NATIONAL CARDIAC AUDIT PROGRAMME

NATIONAL AUDIT OF CARDIAC RHYTHM MANAGEMENT (NACRM)

2021 Summary Report

NICOR

BHRS
British Heart Rhythm Society

The National Institute for Cardiovascular Outcomes Research (NICOR)

NICOR is a partnership of clinicians, IT experts, statisticians, academics and managers who, together, are responsible for six cardiovascular clinical audits (the National Cardiac Audit Programme – NCAP) and a number of new health technology registries, including the UK TAVI registry. Hosted by Barts Health NHS Trust, NICOR collects, analyses and interprets vital cardiovascular data into relevant and meaningful information to promote sustainable improvements in patient well-being, safety and outcomes. It is commissioned by the Healthcare Quality Improvement Partnership (HQIP) with funding from NHS England and GIG Cymru/NHS Wales, and additional support from NHS Scotland.

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British Heart Rhythm Society (BHRS)

The British Heart Rhythm Society is an affiliated group of the British Cardiovascular Society. BHRS acts as a unifying focus for doctors and allied health professionals involved in arrhythmia care and electrical therapies in the UK. BHRS recommends standards for hospitals and individuals undertaking device and ablation procedures, and runs formal certification programmes for professionals.

Arrhythmia Alliance

The Arrhythmia Alliance (A-A): working together to improve the diagnosis, treatment and quality of life for all those affected by arrhythmias. A-A is a coalition of charities, patient groups, patients, carers, medical groups and allied professionals. Although these groups remain independent, they work together under the A-A umbrella to promote timely and effective diagnosis and treatment of arrhythmias.

Barts Health NHS Trust

With a workforce of around 17,000 people, Barts Health is a leading healthcare provider in Britain and one of the largest NHS Trusts in the country. The Trust's five hospitals – St Bartholomew's Hospital in the City, including the Barts Heart Centre, The Royal London Hospital in Whitechapel, Newham Hospital in Plaistow, Whipps Cross Hospital in Leytonstone and Mile End Hospital – deliver high quality compassionate care to the 2.5 million people of east London and beyond.

The Healthcare Quality Improvement Partnership (HQIP)

HQIP is led by a consortium of the Academy of Medical Royal Colleges, the Royal College of Nursing and National Voices. Its aim is to promote quality improvement in patient outcomes, and in particular, to increase the impact that clinical audit, outcome review programmes and registries have on healthcare quality in England and Wales. HQIP holds the contract to commission, manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP), comprising around 40 projects covering care provided to people with a wide range of medical, surgical and mental health conditions. The programme is funded by NHS England, the Welsh Government and, with some individual projects, other devolved administrations and crown dependencies.
www.hqip.org.uk/

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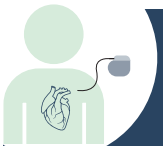
NACRM AT A GLANCE

Data from the period April 2019 to March 2020

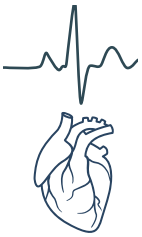


There were >40,000 devices implanted in 175 hospitals in 2019/20, and nearly 20,000 ablation procedures from 61 hospitals (no evidence of change from last year)

Devices

These include pacemaker implants and other devices such as implantable cardioverter defibrillators (ICDs) and complex devices like cardiac resynchronisation therapy (CRT) devices.

In 2019/20, 273 leadless pacemakers and 639 subcutaneous ICD devices were implanted



92% and 94% of patients with sinus node disease and atrioventricular block receive the appropriate type of pacemaker, but not in all hospitals

There is >80% compliance with NICE standards for ICD implantation but some hospitals do not document this consistently

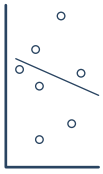
Ablation

Catheter ablation is a procedure 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.

55% of AF ablation is performed by point-by-point radiofrequency ablation and 39% by pulmonary vein isolation using cryoablation

Re-intervention 1 year on

The audit looks at re-intervention rates for pacemakers and ablation.



In 2019/20 there was a 4% 1-year re-intervention rate following pacemaker implantation; 6% for complex devices

There was a 3% 1-year re-intervention rate following simple ablations and 8% for complex atrial and ventricular ablations

Procedure volumes

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.

84% adult NHS pacemaker implant centres meet the standard for procedure volumes but only 66% of adult NHS hospitals meet the standards for complex devices

62% of consultants who implant pacemakers are documented to reach the standards for procedure volumes; only 39% for complex devices

77% of consultants performing ablations meet the standards for procedure volumes; 85% for those performing complex ablations

Executive summary

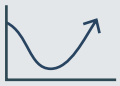
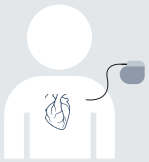
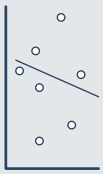
The NACRM report details activity in cardiac rhythm management (CRM) device and ablation procedures for England and Wales and, where possible, Scotland and Northern Ireland in 2019/20.

