Device and Lead Advisories for Patients with Cardiac Implantable Electronic Devices (CIEDs)

Site Applicability:

St. Paul's Hospital Heart Rhythm Device Clinic

Scope:

Specialized

Health care professionals managing patients with cardiac implantable devices (CIEDs);

- CIED Clinic Staff (Clinical Nurse Leader, Registered Nurse and Device Technologists)
- Clinical Nurse Specialist (CNS), Patient Care Manager (PCM)
- Booking and Clerical Staff
- Electrophysiology Physicians, Implanting and follow-up physicians
- Hospital Management/Administration

Need to Know

Clinical Indication:

- This standard operating procedure (SOP) applies to the care of individuals with an implanted cardiac device where a CIED advisory has been issued. This includes pacemakers, defibrillators, associated leads and implantable cardiac monitors.
- Potential advisories include, but are not limited to: hardware or software malfunction leading to inappropriate cardiac device pacing, heating of the leads, current induction errors, movement or dislocation of the device and battery longevity malfunction.
- It is estimated that up to 33% of patients with a CIED will receive an advisory. Most CIED issues can be categorized as programming, device or lead malfunction.
- The term 'Class I Advisory' applies when complete affected device replacement should be considered because of the reasonable probability that the malfunction or potential malfunction could result in death or significant harm to the patient. The term 'Class II Advisory' applies when the advisory involves non-life-threatening malfunctions or potential malfunctions.
- Device or lead replacement is considered if the mechanism of malfunction is known and is potentially recurrent, if the risk of malfunction may potentially lead to patient death or serious harm, and if the risk of replacement is equivalent to or less than the risk of device or lead malfunction.

Procedures:

Communication and Implementation

The PCM, CNL or CNS and CIED Clinic MDs will schedule and hold meetings and educational in-services for relevant staff members related to this SOP in order to achieve successful dissemination and usage of these operations.

General Pathway of Device or Lead Advisory

Industry Advisory Notice

- The device manufacturer will notify the Health Canada of the advisory. Classification of the recall is determined by regulators of Health Canada – Class I or Class II Advisory
- A notice of the advisory will be distributed by the manufacturer to: Canadian Heart Rhythm Society (CHRS), Implanting Physicians and Device Clinics across Canada, and all affected patients on record with the manufacturer

SPH Device Clinic Action Item:

1. CIED Clinic Director, PCM and CNL will share the advisory notification and information with the appropriate CIED clinic team members.

Canadian Heart Rhythm Society (CHRS) Device Committee

- The CHRS Device Committee determines the advisory's classification or category: urgent (requiring a response within 2 business days); semi-urgent (requiring a response within 5 to 10 working days) or routine response to the received advisory (requiring a response within 20 working days).
- Recommendations are then distributed nationwide to their cardiology membership physicians, individual provincial funding bodies, including Cardiac Services British Columbia (CSBC).
- May develop a patient letter draft including clinical recommendations, which can be adapted to each individual clinic or physician office, based on the draft communication provided by the manufacturer

SPH Device Clinic Action Item:

1. CIED Clinic Director, PCM and CNL will disseminate information to all CIED clinic team members.
2. The CNL or designate will start the initial process of identifying affected patients using PaceArt™.

Cardiac Services British Columbia (CSBC)

- Will distribute the CHRS recommendations provincially (to implanting physicians, implant sites, Device Clinics).
- Will distribute a patient list to each CIED clinic or physician office with affected patients. This patient list is obtained through the provincial data base of all implanted device/leads throughout British Columbia.
- Will develop a patient letter draft (including clinical recommendations) which can be adapted to each individual clinic or physician office, based on the draft communication provided by the manufacturer.

SPH Device Clinic Action Item:

1. CIED Clinic Director, PCM and CNL will share information with the all members of the CIED clinic team.
2. CNL, PCM, CNS and CIED Clinic Director will meet and discuss implications on workflow and determine strategy in alignment with CHRS and CSBC directives.
3. CIED Clinic Director and/or PCM to liaise with CSBC leadership regarding available resources and reimbursement from the Cardiac Rhythm Disease Management (CRDM) contract agreements to inform operational planning.

