British Heart Foundation

ICD deactivation at the end of life: Principles and practice

A discussion document for healthcare professionals

Dr James Beattie
Consultant Cardiologist, Heart of England NHS Foundation Trust, Birmingham

Chair, Heart Failure Group, National Council for Palliative Care

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Foreword

The implantable cardioverter defibrillator (ICD) was first introduced to a somewhat sceptical medical community some thirty years ago. Today, it is routinely implanted in patients for the treatment of life threatening ventricular arrhythmias and it has undoubtedly prolonged thousands of lives. But there comes a time when prolongation of life is no longer appropriate. For patients close to death from an irreversible and distressing terminal condition, repeated, automatic defibrillation is both counterproductive and hugely distressing.

The aim of our previous document, I**mplantable cardioverter defibrillator in patients who are reaching the end of life**, published in 2007, was to raise awareness of this emerging issue amongst healthcare professionals. Now, six years later, following a rapid rise in the population with ICDs, when and how to deactivate an ICD is no longer a question faced by a minority of healthcare professionals. Bereaved relatives and healthcare professionals who have witnessed the distressing effects of inappropriate ICD activity in terminally ill patients have requested an updated document that provides appropriate advice and guidance.

This document **ICD deactivation at the end of life: Principles and practice** was compiled by Dr James Beattie, a consultant cardiologist with a longstanding interest in palliative care of patients with heart disease, with input from a number of acknowledged experts from cardiology and the broader palliative care community. The British Heart Foundation is very grateful for their time and thoughtful contributions. The document is aimed at all healthcare professionals who may be involved in the management of terminally ill patients, many of whom will not be in a cardiology department or even in a hospital with one.

Professor Peter Weissberg

Medical Director

British Heart Foundation

1. Introduction

In use since 1980, implantable cardioverter defibrillators (ICDs) protect individuals at risk of sudden cardiac death from life threatening ventricular tachyarrhythmia.

An ICD has a number of key functions:

- 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
- cardioversion of VT.

The benefit of these defibrillators in the prevention of sudden cardiac death in those with inherited and acquired cardiac conditions, is well documented. Due to guideline recommendations, there has been an increase in ICD implantation rates, particularly to prevent sudden cardiac death in those with heart failure due to left ventricular systolic dysfunction[1]. Devices inserted in these individuals are either standalone ICDs, (which are occasionally placed subcutaneously), or combined with cardiac resynchronisation therapy (CRT-D). This is a more sophisticated form of pacemaker with three leads used to improve the coordination of cardiac contractility. ICDs are now encountered in routine clinical practice across all care settings. In 2011, the mean implant rate for these devices across England was 76 per million[2].

While considered beneficial on insertion, the presence of an ICD increasingly leads to dilemmas as recipients age and are subjected to the burdens of progressive heart failure or the development of other life limiting conditions such as cancer or dementia. Such developments raise questions on the continuing benefit of ICD therapy which needs to be reviewed as defibrillation can cause physical discomfort and emotional distress to the patient, and also cause emotional distress to their families[3]. Healthcare professionals have a duty of care to consider withdrawal of non-contributory therapies and the distress caused by resuscitation measures in those near the end of life with a progressive and irreversible decline in their condition[4]. This document builds on the previous British Heart Foundation publication, from 2007, which sought to raise awareness of this issue[5].

High quality end of life care is centred on the needs and priorities of each individual and their families, which are assessed through open, sensitive and culturally relevant communication. A variety of options may be discussed and a consensus developed on their requirements for clinical care and social support. The provision of cohesive multi-agency working led by a designated healthcare professional ensures the delivery of personalised care in a timely manner. Appropriate professional development of all involved in heart disease management is fundamental to delivering effective end of life care.

"…patients are 'approaching the end of life' when they are likely to die within the next 12 months. This includes patients whose death is imminent (expected within a few hours or days) and those with:

- Advanced, progressive, incurable conditions
- General frailty and co-existing conditions that mean they are expected to die within 12 months
- Existing conditions if they are at risk of dying from a sudden acute crisis in their condition
- Life-threatening acute conditions caused by sudden catastrophic events."