Hospitals are measured against standards in the domains of safety, effectiveness, and outcomes.

Detailed information for each hospital is given in the appendices. Previous reports and relevant appendices can be found at the NACRM page on the NICOR website.

KEY MESSAGES

	FOCUS OF ATTENTION	AUDIT FINDING
	**Data submission**	Nearly all NHS adult hospitals in England and Wales have submitted their CRM device and ablation procedures on a regular basis and participate in the validation process. Information governance requirements have led to a temporary suspension of submissions from Scotland, Northern Ireland, and some large private hospitals in England.
	**National activity**	After several years of rapid growth in activity, complex (implantable defibrillator and cardiac resynchronization therapy) device implants have been largely static since 2015/16. Likewise, the total number of ablation procedures has not changed significantly since 2016/17, though a slightly higher proportion of these are for atrial fibrillation.
	**Safety – are hospitals doing enough procedures?**	The proportion of NHS adult hospitals reporting fewer than the recommended minimum number of device implants has halved over the last five years, but remains high (18% for pacemakers and 35% for complex devices). The picture is better for ablation, with very few NHS hospitals reporting inadequate numbers of AF ablations.
	**Safety – are doctors doing enough procedures?**	62% of consultants implanting pacemakers are documented as meeting the national standard, and only 39% of those implanting complex devices, which is of concern. The picture is better for ablation, with 77% and 84% respectively of those undertaking simple and complex ablation meeting the standards.

	**Effectiveness: are hospitals sending complete and high quality data to NICOR?**	Data completeness is gradually improving at a national level, but a significant proportion of hospitals fail to submit complete records. There is a trend towards lower valid submissions in 2019/20.
	**Effectiveness: are hospitals following NICE guidance for device implants?**	Documented adherence to NICE guidance for pacemaker prescription remains excellent. That for ICD indications is good and continues to improve, but documentation of adherence is inadequate in some hospitals.
	**Outcomes: what proportion of patients requires another procedure?**	Re-intervention rates in the UK are good by international standards. However, there is wide variation between hospitals with some large centres having high re-intervention rates.

1 Introduction

The National Cardiac Audit Programme (NCAP) was initiated in 2017, bringing together the six main national cardiovascular registries. The first full report was published in November 2018. The National Audit of Cardiac Rhythm Management (NACRM) could not be reported at that time as the audit was redesigned and required a validation process. The NACRM report has now been incorporated into the NCAP annual reporting cycle.

1.1 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.

1.1.1 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 2 hours for the most complex cases. The main devices are:

- Permanent Pacemaker (PPM): 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 Defibrillator (ICD): 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).

1.1.2 Case study

Steve, aged 76 describes his need for an ICD then an upgrade to CRT-D

"When I was in my 40s I developed angina and needed a bypass operation. I did really well from this and went back to work. About 5 years ago I started to get breathless. An echocardiogram showed my heart wasn't working well and was struggling; I was diagnosed with heart failure.

I was seen by the heart failure team and over time my tablets were adjusted. It made me feel better, but my heart was still struggling. It was explained to me that I was at higher risk of dying suddenly from my heart going out of rhythm and I had an implantable defibrillator put in in early 2017.

Despite all of this I continued to go downhill. In 2019 I was using a mobility scooter as I was so breathless. By 2020 I had been referred to the palliative care doctors by the lung doctors, as I also have some lung damage from smoking.

Then COVID happened and I got lost in the system.

One of the pacing physiologists spotted what was happening when I came back in for a check of my device in early 2021. My heart had started to go more slowly and I used the defibrillator to pace my heart more, which had made things worse. By that stage I was using morphine to help my breathlessness and I had fluid everywhere. The cardiologists admitted me, got rid of the fluid and put a new device in me (a cardiac resynchronisation therapy device). This sped my heart up again and made the heart pump better.

Three months on I am much better. I am no longer using the morphine or the scooter and the fluid has gone away."

1.1.3 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' ablations: These were the first ablation procedures to be developed. AV Node ablation (AVNA) 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 (also known as AV node modification) is curative in the vast majority of patients born with extra connections in the heart that cause arrhythmias known as 'supraventricular tachycardia' (SVT). Finally, ablation of the cavo-tricuspid isthmus (CTI) is a cure for the typical form of atrial flutter, caused by rapid circulation of the cardiac impulse within the right atrium. Most simple ablations can be performed as a day case without general anaesthesia.
- Complex atrial ablations: Apart from typical atrial flutter, the ablation of atrial arrhythmias generally requires a more complex approach, usually with computerised equipment to create a 3D 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. In an increasing proportion of cases, pulmonary vein isolation is performed by freezing using a balloon, rather than using RF energy (see Section 1.9.3).

- Ventricular ablations: 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.

