University Hospitals of North Midlands NHS
NHS Trust

Device deactivation: when to discuss with the patient, when to do it.

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Heart Rhythm Congress
www.heartrhythmcongress.org

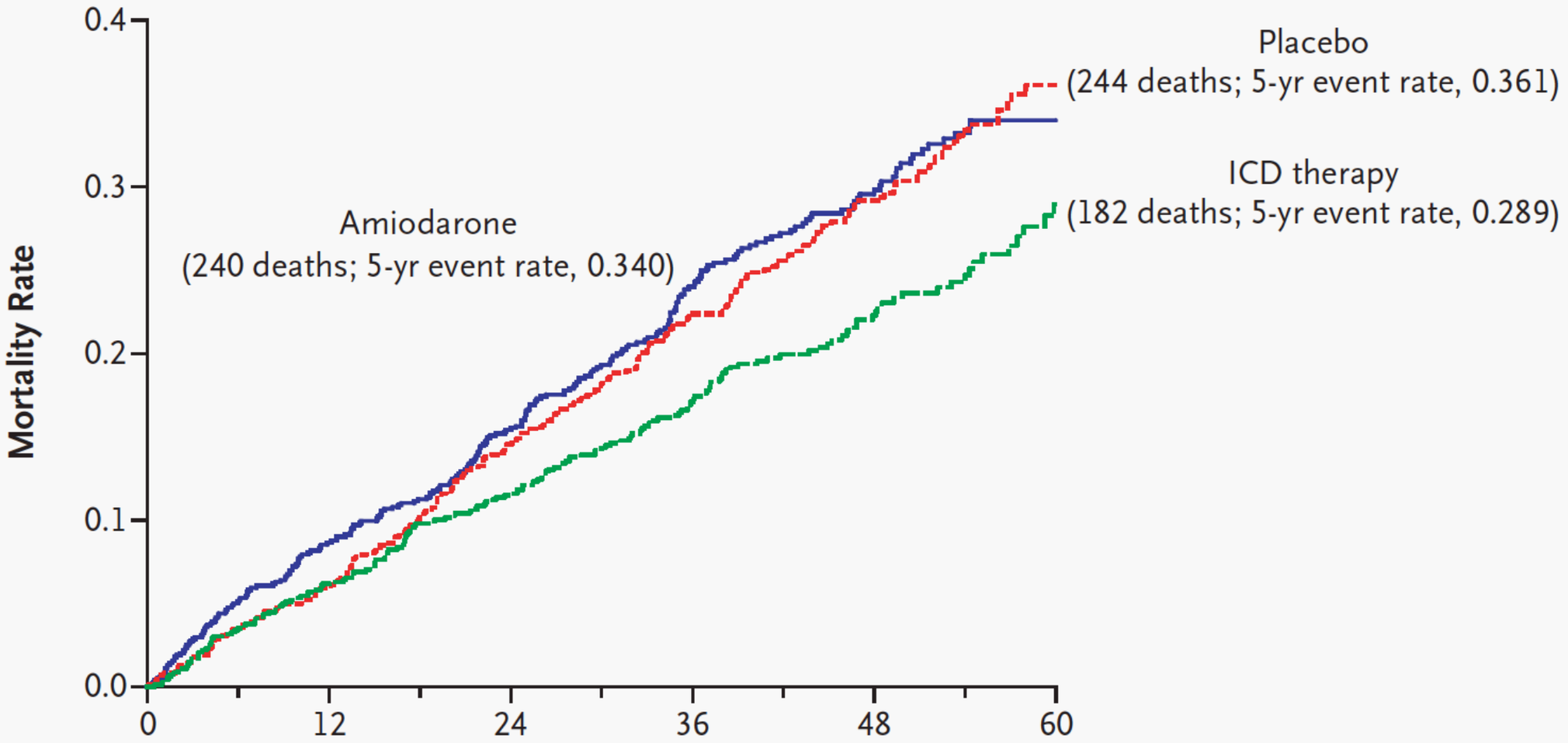
Short Version

Before implant

During follow up

At palliative phase

	Hazard Ratio (97.5% CI)	P Value
Amiodarone vs. placebo	1.06 (0.86–1.30)	0.53
ICD therapy vs. placebo	0.77 (0.62–0.96)	0.007

