ACI NSW Agency for Clinical Innovation

NSW Guidelines for Deactivation of Implantable Cardioverter Defibrillators at the End of Life

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NSW Guidelines for Deactivation of Implantable Cardioverter Defibrillators at the End of Life

Implantable Cardioverter Defibrillators (ICD) are devices which are inserted to prevent sudden cardiac death from life-threatening arrhythmias. The device continuously monitors the electrical rhythm in the heart and if certain arrhythmias are detected, a 'shock' may be delivered to convert the heart back into sinus rhythm.

When an adult patient with an ICD is in the terminal stages of their life, it may no longer be appropriate for the device to remain active and deliver shocks to the heart.

These best practice guidelines have been designed to assist clinicians to manage ICD deactivation, and facilitate a peaceful death, for patients at the end of life.

They have been developed using the available evidence and in consultation with the following key groups:

- Cardiac nurses and cardiologists in both rural and metropolitan areas
- Palliative Care Services
- Community Health Nurses
- Aged Care Facilities
- Industry representatives from device companies
- The Cardiac Society of Australia & New Zealand (CSANZ)
- The National Heart Foundation
- The Australasian Cardiovascular Nurses College
- The Australian Cardiovascular Health and Rehabilitation Association (ACRA)
- The Agency for Clinical Innovation Cardiac Network
- Consumer representatives
- The NSW Ministry of Health.

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Audience All staff in metropolitan and rural, hospital and community settings who are involved in the management of patients with ICDs at the end of life.

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CONTENTS

DEACTIVATION OF IMPLANTABLE CARDIOVERTER DEFIBRILLATORS AT THE END OF LIFE

1. Introduction

Implantable Cardioverter Defibrillators (ICDs) have been shown to improve survival for people at risk of life-threatening arrhythmias (ventricular tachycardia or ventricular fibrillation) and sudden cardiac death[1, 2]. ICDs can provide both pacing and shock (defibrillation) therapy to restore the heart to a normal rhythm. Some of these devices also have the potential to provide a biventricular pacing mode (also known as cardiac resynchronisation therapy), which helps to coordinate the left and right ventricular activity aiming to improve cardiac function and symptoms in patients with ventricular dysynchrony.

As the indications for ICD implantation expand the number of people living with these devices continues to grow[3]. Preserving quality of life during end of life care and ensuring a dignified and peaceful death means that discussion with this patient group regarding ICD deactivation at an appropriate time must be considered.

2. Background

The prevalence of ICDs is increasing with more than 10,000 a month being implanted in the United States alone[4]. In Australia, implantation rates are growing each year and will continue to increase as the population ages[5]. A recent survey reported 3,555 ICD devices were implanted in 2009, which is a 25% increase since 2005[6].

Clinical trials that have been published in the last 10 years demonstrating the survival benefit of ICD implantation in certain populations with heart disease have contributed to the establishment of guidelines from peak cardiac bodies[7,8]. The increasing rate of ICD device implantation can be correlated with the publication of guidelines[9,10].

As a patient ages the likelihood of dying from their cardiac condition or another terminal illness increases. Avoiding an arrhythmic death, through ICD activation, may become undesirable if death by other causes is thought likely and imminent. In these circumstances, it may be appropriate for ICDs to be deactivated near the end of life following discussion with the patient and their family[2].

ICDs exemplify the role that new technology and scientific advancements play in adding to the complexity of end of life care[11]. Withdrawal of life-sustaining therapies usually occurs in acute care settings within a framework of approved and negotiated policies, however, few hospitals or community institutions have policies supporting deactivation of ICDs[12].

3. Ethical and legal issues

The ethical and legal issues relating to the deactivation of implantable cardiac defibrillators at the end of life are similar to concerns that are raised by the withholding or withdrawal of other life-sustaining medical interventions such as decisions to withhold resuscitation (e.g. a No CPR order).

Health professionals are under no obligation to provide treatment that, in the circumstances are unreasonable, in particular, those that offer negligible prospect of benefit to the patient[13]. The same ethical and legal factors should be considered to assist open and sensitive communication with the patient and their family about prognosis, goals of care, relevant consent and documentation mechanisms to avoid the initiation of inappropriate resuscitation. The NSW Ministry of Health has published a number of Policy Directives which provide further details on the legal and ethical issues that should be considered at the end of life, including *Decisions Relating to No CPR Orders* (GL2008_018), *Guidelines for End of Life Care and Decision-Making* (GL 2005_057) and *Consent to Medical Treatment – Patient Information* (PD2005_046).

