Recommendations for Permanent Pacemaker Services in Ontario

2011
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Introduction

The Cardiac Care Network of Ontario (CCN) serves an advisory role to the Ontario Ministry of Health and Long-Term Care (OMHLTC), Local Health Integration Networks (LHINs) and hospitals on matters pertaining to adult cardiovascular care. A key focus of CCN is on best practices and system-wide improvements to support quality of patient care and outcomes. The purpose of this document, Recommendations for Permanent Pacemaker Services in Ontario, is to promote a common standard of care for permanent pacemaker implant procedures and follow-up in Ontario. This document can serve as a resource for LHINs and hospitals to define expectations and metrics for performance to support quality practices in providing permanent pacemaker services. The CCN Heart Rhythm Working Group (HRWG), in collaboration with the Hospital Administrator Working Group has prepared these recommendations to guide the delivery of quality care for permanent pacemaker services in Ontario.

These practice recommendations are based on the expert consensus of the HRWG members, with input from a wide range of clinical and administrative stakeholders, incorporating all relevant scientific evidence from the medical literature. The HRWG realizes that there are many publications that address individual aspects of practice standards (i.e., pacemaker working group guidelines for pacemaker follow-up, the Heart Rhythm Society (HRS) guidelines for training, and the Canadian Heart Rhythm Society (CHRS) guidelines for waiting times). This document will summarize the literature and present an Ontario context to these published guidelines.

It is also a goal of CCN that all pacemaker patients in Ontario receive timely access to safe and appropriate pacemaker implantation and follow-up services consistent with published guidelines. In order to accomplish this goal, it is expected that some centres within the LHINs will require formal linkages with centres outside the LHIN to ensure access to service. Organization of pacemaker services in Ontario will also require careful attention to the geographic distribution of these services so that patient travel will be minimized.

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Pacemakers in Ontario

Surveys of pacemaker practices in the United States and elsewhere have shown a steady increase in pacemaker implantation rates over the past 15 years.\textsuperscript{4} A provincial (Ontario) survey conducted by CCN during the spring of 2010 demonstrated a 10% increase in permanent pacemaker volume over the past three fiscal years.

The CCN Permanent Pacemaker Survey engaged 178 adult acute care hospitals in Ontario. The survey was conducted by means of an on-line survey and had a 97% participation rate. In Ontario, there are currently 35 hospitals that implant permanent pacemakers. North Simcoe Muskoka (NSM) LHIN is currently the only LHIN in Ontario without pacemaker implant services. The hospitals in the NSM LHIN refer their patients mainly to Southlake Regional Health Centre Newmarket, while one hospital refers their patients to Grey Bruce Health Services – Owen Sound for permanent pacemaker services. All LHINs offer pacemaker follow-up services.

Implant Recommendations

\textbf{ORGANIZATION OF IMPLANT CENTRES}

Pacemaker services should be organized according to the level of service and expertise provided at each centre. In the consensus panel document created by CCN in 1998\textsuperscript{5} regarding quality and use of pacemakers and implantable cardioverter-defibrillators (ICDs) in Ontario, it was recommended that pacemaker centres be identified as Type I, Type II or Type III centres. The following presents the recommended class of centres according to level and volume of services.

\textbf{Type I Centre:} A Type I centre is a leading centre in the region with a Ministry of Health and Long-Term Care (MOHLTC)-funded electrophysiology program active in research, education and service coordination responsibilities. Type I centres implant the full range of devices, including single- and dual-chamber pacemakers, ICDs, cardiac resynchronization therapy (CRT) pacemakers and CRT-ICDs, with some also implanting loop event recorders. They perform at least 200 new implants per year (excluding replacement devices) and provide follow-up care for at least 500 patients with the full range of device types, including complex diagnostics. In order to maintain competency in permanent pacemaker implantation, each individual physician must implant a minimum of 50 new devices per year. Type I centres are involved in research specifically related to arrhythmia device therapies. Some Type I centres may perform laser lead extraction.

\textsuperscript{4}Birnie, D. et al. Reasons for Escalating Pacemaker Implants. \url{www.AJConline.org}: 93–97
\textsuperscript{5}CCN Consensus Panel on Population-Based Pacemaker/ICD Services in Ontario. Final Report and Recommendations Oct 1998
Type II Centre: Type II centres implant at least 50 new pacemakers per year (excluding replacement devices) with the capability and expertise to implant both single- and dual-chamber devices. For predictably difficult implants (such as history of difficult lead placement, congenital heart disease, lead upgrades, patients with extremes of BMI, etc.), Type II centres should consider consultation with their Type I centre prior to implant unless the implanter has significant experience in these situations. Follow-up care must be provided either at the Type II centre, with minimum of 200 follow-up patients per year, or at a designated arrhythmia device clinic to which they are closely associated. In order to maintain competency in permanent pacemaker implantation, each individual physician must implant a minimum of 50 new devices per year. Type II centres have linkages with Type I centres for patient referral and consultation for device system management, staff education, and research.

Type III Centre: Type III centres are also known as arrhythmia device clinics (ADC). A Type III centre does not implant devices but maintains a minimum caseload of 200 follow-up patients per year. The ADC maintains linkages with either a Type I or Type II centre for referral and consultation regarding device system management. At a minimum, a Type I centre will maintain linkages with the Type II and any associated ADCs for patient referral and consultation, staff education, and research.

Type I centres are listed in Appendix A, p. 33

SPECIFIC RECOMMENDATIONS:

1. Pacemaker centres should be identified within the LHIN as Type I, II, or Type III centres.
2. Type II and Type III centres must establish formal linkages with Type I centres for advanced device system management and consultation.
3. In order to maintain competency in permanent pacemaker implantation, a physician must implant a minimum of 50 new pacemakers per year.
4. The LHIN should carefully plan for the ongoing provision of service to device patients if one centre ceases either implant or follow-up activity. Simple redistribution to other centres may not be feasible due to volume overload or the distance that would be required for patients to travel in order to receive service. Consideration should be given to a service plan for pacemaker services within the LHIN to ensure ongoing access to follow-up care without interruption of recommended follow-up frequency.
Implant Setting, Equipment and Staffing

**IMPLANT SETTING AND EQUIPMENT**

It is recognized that the actual physical setting for the implant procedure may vary depending on the type of centre (Type I or II) and available resources. However, it is prudent to make some recommendations to ensure safe practice for device implantation.

Devices may be implanted in a variety of settings, including cardiac catheterization laboratories, electrophysiology laboratories, special procedure rooms and operating rooms. In all of these settings, operating room standards for scrub and prep areas, air exchange and staff attire must be observed. Implant settings must have the capacity to administer full anaesthetic delivery and resuscitation, including temporary pacing (external and temporary wire) and external defibrillation.

Dedicated blocks of time in the chosen setting for implant procedures, during regular daytime business hours, are recommended to ensure reasonable time for the implant within the allowable waiting times for this patient population, and to ensure the availability of appropriately trained hospital personnel. Stable implant capacity is essential for adequate planning to ensure trained staff is available for the procedure. Implanting after hours or on call is not recommended and should be the exception, rather than the norm, at each centre, unless it is a clinically urgent situation. Regardless of implanting hours, it is still essential to have adequately trained staff available for the procedure. How hospitals meet this recommendation is dependent on the processes the individual hospitals have in place to manage after-hour service delivery (i.e., on-call pacemaker staff).

