Cardiovascular implanted electronic devices in people towards the end of life, during cardiopulmonary resuscitation and after death

Guidance from the Resuscitation Council (UK), British Cardiovascular Society and National Council for Palliative Care





THE National Council for Palliative Care

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1. Summary statement: Main Messages

This section highlights the main messages. Readers are advised to refer to relevant sections of the full text in order to ensure that these summary points are interpreted and used in context.

1.1 Aspects of routine device management

- Cardiovascular implanted electronic devices (CIEDs) include permanent pacemakers and implantable cardioverter defibrillators (ICDs). They provide effective treatment for many people by reducing symptoms and/or by preventing sudden cardiac death.
- Where there may be a later need to consider deactivation (i.e. in people considering an ICD, including a cardiac resynchronisation therapy-defibrillator (CRT-D) device) this possibility and the reasons for it should usually be explained as part of informed consent to implantation (see <u>section 7.4</u>). At routine review appointments people should have the opportunity to discuss concerns regarding any aspect of their device, including end-of-life decisions (see <u>section 6.4</u>).
- It is recommended that written consent for device implantation and elective replacement is worded so that the recipient surrenders ownership of the device in the event of removal for clinical reasons or after death. Otherwise the device remains the property of the recipient or of their estate (see section 7.14).
- People with implanted devices should carry with them information about the nature of their device, how to obtain expert advice and, where appropriate, how to deal with an emergency (see section 18).

1.2 Towards the end of life

- People with ICDs, including CRT-D devices, who are approaching the end of their life should be given opportunities to discuss the option of deactivation of their device (see section 6). Individual assessment and discussion of the relative benefits and burdens of elective replacement of any device (for battery depletion) is especially important when people are approaching the end of life (see section 10.7, section 12.9).
- The majority of decisions about deactivation towards the end of life arise in people with ICDs, including CRT-D devices (see <u>section 12.4</u>). It is very rarely appropriate to

consider pacemaker deactivation as part of end-of-life care, unless this is requested specifically by the patient (see <u>section 10.5</u>).

- Decisions about deactivation of any device should be shared decisions, with full involvement of the person themselves and of the healthcare team caring for them, and must be based on careful assessment of a person's individual circumstances at the time (see section 7.2).
- When people lack capacity to share in decision-making, decisions must be made in their best interests, must be made according to the law in that jurisdiction and must involve those with legal power to make decisions on behalf of the person. The views of those close to the patient should be considered when making a best-interests decision in such circumstances (see <u>section 7</u>).
- It must not be assumed that having a do-not-attempt-CPR (DNACPR) decision or being identified as dying automatically warrants ICD deactivation, or that ICD deactivation automatically warrants a DNACPR decision (see <u>section 7.13</u>).
- The appropriateness of deactivation and the appropriate timing of deactivation differ with different devices. When considering deactivation it is essential to understand the nature and purpose of the device in each individual person and to involve those responsible for management of the device (see <u>section B</u> paragraph 3).
- Effective and consistent communication with the person with the device, with those close to them, and with all members of the healthcare team is crucial to avoid misunderstanding and to enable good decision-making. Sensitive discussions about device deactivation should be undertaken by professionals competent in such communication. Discussions and decisions about device deactivation, including those at the time of consent to implantation, should be documented fully (see section <u>7.15</u>).
- Discussion of deactivation of an ICD as part of end-of-life care should allow ample time for explanation, for an agreed, shared decision and for planned deactivation by a cardiac devices physiologist in the majority of cases. Use of a magnet to deactivate an ICD may be useful in an emergency setting, after discussion and careful consideration of its consequences (see sections 12.4 – 12.6).

- Healthcare provider organisations should have comprehensive policies governing device management, including deactivation of devices, to ensure that people with devices have prompt access to appropriate care and support, including access to emergency deactivation if required (see section 17).
- Device services should have a clear policy governing safe disposal of devices. If devices are retained by patients (or after death by their estate) they should be given clear information about potential hazards and how to avoid them (see section 16.7).

1.3 During and after cardiopulmonary resuscitation (see section 15)

- No special precautions are necessary when delivering chest compressions and/or ventilation in the presence of an implanted electronic device. When possible, wearing clinical examination gloves is recommended during any delivery of CPR, as a standard part of personal protection against infection.
- When a person with an ICD suffers cardiac arrest in a shockable rhythm, the device is expected to deliver a sequence of shocks to attempt to terminate the arrhythmia. If the device does not deliver such shocks or if the shockable rhythm persists, external defibrillation should be attempted.
- External defibrillator electrodes should not be placed over or close to implanted electronic devices.
- If a person with a pacemaker or ICD has return of spontaneous circulation after receiving CPR, the device should be interrogated and checked (usually by a cardiac devices physiologist) at the earliest opportunity.

1.4 After death (see section 16)

- If a person with a cardiovascular implanted electronic device suffers unexpected or sudden death, interrogation of the device should be considered to obtain information about cardiac rhythm and device behaviour immediately beforehand. This may help to establish the mechanism and cause of death.
- Implantable cardioverter defibrillators, including CRT-D devices, must be deactivated before any attempt is made to remove them or to perform an autopsy, to avoid risk of a shock to the person carrying out that procedure.

 All implanted electronic devices must be removed before cremation, as they may explode when heated to a high temperature. Device services should have arrangements in place to ensure safe disposal of devices after removal.

SECTION A: General, Ethical & Legal Aspects

2. Introduction

The Resuscitation Council (UK) [RC (UK)], the British Cardiovascular Society [BCS] (including the British Heart Rhythm Society and the British Society for Heart Failure) and the National Council for Palliative Care [NCPC] recognise the importance of providing clear and consistent guidance on management of cardiovascular implanted electronic devices (CIEDs) towards the end of life, during cardiorespiratory arrest and after death. This document has been developed to provide guidance for the full range of healthcare professionals who may encounter people with CIEDs in the situations described below and for healthcare managers and commissioners. The authors recognise that some patients and people close to patients may also wish to refer to this document. It is intended as an initial step:

- to help to ensure that people who have CIEDs, or are considering implantation of one, receive explanation of and understand the practical implications and decisions that this entails;
- to promote a good standard of care and service provision for people in the UK with CIEDs in the circumstances described;
- to offer relevant ethical and legal guidance on this topic;
- to offer guidance on the delivery of services in relation to deactivation of CIEDs where appropriate;
- to offer guidance on whether any special measures are needed when a person with a CIED receives cardiopulmonary resuscitation (CPR);

There has been a progressive increase over more than 50 years in the number of electronic devices implanted. This started in 1958 with the first implanted pacemaker and has progressed to include other devices, implanted to reduce or prevent symptoms, to reduce the risk of death, to prevent death by treating cardiac arrest, to monitor the heart's rhythm or

any combination of those objectives. These devices are referred to collectively as cardiovascular implantable electronic devices (CIEDs).

The increasing use of CIEDs has provided considerable benefit but has also created new challenges for patients and those close to patients, and for healthcare personnel caring for them. Particular challenges may arise when people, despite the presence of their implanted device, approach or reach the end of life. This may be due to deterioration in their heart condition (most commonly heart failure) that cannot be reversed by additional treatment or to the development or progression of another terminal or long-term condition such as cancer or chronic lung disease or kidney failure.

With increasing frequency questions arise about possible deactivation of some of these devices as part of end-of-life care, when the continued operation of some devices may be of more burden than benefit to people.

With increasing frequency also, healthcare professionals caring for such people are faced with practical questions as to how devices can be deactivated and what arrangements are in place in their particular locality to provide the equipment and expert support needed to assist with the management of a device. Policies and information about device deactivation are available in some but not all localities.

Practical considerations also arise and may lead to uncertainty when someone with an implanted device suffers a cardiorespiratory arrest and cardiopulmonary resuscitation (CPR) is started. Those involved in attempted resuscitation may not have detail of the implanted device, may not be familiar with the precise nature and purpose of the device, may be unsure whether they should modify how they deliver CPR or may be unsure whether the device presents a risk to the people providing CPR.

Yet further practical considerations concerning the need for device deactivation or removal arise when someone with an implanted cardiovascular device has died.

This joint document will not:

- offer guidance on the selection of patients for implanted devices,
- offer specific guidance on temporary deactivation of CIEDs for other reasons (e.g. during a surgical operation),
- offer detailed guidance on decisions relating to CPR or

• offer detailed guidance on the delivery of CPR,

on all of which topics detailed published guidance is available (see section 19).

The following sections will consider the general principles of deactivation of devices, together with the ethical and legal considerations that apply, and the general principles of good clinical practice, including communication and informed consent for implantation. The nature and purpose of each individual type of device will be described in separate sections, together with the specific actions that are relevant to management of each type of device towards the end of a person's life, during CPR and after death.

3. Methods

This guidance was produced according to the RC (UK) Development Process Manual (2014). The subject was chosen by the Executive Committee of the RC (UK) as the RC (UK) had received several queries concerning management of CIEDs in people towards the end of life, during cardiopulmonary resuscitation and after death. There was no existing detailed guidance on this topic and discussions with the BCS and NCPC showed that there was interest in developing guidance on this topic.

The guidance was developed by a Working Group, convened by the RC (UK) on behalf of the three primary author organisations: RC (UK), BCS and NCPC. Membership of the Working Group is listed in <u>Appendix C</u>.

A scope for the guidance was developed and posted for consultation via the websites of the three primary author organisations. Applications for registration as stakeholders were invited from organisations considered to have a potential interest in the project, and it was made clear that stakeholder registration from any other interested organisation would be welcomed. A list of registered stakeholders is presented in <u>Appendix B</u>. Comments on the scope were received and considered by the Working Group when finalising the content and wording of the scope. Although the initial scope included consideration of ventricular assist devices, during development of the guidance the Working Group decided that these would be better addressed in a separate document, and that this guidance should consider only CIEDs.

Literature Searches were carried out by Drs Soar and Pitcher to identify relevant publications, and updated in August/September 2014 (see <u>Appendix D</u>). In addition, working

group members and stakeholders identified other documents, including local policies, and patient information leaflets. There are no specific trials in this area. Searches identified observational studies, reviews, expert opinion, and case studies. The available evidence to support any intervention was therefore of low or very low quality, with a high risk of bias. The recommendations are therefore based on expert opinion, balancing of benefits and harms, and the values and preferences of the working group and stakeholders. Specific recommendations about the management of CIEDs during cardiopulmonary resuscitation are taken from the <u>Resuscitation Council (UK) Resuscitation Guidelines 2010</u>. These were produced using a NICE-accredited process.

The method used to arrive at recommendations was based on review and discussion of evidence by the Working Group until consensus was achieved. A process of informal consensus was used. Each member of the Working Group had opportunities to express their views and engage in constructive discussions at each stage of development. A draft of the document was made available to all registered stakeholders for a consultation period of 4 weeks, and was also reviewed and commented on by the Patient Advisory Group of the RC (UK). Received comments were considered individually by the Working Group and used to develop the final wording of the document where appropriate. The document was checked by legal experts.

Organisational and financial barriers to implementation were discussed by the Working Group and addressed in relevant sections if appropriate. To support implementation a patient information leaflet on ICD deactivation towards the end of life, and a clinical operational document on ICD deactivation towards the end of life have been developed. The final version of this guidance was agreed by the Working Group.

4. People (patients) considered in this document

The ethical and legal elements of this document apply primarily to adults (aged 18 years and over). These represent the large majority of people with the implanted cardiac devices described further in <u>section B</u>.

The principles of decision-making and refusal of treatment by children and young people and of withdrawing or withholding treatment in a child are described in detail elsewhere (see <u>GMC 2007</u> and <u>Royal College of Paediatrics and Child Health</u>). The legal principles are encapsulated in the Children Act 1989. This states that the child's welfare is paramount and, wherever possible, specific regard should be paid to the ascertainable wishes and feelings of

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the child. Once children reach the age of 16 they are presumed in law to be competent to give consent for themselves for their own medical and social care and any associated procedures, including end-of-life issues. In most respects they should be treated as adults – thus, if a signature is necessary on a consent form, they may sign for themselves (see Family Law Reform Act 1969). However, unless the competent child refuses to consent to such disclosure, it is good practice for competent children to be encouraged to involve their families in decision-making. The ethical and legal situation for children under the age of 16 years is more complex. In this situation it is advisable to ensure involvement of a paediatrician with experience in end-of-life care and decision-making.

Most other elements of this document apply as much to children as to adults.

5. Devices considered in this document

This guidance refers to people with the following cardiovascular implanted electronic devices:

- pacemakers for treatment of bradycardia;
- biventricular pacemakers, also referred to as cardiac resynchronisation therapy (CRT) - for treatment of heart failure – some biventricular pacemakers have only a pacemaker function (CRT-P) and some also have a defibrillator function (CRT-D);
- implantable cardioverter defibrillators (ICDs) for treatment of ventricular arrhythmia predisposing to sudden death – these include those CRT-D biventricular pacemakers that also have a defibrillator function;
- implantable cardiac event recorders (also known as implantable loop recorders or implantable cardiac monitors).

Brief reference will be made also to implantable neurostimulators.

In the remainder of this document, where reference is made to ICD deactivation, that refers to both deactivation of devices implanted primarily as an ICD and deactivation of the ICD function of a CRT-D device.

6. Consideration of deactivation of devices during life

6.1 Maintaining surveillance of the balance of risk and benefit

Any treatment prescribed or provided to a person will have the potential to cause burden or harm as well as to provide benefit. When a device is used as part of a person's treatment it is important to maintain careful consideration of the relative risks and benefits of deactivation in that individual, compared to the relative risks and benefits of leaving the device fully active. If the person has capacity, they must be involved in this decision-making process. If they do not have capacity any decision must be made in their best interests (see sections 7.6, 7.8, 7.9).

6.2 Deactivation towards the end of a person's life

For people with some types of CIED (i.e. ICDs, including CRT-D devices – see <u>section 12</u>), consideration and discussion of deactivation should occur when it is recognised that they are entering or have entered the last few weeks or months of their life. This may be due to progression of their heart condition (usually heart failure) despite their device and all other relevant treatment, or may be due to the development or progression of another terminal condition. One important reason (but not the only reason) for considering deactivation of ICDs and CRT-D devices is to try to spare these people from receiving multiple shocks from their device as they are dying. Such shocks are relatively common during the last few hours or days of life (see <u>Kinch Westerdahl et al</u>). Failure to deactivate an ICD in a dying man in 2012 caused distress to his family and resulted in an out-of-court settlement by the NHS Trust (see <u>Carter</u>).

Care should be taken to ensure that people with heart failure have received appropriate specialist assessment and all relevant treatment for their heart failure before it is accepted that they need to consider end-of-life care (see <u>NICE 2010</u>, <u>NICE 2011</u> and <u>Dickstein et al</u> 2010). Confident recognition that people are approaching the end of life can be difficult in some conditions such as advanced heart failure, despite helpful guidance (e.g. from the <u>Dying Matters Coalition</u>, the <u>National Gold Standards Framework CIC</u> and the <u>Royal College of General Practitioners</u>). Close collaboration among healthcare professionals, especially but not exclusively in general practice, cardiology and palliative care, can help to support patients in the presence of such uncertainty.

The appropriateness of device deactivation and the appropriate time to consider this will vary according to:

- the informed person's wishes and views;
- the person's individual clinical circumstances;
- the type of device (sections 10–14);
- the purpose of the device in each individual (sections 10–14);
- the likely burdens and harms of continued device operation;
- the likely burdens and harms of deactivation.

Careful consideration of all these factors should be an integral part of care planning, intended to ensure that, whenever possible, as they approach the end of their life, people receive the care that they would wish to have in the environment of their choosing.

Decision charts to guide planned and emergency deactivation of ICDs as part of end-of-life care are included in <u>Appendix A</u>.

6.3 Other reasons for deactivation or removal during life

Some people require temporary deactivation of a device when it is delivering treatment inappropriately or incorrectly, whilst measures are taken to achieve correct delivery of treatment. Temporary deactivation of an ICD may be necessary during certain interventions, such as surgery or radiotherapy. This document will not address these indications for deactivation; other guidance on these situations is available (see <u>Stone et al</u>, <u>Brignole et al</u>).

6.4 Documenting discussions about device deactivation

Clear detail of what has been explained about device deactivation to patients and to those close to patients at the time of implantation should be documented in the health record. That documented information should be readily available to all healthcare professionals who may have to discuss these topics again during routine review visits or at a much later date, when patients are approaching the end of their life. At routine review visits patients should be given the opportunity to discuss any concerns or questions that they may have regarding any aspect of their device, including end-of-life decisions, but such discussion should not be forced upon people who have expressed a clear wish that they do not wish to have those discussions. Such expressed wishes should be documented in the health record.

6.5 Requests by patients for device deactivation or removal

In some situations people may request deactivation or even removal of their implanted device, sometimes without understanding the full implications of their request. Any such request requires careful discussion and consideration of the reasons for the request and also explanation of the likely consequences, and whether it is technically possible to comply with the request. Even if the decision of an informed person with capacity seems unwise or illogical to a clinician or to the healthcare team, that does not mean that the decision should not be respected (see <u>section 7.3</u>).

7. Legal and ethical considerations regarding device deactivation

7.1 The importance of individual assessment

There is widespread misunderstanding on the part of people with devices, those close to them, and many healthcare professionals over what will happen when a device is deactivated. This must be assessed and explained carefully on an individual basis. For example, in people with an ICD, deactivation of ability of the device to deliver a shock will have no effect on how they feel and will permit them to die naturally, without experiencing shocks from their device. Further detail of the effects of deactivation of each type of device is provided in <u>sections 10-14</u>.

7.2 Making shared decisions about treatment

Decisions about a person's treatment (including device implantation or deactivation) should be made jointly with any patient with capacity, following explanation of the balance of risks and benefits (see <u>General Medical Council 2008</u> and <u>General Medical Council 2010</u>). As people approach the end of their lives, especially if this is the first time that deactivation has been raised, such discussions are sensitive and often difficult for patients, for those close to patients and for healthcare professionals. This is not a valid reason to avoid discussions about these important decisions.

7.3 Deactivation is withdrawal of treatment

Legislation on assisted dying is currently under consideration, but some people may be concerned that deactivation could be interpreted as such, and analogous to voluntary euthanasia or assisted suicide. That is not the case. Voluntary euthanasia and assisted suicide each involve an active intervention that in itself causes the person's death. The courts have confirmed that, when death follows withdrawal of treatment, the person's underlying condition is deemed the cause of death. Such withdrawal will be lawful, provided that it follows from the person's competent refusal of treatment or, alternatively, is in his or her best interests. In such situations, the healthcare professionals are released from any duty to provide treatment. Parallels may be drawn with withdrawal of other treatments, such as drug therapy, renal dialysis or artificial ventilation, the main difference being that CIEDs are implanted within a person's body (see England et al, Wu). However, implantation is not a basis to see deactivation as morally distinct from withdrawal of any other treatment.

If a person with capacity requests withdrawal of treatment, despite being fully informed of the likely consequences, healthcare professionals must comply with that request, even when

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they consider the request unwise or illogical or when the withdrawal of treatment is contrary to medical advice,. However, should an individual healthcare professional be unwilling to take action where there is a properly established decision to deactivate a device, it will be necessary to identify another healthcare professional to carry out deactivation. The <u>General</u> <u>Medical Council</u> and <u>British Medical Association</u> have each published guidance on withholding and withdrawal of treatment.

Healthcare professionals who undertake clinical work outside the UK should note that laws relating to deactivation of devices differ in some countries. Clinical decisions must comply with the laws of the local jurisdiction.

7.4 Informed consent at the time of implantation (or replacement)

When their views were explored, most people with an ICD believed that it is important to inform patients about the possibility of later deactivation of their device (see <u>Pedersen et al</u>), but many ICD recipients do not consider this, are not given information about it and have misconceptions about the role of their devices (see <u>Fluur et al</u>, <u>Goldstein et al</u>, <u>Marinskis & van Erven</u>, <u>Raphael et al</u>).

The possibility of a later need to deactivate an ICD and the reasons for doing so should usually be explained as part of informed consent prior to implantation in anyone considering an ICD or CRT-D device (see <u>Clark et al</u>, <u>Niewald et al</u>). Obtaining consent from a person for treatment requires provision to that person of sufficient, intelligible information to allow them to make an informed choice (see <u>Carroll et al</u>). The information provided to support the process of informed consent should include explanation:

- of the balance of benefits and harms or burdens of device implantation at the time;
- of how the balance of benefits and risks may change in the future;
- that a time may come when it is best that the treatment (specifically ICD shocks) stops;
- of what ICD deactivation involves, should it be considered in the future.

Provision of such information requires sensitive discussion with patients and, with due regard to confidentiality, those close to them. Healthcare professionals may find discussions about deactivation and end-of-life decisions easier in some settings than in others and easier with some people than with others. The discussion required with, for example, an elderly person with heart failure being offered an ICD will be different from and may be perceived by some as easier than the discussion required with a young person being offered an ICD as

primary prevention for an inherited cardiac condition that has caused them no symptoms. Whilst the information provided and the way in which it is explained should be tailored to the needs and circumstances of each individual, relevant explanation and provision of information should not be withheld from people simply because the healthcare professional perceives that discussion as difficult or considers that the extent and content of information is not yet directly applicable. In exceptional circumstances the clinician seeking consent may consider that providing information and explanation about future deactivation may cause harm, in which case the withholding of information and the reason for it should be considered unethical and unprofessional, and may generate a significant problem for the person themselves and for those responsible for the person's care in the future. Failure to provide such information and might be deemed to be negligent or a violation of the individual's human rights (see <u>General Medical Council guidance on consent and decision-making</u>).

7.5 People who refuse information or discussion

There may be some people who express a clear wish not to receive some or all of the information offered or not to engage in discussion about future decisions and the risks or burdens of treatment (see <u>Agard et al</u>). Should that happen, the person's wishes should be respected, and details of the discussions and the patient's expressed choices in this regard should be documented in their health record.

7.6 Implantation and deactivation of devices in people who lack capacity

If a decision about provision or withdrawal of treatment is being considered in a person who does not have capacity, the decision must be made in the person's best interests. This will require consideration of the person's medical interests, plus his or her wider (social, cultural, religious or family) interests. In most situations, subject to confidentiality, those close to the patient should be consulted when determining the patient's best interests. In some situations, there will be a legal requirement to consult those close to the patient or the patient's nominated representative (e.g. in England and Wales a person who has been given a Lasting Power of Attorney to make decisions of this nature on behalf of the patient). The laws that define the actions required and people who must be consulted in that situation differ among the four nations of the United Kingdom:

 in England and Wales the Mental Capacity Act 2005 (see <u>H M Government 2005</u> and <u>Department for Constitutional Affairs 2007</u>);

- in Scotland the Adults with Incapacity (Scotland) Act (see <u>H M Government 2000</u> and <u>The Scottish Government 2008</u>);
- in Northern Ireland there is no specific statutory provision for decision-making for patients who lack capacity.

All healthcare professionals have a duty to be aware of and act within the laws that apply in their place of work.

7.7 Explanation to patients who regain capacity

Should a decision ever be made to implant a device in a person's best interests, when they do not have capacity, if they subsequently regain capacity it is important that they are offered full information about their device and its benefits and potential burdens, as they would have been before device implantation had they had capacity. In the rare event that they then request deactivation, their request must be respected.

Some people may have sufficient capacity to consent to treatment but may not remember what was discussed. There should be on-going provision of information to patients and to those close to patients in these circumstances. That information, including guidance contained in information leaflets, should contain clear explanation of the possible future need to consider device deactivation.

7.8 The role of a welfare attorney

In England and Wales and in Scotland the laws provide for people to appoint a welfare attorney to make decisions on their behalf about medical treatment in the event of them losing capacity to make such decisions. Where a person has a welfare attorney with such powers the welfare attorney must be involved in making any decision about treatment choices, including choices relating to withdrawal of treatment, and are under a duty to make decisions in the patient's best interests. In England and Wales a personal welfare Lasting Power of Attorney authorises the attorney to give or refuse consent to the carrying out or continuation of life-sustaining treatment only if the document contains express provision to that effect.

7.9 Making a best-interests decision for a person without capacity

Wherever possible, a person who lacks capacity to make a decision should still be involved in the decision-making process. Even if the person lacks capacity to make the decision, they may have views on matters affecting the decision, and on what outcome they would prefer. Their involvement can help those making the decision to work out what would be in the person's best interests.

Whether or not there is a legally appointed welfare attorney or guardian with powers to make decisions about medical treatment on behalf of a person the above laws require the views of those close to the person to be taken into account when making a best-interests decision. The decision-maker must also take into account any evidence regarding the person's previously expressed wishes or beliefs and values, so that a best-interests decision is based as far as possible on what the person would have decided or chosen, had they had capacity. The views of those close to the patient about what the person's best interests are must be considered also. The laws regarding such best-interests decisions apply equally to provision of treatment and to non-provision or withdrawal of treatment. In Northern Ireland there is no such statutory requirement but seeking the views of those close to patients would be regarded as best practice.

7.10 Advance care planning toward the end of life

When people with implanted cardiovascular devices enter the last few weeks or months of their life, the relative risks and benefits of continued treatment from the device should be kept under continuing review in the context of the altered priorities and wishes that patients have in these circumstances. Advance care planning with such people should include consideration of their wishes about both device deactivation and CPR attempts (see below). In England and Wales the <u>Mental Capacity Act</u> provides for people with capacity to make a formal advance decision to refuse treatment (ADRT) in the event that they subsequently lose capacity. In order to be valid an ADRT that refuses life-sustaining treatment must be in writing, be signed and witnessed, and state clearly that the decision applies even if life is at risk. Such an advance decision might include (for example) a decision to refuse continued defibrillatory shocks from an ICD in defined circumstances (see <u>section 12</u>). Such an ADRT would be legally binding in those defined circumstances.

7.11 Pacemaker checks and elective replacement towards the end of a person's life

Whilst it is hardly ever necessary or appropriate to consider deactivation of pacemakers implanted for bradycardia or biventricular pacemakers implanted for treatment of heart failure, some people may choose to stop attending for routine pacemaker checks because they consider the burden of hospital visits for such checks no longer worthwhile. The risk of failing to attend for routine pacemaker checks in these circumstances will usually be low but

will vary from person to person, and it is important to ensure that patients are offered information relevant to their individual circumstances, allowing an informed decision. Good communication and teamwork from all the healthcare professionals involved with the patient is an essential component of good quality care. Some pacemakers can be checked and monitored remotely, without the need for visits to a hospital clinic. Not all pacemakers have this capability and not all pacemaker centres use this type of pacemaker. When a person with such a pacemaker enters the last few weeks or months of their life, it is essential that healthcare professionals work together and communicate effectively to ensure that decisions about the management of the pacemaker are not made purely on the basis of information from remote monitoring, without considering the patient's individual circumstances and wishes. For example, (as discussed in section 10) arrangements for elective generator change for battery depletion should not be made by a pacemaker service solely on the basis of technical information, without regard to the patient's individual clinical circumstances and wishes. It is therefore crucial also that healthcare professionals in other settings and services, including general practitioners, contact pacemaker centres with relevant clinical information when a patient with an implanted electronic device is approaching the end of life.

7.12 ICD checks and elective replacement towards the end of a person's life

If a person with an ICD enters the last few weeks or months of their life, re-evaluation and discussion of its benefit become appropriate for all but the minority of patients who do not wish to engage in such discussions. This is part of planning for their end-of-life care and the healthcare professionals from all disciplines involved with that person should communicate effectively to contribute to this.

As with pacemakers, ICD batteries may become depleted coincidentally in a person who is nearing the end of their life. Elective replacement of the device provides an opportunity to review the balance of benefits and burdens of continued ICD therapy. For some people in the last few weeks or months of life the benefit of elective device replacement may still exceed the burden, but for others it may be better to avoid the burden of elective replacement (see Kramer et al). As with other decisions referred to in this guidance, each decision must be based on careful individual assessment. The views of the informed patient with capacity are a crucial determinant of the decision. Decisions for those who lack capacity must be made in their best interests.

Where ICD deactivation has been decided with the patient, elective ICD generator replacement for battery depletion is unnecessary unless the patient is dependent on the ICD

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for pacing (see sections <u>10</u>, <u>11</u> and <u>12</u>). Where there is agreement not to replace a device in the presence of battery depletion, its removal would not usually be recommended, as the harms and burdens of removal would be likely to exceed any benefit.

7.13 Decisions about ICD deactivation and decisions about CPR

An important relationship to consider is that between decisions to deactivate an ICD and decisions about CPR attempts in the event of cardiorespiratory arrest. A default, without scrutiny, that having a DNACPR decision or being identified as dying automatically warrants ICD deactivation, or that ICD deactivation automatically warrants a DNACPR decision in every person is unethical. All decisions must be based on careful assessment of each individual situation.

In the majority of circumstances as a person nears the end of their life, if there is an agreed decision with a patient or their representative that ICD shocks would present more burden than benefit, the same decision will be made about CPR, given that it is more traumatic and invasive, with less likelihood of a successful outcome. If it has not occurred already a DNACPR decision should be discussed at the same time as discussion of ICD deactivation, but recognising that there may be occasional situations in which the person will wish to be considered for CPR despite choosing to have their ICD deactivated.

Some healthcare professionals express a view that the converse should apply, namely that a DNACPR decision always implies that an ICD should be deactivated. For people with an ICD, a DNACPR decision or the recognition that they might be dying should trigger a discussion about ICD deactivation. However situations may arise in which a fully informed person chooses not to have CPR attempted because of its trauma or relatively low probability of success, but chooses to continue to receive treatment from their ICD for shockable ventricular arrhythmia. There may be situations in people who are nearing the end of life where an ICD is deactivated because it is delivering inappropriate shocks in the absence of ventricular arrhythmia, but the patient still wishes to receive CPR in the event of cardiac arrest. These choices must be respected and kept under review with the opportunity for decisions to be changed as the person's condition progresses.

