About CorHealth Ontario

As of June 22, 2017, we are CorHealth Ontario, an organization formed by the merger of the Cardiac Care Network of Ontario and the Ontario Stroke Network, with an expanded mandate spanning cardiac, stroke and vascular care. CorHealth Ontario proudly advises the Ministry of Health and Long-Term Care, Local Health Integration Networks, hospitals and care providers to improve the quality, efficiency, accessibility and equity of cardiac, stroke and vascular services for patients across Ontario. For more information, visit corhealthontario.ca.

About this Resource

CorHealth Ontario convened a committee, to develop provincial recommendations to promote patient-centred care for people with implantable cardioverter-defibrillators (ICD) engaging in goals-of-care discussions. The committee was co-chaired by Drs. Heather Ross and Stuart Smith and included multidisciplinary representation from experts in both cardiology and palliative care. A number of strategies were used to inform the recommendations in this document, including a review of current clinical guidelines, relevant published literature and published standards and policies from the College of Physicians and Surgeons of Ontario (CPSO), Registered Nurses Association of Ontario (RNAO) and College of Nurses of Ontario (CNO). Please see Appendix A for a list of committee members. A final draft of this document was reviewed by key stakeholders who provided comments and feedback.

Acknowledgements

CorHealth Ontario would like to gratefully acknowledge the contributions of the patients, family members and health care professionals who provided their valuable thoughts and insight into developing this booklet.
Executive Summary

Implantable cardioverter-defibrillators (ICDs) have been utilized for the prevention of sudden cardiac death for about two decades. The ICD continuously monitors the electrical rhythm of the heart and when certain ventricular arrhythmias are detected, a shock may be delivered to stop the arrhythmia and restore the heart back to its normal electrical rhythm. Although the ICD may help prevent sudden cardiac death, patients often report significant pain and discomfort from receiving a shock.

Patients with heart disease and at risk for sudden cardiac death are now living longer, have complex multisystem diseases and may no longer wish to embrace the life-saving therapy associated with a defibrillator. In these situations, shock therapy can be disabled (ICD deactivation) non-invasively to avoid unnecessary pain and discomfort. While the pacing functions that may be associated with quality of life do remain active, these patients will no longer receive a painful shock.

Given the different types of devices available and the multiple options of device programming, general health professionals have ongoing questions as to ICD indications, functionality, benefit and programmability. This knowledge gap has created a mystery surrounding their use, coupled with many misperceptions and evolving myths as to their utility, safety and programmability. Many patients are not fully aware that the choice of ICD deactivation is always available to them and as such, may experience unwanted and painful therapy.

The purpose of this document is to provide provincial recommendations that promote patient-centered, evidence-based best practices for patients with an ICD device that may require shock therapy to be discontinued. These recommendations are organized by four main themes: discussion, decision, deactivation and documentation.
A key objective of goals-of-care discussions is to avoid a patient approaching end-of-life without their views about ICD deactivation being known. These discussions need to elicit a person’s values and goals for care, to ensure that care provided remains person-centered through to end-of-life. Whenever possible, this should be anticipated and undertaken by the health care team that knows the person and not left for health care providers in an urgent or crises situation.

Patients exploring end-of-life options often need to make many decisions, including possible ICD deactivation. These decisions are complex, preference-sensitive and have significant implications. Decisions regarding ICD deactivation require informed consent. Care providers are responsible for informing patients of the expected course of an illness, without conveying false hope and helping patients decide which of the available treatment options are best for them; this is an important part of health care consent. Patients prefer a shared decision-making approach with their care providers. Decisions are not final and patients can change their mind at any point.

Planned deactivation should be the aim in the majority of patients who require ICD deactivation. The process of deactivating an ICD is non-invasive, but requires the availability of a trained health care professional and an ICD programmer device. A specialized magnet can be applied for temporary deactivation in urgent situations.

All discussions and decisions regarding ICD deactivation should be clearly documented in the patient’s health record in a way that is easily accessible by all members involved in the patient’s circle of care.
1.0 Introduction

Although implantable cardioverter-defibrillators (ICDs) have been utilized for the prevention of sudden cardiac death for about two decades, these devices continue to evolve and indications for such devices have expanded. Given the different types of devices that are now available and the multiple options for device programming, general health professionals have ongoing questions as to ICD indications, functionality, benefit and programmability. This knowledge gap has created a mystery surrounding their use coupled with many misperceptions and evolving myths as to their utility, safety and programmability. Many patients are not fully aware that the choice of ICD deactivation is always available to them and, as such, may experience unwanted and painful therapy. With this in mind we have created this document to support health care professionals to provide timely, evidence-based care for their patients.

Through the evolution of health care, patients with heart disease at risk for sudden cardiac death are living longer, have complex multisystem diseases and may no longer wish to embrace the life-saving therapy associated with a defibrillator. They may however, prefer to continue with the pacing component of these devices which may improve their quality of life.

2.0 Purpose

The purpose of this document is to provide provincial recommendations that promote patient-centered, evidence-based best practices for patients with an ICD device that may desire or require high voltage (shock) therapy to be discontinued as part of their plan of treatment.

The recommendations in this document focus on the discussions between health care providers, patients and family members/significant others regarding ICD deactivation in addition to the process of ICD deactivation. Recommendations consider conditions such as planned versus emergency situations and the patient location such as community or hospital settings. Implementing these recommendations may be achieved through a number of strategies in response to local program delivery models, resources, environment and needs of their target population.