1.2 What is covered in this report?

This report serves several functions:

- It provides the official record of CRM device and catheter ablation procedures in the United Kingdom for 2019/20 (along with longer term trends). This facilitates planning by healthcare providers and commissioners.
- The online appendices detail the CRM device and ablation activity at each of the 187 implanting hospitals and 75 ablating hospitals in the UK. They also detail geographical variation in the provision of CRM device therapy across England and Wales (data for Scotland and Northern Ireland are partial as submission to the audit is not obligatory and it was not possible for data collected locally to be shared until further information governance approvals had been sought).
- A number of quality measures are reported for each hospital, relating to data completeness, standards set by the British Heart Rhythm Society, and adherence to NICE guidance on pacemaker and defibrillator therapy (see below).
- We also report total procedure volumes for every operator in the country identified by the General Medical Council (GMC) registration number.
- Uniquely among national cardiac audits, re-intervention rates at one year (two years for ablation) are reported, tracking patients within and between hospitals. This provides an index of complication rates for device implants, and of outcomes for ablation procedures.
- The NACRM data are also important for device surveillance.

1.3 Structure of the report

This report describes activity and outcomes around three key quality improvement themes which run through the wider NCAP report. These are:

- Safety – how can services be made safer?
- Clinical effectiveness – are the best treatments being used and is care being delivered effectively?
- Patient outcomes – what can be done to improve outcomes?

1.4 Methodology

- The audit reports on data relating to CRM procedures (from April 2019 to March 2020) at 174 implanting hospitals and 61 ablating hospitals from across the UK. Detailed figures are given in the Appendices. Annual trends have been calculated using re-analysis of the entire dataset in order to provide consistent methods and to incorporate late-submitted data from previous years.
- Data collection is by financial year, with the aim of analysing and reporting in the following year. Participating hospitals include adult NHS hospitals, children's and private hospitals.
- Details of the audit methodology are given in Appendix 1. As with other NCAP audits, 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 made and analysed before reporting. Centre-specific results and operator statistics are presented as submitted, with details in the Appendices. However, national statistics are calculated after adjudication of these data to make corrections and completions where this can be done with confidence.

1.5 Activity levels and trends

We report our estimates for implants and upgrade procedures for all types of active CRM devices and for all ablation targets, along with trends in recent years, for the UK. These are based on adjudicated data, i.e. correcting for unequivocal errors or omissions in data submission (e.g. devices reported as pacemakers when the generator model and leads leave no doubt that an ICD was implanted).

Device data are reported for the UK overall, and for each constituent nation; ablations are reported for the UK. These statistics are based on the location of the operating hospital rather than the patient's residence. Few patients cross borders for treatment on the NHS, but a number from parts of Wales have historically been treated in England.

Procedure rates based on the residence (postcode) of patients in England and Wales can be seen using interactive maps in Appendices 2 and 3.

1.6 Changes to hospitals reporting device and ablation procedures

Interpretation of procedure volume data depends on an understanding of 'missing' data, chiefly from nations and hospitals that ceased to submit to NICOR while continuing clinical activity. This year's report has been significantly affected by the cessation of submissions from Northern Ireland, some hospitals in Scotland (related to a need to seek further information governance approval to send data), and some large private sector providers. Additionally, some small hospitals have genuinely stopped undertaking procedures while a few new hospitals have opened or started submitting.

This section enumerates these data losses and gives estimates of the impact on our national statistics.

1.6.1 Changes to hospitals reporting device procedures

In 2019/20, 174 hospitals in the UK reported device implants (Appendix 6), six fewer than in 2018/19.

- 'Missing' centres: 9 hospitals in England and Wales that are thought to be implanting failed to submit records in 2019/20, in addition to three private hospitals where activity is unknown. Submissions from the three centres in Northern Ireland have been suspended, and two centres in Scotland stopped submitting. Additionally, a few pacemaker hospitals in Scotland have never submitted.
- 'New' centres: 5 hospitals in England and Wales submitted records that had not done so the previous year.

Details of 'missing' and 'new' centres are given in Table 1.

Table 1: 'Missing' and newly submitting device centres 2019/20

	'Missing' centres (estimated simple, complex implants)	'New' centres (number simple, complex implants)
England and Wales	Chelsea and Westminster* (10,0)	Plymouth (285,176)
	Huddersfield (25,26)	Maidstone (150,63)
	Lewisham* (2,0)	Bath (329,0)
	Lister Stevenage (120,0)	North Tees (37,11)
	Luton and Dunstable (151,0)	Weston Gen. (17,0)
	Pilgrim Grantham* (23,0)	
	Royal Free (8,0)	
	Solihull (155,0)	
	Stepping Hill (82,0)	
	Tunbridge Wells (unknown.)	
	N Durham* (5,0)	
	Whipps Cross (11,0)	
	Neville Hall* (45,0)	
	Royal Gwent (72,0)	
Northern Ireland	Belfast City (44,32)	None
	Belfast Royal (43,23)	
	Craigavon (63,0)	
Scotland	Dumfries* (3,0)	None
	Edinburgh Royal (592,101)	
	Aberdeen (38,6)	
Children's	None	None
Private	Nuffield Bournemouth (unknown.)	None
	Spire Leeds (unknown.)	
	Spire Manchester (unknown.)	