SPH Heart Rhythm Device Clinic

Action Items:

1. SPH CIED Clinic Director will distribute the CSBC and CHRS communication to all members of the SPH Heart Rhythm team including; Device technologists and nurses, PCM, CNS, CIED MD trainees, Staff Physicians and Medical Office Assistants.
2. The CNL or designate will generate PaceArt™ patient list of potentially affected patients.
3. The CNL or designate will obtain an affected patient list directly from the manufacturer and CSBC to reconcile with PaceArt™ data.
4. The CNL or designate will access the 'Advisory Excel Tracking' template on the clinic W drive and enter patient information.
5. The CNS will draft the patient letter (adapted from the patient letter distributed by CSBC) and include Device Clinic specific contact information and clinical recommendations provided by CSBC.

6. CNL and/or PCMs will schedule team meeting with CIED Clinic Director to determine:
    a) Clinical action plan and recommendations for affected patients. This will include urgency of communication with patient (notice by mail or phone call) and clinical follow-up needs.
    b) Operational approach: available appointment spots and/or additional clinics scheduled if required, additional clinical or clerical workload needed, discuss reimbursement available from CSBC and/or vendor, determining if phone calls, emails or Canada Post will be used.
    c) Discuss feasibility/need to contact other CIED clinics/follow-up physician offices of affected patients (e.g. patients implanted at SPH but followed up elsewhere in BC).
    d) Determine clerical support required to distribute letters or assist with phone calls and assign tasks as appropriate.
7. The CNS to discuss approved strategy and progress at the subsequent Heart Rhythm Care Team Meeting.

Expected Outcomes

Patient with an affected device/lead will have appropriate care and management provided by the heart rhythm team.

Follow-up strategy will be modified as needed based on clinic operational and patient needs.

The CIED under advisory will be managed as per CHRS guidelines

Intervention/Algorithm/Pathway

- See Appendix A for graphical description of the above-described Device or Lead Advisory Pathway.
- See Appendix B for role specific checklist of tasks

Documentation

- Cerner and Paceart™ will be used for all patient clinical and device documentation
- Clinic staff members will use the Advisory Excel Tracking tool

Patient and Family Education

- Education for device/lead specific advisory and recommendations will be provided in the patient letter and/or by telephone and at in-person clinic visits.
- All affected patients will also be advised to refer to the CHRS website for additional information if required.

- All patients will be provided contact information for the Heart Rhythm Device Clinic to contact a team member for any questions or concerns.
- Eligible patients will be enrolled in remote monitoring and provided relevant education if required.
- Additional information and further discussion of potential risks associated with a CIED and the potential to receive an advisory will occur with the Electrophysiologist and/or implanting physician at the time of pre-procedure assessments and upon discharge following insertion.

References:

Anderson,S., Newsholme, A.M., Veasey, R., & Patel, N. (2019). 27 CIED advisories: impact and effect on pacing clinic and patient care *Heart* (**105):**A24-A25.Retrieved from https://heart.bmj.com/content/105/Suppl_6/A24

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CIED management. (n.d.). CIED Management | UpBeat.org - powered by the Heart Rhythm Society. Retrieved November 5, 2022, from https://upbeat.org/common-treatments/cied-management

Ottenberg, A. L., Mueller, L. A., & Mueller, P. S. (2013). Perspectives of patients with cardiovascular implantable electronic devices who received advisory warnings. *Heart & Lung : the journal of critical care*, *42*(1), 59–64. https://doi.org/10.1016/j.hrtlng.2012.09.007

Yee, R., Verma, A., Beardsall, M., Fraser, J., Philippon, F., & Exner, D.V. (2013). Canadian Cardiovascular Society/Canadian Heart Rhythm Society Joint Position Statement on the Use of Remote Monitoring for Cardiovascular Implantable Electronic Device Follow-up. *Canadian Journal of Cardiology*,(*29)6 644-651*, https://doi.org/10.1016/j.cjca.2012.11.036

Definitions:

Canadian Heart Rhythm Society (CHRS): a professional organization of Canada's heart rhythm specialists and allied health professionals, engaging in research and education programs in the field of cardiac electrophysiology and providing professional leadership and guidance in clinical practice, including the development of Positions Statements and National Data Registries.

Cardiac Implantable Electronic Devices (CIEDs): A surgically implanted device such as pacemakers, implantable cardioverter-defibrillators (ICDs), and cardiac resynchronization therapy defibrillators (CRT-Ds), for the purpose to prolong life in patients with cardiac conduction abnormalities, arrhythmias, and heart failure (Ottenberg et al., 2014).