Specifically, the objectives of these recommendations are to:

- Improve the care of patients with ICD devices who are approaching end-of-life by avoiding the unnecessary distress that is associated with shock therapy.
- Develop best practice guidelines for planned and emergency deactivation of shock therapy for patients in either hospital or community settings.
- Raise awareness among health care providers in hospitals and community health services of the importance of incorporating information relating to deactivation of ICD shock therapy into discussions with patients and caregivers as well as into organizational policies relating to health care consent.
- Raise awareness for the need to consider the ICD functions when discussing goals-of-care and to inform subsequent decisions for cardiopulmonary resuscitation (CPR).
3.0 Background

3.1 Implantable Cardioverter Defibrillators (ICD) and Cardiac Resynchronization Therapy Defibrillators (CRT-D)

An ICD is often inserted in patients who have survived a cardiac arrest (secondary prevention) or in patients who are at high risk for sudden cardiac death from a ventricular arrhythmia (primary prevention). The ICD continuously monitors the electrical rhythm of the heart and when certain ventricular arrhythmias are detected, a shock may be delivered to stop the ventricular arrhythmia and restore the heart back to its normal electrical rhythm (Figure 1).

Many patients who are at high risk for a ventricular arrhythmia may also have a weak heart muscle and heart failure. They may also benefit from an ICD that has an additional pacemaker wire that will help the heart pump more efficiently. This kind of ICD is known as a Cardiac Resynchronization Therapy device, or CRT-D. A CRT-D can improve symptoms of heart failure and quality of life as well as help prevent sudden cardiac death.

(See Appendix B for additional information regarding ICD and CRT-D devices).

Note: Throughout the document, the term ICD will be used to include both ICD and CRT-D devices.
3.2 Device Programming

An ICD device has a battery life of approximately five to seven years and can be programmed to provide individualized patient settings. The battery life can change depending on the way it is programmed, the amount of pacing required and on the types and numbers of therapies delivered. People with these devices have regular appointments to measure the amount of battery life remaining, check the device settings, ensure the device is functioning properly and evaluate the presence or absences of appropriate or inappropriate shocks. This is accomplished with a trained clinician and the use of a portable computer programmer machine that communicates with the device and allows for downloading and evaluation of stored information (Figure 2).

Most companies that manufacture ICD devices have unique computer programmers and therefore company-specific programmers are required to evaluate the device's performance. There are also company-specific nuances in device programming that can alter ICD deactivation procedures.

3.3 Current State

Implantable defibrillators have been available for prevention of sudden cardiac death since the early 1990s and volumes have continued to grow since then. The Provincial Registry began collecting patient level data in April 2010 for ICD procedures in Ontario. Over the past five years, 70% of devices were implanted for primary prevention of sudden cardiac death, while 30% of devices were implanted in people who have survived a ventricular arrhythmia or cardiac arrest (secondary prevention).

For further information regarding the number and type of device procedures in Ontario, please see the CorHeath Ontario website (corhealthontario.ca). A list of centres that provide ICD clinical services in Ontario is available on the CorHeath Ontario website (corhealthontario.ca) and also listed in Appendix C.

For information regarding clinical indications for ICD and CRT devices, please refer to the most recent guidelines by the Canadian Cardiovascular Society (www.ccs.ca) or the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Heart Rhythm Society (www.hrsonline.org).
4.0 A Patient-Centred Approach

Although the ICD may help prevent sudden cardiac death, patients often report significant pain and discomfort from receiving a shock.\textsuperscript{2,5} Evidence suggests that approximately 30\% of patients receive shock therapy from their device in the last 24 hrs prior to death.\textsuperscript{1} From a cohort of patients with a ‘Do Not Resusitate’ (DNR) order (n=65 patients), 65\% had shock therapy programmed ‘on’ at 24 hours prior to death and 51\% still had shock therapy active one hour before death.\textsuperscript{1} Among the 98 patients who died within the Multicenter Automatic Defibrillator Implantation Trial II (MADIT-2) study, ICD deactivation was performed in 15\% of patients anywhere from 0-71 days prior to death while 37\% of patients who requested hospice care or DNR did not have their ICD deactivated.\textsuperscript{6}

Current literature indicates that patients near end-of-life may no longer want the life-saving shock therapy from their ICD or CRT-D device.\textsuperscript{3,7,8} Many elderly patients are frail or may also have significant co-morbidities, or patients who are terminally ill may prefer treatment that improves quality of life rather than prolong life. As such, the initial life-saving therapy is no longer consistent with their goals-of-care and they may prefer symptom-managed care versus prevention of sudden cardiac death. In these situations, life saving shock therapy can be disabled (‘ICD deactivation’) non-invasively to avoid unnecessary pain and discomfort from ICD shocks that are no longer desired.\textsuperscript{9} Unfortunately many patients are not aware that the choice of ICD deactivation is available to them and may experience unwanted painful therapy.\textsuperscript{3,7,10}

ICD deactivation or not performing a battery change is both ethically and legally acceptable and supported by international guidelines.

Source-Wright, 2012\textsuperscript{11}
4.1 Discussing ICD Deactivation

Health care providers need to engage in conversations that ensure patients are fully aware of their device functions and the potential for ICD deactivation within the context of individual patient goals-of-care.\textsuperscript{9,12-15} Unfortunately these discussions rarely take place in advance, but rather occur in emergent situations immediately preceding death.\textsuperscript{10,16} A patient-centred approach for individuals with an ICD needs to extend beyond care of device performance with greater attention being focused on the patient experience, their values and goals-of-care. A comprehensive plan of treatment needs to include end-of-life discussions, as it provides an opportunity for either the capable patient (or if incapable, the Substitute Decision-Maker) to consent to future treatment, including the withholding or withdrawal of treatment in light of the patient’s current condition.