*Estimated numbers of pacemaker and complex implants at 'missing' centres are based on their last complete submissions where these are available, 'unknown' where not). * Centres thought not to be implanting are asterisked.*

Based on prior activity, it is estimated that 'missing' centres resulted in under-reporting of activity by ≥1492 pacing implants and ≥188 complex device implants/upgrades. As a proportion of total activity, the impact is negligible for NHS activity in England and Wales but significant in Scotland and Northern Ireland (see Section 1.7).

1.6.2 Changes to hospitals reporting EP/ ablation procedures

Sixty-one hospitals in the UK reported undertaking ablation procedures during 2019/20 (Appendix 7). This is eight more than in 2018/19.

- 'Missing' centres: submissions from NHS adult centres improved across the UK, with only one in England and Wales now failing to submit, along with one in Scotland and both in Northern Ireland (from where reporting was suspended). Based on previous activity at 'missing' centres, it is estimated that national activity has been under-reported by at least 2153 ablations.
- 'New' centres: in addition, six NHS adult centres hospitals reported ablations in 2018/19 that had not in 2018/19, along with one children's and one private hospital.

Details of 'missing' and 'new' centres are given in Table 2.

Table 2: 'Missing' and newly submitting ablation centres 2019/20

	'Missing' Centres (estimated number of ablations)	"New" centres (number of ablations)
England and Wales	Leeds General (683)	Maidstone (74)
		Sheffield (193)
		St Cross (Rugby) (283)
		Worcester (25)
Northern Ireland	Belfast City (106)	
	Belfast Royal (446)	
Scotland	Aberdeen Inf. (137)	Edinburgh R.I. (394)
		Glasgow G Jubilee (376)
Children's	Bristol (68)	Alder Hey (60)
Private	Harley St Clinic (313)	Spire Southampton (42)
	Kent Institute (unknown)	
	London Bridge (255)	
	Spire Leeds (unknown)	
	Spire Manchester (unknown)	
	Wellington North (145)	

Estimated numbers of ablation procedures at 'missing' centres are based on their last complete submissions where these are available, 'unknown' where not.

1.7 Device Implant Rates

Total reported implants and implant rates pmp for 2019/20 are shown in Table 3.

