Cardiac Rhythm Management (CRM) Background

Introduction

The National Cardiac Rhythm Management Device audit has evolved from the British Pacing and Electrophysiology Group (BPEG) national registry, and at over 40 years old, is the oldest such registry in the world, with details of over a million procedures. A registry of electrophysiology/catheter ablation procedures commenced in 2004, and participation has been high since 2007. Data are submitted to NICOR by hospitals that undertake device and ablation procedures.

What is Cardiac Rhythm Management?

Cardiac rhythm management (CRM) is the treatment of arrhythmias (heart rhythm disorders). Arrhythmias can cause a range of problems for patients, from palpitations and dizzy spells to blackouts and sudden cardiac arrest. Some arrhythmias are benign and relatively asymptomatic, needing no treatment other than lifestyle advice and reassurance, and some require treatment for their consequences, such as the risk of stroke or heart failure. Many arrhythmias require specific 'antiarrhythmic' treatments. Drugs can be useful in reducing the frequency, severity or symptoms of arrhythmia episodes but rarely abolish them. Their usefulness is also limited by side effects and their potential for adverse effects on the heart and elsewhere. In the last half-century, cardiac implantable electronic devices and catheter ablation have revolutionised the treatment of most arrhythmias, and as a consequence, no new antiarrhythmic drug has been widely used, while the use of many existing drugs has virtually disappeared.

CRM Devices

The term "CRM" is often used to describe treatments based on implanted electronic devices such as pacemakers and defibrillators. Most CRM devices are implanted under the skin, with one to three leads usually threaded down a vein to connect to the heart. The implant procedure usually requires only a local anaesthetic and can take less than 45 minutes for the simplest devices or more than two-hours for the most complex cases. The main devices are:

Permanent Pacemakers (PPMs)

These are the most common type of CRM device and have been used since 1958. PPMs are implanted under the skin and connected to the heart with leads threaded down veins. They monitor the heart rate and, when necessary, give tiny electrical impulses to trigger the heartbeat. PPMs are the only treatment for slow heart rates or episodes when the heart stops altogether (asystole), causing dizzy spells, blackouts, or death.

Implantable Cardioverter Defibrillators (ICDs)

Most sudden cardiac arrests are due to very fast or chaotic beating of the main pumping chamber (ventricular tachycardia or fibrillation), requiring a shock to restore the normal rhythm. An ICD is an implantable device that can do this automatically within seconds. In the 1990s, ICD technology developed allowing ICD implantation to be similar to that of a pacemaker, without the risks of open chest surgery. This and large-scale randomised trials supported the standard use of ICDs to prevent sudden cardiac death. Most ICDs can also act as pacemakers, though a new type (subcutaneous ICD) has no leads in the heart and cannot pace.

Cardiac Resynchronisation Therapy (CRT)

In some patients with heart failure, the ventricles (main pumping chambers) are not only weak but also poorly coordinated. CRT devices pace the left ventricle (the main pumping chamber) from two sites rather than one to improve the coordination of the heartbeat, 'tuning' the heart. CRT use has been widespread since around 2000 and has been proven to be a highly cost-effective treatment to improve symptoms, hospitalisations, and mortality. CRT can be a feature of both pacemakers (CRT-P) and defibrillators (CRT-D).

Catheter Ablation

Pioneering surgeons in the 1970s and 1980s developed operations that permanently eliminated many arrhythmias by destroying the causative foci or pathways in the heart (ablation). These operations proved that a curative treatment is possible but required major cardiothoracic surgical procedures. Nowadays, many arrhythmias can be cured by catheter ablation, in which steerable thin probes (catheters) are threaded along vessels and guided into the relevant locations within the heart. Ablation is then performed, creating a scar most commonly by passing a radiofrequency (RF) electrical current into the tissue, but sometimes by using extreme cold (cryothermy) or other energy sources. Depending on their complexity, catheter ablation procedures can take from one to several hours; patients can usually be discharged the same day or after a single overnight stay. Catheter ablation procedures can be assigned into three groups:

Simple Atrial Ablation

These were the first ablation procedures to be developed. Most simple ablations can be performed as a day case without general anaesthesia.

AV Node Ablation (AVNA)

This is the destruction of the electrical junction between the atria and the ventricles. This prevents fast heart rates due to arrhythmias arising in the atria but renders the patient dependent on a permanent pacemaker. AVNA remains useful in patients for whom other treatments have failed, and in others, improves the efficacy of CRT.

Ablation of Accessory Pathways (APs) and the 'Slow Pathway' (SP) of the AV Node

This is also known as AV Node Modification. It is curative in the vast majority of patients born with extra connections in the heart that cause arrhythmias known as "Supraventricular Tachycardia"(SVT).

Ablation of the Cavotricuspid Isthmus (CTI)

This is a cure for the typical form of atrial flutter caused by the rapid circulation of the cardiac impulse within the right atrium.

"Complex" Atrial Ablation

Apart from typical atrial flutter, the ablation of atrial arrhythmias generally requires a more complex approach, usually with computerised equipment to create a three-dimensional representation of the atria and the arrhythmia (electroanatomic mapping), and guide and record the placement of ablation lesions. Most complex atrial ablations involve isolating the pulmonary veins to treat atrial fibrillation, and this procedure now accounts for around 40% of all catheter ablation procedures.

