Document Development and Approval Policy

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NHS
Dumfries
& Galloway

Deactivation of Implanted Cardiac Devices with shock function-
ICD/CRT-D at the End of Life

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Appendices

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1. PURPOSE AND SCOPE

The purpose of this policy is to provide guidance and clarification, regarding deactivation of ICD devices for palliative care patients, for all staff working in NHS Dumfries and Galloway.

The objectives of this policy are as follows:

- To improve the care of patients with an ICD/ CRT-D who are reaching the end of their life.
- To avoid inappropriate 'Therapy' from their ICD device
- To ensure decisions regarding the deactivation of the patients' ICD device are made according to:
    - Whether the shock function being activated would succeed in sustaining the patients' life, if activated within the patients' current condition.
    - Whether other interventions e.g. CPR would succeed
    - The patient's wishes and best interests.
    - Legislation such as the Human Rights Act (1998) and the Adults with Incapacity Act (Scotland) (2000),
- To make deactivation of ICD decisions transparent and open to examination.
- To Clarify deactivation of ICD situations for clinical staff, in all locations, caring for people who have communication difficulties and other vulnerable groups.
- To ensure patients, and relevant others and staff have information on making decisions about deactivation and they understand the process.
- To encourage and facilitate open, appropriate and realistic discussion with patients and relevant others about deactivation issues of ICDs'
- To ensure that a deactivation decision is communicated to all relevant healthcare professionals and services involved in the patient's care.
- To raise the awareness of the need to consider ICD function when a DNCPR order is in place for a patient

• Scope of the Policy

The scope of this policy is to reach all patients who have an implantable defibrillator which has a shock function (ICD/CRT-D). The implementation of this policy will be carried out in conjunction with appropriate clinical staff which may include GP, Cardiologist/ other Hospital Consultant(s), specialist palliative care contact, heart failure nurse/named nurse, lead cardiac physiologist and social worker. This policy applies to the whole of the organisation.

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2. DOCUMENT AIMS

When is an implantable cardioverter defibrillator (ICD) implanted

Most forms of heart disease will require life long medication and various interventions. An ICD is one form of intervention. It is used for:

- Patients who have a life-threatening ventricular arrhythmia, or
- Those who have been identified as being at risk of developing a life-threatening ventricular arrhythmia.

What is the purpose of implantable cardioverter defibrillators (ICDs)

The purpose of an ICD is to monitor the heart rhythm and respond to arrhythmia. The ICD is implanted to prevent sudden cardiac death due to cardiac arrhythmia.
The functions of the ICD are:

- Automatic administration of defibrillation shocks to terminate ventricular fibrillation (VF) or fast ventricular tachycardia (VT)
- Anti-bradycardia pacing, often used after a defibrillation shock as the heart returns to normal sinus rhythm
- Anti-tachycardia pacing to terminate slower VT.

Some ICDs also have, along with a defibrillation function, a pacing function. The pacing function of such devices should usually not be disabled, even in end of life/dying patients, as withdrawing pacing support may introduce additional symptoms and accelerate the dying process,

Discussing information with the patient

When consenting patients for the fitting of an ICD as well as following current consent guidelines the clinician should include the topic of deactivation. Clinicians should take into consideration patients perceived or expressed wishes to know about the topic of deactivation at the palliative care stage / end of life stage, but in general the topic should be included in the consent process wherever possible
The discussion regarding future deactivation could be initiated at their cardiology review or as clinical circumstances change, depending on how relevant the treatment is and, when appropriate, introduce the possibility of deactivating the defibrillator function to avoid the patient experiencing distressing symptoms'.

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Deactivation of the defibrillator function of the ICD

There are currently specific circumstances when it is advised that a defibrillator function of an ICD is switched off. These include preoperatively, intraoperatively, and for some patients under going radiotherapy may require temporary deactivation.

