

DON'T FAIL ON HEART FAILURE

**The evidence
- and what can be done**

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Executive Summary

- ♥ A person has heart failure if their heart is unable to pump sufficient blood to meet their body's needs. Causes range from hypertension to a heart attack to a virus. Patients suffering heart failure develop increasing breathlessness and fatigue when carrying out daily activities – and ultimately at rest. Consequently, ability to work is greatly impaired along with health and quality of life.
- ♥ Untreated, heart failure has a survival rate similar to cancer - and over a third die within 1 year of diagnosis.
- ♥ Heart failure eventually affects 3 in every hundred women, and 4 in every hundred men.
- ♥ Heart failure currently imposes huge costs on the NHS. It accounts for 5% of all emergency hospital admissions and 2% of all NHS hospital bed days.
- ♥ Implantable devices like ICDs and CRT-Ds have an established role in the treatment of patients, with a large body of high quality evidence supporting their safety and efficacy. In a unique collaboration by medical device manufacturers, 12,000 heart failure patients were followed over a period spanning seven and a half years - in 13 individual randomised clinical trials. The results are published here for the first time: the best and most robust information available on the impact of CRT and ICD in terms of mortality, health related quality of life and hospitalisations.
- ♥ Patients who received CRT-Ds implants had a 42% lower death rate.
- ♥ ICDs also had a dramatic effect. Patients who received ICD implants had a 29% lower death rate.
- ♥ For patients with mild to moderate heart failure, ICDs reduced monthly admission rates to hospital by 20%, and CRT reduced them by 33%.
- ♥ The effect on patients with severe heart failure is even more pronounced, with CRT offering a 40% reduction in monthly admission rates.
- ♥ The UK falls embarrassingly far behind other countries in provision of implantable devices for heart failure patients. There is also huge variation within England and Wales. The implant use suggested by NICE for both devices has not been reached, and the UK remains in the lower quartile of European averages. As a result, heart failure is killing people, lowering quality of life and the UK is spending a lot of money treating it badly.
- ♥ Heart failure should not be viewed as a palliative condition, with sufferers waiting to die. More should be done to improve patients' quality of lives, better manage their condition to reduce unnecessary hospitalisations and save the NHS money, and help reduce mortality.
- ♥ The National Institute for Health and Care Excellence (NICE) is currently reviewing ICDs and CRT-Ds. New and improved guidance can help improve implant rates and ensure the credibility of NICE and the UK as a centre for medical technology innovation. Parliamentarians, clinicians, patient groups and members of the public can all help ensure this.



Heart Failure

A person has heart failure if their heart is unable to pump sufficient blood to meet their body's needs. Causes range from hypertension to a heart attack to a virus.

Untreated, heart failure has a survival rate similar to cancer - and over a third die within 1 year of diagnosis.¹

Patients suffering heart failure develop increasing breathlessness and fatigue when carrying out daily activities – and ultimately at rest. Consequently, ability to work is greatly impaired along with health.

Case study: Lynn, Chester

From leading a very hectic life, the simple act of blackberry picking or walking even a few hundred yards on even ground defeated her. She was told her consultant: *“No more flying, no more stressful working - and by the way it may lead to heart surgery.”*

A patient's account: James, Lancashire

“I had to get used to the idea of heart failure quickly, and learn how to handle the fatigue, breathlessness, and the swelling of feet and ankles. I had to learn the function of a heart that was working at a miserly twenty five per cent efficiency. I felt I was dying in front of my family. In effect I was.”

WHO IS AFFECTED BY HEART FAILURE?

Heart failure eventually affects 3 in every hundred women, and 4 in every hundred men.⁴

At least 605,000 people in the UK are believed to suffer from heart failure.⁵

Heart failure currently imposes huge costs on the NHS. It accounts for 5% of all emergency hospital admissions and 2% of all NHS hospital bed days.²

Patients with heart failure often have a poor quality of life. Over a third experience severe and prolonged depressive illness).

¹ Department of Health Cardiovascular Disease Outcomes Strategy, p.34

² Ibid

³ Ibid

⁴ NICE technology appraisal guidance 120, National Institute for Health and Clinical Excellence, p5

⁵ UK population of 63.1m (2011 census), multiplied by 3% of population aged 65-74, 7% of 75-84 and 14% of those 85+ (Ibid, p5). As this figure does not include under 65s it is an underestimate of the total.