Cardiac Services British Columbia (CSBC): a program established following the transfer of the adult tertiary cardiac provincial mandate and funding from the Ministry of Health Services in 2002 and operates within the Provincial Health Services Authority (PHSA); responsible for planning, coordinating, monitoring, evaluating and, in some cases, funding cardiac services across the province in collaboration with senior administrators and physicians in the regional health authorities

Class I Advisory: complete device replacement should be considered due to the risk of significant harm or death should the device malfunction

Class II Advisory: advisory which involves nonlife-threatening malfunctions or potential malfunctions

Device Advisory: CIED malfunctioning of system components, also known as *recall* and *safety event.*

Electrophysiologist (EP) Physicians: a cardiologist who focuses on testing for and treating problems involving irregular heart rhythms, also known as arrhythmias; they examine your heart's electrical system.

Paceart/Paceart Optima™: a monitoring system that compiles and manages patients' cardiac device data by collecting, storing, and retrieving data from programmers and remote monitoring systems from all major cardiac device manufacturers. Paceart™ captures data from implant, in-clinic checks, and remote transmissions, so whether a patient's data is generated in the hospital, the clinic, or by the patient's monitor, it can be consumed and stored in your Paceart database and sent to your EHR (electronic health record).

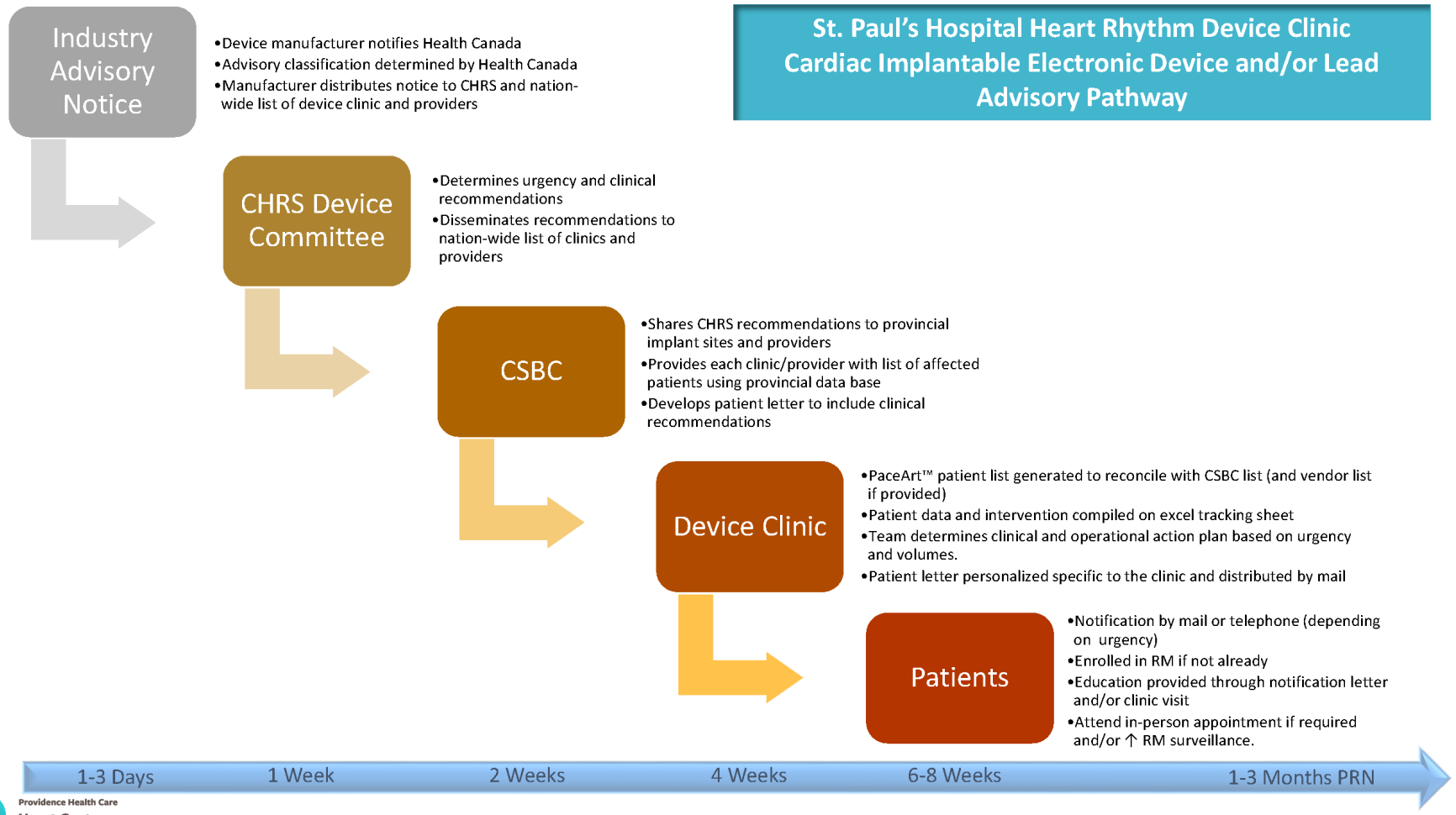
Remote Monitoring (RM): a complement to routine in-clinic assessments; records and stores all incoming data from the CIED, and the data is interpreted to assist in formulating patient specific care plans. Further these alerts can include information and warnings about device integrity (e.g., lead impedance), programming issues (e.g., insufficient safety margins for sensing or capture), or medical data (e.g. arrhythmia events, change in thoracic impedance).

