations can be helpful in drafting a scope of services as well as a medical policy to govern the procedures and provision of care in the lab.

A safe, expeditious, and emergent transfer modality is essential as well. A mechanism for mobilizing the team to contact a surgeon partner, engage conversation with the electrophysiologist, summon the mode of transportation, notify other members of the care team as well as the patient's family, and execute the patient transfer must be thoroughly planned step by step, rigorously rehearsed and timed, and hopefully never used in a real-life situation.

While it can be a challenge getting staff and physicians to prepare and rehearse for a situation that, most likely, will never occur, it is an essential element in readying an organization with the appropriate safety resolutions, whether they be in-house, or at another facility, for performing these specialized procedures. Oftentimes the event of transfer is where problems can occur, or to quote an often-used colloquialism, “the devil is in the details.”

TABLE 1.
Critical Elements for an EP Program Without Open-Heart Surgery: <ul style="list-style-type: none">• Dedicated and qualified medical director;• Defined scope of services;• Proven transfer protocols;• Stringent quality assurance program.
General Elements for an EP Program Without Open-Heart Surgery: <ul style="list-style-type: none">• Diagnostic electrophysiology studies;• Supraventricular arrhythmia;• Ablations that do not puncture or cross septum with a catheter;• Permanent pacemaker insertion for bradyarrhythmia and other appropriate indications;• Insertion of implantable cardioverter-defibrillators and biventricular pacemakers.

Corazon, as well as most industry and professional societies and organizations, consider detailed, written protocols and transfer agreements essential cornerstones of this process. Just like a schematic for a building or a script in a play, these directions, when closely followed, will ensure that everyone and everything is in its place and running smoothly, creating a seamless transition and instilling trust in the program and operators to result in a successful procedural outcome.

Initial and ongoing training for your technical and nursing staff in EP is essential as well; training should address pathophysiology, routine care, emergent interventions, and management of untoward outcomes. As with all of the other components of this process, this training should be organized, delivered in a formal and consistent manner, tracked diligently, and include both classroom or didactic curriculum and "hands-on" clinical practicums/experience. It is very important that the physicians who will be practicing at the facility be integral in the staff education planning process. This process should also include access to the various vendor equipment and devices that will be used in the lab. Most companies who provide these supplies and equipment are more than willing to participate in staff training, even donating sample devices to use during training sessions.

Another important element that is often overlooked when planning any service in a facility that does not have advanced cardiac or other surgery is that the facility typically also does not offer the other complementary services that are traditionally seen with cardiac surgery (such as pulmonology or nephrology). Therefore, it is imperative that any issues in other systems of the body be identified and treated quickly before they can progress to a state where daily intervention by a specialist is needed.

Lastly, a robust data collection and quality reporting program is a must. If you are doing well, you want to know and share that with the marketplace; if you are not doing well, you want to know and fix the problem. With the number of providers growing and the level of transparency in healthcare increasing, quality performance must always be at the top of any agenda.

Corazon recommends the following key data elements that are most valuable to tracking operator and program quality. Typically, an operator's complication rates should not exceed those defined in publications by professional societies or the following thresholds:

- Mortality $\leq 1\%$;
- Stroke $\leq 1\%$;
- Major complications: emergency surgery, transfusion, cardiac arrest, heart failure, cardiac perforation, tamponade, air embolism, pneumothorax, or vascular complication requiring surgical intervention;
- Minor complications: hematoma, infection, or venous thrombosis.

Finally, as with any new program, data should be collected around volumes by type, provider, and referral source, as well as by general complications, delayed starts and prolonged waits for appointments, and other customer service topics. If this seems like a daunting task, don't be dissuaded. EP programs can be excellent extensions of cardiac services lines, and can add levels of prestige to programs that once were limited because they did not offer open-heart surgery services. As with cardiac angioplasty without open-heart surgery, Corazon has helped a number of electrophysiology programs develop in centers where only diagnostic or interventional cardiology services are offered.



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