4. Aim

These guidelines aim to assist clinicians to manage ICD deactivation, and facilitate a peaceful death, for patients at the end of life.

Objectives:

- To improve the care of patients with an ICD who are approaching the end of life by avoiding unwanted prolongation of life and the unnecessary distress that is associated with ICD shock therapy.
- To raise awareness among health care professionals in hospitals and community health services of the importance of incorporating information relating to deactivation of ICDs into discussions with patients and carers as well as into organisational policies relating to end of life care.
- To incorporate discussion on ICD deactivation at the end of life throughout the care continuum including at the initial discussion on implantation, during routine monitoring of the ICD and at the end of life.
- To raise awareness of the need to consider the ICD functions when planning and discussing advance care directives, No CPR orders and the use of an End of Life Care pathway.
- To promote regular assessment and review of patients with deteriorating cardiac disease or who develop another life-limiting illness in all health settings.
- To develop best practice guidelines for the deactivation of ICDs in hospital and community based settings.
- To provide recommendations for patient information, professional education and health care policy.

5. Communication

- Last minute discussions on deactivation of the ICD should be avoided.
- The potential for ICD deactivation (if and when end stage disease is reached) should be part of the informed consent at the time of device insertion. This conversation should involve family and carers and include the objectives of implantation and the limitations of ICD therapy[2].
- Physicians have an obligation to regularly discuss the benefits and risks of ICD therapy in the context of the patient's current illness trajectory.
- Clinicians should consider discussing an Advance Care Directive for all patients who have an ICD.
- Hospital and community facilities should promote clinician training for communicating treatment limitations, Advance Care Planning and end of life care.

There are a number of triggers to initiate a conversation relating to ICD deactivation including[14]:

- Insertion of an ICD.
- Presence of a No CPR order.
- Advanced age with deteriorating quality of life.
- Refractory symptoms of a cardiac condition despite optimal therapy.
- The device is no longer considered to be effective.
- Heart Failure patients who have three episodes of decompensation in 6 months which are related to disease progression.
- A permanent change in the ability to carry out activities of daily living.
- Cardiac cachexia.
- Resistant hyponatraemia.
- Serum albumin < 25g / l.
- Multiple shocks that are related to disease progression.
- Co-morbidities with a poor prognosis e.g. advanced malignancy.
- A change in cognitive function which is related to the patient's disease state.

6. ICD Deactivation

6.1 The indications for deactivation of an ICD are:

- Patient preference.
- Imminent death (an active ICD is inappropriate in the dying phase).
- Withdrawal of anti-arrhythmic medications that is related to a decline in the trajectory of illness.
- While an active No CPR order is in place.

6.2 Informed Consent about device deactivation

There are several important points which should be considered as part of the discussion on Informed Consent about device deactivation[15]:

- Turning off the ICD will not cause death.
- Deactivating the defibrillator (shocking) function of the ICD does not deactivate the pacemaker function of the ICD.
- Deactivating the ICD will not be painful and dying will not be more painful if the device is turned off.
- If the patient's circumstances change following the deactivation, the patient can request re-activation.
- Discussions relating to ICD deactivation should be initiated early, rather than at the terminal stage.
- There may be a logistical delay between the request for deactivation and this process being carried out.
- Delivery of shocks near the end of life may be ineffective, painful to the patient and distressing to patients, their carers and relatives.

6.3 Deactivation Process

- There should be collaboration among health professionals to facilitate timely device management in all hospital and community care settings.
- Any physician or centre that implants ICDs should have a formal pathway to carry out ICD deactivation.
- All health care facilities caring for patients with ICDs should have an appropriate magnet available for temporary deactivation of ICDs.

6.4 Identification of the device

- All patients should be strongly advised to carry their device identification card on their person at all times.
- The patient's permission may be obtained to contact the implanting centre to obtain details about their device.

Public Implanting Centre	Phone
John Hunter Hospital	(02) 4921 3000
Liverpool Hospital	(02) 9828 3000
Nepean Hospital	(02) 4734 2000
Prince of Wales Hospital	(02) 9382 2222
Royal North Shore Hospital	(02) 9926 7111
Royal Prince Alfred Hospital	(02) 9515 6111
St George Hospital	(02) 9113 1111
St Vincent's Hospital	(02) 8382 1111
Westmead Hospital	(02) 9845 5555

Note: If the implanting centre cannot be contacted and there is no other way to obtain details about the device, an over penetrated x-ray of the ICD will show a radiopaque marker which will allow identification of the ICD model and manufacturer.