7.14 Ownership of implanted devices

Disputes over ownership of implanted devices are very rare, but many clinicians are unfamiliar with the position regarding ownership of devices. There is no legislation covering the question of ownership of implanted medical devices, including internal cardiac defibrillators and pacemakers. As far as we are aware, there is currently no case law on this matter in the UK.

In 1983 the Department of Health and Social Security gave guidance in <u>circular HN(83)6</u> on the ownership of various implants, including cardiac pacemakers, and the removal of cardiac pacemakers after death. Although it pre-dates the widespread use of CIEDs other than pacemakers, this guidance has not been revised. In 2011 the Department of Health issued a statement endorsing the 'default position' set out in HN(83)6 that the device is owned by the individual into whom it is implanted.

HN(83)6 states:

'On implantation an implant becomes the property of the person in whom it has been implanted and it remains his or her property even if it is subsequently removed. Following the patient's death it forms part of his or her estate unless there is any specific provision to the contrary'.

This wording may be misleading. The general position of the law is that neither the whole living body nor the whole deceased body are property. There can be property in parts separated from the living and the deceased in particular circumstances. Whilst the law in this area is limited and not altogether clear, one of the main property law doctrines is that only things which are separate from persons (i.e. the body) can be owned and subject to property rights. This doctrinal position has been affirmed by the courts in relation to biomaterials (i.e. items or materials that originated within the body): to be the subject of property rights they must be separate from the person/body. Biomaterials which have been separated from the body may, therefore, in some circumstances become subject to property rights. An external medical device may be classified as personal property. When a device is implanted it becomes part of the living body and, in some cases, becomes integral to the very functioning of the recipient. However, it is difficult to say definitively what its 'property' status is once it become part of the body since this specific point has not been tested in the courts (in England at least). Interrogation of a device to obtain stored data (see sections 16.1-16.3) will be governed by regulations on data management and health records (Quigley M, personal communication).

The question of ownership may arise when an implanted device is removed from the body during life or after death. The notice HN(83)6 provided an agreed modified wording for consent forms for implants to try to avoid the possibility of dispute about the right of a

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healthcare provider organisation or consultant to retain an implant removed for examination or replacement. In the revised form of consent the patient would sign an agreement stating:

'I acknowledge and agree that any implant supplied to and implanted in me as part of this operation or the further or alternative operative measures referred to above, is supplied and implanted subject to the condition that if at any time it is removed by or on behalf of a health authority:

- (a) for the purpose of replacement, or
- (b) where a replacement is not required to enable it to be examined, or
- (c) where in the case of a cardiac pacemaker paragraph (a) or (b) does not apply, after my death the ownership of the implant will vest in that health authority.'

The 2011 statement indicated that in any specific case where such provisions are explicitly made, either on a pre-operative consent form or subsequently, legal ownership may reside with a healthcare provider organisation or party other than the patient or their estate.

To minimise confusion, services and their responsible clinicians involved in device implantation will need to consider modification of the above wording on forms of consent:

- so that it relates accurately to the type of device being offered, should that not be a pacemaker:
- so that ownership is vested in the healthcare provider organisation removing the device (which may have been implanted elsewhere).

In situations where the person's prior agreement has not been obtained, given the legal ambiguities, it is advisable to proceed *as if* the patient has ownership of the device. Therefore, their consent is required for retention of a device that is removed for clinical purposes during life, but also consent should be obtained from the executor(s) of their estate for removal of a device after death, and for retention and disposal of that device. As there may be practical difficulties in identifying and contacting executors, obtaining prior consent from the patient for removal, retention and disposal after death is recommended whenever possible. Should the patient, or after their death the executors or beneficiaries of their estate, choose to keep a device that has been removed, healthcare providers should offer them clear advice on any potential risks or hazards that could result (see <u>section 16.7</u>).

7.15 Communicating and recording information

Effective communication and documentation are essential components of good-quality clinical care. Failures of these elements of care are among the commonest reasons for dissatisfaction, complaint and litigation.

Communication with patients and those close to them about ICD deactivation (including about possible deactivation in the future), as with all aspects of end-of-life care, requires complex, sensitive discussion. This should be undertaken by experienced members of the healthcare team with the competence and knowledge to undertake such conversations. Healthcare organisations have a responsibility to ensure appropriate training for staff who undertake these discussions (see <u>section 8</u>). Communication with patients and those close to patients must be tailored to individual needs. When ICD deactivation is considered, careful explanation of exactly what it involves is needed in all cases, and many people will need firm reassurance that deactivating their ICD will not cause their death and that they will feel no different following deactivation. It is important to ensure also that people understand that if their condition improves or they change their mind, their device can be reactivated.

All discussions and decisions about device deactivation (and all other aspects of end-of-life care) must be communicated effectively among all other members of the healthcare team involved in any person's care, including usually the GP, the cardiology team and the palliative care team, and often other disciplines.

All discussions and decisions about device deactivation must be documented fully. That recorded information must be readily available to those involved in the person's subsequent health care.

When a decision is made with a person that their ICD will be deactivated, this action will often be performed by another healthcare professional (usually a cardiac devices physiologist). It is essential that the decision, the reason for making it and the involvement of the patient and/or those close to them are documented fully, so that the person performing the deactivation has all the information needed to allow them to proceed, and that they then document fully the action taken. This is best achieved using a standard proforma, of which examples in current use are included in some of the policies listed in <u>Appendix A</u>.

8. Discussion of deactivation with patients and those close to them

8.1 Training and competence in communication skills

Formulating individualised end-of-life care plans with or on behalf of patients is always a sensitive process and requires healthcare professionals to be competent in undertaking such discussions. Employers have a duty to ensure that professionals who are required to undertake such discussions are both trained and competent.

8.2 The healthcare professionals who should be involved in the discussion

The appropriate member of the healthcare team to have this conversation will vary. In the vast majority of cases in which deactivation of a device is considered during life the consultant or senior clinician responsible for management of the patient's device should be involved in the decision-making process, but the degree of that involvement or its delegation will vary according to individual circumstances. Good communication within the entire healthcare team and with the patient and those close to them lies at the heart of the process so that there is clear and consistent information and advice and the decisions are agreed and understood by all.

Depending on individual circumstances the healthcare professionals who initiate and undertake these discussions or provide support and information to patients and those close to them may include:

- cardiologists;
- heart failure specialist nurses;
- arrhythmia specialist nurses;
- cardiac physiologists (especially those involved in device management);
- general practitioners;
- non-cardiologist physicians or surgeons;
- palliative care doctors or specialist nurses.

The person who initiates a discussion will usually be a healthcare professional who is closely involved in the person's care and who knows them and their clinical and home circumstances. It may be necessary to involve several members of the healthcare team and to have serial discussions with patients and those close to them before reaching a shared decision that they are comfortable with.

8.3 Multidisciplinary end-of-life care cardiology services

Where available, a multidisciplinary end-of-life care service involving specialist healthcare professionals from cardiology and from palliative care may offer an environment that supports patients and those close to them in various aspects of their end-of-life care planning. The support needed should be considered on an individual basis and may also include help from other healthcare disciplines (e.g. physiotherapy) spiritual advisers or from other agencies (e.g. social workers). Where these specific services are not available development of local clinical pathways can facilitate close multi-specialty collaboration, in particular between cardiology and palliative care services.

8.4 Aims of end-of-life-care planning in people with devices

The objective should be to avoid a person entering their last few weeks or months of life, even acutely or unexpectedly, without a care plan or without their views about device deactivation being known. It is considered bad practice for the healthcare team that knows the person not to have anticipated such a situation and to have left this difficult task to, for example, a hospital acute admission team. Whenever a person with an implanted device presents with an acute clinical problem, early communication with and involvement of those usually responsible for the person's care and the management of their device should be routine.

8.5 Discussions with those close to patients

Involvement of those close to patients in discussions (with due regard for confidentiality) is important, both to provide support for the patient as they make decisions about their end-of-life care and to help their family and carers to understand how the person's 'health journey' is unfolding. Whilst this can present challenges, reasonable effort must be made to engage them in the process. Seeking a single representative is one option, but can present problems if there is discordance within the family. All these interactions and processes should be documented clearly.

8.6 Discussions with those close to patients who lack capacity

Where the person has given legal authority to someone else to make decisions for them (e.g. in England and Wales under a Lasting Power of Attorney) that person must be involved in the decision-making process (see <u>section 7.8</u>).

In all other circumstances where the patient does not have capacity, the role of those close to them is to help healthcare professionals come to a best-interests decision by clarifying, as far as they are able, the patient's wishes, beliefs and values when they had capacity, as well as their own views as to what decisions are in the person's best interests. It is crucial that those close to patients understand clearly that they are not being asked to make a decision to deactivate a device that has been part of the person's treatment.

9. Information that people should receive

9.1 Guiding principles

- Some understanding of the nature and purpose of a device is a pre-requisite to informed decision-making about management of their device from implantation to death.
- Information-giving should be a priority from the time that device implantation is first considered, to give people every opportunity to understand its nature and purpose.
- Information provided must be clear and understandable.
- Good communication requires the professional to ensure that the information given has been understood correctly.

9.2 Verbal communication

As they approach the end of their life most people will need several opportunities to discuss deactivation of their device and contribute meaningfully to a shared decision. Whilst clear conversation is only one component of information-giving, the inclusion of a trusted friend or family member in a discussion may be of help to some people. Where conversations cross languages an independent interpreter may be necessary.

9.3 Written / printed information

Written information is important and should be available in languages relevant to a locality, should be culturally sensitive and should signpost people to additional support or resources. Written information should never be regarded or used as a substitute for a clear, spoken explanation and the opportunities for patients and those close to patients to ask questions and have them answered.

The British Heart Foundation has developed a guide for healthcare professionals on deactivation of ICDs towards the end of life (see <u>Beattie</u>). Other helpful sources of information about the devices under consideration are available from national organisations and in individual healthcare regions and districts. To assist with implementation of this guidance the Working Group has developed a clinical guide on deactivation of ICDs towards the end of life and, in collaboration with the British Heart Foundation and the Arrhythmia Alliance, an information leaflet for patients and carers on deactivating the shock function of an ICD towards the end of life.

SECTION B: Device-specific aspects

Whilst many of the above aspects of ethics, the law and communication are generic to all types of implanted device, there are major differences in the nature and purpose of different types of device, and therefore major differences in the decisions and actions that may be needed as people approach the end of life, after death or in the event of cardiorespiratory arrest. In this section information is included in particular to help non-clinicians and clinicians with no specialist knowledge of devices to understand the types of device, the differences in their nature and purpose, and the resulting differences in clinical decision-making that may be needed.

Information and guidance is provided also for all of the circumstances in which it may or may not be appropriate to consider deactivation or non-replacement of each type of device when people are approaching the end of life, and on the procedures involved in deactivation. Furthermore device-specific information is provided concerning any actions or precautions required by those attempting resuscitation when someone with an implanted device suffers cardiorespiratory arrest.

Healthcare professionals who are or who become involved in the care of patients with implanted devices need clear information about the specific nature and purpose of the device in each individual patient, and should make every effort to obtain such information to assist with decisions about treatment. Furthermore if adjustment of a device is necessary, physiologists and other members of the specialist (usually cardiology) team will need such information, including details of the manufacturer and model of the device. Many people with implanted devices carry such information with them, but if necessary in urgent or emergency situations details should be obtained from the implanting centre, the centre providing ongoing surveillance of the device if that is not the implanting centre or the patient's general practitioner.

It is important to ensure safe disposal of any implantable electronic device after removal during life or after death. This aspect is discussed further in <u>section16.7</u>.

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10. Pacemakers for bradycardia

10.1 Pacemakers for bradycardia: nature and purpose

These pacemakers are implanted to prevent the heart from beating inappropriately slowly. They consist of a "generator" (the pacemaker itself), often implanted under the skin in the pectoral region, and one or two insulated leads that connect the pacemaker to the heart. Single-chamber pacemakers have a single lead, connected either to a lower chamber (ventricle) of the heart, usually the right ventricle, or an upper chamber (atrium), usually the right atrium. The choice of connection to atrium or ventricle will be determined by the underlying condition for which the pacemaker was implanted. Dual chamber pacemakers have two leads, one connected to an atrium and one to a ventricle.

10.2 Pacemakers for bradycardia: reasons for implantation

The majority of such pacemakers are implanted for treatment of sinus node disease ("sick sinus syndrome") or atrioventricular (AV) conduction disease ("heart block"); less common indications include treatment of some forms of severe reflex syncope (such as vasovagal or carotid sinus syncope). In many people the main purpose of the pacemaker is to prevent or reduce symptoms that result from bradycardia, such as syncope, sudden feelings of faintness ("presyncope") or fatigue and breathlessness. In some people (mainly those with advanced AV conduction disease) the pacemaker will also reduce a risk of dying suddenly.

10.3 Pacemakers for bradycardia: non-invasive adjustment

People with pacemakers are not aware of the tiny electrical impulses that the pacemaker uses to stimulate heartbeats. Adjustments to the way in which a pacemaker detects and responds to the heart's natural, spontaneous electrical signals can be made non-invasively without any discomfort, using a programmer that communicates with the generator through the skin overlying the pacemaker.

10.4 Pacemakers for bradycardia: pacemaker dependence

Some people with a pacemaker for advanced AV conduction disease become "pacemakerdependent", meaning that no prompt spontaneous heartbeats occur if the pacemaker ceases to stimulate heartbeats. For these people sudden "switching off" of the pacemaker would be likely to lead to loss of consciousness (until a delayed spontaneous heartbeat occurs repeatedly) or death (if a spontaneous heartbeat does not occur or is not sustained).

10.5 Pacemakers for bradycardia: need for deactivation is rare

It is very rare for people who have pacemakers implanted for bradycardia to need deactivation of their devices during life. As many people with such pacemakers have them implanted to reduce symptoms, continued control of those symptoms remains an important part of their end-of-life care. Some people raise concern that the presence of a pacemaker may delay their death and in some cases prolong suffering, by preventing the heart from stopping, and it is important to explain to them that the pacemaker will not usually prevent or delay natural death as in many cases the final heart rhythm is a ventricular arrhythmia, which would not be prevented by the pacemaker. If a person who is pacing-dependent asks for their pacemaker to be "switched off" it is important that they understand that doing so may lead to their immediate death but could also result in a distressing episode of syncope, during which they may suffer harm, and after which they may be left with continuing burdens such as a new disability or distressing symptoms.

10.6 Pacemakers for bradycardia: method of deactivation

In the exceptionally rare situation where the healthcare team and the patient and/or those close to the patient decide that deactivation of a pacemaker is in the person's best interests this can be performed using a programmer, as described in 10.3 above. Placing a magnet over the pacemaker will not deactivate its pacing function but will cause the pacemaker to fire at a faster than usual rate and will prevent the pacemaker's ability to be inhibited by spontaneous heartbeats. Magnets should not be used in a misguided attempt to deactivate such a pacemaker.

10.7 Pacemakers for bradycardia: management of reduced battery life

One dilemma that is not uncommon arises when it is found that a person who is approaching the end of their life has a pacemaker with reduced battery life, such that elective replacement of the generator (often referred to as a "box change") would usually be advised. As with all clinical decisions the decision whether or not to proceed with generator replacement must be determined by careful assessment of the individual circumstances in each person, and whenever possible patients should contribute to the decision, after receiving the necessary information and explanation to allow them to do so. The relative burdens and benefits of elective replacement versus allowing the battery to run down will be influenced by various factors including:

- the views and wishes of the patient;
- the underlying indication for pacing;
- whether or not the person has become pacing-dependent;

• how soon the person is likely to die;

• options to reprogramme the pacemaker to minimise further battery depletion. Hospitals that provide pacemaker services should ensure that when a pacemaker is found to warrant consideration of generator replacement, the decision to proceed is made on the basis of proper informed consent (or in the person's best interests if he/she lacks capacity), in the full context of the individual person's current clinical circumstances. Automatic listing of patients for generator replacement based only on the state of the pacemaker battery is poor practice and should be avoided.

11. Biventricular pacemakers

11.1 Biventricular pacemakers: nature and purpose

These devices are implanted primarily to try to improve the mechanical pumping action of the heart. They will also provide effective treatment of bradycardia (as above) should this be required. When there is reduced contraction of the left ventricular myocardium this leads to symptoms of the clinical syndromes that are referred to as 'heart failure'. First-line treatment for heart failure is with drug therapy, but for some people with troublesome symptoms from heart failure despite appropriate medication, using a pacemaker that stimulates the right and left ventricles virtually simultaneously produces a more coordinated contraction of the ventricles, resulting in a more effective pumping action and, for many but not all, substantial reduction in the symptoms of heart failure. Use of biventricular pacemakers for this purpose is also referred to as 'cardiac resynchronisation therapy' (CRT). Where the device has no capability other than this pacemaker therapy it is referred to as CRT-P (see also 11.3).

As with pacemakers for bradycardia the generator is usually implanted in the pectoral region. These devices usually have three leads, one connected to the right atrium and one connected to each of the ventricles, but in some people an atrial lead is not required. For further detail see <u>Singh & Gras</u>.

11.2 Biventricular pacemakers: non-invasive adjustment

These pacemakers also use tiny electrical impulses to stimulate the heart and people with this type of pacemaker are not aware of these. Adjustments to the function of biventricular pacemakers can be made non-invasively without any discomfort, in the same way as with pacemakers used to treat bradycardia.

11.3 Biventricular pacemakers: some people also need an ICD

Some people requiring biventricular pacing are also at sufficient risk of sudden death to warrant use of an ICD (see below). Such people have a device capable of delivering defibrillation as well as cardiac resynchronisation (CRT-D). The two functions of these devices can be adjusted or deactivated independently from each other and the balance of benefits and burdens of each can therefore be considered separately in each individual person.

11.4 Biventricular pacemakers: effect of deactivation or failure

Unless the person is pacing-dependent (as described above) a person with a biventricular pacemaker would be unlikely to be aware of any immediate, severe symptoms should the pacemaker be switched off or suddenly cease to function, but cessation of biventricular pacing is likely to be followed by worsening of symptoms of heart failure in those people whose heart failure symptoms were reduced by this treatment.

11.5 Biventricular pacemakers: deactivation and non-replacement

As with pacemakers for bradycardia it is rare for people to require deactivation of the pacemaker function of their devices. Deactivation of a biventricular pacemaker could lead to an increase in symptoms of heart failure and increase the distress of a person as they approach the end of their life. As with pacemakers for bradycardia, careful consideration and discussion of the relative risks and benefits of generator replacement will be needed on an individual basis should battery depletion develop, and there is no place for blanket policies based only on the state of the pacemaker batteries.

11.6 Biventricular pacemakers: methods of deactivation

In the very rare situation where the healthcare team and the patient and/or those close to the patient decide that deactivation of a CRT-P device is in the person's best interests this can be performed using a programmer (usually by a cardiac devices physiologist), as described above. If a person has a CRT-P device, placing a magnet over the pacemaker will not deactivate its pacing function but will cause the pacemaker to fire at a faster than usual rate and will prevent the pacemaker's ability to be inhibited by spontaneous heartbeats. Magnets should not be used in a misguided attempt to deactivate a CRT-P device.

The ICD function of a CRT-D device can be deactivated using a programmer, without interrupting its pacemaker function. Application of a magnet will also suspend

tachyarrhythmia detection and thereby suspend delivery of shocks (and of bursts of very rapid pacing to try to interrupt ventricular tachycardia (VT)) by the device and can be used to provide emergency, temporary deactivation of the defibrillator function of the device without interrupting its biventricular pacemaker function.

These distinctions underline the importance of healthcare professionals who are caring for a person having clear information about the nature and purpose of the implanted device in that individual person, and obtaining timely expert help from a cardiac devices physiologist and/or cardiologist in managing that device.

The factors to be considered in relation to deactivation of the defibrillator function of CRT-D devices are described further in <u>section 12</u>.

11.7 Biventricular pacemakers: management of reduced battery life

Reduced battery life in a CRT-P device should be managed in the same way as for a pacemaker implanted for bradycardia (see <u>section 10.7</u>). Reduced battery life in a CRT-D device should be managed in the same way as for an ICD, with due regard to its pacing function (see <u>section 12.9</u>).

12. Implantable cardioverter defibrillators (ICDs)

12.1 Implantable cardioverter defibrillators: nature and purpose

Implantable cardioverter defibrillators (ICDs) are implanted primarily to deliver a defibrillatory shock when the patient develops a ventricular arrhythmia that is an immediate threat to their life, such as cardiac arrest in ventricular fibrillation (VF). Many of these devices are programmed also to deliver rapid pacing stimuli that may interrupt a ventricular tachycardia (VT) that, if it continues, carries a high risk of causing the person harm or of progressing to cardiac arrest. ICDs may be implanted on the basis of 'secondary prevention' in people who have already suffered one or more episodes of VF or VT, or may be implanted as 'primary prevention' in people who are at high risk of developing VF or life-threatening VT. In addition to the functions described, ICDs have a back-up pacemaker function that will stimulate heartbeats if the person develops bradycardia, in the same way as a pacemaker that is implanted purely to treat bradycardia. As discussed in <u>section 11</u>, some ICDs are implanted as CRT-D devices to deliver biventricular pacing for heart failure as well as to provide a defibrillator function because of a risk of ventricular arrhythmia causing sudden death.

In most patients ICDs are implanted in a similar subcutaneous pectoral position to that used for pacemakers. The devices are larger than pacemakers. Most ICDs utilise transvenous leads in the same way as with pacemakers. A more recent development that may be suitable for some but not all ICD patients is the subcutaneous ICD. This has no transvenous leads. It can deliver a defibrillatory shock, and has limited pacemaker capability. The generator of a subcutaneous ICD is usually implanted in the left lateral chest wall.

12.2 Implantable cardioverter defibrillators: awareness of shock delivery

Although people with ICDs are unaware of the low-energy stimuli from their device when it is acting as a pacemaker, the higher-energy shock needed to defibrillate life-threatening ventricular arrhythmia is unpleasant and painful. In some situations the person will have lost consciousness and collapsed before the device delivers a shock, sparing them the discomfort of the sudden shock, but not the distress or risk resulting from the collapse (unless they lost consciousness whilst asleep). There are also circumstances in which ICD shocks are delivered to patients who are fully conscious, and in some people such shocks may be more likely to occur and may occur repeatedly in those who are approaching the end of life.

12.3 Implantable cardioverter defibrillators: effect of deactivation or device failure

If an ICD suddenly ceases to function completely the patient will be unaware of this, unless they use the ICD also for its function as a pacemaker (see sections <u>10</u> and <u>11</u>). However, if they subsequently develop VF or VT, they will suffer cardiac arrest (or symptoms from the arrhythmia in some cases of VT). If an ICD is deactivated, that involves switching off its tachyarrhythmia detection function, so that it will not deliver a shock or a burst of rapid pacing. Its back-up function as a pacemaker is not deactivated or otherwise affected, so the patient will not feel any different after deactivation.

12.4 Implantable cardioverter defibrillators: decisions about deactivation

The majority of decisions that are needed in relation to device deactivation arise in people with ICDs. The primary reason for having an ICD is to prevent sudden death, so when it is recognised and accepted by a person and their healthcare professionals (and where appropriate by people close to these patients) that the person is approaching the end of their life and that the focus of treatment has shifted to control of symptoms rather than attempts to prevent death, it is usually appropriate to consider and discuss deactivation of the

defibrillator function of the ICD. The aim is to ensure that the person does not experience unpleasant shocks from the device that cause more distress than benefit. In some cases such shocks may prevent a natural death and prevent a relatively peaceful and dignified release from distressing symptoms (for example symptoms of heart failure).

12.5 Implantable cardioverter defibrillators: method of planned deactivation

Tachyarrhythmia detection by an ICD can be deactivated, suspending its defibrillator function without affecting its ability to function as a pacemaker, if it has a pacemaker function. ICDs can be reprogrammed or deactivated using a programmer that transmits signals to the device through the skin overlying the device. These programmers are the same as those used to test and reprogramme pacemakers and are usually operated by cardiac physiologists involved in delivering pacemaker and ICD services. Current programmers are specific to the manufacturer of the device, emphasising the importance of providing a physiologist with details of the individual device whenever possible. These programmers and their operators are usually based in hospital Cardiology Departments, so for most people reprogramming or deactivation of their ICD requires them to attend their local pacemaker/ICD department. However the programmers can be transported, so there may be local arrangements that would allow a cardiac devices physiologist to visit a patient in another healthcare facility or in their home to deactivate an ICD as part of their end-of-life care. In the majority of people approaching the end of life consideration and planning of ICD deactivation should take place in advance, allowing deactivation using a programmer to be performed at an appropriate time. However situations may arise when that has not happened and deactivation is required on a more urgent basis.

12.6 Implantable cardioverter defibrillators: method of emergency, temporary deactivation

Placing a strong magnet on the skin over the ICD generator will suspend tachyarrhythmia detection (and thereby suspend shock delivery) by the device. This can be used to provide emergency, temporary deactivation of its ability to deliver a shock but will not interfere with its ability to function as a pacemaker, where that function is present. Use of a magnet in this way to provide temporary deactivation of defibrillation by an ICD should be regarded as an emergency measure when deactivation as part of end-of-life care is needed without delay, but should not be a usual part of end-of-life care. When a crisis requires emergency use of a magnet in this way as a temporary measure, removal or displacement of the magnet will immediately restore the ability of the ICD to deliver a shock. Therefore it is important that the

magnet is taped securely in position and that repeated checks are made to ensure that it has remained in place.

The ICDs produced by one manufacturer (Biotronik) allow deactivation by a magnet for only 8 hours before the shock function is restored. With this type of ICD (or if the manufacturer is unknown) the magnet should be removed for a few seconds every 7 hours and then taped back into position to ensure continued deactivation. Very rarely, an ICD may have been reprogrammed so that it will not be deactivated by a magnet. In these exceptional circumstances it is expected that this would have been explained to the patient and documented clearly.

Placing a magnet over a pacemaker that does not have an ICD function will not deactivate it but will cause the pacemaker to fire at a faster than usual rate, and will prevent the pacemaker's ability to be inhibited by spontaneous heartbeats. This underlines the importance of knowing exactly the nature of any implanted device and seeking appropriate expert advice before an attempt is made by non-specialists to adjust or inhibit a device.

12.7 Implantable cardioverter defibrillators: explaining deactivation

When a decision about deactivation of an ICD is being considered it is especially important that patients and those close to them have a clear understanding of what is being considered, of the reason for and of the expected effect of deactivation. It is common for people to be alarmed by the false belief that deactivation will lead to immediate death, so sensitive, clear and unambiguous explanation is crucial in this situation, as it is in all aspects of end-of-life care. As emphasised elsewhere, employers should ensure that all involved staff receive formal training and that they achieve and maintain competence in undertaking such discussions.

12.8 Implantable cardioverter defibrillators: local device deactivation policy and services

Local arrangements for ICD deactivation should be recorded clearly as part of the local device management policy. That policy, together with clear instructions on how, where and when to access a magnet, to access help from a cardiac devices physiologist, and to access additional expertise if needed should be readily accessible to all relevant healthcare professionals in all settings, including the community healthcare services, hospitals (especially Emergency Departments, Acute Wards and Assessment Units, Cardiology Wards and Departments) and hospices.

12.9 Implantable cardioverter defibrillators: management of reduced battery life

As with pacemakers, depletion of its battery to a level that would usually warrant elective replacement of an ICD generator will occur in some people with an ICD who are approaching the end of their life. The decision whether or not to proceed with elective generator replacement in these circumstances must be made on an individual basis after careful assessment of all the circumstances, and should usually involve shared decision-making with the patient and/or with those close to them, as discussed in <u>section 7</u>. Factors that will be relevant to this decision will include whether or not the device is required for another purpose (i.e. pacing for bradycardia or cardiac resynchronisation) and whether or not the patient has reached the stage in their end-of-life care where they have accepted that benefits of receiving defibrillatory shocks from their device no longer exceed the potential harms and burdens of generator replacement and continued defibrillator function.

13. Implantable event recorders (also known as implantable loop recorders or implantable cardiac monitors)

13.1 Implantable event recorders: nature and purpose

Implantable event recorders (IERs) are small devices that can record cardiac rhythm over a prolonged period. They are implanted usually under the skin on the front of the chest, overlying the heart, or occasionally (usually for cosmetic reasons) in the axilla. They monitor the heart's rhythm continuously and will record and store episodes of extreme bradycardia and tachycardia automatically. Also, using a 'remote control device', they can be activated immediately following a symptomatic event (such as transient loss of consciousness) to store the rhythm that was present. They do not deliver any therapy.

13.2 Implantable event recorders: removal and non-replacement

As IERs deliver no therapy there is no requirement for or ability to deactivate them, or to consider removal if a person with an IER is approaching the end of life. If a person has an IER in place and is then identified as approaching the end of their life, the need for routine attendance for interrogation of the IER should be considered carefully on an individual basis. Removal of an IER is unlikely to be appropriate during end-of-life care, as the nuisance and discomfort of the procedure will usually outweigh any possible benefit. The battery life of an IER is usually at least 3 years, and many such devices will have fulfilled their intended purpose within that time so will not require elective replacement. If a person with an IER goes on to develop an advanced illness that brings them towards the end of their life it is

unlikely that elective replacement of an IER that has not already fulfilled its purpose would be appropriate.

14. Implantable neurostimulators

14.1 Implantable neurostimulators: nature and purpose

Neurostimulators are implanted for various indications, detailed discussion of which is beyond the scope of this document. They are similar in size and shape to pacemakers. They are attached to the "target" part of the nervous system by a lead, similar to a pacemaker lead. The majority are implanted in the wall of the abdomen. However, in some people neurostimulators may be placed subcutaneously in the chest wall, in positions similar to those used for pacemakers. Since they are similar in outward appearance to a pacemaker this means that they may be mistaken for pacemakers.

