



Coventry & Warwickshire
Cardiovascular Network

Network Guideline Document

ICD CONSENT AT IMPLANTATION AND DEACTIVATION AT THE END OF LIFE

Approved by the

Coventry and Warwickshire Cardiovascular Network Board

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Review Schedule

This document should be reviewed annually to ensure accuracy of contents and reflect developments in cardiology.

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5		

Table of contents

Page

Introduction	3
Discussion and information at the time of consent	4
Transfer of Information	5
Psychological Support of ICD patients	5
Deactivating an ICD when a patient is nearing death	6
Deactivation Decision Tree	8
Deactivation for patients in hospital	9
Deactivation for patients in the community	9
Independent Mental Capacity Advocates and Trust Legal Services	11
Record of Decision and consent to Withdraw ICD therapy	12
Removal of ICD post mortem	13
Members of the working group	14

1) Introduction

The Department of Health continues to expand the group of patients who fit the eligibility criteria for the implantation of an Implantable Cardioverter Defibrillator (ICD)¹. The majority of this patient group are heart failure patients. Devices for heart failure patients include:

- ICD
- cardiac-resynchronization therapy pacemaker (CRT-P) which does not include a defibrillator function in the device
- cardiac-resynchronization therapy and defibrillator (CRT-D).

Also known as the biventricular pacemaker, CRT restores synchrony to the failing heart by pacing both ventricles on a continuous basis. Depending on the indications, a patient can have an ICD on its own or as a combined device (Cardiac Resynchronisation Therapy & Defibrillator (CRT-D). In 2009 there were just over 60 per million population ICD implants for Coventry and Warwickshire patients². This number is expected to grow as our rates of implantation across Coventry and Warwickshire continue to grow.

Recent Audit data completed at UHCW showed there were a total of 129 implants from November 2009 to December 2010:

- 44 were ICD implants
- 46 were CRT-P
- 39 were CRT-D.

Although originally implanted to prevent sudden cardiac death the presence of an ICD at the time of natural death can present problems. Goldstein et al³ found in a group of next of kin contacted after the patient's death that 8% of ICD patients received a shock in the last minutes of life and a further 19% received a shock in the last month. With only 27% of patients having had any discussion about deactivation the authors noted the difficulty for clinicians in having this discussion with patients especially at implantation when it would seem 'out of context to both clinicians and patients'.

With these issues in mind and the advent of the Mental Capacity Act (2005), the Coventry and Warwickshire Cardiovascular Network formed a multidisciplinary working group to address the need for clear procedural guidance that could be adopted across all providers. The group's remit was to produce a policy and guidelines surrounding consent at implantation, consent to deactivate, along with guidelines regarding the operational issues around deactivation outside of hospital in Coventry and Warwickshire.

The Coventry and Warwickshire Cardiovascular Network multidisciplinary working group acknowledge the work of the Kent Cardiac Network and their policy on which this document is based.

This document has benefited from the advice of Julie Midgely UHCW Trust Solicitor.

The British Heart Foundation has produced a useful discussion booklet for any health professional who is involved in caring for dying patients with an ICD⁴.

References

1. NICE Implantable cardioverter defibrillators for arrhythmias Technology appraisal 95, January 2006
2. Heart Rhythm Devices: UK National Survey 2009
3. Goldstein N E, Lampert R, Bradley E, Lynn J, and Krumholz H M *Management of Implantable Cardioverter Defibrillators in End of Life Care* Ann of Internal Medicine 2004 ; 141: 835-8
4. BHF Implantable cardioverter defibrillators in patients who are reaching the end of life, July 2007
5. DoH Mental Capacity Act , April 2005

2) Discussion and information at the time of consent

When counselling patients regarding their suitability for the insertion of an ICD, the potential benefits/limitations/risks of the treatment are discussed and documented. This ensures the patient is fully informed of the role of the device. It is appropriate to explain that the defibrillator function provides electrical therapy (anti-tachy pacing and/or shock therapy) to treat dangerous heart rhythms. A defibrillator function monitors the heart rhythm, acting as a safety net against life threatening arrhythmias. It is important that the patient/carer understands that the devices are not a cure for the underlying heart condition (in heart failure), and will not prevent heart attacks. The ICD protects against life-threatening arrhythmias.

