NICE National Institute for Health and Care Excellence

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

Interventional procedure IPG10437 (IP2064) Extravascular implantable cardioverter defibrillator insertion for preventing sudden cardiac death caused by ventricular arrhythmia

Scope

1 Introduction

The procedure included in this NICE HealthTech evaluation is extravascular implantable cardioverter defibrillator insertion for preventing sudden cardiac death caused by ventricular arrhythmia. Interventional procedures involve making an incision, a puncture or entry into a body cavity, or using ionising, electromagnetic or acoustic energy. NICE makes recommendations based on assessment of the efficacy and safety of new and significantly modified procedures, or established procedures if there is uncertainty about their efficacy or safety. In cases where an interventional procedure involves implanting or using a health technology, the recommendations will focus on the procedure itself rather than the specific technology used.

This is the first time that this procedure is being assessed by NICE interventional procedures.

This scope document describes the context and the scope of the assessment. Questions for the draft scope consultation are in appendix B. The methods and process for the assessment follow the Interventional procedures programme manual and the NICE HealthTech programme manual.

2 Summary of the procedure

When the lower chambers of the heart (ventricles) lose their normal rhythm and beat too fast or irregularly (ventricular arrhythmia), it may cause the heart to suddenly stop (cardiac arrest). This can be detected and treated using an implantable cardioverter defibrillator (ICD). A conventional transvenous ICD involves placing a small device under the skin of the chest, with wires that go through large veins into the heart. This procedure involves placing an extravascular ICD, which does not need wires to be fed through large veins to the heart. The ICD is implanted below the left armpit, with a lead that is placed beneath the breastbone. If the ICD detects a dangerous arrhythmia, it sends 1 or more small electrical shocks to correct the heart rhythm (anti-tachycardia pacing). If the arrhythmia continues, the ICD uses a larger electric shock to reset the heart rhythm back to normal (cardioversion or defibrillation). An extravascular ICD aims to prevent sudden cardiac death in people who have, or are at high risk of developing, life-threatening ventricular arrhythmias.

3 The condition

Arrhythmia is when the heart beats irregularly, or at a faster or slower pace than normal. It is caused by a disruption in the electrical conduction system of the heart, often because of underlying heart disease. Arrhythmias that arise from ventricles (ventricular arrhythmias) can happen unexpectedly and can cause cardiac arrest and sudden death when insufficient blood is pumped out by the heart to sustain life. Ventricular arrhythmias include ventricular tachycardia and ventricular fibrillation. In ventricular tachycardia, the ventricles beat faster than normal meaning there may not be enough time for the ventricles to fill up with blood between beats. In ventricular fibrillation, the ventricles quiver in a rapid uncoordinated way, which causes the heart to stop beating (cardiac arrest). Both ventricular tachycardia and ventricular fibrillation can cause sudden cardiac death.

While ventricular arrhythmia is the most common cause of cardiac arrest (NICE) it is difficult to estimate the incidence of ventricular arrhythmia in the

general population because it is likely to be under-recognised and under-reported.

4 Current practice

Prevention of sudden cardiac death because of ventricular arrhythmia can be primary, which is defined as preventing a first life-threatening arrhythmic event in someone who is at high risk of such an event. Or, it can be secondary, which refers to preventing further life-threatening events in survivors of previous serious ventricular arrhythmias. Primary prevention is challenging because of the need to identify someone with a high level of risk. Risk factors for sudden cardiac death include previous heart attack, heart failure, abnormal heart rhythm, cardiomyopathy, low ejection fraction and a family history of sudden cardiac arrest. Risk assessment may include the use of sudden cardiac death risk prediction models that provide a quantitative estimate of risk.

Treatment with a transvenous implantable cardioverter defibrillator (ICD) is recommended in NICE's technology appraisal guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014). The guidance recommends ICDs as options for:

- treating people with previous serious ventricular arrhythmia, that is, people who, without a treatable cause:
    - have survived a cardiac arrest caused by either ventricular tachycardia or ventricular fibrillation or
    - have spontaneous sustained ventricular tachycardia causing syncope or significant haemodynamic compromise or
    - have sustained ventricular tachycardia without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction of 35% or less but their symptoms are no worse

than class 3 of the New York Heart Association functional classification of heart failure.

- treating people who:
    - have a familial cardiac condition with a high risk of sudden death, such as long QT syndrome, hypertrophic cardiomyopathy, Brugada syndrome or arrhythmogenic right ventricular dysplasia or
    - have undergone surgical repair of congenital heart disease.

It also recommends ICDs as an option for people with heart failure who have left ventricular dysfunction with a left ventricular ejection fraction of 35% or less, depending on New York Heart Association class, QRS duration and presence of left bundle branch block.