Appendices

Appendix A: Advisory Pathway.

Appendix B: Role Specific Tasks

Appendix A: Advisory Pathway



Providence Health Care
Heart Centre

Developed by the St. Paul's Hospital Heart Rhythm Device Team, March 2023

Appendix B: Role Specific Tasks

Device Clinic Physician Lead

- ☐ Share notification of the advisory with all team members once received from Heath Canada and update team with recommendations provided by the CHRS and/or CSBC.
- ☐ After recommendations received from CSBC, attend team meeting with all device team members to determine care strategies and work-flow in alignment with CHRS directives.
- ☐ Distribute planning and recommendations for affected patients and disseminate any ongoing information to Heart Rhythm team members, cardiologists, Medical Office Assistants (MOAs), and program leads.

CNL or nurse designate

- ☐ Start the initial process of identifying affected patients using PaceArt
- ☐ Meet with team members (including physician lead, PCM, CNS) to determine care strategy based on CHRS and CSBC recommendations. And implications for work flow based on preliminary number of affected patients.
- ☐ Access the 'Advisory Excel Tracking' template on the clinic W drive and begin entering patient information obtained from PaceArt
- ☐ Request affected patient list from CSBC and device/lead manufacturer to reconcile with PaceArt™ data.
- ☐ Discuss with team the feasibility/need to contact other CIED clinics/follow-up physician offices of affected patients (consider clinical urgency and volume of affected patients).
- ☐ Maintain ongoing communication (in-person or via email) with PCM and Device Clinic Physician regarding:
  - Clinical action plan and recommendations for affected patients. This will include
  - Urgency of communication with patient (notice by mail or phone call) and clinical follow-up needs.
  - Operational needs of clinic; available appointment spots and/or blitz clinics scheduled if required, additional clinical or clerical workload needed, determining if phone calls to patients or Canada Post letters will be utilized.
- ☐ Continue to utilize Excel tracking spread sheet following intervention with affected patients (in-person or phone visit) to ensure there are no patients that are missed.

Clerical Support

- ☐ Perform tasks as delegated by the CNL such as mailing patient letter or assisting with phone calls to schedule in-person or remote appointments.
- ☐ Document confirmation of any contact with affected patients and mail-out of patient letters in the Excel tracking spreadsheet.

Patient Care Manager

- ☐ Distribute the advisory notification and information with the appropriate CIED clinic team members once received from Health Canada or Device Clinic Physician Lead or CHRS.
- ☐ Schedule a team meeting to determine care strategy based on clinical recommendations and operational needs.
- ☐ Secure nursing/technologist and clerical workload to support the clinic team as needed.
- ☐ Maintain ongoing communication with CNL and Physician Lead regarding addition support or workload needed.

Clinical Nurse Specialist

- ☐ Participate in team meetings to determine care strategies and interventions for affected patients and provide support as needed.
- ☐ Develop the patient advisory information letter based on the template draft distributed by CSBC.
- ☐ Share patient letter with clinic team for final approval and prepare document for mail-out.

APPROVALS		
Executive Director Acute Care		*April 12 2023*
DEVELOPERS/OWNER		
Clinical Nurse Specialist Heart Rhythm Program		*April 12 2023*

REVISION HISTORY			
Revision#	Description of Changes	Prepared by	Effective Date
OO	*Initial Release: April 12 2023*		*April 12 2023*