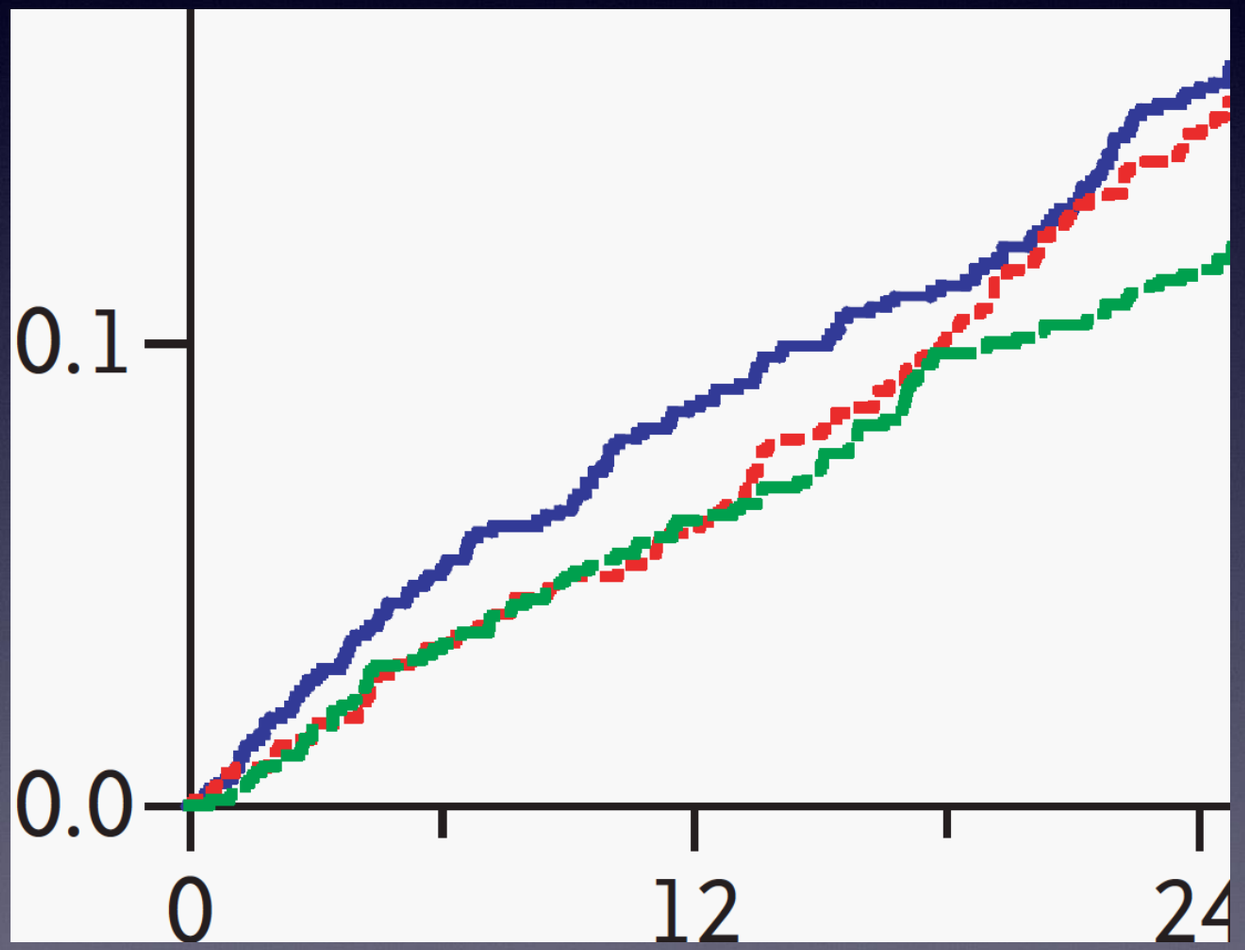


No. at Risk						
Amiodarone	845	772	715	484	280	97
Placebo	847	797	724	505	304	89
ICD therapy	829	778	733	501	304	103

Brady et al. N Engl J Med 2005;352:225-37

ICD in Advanced Heart Failure

- There is little data for ICD usage in end stage heart failure
- All the randomised trials excluded NYHA IV patients
- SCD Heft showed
  - The survival benefit was confined to NYHA II patients
  - There was no survival benefit till 18 months after implant