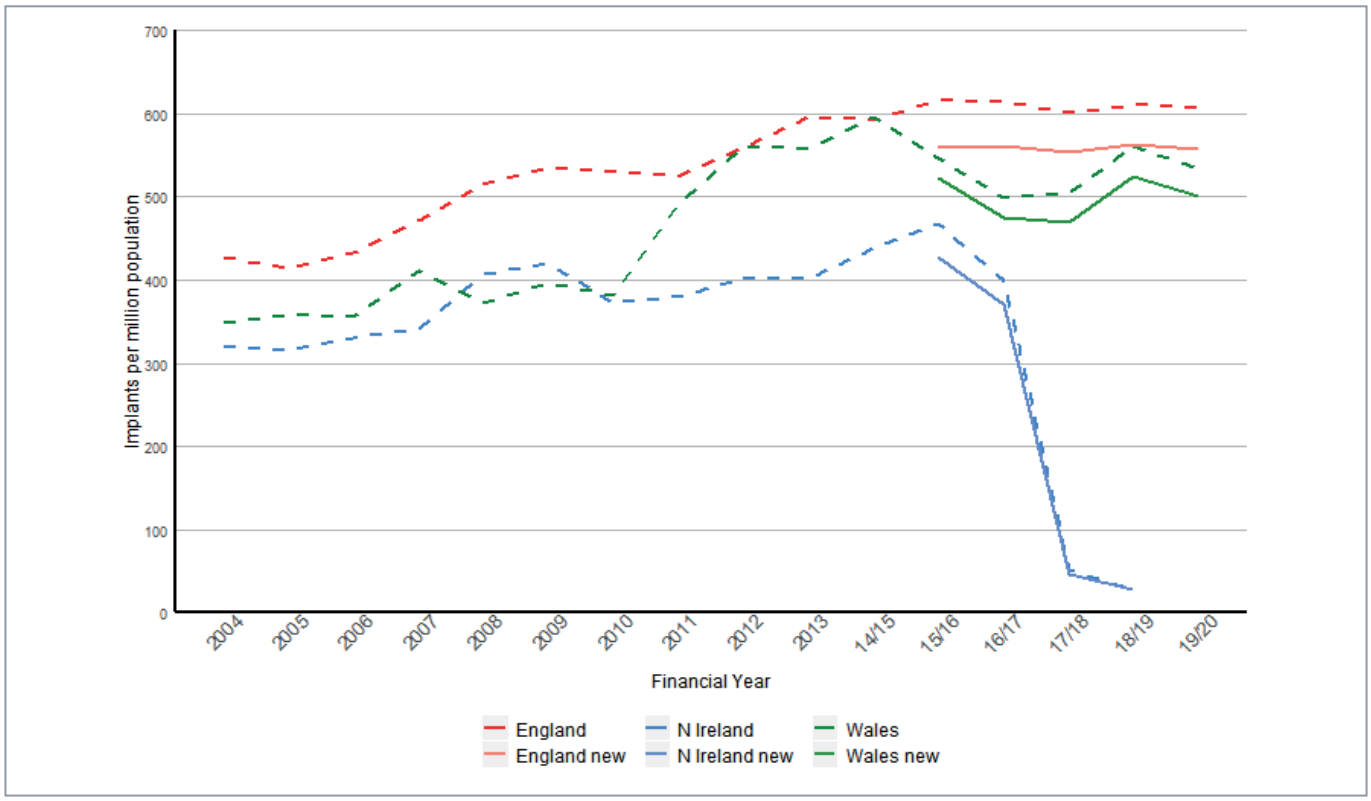
Table 3: Device implants 2019/20

	England	N.I.	Scotland	Wales
Pacemakers (first implants)	31,407 (558)	–	877 (161)	1,577 (500)
ICDs (new and upgrade)	5,304 (94)	–	217 (51)	310 (98)
ICD + CRTD (new and upgrade)	8,982 (160)	–	398 (73)	569 (180)
CRTP + CRTD (new and upgrade)	8,085 (144)	–	338 (62)	502 (159)

Implants per million population in parentheses. Data from Scotland are unreliable because of under-reporting.

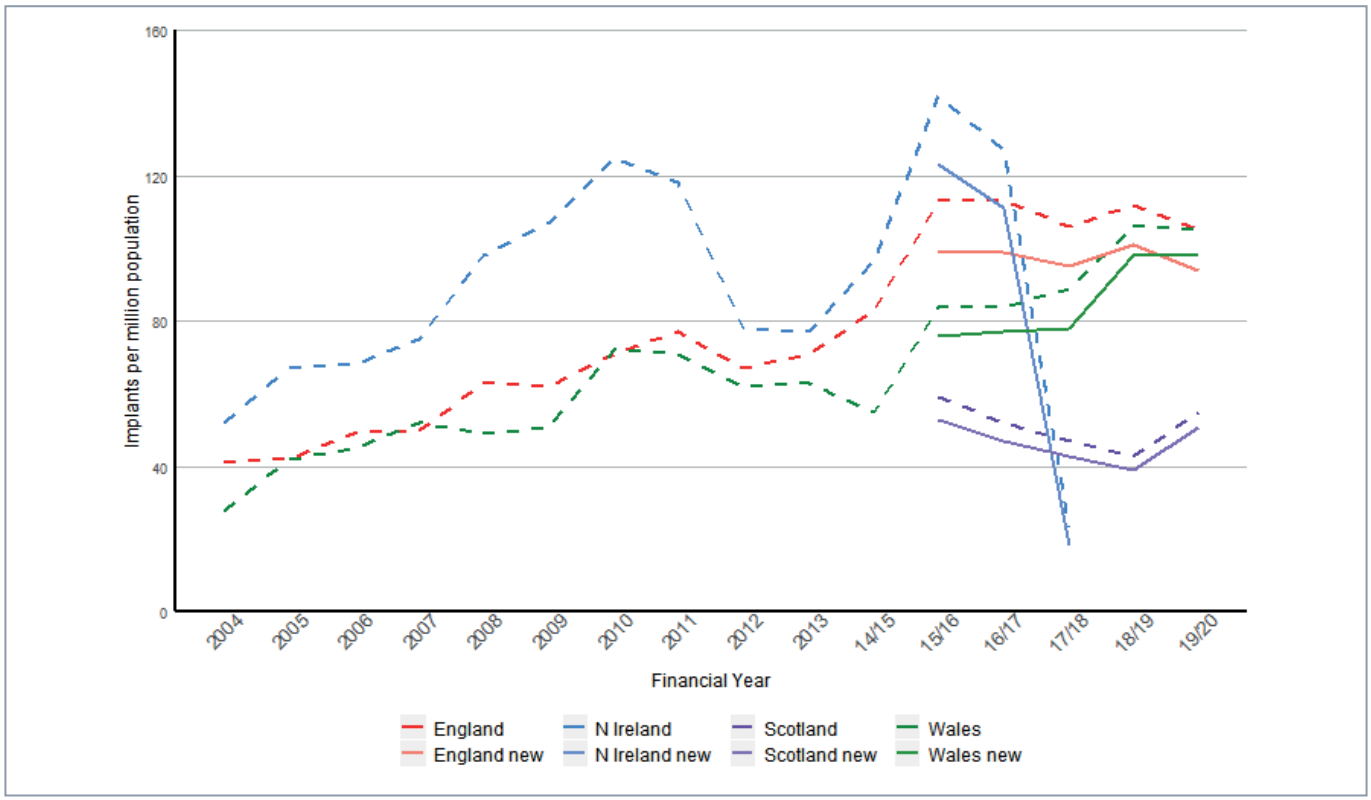
Longer term trends for device implant rates per million population (pmp) are shown in Figure 1.1 to Figure 1.5. In each figure, dotted lines use old counting methods that included device replacements, etc. Solid lines represent first implants (for pacemakers), or first implants of the type (i.e. including upgrades) for complex devices. This calculation has only been possible with the introduction of a new dataset in 2015. The trends include the minority of cases reported in Scotland and Northern Ireland in recent years.