Implant settings will require fluoroscopy with a mobile table or a mobile fluoroscopy system capable of delivering rotational views and storage of images for device implant. Both dual- and single-chamber devices should be available, as well as a full range of lead repair and replacement equipment. Patient-monitoring equipment should include cardiac monitoring, oxygen saturation, non-invasive and invasive blood pressure monitoring, and the device analyzer or programmer.

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Staffing Resources

The following factors should be considered for determining hospital personnel required to provide safe and comprehensive care during pacemaker implant:

- Anaesthesia is not required for all pacemaker implants. Conscious sedation should be available under the direction of the implanting physician. If no anaesthetist is present, a Registered Nurse (RN) wholly dedicated to patient monitoring duties is required.
- Hospital personnel trained in device management are required to operate the device analyzer, programmer, and to support the technical aspects of the implant procedure (device programming, responding to device and lead complications, etc.).
- Hospital personnel assisting with device implant need to be trained in operating room (OR) standard practices for patient management and sterile techniques.
- For information on the role of the device industry representative in the hospital, please refer to the section below, “The Role of the Device Industry Representative in the Hospital.”

**SPECIFIC RECOMMENDATIONS:**

1. OR standards for scrub and prep areas, air exchange, and staff attire must be observed during the device implant procedure.
2. Implant settings must have the capacity to deliver full anaesthetic and resuscitation, including temporary pacing (external and temporary wire) and external defibrillation.
3. A schedule of dedicated hours for the implant setting is recommended to ensure pacemaker implant within recommended waiting times for this patient population and to ensure the availability of appropriately trained hospital personnel.
4. Conscious sedation should be available under the direction of the implanting physician. If no anaesthetist is present, an RN wholly dedicated to patient monitoring duties is required.
5. Hospital personnel trained in device management are required to operate the device analyzer, programmer, and to support the technical aspects of the implant (device programming, responding to device and lead complications, etc.).
6. Hospital personnel assisting with device implant need to be trained in OR standard practices for patient management and sterile techniques.
Pacing Indications

Permanent pacemakers are the cornerstone of therapy for symptomatic bradycardia resulting from sinus node dysfunction; atrio-ventricular block; and high-risk, asymptomatic individuals. They also play a small role in the treatment of conditions such as carotid hypersensitivity and vasovagal syncope. Comprehensive guidelines outlining the appropriate indications for permanent pacemakers were published in 2008 by the joint AHA/ACC/NASPE working group and are fully endorsed by the CCN-HRWG. Since the publication of these guidelines, there has been no new scientific evidence to change the recommendations for the majority of pacing indications; however, for patients with vasovagal syncope, a subsequent randomized, blinded trial called into question the benefit of pacing that was seen in earlier un-blinded studies. As a result, pacing is no longer considered standard therapy for vasovagal syncope; although many clinicians feel that pacing may be useful in very select cases of vasovagal syncope. Additional randomized trials are currently evaluating different pacing algorithms and methods of patient selection for this condition.

It should be noted that the average age of Canadian pacemaker recipients is nearly 80 years and that many have significant co-morbid medical conditions, including dementia. Although pacemaker implantation is now considered minor surgery, the decision to implant a pacemaker must not be based solely on published guidelines for indications, but must involve a careful consideration of co-morbidities, surgical risk, quality of life and patient preference. In some patients with an accepted indication for pacing, but with important co-morbidities, the implantation of a pacemaker may not be appropriate.

Many patients requiring permanent pacing also have evidence-based indications for either an ICD or a CRT pacemaker. It is critical that physicians and surgeons implanting permanent pacemakers consider the possible need for these other two types of device therapy (Figure 1). Centres that do not implant ICD or CRT devices must maintain links and referral consultation services with a Type I centre to ensure appropriate care is provided to these patients.

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Figure 1: Suggested Algorithm for Device Selection in Patients with a Standard Pacing Indication

Standard Indication for Permanent Pacing

1. CAD and LVEF < 30%
2. NYHA II and III and LVEF < 35%
3. History of cardiac arrest or sustained VT

Consider ICD

1. NYHA III and IV heart failure
2. QRS width > 120 msec; and
3. LVEF < 35%

Consider CRT – ICD or CRT – pacemaker

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SPECIFIC RECOMMENDATIONS:

1. The decision to implant a pacemaker must not be based solely on published guidelines for indications, but must involve careful consideration of co-morbidities, surgical risk, quality of life and patient preference.

2. Centres that do not implant ICD or CRT devices must screen patients appropriately according to device indications and refer patients who qualify for these more advanced devices to a centre that implants these devices.

3. Centres that do not implant ICD or CRT devices must maintain links and referral consultation services with a Type I centre to ensure appropriate care is provided to these patients.

MODE SELECTION AND GENERATOR SELECTION

Mode Selection

Over the past 15 years, a number of large randomized trials have been performed to determine the ideal mode of pacing. The three main pacing modes currently available are single-chamber (ventricular), single-chamber (atrial), and dual-chamber. A recent patient-level meta-analysis of these trials has been published and shows a modest reduction in cardiovascular events with the more complex and expensive dual-chamber devices.\(^\text{12,13}\) Dual-chamber devices significantly reduced the incidence of atrial fibrillation in all patient groups, and they modestly reduced stroke, which was of borderline statistical significance. All-cause mortality, cardiovascular mortality and heart failure were not significantly reduced, nor was there a clear benefit in terms of quality of life.\(^\text{14,15}\) A further reduction in atrial fibrillation rates was also seen in the SAVE-PACE Trial\(^\text{16}\), which employed newer dual-chamber algorithms to reduce the frequency of ventricular pacing. As a result of these advances in dual-chamber technology and the increased sophistication of dual-chamber programming, dual-chamber devices are now preferred for the majority of patients with sinus node dysfunction; however, they may not be suitable for all patients with sinus node dysfunction, due to co-morbid illness, limited quality of life, and technical factors.


The benefits of dual-chamber pacing are viewed by the CCN-HRWG as both too modest and costly\textsuperscript{17} to justify recommending the universal use of these devices for all pacemaker recipients; however, the CCN-HRWG recognizes the scientific evidence for an increased role of dual-chamber pacemakers in a significant proportion of pacemaker recipients. Over the last decade in Ontario, the ratio of dual-chamber to single-chamber pacemakers has steadily increased and is currently implanted at a 6:4 ratio. Thus, the CCN-HRWG suggests that most centres should be implanting approximately 60% dual-chamber pacemakers. The CCN-HRWG also appreciates that there are marked differences in the characteristics of pacemaker recipients at the individual implanting centre in Ontario, which will also influence the choice of pacing mode; thus, a variance of the recommended 60% dual-chamber pacemaker implants of up to 15–20% is anticipated. Finally, the CCN-HRWG recognizes that the benefits of dual-chamber pacing are dependent on thoughtful programming of these devices – both at implant and during follow-up. Thus, centres performing follow-up must have expertise in current dual-chamber programming.

**Clinical Trials Related to Mode Selection**

There are several ongoing trials of pacing modes, which will be presented within the next five years. The *Danish Multicenter Randomised Study on Single-Chamber Atrial Pacing versus Dual-Chamber Pacing in Sick Sinus Syndrome* (DANPACE Trial)\textsuperscript{18} will help clarify the role of single-chamber atrial pacing in the treatment of patients with sinus node disease.

Similarly, the *Bi-Ventricular versus Right Ventricular Pacing in Patients with Atrioventricular Block Trial* (BLOCK-HF Trial)\textsuperscript{19} and *Bi-ventricular Pacing for Atrioventricular Block to Prevent Cardiac De-synchronization Study* (BIOPACE Study)\textsuperscript{20} will clarify the role of bi-ventricular pacing in patients with atrioventricular block, both with and without pre-existing heart failure.