Patients with advanced end-stage heart failure requiring palliative and supportive care, frequently exhibit metabolic or biochemical derangement and are at risk of developing complex agonal arrhythmias that may trigger firing of the ICD/ CRT-D. In these circumstances, it would be inappropriate to maintain the ICD/ CRT-D in active defibrillation mode, as the shocks would disturb the patient and cause distress. In order to ensure a peaceful and natural process of death for a patient with an ICD/ CRT-D the doctor caring for the patient should consider deactivating the shock function of the device. Where the patient has capacity this should be done after discussion and their agreement. The Record of the Decision to Withdraw Implantable Cardioverter Defibrillator (ICD) Therapy in an Adult Patient should be completed and held in case notes. (See Record of Deactivation Form)
As the patients with ICD's are approaching the end of life, it is important that sensitive discussions are had with them and their families/carers around the deactivation of their device. Discussion should take place as early as appropriate to enable proactive care management to avoid unnecessary distress and ideally carried out by the health professional best known to them.

DNA CPR orders

In general, maintaining an ICD in defibrillation mode is inconsistent with an active DNA CPR order and is rarely warranted. However it is possible that a competent patient may decline full resuscitation due to loss of dignity incurred during the process but decide that keeping their ICD active is reasonable.

This decision requires to be documented in the patient's notes and hospital records and shared will all key personnel in their care provision. The doctor should review these decisions at regular intervals to ensure that the goals/plan of care remains relevant at all times.

3. RESPONSIBILITIES AND ORGANISATIONAL ARRANGEMENTS

When an ICD device should be deactivated

Generally it is difficult to give an accurate prognosis for a patient with heart failure or a malignant condition. Some patients with heart failure and an ICD device will develop progressive multiple comorbidities – sometimes these can be linked together, as in the case in heart and kidney failure- which may result in periods in rapid decline. Sometimes, though short-term prognosis of these patients is not straight forward. Sometimes the patient's medical stability/status can be fragile and an individuals survival or impending death unpredictable. Such difficulties in prognostication at times of crisis or an apparent deterioration need to be openly discussed and acknowledged, and

highlight the importance of maintaining an awareness of an active ICD and considering the possible confounding effects of this device in optimising patient care.

Raising the issue of ICD deactivation at such times can be difficult for the reviewing health professional - particularly if the patient is deemed incompetent to communicate his or her wishes. In some cases an individual may have completed an advance directive/advance care plan to cover their possible future wishes etc. Health professionals should comply with the patient's wishes, unless there is a valid reason for not doing so.
Medical, nursing and technical staff are in a position to anticipate situations for reviewing a patient's implantable device, and the importance of discussing possible ICD deactivation as the patient's condition changes. It is advocated that the first conversation- regarding deactivation of a device- should take place at the initial implantation. Situations when deactivation of ICD should be considered may include:

- A DNACPR order is in place.
- Withdrawal of anti-arrhythmic medication (in the context of a patient nearing end of life where treatment is now deemed in appropriate)
- Has other comorbidties present.
- Terminal Diagnosis
- Refractory symptoms despite optimal treatment for them
- Fits the 'surprise question' would you be surprised if this patient was alive in the next year
- Dependent for more than three activities of daily living. Quality of life poor.
- Resistant hyponatraemia
- Has a serum albumen less than 25g/1.

It is important to remember that the decision to deactivate the device can be reversed if the clinical situation should change.

Planned deactivation

Patients should ideally have deactivation carried out at the ECG department at NHS Dumfries and Galloway during a pre-arranged clinic appointment. This planned pathway should be followed by the majority of patients requiring deactivation. (See Algorithm 1 & 2)

Emergency deactivation

Patients experiencing an unexpected deterioration should be transferred to the hospital unless their preferred place of care is their home. The DNA CPR order and request for deactivation of device must be communicated to the hospital to ensure patient choice is followed.