14.2 Implantable neurostimulators – deactivation, removal and non-replacement

It is unlikely that a deactivation or removal of a neurostimulator would be warranted as part of end-of-life care. Failure of the neurostimulator to deliver the intended treatment could lead to a relapse of the symptoms for which it was implanted. Should neurostimulator battery depletion develop in a person approaching the end of their life careful consideration should be given to the relative benefits versus the relative harms and burdens of elective device replacement. The situation should be assessed on an individual basis in every person, with full involvement of the experts involved in routine surveillance and management of the device.

SECTION C: Device management during cardiac arrest

15. Actions required during and after cardiopulmonary resuscitation in people with implanted electronic devices

15.1 Cardiopulmonary resuscitation in people with pacemakers, implantable event recorders and neurostimulators

Pacemakers (pacemakers for bradycardia and CRT-P devices), implanted event recorders and neurostimulators present no hazard to people providing cardiopulmonary resuscitation (CPR) for cardiorespiratory arrest. No special precautions are necessary when delivering chest compressions and/or ventilation in the presence of any of these devices.

15.2 Delivery of CPR to a person with an implantable cardioverter defibrillator

In the presence of an ICD (including CRT-D devices) chest compressions and ventilations should be delivered in the recommended, standard way. Although there have been very rare reports of rescuers having felt ICD shocks and experienced transient pain or temporary impairment of nerve conduction (see Stockwell et al 2009), discharge of a shock from an ICD is believed to present no major risk to another person in contact with the patient as the voltages and current flows recorded from the patient's skin surface are relatively low (see <u>Peters et al</u>). Wearing of 'clinical examination' gloves has been recommended (see <u>Nolan et al</u>) in the hope that it may reduce to some degree the risk of receiving any shock, even one of low energy. The degree to which gloves may offer such protection to a person delivering CPR is uncertain at the present time. Wearing of gloves is recommended primarily as one of the elements of personal protection against infection for all those delivering CPR.

15.3 Small risk of lead displacement during CPR

Healthcare professionals who deliver CPR to a patient with an implanted pacemaker or ICD should be aware that there is a small risk that vigorous chest compressions could result in lead displacement within the heart in some circumstances. The risk of this is very low when the leads have been in place for several months or longer, but is greater if the leads have been implanted relatively recently. However in the presence of cardiorespiratory arrest the priority is to provide optimal resuscitation, so the aim should be to deliver good-quality chest compressions, irrespective of the presence of a pacemaker or ICD and irrespective of how recently the leads were implanted.

15.4 External defibrillation and cardioversion

Although modern CIEDs are designed to resist damage by external defibrillation or cardioversion currents, there is a remote possibility of damage when a shock is delivered through a defibrillation pad placed over or close to these implanted devices. With pacemakers and ICDs with transvenous/endocardial leads there is also a theoretical risk of damage to the person's myocardium at the electrode interface due to excess current flow. This may elevate pacing thresholds temporarily or permanently or damage the myocardium temporarily or permanently at the electrode-tissue interface. To minimise this risk it is recommended that defibrillator electrodes are placed as far away as is practicable from the pacemaker or ICD generator without compromising effective defibrillation. A distance of at least 10-15 cm between the edge of the device and the edge of the defibrillator electrode is recommended. Placement of the defibrillator electrodes approximately perpendicular to the device and its leads may reduce the risk of current entering the device circuits. If necessary use of alternative electrode positions (e.g. antero-posterior) may be used to achieve this. Similar precautions are advised in people with neurostimulators implanted in the chest. In people with implantable event recorders it is advisable to avoid placing defibrillator pads directly over the device to minimise the risk of damage to the device itself, despite in-built protection.

15.5 Implantable cardioverter defibrillators: shockable cardiac arrest rhythms

An ICD usually gives no warning before it delivers a shock. During an episode of persistent ventricular tachyarrhythmia an ICD will deliver several shocks before ceasing automatically to give shocks, even if the arrhythmia persists. The precise number of shocks that may be delivered in this situation will vary from one person/device to another, and is often up to 8, sometimes more. The ICD will re-start its discharge sequence if it detects even brief apparent cessation of the tachyarrhythmia (including transient slowing of heart rate below the rate programmed to trigger shocks). This could result in the patient receiving a large number of shocks, causing pain and distress.

During cardiorespiratory arrest in a shockable rhythm, external defibrillation should be attempted in the usual way if the ICD has not delivered a shock, or if its shocks have failed to terminate the arrhythmia.

15.6 Use of external pacemakers in the presence of implanted devices

An external pacemaker may be used for emergency treatment of severe bradycardia and for cardiac arrest in asystole with continued P wave activity on the ECG.

In the presence of an implanted pacemaker or ICD which has failed and is not emitting any pacing stimuli (seen as 'pacing spikes' on an electrocardiogram [ECG] or monitor), an external pacemaker can be applied and used in the usual way. Electrode position will usually be dictated by the possible need for defibrillation through the same electrodes (see <u>section</u> <u>15.4</u>).

If the pacemaker or ICD is emitting pacing stimuli but failing to stimulate the heart ('failure to capture') the pacing spikes from the implanted device may inhibit the external pacemaker. To avoid this the external pacemaker rate must be faster than the programmed rate of the implanted device and/or the external pacemaker must not be set in 'demand' mode.

If an implanted device is delivering pacing stimuli (at an adequate rate), and each is followed by a QRS complex on the ECG but no detectable cardiac output, that is cardiac arrest with 'pulseless electrical activity'. Use of an external pacemaker will be of no benefit in this situation.

15.7 Arrange device check and interrogation after successful CPR

In any patient with an implanted pacemaker or ICD who has return of spontaneous circulation (ROSC) after receiving CPR, an early physiologist's check on the state of the device and its leads should be an integral part of the immediate post-resuscitation care, to ensure that the device continues to function and deliver treatment appropriately.

Pacemakers and ICDs store information about rhythm behaviour. In the presence of one of these devices, or of an implantable event recorder, interrogation of the device following ROSC may provide useful information about the rhythm behaviour that initiated the arrest. That information may be an important guide to choice of further treatment.

SECTION D: Device management after death

16. Actions required after death in people with implanted cardiovascular devices

Local policies should include guidance on how healthcare professionals obtain access to a physiologist to interrogate and/or deactivate a device after death, and the other local arrangements that are in place for device removal, disposal or other management after death. Such policies should make provision for responding appropriately in situations where there is a cultural or religious requirement for early burial or cremation.

16.1 Immediate actions: pacemakers

Whether implanted for treatment of bradycardia or for treatment of heart failure pacemakers usually require no immediate action when someone dies. However a CRT-D device has an ICD function and must be managed as described in 16.2 below.

If death occurs suddenly and unexpectedly in someone with a pacemaker it is important to remember that most pacemakers have a memory function that may provide information about heart rhythm behaviour and device behaviour immediately prior to death, information that may be of help to the Coroner (or in Scotland the Procurator Fiscal) in identifying the mechanism and cause of death. In these circumstances a cardiac devices physiologist (usually from the local pacemaker service) should be asked to undertake an early interrogation of the pacemaker, whenever possible prior to its removal, and the detailed findings should be documented in the patient's medical records.

16.2 Immediate actions: ICDs

When someone dies with an active ICD (including a CRT-D device) in place it is important that the device is deactivated as soon as is practicable and certainly before any attempt is made to perform an autopsy or to remove the device. Cutting through the lead to remove an active ICD would place the operator at risk of receiving a shock. There may also be a risk of the device detecting movement or other artefact as a ventricular arrhythmia and delivering a shock that could be transmitted to the person performing the autopsy or device removal. In most expected deaths it is hoped that end-of-life care planning would have led to deactivation of the device prior to death.

If the death was sudden and not expected at that time, early interrogation of the device by a cardiac devices physiologist should be arranged to seek and document potentially useful information from the ICD, as described in <u>section 16.1</u> above.

16.3 Immediate actions: implantable event recorders

If a person dies suddenly or unexpectedly with an IER in place, its early interrogation should be arranged and the findings documented for the same reason.

16.4 Immediate actions: implantable neurostimulators

No immediate action is needed after death in people with implanted neurostimulators.

16.5 Subsequent actions: autopsy, device removal and cremation

Funeral directors and mortuary attendants who are uncertain about the nature of an implanted device and whether or not it requires deactivation should be encouraged to contact their local pacemaker/ICD service in the first instance as they will usually be able to advise and would need to be contacted anyway to deactivate an ICD that remains active after death.

In a dead person with an active ICD no attempt should be made to undertake an autopsy or remove the device until it has been deactivated, usually by a cardiac physiologist. Temporary deactivation using a magnet is not adequate for these purposes. An ICD that is still active at the time of death should be deactivated as soon as is practicable.

If a person's body is to be cremated it is important that a pacemaker, ICD (once deactivated), IER or neurostimulator is removed prior to cremation. It is necessary only to remove the pacemaker, ICD or neurostimulator generator; the leads may be left in place. The reason for this is that these generators (and IERs) are sealed units, designed to withstand high pressures. However heating to a very high temperature is likely to cause the device to explode, creating some resulting hazard and depriving the deceased person and those close to them of a dignified cremation.

The matter of ownership of the implanted device should be considered (see <u>section 7.14</u>) and, where necessary, appropriate consent should be obtained for removal and retention of an implanted device.

16.6 Subsequent actions: burial

When burial is intended, there is no absolute need to remove any of these electronic devices. In some instances removal may be appropriate to allow testing of the device. As in <u>section 16.5</u> above, where necessary, appropriate consent should be obtained for removal and retention of an implanted device.

16.7 Disposal of implanted devices after removal

The following guidance applies equally to:

- removal of an implanted electronic device during life for clinical reasons (e.g. battery depletion or infection) and
- removal of an implanted electronic device after death (e.g. for testing of the device or to allow cremation to proceed).

A policy for safe disposal of implantable electronic devices after removal should be followed by every device service.

Devices removed and retained in mortuaries or by funeral directors should be returned to the local device service for safe disposal. The majority of explanted CIEDs are returned to physiologists in hospital device services for safe disposal. All device manufacturers have a disposal policy and supply the necessary means for collection and disposal of devices. Device services should be aware of and should use these arrangements.

In the event of an explanted device being retained by a patient or a beneficiary of a deceased patient, consideration should be given to aspects of health and safety that may apply (including any relevant risk in relation to communicable disease and the risk of explosion if the device is heated). The recipient of the device should be given advice on its safe handling and disposal.

SECTION E: Policies, quality standards & further reading

17. Policies governing device management

Healthcare provider organisations should have a policy for device management that crosses all local organisational boundaries, and that includes clear details of:

- The services in that community (and/or at a regional centre if services are not available at all times within the local community) available to support people with implanted cardiac devices and the healthcare professionals caring for those patients, including how to obtain details of any individual patient's device.
- Where the policy is a regional one, specific additional information relating to individual provision at local level within that region.
- Information leaflets and other resources available to enhance that support, and how to access them.
- When to consider device deactivation.
- Who is available to advise on decisions about device deactivation and how they should be contacted regarding those decisions.
- How to contact an appropriate cardiac physiologist, when deactivation of a device is considered necessary.
- What documentation is required to support or validate a decision to deactivate a device and allow deactivation to proceed without delay.
- How to contact an appropriate cardiologist for advice on device management when necessary.
- How and when to contact palliative care services in support of device deactivation as part of end-of-life care.
- How and where to obtain immediate access to a magnet for emergency, temporary ICD deactivation when necessary, and how to apply it.
- Information, guidance and support that should accompany the issue of a magnet to a patient with an ICD in those localities where it is standard practice to issue a magnet to each person with an ICD.
- Circumstances in which reactivation of a previously deactivated device may be appropriate.
- Different actions that are needed during and out of "office hours".
- Different actions that are needed according to the location and condition of the patient.
- Specific duties of or actions required from different healthcare professionals in relation to device deactivation.
- Local arrangements that are in place for disposal of explanted devices.
- Arrangements for training and maintenance of competence of involved staff in undertaking sensitive communication about device management.
- Arrangements for training and maintenance of competence of involved staff in carrying out device deactivation.

• Actions that should be taken concerning device deactivation, removal or disposal when a person with an implanted cardiac device has died.

In addition such policies provide an opportunity to promote a clear understanding of the importance of including explanation of the possible later need for device deactivation as part of the process of obtaining properly informed consent, prior to initial device implantation (see <u>section 7.4</u>). They offer an opportunity to provide healthcare professionals with basic understanding of the nature and purpose of implanted devices, and of the balance of benefits and burdens that form the basis of most decisions to deactivate them. This may help to avoid misunderstandings by healthcare professionals and help them to communicate effectively and avoid misunderstandings by patients and those close to them. They offer also an opportunity to provide guidance on the delivery of CPR to people with implanted devices, and appropriate consideration of DNACPR decisions and other decisions relating to end-of-life care.

It is important that such policies are kept up to date and that healthcare staff have prompt access to current policies and guidance at all times. In particular, if individual contact names or telephone numbers are included, a mechanism should be in place to update these immediately, whenever there is a change of staff or change of contact details. If printed copies of policies are used, they should contain clear warning that they may not be the latest version. Provision of round-the-clock electronic access to the current version of the policy is the recommended approach.

18. Quality standards for device management

All patients with a CIED should have timely access to expert clinical support for their device and should be provided with clear information on how to obtain help whenever they need it. <u>Standards for implantation and follow-up of cardiac rhythm management devices</u> in adults have been defined by the British Heart Rhythm Society (formerly Heart Rhythm UK).

All patients with a CIED should be provided with and encouraged to carry with them information about their device, so that it is available to clinicians in the event of an emergency.

Patients with a CIED should be under regular surveillance in a pacemaker/ICD clinic. The service provided by that clinic should include the provision of information about deactivation of their device should that become necessary or appropriate. The clinic should provide

prompt access for patients requiring device deactivation (or reactivation in occasional cases).

The service should provide immediate round-the-clock access to magnets for emergency deactivation of ICDs, and the location of those magnets should be known to all relevant healthcare staff (especially but not exclusively Emergency Department, Acute Medicine, Cardiac Care Unit and Cardiology hospital staff, Palliative Care professionals and Heart Failure Nurse Specialists). In some localities it is standard practice to issue a magnet to each person with an ICD. Where this is the case, patients and those close to them should also receive information, guidance and on-going support to ensure that the purpose of the magnet is understood, that the likelihood of appropriate use is optimised and the likelihood of inappropriate use is minimised

Arrangements should be in place to provide physiologist-delivered ICD deactivation in another healthcare facility (such as a hospice or nursing home) or in the patient's home, where the patient is sufficiently unwell or close to the end of their life to make travel to a hospital clinic inappropriate.

Arrangements should be in place to provide round-the-clock access to expert cardiological advice to support patients with cardiovascular implanted electronic devices and to support the other healthcare professionals caring for them at any time. If necessary that may require arrangements for access to advice from a regional centre if the relevant expertise is not available locally at all times.

Arrangements should be in place to provide prompt physiologist-delivered ICD deactivation for any patient who has died with an active ICD in place, to allow safe conduct of an autopsy or safe removal of the device to allow cremation.

Arrangements should be in place to provide prompt physiologist-delivered interrogation of pacemakers, IERs or ICDs when a patient with one of these devices dies suddenly and unexpectedly. Those responsible for investigating the cause of such deaths (e.g. Coroners' Pathologists, Medical Examiners) should be aware of these arrangements and of the potential information that may be obtained in this way.

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19. Other guidance and references

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20. Glossary of abbreviations

Each abbreviation is defined at least once in the text, but this glossary is provided also for ease of reference.

ADRT	Advance decision to refuse treatment
AV	Atrioventricular
CIED	Cardiovascular implantable electronic device
CPR	Cardiopulmonary resuscitation
CRT	Cardiac resynchronisation therapy (biventricular pacing)
CRT-D	Cardiac resynchronisation therapy (biventricular pacing) that also has an ICD
	function
CRT-P	Cardiac resynchronisation therapy (biventricular pacing) with no ICD function
DNACPR	Do not attempt cardiopulmonary resuscitation
DNACPR ECG	Do not attempt cardiopulmonary resuscitation Electrocardiogram
ECG	Electrocardiogram
ECG ICD	Electrocardiogram Implantable cardioverter defibrillator
ECG ICD	Electrocardiogram Implantable cardioverter defibrillator Implantable event recorder (known also as an implantable loop recorder or
ECG ICD IER	Electrocardiogram Implantable cardioverter defibrillator Implantable event recorder (known also as an implantable loop recorder or implantable cardiac monitor)
ECG ICD IER ROSC	Electrocardiogram Implantable cardioverter defibrillator Implantable event recorder (known also as an implantable loop recorder or implantable cardiac monitor) Return of spontaneous circulation

Appendix A: Examples of documents relating to device deactivation towards the end of life

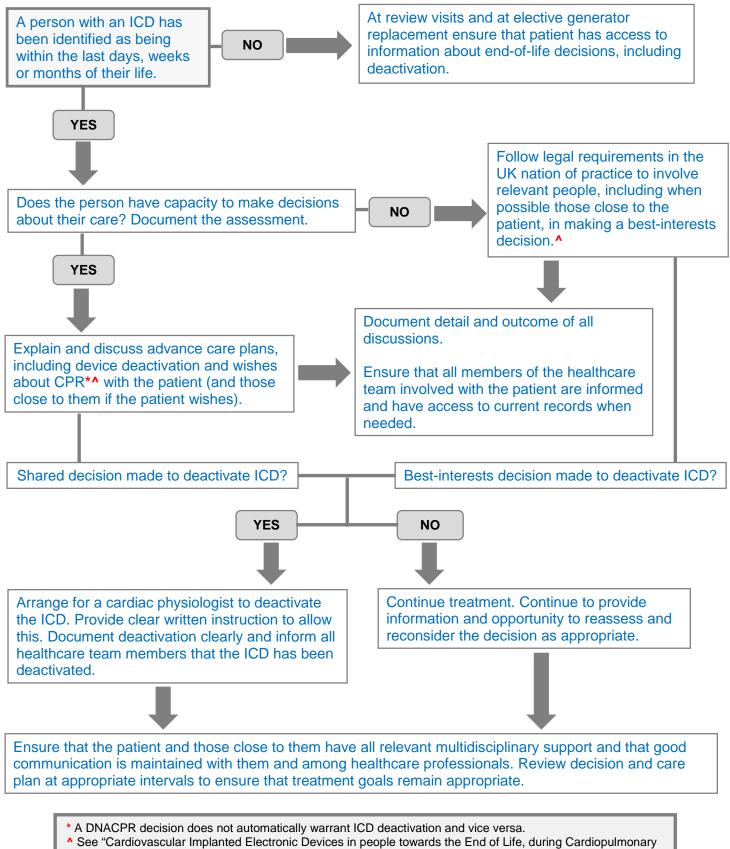
Below are:

- Two algorithms to guide decision-making about deactivation of ICDs in people who have been identified as approaching the end of life:
 - 1. in a planned way
 - 2. in an emergency setting.
- Instructions for application of a ring magnet for emergency ICD deactivation.
- A list of relevant local or regional documents. These are provided for illustration and the content is not necessarily recommended by the authors of this document as conforming to all the standards defined herein.

These may be adapted as necessary for local use.

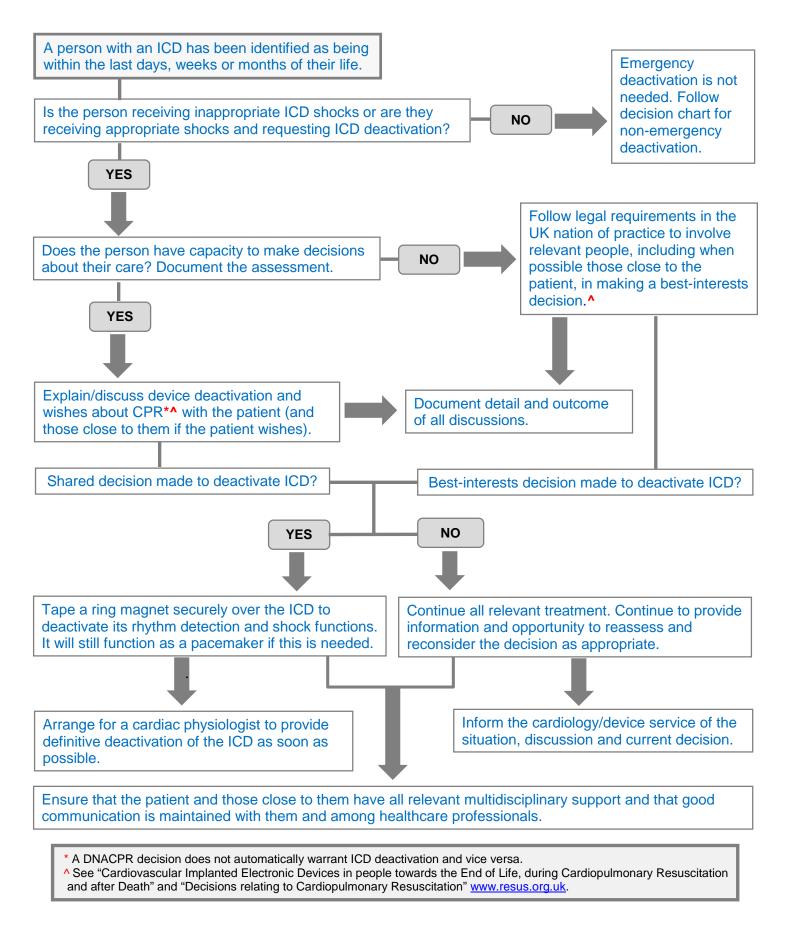
Additional resources will be added as they become available.

Decision chart for ICD deactivation towards the end of a person's life



Resuscitation and after Death" and "Decisions relating to Cardiopulmonary Resuscitation" <u>www.resus.org.uk/</u>.

Decision chart for emergency ICD deactivation

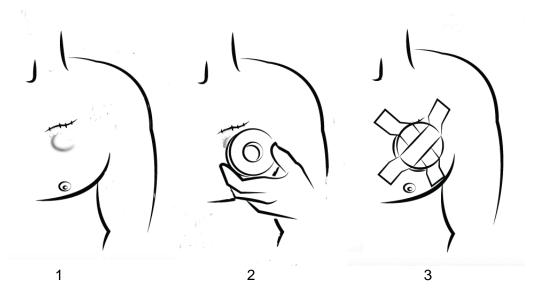


How to de-activate an Implantable Cardiac Defibrillator (ICD) using a ring magnet*

Ring magnets are available from Please contact a Cardiac Physiologist on during office hours.

Magnets are also located in the following areas:

- Hospital: Coronary Care Unit, Emergency Department, Admissions Unit and Ward(s).
- Community: Hospice.
 - 1. Locate the patient's ICD. (This may be located on the left or right side of the patient's chest just below their clavicle, usually seen as a prominent protrusion; less commonly the device may be situated in the patient's abdomen and is more difficult to locate)
 - 2. Place the magnet directly on the skin over the ICD.
 - 3. Secure magnet in place with suitable tape to prevent dislodgement from device.



- 4. With the magnet in place, tachyarrhythmia detection and shock therapy is suspended and the ICD will not deliver a shock.
- 5. If the device has an active audible alarm, this may sound when the magnet is first applied.
- 6. Magnet application does NOT affect the programmed pacemaker function of the device.
- 7. Magnet removal returns the device to its previously programmed operation.

*adapted with thanks from Wye Valley NHS Trust documents

Below are some examples of relevant documents, published by local, regional and national organisations (including one from Australia for comparison). These are presented in no specific order; they are provided for illustration purposes and do not necessarily fulfill all the recommendations of this joint document. At the time of publication of this guidance most documents are accessible from the internet addresses shown or using a search engine but the authors cannot confirm whether they represent the latest version of each document. Most policies refer specifically to ICD deactivation towards the end of life. Guidance on management of pacemakers and other electronic devices has not been included or has been developed separately.

South London Cardiovascular and Stroke Network.

Guidelines for deactivating implantable cardioverter defibrillators (ICDs) in people nearing the end of their life.

www.slcsn.nhs.uk/cardiac-hf.html

North of England Cardiovascular Network. Operational policy for deactivation/reactivation of implantable cardioverter defibrillator (ICD).

Shropshire & Staffordshire Heart and Stroke Network.

The Withdrawal of Implantable Cardioverter Defibrillator therapy (ICD) in an Adult Patient.

Wye Valley NHS Trust.

Implantable Cardiac Defibrillator (ICD) Consent at Fitting and Deactivation at the End of Life Guideline.

Greater Manchester & Cheshire Cardiac & Stroke Network. Operational Policy for the deactivation/reactivation of Implantable cardioverter defibrillator (ICD).

Eastern and Coastal Kent Community Services. **Implantable Cardioverting Defibrillator (ICD) De-activation at End of Life Policy.** <u>www.strodepark.org.uk/wp-content/uploads/2013/07/Do-Not-Attempt-Cardio-Pulmonary-</u> <u>Resuscitation-DNA-CPR-Policy.pdf</u> Coventry and Warwickshire Cardiovascular Network. **ICD consent at implantation and deactivation at the end of life.** <u>www.c-a-s-t-l-e.org.uk/media/9583/c_w_cardovascular_network_icd_de-</u> <u>activation_policy_sept_2012.pdf</u>

New South Wales Agency for Clinical Innovation. NSW Guidelines for Deactivation of Implantable Cardioverter Defibrillators at the End of Life.

www.aci.health.nsw.gov.au

Doncaster and Bassetlaw Hospitals NHS Trust.

Deactivation of Implantable Cardioverter Defibrillator (ICD) and Cardiac Resynchronisation Therapy (CRT) Devices Procedure. www.dbh.nhs.uk

Kent Cardiovascular Network.

ICDs at the end of a patient's life. Arranging for deactivation. A guide for health professionals.

Arrhythmia Alliance.

CRT / ICD Patient Information.

www.heartrhythmcharity.org.uk/www/media/files/For_Patients/120913-ch-FINAL_A-A_ICD_CRT_Patient_Information_Booklet.pdf

Papworth Hospital NHS Foundation Trust.

Deactivating your ICD. A patient's guide.

www.papworthhospital.nhs.uk/content.php?/patients_visitors/patient_information/patient_leaf lets

Papworth Hospital NHS Foundation Trust.

Implantable Cardioverter Defibrillators. Follow-up guide for patients.

www.papworthhospital.nhs.uk/content.php?/patients_visitors/patient_information/patient_leaf lets

Appendix B: Registered stakeholders

- Arrhythmia Alliance Association of Inherited Cardiac Conditions Association for Palliative Medicine of Great Britain and Ireland **British Heart Foundation** British Heart Rhythm Society (formerly Heart Rhythm UK) **British Medical Association** British Society for Heart Failure Cardiomyopathy Association College of Emergency Medicine Coroners Society of England and Wales Council for Professionals as Resuscitation Officers Department of Health Department of Health, Social Services and Public Safety for Northern Ireland Faculty of Intensive Care Medicine Heart of England NHS Foundation Trust Intensive Care Society Medicines and Healthcare Products Regulatory Agency Ministry of Justice National Ambulance Service Medical Directors Group NHS England **NHS** Lothian NHS Scotland **NHS Wales** National Institute for Cardiovascular Outcomes Research Royal College of Anaesthetists **Royal College of General Practitioners** Royal College of Nursing Royal College of Pathologists Royal College of Physicians (London) Sandwell and West Birmingham Hospitals NHS Trust Society for Cardiological Science and Technology Society for Cardiothoracic Surgery in Great Britain & Ireland Syncope Trust And Reflex anoxic Seizures Welsh Cardiovascular Society
- Worcestershire Acute Hospitals NHS Trust

Appendix C: Membership of Working Group

Declared conflicts of interest are shown in italics

Ms Tracey Baker	Transplant & Divisional Support Manager, Royal Brompton & Harefield NHS Foundation Trust.
Dr James Beattie	Consultant Cardiologist, Heart of England NHS Foundation Trust.
	 Member, British Cardiovascular Society. Member, British Society for Heart Failure. Member, Heart Failure Association of the European Society of Cardiology. Fellow, Royal College of Physicians (Glas /Lond). Fellow, European Society of Cardiology. Trustee, National Council for Palliative Care.
	Author of BHF document on ICD deactivation.
Mr Simon Chapman	Director of Policy Intelligence & Public Affairs, National Council for Palliative Care.
Professor Robert George	Consultant Physician in Palliative Care, Guy's & St Thomas' NHS Foundation Trust.
	Professor of Palliative Care, Cicely Saunders Institute, King's College London
	Vice President, Association for Palliative Medicine
Dr James Glancy	Consultant Cardiologist, County Hospital, Hereford.
	Member, British Cardiovascular Society. Resuscitation Council (UK) Instructor.
Mrs Susan Hampshire	Director of Courses Development and Training, Resuscitation Council (UK).
Dr Karen Hogg	Consultant Cardiologist, Glasgow Royal Infirmary.
	Member, British Society for Heart Failure. Member, British Heart Rhythm Society. Clinical lead for the Caring Together Programme.
Ms Sue Jones	Pacing/ICD Service Manager, St George's Healthcare NHS Trust.
	Honorary Fellow, Royal College of Physicians of London.

Dr Nick Linker	Consultant Cardiologist, James Cook University Hospital, Middlesbrough.
	President, British Heart Rhythm Society.
Dr Andrew Lockey	Consultant in Emergency Medicine, Calderdale Royal Hospital, Halifax.
	Honorary Secretary, Resuscitation Council (UK).
	Medical Advisor to 'First on Scene' first aid company. Resuscitation Council (UK) Representative on General Assembly of the European Resuscitation Council (ERC). Vice-chair, ERC Educational Advisory Group (unpaid). Member, ERC ALS and Generic Instructor Course International Course Committees.
Dr Janet McComb	Consultant Cardiologist, Freeman Hospital, Newcastle upon Tyne.
	Research support for a fellow from St Jude Medical (an ICD manufacturer).
Ms Sarah Mitchell	Executive Director, Resuscitation Council (UK).
Mr Gordon Patterson	Member, Patient Advisory Group, Resuscitation Council (UK).
Dr David Pitcher (chair)	Chairman, Resuscitation Council (UK).
	Consultant Cardiologist, University Hospitals Birmingham NHS Foundation Trust. Consultant Cardiologist, St Richard's Hospice, Worcester.
	Member, British Cardiovascular Society. Member, British Heart Rhythm Society (until 2014). <i>Member of NHS Pathways Clinical Governance Group.</i> <i>Member of NICE Quality Standards Committee for Transient</i> <i>Loss of Consciousness.</i> <i>Member of Public Record Standards Body Advisory Board.</i>
Dr Jasmeet Soar	Consultant in Anaesthetics & Intensive Care Medicine, North Bristol NHS Trust.
	Editor, Resuscitation (paid honorarium). ERC ALS Working Group Chair (unpaid). ILCOR Taskforce Co-chair (unpaid).
Ms Sheila Turner	Resuscitation Officer, Papworth Hospital, Cambridge.
	Chair, Council for Professionals as Resuscitation Officers.