Comprehensive written/verbal information should be provided to patients and carers during the pre-implantation discussions and it is recommended that the following information be included:-

a) Deactivation of the defibrillator function of the ICD

After the ICD has been implanted the device can be reprogrammed, and changes can be made to the settings. Circumstances when the ICD needs deactivating include procedures such as angiogram, angioplasty, surgery, radiotherapy and at the end of natural life. Deactivating is done painlessly, takes a few minutes using the portable programmer. The ICD can be reactivated appropriately, for example following surgery. At the end of natural life it should be made clear to the patient that deactivating the ICD is not a surgical procedure. This can be done without discomfort or pain. Deactivating the ICD allows comfort at the end of natural life. Deactivation does not mean the patient will imminently die as the ICD is deactivated but, should a dangerous rhythm occur, the ICD will not treat this.

All devices will deactivate when an appropriate magnet is secured over them.

b) 'Advance Care Planning' (ACP) should be offered to the patient. ACP is the process by which the Clinician for the patient offers the opportunity to plan for future care. The Clinician explains the likely path their clinical condition will take; what potential treatments may be offered to the patient, under what circumstances. The patient may then be in a position to decide whether or not they would choose to accept or decline such treatments. The patient may then feel empowered and document their wishes, with the Clinician's support, via an 'Advance Statement' or 'Advance Decision' (as part

of the 'Advance Care Planning' process). If there are treatments they wish to decline this can be achieved via a more formal 'Advance Decision to Refuse Treatment' (previously known as an Advance Directive).

Staff involved with discussions around ACP and End of Life Care need to have the appropriate competences and/or training in ACP.

The member of staff obtaining consent for the insertion of the ICD needs to ensure there is a written record of issues discussed and the agreed plan and file a copy in the patient's notes.

3) Transfer of Information

Staff should ensure a clear information pathway between the acute hospital, GP and 'out of hours' staff for all areas of Coventry and Warwickshire. Knowledge about whether or not deactivation was discussed at implant and more importantly when deactivation has been carried out should be clearly communicated. Copies of relevant letters

- at implant discussion around deactivating at end of natural life
- following deactivation of an ICD

should be sent to the GP and the patient's local hospital (should this be different from the implant hospital or where deactivation has occurred). A copy of the relevant deactivation consent (recommended sample at end of document) of an ICD should be sent to Morticians at the local hospital.

Each area should ensure that a clear information pathway is known to all staff involved.

4) Psychological support for ICD patients

Having an ICD implanted often follows a very serious event. This event and the implant itself can cause anxiety or fears in some people or their carers. If the ICD shocks, then it is also normal for this to cause distress to the patient and carer. If the distress causes significant problems such as loss of sleep or continued feelings of anxiety patients should be referred for expert help.

The specialist nurse who has experience of counselling patients and carers with ICDs is available for support. Issues may be raised with the GP or the cardiac physiologist who will be able to offer advice and/or direct patients to other appropriate services which may be available.

a) Advice to staff who see patients with ICDs in situ.

When a patient returns to hospital for a technical check of their ICD, this time may also be used to discuss non-technical issues relating to the device. Staff must be aware of the potential problems associated with ICDs. Managers are responsible for ensuring staff have the necessary skills to recognise potential problems and to respond appropriately. Staff should be able to identify worries or associated psychological problems, be able to provide limited support and have enough knowledge to identify when onward referral to more advanced counselling services is appropriate.

Having access to psychological support is essential. The psychologist is able to address issues in depth. Importantly, at the end of natural life the psychologist is invaluable for addressing unmet psychological needs of the patient and family/carers regarding the ICD. This includes issues around deactivation and coming to terms with their prognosis.

5) Deactivating an ICD when a patient is nearing death

When caring for patients 'approaching the end of their life...you must treat patients and those close to them with dignity, respect and compassion, especially when they are facing difficult decisions about care', *section 7, GMC Guidance July 2010: "Treatment and Care towards the End of Life"*.