If there is no device programmer available in the vicinity, a "donut" magnet can be taped in place over the device to disable it. These magnets are very powerful and can be obtained from the ECG Department NHS Dumfries and

Galloway during Monday – Friday 9-5 and ward 8 Medical High Dependency Unit any other time.
This temporary measure can be used until deactivation by a cardiac physiologist/ cardiologist can be arranged. It may be difficult for a patient who is in their last days of life to travel to Dumfries hospital for deactivation, therefore it is the responsibility of the clinician in charge to contact the ECG department to discuss whether they can attend to deactivate the device locally.

This pathway should be restricted to emergency situations only and should not be considered the normal pathway for deactivation.

NB. It is important to note that this magnet deactivation function needs to be activated and does not necessarily happen automatically. It is recommended that you check with the implant centre or ECG department at Dumfries Hospital to ensure that the function is active to avoid emergency situations arising.

4. MONITORING

See Record of Deactivation Form.

5. EQUALITY AND DIVERSITY

The Decision to Withdraw ICD Therapy in an Adult Patient: Explanatory Notes

Introduction

A patient is implanted with a cardioverter defibrillator (ICD) to prevent sudden cardiac death due to certain life-threatening arrhythmias. Sometimes a cardioverter defibrillator is combined with a cardiac resynchronisation therapy (CRT-D) device. The device senses continuously until an arrhythmia is recognised, at which time a shock is delivered to the heart. As a patient with an ICD is diagnosed with advanced disease, often non-cardiac related, and is in the last days of life, it may no longer be appropriate for these shocks to continue being delivered to the heart.

The Decision

The decision to withdraw ICD therapy must be made by the doctor in charge of the patient's care in consultation with the multidisciplinary team and having first obtained a competent patient's consent. If the patients lacks the capacity to consent the doctor must consider whether there is a valid and applicable advance decision in force and/or whether there is an Attorney who has been appointed under a Welfare Power of Attorney (WPA) who can give consent to the withdrawal. If neither is in place the decision must be made on the basis of the patient's "best interests", having first complied with the statutory duty to consult those close to the patient, and those with a proper interest in their welfare e.g. anyone providing care to the patient on an unpaid basis.

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These notes and the algorithms to which they relate provide advice to all involved and in particular, to the doctor in charge who must complete the record of the decision-making process. The advice is based on the General Medical Council's guidance Withholding and Withdrawing Life-prolonging Treatments 2006, supplemented by advice contained in Decisions Relating to Cardiopulmonary Resuscitation 2002, a Joint Statement from the British Medical Association, the Resuscitation Council (UK) and the Royal College of Nursing endorsed by the Department of Health. Legal advice has also been taken to ensure compliance with the provisions of the Adults with Incapacity (Scotland) Act 2000 and the Adult support and protection (Scotland) ACT 2007

Information to be given to Patient at the Time of Implant.

This information should explain to the patient that there might come a time when their ICD should be deactivated. The information should describe the objectives of the ICD and that when the end of life approaches ICD therapy may no longer be appropriate. The patient's views should be canvassed, and noted. If the patient wishes to make a specific advance decision to stipulate a wish that the
ICD be de-activated at a certain point, this should be carefully recorded. The patient should be encouraged to notify relevant parties about the advance decision e.g. GP/close family and friends, and reasonable steps should be taken to ensure it will come to the attention of those treating the patient in the future.

Is the Patient Nearing the End of Life?

This question could be raised by the patient, a member of the family or a member of their care team. This may at times be very difficult but for those placed on the Liverpool Care Pathway (LCP)/ Gold Standards Framework. It would be appropriate to consider ICD deactivation.

Doctor in Charge of Patient's Care

The doctor in charge of the patient's care could be the patient's GP, cardiologist or consultant in another speciality. It is the doctor who is currently co-ordinating any care or treatment that the patient is receiving. If the patient is receiving primary/community care this doctor is likely to be the patient's GP. If the patient is in hospital, it is likely to be the treating consultant. The doctor in charge is responsible for assessing and monitoring the patient's condition, likely prognosis and treatment options. They must take account of current guidance on good clinical practice and the views and assessments of the multidisciplinary team, and consider if a second opinion is necessary or would be helpful in a particular case. They are responsible for initiating the discussion to withdraw ICD therapy subject to all the checks and balances outlined in this guidance.
They must record the key stages of the decision making process on the pro-forma. They should include sufficient detail to ensure that they can give a clear rationale for the decision if ever required in the future.