\textsuperscript{18}Trial completed July 2010. Results not yet published

\textsuperscript{19}Trial is ongoing. Estimated study completion Feb 2013

\textsuperscript{20}Trial is ongoing. Estimated study completion July 2013
The Asymptomatic Atrial Fibrillation and Stroke Evaluation in Pacemaker Patients and the Atrial Fibrillation Reduction Atrial Pacing Trial and A Prospective Study of the Clinical Significance of Atrial Arrhythmias Detected by Implanted Device Diagnostics Trial (TRENDS Trial)\textsuperscript{21} will determine if brief episodes of an atrial arrhythmia, which can be accurately detected by modern dual-chamber pacemakers, are associated with an increased risk of stroke. Initial results of the ASSERT Trial have recently been presented and show that device-detected atrial tachyarrhythmias are strong predictors of stroke. Therefore, the implantation of an atrial lead can serve a valuable diagnostic role in patients who are felt to be at increased risk of stroke.

Finally, The Right Ventricular Apical versus Septal Pacing Trial (RASP Trial)\textsuperscript{22} should provide evidence of the importance of the right ventricular pacing site in long-term preservation of left ventricular (LV) function in patients that require ventricular pacing, and help to clarify the optimal RV pacing site.

The CCN-HRWG recognizes that new pacing technologies will continue to emerge that may mandate changes to current recommendations.

**Generator Selection Indications**

Once the decision has been made to implant a pacemaker, the clinician must decide which of the available pacemaker generators and leads to use.


\textsuperscript{22}Trail is ongoing. Estimated study completion Dec 2012
Table 1: Summary; Appropriateness of Single- or Dual-chamber Pacemakers for the Most Common Pacemaker Indications.

<table>
<thead>
<tr>
<th>PACEMAKER GENERATOR</th>
<th>SINUS NODE DYSFUNCTION</th>
<th>ATRIOVENTRICULAR BLOCK</th>
<th>NEURALLY MEDIATED SYNCOPE OR CAROTID SINUS HYPERSENSITIVITY</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single-chamber atrial pacemaker</td>
<td>No suspected abnormality of atrioventricular conduction and not at increased risk for future atrioventricular block</td>
<td>Not appropriate</td>
<td>Not appropriate</td>
</tr>
<tr>
<td></td>
<td>Maintenance of atrioventricular synchrony during pacing desired</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Single-chamber ventricular pacemaker</td>
<td>Maintenance of atrioventricular synchrony during pacing not necessary</td>
<td>Chronic atrial fibrillation or other atrial tachyarrhythmia or maintenance of atrioventricular synchrony during pacing not necessary</td>
<td>Chronic atrial fibrillation or other atrial tachyarrhythmia</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rate response available if desired</td>
<td>Rate response available if desired</td>
</tr>
<tr>
<td>Dual-chamber pacemaker</td>
<td>Atrioventricular synchrony during pacing desired</td>
<td>Atrioventricular synchrony during pacing desired</td>
<td>Sinus mechanism present</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Suspected abnormality of atrioventricular conduction or increased risk for future atrioventricular block</td>
<td>Atrial pacing desired</td>
<td>Rate response available if desired</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Rate response available if desired</td>
<td>Rate response available if desired</td>
<td></td>
</tr>
<tr>
<td>Single-lead, atrial-sensing ventricular pacemaker</td>
<td>Not appropriate</td>
<td>Desire to limit number of pacemaker leads</td>
<td>Not appropriate</td>
</tr>
</tbody>
</table>
SPECIFIC RECOMMENDATIONS:

1. Implanting centres must either accommodate a significant proportion of dual-chamber pacemaker implants (target 60%, with a 15–20% variance) or have defined and consistent referral strategies so that patients requiring dual-chamber pacing are appropriately implanted.

2. Decisions on mode and generator selection should be made by a physician trained in pacemaker follow-up after assessment of the indication and the patient case, as well as assessment of indications for more complex devices. This may be the implanting physician. In some centres, where the implanting physician does not follow pacemaker patients, the pacemaker follow-up physician should be involved in device selection.

3. Centres performing follow-up must have expertise in current single- and dual-chamber programming and have on site the most current device programmers available to meet the needs of the different pacemakers available.

Complications Monitoring and Benchmarking

The implantation of a cardiac pacemaker has become a “routine” procedure, often with same-day discharge of the patient and with a very low rate of peri-operative and post-operative complications. However, it is still a surgical procedure with potential complications, including infection, bleeding, hematoma, lead dislodgement, pneumothorax, hemothorax and pericarditis, pericardial effusion, and tamponade. While complete elimination of such complications is impossible, centres should strive for low, yet realistic complication rates. This necessarily implies that pacemaker implant centres must develop and maintain a system for tracking complication rates, and that they routinely review these data and have a strategy in place to address higher-than-expected occurrences of complications or increasing rate trends. The format of this surveillance system is dependent on the size and resources of the implant centre and could be anything from a manual “pen-and-paper” review of implants to the use of electronic databases and registries.
There are few published benchmarks for pacemaker complication rates in the community. Clinical trials provide us with one source of benchmarks (Table 2); however, it should be noted that patients in clinical trials are often not representative of the general population, and in many cases are healthier. One might therefore anticipate that community rates of these complications may be slightly higher than observed in clinical trials. Community-level data will soon be available for the province of Ontario for ICDs, as part of the ICES-ICD Registry; however, similar data for pacemakers are not forthcoming.

Finally, it is clear that complication rates will vary from centre to centre, due to differences in patient population, patient acuity and the presence of trainees (interns, residents and fellows). For example, among patients receiving chronic oral anticoagulation, even with temporary interruption of this therapy, pocket hematoma rates may be as high as 5–10%. Similarly, patients undergoing pulse generator replacement may have a two-fold risk of infection compared to new implants. For these reasons, routine auditing of complications will have a limited value for detecting small-to-moderate differences in complication rates between centres, but will be of greater use to follow trends within individual centres. Individual centres will still be able to use these published complication rates as benchmarks.

The conduction of routine complication audits is critical for identifying problems with the implant facility (i.e., increased infection rate), implant hardware (i.e., excessive lead dislodgements or perforations) and management protocols (i.e., peri-operative anticoagulation). Practice audits are an important part of professional development for physicians and surgeons involved in pacemaker implantation and qualify as Section 5 activities for the Royal College of Physicians and Surgeons’ “Maintenance of Certification” program. The CCN-HRWG would like to propose standard definitions for the common complications to facilitate the collection of complication data in a standardized format across the province. The following complications are felt to require definition:

1. Dislodgement – macroscopic or microscopic movement of a lead requiring surgical repositioning or replacement of the lead, or resulting in the inability to pace and/or sense for leads left in place.
2. Significant Pocket Hematoma – bleeding into a pacemaker/ICD pocket sufficient to require surgical/percutaneous evacuation, interruption of oral anticoagulation, or emergency room visit or hospitalization for management.
3. Infection (Deep) – infection requiring surgical removal of device and/or leads or treatment with intravenous antibiotics.
4. Infection (Superficial) – an infection limited to skin and not involving the pocket, which resolves with observation or treatment with oral antibiotics. Typical examples would include “stitch abscesses.”