‘Single-shot’ catheter ablation for AF

Conventionally AF ablation has been done by making a series of small electrical burns using a ‘point-by-point’ approach. More recently a variety of techniques have been introduced using a shaped catheter or balloon placed in the mouth of each vein, which creates a single circumferential burn. These single-shot techniques are dominated by the ‘cryo balloon’, which produces a scar by freezing. This technique has similar effectiveness and safety profiles for first-time AF ablation cases and has the advantage of being quicker. Single-shot AF ablation using a cryo balloon is becoming more and more common.

Ventricular Ablation

Only around 5% of ablations have ventricular targets, which fall into broadly two groups, focal ventricular arrhythmias (where the object is to locate and eliminate a single focus, usually near the pulmonary or aortic valves) and re-entrant ventricular arrhythmias, usually related to scar from prior myocardial infarction or inflammatory conditions. Ventricular ablations require electroanatomic mapping and can be very lengthy and unpredictable, especially for scar-related arrhythmias.

The Domain Expert Group

More recently, clinical leadership has been provided by the British Heart Rhythm Society (BHRS, the successor to BPEG, and an affiliated group of the British Cardiovascular Society). The NICOR/BHRS Expert Group sets the strategy and provides oversight of the audit. It is chaired by the BHRS audit lead and meets regularly. The Expert Group includes NICOR staff, the BHRS President and Audit Lead, representation from all professional groups involved with CRM device management (doctors, physiologists, and nurses). There is also lay representation, representation from the charity sector and the Medicines and Healthcare Products Regulatory Authority (MHRA).

Confidentiality

Data submitted to NICOR for all the cardiac audits are by their nature patient-identifiable (and need to be to permit centres to check and update records). They are therefore held on a highly secure server. This means that identified centre audit leads are able to use secure logins to see and check their own centre’s data at a patient level. However, these data are not released in a patient identifiable form to any other parties. Even within NICOR the data management team are separate from the analysts and audit leads. Any patient-identifiable data in extracts is encrypted: for example, NHS No is converted into a string of 16 alphanumeric characters. This permits us to identify whether a patient has had more than one procedure, but the string cannot be converted back to identify the NHS number. Dates of birth are not visible, only age (to the nearest year). Postcodes are converted to geographic identifiers. Only aggregated data can be used for analysis or publication. There is a process whereby researchers can obtain data for analysis (DARS process).

Participating hospitals

All NHS hospitals in England are contractually required to submit data to the national cardiac audits held by NICOR. Hospitals in Wales also submit their data. Scotland and Ireland are currently not participating.

Data Collection and IT

As the CRM audit database largely relates to procedures performed, most hospitals collect data at the time of these procedures. Data can either be submitted directly to NICOR via a web portal or collected by hospital information systems and uploaded in batches. As a variety of information systems are used, with at least six major third-party IT providers, changes to the dataset can pose a challenge, and adherence can be delayed. Revised datasets were announced in 2013 and implemented in 2014, but adoption by centres was not complete until 2015. The 2015-16 report was the first to be based entirely on the new dataset.

Definitions

Devices system types: "simple" vs "complex".

In line with NHS commissioning structures and other professional bodies in the world, devices have been classified as devices as:

- *Simple.* Single or dual chamber pacemakers for the treatment of bradycardia. These are commissioned locally.
- *Complex.* Implantable defibrillators (ICD) for patients who have suffered from, or are at high risk of, cardiac arrest, and cardiac resynchronization therapy pacemakers (CRTP) or defibrillators (CRTD) for the treatment of heart failure and risk of cardiac arrest. Complex devices are subject to Specialised Commissioning.

Device procedure types: "first implant" and others

The new device dataset was designed to improve differentiation between different procedure types, including:

- *First implant.* The first time a patient has received any form of pacemaker or defibrillator. Some analyses (e.g. reintervention rates) look only at first implants to achieve a uniform expectation of complication rates.
- *Replacement.* Replacement of the generator, usually due to battery depletion.
- *Upgrade.* A change in function from a simple device to a complex device (e.g. pacemaker to ICD) or from an ICD or CRT pacemaker to a CRT defibrillator. This is, therefore, the first time the patient has received this level of therapy. Most analyses have combined new and upgrade procedures as they represent the first time the patient has received this level of therapy. This is made explicit in each section.

Ablation procedure types: simple and complex

Ablations have been divided into three groups:

- *Simple ablation procedures.* These include procedures where the target(s) are simple: complete AV nodal ablation, AV nodal re-entry, accessory pathways and the cavotricuspid isthmus (CTI).
- *Complex atrial ablation procedures.* All procedures with atrial targets other than listed above. This category includes procedures that additionally have a simple target, (notably the combination of atrial fibrillation and CTI ablation).
- *Complex ventricular ablation procedures.* All procedures with a ventricular target, including those with an additional simple target.

Adoption of New Technologies

Cardiac rhythm management depends on effective and reliable technologies, which evolve continuously. Most of this evolution is iterative, with incremental improvements appearing almost annually.

However, certain innovations are sufficiently radical to justify separate enumeration because:

(i) it may be relevant to subject them to separate scrutiny by audit, and evaluation by NICE;
(ii) there may be implications for cost and service provision, as these technologies often come at increased cost,
(iii) their use may not be identifiable via Hospital Episode Statistics (HES).

We therefore report on three technologies that have been introduced in significant numbers in the last decade.