General Medical Council, 2010[4]

2. Ethical issues

The basic principles of medical ethics are widely considered to be[6]:

- Autonomy – the right of an individual to make their own decisions based on their personal values.
- Beneficence – the obligation to benefit people.
- Non-maleficence – the obligation not to cause harm.
- Justice – fair and equitable treatment based on guidelines, practice, the law and societal norms.

There is a need to recognise that these principles can be potentially conflicting at the end of life. Patient autonomy must be respected by healthcare professionals. Autonomy accords a patient the right to make decisions about their own treatment. We have a duty of care to assist patients in such decision making with the provision of impartial information on their treatment options, including the option to stop or refuse treatment. The full implications of ICD therapy, including the option of deactivation, must be discussed with the patient pre-implantation to ensure the validity of informed consent. High quality clinical practice emphasises the importance of shared decision making between healthcare professionals and patients, and if appropriate their families, throughout the course of the person's illness. A patient with mental capacity has a legal and ethical right to request withdrawal of medical interventions, including ICD therapy, which sustain life[6, 7]. Paternalism can potentially undermine autonomy and this occurs when clinicians assume responsibility for treatment decisions without patient involvement. This is only considered justified if patients lack mental capacity and then the best interests standard applies.

Healthcare professionals have a duty to provide beneficial treatment without causing disproportionate harm. When initiating ICD therapy there is a tacit acceptance that in achieving the greater benefit of preventing sudden death (beneficence) there is a justifiable trade off when the patient may be subjected to uncomfortable shocks (maleficence) by the defibrillator when it detects VF or VT. The consent process for ICD insertion also requires explanation of the background to this justification. Towards the end of life, however, the physical and psychological harm caused by such shocks may outweigh the benefits when the previously appropriate treatment becomes burdensome. The goals of care can change and, if clinically appropriate, it is ethically acceptable to withdraw such therapy if that is consistent with the patient's preferences (autonomy). The principle of autonomy requires that the care and treatment a patient receives is consistent with their individual and cultural values.

Justice obliges healthcare professionals to distribute resources equitably, and to fulfil their personal and professional duties of care in a manner supported by societal norms, the law, conditions of employment and professional registration standards that include a code of conduct.

"Generally, medical organisations are more attentive to developing indications for use of new technologies than to assessing appropriate treatment withdrawal…Implanted cardioverter defibrillators represent another new life-extending technology for which examination of its ethical implication lags behind its use."

Dr Jeffrey Berger, 2005[8]

Information exchange and valid informed consent

Studies of ICD recipients suggest that any discussion pre-implantation tends to emphasise the perceived benefits of the procedure. Risk of fatal arrhythmia, prognosis relevant to the underlying cardiac pathology including heart failure, patient preferences and alternative treatment options often remain unexplored[9]. The overall mortality of older patients with multiple comorbidities is unlikely to be reduced and patients with advanced heart failure are less prone to sudden cardiac death. Generally, healthcare professionals propose a guideline driven default prescription of ICD therapy and patients accept this treatment plan[10]. Patients can

feel either disempowered or enthralled by the high-technology nature of the device with which they can develop a complex psychological relationship, and often overrate its life-saving capability (halo effect)[11].

The concerns of the implanting team, who the patient may meet for the first time when admitted for device therapy, may be largely confined to confirmation of clinical eligibility. The formal consent process may be limited to a technical explanation and a description of risks relevant to the peri-procedural period[12]. This phase of active intervention may be considered an inappropriate time to first open discussion with a patient on some of the complex issues related to ICD therapy for individuals.

ICD recipients also tend to focus on the prevention of sudden cardiac death rather than considering the effect the implant might have on the character or quality of their death from any other cause[13, 14]. It is suggested that only 4% of implant centres discuss deactivation at the time of implantation[15], despite recommendation that possible later ICD deactivation towards the end of life should be discussed as part of the consent process prior to the procedure[16].