An ICD system consists of a defibrillator with pacing function, which contains a battery, capacitor and electronic circuitry, and 1 or more leads. The device senses and detects arrhythmias and delivers pacing impulses or defibrillating shocks to the heart as necessary, to restore a normal rhythm. A conventional transvenous ICD consists of a defibrillator under the skin below the clavicle (collarbone) and 1 or more leads passed through a vein into the heart and across the valve. This enables the device to act as a long-term pacemaker as well as a defibrillator.

If a conventional transvenous ICD is unsuitable, for example because of an increased risk of infection associated with indwelling leads, an entirely subcutaneous ICD may be an option. This is recommended in NICE HealthTech guidance on subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death (2017). A subcutaneous ICD differs from a transvenous ICD in that a single lead is placed just under the skin, on top of the breastbone, and is not directly attached to the heart. The single lead includes sensing ring electrodes and a shocking coil. However, unlike a conventional transvenous ICD, the subcutaneous device is not designed to provide anti-tachycardia pacing or long-term pacing. An

extravascular ICD is a third type of ICD that has been developed more recently and is the subject of this guidance. Further details are provided in section 6 below.

5 Unmet need

There is an unmet need for a device that has the performance and longevity of a transvenous ICD and can be easily inserted closer to the heart without passing through veins.

In a conventional transvenous ICD, 1 or more leads from the defibrillator are placed through a vein to the heart. This is associated with complications such as systemic infection, vascular injury, blood clots, pneumothorax, haemothorax, and cardiac tamponade. In a subcutaneous ICD, there is no vascular or heart access, so the implant procedure is simpler and there is a lower risk of complications. But the defibrillator is larger, the battery lifespan is shorter, and it cannot treat bradycardia or provide anti-tachycardia pacing. An extravascular ICD is smaller than a subcutaneous ICD and potentially has a longer battery life but still has the advantage of no vascular or heart access. Unlike a subcutaneous ICD, an extravascular ICD can also provide anti-tachycardia pacing and limited bradycardia pacing.

6 The procedure

An extravascular ICD system consists of an ICD device and a lead. The lead includes defibrillation coils and pacing or sensing ring electrodes and is shaped so that these are optimally placed relative to the heart.

Extravascular ICD implantation is usually done under general anaesthesia. A small cut is made just below the tip of the sternum (breastbone). The lead is pushed through the cut, into the space under the breastbone, and sits between the breastbone and the heart. A second cut is then made under the left armpit, and the free end of the lead is guided through to be joined to the ICD. After the ICD has been individually programmed, it is tested and then placed under the skin in the left armpit and the cut is closed.

The battery is projected to last for at least 10 years, but when its power falls to a low level the whole ICD needs to be replaced (in common with other types of ICD). The old ICD is removed through a cut over the original scar. The existing lead is fastened to the new ICD, which is programmed and tested and then put into place.

6.1 Innovative aspects of the procedure

The extravascular ICD has the potential to avoid certain complications associated with the transvenous leads used in conventional ICDs and reduce the risk of vascular injury. The lead of an extravascular ICD system is placed under the breastbone and is closer to the heart than the lead of a subcutaneous ICD. This means that it uses less energy for defibrillation. Unlike a subcutaneous ICD, it can offer anti-tachycardia pacing and pause-prevention pacing (backup bradycardia pacing). It is smaller than a subcutaneous ICD and similar in size to a conventional transvenous ICD. The projected extended battery life of an extravascular ICD may mean that the number of replacement procedures will be reduced compared to subcutaneous ICDs.

6.2 Current known use of the procedure

According to the NHS England Hospital Episode Statistics, in the financial year of 2024 to 2025 there were 662 finished consultant episodes for 'Implantation of subcutaneous cardioverter defibrillator' (K72.1), 314 finished consultant episodes for 'renewal of subcutaneous cardioverter defibrillator' (K72.3), 23 finished consultant episodes for 'Other specified other cardioverter defibrillator' (K72.8) and 2 finished consultant episodes for 'Unspecified other cardioverted defibrillator' (K72.9) in England. It is not known if any of these were extravascular ICDs. According to the National Institute for Cardiovascular Outcomes Research (NICOR), there were 732 'non-transvenous ICD implants' in the financial year 2024 to 2025.

7 Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

- Older age, male sex and white ethnicity were associated with an increased risk of ventricular arrhythmias in a prospective cohort study of about 500,000 people in the UK (Khurshid S, 2018).

- Ventricular arrhythmias are most common in people with underlying heart disease. The incidence and prevalence of heart failure increases with age and the average age at first diagnosis is 76 years (NICE).

- People with ventricular arrhythmia may be covered by the Equality Act 2010 if their symptoms have a substantial adverse effect on day to day activities for longer than 12 months.