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Table 2: Complication Rates for Ventricular and Atrial-Based (Atrial or Dual-Chamber) Pacing (excluding MOST and PASE studies)*

<table>
<thead>
<tr>
<th>COMPLICATION</th>
<th>VENTRICULAR (N = 2598)</th>
<th>ATRIAL-BASED (N = 2216)</th>
<th>P-VALUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pneumothorax</td>
<td>1.1 % (29)</td>
<td>1.6 % (35)</td>
<td>0.17</td>
</tr>
<tr>
<td>Hematoma</td>
<td>0.3 % (7)</td>
<td>0.1 % (3)</td>
<td>0.36</td>
</tr>
<tr>
<td>Pericardial tamponade**</td>
<td>0 % (0)</td>
<td>0 % (0)</td>
<td>NS</td>
</tr>
<tr>
<td>Peri-operative death</td>
<td>0.5 % (13)</td>
<td>0.7 % (15)</td>
<td>0.34</td>
</tr>
<tr>
<td>Lead dislodgment</td>
<td>0.8 % (21)</td>
<td>2.1 % (47)</td>
<td>0.0001</td>
</tr>
<tr>
<td>Loss of capture</td>
<td>0.2 % (5)</td>
<td>0.5 % (11)</td>
<td>0.08</td>
</tr>
<tr>
<td>Pacemaker infection</td>
<td>0.5 % (14)</td>
<td>1.2 % (27)</td>
<td>0.012</td>
</tr>
<tr>
<td>Lead fracture</td>
<td>2.9 % (75)</td>
<td>3.2 % (72)</td>
<td>0.50</td>
</tr>
<tr>
<td>Implant complication rate ***</td>
<td>3.2 % (75)</td>
<td>6.2 %</td>
<td></td>
</tr>
</tbody>
</table>

* Data on each complication not available for all included studies.
** 3 cases (0.1 %) in overall database – including PASE and MOST studies.
*** Total number of complications (excluding lead fracture) divided by number of patients in each group.

SPECIFIC RECOMMENDATIONS:

1. Implanting centres must maintain a record of complications based on the above-mentioned definitions and review trends yearly, or more frequently, depending on implant volumes.
2. Implanting centres should benchmark against published complication rates and review individual centre trended rates to identify quality improvement strategies for discrepancies or significant trends.
3. ADCs must communicate complications to the implanting centre to ensure all complications are documented for quality assurance purposes and appropriate action is taken to rectify the complication.
4. Antibiotic prophylaxis is required for all pacemaker implants according to the centre-specific protocol.

Resource Requirements for Pacemaker Clinics

The Canadian Working Group on Cardiac Pacing published guidelines in 2000\textsuperscript{26} to direct appropriate and comprehensive care for patients with permanent pacemakers. Most of these guidelines still apply, with updates to match current technology. Included here are some specific recommendations that assist with planning and monitoring the adequacy of pacemaker services.

**HUMAN RESOURCES**

As presented in earlier sections, ongoing clinical trials highlight the emerging potential of pacemakers; however, they also stress the need to have trained personnel who can properly interpret findings. Appropriate human resources required for pacemaker follow-up appear in published guidelines.\textsuperscript{27} The following are expected resources to be provided for each type of centre.

**Medical Director or Most Responsible Physician (MRP):** All centres providing device follow-up must have a Medical Director or MRP identified. The Medical Director/MRP is responsible for ensuring that all aspects of pacemaker care meet established guidelines (adherence to pacemaker implant clinical guidelines, frequency and content of follow-up, policies and procedures, database and clinical records, outcomes monitoring, adequate supervision of nursing and allied health professionals (AHPs) and quality improvement initiatives). In Type I or II centres, this accountability may be shared with a Clinical Manager. In addition, the Medical Director/MRP is responsible for the scope of practice of the nursing and AHPs, including the Delegation of the Controlled Act of Application of Energy (pacemaker follow-up/threshold testing). Medical Directors or MRPs of ADCs should have an established link with a Medical Director in a Type I or II centre for assistance with policies, procedures and standards of care. Medical Directors should ideally have a fellowship in cardiology and have demonstrated competence in cardiac pacing; however, we do recognize this is not always possible in smaller centres, where the implanting physicians are often internists and/or general surgeons. The physician in charge of ADCs that do not have these qualifications should establish a link with a Medical Director in a Type I or Type II centre.

\textsuperscript{26}Fraser, J. et al. Guidelines for pacemaker follow-up in Canada: A consensus statement of the Canadian Working Group on Cardiac Pacing. \textit{Can J Cardiol} Mar 2000: 16(3)

\textsuperscript{27}Fraser, J. et al. Guidelines for pacemaker follow-up in Canada: A consensus statement of the Canadian Working Group on Cardiac Pacing. \textit{Can J Cardiol} Mar 2000: 16(3)
Pacemaker Follow-up Physicians and/or Nurse Practitioners (NP): These physicians and NPs provide support to the nursing and AHPs performing device follow-up. They must be clearly identified and immediately accessible within a reasonable timeframe to respond to issues during clinic hours. As per guidelines, these individuals should have demonstrated competency in cardiac pacing, and perform at least 50 follow-ups per year.\(^{28}\) The programming of devices is the responsibility of the pacemaker follow-up physician, and may be delegated through use of medical directives to NPs, RNs or AHPs, with clear outline of the scope of practice. NPs may function with greater independence and responsibility for a wide range of device management, but currently require delineation in scope of practice through medical directives or practice agreements, supported by the MRP.

Registered Nurses and Allied Health Professionals: The role and knowledge requirements of the RN and AHP in device follow-up are outlined in published guidelines.\(^{29}\) Adequate resources must be available to provide quality care according to the guidelines. In addition, surge capacity must be built into staffing to accommodate additional demand of service in relation to advisory management.

a. **Staffing Mix:** Pacemaker Clinic (and Pacemaker OR) staff comes from a range of health care backgrounds, including technician, technologist and nursing, and all groups may have a role to play in device management. A clear scope of practice must be identified in clinic policies and procedures, and must be appropriate to the level of knowledge and understanding of the professional in the setting. This may differ depending on the educational preparation of the individual staff member. Guidelines require symptom assessment and targeted physical assessment of patients during a pacemaker clinic follow-up that is within the scope of nursing. If the AHP is not trained in these aspects, then this must be provided by the pacemaker follow-up physician/NP, or an RN on the team. It is suggested that a mix of RN and Technologist staff will best meet the needs of this patient population.

b. **Educational Preparation:** Educational preparation for RNs and AHPs working in the heart rhythm environment is varied but must consist of a strong background in cardiovascular physiology, electrocardiography and rhythm interpretation. As there are currently no accredited programs to prepare nursing and AHPs specifically for device management, a period of intensive training is required, which may take three months of direct supervision, and up to six months of mentorship, with a competent RN, AHP, or physician mentor, with regular practice at least two days per week. Opportunities to attend industry-sponsored training seminars should be provided to the RN or AHP who is learning device management. Demonstration and documentation of competence in the concepts and content of pacemaker follow-up


(continues on next page)
is required prior to independent practice. In addition to testing, documentation and demonstration of threshold testing is required as a delegated medical act (Controlled Act Application of Energy). It is highly encouraged that device clinics support RNs and AHPs to attain Heart Rhythm Society Certification (Certified Cardiac Device Specialist – CCDS) in device follow-up within three years of practice, and it is anticipated that this may become the standard to maintain competency.