- Device deactivation options should be included in the order of pre-implantation informed consent.
- At the time of implantation of an ICD/CRT-D, the possibility that the patient's health may deteriorate to such an extent that device deactivation may be appropriate should be discussed.

European Heart Rhythm Association, 2010[16]

Some implant centres now provide patients with written information about ICD deactivation prior to the procedure. This reinforces informed consent as well as the process of advance care planning which should be encouraged[17, 18]. Advance care planning allows patients to make decisions regarding their future care and treatment for the end of their life or when they may no longer have mental capacity[19]. A pre-procedure discussion on ICD deactivation facilitates revisiting the issue in the future following changes in health status, including an increase in device shocks and when planning end of life care[20].

The question of ICD deactivation requires urgent review if the patient is felt to be in the last year of life and is registered on the Gold Standards Framework in primary care. ICD handling should be incorporated in local Do Not Attempt Resuscitation (DNAR) policies and deactivation considered if such a decision, regarding resuscitation, is enacted. In general, maintaining an ICD in active defibrillation mode is inconsistent with a DNAR order unless it is the patient's specific wish.

Decision making, capacity and multidisciplinary working

Algorithms, which outline decision making relevant to ICD deactivation, can be found in Appendices 1 and 2 for competent patients and those lacking capacity. These offer a synthesis derived from policies developed

"A person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

An inability of a patient to make decisions is assumed if any one of the following features applies:

If he / she is unable—
a. to understand the information relevant to the decision,
b. to retain that information,
c. to use or weigh that information as part of the process of making the decision, or
d. to communicate his decision (whether by talking, using sign language or any other means)."

Mental Capacity Act (2005) (21)

from various cardiac networks across England, some of which are accessible via www.nhsimprovement/heart. Capacity must be assumed for all individuals, but if loss of capacity is suspected, a two-stage test of capacity is enshrined in the Mental Capacity Act (2005)[21].

Whether or not the patient is found to exhibit decision-making capacity, a multidisciplinary team (MDT) approach to ICD deactivation at the end of life is essential. This ensures both comprehensive assessment of this intrinsically complex situation and identification of a patient's care needs. Composition of the MDT will depend on a patient's comorbidities but if heart failure is the principal diagnosis, the heart failure specialist should lead the MDT. Specialist palliative care involvement is essential. Consideration should also be given to whether it is appropriate for the patient, or their representative, to attend any MDT meeting to safeguard their autonomy and ensure their wishes are considered and documented.

Initiating the conversation

If the patient or their representative does not participate in the MDT meeting convened to consider the option of ICD deactivation, then a consultation should be arranged with them after the meeting, without delay, when an unhurried discussion should take place with them in privacy, and in an appropriate environment. This discussion is often undertaken by a heart failure nurse specialist who is already known to them and who has received formal training in advanced communication skills. This nurse is usually well placed to assess the patient and family's insight into the condition and prognosis. The nurse is also often best placed to ensure patient and their families understand why the question of device deactivation has been raised and may be a reasonable option. This is a difficult and often unexpected conversation for many patients. More than one meeting may be required before a patient understands the consequences of this proposed revised treatment plan on the remainder of their lives, and has all the information and support they need to participate in the decision making process. This includes reassurance that ICD deactivation is painless, only discontinues the shock component of the ICD and does not cause or hasten death or any change in their general condition. Patients should be assured that they will continue to receive all the care and support they need from their established cardiology team, and that consideration may be given to reactivation of the ICD should their condition unexpectedly improve.

- Device implantation centres are strongly encouraged to follow a local policy for the management of end of patient life.
- All device follow up centres (including those which only follow up pacemakers) should have a policy in place for deactivation of ICD function in ICD and CRT-D devices which should include the facility for domiciliary visits.
- Device therapy termination should be a consensus between the physician normally responsible for patient care e.g. oncologist, device consultant, GP, device physiologist, the patient and where possible a representative for the patient (e.g. a relative).
- Different levels of device therapy termination should be considered specific to the individual case and informed consent must be documented.