4.1.1 When Should ICD Deactivation be Discussed with Patients/Family Members?

The CPSO states that physicians have an obligation to have discussions early, at a time that is appropriate and acceptable to the individual patient and their family/significant others. This includes discussing a person’s wishes and preferences for end-of-life, their current clinical status, prognosis and all other treatment options enabling them to contemplate these options and make informed decisions as required.\textsuperscript{18,19}

Often such discussions are sensitive and patients may not be ready to participate. However, in a study of patients with an ICD attending the Heart Function Clinic at the University Health Network in Toronto, patients identified three stages where they felt ICD deactivation should be discussed:

1. Prior to implantation;
2. With any significant deterioration, but while they were of sound mind to engage and communicate preferences; and
3. At end-of-life.\textsuperscript{7}
Specific decision points or triggers for conversations about possible device deactivation may include the following situations:

- Prior to implantation at the time of consultation, as part of the informed consent process;
- When requested by a patient or family member;
- During assessment for device replacement (elective replacement due to battery depletion or advisory);
- Multiple shocks being delivered as a result of disease progression;
- A change in clinical status; worsening of condition or new comorbid condition with a poor prognosis (e.g. advanced malignancy);
- Repeated hospitalizations for heart failure;
- Repeated emergency department visits;
- Refractory symptoms of a cardiac condition despite optimal therapy;
- Deemed ineligible for advanced heart failure therapies (e.g. mechanical circulatory support or transplant);
- Deteriorating quality of life;
- The presence of a DNR order;
- When referred to hospice or a nursing home facility; and
- At a minimum, during annual device clinic visit, or during other device clinic visits.

While these are useful triggers for this conversation, goals-of-care discussions can take place anytime when a patient or health care provider feels it is necessary. When patients were asked about their preference for the timing of these conversations, they did not feel that it was appropriate to have the first discussion about ICD deactivation when death was imminent, supporting the need for earlier review.⁷

Note: For information regarding documentation and communication of these discussions and decisions among members of the health care team, please see Section 6, page 18.

A key objective of these conversations is to avoid a patient approaching end-of-life without their views about deactivation being known.

Whenever possible, this should be anticipated and undertaken by the health care team that knows the person and not left for acute care providers in an urgent or crisis situation.

Source-British Cardiovascular Society, 2015²⁰
Recommendation: Care of patients with an ICD needs to include timely discussions regarding goals-of-care to inform decisions related to device therapy.

When asked about preferences for ICD deactivation discussions, most patients prefer the health care team to initiate this discussion.7 However, patients with an ICD often have multiple care providers which can contribute to uncertainty as to who will have the central conversation with the patient/family. In addition, care must be taken not to make assumptions that another health care provider will, or has, discussed ICD deactivation with the patient/family.

Goal: Discussing the possibility of ICD deactivation should take place in a timely manner and at a time point that is appropriate and acceptable to the individual patient and their family/significant others.19

Goal: Patients are informed, satisfied with current decisions about the role of their cardiac device in their plan of treatment and aware that these decisions can be revisited.21

This process needs to consider:

• General education about the device that includes deactivation;
• When to have discussions regarding possible deactivation;
• Who should participate in these discussions (e.g. medical, patient, family, other HCP);
• How to talk about this topic (shared decision-making) and
• What information should be included in the conversation (e.g. the nature of the treatment, expected benefits and risks, potential side effects, alternative options and likely consequences of not having the treatment).

Question to ask in order to meet this recommendation:

Is there a process in place to:

☐ Provide patients/significant others with information regarding the functions of their device that include the availability of deactivation?
☐ Identify and engage interested patients in goals-of-care discussion(s) to inform decisions regarding device therapy?
☐ Ensure there is an opportunity for physicians to facilitate decision-making and obtain informed consent by providing necessary medical information about their device therapy?
☐ Ensure there is an opportunity for nurses and allied health members (e.g. social worker) to engage in conversations with patients about goals-of-care and ensure patients/significant others have sufficient information to make an informed decision about their device therapy?
☐ Recognize that patients’ preferences and goals-of-care may change over time and hence is there an opportunity to revisit previous decisions regarding device therapy? (e.g. during critical points in their illness trajectory or significant life events)
☐ Ensure these discussions occur in a timely fashion?
☐ Promote a shared decision-making approach between health care providers and patients?
Goals-of-care discussions should focus on the values and goals of the individual patient – what they find valuable and important in their lives and what they hope for in the future.

Source-Leah Steinberg, committee member

4.1.2. How to Talk about the Option of ICD Deactivation

Initiating goals-of-care discussions and conversations about end-of-life can be difficult and uncomfortable for physicians and other health care providers. Goals-of-care discussions should focus on the values and goals of the individual patient – what they find valuable and important in their lives and what they hope for in the future (e.g. attending an important family event in the future). These conversations don’t always follow a straight line and may occur over several visits. Furthermore, discussions about goals-of-care are dynamic processes and a person’s goals and values should be revisited over time.

There is no ‘one way’ to have conversations about ICD deactivation and end-of-life preferences; however, there are some guiding principles for working through these discussions highlighted in Appendix D.

Over time, an ICD may become inconsistent with patient’s goals, especially if their health deteriorates. Within the discussion about patient preferences, clarification regarding uncertainties related to the process and outcome of deactivation are often necessary. See Table 1 on the following page for a summary of the common myths regarding ICD deactivation with subsequent clarification.
Table 1. Common Myths Regarding ICD Deactivation