Brady et al. N Engl J Med 2005;352:225-37

ICD in Advanced Heart Failure

- Widely accepted that ICDs should not be implanted in patients in their last year of life

- But many patients may progress to end stage HF in the years after ICD implantation

- In the MADIT-2 trial the efficacy of ICDs was maintained after the 1st HF hospitalisation but attenuated with further hospitalisations

When do discussion actually take place

- There is a gap between the guidelines and real life clinical practice
- In one series of interviews with 15 ICD patients, none remembered a conversation about ICD deactivation prior to implantation
- EHRA conducted a survey of 47 ICD implanting centres in 2010. Only 4% of cardiologist discussed ICD deactivation prior to implantation

Goldstein NE, Mehta D, Siddiqui S, et al. ‘That’s like an act of suicide’ patients’ attitudes toward deactivation of implantable defibrillators. J Gen Intern Med 2008;23 suppl 1:7–12.
Marinskis G, van Erven L; EHRA Scientifi c Initiatives Committee. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. Europace 2010;12:1176–1177

When do discussion actually take place

- In the EHRA survey only
  - 11% of cardiologist were regularly involved in ICD deactivations
  - 4% provided written information about options for ICD management in terminally ill patients.

Marinskis G, van Erven L; EHRA Scientifi c Initiatives Committee. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. Europace 2010;12:1176–1177

When do discussion actually take place

- Deactivation discussion occur more frequently as patients deteriorate.
- In a retrospective study of a 100 patients who had died with an ICD, deactivation had been discussed with 27% of patients before death
  - When discussions occurred they were close to death
    - 74% in the last days of life
    - 22% in the last hours of life
    - 4% in the last minutes of life
- Even in hospices only 47% of patients had their ICD deactivated whilst receiving hospice care

Pettit et al BMJ Supportive & Palliative Care 2012;**2**:94–97

Why is there a delay in deactivation?

- In the EHRA survey
  - 83% of cardiologist thought a ICD should be deactivated after multiple shocks in dying patients
  - Only 49% of these felt that ICD should be deactivated in end stage heart failure

Marinskis G, van Erven L; EHRA Scientifi c Initiatives Committee. Deactivation of implanted cardioverter-defibrillators at the end of life: results of the EHRA survey. Europace 2010;12:1176–1177

Why is there a delay in deactivation?

- In a US study of 147 doctors with experience of ICD management
  - 86% felt comfortable dealing with patients at the end of life
  - 62% lacked confidence in predicting the possibility of ICD shocks near the end of life
  - Interestingly most physicians thought their patients understood why they had a ICD and were aware of ICD deactivation as a option

Pettit et al BMJ Supportive & Palliative Care 2012;**2**:94–97

Patient Views

- Very limited data on patient attitudes
- In a series of interviews in the US
  - Most patients were keen to talk about their ICD but reluctant to engage in conversations about deactivation
  - Several patients thought that their physicians should take such decisions
  - Only a few patients knew that the shock function of their ICD could be deactivated

Box 2 Patients have limited understanding about their condition

Patients have limited understanding of their diagnosis:
The left ventricle isn't working properly. When I had the heart attack it damaged it a bit so that is what I was told, that is all I know. Female, age 72

Patients have limited understanding of their prognosis:
I mean I'm not an expert but I've got an idea of what's happening. I know what's caused this, it doesn't scare me. I mean if it was killing me, well it is, I suppose, but I just forget that bit. I don't think I'm going to die next week. Male, age 67

Patients have limited understanding of implantable cardioverter defibrillator function:
I have got a what do you call it fitted, a defibrillator which helps to keep you alive and the medicine that they will give me will hopefully monitor my heart system. But that is what they have told me. I am actually quite floored with it. Male, age 65