Access to continuing education is essential to ensure maintenance of competencies in device management, due to the rapidly changing technologies. RNs and AHPs should continue to follow patients of all types (single- and dual-chamber) on a regular basis to maintain competence.

c. **Clerical**: Resources should be adequate to maintain complete patient records, timely scheduling and database management to ensure patients are not lost to follow-up.

### Documentation and Database Requirements

Each follow-up centre must have plans for documentation of care in adherence to published guidelines. In addition, each centre must have sufficient database resources to enable easy and timely access to patient data in the event of device or lead advisory. Documentation and database records must be in adherence to provincial and federal health information privacy legislation.

**EQUIPMENT RESOURCES**

Physical and equipment resources at the centre should be sufficient to support pacemaker follow-up and be consistent with published guidelines. Further diagnostic support should be available, either on site or through referral within a reasonable geographic distance. These requirements for diagnostic support may include radiology, exercise treadmill-testing, echocardiography, and tilt table testing. Electrophysiology consultation, studies and ablation may be required in certain cases through referral to a Type I centre. ADCs may be located as a stand-alone clinic, as long as they conform to the service plan requirements.

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SPECIFIC RECOMMENDATIONS:

1. All centres providing device follow-up must have a Medical Director or MRP identified.
2. The physician or NP providing support to the follow-up clinic must be clearly identified and immediately accessible within a reasonable timeframe to respond to patient and device issues during clinic hours.
3. Adequate resources must be available to provide quality care according to guidelines. In addition, surge capacity must be built into staffing to accommodate additional demand of service in relation to advisory management.
4. Pacemaker clinic (and pacemaker OR) staff come from a range of health care backgrounds, including technician, technologist and nursing, and all groups may have a role to play in device management. A clear scope of practice must be identified in clinic policies and procedures, and must be appropriate to the level of knowledge and understanding of the professional in the setting.
5. Educational preparation for RNs and AHPs is varied but must consist of a strong background in cardiovascular physiology, electrocardiography and rhythm interpretation.
6. It is highly encouraged that device clinics support RNs and AHPs to attain Heart Rhythm Society Certification (Certified Cardiac Device Specialist – CCDS) or equivalent, in device follow-up within three years of practice.
7. Access to continuing education is essential to ensure maintenance of competencies in device management. RNs and AHPs should continue to follow patients of all types (single- and dual-chamber) on a regular basis to maintain competence.
8. Clerical resources should be adequate to maintain complete records, scheduling and database management to ensure patients are not lost to follow-up.

Content and Frequency of Comprehensive Device Follow-up

The MRP and, in some cases, the Clinical Manager share accountability for quality of care in the device follow-up clinic. In 2008, the Heart Rhythm Society published a consensus document description of techniques, indications, personnel, frequency and ethical considerations for cardiovascular implantable electronic device follow-up. Hospital policies and procedures for device follow-up should reflect adherence to these guidelines.

Patients who have significant cardiac symptoms, identified at the time of device follow-up, may require either assessment within the follow-up clinic by a qualified practitioner, or appropriate referral to another health care provider (such as their cardiologist, heart failure clinic or their family physician). Sufficient information should be provided to these other health care providers to ensure comprehensive care and adequate triage of the patient to appropriate follow-up.

**CONTENT OF FOLLOW-UP**

Direct patient follow-up is desirable, rather than trans-telephonic monitoring, which only provides basic device battery information and function. However, trans-telephonic monitoring is a valuable resource for those patients who live in remote geographical areas and can get to the pacemaker follow-up clinic only periodically. Emerging technology allows for more complete remote monitoring in some centres, but in the absence of such technology, in-clinic visits should be regularly scheduled according to guidelines.

The major goals of permanent pacemaker monitoring programs can be divided into four categories: patient-related, device-related, disease-related and communication-related objectives. These include:

- Providing patient and family education and reassurance
- Maintaining patient records and institutional databases
- Ensuring that device clinics have access to the patient’s health history, either through a hospital chart or a history documented on the device chart, including medication reconciliation when necessary
- Assessing and optimizing permanent pacemaker system performance and safety;
- Identifying and correcting any device system abnormalities
- Anticipating the need for, and planning elective permanent pacemaker replacement when feasible
- Monitoring cardiac arrhythmias and physiologic parameters
- Communicating information related to pacemaker replacement, when monitoring, to involved physicians and other health care providers where appropriate
Table 3: Four Categories of Pacemaker-Monitoring Goals

<table>
<thead>
<tr>
<th>PATIENT-RELATED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Optimize the patient’s quality of life</td>
<td></td>
</tr>
<tr>
<td>■ Optimize pacemaker/ICD system function to meet the patient’s clinical requirements</td>
<td></td>
</tr>
<tr>
<td>■ Identify patients at risk and initiate appropriate follow-up with field safety corrective action/safety alerts</td>
<td></td>
</tr>
<tr>
<td>■ Triage non-pacemaker-related health problems and make appropriate referrals</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PACEMAKER-RELATED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Document appropriate pacemaker function</td>
<td></td>
</tr>
<tr>
<td>■ Identify and correct abnormal pacemaker behaviour</td>
<td></td>
</tr>
<tr>
<td>■ Maximize pulse generator longevity while maintaining patient safety</td>
<td></td>
</tr>
<tr>
<td>■ Identify pacemakers approaching end of battery life to identify leads at risk of failure and to organize pacemaker replacements in a non-emergent manner</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DISEASE-RELATED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Document the nature and frequency of arrhythmias over time and correlate with patient symptoms to determine the appropriateness of pacemaker response to these arrhythmias</td>
<td></td>
</tr>
<tr>
<td>■ Document (where feasible) hemodynamic status, transthoracic impedance, patient activity and other physiologic parameters over time as part of chronic disease monitoring in heart failure</td>
<td></td>
</tr>
<tr>
<td>■ Monitor response to therapy</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COMMUNICATION-RELATED</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>■ Maintain a patient database</td>
<td></td>
</tr>
<tr>
<td>■ Timely communication with the patient and relevant health care providers of pacemaker and disease-related information</td>
<td></td>
</tr>
<tr>
<td>■ Provide technical expertise and education to colleagues, patients and community</td>
<td></td>
</tr>
</tbody>
</table>

**Automated Device Functions**

Traditionally, at each visit, the function of the device, thresholds and sensing have been assessed. However, devices have become increasingly complex in terms of both automation and diagnostics. Each clinic should develop standards for use of these automated functions (i.e., threshold assessment and sensing). It may not be necessary to perform specific threshold and sensing testing during the monitoring period in devices that have these capabilities. Assessment of trending data of lead performance, and all automated testing, is essential.

DIAGNOSTICS

Current generation devices have advanced diagnostics that help track clinical situations. RNs, AHPs and follow-up physicians/NPs need to be fully aware of the diagnostics in each device in order to use them to full advantage in optimizing device function and enhancing patient care. Some special cases appear below:

A. Atrial Fibrillation (AF): Dual-chamber devices have the ability to track AF events and provide diagnostics as to frequency and duration of AF episodes. True AF should be confirmed by electrogram (EGM) evaluation in devices that can save these episodes (or by holter monitoring, event or loop recorders in devices that do not have this capability) to ensure that atrial over-sensing is not misinterpreted as AF. In patients at risk for AF (patients with hypertension, the elderly, coronary artery disease or heart failure) the mode switch should be enabled unless this interferes with required device function. Although no current research exists to determine the burden of AF that requires anticoagulation, the ASSERT Trial is ongoing and is expected to help answer this question. Until this is available, communication within the patient’s health care team (cardiologist, internist, family physician) is essential to assess stroke risk and need for anticoagulation. Device clinics must either relay the information to the patient’s physicians, or treat the patient according to this risk assessment.