6.5 Contact numbers

The ICD manufacturers may be contacted to obtain information on specific devices. Contact details (24 hour) for the manufacturers that most frequently provide devices in NSW are listed:

ICD Manufacturer 24 hour contact details	
Biotronik	1800 227 346
Boston / Guidant	1800 245 559
Medtronic	1800 643 193
Sorin	1800 452 650
St Jude	(02) 9966 7475
Details are correct on 14 February, 2013	

7. Management plan for deactivation of ICDs

7.1 Decision to deactivate ICD therapy

- The decision to deactivate an ICD should be made in consultation with the medical officer in charge of the patient's care.
- The decision to deactivate the device must be carried out in collaboration with a cognisant patient and their families or the nominated legal guardian when the patient is not capable of participating in this process.
- Members of the multidisciplinary team should participate in the deactivation process if appropriate, for example, referral to the Palliative Care Team for ongoing comfort measures. If deactivation is to occur in the hospital setting, a Social Worker should be available to provide support to the patient and their family.

7.2 Documentation in the medical record

- A written order from a medical practitioner is required to confirm that deactivation of the ICD is to be carried out. The order must include clear documentation of the specific therapies that are to be deactivated as well as therapies that are NOT to be deactivated.
- The details of the deactivation must be clearly recorded in the patient's medical notes or resident care documents.

7.3 Consent to Deactivate the ICD

- Informed consent must be obtained from the patient or their legally-defined surrogate decision-maker to deactivate the device and this process must be documented.

7.4 People Present During Deactivation of an ICD

- A cardiac technician/scientist (either hospital or pacemaker company) will generally be present to reprogram the ICD and the medical officer will be in attendance in metropolitan facilities. In rural facilities, deactivation will usually be carried out by nursing staff (as detailed in section 8).
- The patient's carer, family or other support people should be encouraged to be with the patient during the deactivation process.

* *Personnel, including medical practitioners and industry representatives, who do not wish to participate in deactivation are responsible for identifying qualified individuals who are willing to carry out this request.*

7.5 Sharing Information About Deactivation of an ICD

- The patient's primary carer must be notified about the deactivation of the ICD if they have not already been informed.

7.6 Temporary ICD deactivation of defibrillator function by bar or clinical ring magnet

- All ICDs have a magnet sensitive switch that responds to a bar (or clinical ring) magnet.
- A bar (or clinical ring) magnet that is placed directly over the ICD device will temporarily deactivate the defibrillator function (the magnet may be taped in place)[16].
- If practical, the ICD device should be deactivated with a programmer (which is a small suitcase sized machine, specific to each company) as soon as possible.
- The defibrillator function will be reactivated if the bar (or clinical ring) magnet is removed.
- The magnet **will not** affect the pacing function of the device.
- ICD devices from all manufacturers will respond in this way.
- Some ICD models may beep continuously or intermittently for a period of time after the magnet is placed over the device.
- Bar (or clinical ring) magnets may be obtained from ICD manufacturers.

8. Recommended Implementation Plan for Health Care Facilities

It is strongly recommended that all facilities likely to care for patients with ICDs have a bar or clinical ring magnet available in case there is the need for temporary deactivation of the defibrillator function.

The magnet should be kept on the Resuscitation Trolley and its availability must be regularly checked with the other emergency equipment. If the magnet is missing, immediate steps must be taken to retrieve or replace it.

If your facility does not have a Resuscitation Trolley, the magnet should be placed in a central location which is easily accessible for staff and its availability must be checked regularly.

Metropolitan Hospitals

- Identify designated contact people in the hospital to provide advice and consultation relating to deactivation of ICDs (these may include cardiology and palliative care teams and cardiac technicians).
- A list of contact details for technician support out of hours should be developed by all facilities.
- If there is a delay in suitably qualified staff deactivating the ICD with the assistance of a programmer, a bar (or clinical ring) magnet may be applied directly over the device to temporarily deactivate the defibrillator function.