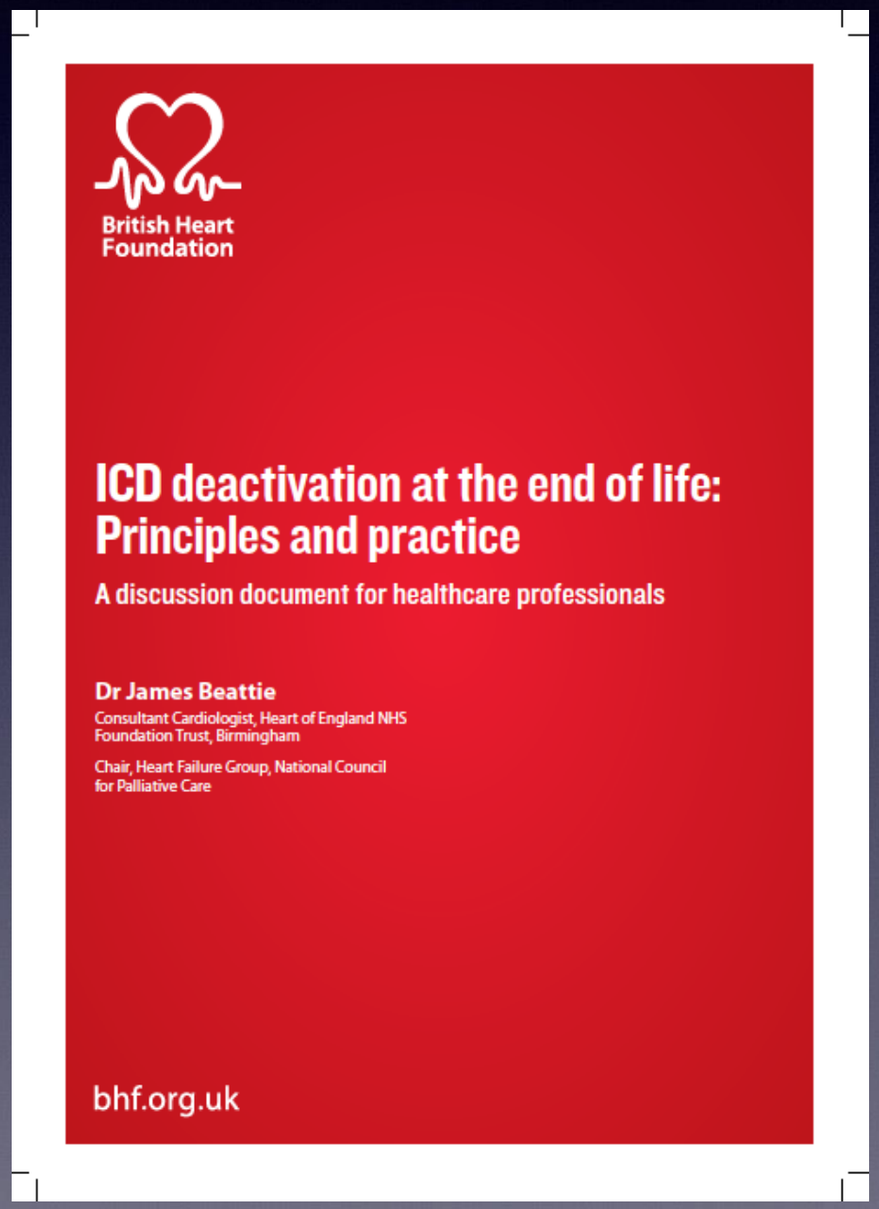
Pettit et al BMJ Supportive & Palliative Care 2012;**2**:94–97

- Research has cast doubt on the common assumption that older individuals with end-stage heart failure favour quality of life over longevity

- Among 622 patients aged >60 with chronic heart failure
  - 74% were not willing to trade survival time for improved quality of life
  - 51% wished to be resuscitated if necessary