Leadless Cardiac Pacemakers (LCPs)

A disadvantage of conventional pacemakers is the need for one or more leads that pass down a vein from the device (placed under the skin below the collarbone) to the heart. Occasionally, these can become damaged or infected, necessitating their replacement. This can be difficult and risky because the leads are bound to the veins and heart by scar tissue.

There are two recent innovations that are being tracked. A recent innovation is a pacemaker sufficiently small to be directly attached to the inside of the right ventricle. However, they avoid the need for leads and appear to have a significantly lower risk of infection. Initially, only ventricular pacing was possible, but now devices able to maintain AV synchrony are available.

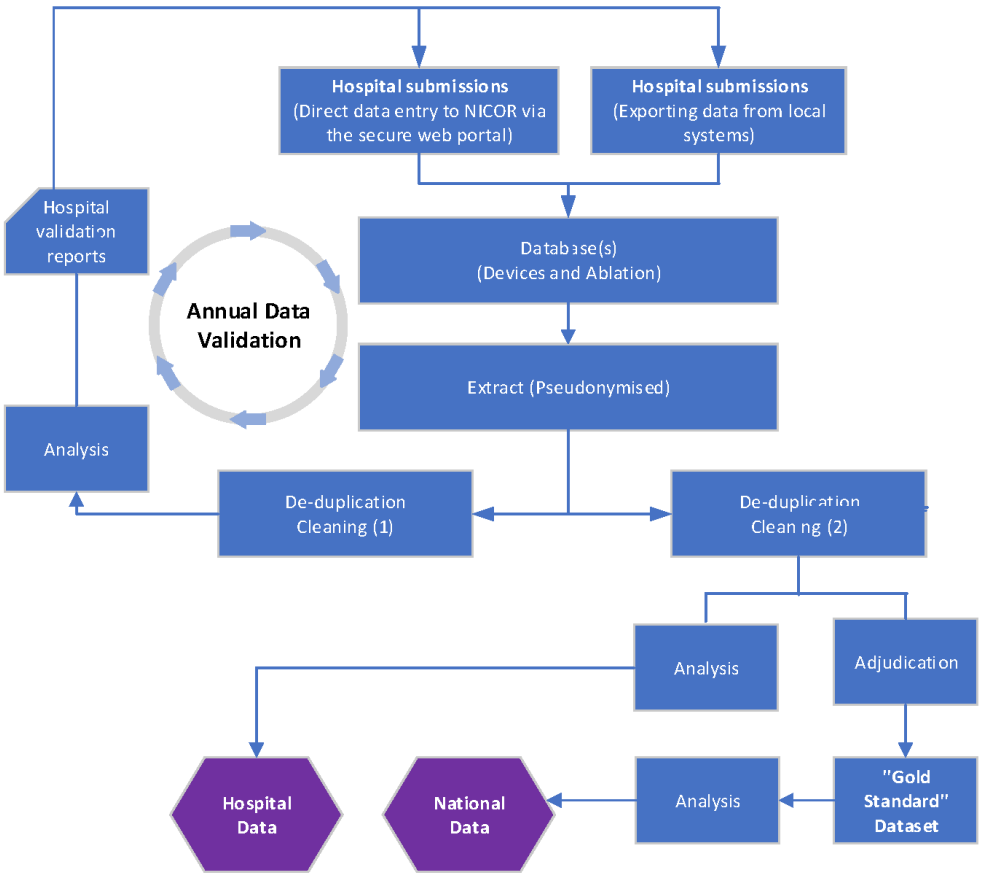
NICE published interventional procedure guidance in 2018.[1] Further guidance was produced by the British Heart Rhythm Society.[2] Three models of LCP have been implanted, Micra® (Medtronic), Aveir (Abbott) and Nanostim® (Abbott); market release of the latter was suspended in 2018.

A further innovation is ultrasound-powered pacing of the left ventricle (WiSE®, EBR systems). This is used as an adjunct to conventional pacing (with a transvenous lead in the right ventricle) to achieve cardiac resynchronization therapy in cases where this is impossible conventionally (using a lead in a branch of the coronary sinus). A transmitter outside the rib cage detects the right ventricular pacing pulse and ‘pings’ a focused ultrasound pulse to a small receiver electrode fixed to the interior of the left ventricle.

Data Processing

The flow for data processing is shown below in Figure 1.

Figure 1. Data Processing Flows



Data Submission centres submit their records either by typing directly into the NICOR portal, or by uploading using comma-separated variable (.csv) files generated from local IT systems.

- *First extract.* This is prepared using all relevant fields; any patient-identifiable data are pseudonymised (see “confidentiality” earlier in this Appendix).
- *De-duplication.* Identified duplicate records are removed (the number of these is shown at the beginning of each individual centre report).
- *Cleaning.* Data quality among the approximately 100,000 records submitted each year is variable, and minor errors in syntax are common. Corrections are made, where this can be done without ambiguity or risk of error.
- *Validation analysis.* The analytic process for individual centre reports run to produce a first draft.

- *Validation.* Each centre is sent the validation report, showing how its data would look once analysed; a month is allowed for centres to correct their data.

- *Final extract.* A second, final extract is prepared, de-duplicated, and cleaned using identical methods.