A patient's story: **Emma, Leeds**



Heart failure has changed my life completely. I can only work part time (I have to do so as we cannot get any help as I "am not ill enough") even though everyday tasks take me much longer. I cannot make plans too far ahead and am often too tired to even socialise or undertake housework due to the extreme fatigue I suffer from along with the arrhythmias which appear at any time of the day or night.

I had been finding it increasingly difficult to walk anywhere at all, could not breathe laying down

flat at night and was breathless even just talking. I did attend the ante-natal clinic at my local NHS hospital who kept me waiting 2.5 hours to have me in and out of there in 5 minutes, telling me that I was simply pregnant and that was to be expected! Having been pregnant before I knew that I had not experienced that and was extremely worried. My midwife then became extremely concerned as did my GP who sent a letter and me back to my local hospital A&E department. If he had not insisted and done this, myself and my son may not have been here today, I truly believe he saved my life and that of my then unborn child.

Once in the hospital every test imaginable was run, with my heart being the last thing they checked as I was "far too young for it to be my heart" (I was 31 years old at this point). I had to have a nurse wait outside the bathroom and be taken everywhere in a wheelchair as I was having life-threatening arrhythmias constantly even whilst sleeping or sitting doing nothing.

The Peri-Partum Cardiomyopathy I was diagnosed with meant I could not have any more children and at age 31 had to be sterilised which as there was not enough known about the disease I was pressured into doing so only being given half an hour to decide as it was done at the same time as they delivered my son. I have since been advised this should not have happened so it makes me extremely angry that I had that choice taken away from me.

I worry that I will not see my youngest son grow up, he even thought until recently that all mummies had poorly hearts as that is all he'd ever known, this makes me very sad.



Implantable cardioverter defibrillators and cardiac resynchronisation therapy

Implantable devices have an established role in the treatment of patients, with a large body of high quality evidence supporting their safety and efficacy.

Many people with heart failure also suffer from abnormal rhythms in their heart which can prove fatal. ICDs jolt the heart back into its natural rhythm when it goes out of rhythm. CRT-Ds help pace the heart to enable it to pump blood more efficiently and include a defibrillation function, offering protection from sudden cardiac death.

ICDs

Implantable cardioverter defibrillators (ICD) continuously monitor the heart for arrhythmia and maintain normal heart rate using small, painless electrical signals. They deliver high energy shock therapy (defibrillation) in the event of a potentially life-threatening arrhythmia, protecting against sudden cardiac death.

CRT

Cardiac resynchronisation therapy (CRT) uses electrical stimulation to resynchronise the contraction of the ventricles, thereby improving pumping efficiency. Devices that deliver CRT alone are known as CRT-P. While they improve HF symptoms, they do not offer direct protection against sudden cardiac death.

CRT-Ds

CRT-D devices combine CRT with a defibrillation function, offering protection from sudden cardiac death in addition to the benefits of CRT.



A patient's story: Stephanie, Sunderland



Stephanie was 22 - and her first child Olivia just 14 months old - when she collapsed, looking and feeling awful. She was rushed to hospital with severe heart failure. After spending three weeks in hospital she was put on drug treatments and discharged.

Over the next five years she was treated at her local hospital but had several more collapses and emergency admissions to hospital with severe heart failure. Doctors told her she might have myocarditis and she should not become pregnant again.

After a very severe bout of heart failure, she was referred to experts at the Freeman Hospital in Newcastle. There she was diagnosed with dilated cardiomyopathy and given an implantable cardioverter defibrillator (ICD) with a bi-ventricular pacemaker. Her heart function began to improve and she started to feel much better.

Three years later, when she was 31, she discovered she was pregnant again. She was looked after by a team of specialists and despite having problems in the early months, the birth with epidural was straightforward.

Baby Owen was a healthy 6lbs but Stephanie's heart function suffered and she spent two months in hospital recovering. But soon her heart function improved again: so much so that by 2012, when she needed a new ICD, doctors said she did not need one. But she still suffers every day from heart failure symptoms, mostly tiredness, and struggles to keep up with her family and friends.