Figure 1.1: Pacemaker implants per million population, 2004 – 2019/20



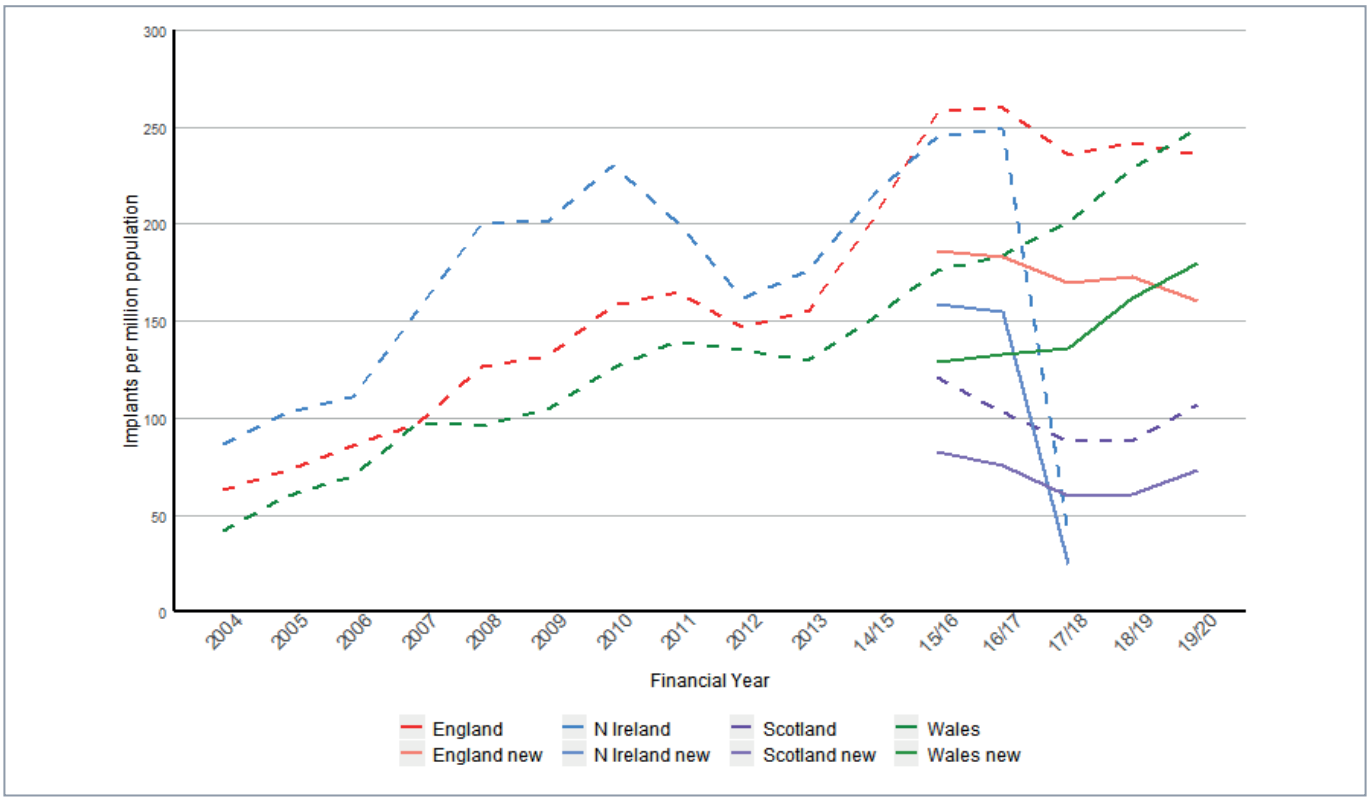
Implant rates rose between 2004 and 2014 but have since been fairly stable. This mirrors a halt in increasing life expectancy.[1] Implants in N Ireland were at slightly lower levels up to 2017/18 but reporting in the last two years has been suspended. Scottish implants are not shown as a number of hospitals have never participated in the audit.