- *Adjudication.* Some key fields are noted to be incomplete or clearly incorrect in a minority of records. Adjudicated versions of these fields are generated as follows:
    - *Device system type.* Where the stated device system type is clearly incompatible with the stated generator model (e.g. the system type is stated to be a dual chamber pacemaker, but the generator model is a dual chamber defibrillator), the record is adjudicated, where necessary using other fields, such as the number and types of leads.
    - *Device procedure type.* Where this is missing or clearly incorrect, based on compatibility with other fields, the record is adjudicated where possible.
    - *"Ablation performed?".* This field is intended to distinguish procedures in which an ablation was performed from those that were purely diagnostic or where ablation was not attempted for various reasons. In a proportion of cases (enumerated for each centre in its report) this field was incomplete or clearly incorrect based on other data. Adjudication is performed where possible.

  Where adjudication of a field cannot be performed with a high degree of confidence, the field is adjudicated as "unknown".

- *Final analysis.* The code is run to produce the final centre reports and the national report with its appendices. Note that unadjudicated data was used for all reporting relating to centres (so that their analyses reflect their data quality/completeness). However, the results for the national trends and the maps of implant and ablation rates across England and Wales use adjudicated data.

Generation of Interactive Maps

The maps show the rates of various categories of device and ablation procedures for England and Wales, according to the submitted postcode of residence of each patient. To preserve confidentiality, the postcode is converted to geographic indicators when generating the final data extract.

To make comparisons of procedures across geographical areas, numbers are aggregated by Integrated Care Systems (ICSs) (England) or Local Health Boards (Wales), based on the patient's residence.

For devices (but not ablations), rates are age and sex-adjusted using the indirect standardisation method.[3] Expected deaths were calculated by multiplying the England & Wales age-specific implant rates (in five-year age-bands) by the corresponding age-specific population for the corresponding year in each geography. The indirectly standardised rates are calculated by dividing the observed numbers of device implants by the expected numbers to create a standardised incidence ratio and the ratio is then multiplied by the England and Wales crude device implant rate to create the rates.

Byar's method[4] gives very accurate approximate confidence intervals for counts based on the assumption of a Poisson distribution. This method is used to show confidence around the indirectly standardised rates.

Of note, estimates for geographical areas are based on the patient's postcode of residence. Due to incomplete data, there are a small number of records that have not been mapped to a geographic location.

Where the numbers of devices implanted each year within geographies are less than 6, no rate has been calculated.

Quality Improvement Measures

Basic Information About the Metrics

The annual reports run from 1 April to 31 March (financial year) not January to January.

Annual trends are calculated by re-analysis of the entire dataset, to provide consistent methods and to incorporate late-submitted data from previous years. This accounts for minor changes in procedure counts from prior reports.

Participating hospitals include adult NHS hospitals, children, and private hospitals, although not all of these contribute.

At the end of the data collection, the data are extracted, and validation reports are sent to submitting centres to allow an opportunity for correction and completion. Following the validation period, a final data extract is completed and analysed before reporting.

Centre-specific results and operator statistics are presented *as submitted*, with details in the Appendices.

National statistics are calculated after the *adjudication* of these data. We correct for unequivocal errors in data submission (e.g. devices reported as pacemakers when the generator model and leads leave no doubt that an ICD was implanted).

Device and ablation data are reported for England and Wales. These statistics are based on the location of the operating hospital rather than the patient's residence. Note that although implant rates generally appear lower in Wales than in England, a proportion of Welsh patients are treated in English centres (especially Liverpool).

Procedure rates based on the residence (postcode) of patients in England & Wales can be seen using interactive maps.

Quality Standards

The following documents have been used to define the standards for device implantation and ablation:

1. Standards for Implantation and Follow-up of Cardiac Rhythm Management Devices in Adults. January 2018. British Heart Rhythm Society. https://bhrs.com/wp-content/uploads/2019/10/BHRS-standards-January-2018-Implantation-and-Follow-Up-of-CRM-Devices-in-Adults.pdf.

2. Standards for Interventional Electrophysiology Study and Catheter Ablation in Adults. April 2020. https://bhrs.com/wp-content/uploads/2020/04/British-Heart-Rhythm-Society-Standards-Ablation-2020-1.pdf

3. Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block. National Institute for Health and Care Excellence. 2014. https://www.nice.org.uk/guidance/ta324

4. Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure. National Institute for Health and Care Excellence. 2014. https://www.nice.org.uk/guidance/ta314

We have developed a variety of measures to answer five questions:

1. Is the data correct – data completeness and validity?
2. Are hospitals doing enough – hospital volumes assessed by BHRS standards?
3. Are operators doing enough – operator volumes assessed by BHRS standards?
4. Are devices going in for the right reasons – adherence to NICE guidelines?
5. Are the rates of complications acceptable?

Data Completeness and Validity

Quality Standard 1 (Data Completeness)

Hospitals should achieve ≥90% completeness in each of six data domains for device and ablation procedures.

Individual hospital reports (Appendices 3 and 4) detail completeness for a large number of fields (24 for device procedures and 30 for ablations) in order to help hospitals identify their data deficiencies. These fields have been distilled into six domains:

1. *Demographics:* the average completeness of NHS Number and Postcode, essential for analyses of re-intervention rates and maps of geographic provision. The other four demographic fields are technically mandatory and, therefore, 100% by definition.

   1.03 NHS Number, 1.04 Surname, 1.05 Forename, 1.06 DOB, 1.07 Sex, 1.09 Postcode

2. *Clinical (simple):* the average completeness over four fields that describe the clinical indication for simple device therapy, or six fields that describe the clinical indication for simple ablation.