<table>
<thead>
<tr>
<th>Myth</th>
<th>Clarification</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD deactivation is considered similar to Medical Assistance in Dying (MAID) or euthanasia.</td>
<td>The intent of device deactivation is not to hasten death, but rather, to avoid painful and unwanted shocks.</td>
</tr>
<tr>
<td>Patients often think they need the ICD in order to stay alive – that without it, their heart would stop.</td>
<td>For the vast majority of patients turning off the ICD will NOT cause immediate death or hasten death. However, in situations when the ICD is actively delivering shocks for life-threatening arrhythmias, disabling the device may result in imminent death.</td>
</tr>
<tr>
<td>Deactivating an ICD requires surgery.</td>
<td>Deactivating an ICD is non-invasive. The ICD shock function is turned off by a trained clinician using a manufacturer’s specific programmer.</td>
</tr>
<tr>
<td>Turning off the device will be painful.</td>
<td>Turning off the ICD will not be painful.</td>
</tr>
<tr>
<td>If the shock therapy is turned off, so will the pacemaker.</td>
<td>The shock and pacing functions are separate. There is no reason to turn off the pacing portion of the device when deactivating the shock function.</td>
</tr>
<tr>
<td>Touching a patient during shocks will also cause pain to that person.</td>
<td>Touching a patient receiving shocks will not result in harm or pain; however some discomfort is possible.</td>
</tr>
<tr>
<td>Turning off the shock function is permanent.</td>
<td>The shock function can be re-enabled non-invasively at any time. This can be done by a trained clinician using a manufacturer’s specific programmer.</td>
</tr>
<tr>
<td>Any magnet can be used for ICD deactivation.</td>
<td>A specific medical grade magnet must be used to deactivate the shock function of an ICD. Each hospital’s Emergency Department should have them easily accessible.</td>
</tr>
<tr>
<td>ICD deactivation can be done over the telephone.</td>
<td>The shock function of an ICD can only be disabled in person by a trained clinician and a manufacturer’s specific programmer, or temporarily with a magnet.</td>
</tr>
<tr>
<td>Once the magnet is applied, it can be removed and shock therapies are still turned off.</td>
<td>In most cases, shock therapy will resume when the magnet is removed. For specific instructions for magnet use by device manufacturer, please see Appendix F.</td>
</tr>
</tbody>
</table>

Sources: MacIver, 2016; Lampert, 2010

In the event of a conflict of interest between the wishes of the health care provider’s beliefs and the values of the patient, the HCP must make alternative arrangements to support the patient and their decision-making.21

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4.1.3. Shared Decision-Making

As a person thinks about end-of-life, they will need to consider a number of decisions, including the possibility of ICD deactivation. These decisions are complex, preference-sensitive and have significant implications. Care providers are responsible for informing patients of the expected course of an illness, without conveying false hope and helping patients decide which of the available treatment options are best for them; this is an important part of health care consent. When making these difficult decisions, clinicians need to support them by verifying their understanding and eliciting their preferences. Decisions regarding ICD deactivation requires informed consent.

Mounting evidence suggests that patients prefer a shared decision-making approach with their care providers. Key points to consider:

- “Shared decision-making is the process through which health care providers and patients/family members share information with each other and work towards decisions about treatment chosen from medically reasonable options that are aligned with the patients’ values, goals and preferences”.17
- “Achieving shared decision-making depends on building a good relationship in the clinical encounter so that information is shared and patients are supported to deliberate and express their preferences and views during the decision-making process”.27
- Decision aids are intended to help patients consider options from their perspective, describe their available options, and help them understand these options as well as their possible benefits and harms.26

Resources:

There are tools and resources available to assist health care professionals with engaging in serious illness conversations, goals-of-care discussions and shared decision-making. It is important to note that there is significant variation in definition and implementation of both Advance Care Planning and goals-of-care discussions between jurisdictions that relate to the different legal and regulatory environments.
Website:

- Advance care planning: Go to the website Speak up Ontario (www.speakupontario.ca)
  
  A decision aid to prepare patients and their families for shared decision-making about Cardiopulmonary Resuscitation (CPR) can be accessed from the Speak Up Ontario website. Type CPR decision aid in the search box.

- An inventory of decision aids for many health topics is available from the Ottawa Hospital Research Institute. You can get to the website by typing in ‘decision aids and Ottawa Hospital’ in a search engine or go directly to the website at https://decisionaid.ohri.ca

- The Canadian Hospice Palliative Care Association has a number of resources. The website is www.chpca.net

The article, “Communication about serious illness care goals: a review and synthesis of best practices” Bernacki & Block, 2014. A conversation guide is provided on page E7. This article includes some excellent tips and suggestions and can be accessed online by visiting: https://goo.gl/cxR9o5

Addendum: An Advance Care Plan is not recognized as a legal document in Ontario.

4.2 Holistic Patient Care

Discussing the ICD functions and potential deactivation is just one part of caring for patients with advanced heart failure. These patients may also suffer from symptoms such as pain, anorexia, depression and anxiety, similar to patients with metastatic cancer. If patient/family needs become complex, referral to palliative care services may be required to facilitate a needs assessment to assist in the care coordination required for optimizing the patient experience with symptom management and end-of-life wishes.
5.0 Practicalities of ICD Deactivation

An increased focus on assessing the need for elective or planned ICD deactivation may reduce the need for emergency deactivation in the community and avoid potential delays that may exacerbate patient and family distress.

Source-British Heart Foundation, 2015

5.1 Planned ICD Deactivation

Planned deactivation should be the aim in the majority of patients who require ICD deactivation. This is performed with a specially trained person using a programmer. Whenever possible, planned deactivation is performed in the ICD clinic/department.

5.2 Unplanned or Urgent ICD Deactivation

Situations may arise in which a person is terminally ill or unexpectedly approaching end-of-life (e.g. catastrophic event) and urgent or unplanned deactivation is necessary. In these situations, the ICD shock function can be temporarily deactivated by taping a specific medical grade magnet securely on the patient’s skin overlying the device. The magnet will not turn off any pacing functions. Although the magnet will provide temporary ICD shock deactivation, arrangements for ICD deactivation using a programmer and trained personnel should be enacted as prolonged magnet application can be uncomfortable and contribute to underlying skin breakdown. Ideally deactivation programming should occur at a location that is best suited for the patient.

All hospital emergency departments should be equipped with specific medical grade magnets. In addition, it is recommended that the following settings and providers obtain magnets:

- Palliative Care Centres
- Long-Term Care Facilities
- Family Health Teams
- Emergency Medical Services
- Hospice
- Home visiting palliative care physician/nurse practitioner
In cases where the magnet cannot be obtained in time to stop the device from delivering shocks, health care providers will observe the device delivering a number of shocks until the device exhausts itself. Possible scenarios include:

- Sustained ventricular arrhythmias – The device will keep delivering repeated shocks in succession until the device exhausts itself. This may take up to 15 minutes depending on the manufacturer. The pacing functions will remain active and pacing spikes may be noted on the electrocardiogram for patients who are being mechanically monitored.