Heart Rhythm UK, 2013[22]

3. Practicalities of ICD deactivation

Hospital based deactivation

The local centre the patient attends for device follow up should assume the primary responsibility and have the capability to undertake ICD deactivation and ensure it is performed in a timely manner. All hospitals, however, should have a service level agreement with their local centre to provide the deactivation service regardless of where it was implanted or where follow up takes place.

Some healthcare professionals may decline to be involved with device deactivation based on personal beliefs[23, 24]. Although such views must be respected, they cannot be allowed to affect care that provides comfort and dignity at end of life and an alternative healthcare professional, prepared to adjust the device, should be involved if this is consistent with the patient's wishes.

If a patient is at home and can travel, elective deactivation can take place in the cardiology device clinic with the patient's formal consent as per local protocol. It is performed by a cardiac physiologist who will re-programme the device by disabling anti-tachycardia monitoring and the device response (shock therapy).

If a patient is in hospital and too ill to be transferred, ICD deactivation can take place at the bedside and local protocols should ensure this option can be met. Even if ICD services are not provided within the admitting hospital, local arrangements should include contingencies to obtain services from another centre.

It is essential that device deactivation is formally documented as determined by local arrangements, and all relevant personnel involved in the patient's care must be informed, including ambulance and out of hours health services. It is good practice for the patient to be provided with written documentation they can retain for reference.

Device deactivation in the community

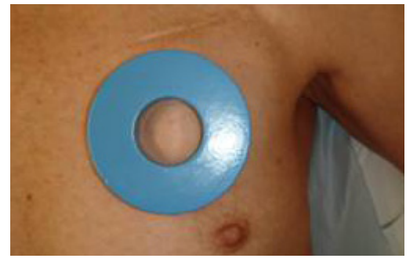
Device deactivation in the community needs to be included in local protocols but may pose greater logistic challenges in service configuration to access trained staff and hardware.
Many patients would choose to be cared for and die at home or in a nursing home if that is their usual place of residence. Sometimes those with progressive conditions can deteriorate suddenly, rendering them too ill to justify the discomfort and distress involved in transfer to hospital. The same process of decision making through MDT team working and a formal informed consent process applies irrespective of the clinical setting. Either the GP or specialist nurse caring for the patient in primary care will play a central role in liaising with cardiac services to ensure the cardiac physiologist undertakes the deactivation process. Hospital based ordinarily, Crown Immunity through Trust employment ensures that the cardiac physiologist is covered to provide this outreach service. It is recommended that the patient's GP or specialist nurse is present during the deactivation procedure to provide information and support, and it is important to ensure that palliative care services are involved before this takes place.

Patients with active ICDs are increasingly admitted to hospices. Formal deactivation protocols, the presence of a magnet (see image) and provision of appropriate staff training must be undertaken and alignment with local cardiology services must be in place to facilitate full device deactivation[25, 26].

An increased focus on assessing the need for elective ICD deactivation at the end of life may reduce the need for emergency deactivation in the community, improving the efficiency of staffing arrangements, and avoiding potential delays that may exacerbate patient and family distress.

Emergency deactivation

As illustrated, this can be achieved with the secure placement of a doughnut magnet on the chest, over the device, (with the use of adhesive tape) which closes the reed switch. This may be particularly important when the ICD is repeatedly shocking someone close to death which is distressing for both the patient and their family. Easy access to magnets in all clinical areas must be addressed in local protocols as must the training of staff in their use. However, it must be emphasised that this is only a temporary measure and full deactivation needs to be undertaken as a matter of urgency.



It is also recommended that Trust ICD deactivation protocols are easily accessible and linked to their resuscitation policy. Heart Rhythm UK highlights the importance of 24 hour cover for all aspects of ICD device management including device deactivation[21]. While for some the change in condition is sudden, for others the deterioration can be anticipated and this should be taken into account so that a distressing experience for the patient and their family can be avoided if at all possible.