   X2.01.Underlying.heart.dis, X2.02.Prev.surg.or.interventn, X2.03.Structural.congen.HD, X2.04.Documented.prior.AF, X2.05.Other.doc..arrhythmia, X2.06.Indication.for.proced

3. *Clinical (complex):* the average completeness over fields that describe the clinical indications for complex devices or for AF ablations. These fields are not required for simple devices and other ablations.

   4.01 LA size/vol, 4.03 Rhyt at start, 4.04 Prev AADS

4. *GMC:* the mean completion rate of GMC Registration Number for first operator and responsible consultant.

X3.04.First.Op.GMC, X3.10.Cons.GMC

5. *Procedure:* the mean completion rate of two fields key to all other analyses: intervention (what procedure was done) and system type (pacemaker, defibrillator, etc.).

X3.01.Procedure.time
X3.02.Procedure.urgency
X3.12.Ablation.procedure
X3.13.Mapping.techniques
X3.16.Fluoro.time..min
X3.18.Proc.duration
X3.19.Ablation.attempted
X3.21.Ablation.energy.source
X3.23.Transseptal.approach
X3.24.Epicardial.approach
X3.26.Success
X3.2.Acute.complication

6. *Generator (device procedures only):* the mean completion rate for the generator model.

Quality Standard 2 (Validity)

Hospitals should achieve ≥90% validity in each of two data domains for device and ablation procedures. Two further measures have been derived to test the validity of key fields, which are essential to most of the analyses in this report:

1. *System validity (device procedures):* consistency between the system type and the generator model (e.g. if the stated system type is a single chamber pacemaker, but the stated generator model is a single chamber defibrillator, this is invalid).

2. *Ablation validity (ablation procedures):* consistency and completeness of the fields 'ablation performed?' (e.g. if this is "no" or blank, but there are consistent data elsewhere in a record to indicate that an ablation was in fact performed, this counts as invalid).

Hospital Volumes for Device and Ablation Procedures

International studies have demonstrated that outcomes tend to be poorer in hospitals undertaking low volumes of device and ablation procedures.[5-8] The British Heart Rhythm Society publishes standards documents for hospitals and clinicians undertaking these procedures in adults. These include minimum recommended procedure volumes, which are stringent by international standards. The standards documents are regularly reviewed.

Quality Standard 3 (Device Implantation)

BHRS Standard (2018) recommended that pacing centres undertake a minimum of 80 device implants per year. Training centres should perform more than 100 device implants per year.

Quality Standard 4 (Complex Device Implantation)

BHRS Standard (2018) recommended that complex device centres undertake a minimum of 60 such procedures (ICD and CRT implant/upgrades) per year (80 is desirable).

Quality Standard 5 (All Ablation)
BHRS Standard (2020) recommended that ablation centres undertake a minimum of 100 ablation procedures per year in total.

Quality Standard 6 (AF Ablation)
BHRS Standard (2020) recommended that centres undertaking AF ablation should perform a minimum of 50 such cases per year.

Operator Volumes for Device and Ablation Procedures
Studies have demonstrated that device and ablation procedure outcomes tend to be poorer when undertaken by low-volume operators.[9-12] The British Heart Rhythm Society has made recommendations for individual specialists undertaking device (2018) and ablation procedures (2020) in adults. The standards documents are regularly reviewed.

Quality Standard 7 (Device Implantation)
The minimum volume for an implanting specialist is 35 total new devices per year.

Quality Standard 8 (Defibrillator/Cardiac Resynchronization Therapy)
For those who are non-CRT implanters, it is recommended that operators implant 60 devices per year, of which 30 must be new ICD implants or upgrades. If the operator implants CRT devices, again, 60 device implants per annum are recommended, of which 20 should be new CRT-P/D implants or upgrades. If the consultant is training a registrar, they should perform a minimum of 30 ICD or CRT implants or upgrades per year, and 40 is desirable.

Quality Standard 9 (All Ablation)
An operator undertaking catheter ablation should perform at least 50 ablation procedures per year.

Quality Standard 10 (Simple Ablation)
An operator performing simple ablations should perform at least 25 simple ablations per year.

Quality Standard 11 (Complex Ablation)
For those undertaking complex procedures (generally AF ablation), the recommendation is at least 25 such procedures from a total of at least 50 procedures per year. ≥50 complex procedures are desirable. Operators performing single-shot atrial fibrillation ablation should be performing a minimum of 25 ablations using that technique each year.

Finally, the “grade” of the Operator is recorded – for example cardiologist or trainee. The details are taken from the GMC list of registered medical practitioners. This recognises those with a CCST or who are registered trainees. A proportion of operators are “unknown”, and they are probably clinical fellows, staff grades, associate specialists or similar.

Adherence to NICE Guidelines
NICE Technology Appraisals make recommendations for the type of pacemaker to be used for the treatment of slow heart rates. It has also published a technology appraisal for the appropriate implantation of ICDs to prevent sudden arrhythmia death and Cardiac Resynchronisation Therapy.

Quality Standard 12 (Pacing for Sinus Node Disease in the Absence of Atrial Fibrillation)
90% of pacemaker implants should be dual chamber.

Quality Standard 13 (Pacing for Atrioventricular Block in the Absence of Atrial Fibrillation)
90% of pacemaker implants should be dual chamber.