Figure 1.2: Defibrillator implants, 2004 – 2019/20



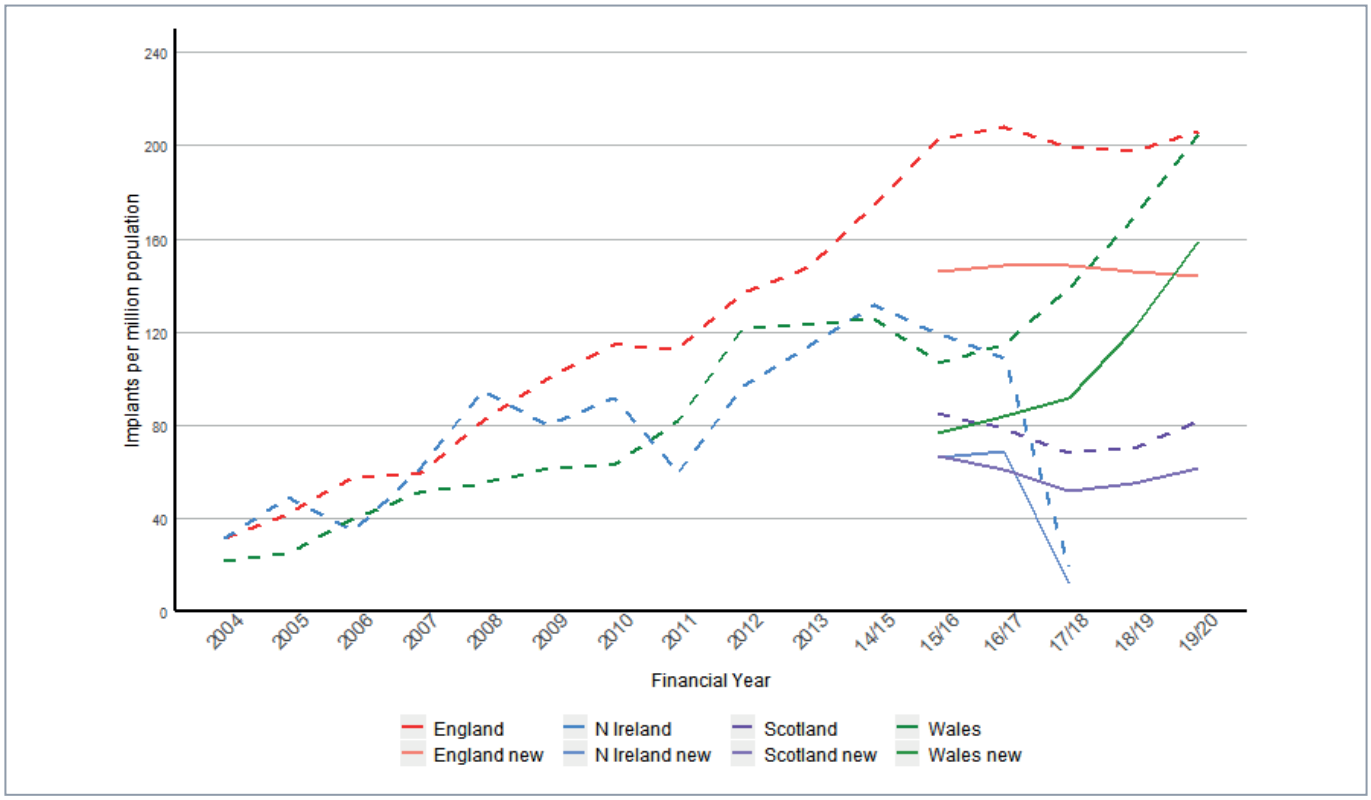
Implants of ICDs (excluding CRTD) are shown. Following a steady rise in response to NICE guidance in 2006, implant rates have not changed significantly in England over the last five years, while implants in Wales now match those in England. Reporting from N Ireland has been suspended since 2017/18.