She said: *"With appropriate care, treatment and support, things can get better."*



How ICDs and CRT-Ds help heart failure patients and the NHS

In a unique collaboration by medical device manufacturers, 12,000 heart failure patients were followed over a period spanning seven and a half years - in 13 individual randomised clinical trials. The result is the best and most robust information available on the impact of CRT and ICD in terms of mortality, health related quality of life and hospitalisations. They are published here for the first time.

In 2006, ICDs were judged by the National Institute for Clinical Excellence to provide good value for money in secondary prevention of sudden cardiac death. No studies have emerged in the last seven years to contradict this evidence base and meanwhile the price has dropped in real terms, strengthening the conclusions NICE reached about the value of ICDs. The focus of the new research was therefore on primary prevention.

Death rates

CRT-Ds save the most lives. Patients who received CRT-D implants had a 42% lower death rate compared to patients who receive the best known drugs – known as Optimal Pharmacologic Therapy (a hazard ratio of 0.58).

ICDs also had a dramatic effect. Patients who received ICD implants had a 29% lower death rate compared to patients who receive OPT (a hazard ratio of 0.71).

CRT-Ds and ICDs therefore bring down a very high death rate. Without the devices, 85% of heart failure patients in the bottom fifth for predicted survival time died within four years. Even for those in the top fifth for predicted survival time, 15% died within four years.



Younger patients and male patients appear to benefit more from ICDs, but less than other groups from CRT. This is likely to be due to the relatively higher rate of sudden cardiac death relative to other causes in younger and male patients.

Hospitalisation rates

ICDs and CRT-Ds reduce admissions to hospital – which is better for patients, medical staff and the NHS.

For patients with mild to moderate heart failure (NYHA classes I, II and III), ICD therapy reduced monthly admission rates to hospital by 20%, and CRT reduced them by 33%.

The effect on patients with severe heart failure (NYHA class IV) is even more pronounced, with CRT offering a 40% reduction in monthly admission rates.

A patient's story:

Janey, London

In April 2009 I gave birth to a beautiful baby boy. Within 4 months I noticed that I was getting breathless pushing the buggy uphill.

However, I started waking up at night struggling to breath. During a period when my son was no longer waking me up and I was tired I considered this unusual. Still, at first, I thought it might pass and, not one to run to the GP at the sight of any small ailment, I continued. But as it started to happen every night and I could anticipate that it would happen, I booked a GP appointment.

The GP on duty looked at me, said that I had a clear chest and told me I was stressed as a new mother. He said to try blowing into a brown paper bag whenever it happened. I was dismissed and my symptoms not investigated sufficiently if at all.

I struggled throughout the holiday, struggling to walk downhill with the buggy or even carrying anything; lying down doing nothing was even a struggle as I felt continuously short of breath. We decided to fly back home early.

I went to A and E at Barnet Hospital on my return home and was immediately admitted. A chest X-ray showed a hugely inflated heart and my oxygen levels dropped on a short walk. I was diagnosed with dilated cardiomyopathy and admitted overnight. No one took the time to explain to me exactly what was wrong and I felt

alone and frustrated that I didn't understand what was going on.... one of the key things simply not understood by others about heart failure. That and that people who often look fine on the outside aren't necessarily functioning well or feeling well on the inside.

I feel I have accomplished so much having returned to work as a solicitor in London (albeit on a part time basis) whilst bringing up my son rather than accepting never working again. However, it is an uphill walk to the bus stop and to the tube station which I cannot cope with on top of the tube commute so I pay £5 each day to park at the station car park. This is becoming a heavy financial burden which may eventually outweigh staying at work and paying for nursery fees.

Usual tasks others take for granted such as doing the washing, hanging it up, cooking dinner, going to the shops for groceries, changing bed sheets etc can be a struggle.

Every day I commute on the tube to work, I struggle with not getting a seat at times as I look fine on the outside and find it difficult to ask others for a seat as knowing they too look fine on the outside means little.



What can be done?

Falling device costs and increasing battery life ought to mean that more patients can be helped each year. In practice, implant rates are often determined by other factors, and the UK falls embarrassingly far behind other countries in provision and care for heart failure patients.

- In England and Wales, total new implants of ICDs are 72 per million people.
- For new and replacement CRT (CRT-P and CRT-D combined), the rate is 114 per million people.