Post mortem device handling

If the ICD is still active when the patient dies, or if only temporary deactivation has been achieved, the device still needs to be fully deactivated after death, by the local cardiac physiologist, to avoid the risk of electric shock to clinicians and mortuary workers[26]. A proforma confirming complete deactivation should be incorporated in local Last Offices documentation. Like pacemakers, ICDs must also be explanted prior to cremation of the body due to the risk of lithium battery explosion[27].

Unless local guidelines state differently, Department of Health guidance, outlined in Health Notice HN(83)6 of 1983 and still in force, implies that implanted electronic devices should be accorded a legal status as intrinsic to the deceased's estate[28]. Explantation and disposal of the device may, therefore, need to be discussed and agreed with next of kin or the appointed executor. Such processes can impact the bereavement process and may be addressed by including a statement on device handling after death within the procedural consent form, a copy of which is retained in the clinical notes.

4. Recommendations

- ICD deactivation at end of life needs to be part of the pre-implantation consent and counselling process, and formalised in advance care planning if the patient is agreeable[15].
- A comprehensive assessment of the overall benefits and implications of ICD therapy should be undertaken based on a patient's needs and preferences, prior to implantation.
- Shared decision making needs to take place allowing valid informed consent prior to the implantation process.
- The appropriateness of maintaining device therapy must be regularly reviewed as part of monitoring of the patient's progressive disease trajectory, if there is any change in clinical status including the development of a life limiting disease, and when the ICD generator box is considered due for replacement[29, 30].
- The development of local robust protocols for implementing ICD deactivation is essential and should refer to a MDT approach, staff training, the provision of 24 hour device-related cover, and appropriate exchange of information with the patient and all involved in their care.

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Written by:
Dr James Beattie, Consultant Cardiologist, Heart of England NHS Foundation Trust, Birmingham, UK and Chair, Heart Failure Group, National Council for Palliative Care.

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Appendix I: Decision algorithm for the deactivation of ICD therapy in the adult patient with decision-making capacity at the end of life

Patient receives ICD. Pre-implantation discussion and consent process incorporates oral and written information that withdrawal of ICD therapy may be appropriate when they are nearing the end of life.

Review of device status and possibility of device deactivation revisited at intervals along the disease trajectory if patient comfortable with this discourse.

Patient with ICD and progressive disease now shows signs of irreversible clinical deterioration and likely to be in a terminal phase of illness.

Following comprehensive clinical assessment, treatment options and care needs discussed at MDT by doctor with overall responsibility for patient's care.

Assessment of patient's capacity to contribute to decision making if considered suspect

Patient competent

Patient has lost capacity

Go to Appendix 2

The patient and (subject to his/her consent) their close persons are informed that it may be now appropriate to consider withdrawal of this therapy.

Patient requests ICD therapy to remain active.

Patient consents to ICD deactivation.

ICD therapy maintained. Continue to support patient but review general resuscitation status. Seek legal opinion on policy if device is actively rendering harm or if this is anticipated.