B. Right Ventricular Pacing: The DAVID Trial\textsuperscript{33} identified the risks of right ventricular pacing in patients with low EF, causing worsening dysynchrony and heart failure. In patients who have adequate AV conduction, every attempt should be made to ensure right ventricular pacing is minimized, especially in patients with compromised EF. Devices have various algorithms to encourage intrinsic conduction, and the amount of right ventricular pacing should be assessed and algorithms optimized at each visit. The target for minimal right ventricular pacing is less than 40%.

C. Pacemaker Syndrome and Chronotropic Incompetence: In patients with single-chamber devices who exhibit signs of pacemaker syndrome (fatigue, lethargy, palpitations), consideration should be given to upgrading these patients to dual-chamber devices, once all other causes are ruled out. In patients with dual- or single-chamber devices, with signs and symptoms of chronotropic incompetence (exercise intolerance, flat histograms with minimal heart rate excursion, symptomatic with sustained exertion), consideration should be given to the addition of rate response algorithms. This may require exercise treadmill testing to verify poor heart rate excursion, or to assess optimal rate response function of the device and settings.

\textsuperscript{33} Willkof, B.L. et. al. Dual-Chamber Pacing or Ventricular Backup Pacing in Patients With an Implantable Defibrillator. The Dual Chamber and VVI Implantable Defibrillator (DAVID) Trial. \textit{JAMA} Dec 2002: 288(24): 3115–23
SPECIFIC RECOMMENDATIONS:

1. Implanting centres must have appropriately trained pacemaker clinic staff who can conduct current dual-chamber programming and appropriately interpret pacemaker diagnostics.

2. Clinics should have established guidelines for optimizing programming and/or referral to the MRP/NP for assessment of complex diagnostics.

FREQUENCY OF FOLLOW-UP

Many factors determine the timing and frequency of follow-up, and established guidelines exist to guide appropriate frequencies. Adequate system resources need to be in place to ensure follow-up schedules meet these guidelines, allowing for additional unplanned visits due to patient or device status (see Table 4), and in some cases, for advisory management. A system for tracking regular follow-up of patients ensures patients are not lost to follow-up, and is recommended.

Follow-up frequency is generally divided into three main categories with the following minimal follow-up frequencies:\textsuperscript{34}

- **Post Implantation**: Within 72 hours after pacemaker implantation
- **Early Surveillance Period** (2–12 weeks post implantation): If there is follow-up to manage sutures at 2 weeks, a second visit for output reduction may be required at 12 weeks
- **Maintenance Period** (6 months to first indicator of battery depletion): Yearly follow-up
- **Intensified follow-up** (Initial Signs of Battery Depletion to Battery Change): Every 1–3 months (consult device-specific manufacturer)

\textsuperscript{34}Fraser, J. et al. Guidelines for pacemaker follow-up in Canada: A consensus statement of the Canadian Working Group on Cardiac Pacing. *Can J Cardiol* Mar 2000: 16(3)
Table 4: Factors Determining the Type and Frequency of Pacemaker Follow-Up

<table>
<thead>
<tr>
<th>PATIENT-RELATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stability of rhythm and cardiovascular symptoms</td>
</tr>
<tr>
<td>Specific issues requested by the patient, family or local physician to the pacemaker clinic</td>
</tr>
<tr>
<td>Change in anti-arrhythmic or heart failure therapy</td>
</tr>
<tr>
<td>High or unstable pacing thresholds</td>
</tr>
<tr>
<td>Frequency of arrhythmia episodes</td>
</tr>
<tr>
<td>Patient’s inability to accurately report symptoms</td>
</tr>
<tr>
<td>Planned surgeries/medical interventions</td>
</tr>
<tr>
<td>Patient distance from follow-up clinic</td>
</tr>
<tr>
<td>Other medical/social factors</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PACEMAKER-RELATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Historical reliability of the pacemaker system (consider lead and pulse generator independently)</td>
</tr>
<tr>
<td>Age of pacemaker</td>
</tr>
<tr>
<td>Programmed parameters (factors that influence battery longevity, pacing thresholds, pacing frequency, frequency of shock therapy)</td>
</tr>
<tr>
<td>Complexity of the pacing system</td>
</tr>
<tr>
<td>Arrhythmia/heart failure diagnostics (including physiologic monitoring, transthoracic impedance, patient activity)</td>
</tr>
<tr>
<td>Medications that may influence pacing threshold, arrhythmia detection</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DISEASE-RELATED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency and severity of symptoms</td>
</tr>
<tr>
<td>Changes in cardiovascular therapy</td>
</tr>
</tbody>
</table>
Remote Monitoring

New technology supporting complete remote acquisition of follow-up data from the patient’s device is emerging as an acceptable strategy to enhance patient access to care, especially in remote areas. Patients download device information through their phone line to a secure Internet site that the device-monitoring personnel can access. In some cases, this may enhance the support of arrhythmia device clinics by Type I or II centres. Clinic policies should clearly identify the parameters and procedures for remote monitoring. Patients may be asked to sign a contract, to ensure they are aware of the appropriate process when downloading information, and to ensure that a competent individual is available to review the information within a reasonable period of time. In addition, clear practice regarding communication with the patient following review of their device information should be identified.

Most pacemaker manufacturers now have systems in place to allow remote pacemaker follow-up. The real advantages of these systems are the ability to have more-regular but less-intrusive follow-up and the potential to troubleshoot in a more expeditious manner. Programming of devices remotely carries a number of regulatory issues and concerns with safety, and for those reasons35, is currently not available. Remote monitoring is not intended to completely replace in-clinic device follow-up, and sufficient patient contact is required to optimize programming and enhance device function. Patients with cardiac devices should be seen, at minimum, once per year in clinic, if they are also followed remotely. Remote follow-up is indicated when the patient’s medical condition is stable and no device programming is anticipated, during intensified follow-up to plan elective replacement, and in the case of a device advisory where more frequent monitoring of the system is required.36

Device Advisory Management

In addition to enabling adequate database facilities to track patients, device follow-up clinics need a clearly identified process for the management of device and/or lead system advisories. This should include a clear assessment of potential patient risk, both in the general device population, and individually for specific groups of patients (i.e., pacemaker-dependent or other criteria). Based on the risk assessment, the Medical Director or MRP should develop a management plan for each advisory to include patient notification and assessment, treatment plans, and device replacement in selected cases. The Canadian Heart Rhythm Society Device Advisory Committee (CHRS – DAC) publishes recommendations on their website37 for the management of device advisories to guide practice. In addition, Type II centres and ADCs should link with their respective Type I centre to ensure a consistent management plan. Implant centres should keep record of the transfer of patients to other clinics, and are responsible for notifying the referring clinic of any device advisory information received. All actions and treatment plans should be clearly documented in the patient chart.