In the United States, there are 577 CRT-D or ICD implants per 1 million. The European average is 155 per million. In the UK, there are only 104 implants per million.⁶ At 70 per million population, the UK ranks well below countries such as Poland and Slovakia for ICD implant rates (which exceed 140 and 90 per million respectively).⁷

Device implantation rates also vary considerably within England and Wales:

- From 34 to 131 per million population for new ICDs; and
- From 68 to 182 per million for new and replacement CRT devices.

The implant use suggested by NICE for both devices has not been reached, and the UK remains in the lower quartile of European averages. As a result, heart failure is killing people, lowering quality of life and the UK is spending a lot of money treating it badly.

Heart failure should not be viewed as a palliative

condition, with sufferers waiting to die. More should be done to improve patients' quality of lives, better manage their condition to reduce unnecessary hospitalisations and save the NHS money, and help reduce mortality.

The National Institute for Health and Care Excellence (NICE) is currently reviewing ICDs and CRT-Ds. New and improved guidance can help improve implant rates and ensure the credibility of NICE and the UK as a centre for medical technology innovation.

Parliamentarians, clinicians, patient groups and members of the public can help by writing to Health Ministers, to NICE and to NHS England supporting improved patient access to medical technology for treating heart failure, including ICDs and CRT-Ds. For further information and draft letters, please contact James Gittings at james@pbpoliticalconsulting.com and 020 7731 6963.



⁶ *European utilization of the implantable defibrillator: has 10 years changed the 'enigma'?*, A. John Camm and Seah Nisam, *European Society of Cardiology* (2010) 12, pp.1064-1065

⁷ *Cardiac Rhythm Management UK National Clinical Audit Report 2011*, David Cunningham, Richard Charles, Morag Cunningham, Tracy Whittaker, UCL/NICOR, p28

Glossary

CRT

Cardiac resynchronisation therapy (CRT) uses electrical stimulation to resynchronise the contraction of the ventricles, thereby improving pumping efficiency. Devices that deliver CRT alone are known as CRT-P. While they improve HF symptoms, they do not offer direct protection against sudden cardiac death.

CRT-D devices combine CRT with a defibrillation function, offering protection from sudden cardiac death in addition to the benefits of CRT.

Hazard ratio

In drug and technology studies, the ratio of death rates of the treated population to the control population – either untreated or receiving a different treatment.

The lower the hazard ratio, the better the technology or drug compares to the alternative. If the treated population dies at half the rate of the control population, the hazard ratio is 0.5. If the treated population dies at twice the rate of the control population, the hazard ratio is 2.

ICD

Implantable cardioverter defibrillators (ICD) continuously monitor the heart for arrhythmia and maintain normal heart rate using small, painless electrical signals. They deliver high energy shock therapy (defibrillation) in the event of a potentially life-threatening arrhythmia.

NICE

The National Institute for Health and Care Excellence. NICE approves and denies medical technology and treatments to NHS patients. It makes its decisions based on its assessments of their cost and the years and quality of life patients gain from the treatment relative to the cost and quality of life gains of alternative treatments.

NYHA classes I, II, III, IV

See Appendix

OPT

Optimal Pharmacologic Therapy. The best known drug treatment for a condition.

Primary prevention

The prevention of illness or disease in susceptible individuals or populations.

Real terms

Adjusted for inflation. A real terms price increase means the price rose higher than inflation. A real terms price decrease means the price rose by less than inflation, although it may still be a higher nominal price.

Secondary prevention

Medicine aimed at preventing the progress of an illness or disease.



Appendix: NYHA Classification – The Stages of Heart Failure⁸

In order to determine the best course of therapy, physicians often assess the stage of heart failure according to the New York Heart Association (NYHA) functional classification system. This system relates symptoms to everyday activities and the patient's quality of life.

Heart Failure Class I (Mild)

No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or dyspnea (shortness of breath).

Heart Failure Class II (Mild)

Slight limitation of physical activity. Comfortable at rest, but ordinary physical activity results in fatigue, palpitation, or dyspnea.

Heart Failure Class III (Moderate)

Marked limitation of physical activity. Comfortable at rest, but less than ordinary activity causes fatigue, palpitation, or dyspnea.

Heart Failure Class IV (Severe)

Unable to carry out any physical activity without discomfort. Symptoms of cardiac insufficiency at rest. If any physical activity is undertaken, discomfort is increased.

⁸ Questions About HF, Heart Failure Society of America, at http://www.abouthf.org/questions_stages.htm