- Intermittent or recurrent ventricular arrhythmias – When arrhythmias come and go, shocks are delivered intermittently with each arrhythmia. In this scenario, shocks theoretically can occur intermittently for hours.

Note: For patients who were not successfully resuscitated, an ICD device that has not been disabled may continue to deliver ‘shock therapy’ after patient death until the ICD device exhausts itself. This can be rather distressing for family members. In these cases, a magnet could be placed over the device to stop the device from delivering shocks immediately following patient death.

Note: Some health care professionals may decline to be involved with device deactivation based on personal beliefs. Although such views must be respected, they cannot be allowed to affect care that provides dignity and comfort at end-of-life. The health care professional declining to be involved needs to arrange for an alternative health care professional who will be prepared to adjust the device settings should the need arise.

See treatment algorithm for planned and unplanned device deactivation in Appendix E.

For more detailed instructions on magnet application, please see Appendix F.

To purchase magnets, call the manufacturer’s number and ask for customer service (Please see Table 2 below).

Table 2. Manufacturer Contact Information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Phone Numbers</th>
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</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>1-888-620-0069</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>1-800-268-4487</td>
</tr>
<tr>
<td>LivaNova (ELA/Sorin)</td>
<td>1-800-352-6466</td>
</tr>
<tr>
<td>Medtronic</td>
<td>1-888-879-0977</td>
</tr>
<tr>
<td>Abbott (formerly St. Jude Medical)</td>
<td>1-800-276-4170</td>
</tr>
</tbody>
</table>

Note: These numbers were accessed February 2017. It is possible that these contact numbers may change over time.
6.0 Documentation and Communication

**Recommendation**: All discussions and decisions regarding ICD deactivation shall be clearly documented in the patient’s health care record in a way that is easily accessible by all members involved in the patient’s circle of care.

**Goal**: The patient/family members/Substitute Decision-Maker and health care providers in the patient’s circle of care are able to provide clear and consistent information and advice ensuring the decisions are informed, agreed to and understood by all.

**Goal**: All members involved in the patient’s circle of care are aware of the patient’s plan of treatment as it relates to ICD deactivation decisions.

**Questions your organization needs to ask in order to meet this recommendation:**

- Is there a process in place to ensure a standardized approach for documenting discussions and decisions regarding ICD deactivation in the patient’s health care record?
- Is the documentation completed in accordance with the institution’s policies and procedures and according to relevant College Standards?
- If ICD deactivation is requested, is there a process in place to:
  - Obtain informed consent?
  - Communicate all necessary information to the ICD implanting centre?
  - Arrange for planned and urgent requests for trained personnel with a device programmer to deactivate the device?
  - Provide ICD deactivation with a magnet in urgent or emergent situations?
  - Make arrangements for ICD deactivation in a location that optimizes the patient experience which may include home, hospice palliative care centres, or long-term care facilities?
- Is there a process in place to ensure the above questions include situations when the patient has an appointed Substitute Decision-Maker acting on the patient’s behalf?
- Is there a process in place to ensure necessary documents and communication methods include situations when a patient requests ‘reactivation’ of ICD shock therapy?
7.0 Post Mortem Handling

Device deactivation is preferred to take place prior to transfer to funeral home; however, the ICD may be required to be deactivated after transfer.

In most cases, the deceased patient can be buried with the ICD. There are some cases where the ICD may need to be removed (explanted). These situations may include, but are not limited to:

- Cremation: ICDs must be removed prior to cremation as the device will explode when in contact with high temperatures and pose a risk to crematorium staff. The leads (wires) do not need to be removed.
- In situations where the funeral home or crematorium staff need to explant a device and do not know if the device has been disabled, it is recommended that double gloving with latex, neoprene, or plastic be used to avoid electrical shock from the device;33
- At the request of the patient’s family;
- Further device analysis is requested.

*If the device is to be removed or explanted, the following recommendations for removal should be followed:*

- Turn off shock therapy
- Remove the device and disconnect the leads (the leads do not need to be removed)
- Place in biohazard waste packaging
- Return to manufacturer for device analysis
APPENDIX A: COMMITTEE MEMBERS AND REVIEWERS

Co-Chairs:

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Dr. George Heckman, MD, MSc, FRCP

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Ms. Julia Johnston, RN (EC), BScN, MN, NP-Adult, CHPCN(C)
Dr. Peter Liu, MD, FRCP
Dr. Susanna Mak MD, PhD, FRCP
Dr. Michael McDonald, MD, FRCP
Dr. Robert McKelvie, MD, PhD, FRCP
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Dr. Stephanie Poon, MD, MSc, FRCP
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Dr. Karen Harkness, RN, PhD, CCN(C), CHFN, Clinical Lead Heart Failure and Cardiovascular Chronic Disease Management
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APPENDIX B: ADDITIONAL INFORMATION ABOUT DEVICES

Implantable Cardioverter-Defibrillator

An implantable cardioverter-defibrillator (ICD) is a device that is used to treat life threatening ventricular arrhythmias. The ICD continuously monitors the electrical rhythm of the heart and when certain ventricular arrhythmias are detected, a shock may be delivered to stop the ventricular arrhythmia and restore the heart back to a normal electrical rhythm. An ICD is mainly used to prevent sudden cardiac death. Implantable cardiac devices are larger in size and volume compared to pacemakers due to both the battery and capacitors (voltage holding tank for the charge) needed to deliver high voltage therapies. When the battery is near end-of-life, the entire generator or ‘can’ is replaced.

Legend

1. Right Atrium (RA)
2. Right Ventricle (RV)
3. Left Ventricle (LV)
4. Leads: Deliver electrical signals to the heart for pacing or shock therapy
5. Generator: Contains the battery, the capacitor, & the ‘computer’ which is used to program specific pacing and shock therapies

Most people with an ICD have a lead that goes into the right ventricle. Some may also have a lead that goes into the right atrium.