Quality Standard 14 (ICDs for Primary Prevention)
80% of ICD implants for primary prevention should be documented to meet at least one of the NICE criteria:

- Left ventricular dysfunction ≤35% despite optimum medical therapy and who are not in NYHA functional class IV.
- A familial cardiac condition with a high risk of sudden death.
- Prior surgical repair of congenital heart disease.

Quality standard 15 (ICDs for Secondary Prevention)
80% of ICD implants for secondary prevention should be documented to meet at least one of the NICE criteria:

- Prior cardiac arrest caused by ventricular tachycardia (VT) or fibrillation.
- Sustained VT causing syncope or significant haemodynamic compromise.
- Sustained VT and left ventricular ejection fraction ≤35%.

Procedural Success and Complication Rates
Inpatient complication rates are not an ideal quality measure as many implant-related complications present at a later stage. Re-interventions in the first year following implants are usually the result of procedural complications and can be used as an index thereof. Although most re-interventions within a year of a first device implant reflect complications from the original procedure, a proportion are due to other clinical factors such as a changed indication or occasionally manufacturer advisories/recalls. Similarly, when a repeat ablation is required in one or two years (the latter value is used, due to prolonged NHS waiting times) that can be a surrogate marker of procedural success.

Quality Standard 16 (Pacemakers)
The rate of re-interventions within a year of a first pacemaker implant should be below the 95% upper control limit (national mean + 2 standard errors).

Quality Standard 17 (Complex Devices)
The rate of reinterventions within a year of a first complex device (ICD or CRT) implant should be within the 95% control limit (national mean + 2 standard errors).

Quality Standard 18 (Catheter Ablation)
The frequency with which patients undergo a repeat procedure (i.e. to the same or related target) within a year of catheter ablation should be within the 95% control limit (national mean + 2 standard errors).

Templates for Quality Standards

There are a number of templates included in the reports. They are reproduced here:

QI Metric Description/Name	**Data Completeness and Validity (1-2)**
Why is this important?	A key indicator of an effective service with good governance is compliance with audit. This means complete, accurate and valid data entry.
QI theme	Effectiveness
What is the standard to be met?	**Quality Standard 1** Hospitals should achieve ≥90% completeness in each of six data domains for device and ablation procedures (completeness). **Quality Standard 2** Hospitals should achieve ≥90% validity in key data domains for device and ablation procedures.
Key references to support the metric	N/A
Numerator	**Data Completeness** For each domain, the average of fields completed. **Data Validity** Devices: records in which the stated system type matches capability of the generator model Ablation: records in which 'ablation attempted' matches other related entries
Denominator	Number of records
Trend	
Variance	

QI Metric Description/Name	**Hospital Activity Volumes (3-6)**
Why is this important?	International studies have demonstrated that outcomes tend to be poorer in hospitals undertaking low volumes of device and ablation procedures. The British Heart Rhythm Society publishes standards documents for hospitals and clinicians undertaking these procedures in adults. These include minimum recommended procedure volumes, which are stringent by international standards. The standards documents are regularly reviewed.
QI theme	Safety
What is the standard to be met?	**Quality Standard 3 (Device Implantation)** BHRS Standards (2018) recommend that pacing centres undertake a minimum of 80 device implants per year. Training centres should perform more than 100 device implants per year.

	Quality Standard 4 (Complex Device Implantation) BHRS Standards (2018) recommend that complex device centres undertake a minimum of 60 such procedures (ICD and CRT implant/upgrades) per year (80 is desirable). **Quality Standard 5 (Catheter Ablation)** BHRS Standards (2020) recommend that ablation centres undertake a minimum of 100 ablation procedures per year in total. **Quality Standard 6 (AF Ablation)** BHRS Standards (2020) recommend that centres undertaking AF ablation should perform a minimum of 50 such cases per year.
Key references to support the metric	References as above are in reference list at end of report.
Numerator	Pacemaker implants and complex device (ICD, CRTP, CRTD) implants/upgrades, simple and complex ablations.
Denominator	n/a
Trend	
Variance	

QI Metric Description/Name	**Operator volumes for device and ablation procedures (7-11)**
Why is this important?	Studies have demonstrated that device and ablation procedure outcomes tend to be poorer when undertaken by low-volume operators. The British Heart Rhythm Society has made recommendations for individual specialists undertaking device (2018) and ablation (2020) procedures in adults. The standards documents are regularly reviewed.
QI theme	Safety
What is the standard to be met?	**Quality Standard 7 (Pacemaker Implantation)** The minimum volume for an implanting specialist is 35 total new/upgrade devices per year. **Quality Standard 8 (Defibrillator/Cardiac Resynchronisation Therapy)** For those who are non-CRT implanters, it is recommended that operators implant 60 devices per year, of which 30 must be new ICD implants or upgrades. If the operator implants CRT devices, again, 60 device implants per annum is recommended, of which 20 should be new CRT-P/D implants or upgrades. If the consultant is training an SpR they should perform a minimum of 30 ICD or