'Following established ethical and legal (including human rights) principles, decisions concerning potentially life-prolonging treatment must not be motivated by a desire to bring about a patient's death, and must start from a presumption in favour of prolonging life. This presumption will normally require you to take all reasonable steps to prolong a patient's life. However, there is no absolute obligation to prolong life irrespective of the consequences for the patient, and irrespective of the patient's views if they are known or can be found out', *section 10, GMC Guidance "Treatment and Care towards the End of Life", July 2010*.

'In order to ensure a peaceful death for a patient with an ICD who is reaching the end of their natural life the doctor caring for the patient should consider deactivating the defibrillator function of the ICD when they judge it to be no longer clinically indicated. Where the patient has capacity this should be done after discussion with the patient and the doctor explaining their reasons to the patient'.

For further details see section 14, GMC Guidance "Treatment and Care towards the End of Life", July 2010:

Some clinicians may have concerns regarding deactivation of ICDs when capacity to consent is compromised. The following GMC Guidance may be useful for doctors in such circumstances:

GMC Guidance "Treatment and Care towards the End of Life" July 2010, Section 15:

'If you assess that a patient lacks capacity to make a decision you must:

- a) Be clear what decisions about treatment and care have to be made
- b) Check the patient's medical record for any information suggesting that they have made a potentially legally binding advance decision or directive refusing treatment
- c) Make enquiries as to whether someone else holds legal authority to decide which option would provide overall benefit for the patient (an attorney or other 'legal proxy') *as long as that proxy has the appropriate legal powers to make health-related decisions on behalf of that patient*
- d) 'Take responsibility for deciding which treatment will provide overall benefit to the patient, when no legal proxy exists, and you are the doctor with responsibility for the patient's care. You must consult those close to the patient and members of the healthcare team to help you make your decisions.

'In England and Wales, if there is no legal proxy, close relative or other person who is willing or able to support or represent the patient and the decision involves serious medical treatment (*see MCA Code of Practice*) the doctor must approach their employing ...organisation about appointing an Independent Mental Capacity Advocate (IMCA) as

required by the Mental Capacity Act 2005 (MCA). The IMCA will have authority to make enquiries about the patient and contribute to the decision by representing the patient's interests but cannot make a decision on behalf of the patient.'

GMC Guidance July 2010: "Treatment and Care towards the End of Life", Section 16

If a patient (or legal proxy or other person involved in the decision making) asks for a treatment that the doctor considers would not be clinically appropriate or of overall benefit to the patient the 'doctor should explain the basis for this view and explore the reasons for the request. If after discussion the doctor still considers that the treatment would not be clinically appropriate and of overall benefit, they are not obliged to provide it. However, as well as explaining the reasons for their decision, the doctor should explain to the person asking for the treatment the options available to them. These include the option of seeking a second opinion...'

GMC Guidance: "Treatment and Care towards the End of Life" July 2010, Section 16

The term 'overall benefit' is used to 'describe the ethical basis on which decisions are made about treatment and care for adult patients who lack capacity to decide'.

GMC Guidance: "Treatment and Care towards the End of Life" July 2010, Section 5

'The benefits of a treatment that may prolong life, improve a patient's condition or manage their symptoms must be weighed against the burdens and risks for that patient' [in order] 'to reach a view about its overall benefit'. The benefits, burdens and risks associated with a treatment are not always limited to clinical considerations' [there may be] 'other factors relevant to the circumstances of each patient'.

GMC Guidance: "Treatment and Care towards the End of Life" July 2010, Section 40-41

Deactivation of the defibrillator mode of an ICD does not deactivate the pacing mode and in itself does not end a patient's life but will allow for a natural death without the risk of unnecessary shocks.

The continued activation of an ICD when a patient is dying can deliver shocks to the patient which can be distressing to patients, relatives and carers. Therefore consideration of deactivation at this time can be seen as in the 'best interests' of the patient and will be included in the end of life care planning documentation.

The GMC Guidance "Treatment and Care towards the End of Life" July 2010

'Some members of the healthcare team or people close to the patient may find it more difficult to contemplate withdrawing a life-prolonging treatment than to decide not to start the treatment in the first place...You should not allow these anxieties to override your clinical judgement and lead you either not to start treatment that may be of some overall benefit to the patient, or to continue treatment that is of no overall benefit'...'You should also explain...that the patient's condition will be monitored and managed to ensure that they are comfortable and as far as possible free of pain and distressing symptoms.'