• Single chamber ICD: lead in the right ventricle
• Dual chamber ICD: lead that goes into the right atrium and right ventricle
Cardiac Resynchronization Therapy

Some patients with heart failure may benefit from a device that paces both the right and left ventricles. The biventricular pacing will help the heart pump more efficiently and is known as Cardiac Resynchronization Therapy (CRT).

A CRT-D device provides both biventricular pacing as well as defibrillator capabilities. A CRT-D device is used to improve symptoms of heart failure and quality of life as well as preventing sudden cardiac death.

A CRT-P device provides biventricular pacing to improve symptoms of heart failure and quality of life; however, it does not have any defibrillator or shock functions.

Legend

1. Right Atrium (RA)
2. Right Ventricle (RV)
3. Left Ventricle (LV)
4. Leads: Deliver electrical signals to the heart for pacing or shock therapy
5. Generator: Contains the battery, the capacitor, & the 'computer' which is used to program specific pacing and shock therapies
6. LV lead in left coronary vein

All people with a CRT-D have a lead in the right ventricle with an addition lead placed in a left coronary vein (coronary sinus) to pace the left ventricle.

Some people may have an additional lead that goes into the right atrium.
**Subcutaneous Defibrillators**

Some patients at risk for sudden death only require a simple defibrillator or ‘shock box’ to detect and restore sinus rhythm in the event of a life-threatening ventricular arrhythmia.

These types of devices are known as subcutaneous defibrillators (S-ICD).

Unlike other ICD and CRT-D devices, subcutaneous defibrillators do not have any pacemaker functions for a slow heart rate.

**ICD and Pacemaker Functions**

All ICD devices, excluding subcutaneous defibrillators provide pacing functions. Different kinds of pacemaker options are available, depending on the needs of the patient. Pacemaker functions are *not* deactivated if shock therapy is deactivated.

The number of leads will determine what kind of pacemaker options are available. These include:

a. Single chamber defibrillators

b. Dual chamber defibrillators

c. Triple chamber defibrillators (resynchronization or CRT devices)

a. Single chamber devices (lead in right ventricle) offer simple ‘back up pacing’ if the heart rate goes extremely slow.

b. Dual chamber devices (lead in right atrium and right ventricle) offer more sophisticated dual chamber pacing for patients who also have bradycardia or chronotropic incompetence and require the pacemaker functionality. For patients who have both supraventricular and ventricular arrhythmias, these dual chamber devices are better able to discriminate between a non-life-threatening arrhythmia from the atria versus a ventricular arrhythmia and prevent an inappropriate painful shock.

c. A subset of patients with symptoms of heart failure, a wide QRS complex duration of greater than 130ms and poor quality of life from heart failure, may benefit from resynchronization therapy. Resynchronization therapy utilizes pacing in the right ventricle and an additional pacing lead positioned in a left coronary vein causing the left ventricle to contract synchronously with the right ventricle. By coordinating the contraction of both ventricles, cardiac output and pump efficiency are increased, thus improving heart failure symptoms and quality and quantity of life. These devices may also have a third lead positioned in the right atrium.

All of these devices can be customized to suite each patient’s needs and requirements. They are programmed to optimize the treatment delivered and also to avoid inappropriate shocks.
**APPENDIX C: CARDIAC CENTRES THAT PROVIDE IMPLANTABLE DEFIBRILLATOR CLINICAL SERVICES**

To contact the Arrhythmia team, either call the office directly or call the main hospital number and ask for Heart Rhythm or Arrhythmia services. If your request is urgent, call the main hospital number and ask for the Electrophysiologist on call.

<table>
<thead>
<tr>
<th>Cardiac Centre</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hamilton Health Sciences (General Site)</td>
<td>905-527-4322 x 46796</td>
</tr>
<tr>
<td>Health Sciences North</td>
<td>705-523-7100 x 1222 or 1225</td>
</tr>
<tr>
<td>Kingston General Hospital</td>
<td>613-548-1399</td>
</tr>
<tr>
<td>London Health Sciences (University Campus)</td>
<td>519-685-8500 x 35303</td>
</tr>
<tr>
<td>Rouge Valley Health System (Centenary Site)</td>
<td>416-284-8183 x 5327</td>
</tr>
<tr>
<td>St. Mary’s General Hospital</td>
<td>519-749-6578 x 1500</td>
</tr>
<tr>
<td>St. Michael’s Hospital</td>
<td>416-864-6060 x 2526</td>
</tr>
<tr>
<td>Southlake Regional Health Centre</td>
<td>905-895-4521 x 2572</td>
</tr>
<tr>
<td>Sunnybrook Health Science Centre</td>
<td>416-480-4469</td>
</tr>
<tr>
<td>Trillium Health Partners (Mississauga Site)</td>
<td>905-848-7580 x 2903</td>
</tr>
<tr>
<td>University Health Network (Toronto General Site)</td>
<td>416-340-4800 x 8433 or 6975</td>
</tr>
<tr>
<td>University of Ottawa Heart Institute-Heart Rhythm</td>
<td>613-761-4436</td>
</tr>
</tbody>
</table>

**Note:** These numbers were accessed in February 2017. It is possible that these contact numbers may change over time. Please refer to CorHealth Ontario at corhealthontario.ca for the most current contact information.
APPENDIX D: GUIDING PRINCIPLES FOR GOALS-OF-CARE DISCUSSIONS

**Introduction:** It is important to introduce yourself, sit down if possible and make sure the patient is comfortable and able to talk.

**Learning about the patient’s illness understanding:** This step is not only about patient knowledge, but about the patient’s feelings and what the events mean in the context of their life. Be patient with this step, because often patients and their families know more than they say at first and it is much more powerful to have them say the words than for you to say it to them. It is this step that helps you understand what the patient needs next. You may find it useful to rephrase their statement and then utilize pauses.