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Consultant Cardiologist (Congenital Heart Disease) Bristol Royal Hospital for Children

for reviewing the document from a paediatric perspective and contributing to the wording of section 4.

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Centre for Health, Ethics and Law, Southampton Law School, University of Southampton

and

Professor Richard Huxtable

Professor of Medical Ethics and Law Deputy Director, Centre for Ethics in Medicine School of Social and Community Medicine, University of Bristol

for reviewing and editing the document from a legal perspective.

Professor Margaret Brazier

Professor of Law School of Law, University of Manchester

and

Dr Muireann Quigley

Senior Lecturer in Biomedical Ethics & Law Centre for Ethics in Medicine, University of Bristol

for advice regarding ownership of implanted devices.

Appendix D: Literature review

PICO questions:

Population	In a patient with a CIED
Population	 In a patient with a CIED
Intervention	 does any specific approach to end-of life care
Comparator	 as opposed to standard care
Outcome	- improve outcome (e.g. improved acceptance by patients, relatives, staff and
	other groups)?
Р	 In a patient with cardiac arrest who has a CIED
I	 Does any specific resuscitation intervention
С	 Compared with standard BLS or ALS
0	 Improve survival (ROSC, survival to discharge, 30 days, 90 days, 180 days
	+ good neurological outcome) or decrease the risk to rescuers from
	accidental electrical shocks?
Р	 When a person with a CIED dies
I	 Does any specific intervention
С	 Compared with standard care after death
0	 Improve outcome (e.g. decreased risk to mortuary staff or others,
	decreased hazard during cremation) or ensure compliance with legal
	requirements or provide worthwhile information regarding cause of death?

Inclusion/Exclusion Criteria

Inclusion criteria were systematic reviews with or without meta-analyses, randomised controlled trials (RCTs), quasi-RCTs, controlled clinical trials (CCTs), controlled before-after (CBA) designs, interrupted time series (ITS) studies, and case-series discussion papers, non-research letters and editorials and case studies. Animal studies were excluded.

Summary of PubMed searches (further details can be found below)

1. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Terminal care"[MeSH]))

Limits: Human, English, 11 September 2014

Identified 129 articles

21 articles excluded as not related to CIED management towards the end of life.

2 references excluded as they were abstracts of presented papers.

106 relevant publications identified and reviewed:

Literature reviews	4
Personal reviews, discussion articles, editorials	41
Consensus statement	1
Observational studies	11
Surveys	19
Focus group study	1
Case reports	9
Letters, responses, short communications	19
Summary for patients	1

2. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND deactivation

No limits, 15 August 2014

Identified 94 articles

28 articles excluded as not related to device deactivation towards the end of life.

66 relevant publications identified and reviewed:	
Reviews	27
Systematic review	1
Guideline	1
Observational studies:	
Patient features and outcomes	З,
Avoiding inappropriate shocks by deactivation	1
Advanced directives and ICDs	1
Patient surveys/interviews/focus groups	7
Nurse survey	1
Physician survey	4
Clinical team members (multidisciplinary) survey	1
Hospice survey	1
Case reports:	
Single	5
Two cases	
Letters	11

3 further articles identified from reviewing articles (1 guideline, 2 opinions).

3. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND magnet

No limits, 16 August 2014

Identified 165 articles 159 not relevant

6 articles (all reviews) identified and reviewed.

4. ((("Defibrillators, Implantable"[Mesh]) OR ("Pacemaker, Artificial"[Mesh])) AND (battery AND (("Palliative Care"[Mesh]) OR ("Hospice and Palliative Care Nursing"[MeSH]) OR ("Terminal Care"[MeSH]))))

No limits, 16 August 2014

1 article identified and reviewed

5. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND (chest compression OR accidental shock)

No limits, 16 August 2014

17 articles identified, 15 excluded2 case reports of relevance identified and reviewed:

Embase and Medline searches on 16 August limited to RCTs did not identify any additional trials.

6. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Cardiopulmonary resuscitation"[MeSH]))

Limits: Human, English, 12 September 2014

Identified 126 articles

120 articles excluded as not related to performance of or outcome from CPR in people with CIEDs.

6 relevant publications identified and reviewed:

Literature reviews	1
Observational studies	1
Case reports	4

7. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Autopsy"[MeSH])

Limit: Human, 08 September 2014

Identified 178 articles

Most articles excluded as not related to management of CIEDs after death and/or not in English.

12 relevant studies identified and reviewed:	
Editorials/overviews	5
Literature review	1
Observational studies	2
Case reports	4

8. (("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Cremation"[MeSH])

Limits: Human, English, 08 September 2014

Identified 11 articles

5 articles excluded as not related to management of CIEDs after death.

6 relevant studies identified and reviewed:

Editorial reviews	2
Observational studies	2
Survey of funeral directors, patients, members of the public	1
Survey of crematoria	1

Literature searches - detail

1. PubMed search up to 11 September 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Terminal care"[MeSH]))

Limits: Human, English

Identified 129 articles

21 articles excluded as not related to CIED management towards the end of life.

2 references excluded as they were abstracts of presented papers.

106 relevant publications identified and reviewed:

Literature reviews	4
Personal reviews, discussion articles, editorials	41
Consensus statement	1
Observational studies	11
Surveys	19
Focus group study	1
Case reports	9
Letters, responses, short communications	19
Summary for patients	1

 Features and outcomes of patients who underwent cardiac device deactivation. Buchhalter LC, Ottenberg AL, Webster TL, Swetz KM, Hayes DL, Mueller PS. JAMA Intern Med. 2014 Jan;174(1):80-5. doi: 10.1001/jamainternmed.2013.11564.

IMPORTANCE: Little is known about patients who undergo cardiovascular implantable electronic device deactivation.

OBJECTIVE: To describe features and outcomes of patients who underwent cardiovascular implantable electronic device deactivation.

DESIGN, SETTING, AND PARTICIPANTS: Retrospective review of medical records of 150 patients at a tertiary academic medical center (Mayo Clinic, Rochester, Minnesota). EXPOSURE Cardiovascular implantable electronic device deactivation.

MAIN OUTCOMES AND MEASURES: Demographic and clinical data and information regarding advance directives, ethics consultations, palliative medicine consultations, and cardiovascular implantable electronic device deactivations.

RESULTS: Of the 150 patients (median age, 79 years; 67% were male), 149 (99%) had poor or terminal prognoses. Overall, 118 patients (79%) underwent deactivation of tachycardia therapies only, and 32 (21%) underwent deactivation of bradycardia therapies with or without tachycardia therapies (6 patients [4%] were pacemaker-dependent). Half of the deactivation requests (51%) were made by surrogates. A majority of deactivations (55%) were carried out by nurses. Although 85 patients (57%) had advance directives, only 1 mentioned the device in the directive. Ethics consultations occurred in 3 patients (2%) and palliative medicine consultations in 64 (43%). The proportions of patients who died within 1 month of device deactivation were similar for those who underwent deactivation of tachycardia therapies only and those who underwent deactivation of bradycardia therapies with or without tachycardia therapies (85% vs 94%; P = .37).

CONCLUSIONS AND RELEVANCE: Most requests for cardiovascular implantable electronic device deactivation were for implantable cardioverter-defibrillator-delivered tachycardia therapies only. Many of these requests were made by surrogates. Advance directives executed by patients with these devices rarely addressed device management. Regardless of device therapy, most patients died shortly after device deactivation. Hence, a device deactivation decision may reflect the seriousness of a given patient's underlying illness. Patients with devices should engage in advance care planning to ensure that future care is consistent with their preferences.

- Deathbed shock: causes and cures. Butler K, Puri S. JAMA Intern Med. 2014 Jan;174(1):88-9. doi: 10.1001/jamainternmed.2013.11125.
 Comment on: Features and outcomes of patients who underwent cardiac device deactivation. [JAMA Intern Med. 2014]
- The antidote for unprepared patients: a caring clinician. Matlock DD, Mandrola JM. JAMA Intern Med. 2014 Jan;174(1):86-7. doi: 10.1001/jamainternmed.2013.9196. Comment on: Features and outcomes of patients who underwent cardiac device deactivation. [JAMA Intern Med. 2014]
- Implantable cardioverter-defibrillator therapy before death: high risk for painful shocks at end of life. Kinch Westerdahl A, Sjöblom J, Mattiasson AC, Rosenqvist M, Frykman V. Circulation. 2014 Jan 28;129(4):422-9. doi: 10.1161/CIRCULATIONAHA.113.002648. Epub 2013 Nov 15.

BACKGROUND: Several trials have demonstrated improved survival with implantable cardioverter-defibrillator (ICD) therapy. The cause and nature of death in the ICD population have been insufficiently investigated. The objective of this study was to analyze ICDs from deceased patients to assess the incidence of ventricular tachyarrhythmias, the occurrence of shocks, and possible device malfunction.

METHODS AND RESULTS: We prospectively analyzed intracardiac electrograms in 125 explanted ICDs. The incidence of ventricular tachyarrhythmia, including ventricular fibrillation. and shock treatment was assessed. Ventricular tachyarrhythmia occurred in 35% of the patients in the last hour of their lives; 24% had an arrhythmic storm, and 31% received shock treatment during the last 24 hours. Arrhythmic death was the primary cause of death in 13% of the patients, and the most common cause of death was congestive heart failure (37%). More than half of the patients (52%) had a do-not-resuscitate order, and 65% of them still had the ICD shock therapies activated 24 hours before death. Possible malfunctions of the ICD were found in 3% of all patients.

CONCLUSIONS: More than one third of the patients had a ventricular tachyarrhythmia within the last hour of life. Cardiac death was the primary cause and heart failure the specific cause of death in the majority of the cases. Devices remained active in more than half of the patients with a do-not-resuscitate order; almost one fourth of these patients received at least 1 shock in the last 24 hours of life.

Comment in: Device therapy: ICDs in patients with a DNR order. [Nat Rev Cardiol. 2014]

Implantable cardioverter-defibrillator shocks in dying patients: disturbing data from beyond the grave. [Circulation. 2014]

- Implantable cardioverter-defibrillator shocks in dying patients: disturbing data from beyond the grave. Lampert R. Circulation. 2014 Jan 28;129(4):414-6. doi: 10.1161/CIRCULATIONAHA.113.006939. Epub 2013 Nov 15. Comment on: Implantable cardioverter-defibrillator therapy before death: high risk for painful shocks at end of life. [Circulation. 2014]
- Deactivation of implantable cardioverter-defibrillators at end of life. Pettit SJ, Jackson CE, Gardner RS.Future Cardiol. 2013 Nov;9(6):885-96. doi: 10.2217/fca.13.81.

It is inevitable that all patients with implantable cardioverter-defibrillators (ICDs) will die during extended follow-up. End-of-life care planning may become appropriate as

a patient's condition deteriorates. There is concern about multiple futile shocks in the final hours of life, although the incidence of this problem has been estimated at only 8-16%. Despite broad consensus that ICD deactivation should be discussed as part of end-of-life care planning, the effect of ICD deactivation, in particular whether life expectancy is altered, is uncertain. Many clinicians are reluctant to discuss ICD deactivation. Many patients have misconceptions regarding ICD function and value longevity above quality of life. As such, ICD deactivation is often discussed late or not at all. The management of ICDs in patients approaching death is likely to become a major problem in the coming years. This article will discuss directions in which clinical practice might develop and areas for future research.

- Managing with pacemakers and implantable cardioverter defibrillators. Lampert R. Circulation. 2013 Oct 1;128(14):1576-85. doi: 10.1161/CIRCULATIONAHA.113.001555.
- Patient preferences for deactivation of implantable cardioverter-defibrillators.
 Beattie JM, Flynn TN, Clark AM. JAMA Intern Med. 2013 Sep 9;173(16):1556-7. doi: 10.1001/jamainternmed.2013.8141.
 Comment on: Patient preferences for deactivation of implantable cardioverter-defibrillators. [JAMA Intern Med. 2013]
- End-of-life care in patients with implantable cardioverter defibrillators: a MADIT-II substudy. Sherazi S, McNitt S, Aktas MK, Polonsky B, Shah AH, Moss AJ, Daubert JP, Zareba W. Pacing Clin Electrophysiol. 2013 Oct;36(10):1273-9. doi: 10.1111/pace.12188. Epub 2013 Jun 3.

BACKGROUND: Implantable cardioverter defibrillator (ICD)-delivered shocks can cause substantial distress, warranting consideration of ICD deactivation at end of life. This study was designed to describe the patterns of end-of-life management in patients with ICDs.

METHODS: There was a retrospective chart review of 98 patients who died in the ICD arm of multicenter automated defibrillator implantation trial II (MADIT II). The pattern of ICD management and the frequency of ICD shocks delivered before death were reviewed.

RESULTS: We identified three groups: Group 1 consisting of individuals who underwent ICD, deactivation, 15 (15%); Group 2 patients without ICD deactivation who were in hospice or with "do not resuscitate" (DNR) orders, 36 (37%); and Group

3 patients without ICD deactivation who were not in hospice care and did not have DNR orders, 47 (48%). Out of 15 deactivations, 11 (73%) occurred in the week before death. None of the patients in Group 1 received an ICD shock in the 24-hour period before death. However, one (3%) patient from Group 2 and nine (19%) patients from Group 3 had shocks during the 24 hours before death (P = 0.03). In the last week before death, three (20%), two (6%), and six (13%) patients received ICD shocks in the three groups, respectively (P = 0.28).

CONCLUSIONS: In patients with terminal conditions who are at risk for imminent death, active management of the patient's ICD, including timely discussions regarding ICD deactivation, may reduce the risk of ICD shocks during the end of life.

 Failing the failing heart: a review of palliative care in heart failure. Shah AB, Morrissey RP, Baraghoush A, Bharadwaj P, Phan A, Hamilton M, Kobashigawa J, Schwarz ER. Rev Cardiovasc Med. 2013;14(1):41-8.

Heart failure (HF) is the most common reason for hospital admission for patients older than 65 years. With an aging population and improving survival in heart failure patients, the number of people living with HF continues to grow. As this population increases, the importance of treating symptoms of fatigue, dyspnea, pain, and depression that diminish the quality of life in HF patients becomes increasingly important. Palliative care has been shown to help alleviate these symptoms and improve patients' satisfaction with the care they receive. Despite this growing body of evidence, palliative care consultation remains underutilized and is not standard practice in the management of HF. With an emphasis on communication, symptom management, and coordinated care, palliative care provides an integrated approach to support patients and families with chronic illnesses. Early communication with patients and families regarding the unpredictable nature of HF and the increased risk of sudden cardiac death enables discussions around advanced care directives, health care proxies, and deactivation of permanent pacemakers or implantable cardioverter defibrillators. Cardiologists and primary care physicians who are comfortable initiating these discussions are encouraged to do so; however, many fear destroying hope and are uncertain how to discuss end-of-life issues. Thus, in order to facilitate these discussions and establish an appropriate relationship, we recommend that patients and families be introduced to a palliative care team at the earliest appropriate time after diagnosis.

 Patients' perspective on deactivation of the implantable cardioverter-defibrillator near the end of life. Pedersen SS, Chaitsing R, Szili-Torok T, Jordaens L, Theuns DA. Am J Cardiol. 2013 May 15;111(10):1443-7. doi: 10.1016/j.amjcard.2013.01.296. Epub 2013 Mar 12.

Recent guidelines have emphasized the importance of discussing the issue of deactivation near the end of life with patients with an implantable cardioverterdefibrillator (ICD). Few studies have examined the patient perspective and patients' wishes. We examined patients' knowledge and wishes for information; and the prevalence and correlates of a favorable attitude toward deactivation. Three cohorts of ICD patients (n = 440) extracted from our institutional database were asked to complete a survey that included a vignette about deactivation near the end of life. Of the 440 patients approached, 294 (67%) completed the survey. Most patients (68%) were aware that it is possible to turn the ICD off, and 95% believed it is important to inform patients about the possibility. Of the patients completing the survey, 84% indicated a choice for or against deactivation. Psychological morbidity was not associated with a response in favor or against deactivation (p >0.05 for all). The wish for a worthy death near the end of life was an independent associate of a favorable attitude toward deactivation (odds ratio 2.14, 95% confidence interval 1.49 to 3.06, p <0.0001), adjusting for the importance of avoiding shock-related pain, anxiety, and poor quality of life and other potential confounders. In conclusion, most ICD patients seemed to favor device deactivation at the end of life, primarily owing to the wish for a worthy death. This finding indicates that patients have thought about the issue of deactivation near the end of life and might welcome the chance to discuss it with their physician.

Deactivation of implantable cardioverter-defibrillators: results of patient surveys.
 Herman D1, Stros P, Curila K, Kebza V, Osmancik P. Europace. 2013 Jul;15(7):963 doi: 10.1093/europace/eus432. Epub 2013 Feb 27.

AIMS: The indications for implantable cardioverter-defibrillators (ICDs) have been expanding, especially for primary prevention of sudden cardiac death. Implantable cardioverter-defibrillator saves lives; however, in near end-of-life situations linked to incurable diseases, the question arises as to whether or not to turn off the ICD to avoid excessive numbers of shocks as the heart begins to fail. This study examined the wishes of a cohort of ICD recipients. METHODS AND RESULTS: Consecutive recipients of ICDs for primary or secondary prevention of sudden cardiac death were examined during a routine out-patient follow-up visit. Subjects completed a written survey about expected ICD benefits, feelings and circumstances under which they would want to deactivate the device. One hundred and nine patients fully completed the survey. Mean age was 67.6 ± 8.7 years, 91 (83.5%) were male and the mean systolic ejection fraction was 31.5 ± 10.9%. The severity of symptoms of heart failure according to the New York Heart Association classification was 2.1 ± 0.59 at implantation. Ninety-nine (90.8%) patients felt more secure and safe following ICD implantation and 66 (60.6%) patients reported a sense of improved health status after implantation. Thirty-one (28.4%) patients had experienced an ICD shock. Fifty (45.9%) patients indicated that they had never considered ICD deactivation during near end-of-life situations. This topic had been discussed with only eight (7.3%) patients. Forty-four (40.1%) patients wanted more information about ICD deactivation. On the other hand, 10 (41.7%) patients from secondary prevention and 19 (22.4%) from primary prevention groups categorically refused more information or further discussion on this topic (P = 0.058). CONCLUSION: Most ICD recipients felt safer following ICD implantation and most wanted more information regarding ICD deactivation. However, a significant number of patients (especially, secondary prevention patients) had no interest in receiving additional information about this topic.

 Ethical considerations for discontinuing pacemakers and automatic implantable cardiac defibrillators at the end-of-life. Morgenweck CJ. Curr Opin Anaesthesiol. 2013 Apr;26(2):171-5. doi: 10.1097/ACO.0b013e32835e8349.

PURPOSE OF REVIEW: As the use of intracardiac devices has increased, the awareness of the burdens of the devices, especially the uncomfortable defibrillator shocks, has also increased. Some patients have requested device deactivation and some physicians have expressed reluctance to do so. This review will update physicians about the ethical acceptability of removal of intracardiac devices.

RECENT FINDINGS: The American Heart Rhythm Society released a consensus statement about the ethical removal of intracardiac devices. Subsequent surveys of patients and physicians demonstrate significant misunderstandings about deactivation.

SUMMARY: Physicians ought to initiate a deactivation conversation, ideally at the time of implantation. Sharing case studies about the deactivation process will enable physicians to enhance their ability to guide patients and family through thoughtful

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decision-making. Guidelines for deactivation should be promulgated throughout institutions that serve patients with intracardiac devices.

- Deactivating cardioverter defibrillators near the end of life. [No authors listed].
 BMJ. 2013 Jan 30;346:f558. doi: 10.1136/bmj.f558.
- Defibrillators, deactivation, decisions, and dying. Matlock DD, Allen LA. JAMA Intern Med. 2013 Mar 11;173(5):375-94. doi: 10.1001/jamainternmed.2013.2130.
 Comment on: Patient preferences for deactivation of implantable cardioverterdefibrillators. [JAMA Intern Med. 2013]
- Patient preferences for deactivation of implantable cardioverter-defibrillators. Dodson JA, Fried TR, Van Ness PH, Goldstein NE, Lampert R. JAMA Intern Med. 2013 Mar 11;173(5):377-9. doi: 10.1001/jamainternmed.2013.1883.
 Comment in: Patient preferences for deactivation of implantable cardioverter-defibrillators. [JAMA Intern Med. 2013]
 Defibrillators, deactivation, decisions, and dying. [JAMA Intern Med. 2013]
- Ethical challenges in advanced heart failure. Kini V, Kirkpatrick JN. Curr Opin Support Palliat Care. 2013 Mar;7(1):21-8. doi: 10.1097/SPC.0b013e32835c4915.

PURPOSE OF REVIEW: Advanced heart failure (AHF) is an increasingly important field. Both the population of AHF patients and the therapeutic and diagnostic interventions available are expanding, creating a host of difficult ethical challenges. This article discusses these important issues and proposes an approach to caring for AHF patients.

RECENT FINDINGS: Recent guidelines and clinical trials describe the benefits of costly and invasive therapies for AHF, such as ventricular assist devices and cardiac resynchronization therapy which prolong life and improve symptoms but may create burdens and conflict over deactivation at the end of life. Prognostication, informed consent, and early involvement of palliative care are central to addressing the decision-making challenges raised by these devices. Societal concerns such as cost-effectiveness and distributive justice will play an increasingly important role in the dissemination of these devices.

SUMMARY: More research, increased end-of-life education, emphasis on advance directives, a more comprehensive informed consent process, and a true multidisciplinary approach are needed to provide optimal care for patients with AHF.

 Patients' experiences of the implantable cardioverter defibrillator (ICD); with a focus on battery replacement and end-of-life issues. Fluur C, Bolse K, Strömberg A, Thylén I. Heart Lung. 2013 May-Jun;42(3):202-7. doi: 10.1016/j.hrtlng.2012.11.006. Epub 2012 Dec 27.

BACKGROUND: ICD deactivation at end-of-life is technically uncomplicated. However, it may present a psychological challenge to healthcare professionals, patients, and next-of-kin.

OBJECTIVE: This study explored patients' experiences of complex issues of battery replacement and deactivation of the ICD.

METHODS: Semistructured interviews were administered to 37 medically stable ICDrecipients.

RESULTS: The ICD-recipients lived with an uncertain illness trajectory, but the majority had not reflected on battery replacement or elective ICD deactivation. Healthcare professionals had rarely discussed these issues with patients. However, this was consistent with the ICD-recipients' wishes. Many patients had misconceptions about the lifesaving capacity of the ICD and the majority stated that they would not choose to deactivate the ICD, even if they knew they were terminally ill, and it meant they would receive multiple shocks.

CONCLUSION: The ICD-recipients tended not to think about end-of-life issues, which imply that many patients reach the final stages of life unaware of the option of ICD deactivation.

19. Cardiovascular implantable electronic devices: patient education, information and ethical issues. Manaouil C, Gignon M, Traulle S. Med Law. 2012 Sep;31(3):355-63.

Cardiovascular implantable electronic devices (CIED) are implanted increasingly frequently. CIEDs are indicated for the treatment of bradycardia, tachycardia and heart failure and therefore improve quality of life and life expectancy. CIED can treat ventricular arrhythmias that would be fatal without immediate care. However, CIEDs raise several patient education, medico-legal, and ethical questions that will be addressed in this article. Information is a patient's right, and necessary for informed consent. When implanting a CIED, the patient must be educated about the need for the device, the function of the device, any restrictions that apply postimplant, and postimplant follow-up methods and schedules. This transfer of information to the patient makes the patient responsible. The occupational physician can determine whether a patient wearing a CIED is able to work. Under current French law, patients

are not prohibited from working while wearing a CIED. However, access to certain job categories remains limited, such as jobs involving mechanical stress to the chest, exposure to electromagnetic fields, or jobs requiring permanent vigilance. Pacemakers and defibrillators are medical treatments and are subject to the same ethical and clinical considerations as any other treatment. However, stopping a pacemaker or a defibrillator raises different ethical issues. Implantable Cardioverter Defibrillator shocks can be considered to be equivalent to resuscitation efforts and can be interpreted as being unreasonable in an end-of-life patient. Pacing is painless and it is unlikely to unnecessarily prolong the life of a patient with a terminal disease. Patients with a CIED should live as normally as possible, but must also be informed about the constraints related to the device and must inform each caregiver about the presence of the device. The forensic and ethical implications must be assessed in relation to current legislation.

 Deactivation of pacemakers and implantable cardioverter-defibrillators. Kramer DB, Mitchell SL, Brock DW. Prog Cardiovasc Dis. 2012 Nov-Dec;55(3):290-9. doi: 10.1016/j.pcad.2012.09.003.

Cardiac implantable electrical devices (CIEDs), including pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs), are the most effective treatment for lifethreatening arrhythmias. Patients or their surrogates may request device deactivation to avoid prolongation of the dying process or in other settings, such as after devicerelated complications or with changes in health care goals. Despite published guidelines outlining theoretical and practical aspects of this common clinical scenario, significant uncertainty remains for both patients and health care providers regarding the ethical and legal status of CIED deactivation. This review outlines the ethical and legal principles supporting CIED deactivation, centered upon patient autonomy and authority over their own medical treatment. The empirical literature describing stakeholder views and experiences surrounding CIED deactivation is described, along with implications of these studies for future research surrounding the care of patients with CIEDs.

 Life-saving devices reach the end of life with heart failure. Matlock DD, Stevenson LW. Prog Cardiovasc Dis. 2012 Nov-Dec;55(3):274-81. doi: 10.1016/j.pcad.2012.10.007. The new millennium has seen a dramatic increase in use of potentially life-prolonging devices such as implantable cardioverter-defibrillators (ICDs) and ventricular assist devices (VADs) among patients with advanced heart failure. Most patients who receive these devices will have them in place when they die. Clinicians who care for these patients must commit through the entire course of therapy, including the end-of-life. Discussions about device deactivation should be the standard of care and this discussion should take place prior to implantation, during annual heart failure reviews, after major milestones, and when the end-of-life appears to be approaching. Turning off ICDs and turning off VADs in response to patient or proxy requests are legally the same although they may be perceived differently, as disconnection of the VAD is more likely to cause immediate death. This article discusses the evidence around device deactivation at the end-of-life and offers suggestions for improvement.

22. The deactivation of implantable cardioverter-defibrillators: medical, ethical, practical, and legal considerations. Carlsson J, Paul NW, Dann M, Neuzner J, Pfeiffer D. Dtsch Arztebl Int. 2012 Aug;109(33-34):535-41. doi: 10.3238/arztebl.2012.0535. Epub 2012 Aug 20.

BACKGROUND: Implantable cardioverter-defibrillators (ICDs) cannot prevent death from progressive heart failure or non-cardiac disease. Patients with ICDs may receive defibrillation therapy from their devices in the last days of their lives, when such therapy does not accord with the goal of palliative treatment, but rather lowers these patients' quality of life and compromises their dignity.

METHODS: We present a case report and a selective review of pertinent literature retrieved by a PubMed search, including two up-to-date consensus documents.

RESULTS: One-third to two-thirds of all ICD patients receive defibrillation therapy in the final days of their lives. Patients and their physicians rarely discuss deactivating the ICD. The ethical aspects of such decisions need to be considered. As a practical matter, it is possible to deactivate certain types of electrotherapy selectively, while leaving others active. There are logistical considerations as well.

CONCLUSION: Automatic defibrillation therapy in a terminally ill patient with an ICD is painful and distressing, serves no medical purpose, and should be avoided. This issue should be discussed with ICD patients and their families. Institutions caring for terminally ill patients, as well as cardiology units where ICD patients are treated, should develop ethically and legally well-founded protocols for dealing with the question of ICD deactivation.

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 Documented consent process for implantable cardioverter-defibrillators and implications for end-of-life care in older adults. Niewald A, Broxterman J, Rosell T, Rigler S. J Med Ethics. 2013 Feb;39(2):94-7. doi: 10.1136/medethics-2012-100613. Epub 2012 Nov 8.

Implantable cardioverter defibrillators (ICDs) reduce mortality in selected patients at risk for life-threatening heart arrhythmias, and their use is increasingly common. However, these devices also confer risk for delivery of unexpected painful shocks during the dying process, thus reducing the quality of palliative care at the end of life. This scenario can be avoided by ICD deactivation in appropriate circumstances but patients will remain unaware of this option if not informed about it. It is not known how often end-of-life implications are discussed with patients prior to ICD implantation, when focus is primarily on the short-term potential complications of the device placement procedure itself. We conducted a retrospective chart review to determine how often end-of-life implications were discussed with patients as part of the informed consent process. We evaluated consent forms and related other chart documentation for 91 patients (ranging from age 60 to 89 years) undergoing first-time ICD placement at a mid-western academic medical center from 2006-2008. Only one chart documented any discussion of end-of-life implications, in a case where the issue was raised by a patient who noted that quality of life was their main focus. Consent was provided by a health care surrogate in only four of the 91 cases. In conclusion, patients giving consent for ICD implantation may be uninformed about the device's potential future impact on end-of-life care, the dying process, and the option for device deactivation. Truly informed consent requires that both short- and long-term potential implications be reviewed with patients.

