

# Implementation of a Highly-Performing Electrophysiology Device Implant Program: Is There a Role for Niche Hospitals?

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Good Samaritan Hospital (GSH) and Lebanon Cardiology Associates (LCA) recently partnered to create a community hospital EP program caring for elderly, ill patients, and experienced lower overall implant complications compared to available national trials and single academic centers. Find out more information here.

## Background

After approximately two years of planning, Good Samaritan's invasive cardiac EP lab was opened on July 1, 2008. There are two full-time technologists (David Lugg, BS, RCIS and Douglas Hollis, RCIS) and one full-time nurse (Robert Gray, BSN, RN). In addition, we have one part-time technologist, Michelle Stoner, BS, CVT, who still participates in traditional coronary and peripheral interventional cardiology procedures.

Jeffrey L. Williams, MD, MS, FACC is the Director of Cardiac Electrophysiology and is board-certified in Internal Medicine, Cardiovascular Disease and Clinical Cardiac Electrophysiology. In July 2009, he was joined by Co-Director of Electrophysiology Robert Stevenson, MD, who is board-certified in Internal Medicine, Cardiovascular Disease, and Nuclear Cardiology. Julie Miksit, RN, BSN, MBA is the Assistant VP of Cardiovascular Services at Good Samaritan. Alicia Wike, RN, is the Cardiac Catheterization and EP Lab Supervisor, and the manager of the Cardiac Catheterization and EP Labs is Jennifer Hemperly, RN.

The implementation of the GSH EP device implant program is best described using key premises outlined by the Baldrige National Quality Program: leadership, strategic planning, customer focus, workforce focus, process management, measurement/analysis/knowledge management, and results (Figure 1).<sup>1</sup> Of note, GSH also utilizes Lean Six Sigma<sup>SM</sup> principles for certain process improvements.

We routinely perform ablations for supraventricular tachycardia, ventricular tachycardia, and atrial fibrillation in our state-of-the-art procedure room; however, our device implant program is the focus of this report.

## Leadership and Planning

The implementation of the Good Samaritan EP program began 18 months prior

to program inception in July 2008. Dr. Williams and Mrs. Miksit began a systematic planning strategy for lab implementation with the full support of Good Samaritan and Lebanon Cardiology Associates. The demographics of the area, especially serving Health Professional Shortage Areas, necessitated the Good Samaritan EP lab have capabilities to perform all aspects of device implantation. Electrophysiology equipment acquisition was based upon the desire of Good Samaritan Hospital and Lebanon Cardiology Associates to offer state-of-the-art cardiovascular care to the Lebanon Valley community. The Good Samaritan Hospital's invasive cardiac electrophysiology laboratory is 800 square feet and fully-equipped to function as a cardiothoracic surgical suite. We have our own anesthesia equipment that consists of a traditional ventilation machine and full anesthesia cart (Dräger Fabius® Tiro compact anesthesia system, Draeger Medical, Inc., Telford, PA) and the Monsoon Jet Ventilator (ACUTRONIC Medical Systems AG, Switzerland). The fluoroscopy system is a GE Innova 2100 single-plane unit (GE Healthcare, United Kingdom).

Effective supply chain management processes (e.g., vendor relations/contracts) were instituted and elaborated prior to inception of program. Staff education plans were determined and pre-implementation training sessions were held with Dr. Williams prior to his arrival at GSH. Staff education and training goals were outlined prior to implementation, and these discussions hinged upon the required implant capabilities of our EP lab. Community education is just as important as staff education; Drs. Williams and Stevenson are very involved with community/provider education and regularly perform outreach talks to raise awareness of sudden death and arrhythmias. We have recently instituted a monthly staff education seminar that covers all aspects of electrophysiology commonly encountered during hospital care.

## Electrophysiology Staffing/Workforce

Staffing of the Good Samaritan EP laboratory was decided upon after discussing the role of anesthesia services. There is data to suggest that patients undergoing invasive electrophysiology procedures may require deep conscious sedation that often is converted to general anesthesia.<sup>2</sup> Thus, our initial staffing was based upon anesthesia providers (MDs, CRNAs) performing procedural sedation. Indeed, the majority of device implantations were sedated by anesthesia services rather than EP lab staff.