Multidisciplinary Team

The multidisciplinary team consists of all members of staff involved with the patient's care/treatment. This group includes GP, consultant(s), and palliative care team, and specialist nurse, district/home/ward nurse and social worker. Appropriate team members should be involved with the assessment of the patient to incorporate all aspects of the patient's condition, prognosis, treatment and care in liaison with the doctor in charge.

Second Opinion

The doctor in charge should consider seeking a second opinion where, for example, the patient's condition is complex or is not progressing as expected or where clinical scenarios change and it may become necessary to change/restart treatment that has been withdrawn. It must be recognised that patients might change their minds about decisions. A second opinion may also be useful where the position regarding the patient's capacity is in doubt or where the views of the doctor in charge regarding capacity are challenged. A consultant cardiologist at the local hospital can be contacted for further advice.

Discussion with Patient

The doctor in charge should always discuss matters with the patient or with carers if patient lacks capacity. The discussion must be sensitive to the patient's needs and their current situation. Sufficient time should be taken to consider all aspects of the patient's care requirements. The patient may wish to involve those close to them or their religious or spiritual adviser, which should be accommodated wherever possible. However, if the patient does not wish to know all the details of their condition, their wishes should be respected as far as possible, whilst still ensuring that the patient is provided with sufficient information to provide informed consent to withdrawal of treatment.

Adults with capacity

Adult patients are presumed to be competent to make decisions about their own health care, unless there is evidence to the contrary. This means they have the right to decide how much weight to attach to the benefits, burdens, risks, and the overall acceptability of any treatment. In short, they have the legal right to refuse treatment, even life-sustaining treatment, provided they are competent and their decision is informed, i.e. they understand fully its consequences. Adult patients can, whilst they have capacity to make their own decisions, express their wishes about treatment which is proposed in the future at a time when they will have lost capacity to make decisions. This is done by making an advance decision to refuse specific types of treatment.

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Patients who may lack capacity

- A person must be given all appropriate help (e.g. communication aids/specialist support) to make their own decision before it is concluded that they are incapable of making their own decisions;
- Individuals must retain the right to make what might be seen as eccentric or unwise decisions without these prompting assumptions that they may lack capacity;
- Anything done for or on behalf of a person without capacity must be in their best interests;
- When deciding what is in the person's best interests, consideration must be given to whether the desired aim can be achieved by different means, which are likely to be less intrusive/restrictive of the person's basic rights and freedoms. Evidence that a patient may not have capacity should be carefully assessed.

Test for capacity

To determine if a person lacks capacity to make particular decisions, the Adults with Incapacity act sets out a two-stage test of capacity:

Stage 1: Does the person have an impairment of, or a disturbance in the functioning of, their mind or brain?

Stage 2: If so, does the impairment or disturbance mean that the person is unable to make a specific decision when they need to?
The Act defines a person as unable to make a decision if they cannot:

a) Understand the information relevant to the decision (A person will not be deemed unable to understand the relevant information if they can understand an explanation of it given in a way that is appropriate to their circumstances, using simple language, visual aids etc.);
b) Retain that information (For a period long enough to make the decision in question);
c) Use or weigh that information as part of the decision-making process; or
d) Communicate their decision (By talking, using sign language or any other means). If a person cannot do any one or more of the above, they can be assumed to lack capacity. The decision must be made freely without the person being under pressure to reach a particular conclusion such as they effectively have no choice about the decision.

Decision making where patient lacks capacity

Where an adult patient does not have capacity at the material time to give/withhold consent for the particular action proposed, it should be considered whether:

a) There is a valid and applicable advance decision in force, which is relevant to the decision to withdraw ICD therapy.