**Giving information:** The information patients and caregivers need and can absorb often depends on their illness understanding. Be flexible in how you give information, i.e. maybe they would benefit from seeing test results or images, perhaps they need questions answered first before they can absorb information. Give information in short pieces – one or two sentences at a time and pause to see how the information is being heard and to allow for emotions. If they are experiencing strong emotions, they will not be able to engage with you on a cognitive level, so you have to manage the emotions, then re-approach the information-giving segment. It is also valuable to ask them how they like to get information – do they want statistics? Would they rather speak about the big picture?

**Acknowledge and explore fears, values, beliefs, wishes and goals:** Once you think patients are ready to discuss their goals, there are many ways to do this; the most important is that it flows from the conversation. If patients are not ready to discuss this, it is often best to give them some time to feel more prepared.

In this phase, you are trying to understand what people need help with – what they are worried about, what resources they need and what they hope to achieve in the future. For example are they hoping for a cure, or for more time to be with family? Are they hoping for comfort and time at home?

Do they want statistics? Would they rather speak about the big picture?

**Recommend treatments to meet goals:** Try to focus on the things that we will do rather than the things that we won’t.

**Source:** Just Ask: A Conversation Guide to Goals of Care Conversations

**Note:** The following article from the Heart Rhythm Society has some helpful tables (Table 1 and Table 2) with some very specific suggested phrases when communicating with patients/family members about goals-of-care related to an ICD.


http://www.heartrhythmjournal.com/article/S1547-5271(10)00408-X/pdf
APPENDIX E: TREATMENT ALGORITHM FOR PLANNED AND UNPLANNED DEVICE DEACTIVATION

Identify Triggers for Discussion (See opposite page)

- Discussion Decision +/- Deactivation
- Documentation

ICD deactivation not within goals-of-care

Yes

Urgent

(Yes)

Access to Trained HCP and Programmer on site?

- Yes
- No

Yes

Obtain Magnet

HCP applying Magnet

- Confirm: Discussion + Decisions
- Apply Magnet
- Documentation

No

Contact Trained HCP with Programmer

Arrange for deactivation by trained HCP with Programmer

Yes

Contact Arrhythmia Team

HCP: Health Care Professional
Choice of Pathway
Recommendation Pathway

Urgent

(Death imminent within 24 hours)

Yes

No

Trained HCP + Programmer

- Confirm: Discussion + Decision
- Perform Deactivation
- Documentation

Ideally deactivation should occur at a location that is best suited for the patient

A physician order is required for ICD deactivation to occur
**Decision Points or Triggers for Conversations About Device Deactivation**

- Prior to implantation at the time of consultation, as part of the informed consent process;
- When requested by a patient or family member;
- Device replacement (elective replacement due to battery depletion or advisory);
- Multiple shocks being delivered as a result of disease progression;
- Change in clinical status such as worsening of condition or new comorbid condition with a poor prognosis (e.g. advanced malignancy);
- Hospitalizations for heart failure;
- Emergency department visits;
- Refractory symptoms of a cardiac condition despite optimal therapy;
- Deemed ineligible for advanced heart failure therapies (e.g. mechanical circulatory support or transplant);
- Deteriorating quality of life;
- Presence of a DNR order;
- Referral to hospice or long-term care facility; and
- At minimum, annual review or during scheduled device clinic visits.

**Device Algorithm: ICD Deactivation Key Processes (4Ds)**

**Discussion**
- Focus on values and goals of the individual patients as well as what they find important in their lives
- Clarify uncertainties related to the process and outcomes of deactivation
- Conversations may take place over several visits

**Decision**
- A shared decision-making process is preferred by patients
- Goals-of-care discussions are dynamic and decisions should be reviewed and revised as necessary over time
- Informed consent is required when patients request ICD deactivation

**Deactivation**
- Requires a physician order and informed consent
- Deactivation is accomplished by a trained health care professional using a manufacturer specific laptop programmer
- A specialized magnet can be applied for temporary deactivation in urgent situations (all emergency departments should be equipped with a magnet)

**Documentation**
- Needs to include all discussions, decisions and actions taken regarding ICD deactivation
- Needs to provide what rationale and advice was given that addressed the patient’s specific health care needs and goals, to ensure consistent information is provided by all team members
- Needs to be easily accessible by all members involved in their care
APPENDIX F. MAGNET APPLICATION INSTRUCTIONS

Magnet Application for Implantable Cardioverter Defibrillators (ICDS)

- **LOCATE THE ICD:** it is usually located in the upper left chest area, under the collarbone but sometimes the ICD is located on the right side of the chest. In rare instances it may be located in the abdomen. Subcutaneous ICDs are usually located along the left mid axilla area.

- **PALPATE THE ICD:** to ensure that you have the correct magnet placement location, ensure that you can feel the ICD under the skin. Place the magnet directly over the ICD and secure it with any type of tape (see Figures below).

- **SECURE THE MAGNET:** if the magnet were to lose connection with the ICD, the therapies you are suspending will no longer be suspended.

- **SUSPEND THE ICD:** Once the magnet is placed, tachyarrhythmia detection and therapy will be suspended so the ICD will not deliver any anti-tachycardia pacing (ATP) or shocks for ventricular arrhythmias. After magnet placement you may or may not hear a tone coming from the device. Not all devices will have this tone or ringing feature. If you hear a tone, it lasts for approximately 10-20 seconds which indicates the magnet has been properly placed.

  Pacemaker functions for a slow heart rate are NOT affected by the magnet. Even when the magnet is in place the patient will continue to receive the programmed pacing for a slow heart rate at the programmed rate.

- **REMOVAL OF THE MAGNET** will restore all anti-tachycardia detection and shock therapy.

- **SKIN INTEGRITY:** assessment of skin integrity is required for magnet application longer than 24 hours.

**Magnet taped directly over ICD**

**S-ICD Magnet Placement**

For patients with an S-ICD, please call 1-800-CARDIAC for additional instructions for temporary deactivation using a magnet.