 Ethical and legal perspective of implantable cardioverter defibrillator deactivation or implantable cardioverter defibrillator generator replacement in the elderly. Wright GA, Klein GJ, Gula LJ. Curr Opin Cardiol. 2013 Jan;28(1):43-9. doi: 10.1097/HCO.0b013e32835b0b3b.

PURPOSE OF REVIEW: Implantable cardioverter defibrillator (ICD) implantation has become a common and standard treatment for primary and secondary prevention of sudden cardiac death in patients with poor left ventricular ejection fraction across the world. Circumstances, of course, change after the initial implant as patients age. This raises legal and ethical questions about deactivating or not replacing ICD generators when the likelihood of meaningful benefit has diminished. RECENT FINDINGS: Health professionals are reluctant to discuss the end-of-life planning with patients who have ICDs. Older patients are more likely to have multiple comorbidities that worsen or accumulate further after initial implantation and attenuate the survival benefit of ICDs. Joint guidelines suggest physicians educate patients during the initial consent process about the possibility of deactivating ICDs after implantation if their individual situation changes to the point of futility. SUMMARY: ICD deactivation and nonreplacement are unavoidable issues that require clarity for meaningful and ethical implementation. This is an ongoing process.

 Quality of life and end-of-life issues for older patients with implanted cardiac rhythm devices. Lampert R. Clin Geriatr Med. 2012 Nov;28(4):693-702. doi: 10.1016/j.cger.2012.07.005.

This article provides an overview of quality of life (QOL) and end-of-life issues that pertain to older patients with implanted cardiac rhythm devices. Most patients with implantable cardioverter-defibrillators (ICDs) enjoy similar QOL to that of other patients with cardiac diseases, especially in the absence of ICD shocks. Conventional pacemakers. as well as devices incorporating cardiac resynchronization, can improve QOL in appropriately selected patients regardless of age. In patients approaching the end of life, all devices, but especially ICDs, can adversely impact QOL in patients and families. All patients should have the opportunity to discuss the option of device deactivation.

- Lost in translation: examining patient and physician perceptions of implantable cardioverter-defibrillator deactivation discussions. Mitar M, Alba AC, MacIver J, Ross H. Circ Heart Fail. 2012 Sep 1;5(5):660-6.
- ICD deactivation: review of literature and clinical recommendations. Thanavaro JL. Clin Nurs Res. 2013 Feb;22(1):36-50. doi: 10.1177/1054773812443893. Epub 2012 May 28.

Implanted cardioverter defibrillators (ICDs) are an essential part of the management for patients at risk for life threatening arrhythmias. Despite new technologies, all patients ultimately will reach the end of their lives, either because of underlying cardiac disease or another terminal illness. Having an ICD at the end of life may deny a patient the chance of sudden cardiac death and result in a slower terminal disease and pain and anxiety due to shocks from their device. The purpose of this article is to present a focused literature review on the barriers surrounding deactivation of ICDs and to summarize the recommendations of the Heart Rhythm Society Consensus Statement on the management of ICDs in patients nearing end of life or requesting withdrawal of therapy.

- 28. Deactivation of implantable cardioverter-defibrillators in terminal illness and end-of-life care. Raphael CE. Am J Cardiol. 2012 May 1;109(9):1384. doi: 10.1016/j.amjcard.2012.02.007.
 Comment on: Deactivation of implantable cardioverter defibrillators in terminal illness and end of life care. [Am J Cardiol. 2012]
- The use of advance directives among patients with implantable cardioverter defibrillators. Tajouri TH, Ottenberg AL, Hayes DL, Mueller PS. Pacing Clin Electrophysiol. 2012 May;35(5):567-73. doi: 10.1111/j.1540-8159.2012.03359.x. Epub 2012 Mar 20.

BACKGROUND: We aimed to determine the prevalence of advance directives (ADs) among patients with implantable cardioverter defibrillators (ICDs) and of ADs that addressed ICD management at the end of life.

METHODS: The medical records of all patients who underwent ICD implantation during 2007 at a single institution were reviewed retrospectively to determine the number of patients with an AD and the number of ADs mentioning the ICD specifically (i.e. ICD management at end of life).

RESULTS: During 2007, 420 patients (males, 71%) underwent ICD implantation at our institution (mean age [range] at implantation, 63 [1-90] years). Primary prevention was the most common indication for device therapy (254 patients [61%]). Overall, 127 patients (30%) had an AD, with 83 ADs (65%) completed more than 12 months before ICD implantation and 10 (8%) completed after it. Several life-sustaining treatments were mentioned in the ADs: tube feeding, 46 (37%); cardiopulmonary resuscitation, 25 (20%); mechanical ventilation, 22 (17%); and hemodialysis, nine (7%). Pain control was mentioned in 58 ADs (46%) and comfort measures in 38 (30%). However, only two ADs (2%) mentioned the ICD or its deactivation at end of life.

CONCLUSIONS: About one-third of patients with ICDs had an AD, but only a couple ADs mentioned the ICD. These results suggest that clinicians should not only encourage patients with ICDs to complete an AD, but also encourage them to address ICD management specifically. Not addressing ICD management in an AD may result in ethical dilemmas during end-of-life care.

 Pacemaker deactivation: withdrawal of support or active ending of life? Huddle TS, Amos Bailey F. Theor Med Bioeth. 2012 Dec;33(6):421-33. doi: 10.1007/s11017-012-9213-5.

In spite of ethical analyses assimilating the palliative deactivation of pacemakers to commonly accepted withdrawings of life-sustaining therapy, many clinicians remain ethically uncomfortable with pacemaker deactivation at the end of life. Various reasons have been posited for this discomfort. Some cardiologists have suggested that reluctance to deactivate pacemakers may stem from a sense that the pacemaker has become part of the patient's "self." The authors suggest that Daniel Sulmasy is correct to contend that any such identification of the pacemaker is misguided. The authors argue that clinicians uncomfortable with pacemaker deactivation are nevertheless correct to see it as incompatible with the traditional medical ethics of withdrawal of support. Traditional medical ethics is presently taken by many to sanction pacemaker deactivation when such deactivation honors the patient's right to refuse treatment. The authors suggest that the right to refuse treatment applies to treatments involving ongoing physician agency. This right cannot underwrite patient demands that physicians reverse the effects of treatments previously administered, in which ongoing physician agency is no longer implicated. The permanently indwelling pacemaker is best seen as such a treatment. As such, its deactivation in the pacemaker-dependent patient is best seen not as withdrawal of support but as active ending of life. That being the case, clinicians adhering to the usual ethical analysis of withdrawal of support are correct to be uncomfortable with pacemaker deactivation at the end of life.

 The ethics of deactivating a pacemaker in a pacing-dependent patient: reflections on a case study. Malpas PJ, Cooper L. Am J Hosp Palliat Care. 2012 Nov;29(7):566-9. doi: 10.1177/1049909111432624. Epub 2012 Jan 12.

The decision to deactivate a pacemaker in a pacing-dependent patient is troubling for some health professionals who may regard such interventions as hastening death and therefore ethically impermissible. This may be especially concerning in situations where a patient is unable to clearly state what their preferences may be and the decision--were it to be made--will almost certainly result in the patient's immediate death. In this discussion, we reflect on some of the ethical aspects that arise when JP, a 75-year-old woman who is pacing dependent, suffers a significant brain injury, and the family request that her pacemaker be deactivated. Taking into account the clinical reality of her situation, the united wishes and loving concern of her husband and family, and their substituted judgment regarding her likely preferences, we claim that the decision to deactivate her pacemaker was ethically sound.

32. ICDs near end of life: risk versus benefit- a review. Singh B, Singh J. Am J Hosp Palliat Care. 2012 Sep;29(6):421-30. doi: 10.1177/1049909111432135. Epub 2012 Jan 4.

The number of annual implantable cardioverter defibrillator (ICD) implants has substantially increased over the last 5 years and is expected to grow rapidly. Implantable cardioverter defibrillators have a proven mortality benefit by terminating the life-threatening arrhythmias, even near end of life. In patients with moderate/severe symptomatic heart failure, enough clinical literature representing mortality benefits has been published, but limited numbers of studies have reviewed the dwindling risk-benefit profile near end of life, studying quality of life (QoL)/psychosocial impact. Criteria outlining either continued use or deactivation policy/procedures near end of life have not been clearly defined and/or largely implemented, which in turn requires more focused research using multifactorial approach to determine improved patient-centered outcomes.

33. Do implantable cardioverter defibrillators complicate end-of-life care for those with heart failure? Waterhouse E, Ahmad F. Curr Opin Support Palliat Care. 2011 Dec;5(4):307-11. doi: 10.1097/SPC.0b013e32834d2cce.

PURPOSE OF REVIEW: We know deactivating implantable cardioverter defibrillators (ICDs) is permissible and should not complicate end-of-life care. However, patients and healthcare professionals still struggle with this concept. This review looks at the recent literature to find possible reasons behind this.

RECENT FINDINGS: ICD use is on the increase and is not always in accordance with best practice guidelines. The number of clinicians having conversations about deactivation is variable, but most of them agree that it is ethical and legal. Difficulty in initiating conversations is mainly due to lack of training, viewing ICDs as being different to conventional treatments and lack of clarity about legality. Patients' knowledge around deactivation and its ethical and legal standing is low. This can be improved by giving information about end-of-life options at the time of implantation and incorporating these within care plans. Use of ICDs should be reviewed in context of disease status and patients' goals.

SUMMARY: Deactivation of ICDs at end of life throws up challenges for clinicians and patients. This review points toward a need for communication training for clinicians and early initiation of discussion around the time of ICD insertion, as well improving clinicians' and patients' knowledge of the ethics and legality of deactivation.

- 34. When is deactivating an implanted cardiac device physician-assisted death? Appraisal of the lethal pathophysiology and mode of death. Rady MY, Verheijde JL. J Palliat Med. 2011 Oct;14(10):1086-8; discussion 1089-90. doi: 10.1089/jpm.2011.0161.
- 35. CE test 2.6 hours: deactivation of ICDs at the end of life: a systematic review of clinical practices and provider and patient attitudes. Contrada E. Am J Nurs. 2011 Oct;111(10):36-7. doi: 10.1097/01.NAJ.0000406416.79933.35.
- Implantable cardioverter-defibrillator recipient attitudes towards device deactivation: how much do patients want to know? Raphael CE, Koa-Wing M, Stain N, Wright I, Francis DP, Kanagaratnam P. Pacing Clin Electrophysiol. 2011 Dec;34(12):1628-33. doi: 10.1111/j.1540-8159.2011.03223.x. Epub 2011 Sep 28.

BACKGROUND: Patients receiving implantable cardioverter-defibrillators (ICDs) often have severely impaired left ventricular function and a poor prognosis. Having an ICD in situ effectively denies them the possibility of a quick, arrhythmic death. It is still unclear if and when the end of life and device deactivation should be discussed with patients and how much patients want to know prior to ICD implantation.

METHODS: Patients with an active ICD for chronic heart failure were interviewed regarding their attitude toward the ICD, their recollection of the consent procedure, and how they felt the end of life should be discussed with ICD patients (n = 54). Patients who had received ICD therapies (n = 25) were reviewed as a subgroup with extended questions regarding attitudes toward device deactivation.

RESULTS: Fifty-four patients were recruited. Most patients were not aware that the ICD could be deactivated. The vast majority of patients (84%) wanted to be involved in the deactivation decision; 40% felt this discussion should be prior to ICD implantation but others felt the discussion should only occur if the patient was terminally ill (16%) or in the last few days of life (5%).

CONCLUSION: Patients with ICDs are routinely counseled about the benefits of ICDs, but options for device deactivation are not well understood by patients. Most patients would like to be involved in deactivation decisions and we feel this should be discussed well in advance.

 Deactivation of implantable cardioverter defibrillators in terminal illness and end of life care. Kirkpatrick JN, Gottlieb M, Sehgal P, Patel R, Verdino RJ. Am J Cardiol. 2012 Jan 1;109(1):91-4. doi: 10.1016/j.amjcard.2011.08.011. Epub 2011 Sep 22.

Cardiology professional societies have recommended that patients with cardiovascular implantable electronic devices complete advance directives (ADs). However, physicians rarely discuss end of life handling of implantable cardioverter defibrillators (ICDs), and standard AD forms do not address the presence of ICDs. We conducted a telephone survey of 278 patients with an ICD from a large, academic hospital. The average period since implantation was 5.15 years. More than 1/3 (38%) had been shocked, with a mean of 4.69 shocks. More than 1/2 had executed an AD, but only 3 had included a plan for their ICD. Most subjects (86%) had never considered what to do with their ICD if they had a serious illness and were unlikely to survive. When asked about ICD deactivation in an end of life situation, 42% said it would depend, 28% favored deactivation, and 11% would not deactivate. One quarter (26%) thought ICD deactivation was a form of assisted suicide, 22% thought a do not resuscitate order did not mean that the ICD should be deactivated, and 46% responded that the ICD should not be automatically deactivated in hospice. The answers did not correlate with any demographic factors. Almost all (95%) agreed that patients should have the opportunity to execute an AD that directs handing of an ICD. When asked who should be responsible for discussing this device for an AD, 31% said electrophysiologists, 45% said general cardiologists, and 14% said primary care physicians. In conclusion, the results of the present study highlight the lack of consensus among patients with an ICD on the issue of deactivation at the end of a patient's life. These findings suggest cardiologists should discuss end of life care and device deactivation with their patients with an ICD.

 Original research: deactivation of ICDs at the end of life: a systematic review of clinical practices and provider and patient attitudes. Russo JE. Am J Nurs. 2011 Oct;111(10):26-35. doi: 10.1097/01.NAJ.0000406411.49438.91. BACKGROUND: The implantable cardioverter-defibrillator (ICD) has become a standard treatment for people at risk for life-threatening cardiac arrhythmias. To restore normal heart rhythm, the ICD delivers a high-energy, painful electrical shock. Because the device is so effective in treating sudden cardiac arrest, people with ICDs are more likely to die from other causes. But their deaths can be needlessly painful if the ICD delivers shocks during the active phase of dying. Although device deactivation is an option, no formal practice protocols address this, and advance planning discussions don't often include potential ICD deactivation.

OBJECTIVE: The purpose of this systematic review was twofold: to identify factors that delay ICD deactivation discussions and to identify ways to promote timely deactivation discussions and thus foster better patient-centered, end-of-life care for people with ICDs.

METHODS: Using relevant search terms, a literature search for articles on the topics of interest was performed in multiple databases. The search was limited to articles published in English in peer-reviewed journals between January 1, 1999, and October 31, 2010. Reference lists of applicable articles were also examined for any additional relevant studies. After applying inclusion and exclusion criteria, 14 studies investigating the topics of interest were identified and are included in this review.

FINDINGS: Providers' knowledge deficits about ICD functions and attitudes about ICD deactivation in terminally ill patients can adversely affect the timing of deactivation discussions. Providers' reluctance to discuss deactivation may stem in part from personal discomfort and lack of experience with this option. ICDs may be viewed differently from other life-sustaining measures. Providers may also feel ill prepared to initiate a discussion about deactivation with patients; some might prefer expert guidance or that others initiate such discussion. There's evidence that ICD deactivation is most often performed by an industry representative, and that continuity of care is lost. Although there's been scant research on patient attitudes about ICD deactivation, it appears that patients lack sufficient knowledge of ICD function to make informed decisions about deactivation. A complex psychological relationship may exist between patients and their ICDs. Deactivation discussions occur more frequently when a formal institutional policy exists. ICD deactivation in terminally ill patients is more likely when deactivation is discussed as part of an interdisciplinary approach to care.

CONCLUSIONS: Both patients and providers need better knowledge of ICD functions and options at the end of life in order to foster more timely discussion of device deactivation. More research is needed, in particular regarding patient attitudes toward ICD deactivation. Formal ICD deactivation policies should be developed to

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guide providers. A comprehensive and interdisciplinary approach to deactivation discussions should be considered.

39. Is pacemaker deactivation at the end of life unique? A case study and ethical analysis. Whitlock SN, Goldberg IP, Singh JP. J Palliat Med. 2011 Oct;14(10):11848. doi: 10.1089/jpm.2011.0084. Epub 2011 Sep 1.

Although there has been considerable controversy regarding the deactivation of pacemakers near the end of life, clinicians can expect to face more requests for pacemaker withdrawal as the number of implants grows. Despite a clear ethical and legal precedent, these requests may elicit significant psychological and moral distress on the part of the clinical team. We illustrate some of the difficulties clinicians may face by describing the case of a patient with end-stage heart failure who asked to have her pacemaker turned off near the end of life. We discuss the challenges in determining pacemaker dependency, differing attitudes toward deactivating pacemakers versus other cardiac devices, and how the issues of perceived burden and timing of death may contribute to a clinician's sense of moral distress.

40. Urgent implantable cardioverter defibrillator deactivation by unconventional means.
Beets MT, Forringer E. J Pain Symptom Manage. 2011 Dec;42(6):941-5. doi: 10.1016/j.jpainsymman.2011.02.025. Epub 2011 Jun 23.

Increasing numbers of patients are receiving implantable cardioverter defibrillators (ICDs); the devices remain fully functional in most terminally ill patients at the time of death. We describe a case of a terminally ill patient with repeated defibrillations who requested urgent ICD deactivation. Nonmedical magnets available in the facility were used to deactivate the ICD and terminate the defibrillations. We then studied various magnetic field sources commonly available in homes, such as ceramic magnets, cell phones, computer hard drives, headsets, and earbuds that potentially may be used to temporarily deactivate an ICD until a device technician is available for reprogramming. We conclude that commonly available magnetic sources may potentially be used to deactivate an ICD. The clinical usefulness of this is speculative and limited to conditions when the need to turn off the device is urgent, and a delay in reprogramming is anticipated.

 Implantable cardiac defibrillators and end-of-life care--time for reflection, deliberation and debate? Sheehan M, Newton PJ, Stobie P, Davidson PM. Aust Crit Care. 2011 Nov;24(4):279-84. doi: 10.1016/j.aucc.2011.01.001. Epub 2011 Jun 14.

Heart failure (HF) is a common condition associated with high rates of morbidity and mortality. Implantable cardiac defibrillators (ICDs) are an important management strategy in HF management and decrease mortality for both primary and secondary prevention. An emerging body of literature identifies the challenges of managing ICDs at the end of life. This report discusses a critical incident experienced by a HF team in a referral centre and outlines the issues to be considered in advancing discussion and debate of managing ICDs at the end of life. Engaging in debate, discussion and consensus guidelines is likely to be crucial in minimising distress and burden for clinicians, patients and their families alike.

42. The ethics of pacemaker deactivation in terminally ill patients. Bevins MB. J Pain Symptom Manage. 2011 Jun;41(6):1106-10. doi: 10.1016/j.jpainsymman.2011.03.003.

A core principle of American medical ethics holds that an informed and capacitated patient has the right to have treatments withdrawn or withheld. Nevertheless, many clinicians remain reluctant to honor a request to deactivate a patient's pacemaker. This article describes a case in which a patient was denied her request for pacemaker deactivation. Several reasons for this reluctance are discussed, including historical, practical, and ethical considerations for opposing pacemaker deactivation. Ultimately, however, from an ethical standpoint, pacemaker deactivation is similar to withdrawal of other therapies. Fortunately, a recent expert consensus statement supports a patient's right to have her pacemaker deactivated. Pacemaker deactivation should only be performed after robust informed consent, which must include discussion of risks, benefits, and all viable alternatives based on the patient's values and goals.

- Ethical issues on defibrillator deactivation in end-of-life patients. Facciorusso A, Stanislao M, Fanelli M, Valori VM, Valle G. J Cardiovasc Med (Hagerstown). 2011 Jul;12(7):498-500. doi: 10.2459/JCM.0b013e3283483724.
- 44. Pacemakers and end-of-life decisions. Lampert R, Hayes D. JAMA. 2011 May 11;305(18):1858-9; author reply 1859. doi: 10.1001/jama.2011.581.

Comment on: A piece of my mind. Life imitates work. [JAMA. 2011]

- 45. A piece of my mind. Life imitates work. Powell T. JAMA. 2011 Feb 9;305(6):542-3.doi: 10.1001/jama.2011.98.Comment in: Pacemakers and end-of-life decisions. [JAMA. 2011]
- 46. Ethical and legal views regarding deactivation of cardiac implantable electrical devices in patients with hypertrophic cardiomyopathy. Kramer DB, Kesselheim AS, Salberg L, Brock DW, Maisel WH. Am J Cardiol. 2011 Apr 1;107(7):1071-1075.e5. doi: 10.1016/j.amjcard.2010.11.036. Epub 2011 Feb 4.

Little is known about patients' views surrounding the ethical and legal aspects of managing pacemakers (PMs) and implantable cardioverter-defibrillators (ICDs) near the end of life. Patients with hypertrophic cardiomyopathy (HC) are at heightened risk of sudden cardiac death and are common recipients of such devices. Patients with HC recruited from the membership of the Hypertrophic Cardiomyopathy Association were surveyed about their clinical histories, advance care planning, legal knowledge, and ethical beliefs relating to the withdrawal of PM and ICD therapy. The mean age of the 546 patients was 49.1 years, 47% were women, and 57% had ICDs. Only 46% of the respondents had completed an advance directive, only 51% had a healthcare proxy, and cardiac implantable electrical devices (CIEDs) were commonly not addressed in either (92% and 58%, respectively). Many patients characterized deactivating PMs or ICDs as euthanasia or physician-assisted suicide (29% for PMs and 17% for ICDs), and >50% expressed uncertainty regarding the legality of device deactivation. Patients viewed deactivation of ICDs and PMs as morally different from other life-sustaining therapies such as mechanical ventilation and dialysis, and these views varied substantially according to the CIED type (p <0.0001). The respondents expressed concerns regarding clinical conflicts related to religion, ethical and legal uncertainty, and informed consent. In conclusion, patients who have, or are eligible to receive, CIEDs might require improved advance care planning and education regarding the ethical and legal options for managing CIEDs at the end of life.

 Adverse experiences with implantable defibrillators in Oregon hospices. Fromme EK, Stewart TL, Jeppesen M, Tolle SW. Am J Hosp Palliat Care. 2011 Aug;28(5):304-9. doi: 10.1177/1049909110390505. Epub 2010 Nov 25.

BACKGROUND: Implantable cardioverter-defibrillators (ICDs) improve survival in patients at risk for recurrent, sustained ventricular tachycardia or fibrillation. Unless

deactivated, ICDs may deliver unwanted shocks to terminally ill patients near the time of death. This study sought to determine the frequency and nature of adverse experiences with ICDs in hospice programs and what preventative measures the programs had taken.

METHOD: A mailed survey to all 50 Oregon Hospice Programs in August 2008.

RESULTS: 42 (84%) of 50 programs participated. In all 36 (86%) of 42 programs reported having taken care of a patient with an ICD in the preceding 4 years. The average number of patients with ICDs per program increased from 2.2 (SD 2.5) in 2005 and 2006 to 3.6 (SD 3.7) in 2007 and 2008. Of the 36 programs who had cared for a patient with an ICD, 31 (86%) reported having some kind of adverse experience. These ranged from unwanted shocks delivered (64%), patient/family distress related to the decision to deactivate the ICD (47%), and time delay in ICD deactivation (42%). Only 16 (38%) programs had policies for managing ICDs and only 19 (43%) routinely screened new patients for ICDs.

DISCUSSION: As patients near the end of their lives, receiving defibrillating shocks may no longer be consistent with their goals of care. Based on the high frequencies of potentially preventable adverse outcomes documented by this study, we propose that hospices routinely screen patients for ICDs and proactively adopt policies to manage them, rather than in response to an adverse event.

48. Perspectives on withdrawing pacemaker and implantable cardioverter-defibrillator therapies at end of life: results of a survey of medical and legal professionals and patients. Kapa S, Mueller PS, Hayes DL, Asirvatham SJ. Mayo Clin Proc. 2010 Nov;85(11):981-90. doi: 10.4065/mcp.2010.0431. Epub 2010 Sep 15.

OBJECTIVE: To determine the opinions of medical professionals, legal professionals, and patients regarding the withdrawal of implantable cardioverter-defibrillator (ICD) and pacemaker therapy at the end of life.

PARTICIPANTS AND METHODS: A survey regarding 5 cases that focused on withdrawal of ICD or pacemaker therapy at the end of life was constructed and sent to 5270 medical professionals, legal professionals, and patients. The survey was administered from March 1, 2008, to March 1, 2009.

RESULTS: Of the 5270 recipients of the survey, 658 (12%) responded. In a terminally ill patient requesting that his ICD be turned off, most legal professionals (90% [63/70]), medical professionals (98% [330/336]), and patients (85% [200/236]) agreed the ICD should be turned off. Most legal professionals (89%), medical professionals (87%), and patients (79%) also considered withdrawal of pacemaker

therapy in a non-pacemaker-dependent patient appropriate. However, significantly more legal (81%) than medical professionals (58%; P<.001) or patients (68%, P=.02) agreed with turning off a pacemaker in the pacemaker-dependent patient. A similar number of legal professionals thought turning off a device was legal regardless of whether it was an ICD or pacemaker (45% vs 38%; P=.50). However, medical professionals were more likely to perceive turning off an ICD as legal than turning off a pacemaker (85% vs 41%; P<.001).

CONCLUSION: Most respondents thought device therapy should be withdrawn if the patient requested its withdrawal at the end of life. However, opinions of medical professionals and patients tended to be dependent on the type of device, with turning off ICDs being perceived as more acceptable than turning off pacemakers, whereas legal professionals tended to perceive all devices as similar. Thus, education and discussion regarding managing devices at the end of life are important when having end-of-life discussions and making end-of-life decisions to better understand patients' perceptions and expectations.

- 49. Palliative and end-of-life care for patients with chronic heart failure and chronic lung disease. Johnson MJ, Booth S. Clin Med. 2010 Jun;10(3):286-9.
- 50. Managing cardiac devices near the end of life: a survey of hospice and palliative care providers. Morrison LJ, Calvin AO, Nora H, Porter Storey C Jr. Am J Hosp Palliat Care. 2010 Dec;27(8):545-51. doi: 10.1177/1049909110373363. Epub 2010 Aug 16.

Implantable cardioverter defibrillators (ICDs) and pacemakers may change the character of an individual's eventual death. The objective of this study was to explore hospice and palliative care provider attitudes and experience in managing ICDs and pacemakers for patients near the end of life. A voluntary survey was distributed to session attendees at a national conference. Doctors and nurses surveyed overwhelmingly agreed it is appropriate to disable these devices in a terminally ill patient who does not wish to be resuscitated or prolong life. However, respondents emphasized a less defined burden for pacemakers. Respondents also reported limited involvement in such cases and few institutional protocols. As more terminal patients have these devices, research and education on device management protocols/guidelines and on provider communication skills are critical.

51. EHRA Expert Consensus Statement on the management of cardiovascular implantable electronic devices in patients nearing end of life or requesting withdrawal

of therapy. Padeletti L, Arnar DO, Boncinelli L, Brachman J, Camm JA, Daubert JC, Hassam SK, Deliens L, Glikson M, Hayes D, Israel C, Lampert R, Lobban T, Raatikainen P, Siegal G, Vardas P; Reviewers:, Kirchhof P, Becker R, Cosio F, Loh P, Cobbe S, Grace A, Morgan J; EuropeanHeart RhythmAssociation; Heart Rhythm Society. Europace. 2010 Oct;12(10):1480-9. doi: 10.1093/europace/euq275. Epub 2010 Jul 30. Erratum in Europace. 2011 Apr;13(4):599. Kassam, Sarah [corrected to Hassam, Sarah K].

The purpose of this Consensus Statement is to focus on implantable cardioverterdefibrillator (ICD) deactivation in patients with irreversible or terminal illness. This statement summarizes the opinions of the Task Force members, convened by the European Heart Rhythm Association (EHRA) and the Heart Rhythm Society (HRS), based on ethical and legal principles, as well as their own clinical, scientific, and technical experience. It is directed to all healthcare professionals who treat patients with implanted ICDs, nearing end of life, in order to improve the patient dying process. This statement is not intended to recommend or promote device deactivation. Rather, the ultimate judgement regarding this procedure must be made by the patient (or in special conditions by his/her legal representative) after careful communication about the deactivation's consequences, respecting his/her autonomy and clarifying that he/she has a legal and ethical right to refuse it. Obviously, the physician asked to deactivate the ICD and the industry representative asked to assist can conscientiously object to and refuse to perform device deactivation.

52. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. Marinskis G, van Erven L; EHRA Scientific Initiatives Committee. Europace. 2010 Aug;12(8):1176-7. doi: 10.1093/europace/euq272.

This survey assesses the current opinion on and practice of the management of terminally ill patients with implanted cardioverter-defibrillators (ICDs) in 47 large European centres. The principal findings of this survey were that most physicians (62%) from European centres who responded to this survey would consider deactivating ICDs at the patient's end of life. In these circumstances, multiple appropriate ICD shocks may be an indication to deactivate an ICD (83% positive answers). Remote deactivation by a remote monitoring system is not considered appropriate by 68%. Practices of deactivating procedure differ and approach to standardized clinical scenarios is inhomogeneous. Patients are provided with

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surprisingly little information on the possibility of deactivation of ICDs since this subject is only actively discussed in 4% of centres.

 Ethical and legal views of physicians regarding deactivation of cardiac implantable electrical devices: a quantitative assessment. Kramer DB, Kesselheim AS, Brock DW, Maisel WH. Heart Rhythm. 2010 Nov;7(11):1537-42. doi: 10.1016/j.hrthm.2010.07.018. Epub 2010 Jul 19.

BACKGROUND: Despite the high prevalence of pacemakers and implantable cardioverter-defibrillators, little is known about physicians' views surrounding the ethical and legal aspects of managing these devices at the end of life.

OBJECTIVE: The purpose of this study was to identify physicians' experiences and views surrounding the ethical and legal aspects of managing cardiac devices at the end of life.

METHODS: Survey questions were administered to internal medicine physicians and subspecialists at a tertiary care center. Physicians were surveyed about their clinical experience, legal knowledge, and ethical beliefs relating to the withdrawal of PM and ICD therapy in comparison to other life-sustaining therapies.