Pettit et al BMJ Supportive & Palliative Care 2012;**2**:94–97

ICD deactivation guidelines


British Heart Foundation

ICD deactivation at the end of life: Principles and practice

A discussion document for healthcare professionals

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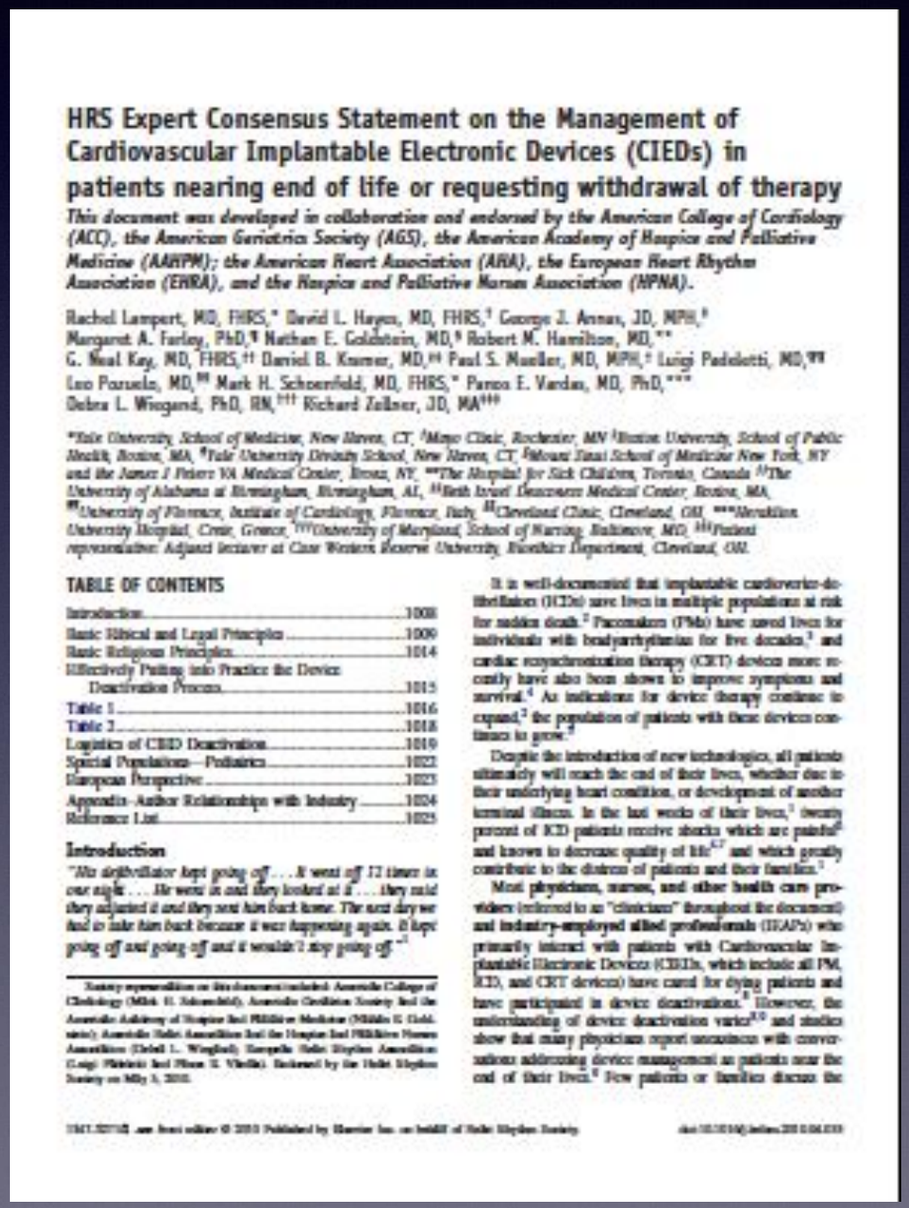
bhf.org.uk


HRS Expert Consensus Statement on the Management of Cardiovascular Implantable Electronic Devices (CIEDs) in patients nearing end of life or requesting withdrawal of therapy

This document was developed in collaboration and endorsed by the American College of Cardiology (ACC), the American Geriatrics Society (AGS), the American Academy of Hospice and Palliative Medicine (AAHPM); the American Heart Association (AHA), the European Heart Rhythm Association (EHRA), and the Hospice and Palliative Nurses Association (HPNA).

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Introduction

"My defibrillator kept going off . . . It went off 12 times in one night . . . He went in and they looked at it . . . they said they adjusted it and they sent him back home. The next day we had to take him back because it was happening again. It kept going off and going off and it wouldn't stop going off."[1]

It is well-documented that implantable cardioverter-defibrillators (ICDs) save lives in multiple populations at risk for sudden death.[2] Pacemakers (PMs) have saved lives for individuals with bradyarrhythmias for five decades,[3] and cardiac resynchronization therapy (CRT) devices more recently have also been shown to improve symptoms and survival.[4] As indications for device therapy continue to expand,[5] the population of patients with these devices continues to grow.[6]

Despite the introduction of new technologies, all patients ultimately will reach the end of their lives, whether due to their underlying heart condition, or development of another terminal illness. In the last weeks of their lives,[7] twenty percent of ICD patients receive shocks which are painful[8] and known to decrease quality of life[8,9] and which greatly contribute to the distress of patients and their families.[1]