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b) There is an attorney who has been appointed under a Welfare Power of Attorney (WPA) who must act in the patient's "best interests" and can give or refuse consent to the proposed action. If there is both an advance decision and a WPA and these are contradictory, legal advice should be sought to confirm which takes priority. If the doctor in charge is concerned that the appointed WPA is not acting in the patient's "best interests" or it is unethical to continue therapy, legal advice should be sought. If there is no valid and applicable advance decision and no WPA is appointed to give or refuse consent, the decision must be made on the basis of "best interests."

"Best Interests"

Clinicians have a duty to provide treatment to those lacking capacity where that treatment is deemed to be in the patient's "best interests." Where adult patients lack capacity to decide for themselves, an assessment of the benefits, burdens and risks, and the suitability of the proposed treatment vis-à-vis other options, including no treatment at all, must be made on their behalf by the doctor in charge, in consultation with the multidisciplinary team. The doctor should discuss matters with the patient and take account of their wishes, where they are known. There is also a statutory duty to consult with those close to the patient unless it is not practical or appropriate to do so. Case law has established that "best interests" means more than just best medical interests; it includes considering all aspects of the individual's life relevant to the decision in question e.g. religious, cultural, political beliefs and values, social, emotional, psychological and personal issues/preferences.

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6. DOCUMENT CONTROL SHEET

DOCUMENT CONTROL SHEET

1. Document Status

Title	**Deactivation of Implanted Cardiac Devices with shock function- ICD/CRT-D at the End of Life**
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Approver	
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2 Document Amendment History