	CRT implants or upgrades per year, and 40 is desirable. **Quality Standard 9 (All Ablation)** An operator undertaking catheter ablation should perform at least 50 ablation procedures per year. **Quality Standard 10 (Simple Ablation)** An operator performing simple ablations should perform at least 25 simple ablations per year. **Quality Standard 11 (Complex Ablation)** For those undertaking complex procedures (generally AF ablation), the recommendation is at least 25 such procedures from a total of at least 50 procedures per year. ≥50 complex procedures is desirable. Operators performing single-shot atrial fibrillation ablation should be performing a minimum of 25 ablations using that technique each year.
Key references to support the metric	References as above are in reference list at end of report.
Numerator	Pacemaker implants and complex device (ICD, CRTP, CRTD) implants/upgrades; simple and complex ablations.
Denominator	n/a
Trend	
Variance	

QI Metric Description/Name	**Adherence to NICE and Other Guidelines (12-15)**
Why is this important?	To reduce morbidity and mortality, NICE and Other guidelines should be followed.
QI theme	Effectiveness
What is the standard to be met?	**Quality Standard 12 (Pacing for Sinus Node Disease in the Absence of Atrial Fibrillation)** Fewer than 10% of devices should be VVI(R) devices. **Quality Standard 13 (Pacing for Atrioventricular Block in the Absence of Atrial Fibrillation)** Fewer than 10% of devices should be VVI(R) devices. **Quality Standard 14 (ICDs for Primary Prevention)** 80% of ICD implants for primary prevention should be documented to meet at least one of the NICE criteria: • Left ventricular dysfunction ≤35% despite optimum medical therapy and

	who are not in NYHA functional class IV. • A familial cardiac condition with a high risk of sudden death. • Prior surgical repair of congenital heart disease. **Quality standard 15 (ICDs for Secondary Prevention)** 80% of ICD implants for secondary prevention should be documented to meet at least one of the NICE criteria: • Prior cardiac arrest caused by ventricular tachycardia (VT) or fibrillation. • Sustained VT causing syncope or significant haemodynamic compromise. • Sustained VT and left ventricular ejection fraction ≤35%.
Key references to support the metric	References as above are in reference list at end of report.
Numerator	Patients documented to meet the above criteria.
Denominator	Patients undergoing first pacemaker and ICD implants.
Trend	
Variance	

QI Metric Description/Name	**Procedural Success and Complication Rates (16-18)**
Why is this important?	It is clear that patients and clinicians want a successful procedure without complications. There are no absolute standards that can be set. Therefore, relative standards have been adopted.
QI theme	Outcomes
What is the standard to be met?	Quality Standard 16 (Pacemakers) The rate of re-interventions within a year of a first pacemaker implant should be below the 95% upper control limit (national mean + 2 standard errors). Quality Standard 17 (Complex Devices) The rate of reinterventions within a year of a first complex device (ICD or CRT) implant should be within the 95% control limit (national mean + 2 standard errors). Quality Standard 18 (Catheter Ablation) The frequency with which patients undergo a repeat procedure (i.e. to the same or related target) within a year of catheter ablation should

	be within the 95% control limit (national mean + 2 standard errors).
Key references to support the metric	References as above are in reference list at end of report.
Numerator	All device re-interventions in the year following an index procedure, at the implanting hospital or elsewhere. All repeat ablations in the year or two years following an index procedure, at the ablating hospital or elsewhere.
Denominator	All first pacemaker and complex (ICD±CRT) implants. All catheter ablations, divided into simple, complex atrial, and ventricular targets.
Trend	
Variance	

Further Detail on the Logic of Calculations – Devices

Reported Activity

To calculate reported activity, data is used from two fields. The first field is "3.11, intervention category". The second is "3.12, maximum system capability". These two are combined together as follows:

From 3.11, intervention category, the following are included (numbers 1-5):

- New system (first implant)
- Generator change
- Upgrade
- Generator + lead change
- Downgrade

From 3.12, maximum system capability:

- Pacemaker: AAIR, VVIR, DDDR.
- ICD: ICD-VR, ICD-DR, ICD-SQ
- CRT-P+D: CRT-P, CRT-D

Validation

Validation against generator

The purpose of this calculation is to highlight errors (potentially) in the implanted system type. It matches field 3.12, maximum system capability, to field 3.19, make and field 3.20, model, of the generator. Furthermore, it also looks only at entries 1-5 in field 3.11 (as with reported activity).

It is recognised that some "invalid" entries may be correct. For example, a CRT-D generator could be implanted with no LV lead, meaning that the maxim system capability is indeed ICD-DR.

NICE Guidelines

NICE TA324

Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block

https://www.nice.org.uk/guidance/ta324

NICE TA324 states that “Dual-chamber pacemakers are recommended as an option for treating symptomatic bradycardia due to sick sinus syndrome without atrioventricular block”. It is accepted that 100% compliance would be inappropriate, and that a dual chamber system is not appropriate in all cases. The target is 90% compliance. This year that was exceeded in both England and Wales.

NICE TA88 (see below) noted that “Single-chamber atrial pacing is the clinically appropriate pacing mode for people with sick sinus syndrome without atrioventricular block in people who had been fully assessed (for example, using Wenckebach rate testing) for the presence of, and risk factors related to, the development of atrioventricular block.”

The Committee, however, recognised that in certain specific circumstances, single-chamber pacemakers were more clinically appropriate.

The standard that has been set is that on average, 90% of implants should meet guidelines.

Compliance with this recommendation has been calculated as follows:

1. 3.11, intervention = First implant and
2. 3.12, maximum system capability = simple pacemaker and
3. 2.05, atrial rhythm ≠ sustained atrial arrhythmia and
4. 2.04, ECG indication = sinus note disease.