Rural Hospitals, Primary & Community Health, Palliative Care Services and Aged Care Facilities

- A bar (or clinical ring) magnet should be taped directly over the device to temporarily deactivate the defibrillator function when the patient is dying. The magnet should be left in place until the patient is deceased.
- After the patient has died, the magnet must be removed.
- If the patient's ICD is manufactured by Biotronik, the magnet must be applied for 8 hours and then removed for 30 seconds as the device will reactivate after this time. The magnet may be reapplied for subsequent 8 hour periods providing that it is removed from the device every 8 hours. The 8 hour countdown restarts when the magnet is reapplied to the device.
- In rare cases, the magnet will not inhibit ICD therapy (when the 'Reed Switch' has been set manually for patients who work in environments where there are strong magnetic fields).
- In these circumstances, representatives from the device companies will be able to advise on the deactivation of an ICD in consultation with the patient's medical practitioner or cardiologist (details of ICD manufacturers are provided in section 6.5) using a programmer.
- If additional expert advice is required, the local clinician may contact the registrar on call at the hospital where the ICD was implanted (details for the hospitals that provide ICDs are available in section 6.4).
- It is recommended that staff from funeral homes are informed that the patient has an ICD if they are to be cremated, as the ICD must be removed due to the likelihood of explosion under extreme heat.

Community and Primary Health services (including Medicare Locals), Palliative Care Services and Aged Care Facilities are encouraged to develop a simple flow chart (or adopt the flow chart in Appendix A) to assist staff to manage deactivation of ICDs at the end of life in a timely manner.

Integration with Existing Policies

The *Guidelines for* the *Deactivation of Implantable Cardioverter Defibrillators at the End of Life* should be:

- Linked to the existing NSW Health Guidelines: *Decisions relating to No CPR orders* (GL2008_018), *Guidelines for End of Life Care and Decision-Making* (GL 2005_057) and *Consent to Medical treatment – Patient Information* (PD2005_046).
- Incorporated into local No CPR (or equivalent) policy and End of Life Care Pathway as a prompt for deactivation of an ICD.

9. Key Stakeholders

- Medicare Locals
- Aboriginal Health and Medical Research Council
- Aged Care Facilities
- Industry Representation from Device Companies
- Cardiac Society of Australia & New Zealand (CSANZ)
- Australasian Cardiovascular Nurses College
- Australian Cardiovascular Health and Rehabilitation Association (ACRA)
- National Heart Foundation
- Palliative Care Services
- Community Health Nurses
- Agency for Clinical Innovation (ACI) Cardiac Network
- NSW Ministry of Health.

10. Related documents

Lampert L, et al., *HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in Patients nearing End of Life or Requesting Withdrawal of Therapy.* Heart Rhythm, 2010. 7(7): p. 1008-1026.

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13. NSW Department of Health, *Guidelines for End-of-life-care and decision-making*. 2005: NSW Department of Health.
14. British Heart Foundation, *Implantable cardioverter defibrillators in patients who are reaching the end of life*. 2007.
15. Goldstein, N., et al., *Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients.* Journal of the American College of Cardiology, 2009. 54(4): p. 371-373.
16. Jacob, S., et al., *Clinical Applications Magnets on Cardiac Rhythm Management Devices*. Europace, 2011. 13(9): p. 1222-1230.

Appendix A

Community & Aged Care Facility Process for Deactivation of Implantable Cardioverter Defibrillators (ICD) at the End of Life

1. DISCUSS

DISCUSS the deactivation process with the patient and their family (or legal representative) and document informed consent. Provide ongoing support as required

2. CONFIRM

Medical Officer **CONFIRMS** the decision to Deactivate the ICD and the device is identified

3. DOCUMENT

Medical Officer **DOCUMENTS** which functions are to REMAIN ACTIVE and which functions are to be DEACTIVATED

4. MAGNET

A bar (or clinical ring) **MAGNET** should be taped directly over the device to temporarily deactivate the defibrillator function when the patient is dying. The magnet should be left in place until the patient is deceased

5. CONTACT

If necessary, **CONTACT** the relevant device company, provide written details of deactivation requirements (see suggested questions in Appendix B) and make an appointment for a Medical Officer and the company representative to deactivate ICD

6. DEACTIVATE

ICD Deactivated

7. RECORD

Details of the deactivation must be **RECORDED** in the patient's medical notes or client records

Appendix B

Request Form

Deactivation of Implantable Cardioverter Defibrillator

Client/Patient Contact Details

Name: .....

Address: .....

.....

Phone Number: .....

Contact Details for Person Requesting Deactivation of Device

Name: .....

Position: .....

Phone Number: .....

E-mail Address: .....

Device and Deactivation Details

ICD Brand & Model: .....

Reason for Deactivation: .....

Functions to be Disabled: .....

Expected Deactivation Date: .....

Functions to remain Active: .....

Comments:

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