Establishing a Cryptogenic Stroke Care Pathway Utilizing the LUX-Dx™ Insertable Cardiac Monitor

Eugene Fu, MD[1], Vivek Rai, MD[1], Beth Loessin, MSN, APRN, FNP-C[1], Ananta Pandey, MBA, PMP[2], Karen Tomes, MA RN, PHN[2]
[1]OhioHealth Riverside Methodist Hospital, Columbus, OH [2]Boston Scientific, Arden Hills, MN

BACKGROUND

In 2020, 1 in 6 deaths from cardiovascular disease was due to stroke[1]. Every year, more than 795,000 people in the United States have a stroke[1]. Stroke-related costs in the United States came to nearly $53 billion between 2017 and 2018[1]. This total includes the cost of health care services, medicines to treat stroke, and missed days of work[1].

There are two major subtypes of stroke: hemorrhagic, accounting for 17% and ischemic, accounting for 83% of cases[2]. Cryptogenic strokes account for 15-40% of strokes[2]. Cryptogenic stroke (CS) refers to an ischemic stroke with no identifiable etiology[2]. As thromboembolism from atrial fibrillation (AF) can lead to ischemic strokes, outpatient cardiac monitoring for occult AF is now the standard of care. The detection of AF will lead to anticoagulation therapy that is superior to antiplatelet therapy for the secondary prevention of stroke[3]. Studies have shown that the longer patients are monitored, the more likely AF is detected[3]. In these studies, the rate of detection of AF increased with the duration of monitoring and reached 30% at 3 years using implantable loop recorders[3].

The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record the subcutaneous ECG (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx ICM uses dual-stage algorithms that detect and verify each potential arrhythmia before the health care team gets an alert. Detection parameters can be adjusted for each algorithm based on the chosen reason for monitoring. The LUX-Dx ICM System can be programmed to detect AF, Pause, Tachycardia, Bradycardia, and Atrial Tachycardia (AT), and the LUX-Dx ICM has separately programmable AT and AF algorithms, to provide actionable data and insights, resulting in meaningful clinical benefit. This device is also remotely programmable, so a patient is not required to come in to make critical adjustments.

Patients are provided with a Boston Scientific Mobile Device that includes a preloaded myLUX™ app that connects via Bluetooth® to their LUX-Dx ICM device. Each night—or as needed—the myLUX™ Patient App transmits device data to the LATITUDE Clarity™ Data Management System. The health care team can view and analyze the patient data, plus make key adjustments to detection programming that will update each time the app connects.

THE CHALLENGE

OhioHealth is an integrated delivery network in central Ohio with 35,000 Associates, Physicians and Volunteers serving communities in 47 counties. Health care services include 12 hospitals and 200+ ambulatory sites. Riverside Methodist Hospital is one of OhioHealth's largest hospitals with 1,059-beds. This is a teaching hospital and the first hospital in Ohio, and one of the first in the country, to earn first class designation as a Comprehensive Stroke Center by the Joint Commission in collaboration with the American Heart/American Stroke Association[4].

The Cardiology and Neurology care teams from OhioHealth Riverside Methodist Hospital recognized there were CS patients leaving the hospital without a plan for outpatient remote monitoring for cardiac arrythmias. Led by physician champions from Electrophysiology (Dr. Eugene Fu, MD) and Neurology (Dr. Vivek Rai, MD), a multidisciplinary team was convened to create a reliable CS care pathway with ICM monitoring for AF. Their patient centered goal was to address the need for arrythmia monitoring in CS patients leaving the hospital by enabling patient access to ICM monitoring.

This multidisciplinary team met monthly with representatives from the hospital and outpatient clinics. Members included EP and Neurology providers, APPs, nurses, remote patient monitoring staff, billing and quality management personnel. The agenda included case reviews, workflow mapping, data analysis, establishing patient criteria, increasing access by training APPs on LUX-Dx ICM insertions, reimbursement considerations, and patient/family education. The improvements implemented by this committee are listed below.