The Decision Tree to follow to Withdraw ICD Therapy in an Adult Patient at End of Life

The patient is counselled regarding ICD use and consented for implantation of an ICD. The patient and those close to the patient are given information (oral and written) on the appropriate use and withdrawal of ICD therapy including when nearing the end of life. This should be documented.

The patient is nearing the end of life and/or has a Do Not Attempt Resuscitation order active
(Refer to local hospital/community DNAR policy)

Assessment of patient's condition, likely prognosis and treatment options – which might include Palliative Care – is undertaken by the doctor in charge of the patient's care in consultation with the whole Integrated Cardiology-Palliative Care Multidisciplinary Team

Assessment of the patient's capacity regarding the decision about deactivation of the ICD

Where patient is competent, treatment options including the anticipated benefit and burden of continuing ICD therapy are discussed with him/her.

Where patient lacks the capacity to make decision and has previously indicated wishes in an advance decision or has appointed a personal welfare attorney with lasting powers

Where patient lacks capacity to make decision and it is practicable and appropriate to consult those close to patient.

Where patient lacks capacity to make decision and there is **no person** whom it is practicable or appropriate to consult.

Deactivation of the ICD is deemed to be of greater overall benefit for the patient (ie the burdens/risks of continuing activation of the of ICD outweigh the benefits of the use of ICD)

- a) Patient wishes ICD therapy to be withdrawn
- b) OR lacking capacity there is a written valid and applicable Advance Decision indicating the patient's wishes for ICD therapy to be withdrawn in these specific circumstances
- c) OR Doctor in charge decides ICD therapy should be withdrawn in the patient's 'best interests' for a patient who lacks capacity:
 - o When consent is given by an Attorney appointed under an LPA or by a Deputy appointed by the Court of Protection
 - o OR Taking account of information from those close to the patient regarding what they feel patient would have wanted under these circumstances.

Failure to reach consensus on 'best interests'/ 'overall benefit' to the patient; further discussions and offer 2nd Opinion

PCT/Trust has a duty to provide the patient with access to an Independent Mental Capacity Advocate. See contact details on Page 11

Clinicians may wish to seek legal advice. If so local details can be found on Page 11

Decision to withdraw ICD therapy recorded in writing by doctor. Sample form is on page 12

Decision communicated throughout the patient's care team using local Advance Care Planning tools to communicate between Primary, Secondary Care and Ambulance Service. Personal support given to both patient and those close to them.

Local cardiac physiologist contacted to arrange deactivation of ICD (cardiac physiologist will only do so on receipt of signed form)

Decision reviewed at appropriate intervals. Advance Care Plan reassessed to ensure treatment goals remain appropriate for the patient. Patient consulted throughout and second opinion obtained if patient's condition does not progress as expected.

i) Deactivation for patients in hospital

Hospital cardio respiratory departments will ensure that all departments in their hospital know how to arrange for ICD deactivation during the working day. Out of hours, staff are required to contact CCU for a magnet. Devices need to be considered within hospitals' local "Do Not Attempt Resuscitation" policies.

ii) Deactivation for patients in the community

GPs will have increasing contact with ICD patients towards the end of their life as they should be placed on the practice Supportive and Palliative Care register. Placing a patient on the register will prompt the discussion of "Do Not Attempt Resuscitation" and ICD deactivation.

Patients who are not in hospital at the time of the decision to deactivate should have equal access to deactivation facilities.

This decision should ideally be undertaken when the patient has the mental capacity to do so. Therefore, the procedure can be planned and carried out in a timely fashion.