EP workforce engagement is an important element of our EP program. First and foremost, we foster a culture of open communication that starts in the outpatient setting and culminates when the patient enters the EP lab. Preprocedure patient summaries and timeouts are performed with the EP lab staff to ensure all care providers have full understanding of the patient and the procedure to be performed. We encourage staff participation in the publication and presentation of clinical research to maintain their engagement. Educational opportunities are also identified to address Good Samaritan EP strategic plans; we have formulated an EP technologist

training program that includes a stepwise training program to permit career and skill set advancement.

The EP laboratory workforce environment is constantly monitored for capabilities, capacity, and climate. Assessment of the needs, skills, competencies, and staffing levels is addressed with any new procedure. This allows us to prepare for changing needs/capabilities and prevent/minimize impact of any workforce reduction. Finally, routine fluoroscopic level monitoring and ergonomics are evaluated to improve our workforce safety.

## **Process Management**

### *Outpatient EP Processes*

The majority of our EP laboratory patients are seen in the outpatient setting by the LCA electrophysiologist that will be performing the procedure; the benefits of this continuity of care are obvious. However, there are times when the evaluating physician is not available to perform the procedure (in particular, the inpatient setting), and in these instances, there is a physician-to-physician patient briefing to ensure continuity of care. All EP consents are procedure-specific, and we attempt to have both patient and family members sign consents. Preprocedure order sets are filled out by the implanting electrophysiologist when a patient is consented for a procedure.

### *EP Laboratory Work Processes*

Standardization of work processes simplifies procedural setup and completion while allowing a system that permits identification of inefficiencies. All consents are procedure-specific, and standardization of procedure processes and order sets are essential. We have standardized pre- and post-implant order sets (Figure 2) that have been shown to improve care processes in other fields.<sup>3,4</sup> In addition, we have standardized post-implant intravenous heparin protocols for patients at high risk for thromboembolism post-procedurally (e.g., mechanical valves). Finally, we have standardized EP laboratory hospital discharge instructions, which offer particular instructions on wound care and device care/follow-up.

### *EP Laboratory Process Management*

We have performed Olympic averaging for EP device implant cases to optimize standard procedure scheduling times (e.g., dual-chamber pacemaker allotted 90 minutes and dual-chamber defibrillator allotted 120 minutes). These times are adjusted with physician discretion in certain complex circumstances (e.g., persistent superior vena cava or single-chamber devices). We monitor on-time starts for both initial anesthesia evaluation and electrophysiologist preprocedure timeouts. In particular,

GSH utilized Lean Six Sigma<sup>SM</sup> DMAIC approach to successfully improve our EP procedural start times. Finally, we follow Surgical Care Improvement Project (SCIP) guidelines by monitoring antibiotic administration time prior to skin incision. We also participate in the ACC NCDR<sup>®</sup> ICD Registry<sup>™</sup>.

## **Patient (and Customer) Focus**

### *Patient/Customer Engagement*

We first identified service offerings to meet and exceed our patients' expectations. This mandated that our EP device implant program offer the full gamut of procedures, including single-, dual-chamber, and biventricular pacemakers and defibrillators as well as implantable loop recorders. A culture of positive patient experiences is a focus of both Lebanon Cardiology Associates and Good Samaritan Hospital. This system-wide attitude is used as a means to keep us current with health care service needs and direction. Again, we routinely participate in patient health education outreach talks and have an active role in the American Heart Association's Lebanon Division (Dr. Williams and Mrs. Miksit serve on the AHA Board as the Medical Director and Hospital Liaison, respectively).

Obviously, patients are the main focus; however, we are cognizant of other stakeholders in the health care continuum. These include the patients' families, the community-at-large, payors, employers, and vendors. We have identified key patient/stakeholder communication mechanisms. The Good Samaritan Continuing Medical Education program focuses on both patient and provider education, and recently, Good Samaritan and Lebanon Cardiology Associates teamed to offer the 2010 Lebanon Valley Cardiovascular Symposium. Faculty from around the country were invited to discuss current state-of-the-art cardiovascular care issues with over 40 care providers in our region.

### *Voice of the Customer*

Our patient focus hinges on our ability to listen, determine the level of satisfaction, and use these data to improve our services. We routinely survey EP patients using Press-Ganey satisfaction surveys. The Press-Ganey scores allow us to identify our weaknesses and strengths, improve marketing, and identify opportunities for innovation. Indeed, our patient focus is evident, as we recently had a patient travel over 150 miles from Delaware for our EP services.