Version	Section(s)	Reason for update
1.1		
1.2		

3. Distribution

Name	Responsibility	Version number

4. Associated documents

E.g. national legislation, guidance or standards

5. Action Plan for Implementation

Action	Lead Officer	Timeframe

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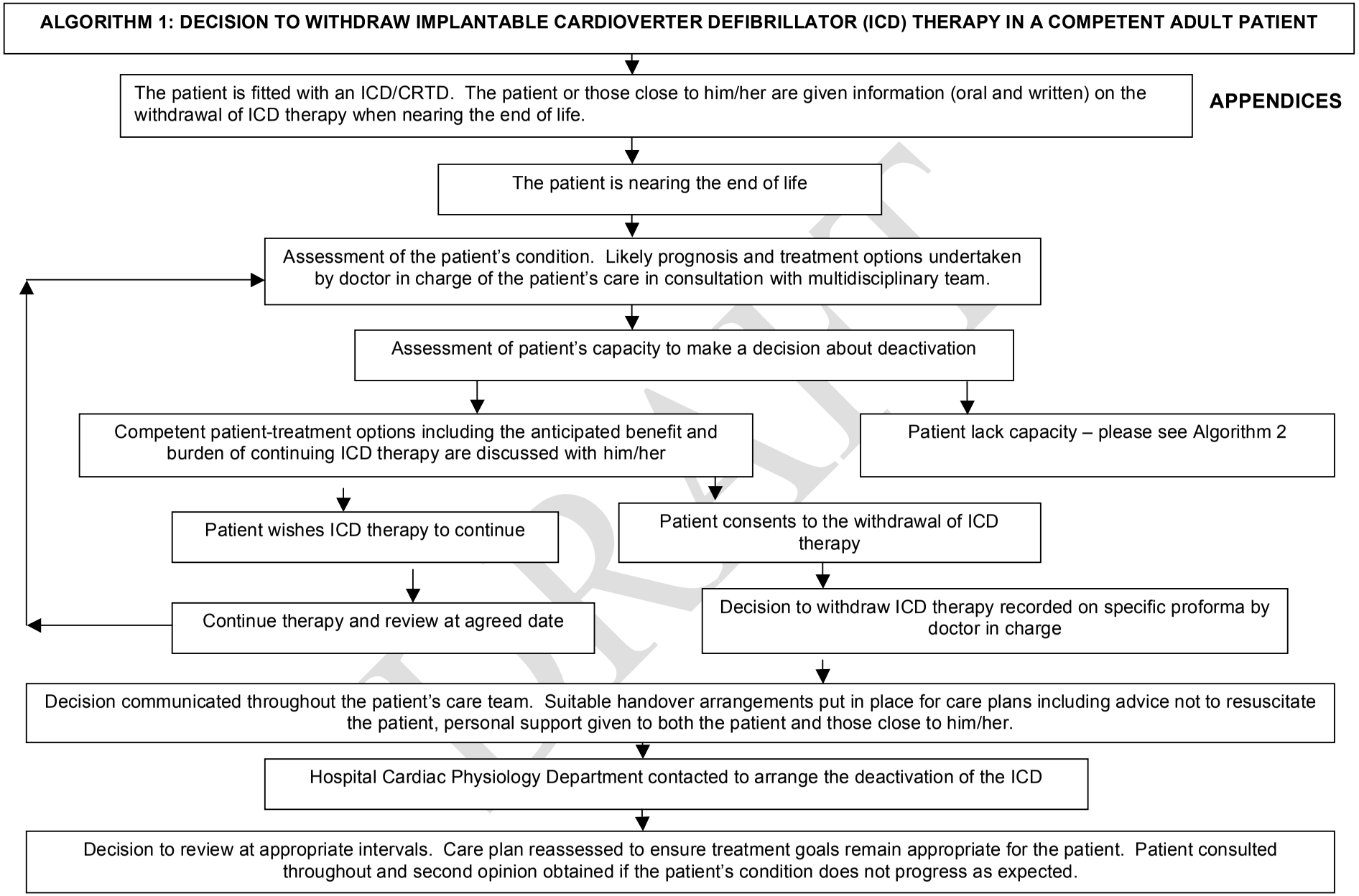
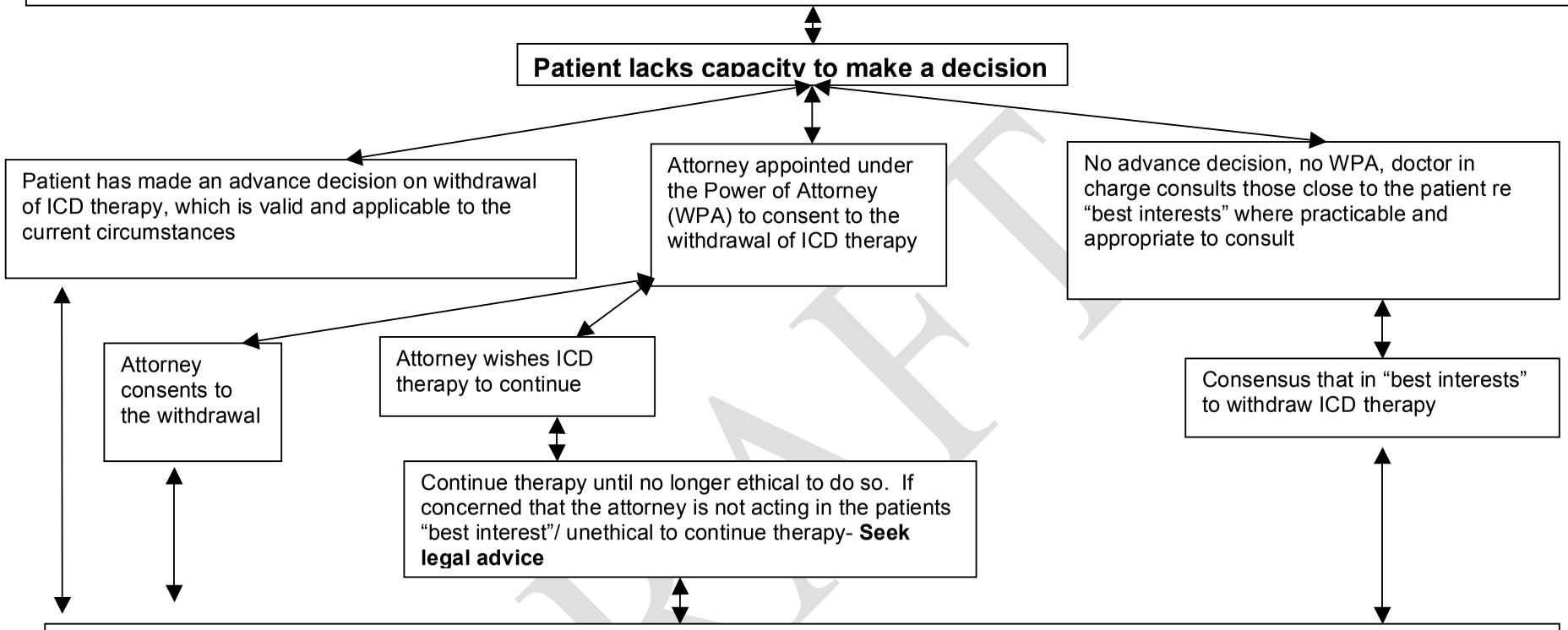