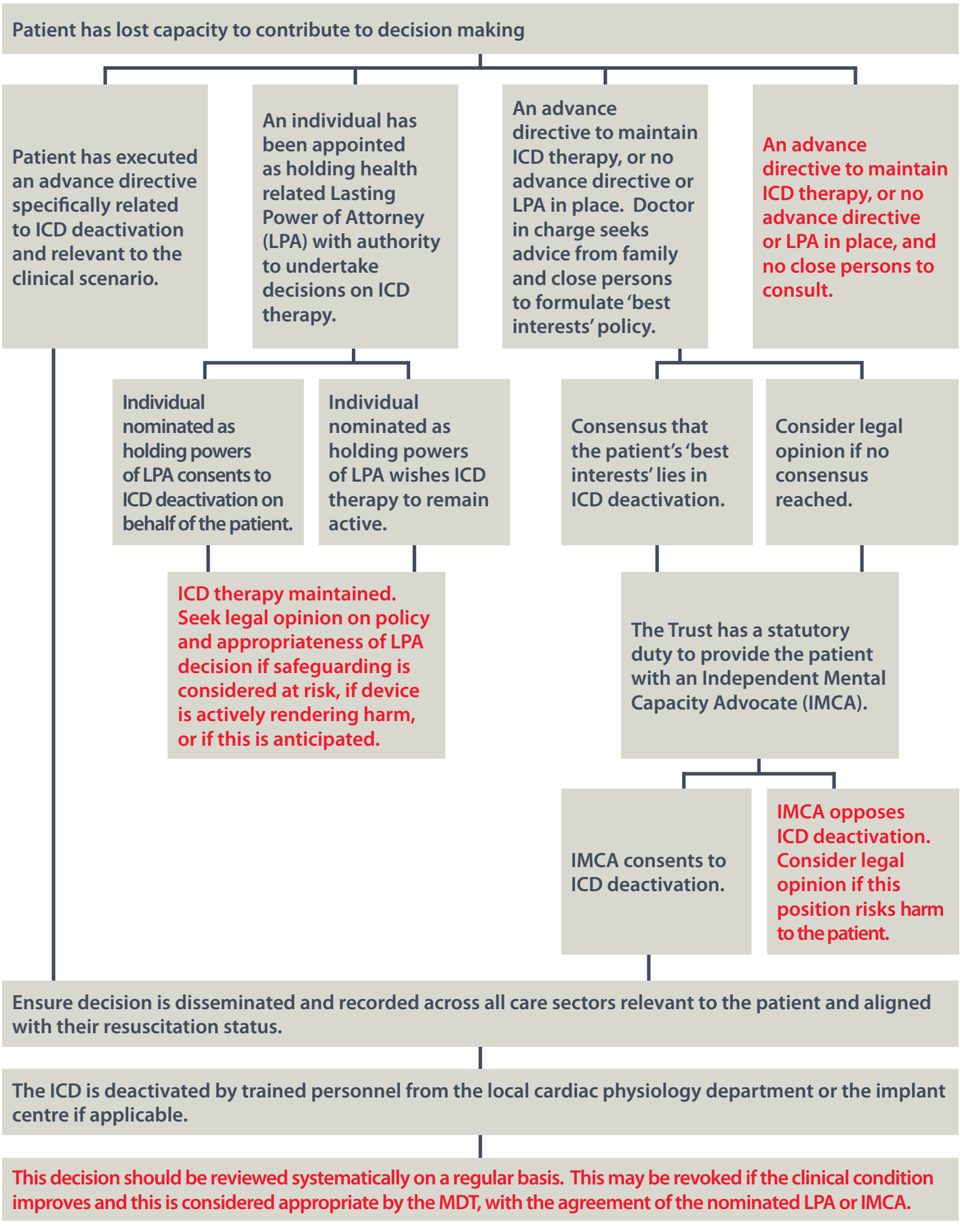
This decision and patient's written consent for this action should be recorded on a locally produced document and filed in the clinical notes. The patient should retain a personal copy.

Ensure decision is disseminated and recorded across all care sectors relevant to the patient and aligned with their resuscitation status.

The ICD is deactivated by trained personnel from the local cardiac physiology department or the implant centre if applicable.

This decision should be reviewed systematically on a regular basis. This may be revoked on patient request (subject to the conditions above) or if the clinical condition improves and this is considered appropriate by the MDT, with the patient's agreement.

Appendix 2: Decision algorithm for the deactivation of ICD therapy in the adult patient with decision-making capacity at the end of life



British Heart Foundation

Coronary heart disease is the UK's single biggest killer.

For over 50 years we've pioneered research that's transformed the lives of people living with heart and circulatory conditions. Our work has been central to the discoveries of vital treatments that are changing the fight against heart disease.

But so many people still need our help.

From babies born with life-threatening heart problems to the many Mums, Dads and Grandparents who survive a heart attack and endure the daily battles of heart failure.

Join our fight for every heartbeat in the UK. Every pound raised, minute of your time and donation to our shops will help make a difference to people's lives.

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