Magnet response by manufacturer and technical service contact information are provided on the following page.
# Magnet Response by Manufacturer

To purchase a magnet, please contact the manufacturer.

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Tachycardia Therapies</th>
<th>Are Tones Audible with Magnet On?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>Suspends**</td>
<td>None</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>Suspends</td>
<td>Yes-beeping tones</td>
</tr>
<tr>
<td>LivaNova (previous ELA/Sorin)</td>
<td>Suspends</td>
<td>None</td>
</tr>
<tr>
<td>Medtronic</td>
<td>Suspends</td>
<td>Yes - have tone audible for 30 seconds Normal magnet response = steady tone Beeping or oscillating tones = ALERT Call ICD manufacturer or implanting Centre</td>
</tr>
<tr>
<td>Abbott (formerly St. Jude Medical)</td>
<td>Suspends</td>
<td>None</td>
</tr>
</tbody>
</table>

**Biotronik Lumax ICD devices: The magnet must be removed for a few seconds after 8 hours of application then reapplied. If NOT removed after 8 hours of magnet application, the device will automatically reactivate shock therapy.

**Magnet removal will restore shock and anti-tachycardia therapies**

# Manufacturer Contact Information

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Phone Numbers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biotronik</td>
<td>1-888-620-0069</td>
</tr>
<tr>
<td>Boston Scientific</td>
<td>1-800-268-4487</td>
</tr>
<tr>
<td>LivaNova (ELA/Sorin)</td>
<td>1-800-352-6466</td>
</tr>
<tr>
<td>Medtronic</td>
<td>1-888-879-0977</td>
</tr>
<tr>
<td>Abbott (formerly St. Jude Medical)</td>
<td>1-800-276-4170</td>
</tr>
</tbody>
</table>

**Note:** These numbers were access July 2017. It is possible that these contact numbers may change over time.

**Note:** Any health care industry magnet will be effective, regardless of the specific ICD device manufacturer.
APPENDIX G: GLOSSARY OF TERMS

**Advance Care Planning** has been described in Ontario as a process that involves the capable patient:

1. Identifying their future Substitute Decision-Maker (SDM) by either:
   a. Confirming that he or she is satisfied with their default/automatic SDM in the hierarchy list that is in section 20 of the Health Care Consent Act ([www.ontario.ca](http://www.ontario.ca))
   OR
   b. Choosing someone specific to act as a SDM by preparing a Power of Attorney for Personal Care (POAPC) naming that person.

2. Expressing their wishes, values and beliefs and more generally how they would like to be cared for in the event of incapacity to give or refuse consent.

**Cardiopulmonary resuscitation (CPR)** is a potentially lifesaving intervention that is provided with the intention of reversing or interrupting a potentially fatal event (e.g., cardiac or respiratory arrest). CPR is often understood to include chest compressions, artificial ventilation (including intubation) and defibrillation.¹⁸

**Goals-of-care:** A discussion between a person (or their Substitute Decision-Maker if the person lacks capacity) and health care provider(s) addressing the person’s goals for their care in the context of health care consent and decision-making in advanced illness. These discussions need to outline the person’s values, beliefs, wishes, perception of quality of life and what he or she of current health conditions, prognosis and likely course of events if his or her goals-of-care are applied to potential treatment decisions. The goals-of-care discussions provides the foundation for shared decision-making.

The **Health Care Consent Act** (HCCA) is an Ontario law that has to do with the capacity to consent to treatment. The HCCA states that a person has the right to consent to or refuse treatment if they have mental capacity. In order to have capacity, a person must have the “ability” to understand and appreciate the consequences of the treatment decision. The law says that “a person is capable with respect to a treatment, admission to a care facility or a personal assistance service if the person is able to understand the information that is relevant to making a decision about the treatment, admission or personal assistance service, as the case may be and able to appreciate the reasonably foreseeable consequences of a decision or lack of decision.”

[https://www.ontario.ca/laws/statute/96h02](https://www.ontario.ca/laws/statute/96h02) (retrieved November 29, 2017)
Medical Assistance in Dying (MAID) in accordance with federal legislation, medical assistance in dying includes circumstances where a medical practitioner or nurse practitioner, at an individual's request; (a) administration of a substance that causes an individual's death; or (b) prescribes a substance for an individual to self-administer to cause their own death. [http://ocfp.on.ca/tools/medically-assisted-dying](http://ocfp.on.ca/tools/medically-assisted-dying) (Retrieved October 11, 2016.)

**Potentially life-saving treatment** is treatment that is provided with the intention of reversing or interrupting a potentially fatal event (e.g., cardiopulmonary resuscitation, etc.).

**Life-sustaining treatment** is any medical procedure or intervention which utilizes mechanical or other artificial means to sustain, restore, or supplant a vital function essential to the life of the patient (e.g., mechanical ventilation, medically assisted nutrition and hydration, etc.).

**Palliative care** is active total care that improves the quality of life of patients and their families facing life-threatening illnesses or life-limiting chronic conditions, with a focus on relieving pain and other symptoms and addressing psychological, social and spiritual distress; it is applicable in all phases of illness, from early in the course of illness to bereavement.

**Substitute Decision-Maker (SDM)** is someone who makes health care decisions on behalf of a patient if they are incapable of health care decision-making. The Health Care Consent Act provides a hierarchy that lists who the automatic Substitute Decision Maker(s) would be if a person became mentally incapable. If a person is not satisfied with the person provided in the list, they must prepare a Power of Attorney for Personal Care.
APPENDIX H: REFERENCES AND SUPPORTING DOCUMENTS

References


Additional Supporting Documents:


RNAO (2011). End-of-life Care During the Last Days and Hours. http://rnao.ca/bpg/guidelines/endpointcare-during-last-days-and-hours


Southlake Regional Health Care Centre- Steps to ICD Deactivation, Draft version 2015.

Liability

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Our Vision:
The best cardiac, stroke and vascular care for all Ontarians.