Meeting guidance (or not has been calculated as follows:

1. Meeting guidance = number of records where the recommended system type (3.12 = AAIR or DDDR) has been implanted.
2. Not meeting guidance = number of records where another system (3.12 = VVIR or VDDR) has been implanted.
3. Indeterminate = number of records where compliance cannot be adjudicated due to missing or invalid data.

NICE TA88

Dual-chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block

https://www.nice.org.uk/guidance/ta88

NICE TA88 states that “for most people who have sick sinus syndrome with atrioventricular block, and for those with atrioventricular block without continuous atrial fibrillation, dual-chamber pacing is preferred to single-chamber pacing.”

The Committee, however, recognised that in certain specific circumstances, single-chamber pacemakers were more clinically appropriate.

The standard that has been set is that, on average, 90% of implants should meet guidelines.

Compliance with this recommendation has been calculated as follows.

1. 3.11, intervention = first implant and
2. 3.12, maximum system capability = simple pacemaker and
3. 2.05, atrial rhythm ≠ sustained atrial arrhythmia and
4. 2.04, ECG indication = AV block or conduction disease.

Meeting guidance (or not has been calculated as follows:

1. Meeting guidance = number of records where the recommended type has been implanted (3.12 = DDDR or VDDR).
2. Not Meeting guidance = percentage of records where another system type has been implanted (3.12 = AAIR or VVIR).
3. Indeterminate = number of records where compliance cannot be adjudicated due to missing or invalid data.

NICE TA314

Implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure

https://www.nice.org.uk/guidance/ta324

NICE TA314 details the indications for ICD therapy for both primary and secondary prevention. The indications are as follows.

Primary Prevention

Implantable cardioverter defibrillators (ICDs), cardiac resynchronisation therapy (CRT) with defibrillator (CRT-D) or CRT with pacing (CRT-P) are recommended as treatment options for people with heart failure who have left ventricular dysfunction with a left ventricular ejection fraction (LVEF) of 35% or less as specified in the table below.

Treatment options with ICD or CRT for people with heart failure who have left ventricular dysfunction with an LVEF of 35% or less (according to NYHA class, QRS duration and presence of LBBB)

	NYHA class			
QRS duration	**I**	**II**	**III**	**IV**
<120 milliseconds	**ICD if there is a high risk of sudden cardiac death**			**ICD and CRT not clinically indicated**
120–149 milliseconds without LBBB	ICD	ICD	ICD	CRT-P
120–149 milliseconds with LBBB	ICD	CRT-D	CRT-P or CRT-D	CRT-P
≥150 milliseconds with or without LBBB	CRT-D	CRT-D	CRT-P or CRT-D	CRT-P
LBBB, left bundle branch block; NYHA, New York Heart Association				

The standard that has been set is that, on average, 90% of implants should meet guidelines.

Compliance with this recommendation has been calculated as follows.

1. 3.11, intervention = first implant and
2. 3.12, maximum system capability = ICD-VR or ICD-DR or ICD-SQ and
3. 2.08, ICD indication = primary prevention and
4. 2.02, Aetiology = cardiomyopathy, **other** than HCM, ARVC, Amyloid, Sarcoid, Other, Channelopathy, Structural congenital heart disease, and
5. 2.07, LV function = poor and
6. 2.06, functional status ≠ NYHA class IV.

Secondary Prevention

Implantable cardioverter defibrillators (ICDs) are recommended 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 (VT) or ventricular fibrillation **or**
    - have spontaneous sustained VT causing syncope or significant haemodynamic compromise **or**
    - have sustained VT without syncope or cardiac arrest, and also have an associated reduction in left ventricular ejection fraction (LVEF) of 35% or less but their symptoms are no worse than class III of the New York Heart Association (NYHA) 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.

The standard that has been set is that, on average, 90% of implants should meet guidelines.

Compliance with this recommendation has been calculated as follows.

1. 3.11, intervention = first implant and
2. 3.12, maximum system capability = ICD-VR or ICD-DR or ICD-SQ and
3. 2.08, ICD indication = secondary prevention and
4. 2.03, pre device symptom = syncope and
5. 2.04, ECG indication for device = non-sustained VT/VF, sustained VT/VF, or Torsades des Pointes **or**
6. 2.04, ECG indication = sustained VT/VF and
7. 2.07, LV function = poor.

Meeting guidance (or not has been calculated as follows:

1. Meeting guidance = number of records where the above criteria have been met.
2. Not Meeting guidance = percentage of records where the above criteria have not been met.
3. Indeterminate = number of records where compliance cannot be adjudicated due to missing or invalid data.

Meeting guidance (or not has been calculated as follows:

1. Meeting guidance = number of records where the above criteria have been met.
2. Not Meeting guidance = percentage of records where the above criteria have not been met.
3. Indeterminate = number of records where compliance cannot be adjudicated due to missing or invalid data.

One-year all-cause re-intervention – devices

To indicate complications, all-cause re-intervention in the first 12-months of a first device implant is reported.

The complication is ascribed to the implanting centre, not the centre undertaking re-intervention.

Patients are tracked by NHS Number and Hospital Number.

Only centres with ≥ 90% completeness of NHS Number in both years (2020-21 and 2021-22) are included in the analysis.

It is recognised that re-intervention does not always reflect a complication from the original procedure.

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