Most physicians, nurses, and other health care providers (referred to as "clinicians" throughout the document) and industry-employed allied professionals (IEAPs) who primarily interact with patients with Cardiovascular Implantable Electronic Devices (CIEDs, which include all PM, ICD, and CRT devices) have cared for dying patients and have participated in device deactivations.[1] However, the understanding of device deactivation varies[9,10] and studies show that many physicians report uncertainty with conversations addressing device management as patients near the end of their lives.[9] How patients or families discuss the

Before implant

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

European Heart Rhythm Association, 2010[16]

Table 2 Steps for your conversation

Timing of conversation	Points to be covered	Helpful phrases to consider
Prior to Implantation	• Clear discussion of the benefits and burdens of the device. • Brief discussion of potential future limitations or burdensome aspects of device therapy • Encourage patients to have some form of advance directive • Inform of option to deactivate in the future	"It seems clear at this point that this device is in your best interest, but you should know at some point if you become very ill from your heart disease or another process you develop in the future, the burden of this device may outweigh its benefit. While that point is hopefully a long way off, you should know that turning off your defibrillator is an option."

ICD deactivation at end of life needs to be part of the pre-implantation consent and counselling process, and formalised in advance care planning if the patient is agreeable[15].

A comprehensive assessment of the overall benefits and implications of ICD therapy should be undertaken based on a patient's needs and preferences, prior to implantation.

During follow up

- The appropriateness of maintaining device therapy must be regularly reviewed as part of monitoring of the patient's progressive disease trajectory, if there is any change in clinical status including the development of a life limiting disease, and when the ICD generator box is considered due for replacement[29, 30].

After an episode of increased or repeated firings from an ICD	• discussion of possible alternatives, including adjusting medications, adjusting device settings, and cardiac procedures to reduce future shocks in context of goals of care	"I know that your device caused you some recent discomfort and that you were quite distressed. Lets see if we can find a correctable reason why this may be happening, and discuss options to decrease the number of firings."
Progression of cardiac disease, including repeated hospitalizations for heart failure and/or arrhythmias	• re-evaluation of benefits and burdens of device • assessment of functional status, quality of life, and symptoms • Referral to palliative and supportive care services	"It appears as though your heart disease is worsening. We should really talk about your thoughts and questions about your illness at this point and see if your goals have changed at all."

At palliative phase

When patient/surrogate chooses a Do Not Resuscitate Order	• re-evaluation of benefits and burdens of device • exploration of patient's understanding of device and how s/he conceptualizes it with regards to external • defibrillation • Referral to palliative care or supportive services	"Now that we've established that you would not want resuscitation in the event your heart was to go into an abnormal pattern of beating, we should reconsider the role of your device. In many ways it is also a form of resuscitation. Tell me your understanding of the device and let's talk about how it fits into the larger goals for your medical care at this point."
Patients at End of Life	• re-evaluation of benefits and burdens of device • discussion of option of deactivation addressed with all patients, though deactivation *not* required	"I think at this point we need to re-evaluate what your [device] is doing for you, positively and negatively. Given how advanced your disease is we need to discuss whether it makes sense to keep it active. I know this may be upsetting to talk about, but can you tell me your thoughts at this point?"