RESULTS: Responses were obtained from 185 physicians. Compared to withdrawal of PMs and ICDs, physicians more often reported having participated in the withdrawal or removal of mechanical ventilation (86.1% vs 33.9%, P <.0001), dialysis (60.6% vs 33.9%, P <.001), and feeding tubes (73.8% vs 33.9%, P <.0001). Physicians were consistently less comfortable discussing cessation of PMs and ICDs compared to other life-sustaining therapies (P <.005). Only 65% of physicians correctly identified the legal status of euthanasia in the United States, and 20% accurately reported the legal status of physician-assisted suicide in the United States. Compared to deactivation of an ICD, physicians more often characterized deactivation of a PM in a pacemaker-dependent patient as physician-assisted suicide (19% vs 10%, P = .027) or euthanasia (9% vs 1%, P <.001).

CONCLUSION: In this single-center study, internists were less comfortable discussing cessation of PM and ICD therapy compared to other life-sustaining therapies and lacked experience with this practice. Education regarding the legal and ethical parameters of device deactivation is needed.

54. Complexities of defibrillator deactivation. Dev S, Galanos AN; Duke Supportive Cardiology Group. Ann Intern Med. 2010 Jul 20;153(2):133-4; author reply 134. doi: 10.7326/0003-4819-153-2-201007200-00017.

Comment on: Brief communication: Management of implantable cardioverterdefibrillators in hospice: A nationwide survey. [Ann Intern Med. 2010]

55. End-of-life options for patients with advanced heart failure. Goldfinger JZ, Adler ED. Curr Heart Fail Rep. 2010 Sep;7(3):140-7. doi: 10.1007/s11897-010-0017-5.

Heart failure is a progressive disease with significant morbidity and mortality, but prognostication often is difficult. Many of the evidence-based therapies for heart failure provide symptomatic benefit, but may have intolerable side effects for patients with advanced disease. At the end of life, there is evidence of varying strengths for pharmacologic and nonpharmacologic relief of common symptoms like dyspnea, fatigue, pain, and depression. Patients also may benefit from inotropic therapy, ventricular assist devices, and hospice care. It is important for physicians to encourage patients to formulate advance directives, including decisions about do not resuscitate orders and deactivation of implantable cardioverter-defibrillators and ventricular assist devices.

56. Medicolegal issues arising when pacemaker and implantable cardioverter defibrillator devices are deactivated in terminally ill patients. McGeary A, Eldergill A. Med Sci Law. 2010 Jan;50(1):40-4.

The number of patients receiving pacemakers and implantable cardioverter defibrillator (ICD) devices continues to increase dramatically. In this paper, the issue of when it is appropriate to deactivate these devices if the patient becomes terminally ill and the medicolegal implications of this action are examined. This appears to constitute a withdrawal of treatment. However, the issue has never come before the courts and therefore no medicolegal guidance exists on the point. This paper highlights a lack of knowledge among health-care staff regarding switching off electromechanical devices in terminally ill patients. We propose some guidance and recommendations for dealing with this issue when it arises in practice, and highlight some important differences between pacemakers and ICDs that will influence decision-making. Conclusions are expressed regarding how this issue should be dealt with in the postmortem setting and in the antemortem setting, where the issue of capacity and consent will influence decisions regarding deactivating these devices.

57. Brief communication: Management of implantable cardioverter-defibrillators in hospice: A nationwide survey. Goldstein N, Carlson M, Livote E, Kutner JS. Ann

Intern Med. 2010 Mar 2;152(5):296-9. doi: 10.7326/0003-4819-152-5-201003020-00007.

BACKGROUND: Communication about the deactivation of implantable cardioverterdefibrillators (ICDs) in patients near the end of life is rare.

OBJECTIVE: To determine whether hospices are admitting patients with ICDs, whether such patients are receiving shocks, and how hospices manage ICDs.

DESIGN: Cross-sectional survey.

SETTING: Randomly selected hospice facilities.

PARTICIPANTS: 900 hospices, 414 of which responded fully.

MEASUREMENTS: Frequency of admission of patients with ICDs, frequency with which patients received shocks, existence of ICD deactivation policies, and frequency of deactivation.

RESULTS: 97% of hospices admitted patients with ICDs, and 58% reported that in the past year, a patient had been shocked. Only 10% of hospices had a policy that addressed deactivation. On average, 42% (95% CI, 37% to 48%) of patients with ICDs had the shocking function deactivated.

LIMITATION: The study relied on the knowledge of hospice administrators.

CONCLUSION: Hospices are admitting patients with ICDs, and patients are being shocked at the end of life. Ensuring that hospices have policies in place to address deactivation may improve the care for patients with these devices. The authors provide a sample deactivation policy.

Comment in: Complexities of defibrillator deactivation. [Ann Intern Med. 2010]

- 58. Further barriers to conversations about deactivation of implantable cardioverterdefibrillators. Raphael C, Kanagaratnam P, Francis DP. J Am Coll Cardiol. 2010 Feb 16;55(7):701-2; author reply 702. doi: 10.1016/j.jacc.2009.09.044. Comment on: Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients: results of a nationwide survey comparing cardiology specialists to primary care physicians. [J Am Coll Cardiol. 2009]
- 59. Understanding ethical issues, ICD, and DNR orders: an obstacle to imminent death? Mullen MA, Gow RM. Heart Rhythm. 2010 Jun;7(6):858-60. doi: 10.1016/j.hrthm.2010.02.009. Epub 2010 Feb 11.
- 60. Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating permanent pacemaker in patients

with terminal illness. Patient autonomy is paramount. Zellner RA, Aulisio MP, Lewis WR. Circ Arrhythm Electrophysiol. 2009 Jun;2(3):340-4; discussion 340. doi: 10.1161/CIRCEP.109.848523.

Comment on: Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness. An ethical distinction. [Circ Arrhythm Electrophysiol. 2009]

- 61. Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness. An ethical distinction. Kay GN, Bittner GT. Circ Arrhythm Electrophysiol. 2009 Jun;2(3):336-9; discussion 339. doi: 10.1161/CIRCEP.108.821975. Comment in: Should implantable cardioverter-defibrillators and permanent pacemakers in patients with terminal illness be deactivated? Deactivating permanent pacemakers in patients with terminal illness. Patient autonomy is paramount. [Circ Arrhythm Electrophysiol. 2009]
- 62. Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients: results of a nationwide survey comparing cardiology specialists to primary care physicians. Goldstein N, Bradley E, Zeidman J, Mehta D, Morrison RS. J Am Coll Cardiol. 2009 Jul 21;54(4):371-3. doi: 10.1016/j.jacc.2009.04.030. Comment in: Further barriers to conversations about deactivation of implantable cardioverter-defibrillators. [J Am Coll Cardiol. 2010]
- 63. Implantable cardioverter-defibrillator deactivation at the end of life: a physician survey. Kelley AS, Reid MC, Miller DH, Fins JJ, Lachs MS. Am Heart J. 2009 Apr;157(4):702-8.e1. doi: 10.1016/j.ahj.2008.12.011. Epub 2009 Feb 23.

BACKGROUND: Among older adults, implantable cardioverter-defibrillator (ICD) use is increasing. ICD shocks can occur at end of life (EOL) and cause substantial distress, warranting consideration of ICD deactivation discussions. This nationwide physician survey sought to (1) determine if physicians discuss ICD deactivation at the EOL, (2) identify predictors of those discussions, and (3) ascertain physicians' knowledge/attitudes about ICD use.

METHODS: We surveyed 4,876 physicians stratified by specialty (cardiologists, electrophysiologists, general internists, and geriatricians). The mailed survey

presented 5 vignettes (eg, end-stage chronic obstructive pulmonary disease, advanced dementia) wherein ICD deactivation might be considered and 17 Likert-scaled items.

RESULTS: Five hundred fifty-eight (12%) physicians returned surveys. Respondents were largely men (77%) and white (69%). Most physicians (56%-83%) said they would initiate deactivation discussions in all 5 vignettes, whereas significantly more (82%-94%) would discuss advance directives and do not resuscitate status. In logistic regression analyses, a history of prior deactivation discussions was an independent predictor of willingness to discuss deactivation (adjusted OR range, 2.8-8.8) in 4 of the 5 vignettes. General internists and geriatricians were less likely than electrophysiologists to agree that ICD shocks are painful and to distinguish between the ICD's pacing and defibrillator functions. Finally, most physicians believed that informed consent for ICD implantation should include information about deactivation (77%) and endorsed the need for expert guidance in this area (58%).

CONCLUSIONS: Most physicians would discuss ICD deactivation at EOL. The strongest predictor of this was a history of prior discussions. Knowledge about ICDs varies by specialty, and most expressed a desire for more expert guidance about ICD management at EOL.

 Physicians' preferences and attitudes about end-of-life care in patients with an implantable cardioverter-defibrillator. Sherazi S, Daubert JP, Block RC, Jeevanantham V, Abdel-Gadir K, DiSalle MR, Haley JM, Shah AH. Mayo Clin Proc. 2008 Oct;83(10):1139-41. doi: 10.4065/83.10.1139.

Clinical guidance is deficient regarding deactivation of implantable cardioverterdefibrillators (ICDs) in patients with terminal illnesses. We hypothesized that many physicians are apprehensive about discussing ICD deactivation with their dying patients. Thus, we conducted an anonymous survey of all the physicians in the Department of Medicine at Unity Health System in Rochester, NY. The survey collected information about the knowledge and preferences of these physicians regarding the medical, ethical, and legal issues involved in caring for patients with an ICD and terminal illness. Of the 204 surveys distributed, 87 (43%) were returned. Among the physicians who responded, 64 (74%) reported experience caring for a patient with an ICD and terminal illness. Forty physicians (46%) either thought it was illegal or were not sure if it was legal to deactivate an ICD in these circumstances. However, if reassured about the legality of discontinuing ICD therapy, 79 (91%) of these same respondents said that they would be willing to discuss voluntary ICD deactivation with their dying patients. With increased knowledge about managing the withdrawal of this potentially life-prolonging therapy, physicians are likely to become more skilled at caring for dying patients with an ICD.

Management of patients with ICDs at the end of life (EOL): a qualitative study. Kelley AS, Mehta SS, Reid MC. Am J Hosp Palliat Care. 2008 Dec-2009 Jan;25(6):440-6. doi: 10.1177/1049909108320885. Epub 2008 Sep 23.

PURPOSE: Implantable cardioverter defibrillator shocks at the end of life are distressing and warrant consideration of implantable cardioverter defibrillator deactivation discussions. A nationwide survey collected physicians' comments regarding such discussions.

METHODS: Vignettes ascertained respondents' practices regarding implantable cardioverter defibrillator deactivation discussions. Respondents' comments were analyzed to identify themes.

RESULTS: About 177 respondents (32%) provided 310 comments. One third reported that initiating the discussion would depend on specific circumstances, such as do not resuscitate status (35%); 21% advocated life-prolonging therapies; 17% said the patient/family or another physician should initiate the discussion; and 9% expressed inadequate education/awareness about implantable cardioverter defibrillator functions. Geriatricians and general internists expressed inadequate knowledge most frequently (12 writers, 75% in this theme), while electrophysiologists most frequently suggested further treatments/procedures (22 writers, 58%), and another doctor (13 writers, 76%) or the patient (8 writers, 62%) should begin the discussion.

CONCLUSIONS: Improving the end of life care for patients with implantable cardioverter defibrillators will require additional physician education and increased commitment by subspecialists to deactivation discussions.

- 66. Ethical considerations of patients with pacemakers. Bharadwaj P, Ward KT. Am Fam Physician. 2008 Aug 1;78(3):398-9.
 Comment in: The ethical dilemma of life-prolonging medical devices. [Am Fam Physician. 2010]
- Deactivation of automatic implantable cardioverter-defibrillators in hospice and home care patients at the end of life. Kirk TW. Home Healthc Nurse. 2008 Jul-Aug;26(7):431-7. doi: 10.1097/01.NHH.0000326324.09466.97.

For patients at the end of life, active automatic implantable cardioverter-defibrillators (AICDs) may no longer achieve the treatment goals present at the time of implantation. It is possible to deactivate AICDs in patients with terminal and life-limiting diagnoses, thereby preventing the pain and distress of nontherapeutic discharge. This article presents a moral argument for the right of such patients to have their AICDs deactivated. It then explains that hospice and home care agencies have an obligation to address AICD deactivation at a policy level and offers recommendations for doing so.

 Physician attitudes toward end-stage heart failure: a national survey. Hauptman PJ, Swindle J, Hussain Z, Biener L, Burroughs TE. Am J Med. 2008 Feb;121(2):127-35. doi: 10.1016/j.amjmed.2007.08.035.

BACKGROUND: Despite recent improvements in medical therapies, heart failure remains a prevalent condition that places significant burdens on providers, patients, and families. However, there is a paucity of data published describing physician beliefs about heart failure management, especially in its advanced stages.

METHODS: In order to better understand physician decision-making in end-stage heart failure, we used a stratified random sampling of physicians obtained from the Master File of the American Medical Association to survey cardiologists (n=600), geriatricians (n=250), and internists/family practitioners (n=600).

RESULTS: Response rate was 59.6% (highest among geriatricians). The vast majority (>90%) of respondents cited similarities between the clinical trajectory of end-stage heart failure and lung cancer or chronic obstructive pulmonary disease; however, only 15.7% stated that they could predict death at 6 months "most of the time" or "always." Inpatient volume was a predictor of confidence in predicting mortality (odds ratio=1.38, 95% confidence interval, 1.36-1.40). Less than one quarter of respondents formally measure quality of life. The experience with deactivation of implantable cardioverter defibrillators was limited: 59.8% of cardiologists, 88.0% of geriatricians, and 95.1% of internal medicine/family practice physicians have had 2 or fewer conversations with patients and families about this option.

CONCLUSIONS: Significant gaps in knowledge about and experience with end-stage heart failure exist among a large proportion of physicians. The growing prevalence and highly symptomatic nature of heart failure highlight the need to further evaluate and improve the way in which care is delivered to patients dying from the disease.

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69. Within you/without you: biotechnology, ontology, and ethics. Sulmasy DP. J Gen Intern Med. 2008 Jan;23 Suppl 1:69-72. doi: 10.1007/s11606-007-0326-x.

As Implantable Cardioverter Defibrillators (ICDs) have become more common, ethical issues have arisen regarding the deactivation of these devices. Goldstein et al., have shown that both patients and cardiologists consider ICD deactivation to be different from the discontinuation of other life-sustaining treatments. It cannot be argued ethically that ICDs raise new questions about the distinction between withholding and withdrawing treatment, and neither the fact that they are used intermittently, nor the duration of therapy, nor the mere fact that they are located inside the body can be considered unique to these devices and morally decisive. However, frequent allusions to the fact that they are located inside the body might provide a clue about what bothers patients and physicians. As technology progresses, some interventions seem to become a part of the patient as a unified whole person, completely replacing body parts and lost physiological functions rather than merely substituting for impaired structure and function. If a life-sustaining intervention can be considered a "replacement"--a part of the patient as a unified whole person--then it seems that deactivation is better classified as a case of killing rather than a case of forgoing a life-sustaining treatment. ICDs are not a "replacement" therapy in this sense. The deactivation of an ICD is best classified, under the proper conditions, as the forgoing of an extraordinary means of care. As technology becomes more sophisticated, however, and new interventions come to be best classified as "replacements" (a heart transplant would be a good example), "discontinuing" these interventions should be much more morally troubling for those clinicians who oppose euthanasia and assisted suicide.

Comment on: "That's like an act of suicide" patients' attitudes toward deactivation of implantable defibrillators. [J Gen Intern Med. 2008]

"It's like crossing a bridge" complexities preventing physicians from discussing deactivation of implantable defibrillators at the end of life. [J Gen Intern Med. 2008]

70. "That's like an act of suicide" patients' attitudes toward deactivation of implantable defibrillators. Goldstein NE, Mehta D, Siddiqui S, Teitelbaum E, Zeidman J, Singson M, Pe E, Bradley EH, Morrison RS. J Gen Intern Med. 2008 Jan;23 Suppl 1:7-12. doi: 10.1007/s11606-007-0239-8.

OBJECTIVE: To understand potential patient barriers to discussions about implantable cardioverter defibrillator (ICD) deactivation in patients with advanced illness.

DESIGN: Qualitative focus groups.

PARTICIPANTS: Fifteen community-dwelling, ambulatory patients with ICDs assigned to focus groups based on duration of time since implantation and whether they had ever received a shock from their device.

APPROACH: A physician and a social worker used a predetermined discussion guide to moderate the groups, and each session was audiotaped and subsequently transcribed. Transcripts were analyzed using the method of constant comparison.

RESULTS: No participant had ever discussed deactivation with their physician nor knew that deactivation was an option. Patients expressed a great deal of anxiety about receiving shocks from their device. Participants discussed why they needed the device and expressed desire for more information about the device; however, they would not engage in conversations about deactivating the ICD. One patient described deactivation "like an act of suicide" and all patients believed that the device was exclusively beneficial. Patients also expressed a desire to have their physician make the decision about deactivation.

CONCLUSIONS: None of the patients in our study knew that they might need to deactivate their ICD as their health worsens. These community-dwelling outpatients were not willing to discuss the issue of ICD deactivation and their attitudes about deactivation might impede patients from engaging in these conversations. These findings are in contrast to findings in other advance care planning research and may be related to the unique nature of the ICD.

Comment in: A potential barrier to discussing deactivation of implantable cardioverter defibrillators was patients' lack of knowledge. [Evid Based Nurs. 2008] Within you/without you: biotechnology, ontology, and ethics. [J Gen Intern Med. 008]

71. "It's like crossing a bridge" complexities preventing physicians from discussing deactivation of implantable defibrillators at the end of life. Goldstein NE, Mehta D, Teitelbaum E, Bradley EH, Morrison RS. J Gen Intern Med. 2008 Jan;23 Suppl 1:2-6. doi: 10.1007/s11606-007-0237-x.

OBJECTIVE: To understand potential barriers to physician-initiated discussions about Implantable Cardioverter Defibrillator (ICD) deactivation in patients with advanced illness.

DESIGN: Qualitative one-on-one interviews.

PARTICIPANTS: Four electrophysiologists, 4 cardiologists, and 4 generalists (internists and geriatricians) from 3 states.

APPROACH: Clinicians were interviewed using open-ended questions to elicit heir past experiences with discussing deactivating ICDs and to determine what barriers might impede these discussions. Transcripts of these interviews were analyzed using the qualitative method of constant comparison.

RESULTS: Although many physicians believed that conversations about deactivating ICDs should be included in advance care planning discussions, they acknowledged that they rarely did this. Physicians indicated that there was something intrinsic to the nature of these devices that makes it inherently difficult to think of them in the same context as other management decisions at the end of a patient's life. Other explanations physicians gave as to why they did not engage in conversations included: the small internal nature of these devices and hence absence of a physical reminder to discuss the ICD, the absence of an established relationship with the patient, and their own general concerns relating to withdrawing care.

CONCLUSION: Whereas some of the barriers to discussing ICD deactivation are common to all forms of advance care planning, ICDs have unique characteristics that make these conversations more difficult. Future educational interventions will need to be designed to teach physicians how to improve communication with patients about the management of ICDs at the end of life.

Comment in: Within you/without you: biotechnology, ontology, and ethics. [J Gen Intern Med. 2008]

72. Withdrawal of cardiac medications and devices. Wiegand DL, Kalowes PG. AACN Adv Crit Care. 2007 Oct-Dec;18(4):415-25.

Withdrawal of life-sustaining therapies such as cardiac medications, pacemakers, internal cardioverter defibrillators, and ventricular assist devices occurs in patients with advanced cardiac disease as goals of treatment transition from active to less aggressive. This article defines life-sustaining therapies and describes ethical and legal considerations related to withdrawal of cardiac medications and cardiac devices. Healthcare providers need to anticipate clinical situations in which implantable cardiac devices and medications are no longer desired by patients and/or are no longer medically appropriate. Discussions are important between patients, families, and healthcare providers that focus on each patient's condition, prognosis, advance directives, goals of care, and treatment options. Critical care

nurses support each patient and his or her family and work with other members of the healthcare team to achieve a peaceful death.

73. The ethical and legal implications of deactivating an implantable cardioverterdefibrillator in a patient with terminal cancer. England R, England T, Coggon J. J Med Ethics. 2007 Sep;33(9):538-40.

In this paper, the ethical and legal issues raised by the deactivation of implantable cardioverter-defibrillators (ICDs) in patients with terminal cancer is considered. It is argued that the ICD cannot be well described either as a treatment or as a non-treatment option, and thus raises complex questions regarding how rules governing deactivation should be framed. A new category called "integral devices" is proposed. Integral devices require their own special rules, reflecting their position as a "halfway house" between a form of treatment and a part of the body. The practical problems faced by doctors working in palliative medicine with regard to the deactivation of ICDs are also considered.

Comment in: The ethics of implantable devices. [J Med Ethics. 2007]

- T4. Implantable cardioverter-defibrillators and hospice care. Kirk TW. IEEE Eng Med Biol Mag. 2007 Jul-Aug;26(4):82-4.
- 75. End-of-life decisions in ICD patients with malignant tumors. Kobza R, Erne P. Pacing Clin Electrophysiol. 2007 Jul;30(7):845-9.

BACKGROUND: The results of multiple implantable cardioverter-defibrillator (ICD) studies have demonstrated a survival benefit in specific high-risk populations, leading to the expansion of ICD implantation rates worldwide. Because the ICD reduces the incidence of sudden cardiac death, patients with these devices more often die of non-arrhythmic causes. For those with a malignancy, little is known about their preferences for disabling ICD therapy.

METHODS: The objective of the present study was to evaluate whether patients with an ICD and a malignant tumor desire deactivation of their ICD in order to have a death without ICD interventions, which are life-prolonging, bothersome, and prevent a peaceful death. All deceased patients having had an ICD implanted at our institution were retrospectively analyzed with respect to whether the option of disabling ICD therapy had been discussed and whether the ICD had been deactivated. RESULTS: Two hundred and seventy-two patients received an ICD at our institution between January 1, 1994, and January 31, 2007. Thirty-six of the patients have died, and of these eight had a malignant tumor. In six of these eight patients (75%) the option of disabling their ICD therapy was discussed extensively; none wished to abandon the possibility of terminating a malignant arrhythmia by the ICD.

CONCLUSIONS: With the use of ICDs, patients with heart failure are more frequently protected from arrhythmic death, and consequently treating physicians are increasingly confronted with ICD patients presenting with a malignant tumor or other noncardiac terminal disease. In these situations, dialogue between the treating physician and the patient about the possibility of withdrawing ICD therapy is important to terminal care. The physician must be aware that the patient's attitude may contrast with his/her own, and that the patient may be resolute in maintaining ICD protection from arrhythmic death.

76. Socio-economic analysis of cardiac resynchronization therapy. Field ME, Sweeney MO. J Interv Card Electrophysiol. 2006 Dec;17(3):225-36. Epub 2007 Mar 20.

The field of electrical device therapy has benefited from two basically independent of investigation demonstrating mortal benefit from either cardiac lines resynchronization therapy (CRT) or implantable cardioverter-defibrillator (ICD) therapy in patients with heart failure. Current clinical evidence data is insufficient to conclude that CRT-defibrillation (CRTD) offers an advantage over CRT-pacing (CRTP) alone. The cost of adding a defibrillator to the CRTP device is substantial and will act as a barrier to wide scale penetration. Annualized sudden death rates are very low in certain primary prevention populations. Consequently, the potential for overtreatment is very large and the negative costs of ICD therapy are distributed equally among those patients who will have a life saving benefit and those who were "destined" never to require the therapy. The perception that these costs are acceptable if lives are saved is commonly cited as justification for expensive therapy on a population scale, but there is an important and practical difference between costs per unit life saved and costs among patients who really never needed the device. Until the a priori predictors of volumetric response to CRT are better understood, the use of CRTD in class IV patients should be discouraged since ICD therapy is unlikely to extend life in volumetric non-responders. Similarly, the use of CRTD in patients who are "destined" for significant volumetric response is probably unwise since their risk of sudden death is minimized due to favorable substrate modification. Clinical trials comparing conventional ICDs, CRTP and CRTD are

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necessary to rationalize use of expensive hardware resources among different patient populations. Additionally, the importance of patient preference regarding end of life care should receive greater emphasis. While CRTP may be considered palliative in terminal heart failure, the decision to offer CRTD must include a discussion with the patient regarding mode of death and the potential for the defibrillator to replace a sudden and peaceful death with a prolonged death from progressive pump failure.

- 77. Deactivation of advanced lifesaving technologies. Lipman HI. Am J Geriatr Cardiol. 2007 Mar-Apr;16(2):109-11.
- Withdrawing implantable defibrillator shock therapy in terminally ill patients. Lewis WR, Luebke DL, Johnson NJ, Harrington MD, Costantini O, Aulisio MP. Am J Med. 2006 Oct;119(10):892-6.

PURPOSE: The purpose of this study is to review a multidisciplinary strategy used to identify patients with terminal illnesses and initiate withdrawal of implantable cardioverter defibrillator (ICD) shock therapy as part of a comprehensive comfort care approach. With indications for ICDs increasing, more patients are receiving devices. Once protected from an arrhythmic death, these patients may develop other terminal diseases such as cancer or congestive heart failure. It is appropriate to withdraw defibrillator shock therapy when such patients desire only comfort care.

METHODS: The charts of ICD patients who had died were reviewed. Two groups emerged: Group 1 (20) included patients whose defibrillator was turned off through the comprehensive comfort care approach. Group 2 (43) included patients whose clinical course was so rapid that the defibrillator was not turned off. Pacing therapy was not withdrawn in either group.

RESULTS: Defibrillator discharges, cause of death, and time from ICD discharge to death were compared. Group 2 patients died more acutely than Group 1. Group 1 experienced fewer shocks prior to death when compared to Group 2. Comparing pacemaker dependent and non-dependent patients, there was no difference in the time between therapy discontinuation and death.

CONCLUSION: This is the largest study to date to review the characteristics of patients with ICDs and terminal illness. Only one-third of terminally ill patients with ICDs were able to have shock therapy withdrawn as part of a comfort care strategy. These patients experienced fewer shocks in the final days of their illness.

- 79. Deactivation of an implantable cardioverter defibrillator in a dying patient. Bogan C, Kieran T, O'Brien T, Fahy G. Ir Med J. 2006 May;99(5):155-6.
- Quality of death: implantable cardioverter defibrillators and proactive care. Sears SF, Sowell LV, Kuhl EA, Handberg EM, Kron J, Aranda JM Jr, Conti JB. Pacing Clin Electrophysiol. 2006 Jun;29(6):637-42.

OBJECTIVES: The purpose of this paper is to discuss quality of death (QOD) among patients with congestive heart failure (CHF) and implantable cardioverter defibrillators. We outline recommendations that enhance QOD from the device patient and specialty cardiology perspectives.

BACKGROUND: Contemporary treatment of CHF patients routinely includes both pharmacologic therapy and the use of cardiac devices. The implantable cardioverter defibrillator prevents premature death in heart failure patients, though not death itself. CONCLUSIONS: Active discussion and consideration of patient's QOD is indicated in implantable cardioverter defibrillator patients to prevent unnecessary treatment and to increase control over perceived quality of life by patients and family.

81. Hastening death and the boundaries of the self. Jansen LA. Bioethics. 2006 Apr;20(2):105-11.

When applying moral principles to concrete cases, we assume a background shared understanding of the boundaries of the persons to whom the principles apply. In most contexts, this assumption is unproblematic. However, in end-of-life contexts, when patients are receiving 'artificial' life-support, judgments about where a person's self begins and ends can become controversial. To illustrate this possibility, this paper presents a case in which a decision must be made whether to deactivate a patient's pacemaker as a means to hasten his death. After discussing some common moral principles that are often applied to resolve ethical problems at the end of life and after explaining why they are of no help here, the paper argues that the correct analysis of this case, and of cases of this sort, turns on considerations that relate to the constitution of the self. These considerations, the paper further argues, sometimes resist resolution. The constitution of the self is fixed in large measure by our concepts and social conventions, and these do not always provide determinate grounds for delimiting the boundaries of the self. 82. End-of-life and other ethical issues related to pacemaker and defibrillator use in the elderly. Basta LL. Am J Geriatr Cardiol. 2006 Mar-Apr;15(2):114-7.

In the past decade, the rate of implantation of pacemakers and cardioverterdefibrillators in the elderly with cardiac impairment has soared. As patients near the end of life, interventions become more complicated and expensive, and less effective. In this context, "informed consent" requires consideration of issues different from those faced in more routine settings. Informed consent requires full disclosure, patient competence, and free exercise of will-but in practice, few patients or their families are in a position to make fully informed decisions about highly complex treatments at the end of life. Physicians continue to bear the responsibility of advising patients about sophisticated interventions or, alternatively, palliative care. Physician training, with its narrow focus on the treatment of disease with drugs and technology, has not prepared physicians to advise patients on issues arising from the availability of multiple interventions at the end of life. Professional societies can fill a gap by developing programs and materials to help physicians treat their dying patients in a high-technology era.

- 83. And it can go on and on and on... Looi YC. J Pain Symptom Manage. 2006 Jan;31(1):1-2.
- 84. Discontinuing implantable cardiac devices & the ERDs. Slosar JP. Health Care Ethics USA. 2005;13(2):E2.

Ethics committees are used [sic] to questions concerning the withdrawal of lifesupport. Such questions become increasingly complex when that life-support is implantable, like a pacemaker. This essay seeks to address the question of under what, if any, circumstances it would be permissible to discontinue the use of such implantable devices.

- 85. Deactivating implantable cardioverter defibrillators. Lynn J. Ann Intern Med. 2005 Nov 1;143(9):691; author reply 691.
 Comment on: The ethics of deactivating implanted cardioverter defibrillators. [Ann Intern Med. 2005]
- Deactivating implantable cardioverter defibrillators. Ross HM. Ann Intern Med. 2005 Nov 1;143(9):690; author reply 691.