- The risk of sudden cardiac death due to any cause is higher in men than in women, but women are less likely to receive cardiopulmonary resuscitation, and have lower survival rates at each successive stage of care (Resuscitation Council UK).

- The incidence of sudden cardiac death due to any cause increases with age (Zeppenfeld 2022). Most (59%) out of hospital cardiac arrests happen in people aged over 65 years (Association of Ambulance Chief Executives).

- There are higher rates of out of hospital cardiac arrests due to any cause in areas with higher proportions of people from non-white ethnic backgrounds, lower educational attainment and employment status (Association of Ambulance Chief Executives).

- Poverty, poor diet, higher incidence of smoking and higher rates of mental illness are all associated with higher incidence of cardiac arrest due to any cause (Resuscitation Council UK).

- This procedure may have particular benefit for children because of its smaller size than a subcutaneous ICD and potentially longer battery life.

- The procedure could increase access to an ICD for people when an alternative ICD is unsuitable.

- Extravascular ICDs are only available in UK centres with trained specialists that have a surgical backup.

8 Decision problem

The key objective for this evaluation is to assess the efficacy and safety of extravascular implantable cardioverter defibrillator insertion for preventing sudden cardiac death to determine whether it works well enough and is safe enough for use in the NHS.

Table 1: Decision problem

Population	People at high risk of sudden cardiac death because of ventricular arrhythmia who are eligible for an ICD, including people who have already had a sudden cardiac arrest.
Intervention	Extravascular ICD implant insertion
Key efficacy outcomes (may include but are not limited to)	• Defibrillation efficacy • Appropriate anti-tachycardia pacing or shock delivery • Electrical performance (pacing capture thresholds, pacing impedance, sensing amplitudes) • Quality of life • Device or battery durability and longevity • Survival

Key safety outcomes (may include but are not limited to)	• Lead migration or dislodgement • Lead abrasion or fracture • Wound or device pocket infection • Device malfunction • Pain or discomfort • Haematoma or haemorrhage • Haemothorax • Pneumothorax • Pericardial effusion or pericarditis • Cardiac perforation or tamponade • Allergic reaction • Bradyarrhythmia • Cardiac arrest • Device migration • Psychological distress, including anxiety and depression, from anticipating a shock or having inappropriate shocks • System revision • Death • Inappropriate shocks

9 Other issues for information

There is currently 1 extravascular ICD available on the NHS, the Aurora EV-ICD system (Medtronic). According to the company's website, it is indicated for 'people who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias'. The company's website also states that conditions eligible for an EV-ICD include 'previous ventricular tachyarrhythmias, coronary disease with left ventricular dysfunction, cardiomyopathy, inherited primary arrhythmia syndromes, and congenital heart disease' (Medtronic).

10 NICE team

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Appendix A: Related evidence or guidance

Relevant registries or emerging key trials

French COhoRte Extra-Vascular Implantable CardiovErter DefibrillatoR (FOREVER) ClinicalTrials.gov identifier: NCT06739239. Status: recruiting. Indication: sudden cardiac death due to cardiac arrhythmia. Estimated n=1,000. Trial design: Prospective cohort. Device: Extravascular ICD. Study completion date December 2030. Country: France

Enlighten Study: The EV-ICD Post Approval Registry. ClinicalTrials.gov identifier: NCT06048731. Status: active, not recruiting. Indication: ventricular arrhythmia, tachycardia. Estimated n=1,000. Trial design: Prospective cohort. Device: Aurora EV-ICD. Primary completion date May 2030, Study completion date October 2037. Countries: Austria, Belgium, Canada, Czechia, Denmark, Finland, France, Germany, Greece, Hong Kong, Hungary, Israel, Italy, Kuwait, Netherlands, New Zealand, Poland, Portugal, Saudi Arabia, Spain, Sweden, Switzerland, UK, US.

Observational BELgian Registry of Implanted EV-ICD to Evaluate Parameters and Complications of the New Device in Real World Settings (BELIEVE). ClinicalTrials.gov identifier: NCT07156851. Status: not yet recruiting. Indication: previous or planned EV-ICD implantation. Estimated n=100. Trial design: Prospective cohort. Device: EV-ICD. Primary completion date July 2040, Study completion date July 2040. Countries: Belgium.

Related NICE guidance, standards or indicators

NICE clinical guidelines

Chronic heart failure in adults: diagnosis and management (2018, last updated 2025) NICE guideline 106

NICE HealthTech guidance

Subcutaneous implantable cardioverter defibrillator insertion for preventing sudden cardiac death (2017) NICE HealthTech guidance 460

Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia (2009) NICE HealthTech guidance 187

NICE Technology appraisal guidance

Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (2014) NICE Technology appraisal guidance 314.