OhioHealth Cryptogenic Stroke LUX-Dx Cardiac Monitoring Improvements

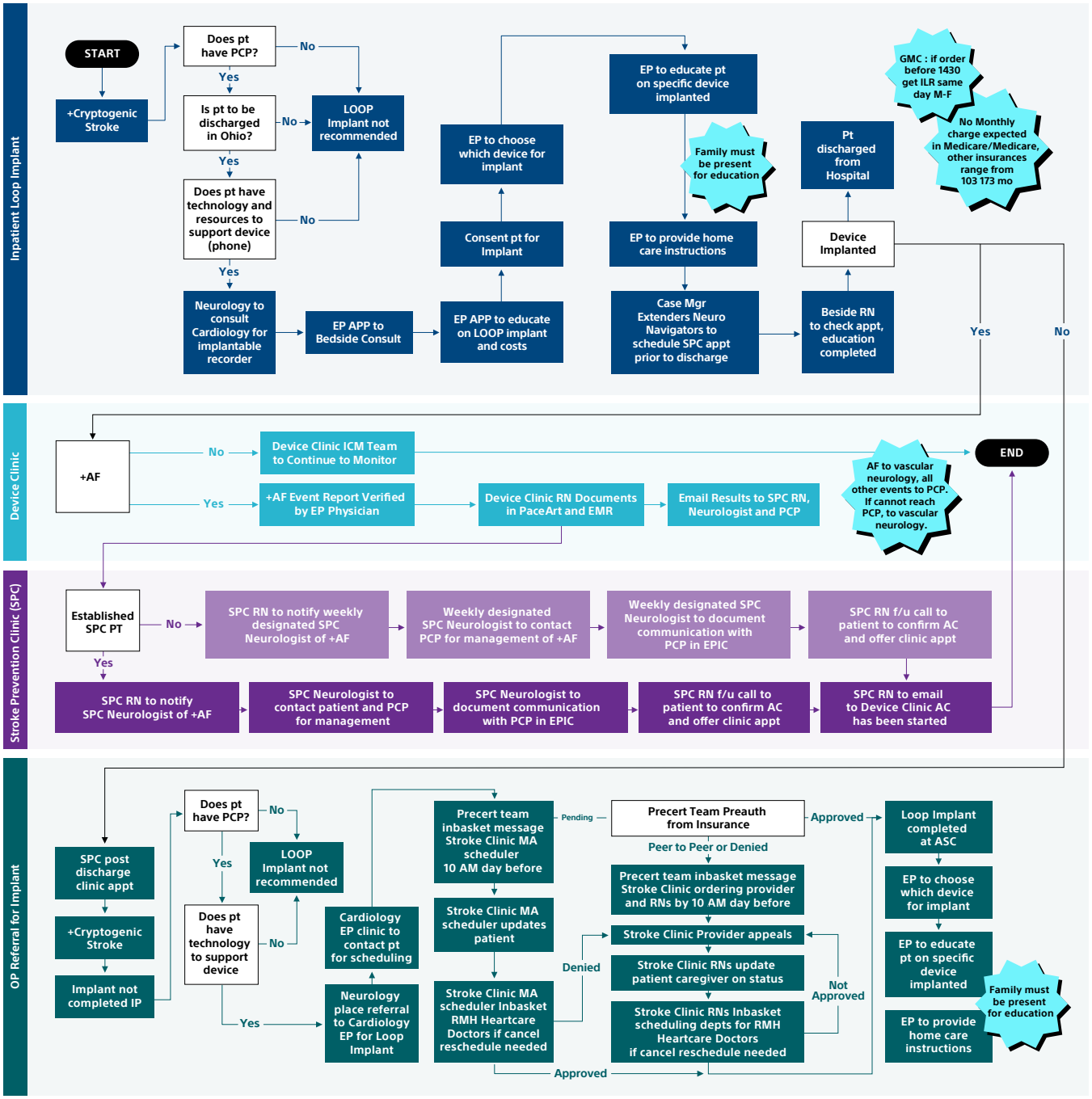
- Establish patient criteria for ICM insertion after standard testing e.g., CT, CT Angio, MRI, Echo
- Train APPs on LUX-Dx insertions at the bedside
- Create an EMR decision support tool to proactively identify ICM patients
- Provide Patient choice for OP AF monitoring with an ICM vs. a wearable heart monitor
- Receive prior authorization for ICM insertion and precertification for ICM remote monitoring
- Instruct Family to be present at the time of ICM insertion for education and follow-up plan
- Provide LUX-Dx ICM patient/caregiver education including the myLUX Patient Kit with Mobile Device
- Ensure Patient has EMR access to view remote monitoring documentation
- Notify Electrophysiology (Device) clinic to interpret and triage ICM data by technicians and exercise physiologists
- De novo AF is validated by EP who then notifies Neurology
- Neurology determines anticoagulation therapy for de novo AF
- Ongoing AF Management is established by Primary Cardiologist or Primary Care

OBSERVATION

The OhioHealth Cryptogenic stroke care pathway has been a result of a multidisciplinary collaboration between EP and Neurology. The new workflow with Advanced Practice Providers inserting the LUX-Dx ICMs has been a positive change impacting the coordination of outpatient cardiac monitoring when a patient experiences a CS. Based on a cost and clinical benefit analysis, most of these procedures are occurring in the hospital setting prior to patient discharge[5].

In a 6-month timeframe (September 2022 to February 2023), the OhioHealth team saw an increase of 54 CS patients with the LUX-Dx ICM System (271 to 325 patients). With the signal quality, dual stage algorithms and remote programming capabilities of the LUX-Dx ICM fitting seamlessly into their workflow, the OhioHealth care team is managing a growing population of CS patients with the LUX-Dx system.