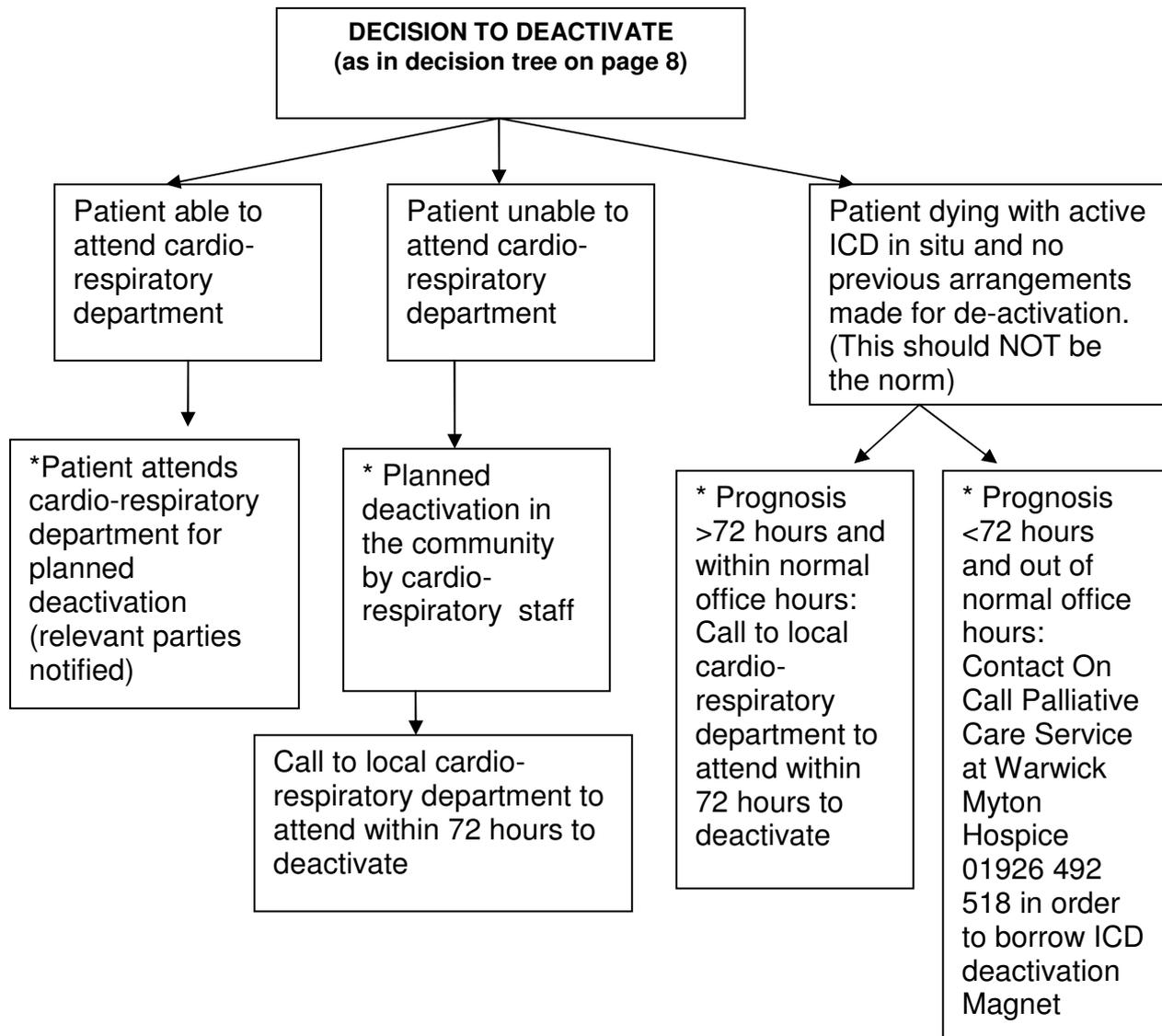
Cardio respiratory departments should be able to accommodate these requests within a short timescale i.e. 1-3 days, maximum 72 hours.

Under exceptional circumstances where a patient is deemed to be imminently dying and not fit to be moved temporary deactivation with a magnet may be considered. When using a magnet, this must be securely placed over the ICD.

If the magnet is removed/falls off this will reactivate the ICD.

The pathway below sets out the options for deactivation for patients in the community:-

Deactivation for patients in the community (including Hospices)



- The decision to deactivate made by the doctor currently caring for the patient needs to be recorded e.g. Record of Decision form is completed – which needs to be made available to the cardiac physiologist prior to undertaking the deactivation.

De-activation in the community is best facilitated by a heart failure nurse specialist, an arrhythmia nurse specialist or community matron in conjunction with the patient's GP or deputising GP.