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35Roberts, P. Follow-up and Optimisation of Cardiac Pacing. Heart Sept 2005: 91(9): 1229–34
37http://www.chrsonline.ca/patients/advisories.htm
The CHRS – DAC was commissioned to respond to advisories regarding cardiac rhythm device and lead performance on behalf of the CHRS. In the event of an advisory, the DAC Chair uses an e-mail network to disseminate advisory information to committee members broadly representative of the Canadian device community. A consensus recommendation is prepared by the Committee and made available to all Canadian centres on the CHRS website after approval by the CHRS executive. This collaborative approach using an e-mail network has proven very efficient in providing a rapid national response to device advisories. The network is an ideal tool to collect specific data on implanted device system performance and allows for prompt reporting of clinically relevant data to front-line clinicians and patients.38

Because the number of implantable cardiac devices has dramatically increased, device alerts and advisories have become a part of routine clinical practice. When physicians are faced with the management of patients with an implanted device under advisory, major concerns are how to manage the patient and whether the device needs to be replaced.39 There have been a number of variations in the types of device (pacemaker and ICD) advisories including both hardware and software problems. Table 5 below provides a breakdown in the type of problems commonly seen in device advisories.

Table 5: General Classes of Device Malfunction40*

<table>
<thead>
<tr>
<th>MALFUNCTION TYPE</th>
<th>PACEMAKER, %</th>
<th>ICD, %</th>
<th>TOTAL, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardware</td>
<td>74.8</td>
<td>85</td>
<td>79.8</td>
</tr>
<tr>
<td>Firmware</td>
<td>5.7</td>
<td>1.5</td>
<td>3.6</td>
</tr>
<tr>
<td>Miscellaneous</td>
<td>15.1</td>
<td>8.4</td>
<td>11.8</td>
</tr>
<tr>
<td>Inconclusive</td>
<td>4.8</td>
<td>5.1</td>
<td>4.7</td>
</tr>
</tbody>
</table>

*Note: this table includes no information about lead malfunction

40 Amin, M.S., Ellenbogen, K.A. Focus on Management of Pacemaker and ICD Advisories, Recalls, and Alerts. Current Treatment Options in Cardiovascular Medicine Feb 2007: 9(1)
DECISION GUIDELINES FOR DEVICE ADVISORIES

1. Consider device/lead replacement if:
   - The mechanism of malfunction is known and is potentially recurrent
   - The risk of malfunction is likely to lead to patient death or serious harm
   - The risk of replacement is less than, or at least not substantially greater than, the risk of device malfunction

2. Consider device/lead replacement in patients who are pacemaker dependent;

3. Consider device replacement if the predicted end of life (EOL) is approaching;

4. Consider conservative management with periodic non-invasive device monitoring when the rate of device malfunction is very low in patients who are not pacemaker dependent;

5. Provide routine follow-up for patients with a device malfunction that has been mitigated or corrected by reprogramming the software; and

6. Consider conservative management with periodic non-invasive device monitoring in patients where operative intervention risk is high or in patients who have other significant competing morbidities, even when the risk of device malfunction or patient harm is substantial.

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41 Heart Rhythm Oct 2006: 3(10)
Figure 2: below is a suggested algorithm to be followed in the event of a device advisory.

ARRHYTHMIA MEDICAL DEVICE ADVISORY PROCESS CHALLENGES

Written Confirmation of Advisory Notification Received

Within 24 Hours

Establish core investigation team
Suggested to include:
- Medical Director or MRP
- Follow-up physician or NP
- Allied health professional or RN Manager
- Other key team members as the centre identifies

Purchasing Risk Management Corporate Communications

Patient Advocate Biomedical Engineering Health Records

CLINICAL PLAN (POINT PERSON)
- Patient identification
- Review charts
- Patient notification letter
- Patient assessment
- Documentation of clinical visit on face sheet or dictated note to chart
- Maintain advisory binder

NO PROCEDURE
- Continue follow-up visits
- Documentation
- Book appointment
- Documentation
- Follow-up visits

RISK MANAGEMENT
- Consult
- Legal advice as necessary

CORE INVESTIGATION TEAM
Med. Director, Manager, Triage Coordinator, Resource RN, ACNP, Point Person, meet within one week. Core Investigation Team links with Type 1 centre for consultation on management of the advisory

PROGRAM PLAN (CORE TEAM)
- Develop patient notification & device company letter (send to patient, Purchasing, Risk Management)
- Medical Director fields questions
- Collaborating approach with Purchasing & Industry
- Establish reimbursement costs
  - Assessment appointment
  - Procedure & operative cost
  - Follow-up appointments

DEBRIEFING

Leadership Team Purchasing Risk Management Patient Advocate/Corporate Communications
SPECIFIC RECOMMENDATIONS:

1. Each hospital that implants or follows pacemakers should develop an electronic database for all device patients that includes device and lead models, together with serial numbers, that will allow for easy and reliable identification of the patients affected by a device recall or advisory. There are commercially available database systems for pacemaker and ICD documentation and tracking.

2. Each hospital establishes a policy and procedure for managing device advisories to include consultation where appropriate (CHRS recommendations, Type I centre consultation) and coordinated management strategy. Type I centres have a responsibility to develop recommendations on specific advisory management with their Type II and Type III centres.

3. Each LHIN should develop a policy to deal with device recalls and advisories to include:
   a. A communication strategy to advise patients of the advisory;
   b. Required action to be taken in order to deal with the advisory;
   c. Risk management documentation process; and
   d. An electronic documentation system to allow these patients to be tracked and monitored.

4. All centres offering pacemaker follow-up services should have a link with the Canadian Device Advisory Committee, to ensure they receive recommendations on advisories as they occur.

Roles of the Device Industry Representatives in the Hospital

Implanting centres should establish specific written policies governing the presence of industry-employed allied professionals in the hospital, including the pacemaker clinic, cardiac catheterization laboratories, electrophysiology laboratories, special procedure rooms, and operating rooms.
Device industry personnel should not be involved in the delivery of routine pacemaker care, either in the implant or the follow-up setting, but rather should serve in an advisory role. Hospitals and clinics should ensure they have their own adequately trained staff to support pacemaker care activities and provide direct patient care independently. Industry personnel may provide education and technical training/support to the pacemaker follow-up team. Industry personnel should not provide direct patient care, including lead testing at implant or device programming at either implant or follow-up, in their support role.  

In cases where industry allied professionals are asked to support patients – in remote areas that do not have trained personnel or who are in an emergency situation – the responsibility for programming rests with the physician, even in situations where remote programming is performed. If the assistance of an electrophysiologist or follow-up physician is required, then this must occur as physician-to-physician communication.

**SPECIFIC RECOMMENDATIONS:**

1. Device industry personnel should not be an integral part of pacemaker care in implant or follow-up, but may provide a training or technical support role.
2. Device industry allied professionals may be required to provide some care to patients in remote areas but should be under direct supervision by the attending physician; and if consultation is required, the attending physician should consult with an experienced pacemaker follow-up physician for directions on management or programming.

**Training and Competency Maintenance for Implanting Physicians**

Historically pacemakers were implanted using a surgical thoracotomy approach; however, the transvenous approach is now the standard for pacemaker implantation, except in special circumstances. With the change in implanting procedure, there has been a simultaneous change from implanting by surgeons to implanting by cardiologists. According to the recent survey of cardiac pacing centres conducted by the CCN, more than 52% of pacemaker implants are performed by cardiologists, 19% by cardiac surgeons, 15% by vascular surgeons, 11% by general surgeons, 2% by internists and 1% by thoracic surgeons.

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Implanting of a cardiac implantable electronic device has five distinct components:
1. Proper indications;
2. The surgical element of implantation;
3. Venous access;
4. Intra-cardiac manipulation of leads and lead placement; and
5. Electrophysiological interpretation during implantation.

Any proposed criteria for proper training should include these key elements in addition to providing knowledge and a skill base in pre-implantation and post-implantation concerns.