Comment on: The ethics of deactivating implanted cardioverter defibrillators. [Ann Intern Med. 2005]

- 87. Deactivating implantable cardioverter defibrillators. Beattie JM, Connolly MJ, Ellershaw JE. Ann Intern Med. 2005 Nov 1;143(9):690-1; author reply 691.
 Comment on: The ethics of deactivating implanted cardioverter defibrillators. [Ann Intern Med. 2005]
- Pacemakers and end-of-life decisions. McQuoid-Mason D. S Afr Med J. 2005 Aug;95(8):566, 568.
- 89. Withdrawal of life-sustaining low-burden care. McCullough LB, Richman BW, Jones JW. J Vasc Surg. 2005 Jul;42(1):176-7.

A 90-year-old diabetic man with unreconstructable peripheral vascular disease, endstage chronic obstructive pulmonary disease, relentless ischemic rest pain, and severe disability returns to your clinic asking you to deactivate his implanted pacemaker. To do so would likely precipitate his demise, and you ask him if he is aware of this. He tells you that he is and that he has been considering this request since he last saw you 3 months ago. Relief of his chronic pain would require bilateral hip-disarticulating amputations, procedures with a prohibitively high operative mortality rate, particularly with his age and comorbidities. He has been evaluated by a psychiatrist and found to be mentally competent. His treatment by a pain specialist, who used his full armamentarium of high-dose narcotics, electronic devices, nerve blocks, and psychological techniques, has been unsuccessful. You do not reside in Oregon. What is your most ethical course of action?

- 90. EOL considerations in defibrillator deactivation. Grassman D. Am J Hosp Palliat Care. 2005 May-Jun;22(3):179; author reply 179-80.
 Comment on: Pacemaker and defibrillator deactivation in competent hospice patients: an ethical consideration. [Am J Hosp Palliat Care. 2005]
- 91. Next-of-kin responses and do-not-resuscitate implications for implantable cardioverter defibrillators. Morrison LJ, Sinclair CT. Ann Intern Med. 2005 Apr 19;142(8):676-7; author reply 677.
 Comment on: Management of implantable cardioverter defibrillators in end-of-life care. [Ann Intern Med. 2004]

92. The ethics of deactivating implanted cardioverter defibrillators. Berger JT. Ann Intern Med. 2005 Apr 19;142(8):631-4.

Implantable cardioverter defibrillators are life-saving devices for many patients with cardiac disease. Recipients of these devices, nevertheless, often suffer from progressive comorbid and cardiac conditions. Therefore, physicians should anticipate situations in which the defibrillator is no longer desired by the patient or no longer medically appropriate. Near the end of life, many of these patients may decline cardiopulmonary resuscitation. The comanagement of do-not-resuscitate orders and implanted defibrillators can be confusing to patients and physicians alike since the former proscribe the use of electrical cardioversion while the latter provide this precise treatment. Although the use of implanted defibrillators has important ethical implications, few studies have examined these issues, and guidelines have not yet been developed to assist physicians in caring for patients who have received defibrillators. This paper discusses bioethical considerations in disabling implantable cardioverter defibrillators.

Comment in: Deactivating implantable cardioverter defibrillators. [Ann Intern Med. 2005]

Deactivating implantable cardioverter defibrillators. [Ann Intern Med. 2005] Deactivating implantable cardioverter defibrillators. [Ann Intern Med. 2005]

93. Pacemaker and defibrillator deactivation in competent hospice patients: an ethical consideration. Ballentine JM. Am J Hosp Palliat Care. 2005 Jan-Feb;22(1):14-9.

The Denver Community Bioethics Committee (DCBC) is an independent, communitybased group that undertakes ethics consultations for any individual or organization. Its members include adult protection professionals, physicians, elder-law attorneys, chaplains, nurses, social workers, and lay persons. In its 11-year history, the Committee has heard numerous cases concerning end-of-life care, futile treatment, and patients' rights. In 2003, a Colorado hospice provider asked the DCBC for assistance in developing a policy on deactivation of pacemakers and defibrillators in competent hospice patients. The hospice had encountered concerns from some physicians and cardiac care clinicians that deactivating such devices treads the fine line between legitimate withdrawal of burdensome treatment and assisted death. Although the specific deliberations of the DCBC are confidential, this article summarizes contributions from the committee's discussion, as well as independent research undertaken by the author. Comment in: Management of cardiac devices as the end nears. [Am J Hosp Palliat Care. 2005]

EOL considerations in defibrillator deactivation. [Am J Hosp Palliat Care. 2005]

94. Management of cardiac devices as the end nears. Enck RE. Am J Hosp Palliat Care.2005 Jan-Feb;22(1):7-8.Comment on: Pacemaker and defibrillator deactivation in competent hospice

patients: an ethical consideration. [Am J Hosp Palliat Care. 2005]

95. Management of implantable cardioverter defibrillators in end-of-life care. Goldstein NE, Lampert R, Bradley E, Lynn J, Krumholz HM. Ann Intern Med. 2004 Dec 7;141(11):835-8.

BACKGROUND: Implantable cardioverter defibrillators (ICDs) can prevent premature death from an arrhythmia but may also prolong the dying process and make it more distressing.

OBJECTIVE: To describe the frequency, timing, and correlates of discussions about deactivating ICDs.

DESIGN: Retrospective cohort study.

SETTING: Telephone survey.

PARTICIPANTS: Next of kin of patients with ICDs who died of any cause. Of 136 next of kin contacted, 100 (74%) participated.

MEASUREMENTS: Incidence of discussions about deactivating ICDs and timing of last shock from ICD.

RESULTS: Next of kin reported that clinicians discussed deactivating the ICD in only 27 of the 100 cases. Most discussions occurred in the last few days of life. Family members reported that 8 patients received a shock from their ICD in the minutes before death.

LIMITATIONS: This retrospective survey relied on the reports of next of kin.

CONCLUSIONS: Next of kin reported that clinicians discussed deactivating ICDs with few patients. Individuals who choose to receive this device should have the opportunity to choose to discontinue it as death approaches.

Comment in: Next-of-kin responses and do-not-resuscitate implications for

implantable cardioverter defibrillators. [Ann Intern Med. 2005]

Summary for patients in: Ann Intern Med. 2004 Dec 7;141(11):I38.

- 96. Summaries for patients. Implantable cardioverter defibrillators and end-of-life care.
 [No authors listed]. Ann Intern Med. 2004 Dec 7;141(11):I38.
 Original report in: Ann Intern Med. 2004 Dec 7;141(11):835-8.
- 97. Dying and defibrillation: a shocking experience. Nambisan V, Chao D. Palliat Med. 2004 Jul;18(5):482-3.

Palliative Care physicians are frequently involved in the care of patients with significant comorbidity and often have to take coexisting conditions into account when treating patients. An example of an area in which this is particularly relevant and will undoubtedly increase is presented with the case report of a patient with terminal metastatic lung carcinoma and an Implantable Cardioverter Defibrillator (ICD) in place. The role of the ICD in preventing the patient from dying comfortably is discussed, as are means of deactivating the device. We conclude that patients with ICDs and terminal disease should have the issue of deactivation addressed at the earliest possible opportunity as practical difficulties may arise in the emergency setting, especially in the nonhospital environment.

- 98. When is deactivation of artificial pacing and AICD illegal, immoral, and unethical? Silveira MJ. Am J Geriatr Cardiol. 2003 Jul-Aug;12(4):275-6.
- 99. Ethical analysis of withdrawal of pacemaker or implantable cardioverter-defibrillator support at the end of life. Mueller PS, Hook CC, Hayes DL. Mayo Clin Proc. 2003 Aug;78(8):959-63.

OBJECTIVE: To describe a series of terminally ill patients who requested (or whose surrogates requested) withdrawal of pacemaker or implantable cardioverter-defibrillator (ICD) support and the ethical issues pertaining to these requests.

PATIENTS AND METHODS: We performed a retrospective review of the medical records of patients seen at the Mayo Clinic in Rochester, Minn, between January 1996 and June 2002 and identified 6 terminally ill patients who requested (or whose family members requested) withdrawal of pacemaker or ICD support. Potential interventions were an ethics consultation and subsequent withdrawal of pacemaker or ICD support. The study's main outcome measures were death and the context in which it occurred.

RESULTS: The mean age of the 6 patients (3 men, 3 women) was 75.5 years. Five had pacemakers, and 1 had an ICD. Five patients had advance directives that

indicated a desire to withdraw medical interventions if death was inevitable. Two patients and 4 surrogates requested withdrawal of pacemaker or ICD support. One patient died without withdrawal of support despite an ethics consultation that endorsed its permissibility. Another died while an ethics consultation was in progress. The request to withdraw support was granted in 4 patients, all of whom died within 5 days of withdrawal of support.

CONCLUSIONS: Granting terminally ill patients' requests to withdraw unwanted medical support is legal and ethical. Death after withdrawal of support is attributable to the patient's underlying pathology and is not the same as physician-assisted suicide or euthanasia. Clinician familiarity with these concepts may lead to more expeditious withdrawal of unwanted medical support from terminally ill patients.

100. Is it ethical to withdraw low-burden interventions in chronically ill patients? Lane DJ. JAMA. 2000 Sep 20;284(11):1380-1; author reply 1381-2.
Comment on: Decisions to withdraw life-sustaining treatment: a moral algorithm.
[JAMA. 2000]
Withdrawing very low-burden interventions in chronically ill patients. [JAMA. 2000]

- 101. Is it ethical to withdraw low-burden interventions in chronically ill patients? Paola F, Walker RM. JAMA. 2000 Sep 20;284(11):1380; author reply 1381-2.
 Comment on: Decisions to withdraw life-sustaining treatment: a moral algorithm.
 [JAMA. 2000]
 Withdrawing very low-burden interventions in chronically ill patients. [JAMA. 2000]
- 102. Disabling the pacemaker: the heart-rending decision every competent patient has a right to make. Manganello TD. Health Care Law Mon. 2000 Jan:3-15.
- 103. Deactivating the implantable cardioverter-defibrillator: a biofixture analysis. Paola FA, Walker RM. South Med J. 2000 Jan;93(1):20-3.

Automatic implantable cardioverter-defibrillators (ICDs) are becoming increasingly common, as is refusal of resuscitative efforts at the end of life, both by patients and surrogate decision-makers. While it is clear that a terminally ill patient who lacks decisional capacity may, through a surrogate, refuse cardiopulmonary resuscitation (CPR), is it appropriate for physicians to infer from such a refusal that the patient's ICD should be deactivated? A proper answer to this question requires consideration of the nature of consent to a do-not-resuscitate (DNR) order, the context in which

permission is given for the writing of the DNR order, and the ontologic status of implantable devices in general and ICDs in particular. We introduce the concept of "biofixtures" and suggest that a biofixture analysis is a novel way of approaching the difficult ethical issues that may confound the care of patients with implantable devices.

104. Cardiac pacemakers and implantable defibrillators in terminal care. Braun TC,
Hagen NA, Hatfield RE, Wyse DG. J Pain Symptom Manage. 1999 Aug;18(2):126-31.

The use of cardiac pacemakers and arrhythmia control devices is increasingly common. The presence of a previously placed pacemaker or implantable cardioverter-defibrillator (ICD) in a terminally ill patient may result in medical and ethical issues for the patient, family, and healthcare provider. Two cases are presented to illustrate the complex issues that may arise in the terminally ill with a pacemaker or an ICD. Based on these cases and a review of published data, it is likely that the disabling of a previously placed pacemaker will neither hasten nor prolong the natural history of the underlying illness in most instances. There are uncommon but potentially severe adverse effects of disabling the pacemaker; therefore, pacemakers should generally be left intact in terminally ill patients. It is more difficult to generalize as to whether deactivation of an ICD is appropriate; in this case death may be hastened and the decision concerning an ICD will depend on the specific clinical scenario. Patient and family education regarding palliative care treatment goals and the function of pacemakers and other implanted arrhythmia control devices can help to alleviate anxiety surrounding the impact of this technology at the end of life.

- 105. Please, doctor. Turn off my pacemaker. La Farge G. Med Econ. 1997 May 12;74(10):177-80.
- 106. Retiring the pacemaker. Reitemeier PJ, Derse AR, Spike J. Hastings Cent Rep. 1997 Jan-Feb;27(1):24; discussion 24-6.

2. PubMed search up to 15 August 2014

(("Defibrillators, Implantable"[Mesh]) OR ("Pacemaker, Artificial"[Mesh])) AND deactivation

No limits

Identified 94 articles

28 articles excluded as not related to device deactivation towards the end of life.

66 relevant publications identified and reviewed:

Reviews	27
Systematic review	1
Guideline	1
Observational studies:	
Patient features and outcomes	3
Avoiding inappropriate shocks by deactivation	1
Advanced directives and ICDs	1
Patient surveys/interviews/focus groups	7
Nurse survey	1
Physician survey	4
Clinical team members (multidisciplinary) survey	1
Hospice survey	1
Case reports:	
Single	5
Two cases	2
Letters	11

2 further articles identified from reviewing articles (1 guideline, 1 opinion).

51 of these articles were included above in the findings from literature search 1 and are therefore not listed below.

1. Med Law. 2014 Apr;33(1):14-21. I'm getting turned off: emerging consensus on deactivating cardiac implantable electronic devices. Kapp MB.

The surgical insertion of permanent heart rhythm (resynchronization) devices within individuals who have chronic cardiac deficiencies is widespread and increasing. It is predictable that some individuals who have had a permanent heart rhythm device implanted will subsequently reach a point, physically and/or emotionally, at which they (or their surrogates) indicate the desire that their own resynchronization be removed or deactivated. Despite continuing controversy, A professional international

consensus has begun to emerge over the past few years, concerning the fundamental legal and ethical principles that ought to guide clinical practice regarding the deactivation of cardiac implantable electrical devices (CIEDs). The central legal and ethical principles of the emerging professional consensus in this sphere are briefly summarized in this article, along with some thoughts about the challenges of translating those principles into clinical practice for specific patients.

 Ned Tijdschr Geneeskd. 2013;157(43):A6457. [The ICD in the terminal stage]. [Article in Dutch]. Boukes FS, Wiersma T.

ICDs are used to prevent sudden death caused by ventricular fibrillation. The number of patients with an ICD will keep growing. ICD shocks can severely disturb the dying process in terminally ill patients. Patients must be informed about this at the time of ICD implantation. The attending physician is responsible for proactive communication regarding deactivation when death is expected imminently. The decision to deactivate the ICD depends on personal wishes, and has proved to be difficult even if the patient has been well informed. Deactivation at home must be available so that severely ill patients do not need to travel to a hospital.

- J Palliat Med. 2012 Dec;15(12):1291. Deactivation of implanted cardioverterdefibrillators at the end of life in the setting of an outpatient clinic. Köbe J, Wasmer K, Reinke F, Eckardt L. [Letter].
- 4. Int J Palliat Nurs. 2011 Dec;17(12):607-10. ICDs and patients in palliative care: the clinical experience turned into clinical policy. Maher K.

As the global population grows and ages, an increasing number of patients are being referred to specialist palliative care services with multiple comorbidities. A parallel increase in interventional cardiology technology, techniques, and availability means that an increasing minority of these patients are having an implantable cardioverter defibrillator device (ICD) in place. It is essential that issues relating to these devices are discussed early in patients' planning for end-of-life care, as the discharging of a device in a patient who has chosen not to be resuscitated will be contrary to their wishes. These issues are explored here by presenting two case studies with vastly different outcomes that were experienced at a hospice in Australia. Examination of these case studies by the hospice staff culminated in the development of a policy for the home-based palliative care team and the hospice inpatient unit for deactivation of

ICDs according to patients' and caregivers' wishes at a variety of stages of their palliative care journey. Elements of this policy are also presented here as guidance for others looking to implement similar processes.

 J Interv Card Electrophysiol. 2011 Dec;32(3):243-52. "Just Because We Can Doesn't Mean We Should": views of nurses on deactivation of pacemakers and implantable cardioverter-defibrillators. Kramer DB, Ottenberg AL, Gerhardson S, Mueller LA, Kaufman SR, Koenig BA, Mueller PS.

PURPOSE: This study aims to identify nurses' concerns about the clinical, ethical, and legal aspects of deactivating cardiovascular implantable electronic devices (CIEDs).

METHODS: We used focus groups to discuss decision making in CIED management.

RESULTS: Fourteen nurses described the informed consent process as overly focused on procedures, with inadequate coverage of living with a device (e.g., infection risks and device shocks). Elderly patients were especially vulnerable to physician or family pressure about CIED implantation. Nurses believed that initial advance care planning discussions were infrequent and rarely revisited when health status changed. Many patients did not know that CIEDs could be deactivated; it was often addressed reactively (i.e., after multiple shocks) or when patients became too ill to participate in decision making. Nurses generally were supportive of CIED deactivation when it was requested by a well-informed patient. However, nurses distinguished between withholding versus withdrawing treatment (i.e., turning off CIEDs vs. declining implantation). Although most patients viewed their device as lifesaving, others perceived them as a "ticking time bomb."

CONCLUSIONS: Nurses identified concerns about CIED decision making from implantation through end-of-life care and device deactivation and suggested avenues for improving patient care including early and regular advance care planning.

 Nat Rev Cardiol. 2011 Jul 26;8(12):694-705. Effective communication and ethical consent in decisions related to ICDs. Clark AM, Jaarsma T, Strachan P, Davidson PM, Jerke M, Beattie JM, Duncan AS, Ski CF, Thompson DR.

This Review examines recommendations and principles that promote good decisionmaking with regard to the insertion, deactivation, and potential malfunction of implantable cardioverter-defibrillators (ICDs). This guidance is important because ICDs are now used for primary and secondary prevention of arrhythmias in more than 20 diverse clinical populations, which accounts for the exponential increase in insertion rates over the past decade. Current guidelines require clinicians to provide personalized, culturally appropriate, and easy to understand information to patients on the benefits and harms of proposed treatment choices; however, obtaining valid informed consent for insertion and deactivation of ICDs is challenging. Initiating early conversations with patients and continuing this dialogue over time, implementation of localized care protocols, increased collaboration (particularly between cardiac and palliative care teams), and the provision of training for all health professionals involved in the care of these patients, can help to ensure that adequate informed consent is maintained throughout their care. In addition to providing information, health professionals should identify and address high levels of anxiety in patients and their next of kin and promote effective communication throughout decision making. In the future, use of standardized checklists or decision aids based on a clear understanding of the principles underlying key topics could support this process.

- Lakartidningen. 2011 Mar 9-15;108(10):536-9. [Deactivation of implantable defibrillators--also an ethical issue. Written routines of the process are necessary as illustrated by the described case report]. [Article in Swedish] Carlsson J, Mansson A, Olsson D.
- Pol Arch Med Wewn. 2010 Dec;120(12):497-502. Management of cardiac electrical implantable devices in patients nearing the end of life or requesting withdrawal of therapy: review of the Heart Rhythm Society 2010 consensus statement. Kramer DB, Ottenberg AL, Mueller PS.

Cardiac implantable electrical devices (CIEDs) are increasingly common interventions for a wide spectrum of cardiovascular diseases. Caring for patients with life-sustaining devices such as CIEDs at the end of life raises legal and ethical challenges. In 2010, the Heart Rhythm Society (HRS) published an expert consensus statement to review the principles and practice of CIED deactivation. This statement addressed a wide range of ethical and legal principles while providing guidance for communication, decision-making, and procedures in a variety of settings. In this article, we provide a summary of the HRS guidelines and highlight the most important features of CIED deactivation for the practicing clinician.

- Heart Rhythm. 2010 Nov;7(11):1543-4. Clinicians' views regarding deactivation of cardiovascular implantable electronic devices in seriously ill patients. Mueller PS. Comment on Heart Rhythm. 2010 Nov;7(11):1537-42.
- 10. AACN Adv Crit Care. 2010 Apr-Jun;21(2):222-6. Ethical and attitudinal considerations for critical care nurses regarding deactivation of implantable cardioverter-defibrillators. Grant M.
- 11. J Card Fail. 2010 Feb;16(2):106-13. Patient expectations from implantable defibrillators to prevent death in heart failure. Stewart GC, Weintraub JR, Pratibhu PP, Semigran MJ, Camuso JM, Brooks K, Tsang SW, Anello MS, Nguyen VT, Lewis EF, Nohria A, Desai AS, Givertz MM, Stevenson LW.

BACKGROUND: Indications for implantable cardioverter-defibrillators (ICDs) in heart failure (HF) are expanding and may include more than 1 million patients. This study examined patient expectations from ICDs for primary prevention of sudden death in HF.

METHODS AND RESULTS: Study participants (n = 105) had an EF <35% and symptomatic HF, without history of ventricular tachycardia/fibrillation or syncope. Subjects completed a written survey about perceived ICD benefits, survival expectations, and circumstances under which they might deactivate defibrillation. Mean age was 58, LVEF 21%, 40% were New York Heart Association Class III-IV, and 65% already had a primary prevention ICD. Most patients anticipated more than10 years survival despite symptomatic HF. Nearly 54% expected an ICD to save >or=50 lives per 100 during 5 years. ICD recipients expressed more confidence that the device would save their own lives compared with those without an ICD (P < .001). Despite understanding the ease of deactivation, 70% of ICD recipients indicated they would keep the ICD on even if dying of cancer, 55% even if having daily shocks, and none would inactivate defibrillation even if suffering constant dyspnea at rest.

CONCLUSIONS: HF patients anticipate long survival, overestimate survival benefits conferred by ICDs, and express reluctance to deactivate their devices even for end-stage disease.

12. J Am Coll Cardiol. 2009 Jul 21;54(4):371-3. Barriers to conversations about deactivation of implantable defibrillators in seriously ill patients: results of a

nationwide survey comparing cardiology specialists to primary care physicians. Goldstein N, Bradley E, Zeidman J, Mehta D, Morrison RS.

 Pacing Clin Electrophysiol. 2008 May;31(5):560-8. Deactivating implanted cardiac devices in terminally ill patients: practices and attitudes. Mueller PS, Jenkins SM, Bramstedt KA, Hayes DL.

BACKGROUND: Clinicians may receive requests to deactivate pacemakers and Implantable cardioverter-defibrillators (ICDs) in terminally ill patients.

METHODS: We describe practices and attitudes regarding deactivation of pacemakers and ICDs in terminally ill patients among physicians, nurses, and others who manage treatment of patients with implanted cardiac devices and among field representatives of device manufacturers. A Web-based survey was provided to Heart Rhythm Society members and to representatives of two manufacturers of implantable cardiac devices. Measurements were the answers of 787 respondents.

RESULTS: Of the respondents, 86.8% reported involvement in requests for ICD deactivation and 77.6% reported involvement in pacemaker deactivation (P < 0.001). Having cared for a terminally ill patient for whom the respondent or a physician had ordered device deactivation was common (95.4% for ICDs vs 84.8% for pacemakers; P < 0.001). Having personally deactivated a device was also common (92.4% for ICDs vs 76.6% for pacemakers; P < 0.001). More respondents said they were comfortable with personally deactivating an ICD than deactivating a pacemaker (56.7% for ICDs vs 34.4% for pacemakers; P < 0.001). Respondents reported that the industry representative is the individual who deactivates the device most of the time (59.3% for ICDs and 49.7% for pacemakers).

CONCLUSIONS: Deactivation of implanted cardiac devices in terminally ill patients is common. Practices and attitudes associated with pacemaker deactivation differ significantly from those associated with ICD deactivation. Professional groups should develop guidelines for managing requests for implanted cardiac device deactivation and should clarify the role of device industry representatives in these deactivations.

14. Crit Care Med. 2000 Oct;28(10 Suppl):N174-80.Emergencies related to implantable cardioverter-defibrillators. Pinski SL.

Implantable cardioverter-defibrillators (ICDs) have become the dominant therapeutic modality for patients with life-threatening ventricular arrhythmias. ICDs are implanted using techniques similar to standard pacemaker implantation. They not only provide

high-energy shocks for ventricular fibrillation and rapid ventricular tachycardia, but also provide antitachycardia pacing for monomorphic ventricular tachycardia and antibradycardia pacing. Devices incorporating an atrial lead allow dual-chamber pacing and better discrimination between ventricular and supraventricular tachyarrhythmias. Intensivists are increasingly likely to encounter patients with ICDs. Electrosurgery can be safely performed in ICD patients as long as the device is deactivated before the procedure and reactivated and reassessed immediately afterward. Prompt and skilled intervention can prove to be life-saving in patients presenting with ICD-related emergencies, including lack of response to ventricular tachyarrhythmias, pacing failure, and multiple shocks. Recognition and treatment of tachyarrhythmia can be temporarily disabled by placing a magnet on top of an ICD. The presence of an ICD should not deter standard resuscitation techniques. Multiple ICD discharges in a short period of time constitute a serious situation. Causes include ventricular electrical storm, inefficient defibrillation, nonsustained ventricular tachycardia, and inappropriate shocks caused by supraventricular tachyarrhythmias or oversensing of signals. ICD system infection requires hardware removal and intravenous antibiotic therapy. Deactivation of an ICD with the consent of the patient or relatives is reasonable and ethical in terminally ill patients.

15. J Pain Symptom Manage. 1999 Aug;18(2):126-31. Cardiac pacemakers and implantable defibrillators in terminal care.

The use of cardiac pacemakers and arrhythmia control devices is increasingly common. The presence of a previously placed pacemaker or implantable cardioverter-defibrillator (ICD) in a terminally ill patient may result in medical and ethical issues for the patient, family, and healthcare provider. Two cases are presented to illustrate the complex issues that may arise in the terminally ill with a pacemaker or an ICD. Based on these cases and a review of published data, it is likely that the disabling of a previously placed pacemaker will neither hasten nor prolong the natural history of the underlying illness in most instances. There are uncommon but potentially severe adverse effects of disabling the pacemaker; therefore, pacemakers should generally be left intact in terminally ill patients. It is more difficult to generalize as to whether deactivation of an ICD is appropriate; in this case death may be hastened and the decision concerning an ICD will depend on the specific clinical scenario. Patient and family education regarding palliative care treatment goals and the function of pacemakers and other implanted arrhythmia

control devices can help to alleviate anxiety surrounding the impact of this technology at the end of life.

2 further articles from reading papers:

HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy. Rachel Lampert, David L Hayes, George J Annas, Margaret A Farley, Nathan E Goldstein, Robert M Hamilton, G Neal Kay, Daniel B Kramer, Paul S Mueller, Luigi Padeletti, Leo Pozuelo, Mark H Schoenfeld, Panos E Vardas, Debra L Wiegand, Richard Zellner, American Heart Association Heart Rhythm 07/2010; 7(7):1008-26.

Kramer D B, Buxton A E, Zimetbaum P J. Time for a change - a new approach to ICD replacement. NEJM 2012; 366: 291-3.

3. PubMed search up to 16 August 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND magnet

No limits

165 articles

(159 excluded as related to peri-operative use, and electromagnetic interference)

6 articles of interest identified and reviewed, all review articles:

 Canadian Cardiovascular Society/Canadian Anesthesiologists' Society/Canadian Heart Rhythm Society joint position statement on the perioperative management of patients with implanted pacemakers, defibrillators, and neurostimulating devices. Healey JS, Merchant R, Simpson C, Tang T, Beardsall M, Tung S, Fraser JA, Long L, van Vlymen JM, Manninen P, Ralley F, Venkatraghavan L, Yee R, Prasloski B, Sanatani S, Philippon F; Canadian Cardiovascular Society; Canadian Anesthesiologists' Society; Canadian Heart Rhythm Society.Can J Cardiol. 2012 Mar-Apr;28(2):141-51. doi: 10.1016/j.cjca.2011.08.121.

There are more than 200,000 Canadians living with permanent pacemakers or implantable defibrillators, many of whom will require surgery or invasive procedures

each year. They face potential hazards when undergoing surgery; however, with appropriate planning and education of operating room personnel, adverse devicerelated outcomes should be rare. This joint position statement from the Canadian Cardiovascular Society (CCS) and the Canadian Anesthesiologists' Society (CAS) has been developed as an accessible reference for physicians and surgeons, providing an overview of the key issues for the preoperative, intraoperative, and postoperative care of these patients. The document summarizes the limited published literature in this field, but for most issues, relies heavily on the experience of the cardiologists and anesthesiologists who contributed to this work. This position statement outlines how to obtain information about an individual's type of pacemaker or implantable defibrillator and its programming. It also stresses the importance of determining if a patient is highly pacemaker-dependent and proposes a simple approach for nonelective evaluation of dependency. Although the document provides a comprehensive list of the intraoperative issues facing these patients, there is a focus on electromagnetic interference resulting from electrocautery and practical guidance is given regarding the characteristics of surgery, electrocautery, pacemakers, and defibrillators which are most likely to lead to interference. The document stresses the importance of preoperative consultation and planning to minimize complications. It reviews the relative merits of intraoperative magnet use vs reprogramming of devices and gives examples of situations where one or the other approach is preferable.

 J Urgent implantable cardioverter defibrillator deactivation by unconventional means. Beets MT, Forringer E. Pain Symptom Manage. 2011 Dec;42(6):941-5.

Increasing numbers of patients are receiving implantable cardioverter defibrillators (ICDs); the devices remain fully functional in most terminally ill patients at the time of death. We describe a case of a terminally ill patient with repeated defibrillations who requested urgent ICD deactivation. Nonmedical magnets available in the facility were used to deactivate the ICD and terminate the defibrillations. We then studied various magnetic field sources commonly available in homes, such as ceramic magnets, cell phones, computer hard drives, headsets, and earbuds that potentially may be used to temporarily deactivate an ICD until a device technician is available for reprogramming. We conclude that commonly available magnetic sources may potentially be used to deactivate an ICD. The clinical usefulness of this is speculative and limited to conditions when the need to turn off the device is urgent, and a delay in reprogramming is anticipated.