6) Mental Capacity Advocates

Independent Mental Capacity Advocate

If the person lacks the mental capacity** to make decisions for themselves and does not have support from family and friends, **a statutory advocate will be required** to ensure the individuals best interest are being met.

Contact details for the statutory advocacy provider is:

http://www.pohwer.net/about_us/contact_us.html

** NB: The person's responsible clinician must assess and record in the clinical case notes that the individual lacks the mental capacity to make informed decisions about their care and treatment before an advocate can be appointed.

Margaret Greer is the named nurse for Safeguarding Adults at UHCW and will also provide advice relating to Mental Capacity issues: margaret.greer@uhcw.nhs.uk

The following have overseen these guidelines:

University Hospitals Coventry & Warwickshire Solicitor:

Julie Midgley

George Eliot Hospital Legal Service Lead:

Alex Palethorpe

Contact via board Secretary 024 76865211.

7) SAMPLE FORM TO BE USED

Record of Decision and Consent to Withdraw Implantable Cardioverter Defibrillator (ICD) Therapy in an Adult Patient

NB: THE CARDIAC PHYSIOLOGIST REQUIRES THIS FORM TO BE COMPLETED BEFORE DEACTIVATING AN ICD

As the doctor currently caring for

Patient Name**NHS number**

Address

DOB

Tick all relevant statements:-

I am satisfied that

- The patient wishes the ICD to be deactivated

- As a member of the Multidisciplinary Team caring for this patient we have consulted all relevant information in order to reach the decision that Deactivation of this patient's ICD is the most appropriate clinical decision to be of overall benefit for the patient. **(Consultant decision)**

- I have the consent of the patient's Attorney (Named) to withdraw ICD therapy. The Lasting Power of Attorney appointing him/her is registered and authorises him/her to make decisions on life sustaining treatment.

- I have the consent of the deputy appointed by the Court of Protection (Named) to withdraw ICD therapy.

- I am satisfied that a written advance refusal of ICD therapy exists, which is valid and applicable to current circumstances and I have the patient's authority to withdraw ICD therapy.

- I am satisfied that the patient lacks capacity to consent to withdrawal of treatment and confirm that I believe it is in the patient's best interests that ICD therapy should be withdrawn. The Multidisciplinary Team and I have attempted to establish/completed the necessary steps to ascertain any relevant views/wishes of the patient prior to becoming incapacitated and have taken account of the views offered by those close to the patient (where available), the IMCA, where applicable, and the views of the multidisciplinary team.