Training for physicians planning to provide pacemaker services must be comprehensive enough to cover all competencies in the field of electrophysiology as they apply to the pacemaker patient. These include, at a minimum, the appropriate history of implants, investigation and ECG diagnosis of arrhythmia, understanding mechanisms of arrhythmias, and pharmacologic management of arrhythmias; as well as patient selection, implantation techniques, complications and their management, knowledge of pacing algorithms and programming, and clinical indications for specific algorithms. Knowledge of ICD and CRT, and their indications, is necessary to ensure appropriate mode and generator selection. It is expected that this level of training can only be provided at a Type I centre with an established training program that covers all key competencies. One year of full-time training is considered necessary to achieve these core competencies in managing device implantation and follow-up.

For device implantation, a minimum of 75 new implants as the primary operator (with an additional 20 pack revisions) is required to establish competency. Follow-up of 100 pacemakers as the primary physician directing programming is required to establish competency in follow-up. It is recognized that these recommendations are based on training programs for electrophysiology, but given the current nature and complexity of the specialty of cardiac pacing, this level of knowledge and skill is required to deliver comprehensive pacemaker care.

In order to maintain competence in pacemaker implantation and follow-up care, a minimum number of implants and follow-ups per year are required.

- Implant at least 50 new pacemakers per year as the primary operator
- Monitoring of operator-specific complications rates
- Supervise at least 100 pacemaker follow-ups per year as the primary physician/programmer

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It is recognized that many currently established programs might not meet these training requirements. Planning for new staff or new programs should adhere to these guidelines and proactively establish training plans for the physicians in these centres. In existing centres, where competencies for the full range of pacemaker services do not exist, the centre needs to establish clear linkages with a Type I centre to ensure patient access to this expertise. Every effort should be made to ensure physicians in existing centres adhere to the competency maintenance guidelines presented in this document to ensure consistent care with published guidelines. In centres where the implanting physician does not have full competencies in cardiac pacing, clear and direct communication with the follow-up physician should be established for each case to ensure appropriate mode, generator selection, and programming.

**SPECIFIC RECOMMENDATIONS:**

1. In order to achieve the required core competencies to manage the complex nature of current arrhythmia devices, a minimum of 12 months training at a Type I centre with a formal training program is necessary.
2. The minimum number of implants to achieve initial competency is 75 new implants as the primary operator, and 20 pack revisions.
3. The minimum number of pacemaker follow-ups to achieve initial competency is 100 devices as the primary physician/programmer.
4. Ongoing competency maintenance requires implant of at least 50 pacemakers per year as primary operator, analysis of operator-specific complication rates, and supervising and directing at least 100 follow-ups per year.
## Appendix A: Type I Pacemaker Device Centres in Ontario

<table>
<thead>
<tr>
<th>Type I Device Centres</th>
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<tbody>
<tr>
<td>Hamilton Health Sciences – Hamilton General Hospital – Hamilton</td>
</tr>
<tr>
<td>Kingston General Hospital – Kingston</td>
</tr>
<tr>
<td>London Health Sciences Centre – University Hospital – London</td>
</tr>
<tr>
<td>Southlake Regional Health Centre – Newmarket</td>
</tr>
<tr>
<td>St. Michael’s Hospital – Toronto</td>
</tr>
<tr>
<td>Sunnybrook Health Sciences Centre – Toronto</td>
</tr>
<tr>
<td>Trillium Health Centre – Mississauga</td>
</tr>
<tr>
<td>University Health Network – Toronto</td>
</tr>
<tr>
<td>University of Ottawa Heart Institute – Ottawa</td>
</tr>
</tbody>
</table>
## Appendix B: Implanting Ontario Hospitals by LHIN: the CCN 2010 Pacemaker Survey (Spring 2010)

<table>
<thead>
<tr>
<th>LHIN</th>
<th>HOSPITAL SITE</th>
</tr>
</thead>
</table>
| LHIN 1 (Erie St. Clair LHIN) | • Bluewater Health (BWH) (Lambton Hospital Group): Mitton Site – Sarnia  
• Hôtel-Dieu Grace Hospital – Windsor  
• Windsor Regional Hospital (WRH): Metropolitan Campus |
| LHIN 2 (South West LHIN) | • London Health Sciences Centre: University Hospital  
• Grey Bruce Health Services (GBHS) – Owen Sound |
| LHIN 3 (Waterloo Wellington LHIN) | • Guelph General Hospital  
• St. Mary’s General Hospital: St. Joseph’s Health System – Kitchener (Hamilton Halton) |
| LHIN 4 (Hamilton Niagara Haldimand Brant LHIN) | • Hamilton Health Sciences (HHS): Hamilton General Hospital  
• Joseph Brant Memorial Hospital – Burlington  
• St. Joseph’s Healthcare – Hamilton  
• Niagara Health System (NHS): Greater Niagara General Site – Niagara Falls  
• Niagara Health System (NHS): St. Catharines General  
• Niagara Health System (NHS): Welland Hospital Site |
| LHIN 5 (Central West LHIN) | • William Osler Health Centre (WOHC) – Brampton |
| LHIN 6 (Mississauga Halton LHIN) | • Trillium Health Centre – Mississauga  
• Halton Health Services (HHS) – Oakville |
| LHIN 7 (Toronto Central LHIN) | • Sunnybrook Health Sciences Centre – Toronto  
• University Health Network (UHN): Toronto General Hospital (TGH)  
• Toronto East General Hospital – Toronto  
• Mount Sinai Hospital – Toronto  
• St. Michael’s Hospital – Toronto  
• St. Joseph’s Health Centre – Toronto |
| LHIN 8 (Central LHIN) | • Southlake Regional Health Centre – Newmarket  
• Humber River Regional Hospital (HRRH): Church Street Site – Weston (Toronto) |
| LHIN 9 (Central East LHIN) | Peterborough Regional Health Centre  
Lakeridge Health Corporation (LHC) – Oshawa  
Rouge Valley Health System (RVHS): Centenary – Toronto  
The Scarborough Hospital (TSH): General Campus – Toronto |
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<td>LHIN 10 (South East LHIN)</td>
<td>Kingston General Hospital</td>
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| LHIN 11 (Champlain LHIN) | Cornwall Community Hospitals (CCH): McConnell Site  
University of Ottawa Heart Institute |
| LHIN 12 | NO PACEMAKER IMPLANT SITES |
| LHIN 13 (North East LHIN) | North Bay General Hospital (NBGH): Scollard Site  
The Sault Area Hospital (SAH) – Sault Ste. Marie  
L’Hôpital Regional de Sudbury Regional Hospital |
| LHIN 14 (North West LHIN) | Thunder Bay Regional Health Sciences Centre (TBRHSC) – Thunder Bay |

Ministry of Health and Long-Term Care

Ministère de la Santé et des Soins de Longue Durée

1. Erie St. Clair / Érié St. Clair  
2. South West / Sud-Ouest  
3. Waterloo Wellington  
4. Hamilton Niagara Haldimand Brant  
5. Central West / Centre-Ouest  
6. Mississauga Halton  
7. Toronto Central / Toronto-Centre  
8. Central/Centre  
9. Central East / Centre-Est  
10. South East / Sud-Est  
11. Champlain  
12. North Simcoe Muskoka / Simcoe-Nord Muskoka  
13. North East / Nord-Est  
14. North-West / Nord-Ouest
Bibliography


Canadian Heart Rhythm Society Device Advisory Committee (DAC) Website: http://www.chrsonline.ca/patients/advisories.htm