- Important to remember a basic ethical point

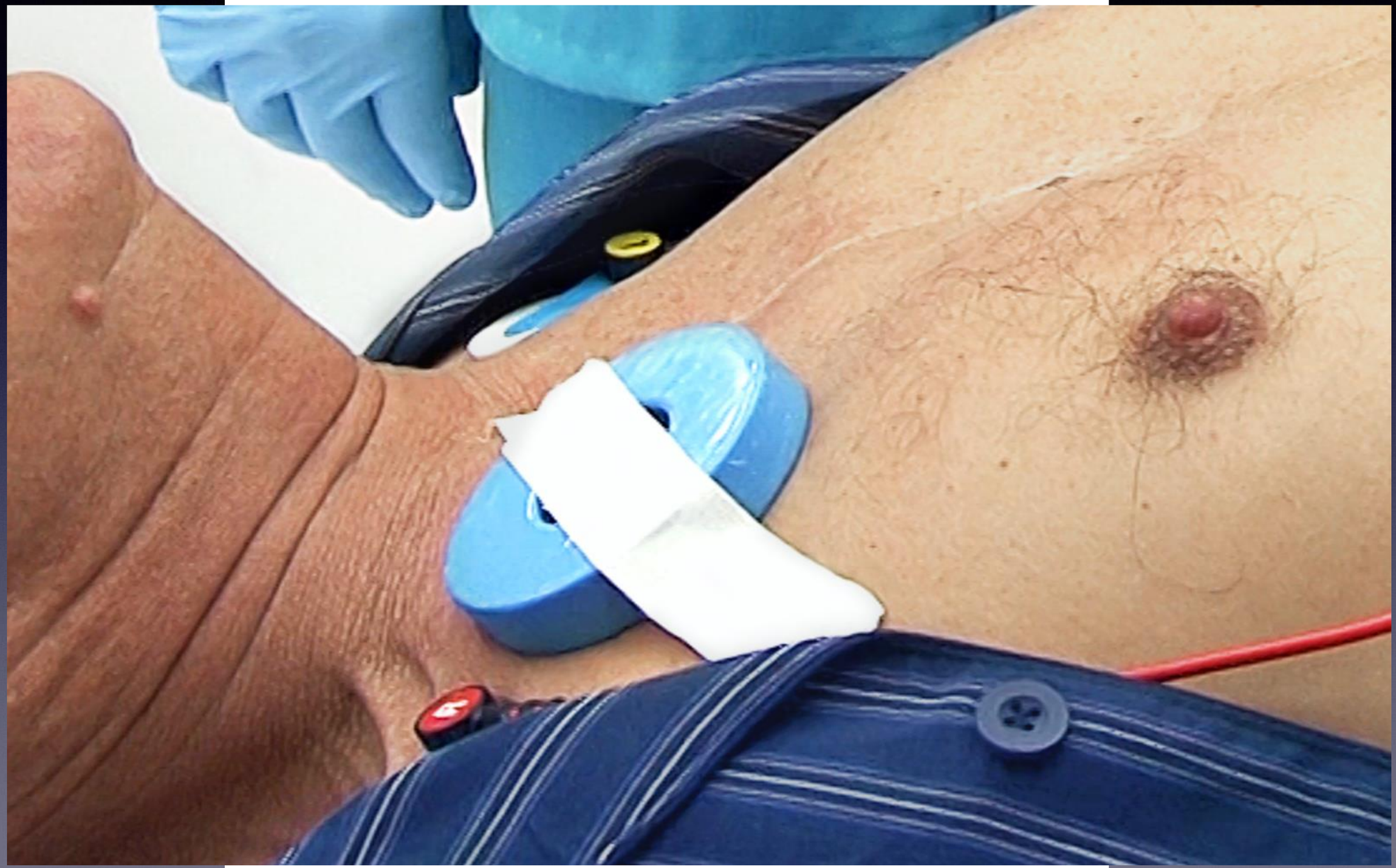
> - *A patient with decision-making capacity has the legal right to refuse or request the withdrawal of any medical treatment or intervention, regardless of whether s/he is terminally ill, and regardless of whether the treatment prolongs life and its withdrawal results in death.*

- Therefore it is important to respect the patient wishes even if they are what we would consider illogical.

- Imagine a patient with end stage heart failure receiving a shock every month
- The clinical team may well feel that that is excessive and affecting quality of life
- Why might the patient think this is ok?

- A shock lasts about 10ms, the physical pain lasts a few seconds
- 1 month =2.5 million seconds
- Therefore physical pain occurs for around 0.0001% of the time

How to perform ICD deactivation



Challenges with ICD deactivation

- Availability of magnet for inhibition of tachycardia therapies
- Availability of programmer and trained staff out of hours
- How to deliver a programmer based deactivation to a patient at home or hospice - who takes the programmer?

Programming options

- The current programming options are limited
  - We can deactivate all therapy (ATP and shocks)
  - No currently programming options to leave ATP on but shocks off

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

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

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

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

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

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

Patient competent

Patient has lost capacity

Go to Appendix 2

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

Patient requests ICD therapy to remain active.

Patient consents to ICD deactivation.

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

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

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

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

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

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

Heart Rhythm UK, 2013[22]

Conclusions

- ICD deactivation should be discussed from the pre implant period all the way through to the end stage phase
- Early planning helps to avoid lack of availability at the time of greatest need
- Discussion with manufactures to improve options should take place
- There is still some scope for improvement

Thank You