ALGORITHM 1: DECISION TO WITHDRAW IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) THERAPY IN A COMPETENT ADULT PATIENT
The patient is fitted with an ICD/CRTD. The patient or those close to him/her are given information (oral and written) on the withdrawal of ICD therapy when nearing the end of life.
The patient is nearing the end of life
Assessment of the patient's condition. Likely prognosis and treatment options undertaken by doctor in charge of the patient's care in consultation with multidisciplinary team.
Assessment of patient's capacity to make a decision about deactivation
Competent patient-treatment options including the anticipated benefit and burden of continuing ICD therapy are discussed with him/her
Patient lack capacity – please see Algorithm 2
Patient wishes ICD therapy to continue
Patient consents to the withdrawal of ICD therapy
Continue therapy and review at agreed date
Decision to withdraw ICD therapy recorded on specific proforma by doctor in charge
Decision communicated throughout the patient's care team. Suitable handover arrangements put in place for care plans including advice not to resuscitate the patient, personal support given to both the patient and those close to him/her.
Hospital Cardiac Physiology Department contacted to arrange the deactivation of the ICD
Decision to review at appropriate intervals. Care plan reassessed to ensure treatment goals remain appropriate for the patient. Patient consulted throughout and second opinion obtained if the patient's condition does not progress as expected.

ALOGRITHM 2: DECISION TO WITHDRAW IMPLANTABLE CARDIOVERTER DEFIBRILLATIOR (ICD) THERAPY IN A PATIENT



1. **Decision to withdraw ICD therapy recorded on specific proforma by doctor in charge.**
2. **Cardiac Physiology department contacted to arrange the deactivation of the ICD**
3. **Decision communicated throughout the patients care team. Suitable handover arrangements put in place for care plans including advice not to resuscitate the patient, personal support given to both the patient and those close to him/her. Where required there is Certificate of Incapacity under Section 47 of the Adults with Incapacity (Scotland) Act 2000**
4. **Decision to review at appropriate intervals. Care plan reassessed to ensure treatment goals remain appropriate for the patient. Patient consulted throughout and second opinion obtained if the patient's condition does no progress as expected.**
5. **"shock" function of ICD is disabled, documented and a review timetable is agreed.**

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Record of Deactivation of Implantable Cardiac Defibrillator

Patients name	Date of Birth	Date & time of request
Address:		
GP details:		
Patients current location:		
Reason for request:		

I confirm that the following points have been discussed and made clear with the patient and/or family:

☐ The device will no longer provide lifesaving therapy in the event of a ventricular arrhythmia

☐ Turning off the device will not cause death

☐ Turning off the device will not be painful, nor will its failure to function cause any pain

☐ There is a plan of care in place meeting the patients wishes

Signature of Consultant / General Practitioner

Printed name and date

I am satisfied that the processes within the ICD deactivation guidelines have been followed and that the patient and family fully understand the deactivation procedure.

Signature of Cardiac Physiologist deactivating the device

Printed name and date

Date and time of deactivation:

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1. Scottish Government. Living and Dying Well, Scotland (2008).

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