Doctor Name
Position

Signature **Date**

Information provided to patient: ___

8) Removal of ICD post mortem

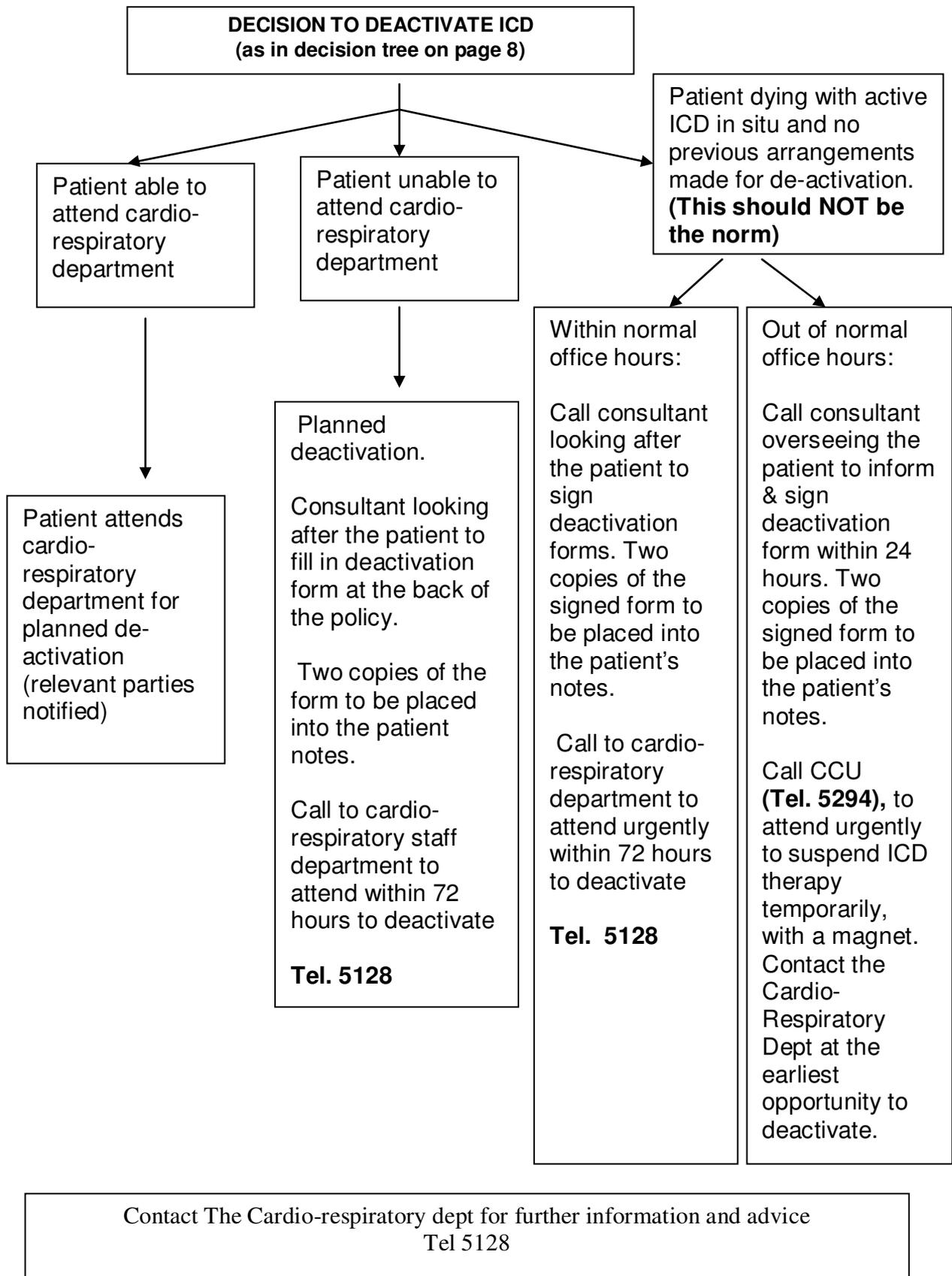
If the body is to be cremated the ICD must be removed to avoid damage to the furnace.

Removal of an active ICD has a high risk of shock injury to the mortician involved and the MDA (Medical Devices Agency) SN2002(35) states:

‘Do not remove an ICD from a cadaver without first disabling all high voltage shock therapies’

Acute trusts should ensure that they are able to advise morticians regarding what devices patients may have and support their deactivation before removal.

Deactivation of ICD's for inpatients at George Eliot Hospital



Appendix Members of the working group (July 2010)

Dr Prithwish Banerjee	Consultant Cardiologist Heart Failure UHCW
Dr Rosie Bronnert	Palliative Medicine Registrar Coventry Myton Hospice
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Shirley Clynick	Lead Cardiac Physiologist – Devices UHCW
Sr Helen Eftekhari	Arrhythmia Nurse Specialist UHCW
Ben Knight	Associate Director Coventry & Warwickshire Cardiovascular Network
Dr Sarah MacLaran	Consultant in Palliative Medicine UHCW / The Myton Hospices
Val Muir	Heart Failure Nurse Community (Coventry)
Dr Dan Munday	Consultant in Palliative Medicine Coventry Community / The Myton Hospices
Pat Noakes	Head of Cardiac Investigations UHCW
Dr Faizel Osman	Consultant Cardiologist/Electrophysiologist UHCW
Dr Jo Poultney	Consultant in Palliative Medicine The Myton Hospices/ Rugby Community
Dr Steph Seeley	GP, Rugby
Lillian Smith-Vincent	Heart Failure Nurse South Warwickshire
Sr Gill Tanner	Heart Failure Nurse Specialist
Sr Kath Warwick	CCU Nurse SWFT
Juelene White	Service Development Manager Coventry & Warwickshire Cardiovascular Network
Rob Wilson	Director Coventry & Warwickshire Cardiovascular Network

Subsequent amendments accepted by Sally Prychart & Dr Venketarama (GEH) 2012