## **Results**

The strength of the system implemented via the partnership between Lebanon Cardiology Associates and Good Samaritan is only as strong as our outcomes. We recently published data from our first 250 consecutive patients who underwent device

implantation in the Good Samaritan Hospital EP laboratory starting with its inception July 2008.<sup>5</sup> Standard procedures for implantation were used. Pacemakers, defibrillators, and generator changes were included; temporary pacemakers were excluded. Major complications were defined as in-hospital death, cardiac arrest, cardiac perforation, cardiac valve injury, coronary venous dissection, hemothorax, pneumothorax, transient ischemic attack, stroke, myocardial infarction, pericardial tamponade, and arterial-venous fistula. Minor complications were defined as drug reaction, conduction block, hematoma or lead dislodgement requiring reoperation, peripheral embolus, phlebitis, peripheral nerve injury, and device-related infection. Complications included those from implant through 6 weeks post-implant. Table 1 depicts these data.

There were no major complications in ICD (n=50) or BiV ICD (n=64) implantations. The total major complication rate for all device implantations was 1 in 250 (0.4%). Minor complications occurred in 3 of 81 (3.7%), 2 of 50 (4%), and 2 of 64 (3.1%), pacemaker, ICD, and BiV ICD implantations, respectively. The total minor complication rate for all device implantations was 7 in 250 (2.8%). There were no major or minor complications in 55 generator changes. Part of our internal performance evaluation is comparing our device implant outcomes to those of comparable centers. We are the first single community hospital to report complication rates of device implantation and there are scant single academic centers that have reported complication rates. A single European center experienced 1.9% and 3.3% rates of major and minor complications for pacemaker implantations.<sup>6</sup> A single U.S. center experienced 2.4% and 4.0% rates of major and minor complications for defibrillator implantations.<sup>7</sup> Indeed, a recent report<sup>8</sup> revealed major complications related to *de novo* defibrillator implantations occurring in 4.1% of procedures. Moreover, we can compare demographics of our patient population to those at Mayo Clinic (Rochester, MN), though data on complication rates is not available. Of 179 patients undergoing ICD implantation in Olmsted County,<sup>9</sup> the mean age, ejection fraction, and creatinine were  $65 \pm 14$  years,  $0.35 \pm 0.16$ , and  $1.38 \pm 1.08$  mg/dl. Indeed, our more elderly patient cohort had lower ejection fractions with a similar level of renal insufficiency.

Biventricular defibrillators are the most complicated implant performed in EP labs, and complications are more common with these implants.<sup>10</sup> We found no single center reports for complication rates of biventricular defibrillators in community hospital or academic center EP programs, but we can compare our results to those from national trials (Figure 3). Patients at Good Samaritan undergoing biventricular ICD implantation were 8-9 years older with worse creatinine than those studied in national trials, yet experienced fewer major and minor complications.

## Discussion

### Value of Care

The success of our EP implant program is the result of a close collaboration between Lebanon Cardiology Associates and the Good Samaritan Hospital. This success also raises some important issues about the current “value” in healthcare. The first step to Performance-Incentive Programs is to shunt resources away from poorly performing centers towards higher-performing centers using currently available metrics. There continues to be a widespread misperception that community centers “cherry-pick” healthier patients from higher-performing academic centers.<sup>11</sup>

A nationally recognized academic center in Philadelphia receives a 4-fold higher reimbursement for a CABG than our center, despite their longer post-surgical length of stay and higher mortality (using risk-adjusted data).<sup>12</sup> A nationally recognized academic center near our facility receives ~39% higher Medicare reimbursement for an acute MI, despite our 95% door-to-balloon (DTB) time of less than 90 minutes (compared to the academic center’s DTB rate of 81%) with no difference in 30-day mortality.<sup>13</sup> As the first community hospital-based EP program to examine pacemaker and defibrillator implant demographics and outcomes, we revealed a more elderly, ill patients with overall rates of complication lower than national trials and available reports from single non-community centers.<sup>5</sup> Major complications have been estimated to cost an additional \$7,251 per implant<sup>14</sup>; a 75% reduction in major complications could save over \$60 million per year (using a conservative estimate of 100,000 ICD implants per year in U.S.).