CENTRAL OHIO Cryptogenic Stroke LOOP Implant Process Map 1.9.23



*OPG HVP PRECERT (Sharon Oden and Amanda Paladeni) **WQ 3587 (Scheduled Procedures) Sharon Oden : A-K Amanda Paladeni L-Z

> **"As APPs we continually strive to do what is best for both our patients and our organization. We worked closely with Neurology to increase awareness regarding the benefit of long-term monitoring for CS patients. With the subsequent rise in the number of patients referred for ICMs for CS, we saw a need to meet the increased demand with a multidisciplinary pathway that would outline a clear referral process and increase access to care by improving efficiency with the ultimate goal of ensuring that patients receive the appropriate arrhythmia monitoring."**
>
> - Beth Loessin, MSN, APRN, FNP-C

LUX-Dx™ Insertable Cardiac Monitor System

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "User's Manual" for more information on Indications, Contraindications, Warnings, Adverse Events, and Operator's Instructions.

INDICATIONS: The LUX-Dx™ Insertable Cardiac Monitor (ICM) is intended to monitor and record subcutaneous electrocardiogram (S-ECG). The recorded S-ECG is used for the clinical evaluation and diagnosis of cardiac arrhythmias. The LUX-Dx is indicated for use in patients that have a known heart condition and are at risk of developing an abnormal heart rhythm, or have symptoms that may suggest a cardiac arrhythmia, such as dizziness, palpitations, syncope, chest pain, and/or shortness of breath. The LUX-Dx has not been tested specifically for pediatric use.

CONTRAINDICATIONS: There are no known contraindications for the insertion of the LUX-Dx insertable cardiac monitor. However, the patient's particular medical condition may dictate whether or not they can tolerate a subcutaneous, chronically- inserted device. LATITUDE Clarity is contraindicated for use with any device other than a compatible Boston Scientific device.

WARNINGS: Concomitant use of the ICM system and implanted electro-mechanical devices [for example implantable neuromodulation/ neurostimulation systems, ventricular assist device (VAD), or implantable insulin pump or drug pump] can result in interactions that could compromise the function of the ICM, the co-implanted device, or both. Electromagnetic interference (EMI) or therapy delivery from the co-implanted device can interfere with ICM sensing and/or rate assessment, resulting in failure to monitor or record when needed. Verify sensing configuration, operation modes, surgical considerations and existing placement of all involved devices prior to any co-implant. To help prevent undesirable interactions, test the ICM system when used in combination with the co-implanted device. Do not expose a patient with an ICM system to diathermy. The interaction of diathermy therapy with an insertable cardiac monitor can damage the device and cause patient injury. The influence of medical equipment on implanted devices varies considerably according to the type of unit and energy levels employed. In situations where the risks are known, always interrogate the device and save data before the procedure, and check device function afterwards. Magnet model 6386 has been tested for use with the ICM system. Use of any other magnets has not been tested and could result in failure to initiate communication with the device. The magnet provided with the ICM system may cause interference with devices sensitive to magnetic fields such as hearing aids, pacemakers, and other implanted devices. It can also permanently disable some magnetic strip cards. Keep the magnet at least 15 cm (6 inches) away from items sensitive to magnetic fields, including the ICM device when the magnet is not being used to initiate communication between the device and the patient or clinic app.
The mobile devices and magnet are MR Unsafe and must remain outside the MRI site Zone III (and higher) as defined by the American College of Radiology Guidance Document for Safe MR Practices. Unless all of the MRI Conditions of Use are met, MRI scanning of the patient does not meet MR Conditional requirements for the inserted device, and significant harm to or death of the patient and/or damage to the inserted device may result. Scanning patients who have other MR Conditional devices is acceptable if all the MR Conditional requirements for each of the implanted devices are met. Do not conduct an MRI scan if any conditions or implants prohibit it. Advise patients to seek medical guidance before entering environments that could adversely affect the operation of the active implantable medical device, including areas protected by a warning notice that prevents entry by patients.

PRECAUTIONS: For specific information on precautions, refer to the following sections of the product labeling: General, Clinical Considerations, Sterilization and Storage, Insertion, Magnet, Device Programming, Environmental and Medical Hazards, Follow-up, Device Removal and Disposal.

POTENTIAL ADVERSE EVENTS: Potential adverse events related to insertion of the device may include, but are not limited to, the following: Device migration, erosion, foreign body rejection phenomena, formation of hematomas or seromas, infection, local tissue reaction, tissue damage. For a list of potential adverse events associated with MRI scanning, refer to the MRI Technical Guide. If any adverse events occur, invasive corrective action and/ or ICM system modification or removal may be required. 92496928 (Rev. B)

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Rhythm Management
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Medical Professionals:
1.800.CARDIAC (227.3422)
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1.866.484.3268

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