 Clinical applications of magnets on cardiac rhythm management devices. Jacob S, Panaich SS, Maheshwari R, Haddad JW, Padanilam BJ, John SK.Europace. 2011 Sep;13(9):1222-30. doi: 10.1093/europace/eur137. Epub 2011 May 26.

The growing indications for permanent pacemaker and implantable cardioverter defibrillator (ICD) implantation have increased the number of patients with these cardiac rhythm management devices (CRMDs). Cardiac rhythm management devices occasionally perform inappropriately in response to electromagnetic interference (e.g. surgical electrocautery) or lead noise over-sensing (e.g. lead fracture). Temporary reprogramming of the CRMDs using device programmers can prevent these untoward device responses. However, these programmers are device manufacturer specific and require technically qualified personnel to operate. This could cause delayed patient care and increased use of resources in certain clinical situations. Alternatively, clinical magnets, when appropriately positioned over the device site, can change the pacing to an asynchronous mode in pacemakers and suspend tachycardia therapies in ICDs. Although readily available, clinical magnets have not been widely used for this purpose, perhaps due to the unfamiliarity with the variable responses of CRMDs to magnet application. This article provides a comprehensive overview of the current literature on the mechanism of action and the specific responses of various CRMDs to clinical magnets.

 Application of a clinical magnet over implantable cardioverter defibrillators: is it safe and useful? Pacing Clin Electrophysiol. 2008 Dec;31(12):1641-4; discussion 1645. doi:10.1111/j.1540-8159.2008.01239.x.

The growing number of implantable cardioverter defibrillator (ICD) implants mean that a high number of patients carrying these devices are attended by physicians. In an attempt to simplify their management, articles have been published on the safety of applying magnets to the ICD in order to avoid the administration of shocks during surgery. However, performance of these procedures without the supervision of expert personnel can be accompanied by serious and potentially fatal complications. We report a case where the use of a clinic magnet over an ICD caused it to switch to "end of life" in the battery indicator and lose some antitachycardia therapies.

 Shock therapy. How donut magnets can suspend inappropriate ICD shocks. Frascone R, Salzman J, Griffith K, Dunbar D.JEMS. 2008 Jul;33(7):104-7. doi: 10.1016/S0197-2510(08)70257-2. EMS crews encounter implantable cardioverter defibrillators (ICDs) daily, but these encounters rarely involve ICDs firing repeatedly on an awake, alert and understandably frightened individual. But that's exactly what happened when an EMS crew from Cottage Grove, Minn., responded to a man with a known heart condition who reported that his implantable defibrillator was firing inappropriately.

 Emergencies related to implantable cardioverter-defibrillators. Pinski SL.Crit Care Med. 2000 Oct;28(10 Suppl):N174-80

Implantable cardioverter-defibrillators (ICDs) have become the dominant therapeutic modality for patients with life-threatening ventricular arrhythmias. ICDs are implanted using techniques similar to standard pacemaker implantation. They not only provide high-energy shocks for ventricular fibrillation and rapid ventricular tachycardia, but also provide antitachycardia pacing for monomorphic ventricular tachycardia and antibradycardia pacing. Devices incorporating an atrial lead allow dual-chamber pacing and better discrimination between ventricular and supraventricular tachyarrhythmias. Intensivists are increasingly likely to encounter patients with ICDs. Electrosurgery can be safely performed in ICD patients as long as the device is deactivated before the procedure and reactivated and reassessed immediately afterward. Prompt and skilled intervention can prove to be life-saving in patients presenting with ICD-related emergencies, including lack of response to ventricular tachyarrhythmias, pacing failure, and multiple shocks. Recognition and treatment of tachyarrhythmia can be temporarily disabled by placing a magnet on top of an ICD. The presence of an ICD should not deter standard resuscitation techniques. Multiple ICD discharges in a short period of time constitute a serious situation. Causes include ventricular electrical storm, inefficient defibrillation, nonsustained ventricular tachycardia, and inappropriate shocks caused by supraventricular tachyarrhythmias or oversensing of signals. ICD system infection requires hardware removal and intravenous antibiotic therapy. Deactivation of an ICD with the consent of the patient or relatives is reasonable and ethical in terminally ill patients.

4. PubMed search up to 16 August 2014

((("Defibrillators, Implantable"[Mesh]) OR ("Pacemaker, Artificial"[Mesh])) AND (battery) AND (("Palliative Care"[Mesh]) OR ("Hospice and Palliative Care Nursing"[MeSH]) OR ("Terminal Care"[MeSH]))))

No limits

1 article identified and reviewed:

1. Fluur C, Bolse K, Strömberg A, Thylén I. Patients' experiences of the implantable cardioverter defibrillator (ICD); with a focus on battery replacement and end-of-life issues. Heart Lung. 2013 May-Jun;42(3):202-7.

5. PubMed search up to 16 August 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND (chest compression OR accidental shock)

No limits

17 articles identified, 15 excluded

2 case reports of relevance identified and reviewed:

- Stockwell B, Bellis G, Morton G, Chung K, Merton WL, Andrews N, Smith GB. Electrical injury during "hands on" defibrillation-A potential risk of internal cardioverter defibrillators? Resuscitation. 2009 Jul;80(7):832-4.
- Siniorakis E, Hardavella G, Arvanitakis S, Roulia G, Voutas P, Karidis C. Accidental shock to rescuer from an implantable cardioverter defibrillator. Resuscitation. 2009 Mar;80(3):293-4.

6. PubMed search up to 12 September 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Cardiopulmonary resuscitation"[MeSH]))

Limits: Human, English

Identified 126 articles

120 articles excluded as not related to performance of or outcome from CPR in people with CIEDs.

6 relevant publications identified and reviewed:	
Literature reviews	1
Observational studies	1
Case reports	4

 Accidental shock to rescuer from an implantable cardioverter defibrillator. Siniorakis E, Hardavella G, Arvanitakis S, Roulia G, Voutas P, Karidis C.Resuscitation. 2009 Mar;80(3):293-4. doi: 10.1016/j.resuscitation.2008.10.032.
 Epub 2008 Dec 27.

A 74-year-old patient with heart failure and pneumonia had a cardiac arrest with an initial rhythm of pulseless electrical activity. He had a surgical scar in the left subclavian area suggesting he had a pacemaker. The patient's electrocardiogram (ECG) showed a paced rhythm. Cardiopulmonary resuscitation (CPR) was started immediately. Ten minutes after starting CPR, the rescuer (not wearing gloves) who was doing chest compressions received an electric shock that threw him backwards and caused neck and back pain.

- Hazards of performing chest compressions in collapsed patients with internal cardioverter defibrillators. Clements PA. Emerg Med J. 2003 Jul;20(4):379-80. The potential dangers to the rescuer performing chest compressions on a patient with an internal cardioverter defibrillator (ICD) are described. Simple measures to avoid these are discussed.
- When an AED meets an ICD... Automated external defibrillator. Implantable cardioverter defibrillator. Calle PA, Buylaert W. Resuscitation. 1998 Sep;38(3):177-83.

The chances of prehospital care providers being confronted with a patient with an implantable cardioverter defibrillator (ICD) are increasing and so care providers must receive proper training. Based on observations made during the resuscitation of a patient with an ICD using an automated external defibrillator (AED) some technical features and possible interactions of ICDs and AEDs are highlighted. Furthermore, we discuss the key points of basic knowledge, safety, and treatment protocols for

cardiac arrest and other situations required for practical training in the ICD for prehospital care providers.

 Implantable cardioverter-defibrillators: implications for the nonelectrophysiologist. Pinski SL, Trohman RG. Ann Intern Med. 1995 May 15;122(10):770-7.
 Comment in: Ann Intern Med. 1995 Dec 1;123(11):892-3.

PURPOSE: To review clinical scenarios in which nonelectrophysiologist physicians may interact with patients who have implantable defibrillators.

DATA SOURCES: Peer-reviewed original articles and reviews addressing aspects of implantable defibrillator therapy that are relevant to the clinician.

DATA SYNTHESIS: The capacity of implantable defibrillators to recognize and treat tachyarrhythmias can be temporarily disabled by placing a magnet on top of all devices. General surgery, radiotherapy, lithotripsy, and electroconvulsive therapy can usually be safely done under continuous electrocardiographic monitoring in patients with implantable defibrillators. The device should be deactivated before the procedure is done and reactivated and reassessed immediately afterward. Magnetic resonance imaging is usually contraindicated in patients with implantable defibrillators. The presence of an implantable defibrillator should not deter standard resuscitation techniques. Multiple defibrillator discharges in a short period of time represent a serious problem. Causes of multiple discharges include ventricular electric storm, inefficient defibrillation, nonsustained ventricular tachycardia, and inappropriate shocks caused by supraventricular tachyarrhythmias or oversensing of signals. These patients should be initially evaluated in a setting that allows electrocardiographic monitoring and cardiac resuscitation. The defibrillator should be deactivated if inappropriate firing is documented. Infections of implantable defibrillator systems are potentially life-threatening, and empiric oral antibiotic therapy should never be given when this possibility exists. Adjustment disorders specific to the defibrillator, including anxiety with secondary panic reaction; defibrillator dependence, abuse, or withdrawal; and imaginary shocks are not uncommon.

CONCLUSIONS: Defibrillator therapy has become increasingly popular and complex. A basic understanding of these devices and skills in the short-term management of device-related problems is valuable for most physicians. These management guidelines will facilitate delivery of optimal care when specialized staff and material resources are not available.

- 5. Electric shock to paramedic during cardiopulmonary resuscitation of patient with implanted cardiodefibrillator. Lechleuthner A. Lancet. 1995 Jan 28;345(8944):253.
- Stability of permanent transvenous dual-chamber pacing electrodes during cardiopulmonary resuscitation. Madigan NP, Mueller KJ, Curtis JJ, Walls JT. Pacing Clin Electrophysiol. 1983 Nov;6(6):1234-40.

For long-term dual-chamber permanent pacing, atrial and ventricular lead stability is essential. In our overall experience with such pacing systems, four patients suffered cardiac arrest at a time distant from their pacemaker implantation. Since all four patients received prolonged closed chest cardiopulmonary resuscitation, we analyzed these events to determine whether dual-chamber endocardial electrodes would remain stable in such traumatic conditions. Reliable atrial and ventricular lead position was confirmed at autopsy in the three patients whose resuscitation attempts were unsuccessful and, in the fourth patient, by continued normal lead position and pacing function post-resuscitation. The keys to this stability include the use of tined atrial and ventricular endocardial leads and specific maneuvers at the time of implantation to verify fixation. Long-term stability of presently available endocardial leads in dual-chamber pacing systems can thus be anticipated.

7. PubMed search up to 8 September 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Autopsy"[MeSH])

Limits: Human

Identified 178 articles

Most articles excluded as not related to management of CIEDs after death and/or not in English.

12 relevant studies identified and reviewed:Editorials/overviews5Literature review1Observational studies2Case reports4

 Implantable cardioverter-defibrillators: is there life after death? Van Heuverswyn FE, Timmers L, Stroobandt RX, Barold SS. Pacing Clin Electrophysiol. 2013 Jan;36(1):2-6. doi: 10.1111/pace.12023. Epub 2012 Oct 27.

No abstract available.

Introduction

The implantable cardioverter-defibrillator (ICD) is the only therapy proven to reduce the risk of sudden cardiac death for both primary and secondary prevention. A recent worldwide survey has shown a substantial increase in the number of ICDs being implanted.¹ This impressive growth poses a significant burden to healthcare systems, as the demand for ICD therapy is likely to parallel the growth in the aging population. Yet, information about the fate of ICDs after death remains scarce. Thousands of ICDs with good battery life end up being buried or are disposed of as medical waste after explantation, never to be analyzed or reused. As physicians, it is our moral duty to be stewards of scarce medical resources. One way to fulfill this duty is the reuse of ICDs in those in need in impoverished nations.

 Destructive device removal - sparks and deletion of therapy history from an implantable cardioverter defibrillator. Kurita T, Ueda S, Okamura H, Noda T, Satomi K, Suyama K, Shimizu W, Aihara N, Miyazaki S, Kamakura S.

Int Heart J. 2009 Nov;50(6):823-7.

A 74-year-old female with a diagnosis of idiopathic dilated cardiomyopathy and ventricular tachycardia died suddenly 9 years after an implantation of an implantable cardioverter-defibrillator (ICD). The destructive removal of an ICD generator and the leads by an uninformed coroner resulted in the loss of the fragile electrograms during the terminal episodes of VT/VF and caused severe charring on the surface of the ICD generator. In order to observe the conditions in which the shock deliveries occurred during the noise detection, we programmed the ICD to deliver the maximum shock energy via a programmer while keeping continuous contact between the device surface and shock lead. The maximum shock energy of 31 Joules produced significant sparks from the surface of the ICD. To avoid the loss of data from an ICD and injury to the patient, widespread notification and education through appropriate scientific societies about the functions of ICDs are highly recommended.

 Electronic medical devices: a primer for pathologists. Weitzman JB. Arch Pathol Lab Med. 2003 Jul;127(7):814-25. Review. CONTEXT: Electronic medical devices (EMDs) with downloadable memories, such as implantable cardiac pacemakers, defibrillators, drug pumps, insulin pumps, and glucose monitors, are now an integral part of routine medical practice in the United States, and functional organ replacements, such as the artificial heart, pancreas, and retina, will most likely become commonplace in the near future. Often, EMDs end up in the hands of the pathologist as a surgical specimen or at autopsy. No established guidelines for systematic examination and reporting or comprehensive reviews of EMDs currently exist for the pathologist.

OBJECTIVE: To provide pathologists with a general overview of EMDs, including a brief history; epidemiology; essential technical aspects, indications, contraindications, and complications of selected devices; potential applications in pathology; relevant government regulations; and suggested examination and reporting guidelines.

DATA SOURCES: Articles indexed on PubMed of the National Library of Medicine, various medical and history of medicine textbooks, US Food and Drug Administration publications and product information, and specifications provided by device manufacturers.

STUDY SELECTION: Studies were selected on the basis of relevance to the study objectives.

DATA EXTRACTION: Descriptive data were selected by the author.

DATA SYNTHESIS: Suggested examination and reporting guidelines for EMDs received as surgical specimens and retrieved at autopsy.

CONCLUSIONS: Electronic medical devices received as surgical specimens and retrieved at autopsy are increasing in number and level of sophistication. They should be systematically examined and reported, should have electronic memories downloaded when indicated, will help pathologists answer more questions with greater certainty, and should become an integral part of the formal knowledge base, research focus, training, and practice of pathology.

 "Natural death" of a patient with a deactivated implantable-cardioverter-defibrillator (ICD)? Junge M, Weckmüller J, Nägele H, Püschel K.

Forensic Sci Int. 2002 Feb 18;125(2-3):172-7.

A 66-year-old patient with terminal heart insufficiency (NYHA IV) received maximum medical therapy, but was also in need of an implantable-cardioverter-defibrillator (ICD). The ICD functioned flawlessly for the whole duration of implantation. It reverted several ventricular tachycardias with anti-tachycardial pacing alone, whereas some needed cardioversion as well. The patient died on the fourth day of hospitalization for a routine check of his ICD. The post-mortem examination revealed,

that the ICD was deactivated and that the data had been erased after the patient's death. By reading off the raw data still stored within the ICD, the erased information could be restored. The stored EGMs showed traces of old ICD interventions as well as a permanent deactivation provoked by exposition to a magnetic field just hours before the patient's death. The problem of archiving and documenting the volatile electronic data inside the ICD is discussed. The need of a full autopsy after telemetric reading of the ICD data, including the explanation of the ICD aggregate and electrodes, as a means of quality assurance and under forensic aspects is emphasized.

 Automatic implantable cardioverter defibrillator rhythm strip data as used in interpretation of a motor vehicle accident. Dolinak D, Guileyardo J. Am J Forensic Med Pathol. 2001 Sep;22(3):256-60.

The automatic implantable cardioverter defibrillator (AICD) is an electronic device that monitors the rhythm of the heart and, upon detecting a life-threatening arrhythmia, shocks the heart in an attempt to restore a normal rhythm. The AICD will electronically store the information of the event. Later, the AICD can be "interrogated" and the information electronically retrieved, with a printout of the rhythm strip obtained. The interrogation is fairly simple and involves a magnetic device placed over the AICD, which in turn is connected to a portable computer, which, with specialized software, can deliver the information in a usable form. Not only can information about the most recent shock be obtained, but also information about previous shocks can be retrieved. This case presentation highlights how such preterminal information retrieved from an AICD helped to interpret the circumstances leading to a death--in this case, a fatal motor vehicle accident. Additionally, driving restrictions that may be placed on individuals with AICDs are discussed.

 Implantable cardioverter-defibrillators and the pathologist: comment and cautionary notes. Walley VM, Bourke ME, Green M, Stinson WA, Veinot JP.

J Forensic Sci. 1998 Sep;43(5):969-73. Review.

This paper briefly reviews the components of, the clinical uses of, the techniques to place, and the complications related to implantable cardioverter-defibrillators (ICDs). Information useful in the specific identification of ICDs is presented. A series of recommendations for the autopsy examination or postmortem explantation of ICDs by the pathologist is given. Because of the serious risk of injury to the pathologist possible with postmortem discharges of ICDs which have not been deactivated, and because of the risk of device explosion if the ICD is incinerated, a number of

cautionary notes are provided. A brief case with occurrence of accidental postmortem discharge of an active ICD is also presented.

 The implantable cardioverter-defibrillator. A potential hazard for autopsy pathologists. Prahlow JA, Guileyardo JM, Barnard JJ. Arch Pathol Lab Med. 1997 Oct;121(10):1076-80.

The implantable cardioverter-defibrillator (ICD) is an implantable electronic device that has been proven to be safe and effective in treating various malignant tachyarrhythmias in susceptible individuals. As the use of ICDs becomes more widespread, more individuals with the implanted devices will be encountered at autopsy. Manipulation of an activated ICD can result in electrical shock. To avoid injury, pathologists must be properly prepared to deal with bodies containing activated ICDs. These devices can also provide valuable information that may be helpful in determining the cause and mechanism of death. Herein, we present information regarding the appropriate guidelines and safeguards for pathologists confronted with an activated ICD.

 Exploration of the precision of classifying sudden cardiac death. Implications for the interpretation of clinical trials. Pratt CM, Greenway PS, Schoenfeld MH, Hibben ML, Reiffel JA. Circulation. 1996 Feb 1;93(3):519-24.

BACKGROUND: As cardiovascular clinical trials improve in sophistication and therapies target specific cardiac mechanisms of death, a more objective and precise system to identify specific cause of death is needed. Ideally, sudden cardiac death would describe patients dying of ventricular tachycardia and ventricular fibrillation. In this context, we explored the precision of current sudden death classification and implications for clinical trials.

METHODS AND RESULTS: Deaths were analyzed in 834 patients who received an automatic implantable cardioverter-defibrillator (ICD). Three arrhythmia experts used a standard prospective classification system to classify deaths into accepted categories: sudden cardiac, nonsudden cardiac, and noncardiac. New aspects to this study included analysis of autopsy results and ICD interrogation for arrhythmias at the time of death. All of the patients receiving the ICD previously had documented sustained ventricular tachycardia/fibrillation or cardiac arrest. Of the 109 subsequent deaths in the 834-patient database, 17 (16%) were classified as sudden cardiac. Compared with the nonsudden cardiac and noncardiac categories, sudden cardiac death was more often identified in outpatients (59% versus 10%) and witnessed less often (41% versus 86%; both P < .001). The autopsy information contradicted and

changed the clinical perception of a "sudden cardiac death" in 7 cases (myocardial infarction [n = 1], pulmonary embolism [n = 2], cerebral infarction [n = 1], ruptured thoracic [n = 1], and abdominal aortic aneurysms [n = 2]). Interpretable ICD interrogation was available in 53% of the deaths (47% unavailable: buried, programmed off, or other technical reasons). When evaluated, only 7 of 17 "sudden deaths" were associated with ICD discharges near the time of death.

CONCLUSIONS: Even in a group of patients with an ICD, deaths classified as sudden cardiac frequently were not associated with ventricular tachycardia or ventricular fibrillation and were often noncardiac. It is possible to create a wide range of sudden cardiac death rates (more than fourfold) using the identical clinical database despite objective, prespecified criteria. Autopsy results frequently reveal noncardiac causes of clinical events simulating sudden cardiac death. ICD interrogation revealed that ICD discharges were often related to terminal arrhythmias incidental to the primary pathophysiological process leading to death.

 Stability of permanent transvenous dual-chamber pacing electrodes during cardiopulmonary resuscitation. Madigan NP, Mueller KJ, Curtis JJ, Walls JT. Pacing Clin Electrophysiol. 1983 Nov;6(6):1234-40.

For long-term dual-chamber permanent pacing, atrial and ventricular lead stability is essential. In our overall experience with such pacing systems, four patients suffered cardiac arrest at a time distant from their pacemaker implantation. Since all four patients received prolonged closed chest cardiopulmonary resuscitation, we analyzed these events to determine whether dual-chamber endocardial electrodes would remain stable in such traumatic conditions. Reliable atrial and ventricular lead position was confirmed at autopsy in the three patients whose resuscitation attempts were unsuccessful and, in the fourth patient, by continued normal lead position and pacing function post-resuscitation. The keys to this stability include the use of tined atrial and ventricular endocardial leads and specific maneuvers at the time of implantation to verify fixation. Long-term stability of presently available endocardial leads in dual-chamber pacing systems can thus be anticipated.

 Complications of defibrillation with permanent pacemaker in situ. Aylward P, Blood R, Tonkin A. Pacing Clin Electrophysiol. 1979 Jul;2(4):462-4.

A permanent demand pacing generator was implanted in the right deltopectoral fossa with unipolar transvenous lead advanced to the right ventricle. Implant and subsequent pacing parameters were normal. Five days later an emergency DC cardioversion was performed with one paddle 2 inches from the generator.

Cardioversion was followed by failure of QRS-sensing and, at immediate explant, rise in stimulation threshold. The pulse generator showed end-of-life characteristics. The patient died 4 days following replacement of the generator and lead. At autopsy, right ventricular infarction was found, presumably relating to current discharge along the lead. Pacemaker analysis showed damage to the protection zener diode and oscillator integrated circuit of the generator during cardioversion.

11. Pacemaker postmortem. Raasch FO. West J Med. 1978 Jan;128(1):48-9. No abstract available.

The cardiac pacemaker stands in the forefront of the bionic age. Thousands of people now live and eventually will die with a complex electrical pulse generator functioning inside their bodies. This generator provides a substitute electrical impulse for the heart's completely or incompletely blocked electrical system. In death, the question sometimes arises whether a pacemaker malfunction or complication contributed in any way. The pathologist, therefore, should examine the pacemaker and its lead as an integral part of an autopsy. He or she always should ask: (1) Was there a signal? (2) Was it effective? (3) Could anything have altered it? The generator should be tested electronically for rate, pulse amplitude, pulse width and R-wave inhibition. Any hospital where pacemakers are implanted should have a device that can test for these. The lead should be inspected in situ before removal to make sure it is in the proper location and is providing a proper myocardial contact. Testing at the lead terminal will establish its continuity with the generator. The history is important to determine if some outside electrical exposure such as electrocautery could have affected the unit. The presence of the pacemaker as a foreign body can complicate matters. The implant site can become infected and the infection may migrate down the lead into the circulatory system. Thrombi may form about the lead and provide a source of emboli. Testing of cardiac pacemakers postmortem not only aids in determining the cause of death but also, on a larger scale, helps prevent other deaths by monitoring for product defects. These should be reported to the Bureau of Medical Devices, Food and Drug Administration.

12. Pacemaker postmortem. Raasch F Jr. Leg Med Annu. 1977:97-110. No abstract available.

8. PubMed search up to 8 September 2014

(("Defibrillators, Implantable"[MeSH]) OR ("Pacemaker, Artificial"[MeSH])) AND ("Cremation"[MeSH])

Limits: Human, English

Identified 11 articles

5 articles excluded as not related to management of CIEDs after death.

6 relevant studies identified and reviewed:	
Editorial reviews	2
Observational studies	2
Survey of funeral directors, patients, members of the public	:1
Survey of crematoria	1

 Implanted cardiac devices are reliably detected by commercially available metal detectors. Holm KF, Hjortshøj S, Pehrson S, Svendsen JH, Riahi S. Scand Cardiovasc J. 2013 Oct;47(5):271-4. doi: 0.3109/14017431.2013.823516. Epub 2013 Aug 12.

OBJECTIVE: Explosions of Cardiovascular Implantable Electronic Devices (CIEDs) (pacemakers, defibrillators, and loop recorders) are a well-recognized problem during cremation, due to lithium-iodine batteries. In addition, burial of the deceased with a CIED can present a potential risk for environmental contamination. Therefore, detection of CIEDs in the deceased would be of value. This study evaluated a commercially available metal detector for detecting CIEDs.

DESIGN: Observational study including pacemaker patients (n = 70) and a control group without pacemaker (n = 95). The investigational device was a hand-held metal detector for detecting metal or electricity wiring.

RESULTS: The metal detector detected the pacemaker in all pacemaker patients and thus exhibited a sensitivity of 100%. The specificity of the metal detector was 86%, and the negative predictive value was 100%. Thirteen individuals without pacemakers were falsely identified as having an implanted device due to implanted prosthetic material or elements of clothing.

CONCLUSION: A simple hand-held metal detector may detect CIEDs with a high sensitivity. It may be of value in detecting CIEDs in deceased persons before burial or cremation. Any signal detected by the metal detector should prompt further investigation of the body and patient files.

 Societal views of pacemaker reutilization for those with untreated symptomatic bradycardia in underserved nations. Gakenheimer L, Lange DC, Romero J, Kirkpatrick JN, Sovitch P, Oral H, Eagle KA, Baman TS. J Interv Card Electrophysiol. 2011 Apr;30(3):261-6. doi: 10.1007/s10840-010-9534-0. Epub 2011 Jan 20.

PURPOSE: Significant healthcare disparities exist between the developed world and low and middle income countries (LMIC), specifically in the field of cardiac electrophysiology. As a result, pacemaker reutilization has been proposed as a viable option for those in LMIC and no other means of obtaining a device. Little data exist regarding the feasibility of establishing a reuse program in addition to understanding the views of society on device reutilization. This study investigated the views of funeral directors, patients with cardiac devices, and members of the general population regarding reutilization of previously implanted pacemakers.

METHODS: Ninety funeral directors in Michigan were surveyed regarding current practice as well as preferences for post-mortem device disposal. One hundred and fourteen patients with devices and 1,009 members of the general population were surveyed regarding post-mortem device handling.

RESULTS: Funeral directors had an average of 21 years of experience with an annual volume of 120 deceased persons per year, with a cremation rate of 35%. When asked about disposal methods of explanted devices, the majority of devices (84%) were discarded as medical waste or stored with no intended purpose, with a total of 171 devices currently in possession at the funeral homes. Eighty-nine percent of funeral directors expressed a desire to donate devices for reuse in LMIC and 10% acknowledged previous device donation. Eighty-seven percent of device patients and 71% of the general population also expressed a desire to donate devices.

CONCLUSIONS: The results of our survey show that a large percentage of funeral directors, patients with implantable devices, and members of the general population support a pacemaker reutilization initiative. This study lends further evidence that collection of devices for reuse is feasible and that establishing a framework for regional pacemaker reutilization program is warranted. If successful, the feasibility of this model should be investigated in other parts of the country in order to alleviate the burden of untreated symptomatic bradycardia in our world.

 Simple hand-held metal detectors are an effective means of detecting cardiac pacemakers in the deceased prior to cremation. Stone JL, Williams J, Fearn L. J Clin Pathol. 2010 May;63(5):463-4. doi: 10.1136/jcp.2009.073684. Epub 2010 Apr 1. The hazard of undetected cardiac pacemakers exploding in crematoria is well described. This short report describes the use of an affordable hand-held metal detector to detect cardiac pacemakers. Over the course of a year, the metal detector located 100% of cardiac pacemakers in a district general hospital mortuary. A simple model using pigskin and fat is also used to demonstrate the effectiveness in vitro. Commercially purchased hand-held metal detectors should be used in all mortuaries responsible for detection and removal of cardiac pacemakers prior to cremation.

 Pacemaker explosions in crematoria: problems and possible solutions. Gale CP, Mulley GP. J R Soc Med. 2002 Jul;95(7):353-5.

The number of artificial cardiac pacemakers is increasing, as is the number of bodies being cremated. Because of the explosive potential of pacemakers when heated, a statutory question on the cremation form asks whether the deceased has a pacemaker and if so whether it has been removed. We sent a questionnaire to all the crematoria in the UK enquiring about the frequency, consequences and prevention of pacemaker explosions. We found that about half of all crematoria in the UK experience pacemaker explosions, that pacemaker explosions may cause structural damage and injury and that most crematoria staff are unaware of the explosive potential of implantable cardiac defibrillators. Crematoria staff rely on the accurate completion of cremation forms, and doctors who sign cremation forms have a legal obligation to provide such information.

 Hidden hazards of cremation. [Editorial: No authors listed]. Br Med J. 1977 Dec 24-31;2(6103):1620-1. No original abstract available.

In recent years the number and variety of metal and plastic objects implanted in patients have increased steadily. Little notice was taken of the presence of surgical hardware post mortem until September 1976, when the mercury zinc batteries in a pacemaker left in a body exploded during cremation with force sufficient to damage the brickwork lining of the cremation chamber. In the course of their duties those working at the crematorium periodically observe the process of cremation, and an explosion on this scale could cause injuries or even death.

Lithium batteries may well replace zinc mercury batteries in pacemakers, and when heated to a high temperature these are even more explosive. A body intended for cremation which contains a pacemaker or a radioactive implant should not, therefore, be released to an undertaker. The pacemaker should be removed, but if it is not possible to remove a radioactive implant the undertaker should be given precise information regarding its nature, size, and location.

6. Pacemakers and cremation. [Editorial: No authors listed]. N Z Med J. 1977 Sep 14;86(595):228. No abstract available.