### Accessibility of Care

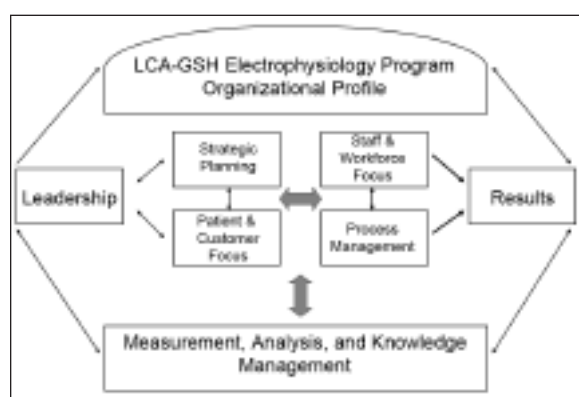
The demonstrated success of a focused community hospital EP implant program is a step toward improving accessibility of care to underserved areas. ICDs continue to be underutilized in small community hospitals due to disparities in resource allocation and regional variation of care providers.<sup>15</sup> Over 50% of patients in our community declined referral for defibrillator implantation prior to availability in our center. Now less than 5% of patients (with Class I indication for defibrillator therapy) decline implantation.

## Conclusion

The use of an established quality performance systems-based structure (Baldrige National Quality Program) enabled Lebanon Cardiology Associates and Good Samaritan Hospital to implement a highly performing EP device implant program. Contrary to current perceptions, these data suggest that our community center may subselect an elderly, ill patient population and can provide high quality, cost-effective, and more accessible care to patients distant from larger medical centers. We anticipate as the emphasis on performance in healthcare grows, there will be a shift in care patterns to “niche” centers that demonstrate a high level of performance.

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**Figure 1. LCA-GSH Electrophysiology Program Organizational Profile. This schematic is organized based upon the core principles of the Baldrige National Quality Program.<sup>1</sup> This structure affords us a framework to assess our program performance and adjust to provide continuous improvement of our processes and outcomes.**

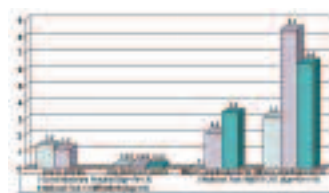
Figure 2 displays two standardized order sets from Good Samaritan Hospital. The top table is the 'Pre-Implant Standardized Order Set' and the bottom table is the 'Post-Implant Standardized Order Set'. Both tables are organized into columns for 'Order Set', 'Order', and 'Status'. They contain numerous medical orders, including medications, lab tests, and procedural instructions, all formatted consistently for ease of use by healthcare providers.

**Figure 2. Standardized pre- and post- device implant order sets.**

	PPM (n=81)	ICD (n=50)	BiV ICD (n=64)	Generator Changes (n=55)
Age (years)	77 +/- 10	67 +/- 12	74 +/- 9	80 +/- 10
Female	47%	16%	22%	56.6%
Creatinine (mg/dL)	1.2 +/- 0.5	1.3 +/- 0.8	1.4 +/- 0.6	1.2 +/- 0.5
Ejection Fraction	0.57 +/- 0.08	0.31 +/- 0.11	0.24 +/- 0.07	0.48 +/- 0.14
< 6 Weeks Major Complications	1/250 (0.4%). CVA in 81 yo female post-PPM day 7 where coumadin held for implant.			
< 6 Weeks Minor Complications	7/250 (2.8%). Lead dislodgements (n=2, LV and RA lead in separate patients), antibiotics reactions (n=2), phlebitis (n=2, subclavian and internal jugular thromboses in separate patients), and device infection (n=1, successfully explanted).			

- PPM = Permanent Pacemaker, ICD = Implantable Cardioverter Defibrillator, BiV = Biventricular, LV=left ventricular, RV=right ventricular, CVA=cerebrovascular accident, SVC=superior vena cava.
- The majority (98%) of implantations were performed via subclavian venous approach with 2.0% via cephalic cutdown. One ICD patient included as failed LV lead had persistent left SVC.
- Passive fixation (tined) leads used in 89% of RV pacing leads and 100% of LV pacing leads; the remainder of leads were active fixation.

**Table 1. Device implant patient demographics and early (≤6 weeks) implant complications.**



**Figure 3. Biventricular implantable defibrillator complication rates for Good Samaritan Hospital. A total of 64 patients underwent biventricular defibrillator implantation in our series. Placement of coronary sinus leads was successful in 97% of our cases compared to an average reported success rate of 90%. Complications at our center (Good Samaritan Hospital) were compared to those from national trials {(MADIT-CRT: *NEJM*, 2009;361:1329-1338), (COMPANION: *NEJM* 2004;350:2140-2150)}. Creatinine was not reported for the COMPANION Trial and there was no available published data for single academic centers.**