Figure 1.3: Implants of a high energy device (ICD + CRTD), 2004 – 2019/20



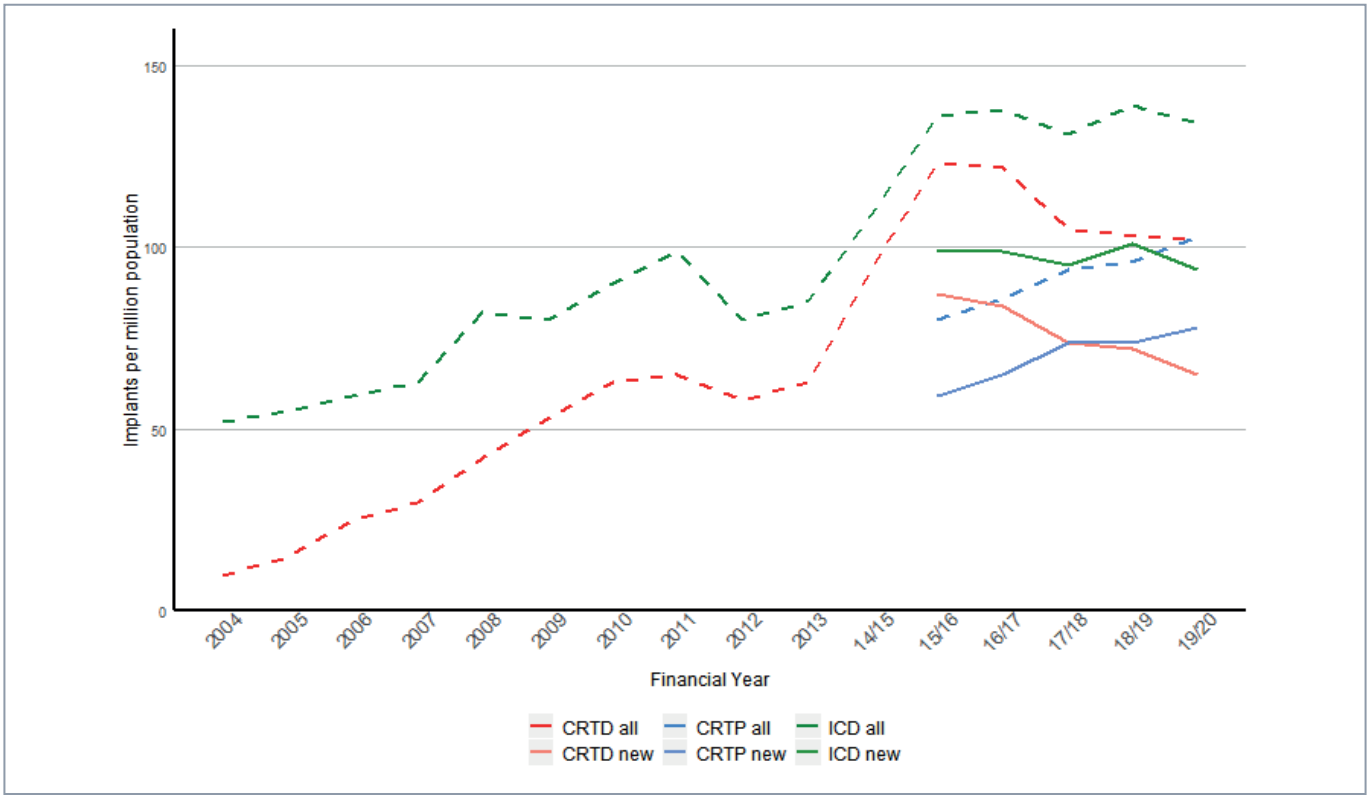
Implants (including upgrades) of ICD and CRTD devices are shown. Implants in England and Wales are now at similar levels, as were those in N Ireland prior to the temporary suspension of reporting. Implants reported from Scotland remain around half this level.

Figure 1.4: Cardiac resynchronisation therapy, 2004 – 2019/20



CRT-P and CRT-D implants and upgrades are shown. Again, rates in England and Wales are now similar, with those from N Ireland somewhat lower prior to the suspension of reporting, and those reported from Scotland were approximately half this level.

Figure 1.5: Case-mix of complex devices, 2004 – 2019/20



Implants and upgrades for ICDs, CRT-P and CRT-D are shown for England only. Reliable historic data are not available for CRTP. Implants were dominated by ICDs in the early 2000s, but the ratio of ICD:CRTD:CRTP has been consistently around 40%:30%:30% in the last three years.

Prior to 2014, data were analysed by calendar year. Since 2014/15 analysis has been by financial year ("2014" = 2014/15) and has used adjudicated data to maximise accuracy (for details of methods see Appendix 1).

The populations of the devolved nations are relatively low (Scotland 5.5m, Wales 3.2m and Northern Ireland 1.9m, compared to England 56.3m, in 2019). Consequently, short term fluctuations in implant numbers (due to changes in local factors and practices) can result in relatively large swings in implant rates. This is particularly seen for Northern Ireland.

Interactive maps of device implant rates by patients' area of residence (rather than site of treatment) can be seen in Appendix 2.

1.8 Catheter Ablation Volumes

The breakdown of ablation procedures reported in the UK over the last six years is given in Table 4. Longer-term trends in ablations, grouped by the category of target, are shown in Figure 1.6, in which the estimated 'missing' data in 2018/19 and 2019/20 are indicated as an extra category.

Total reported catheter ablation procedures in the UK approximately doubled between 2007 and 2012, and increased more slowly over the next five years, and have been fairly stable since 2016.

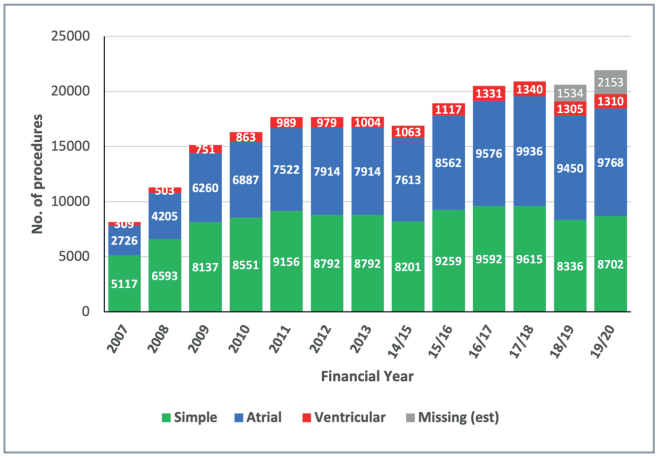
Over this 13-year period, complex atrial ablation (overwhelmingly for AF and tachycardias related to prior AF procedures) has come to dominate while simple and ventricular ablations have been relatively static.

Table 4: Reported catheter ablation volumes 2014 – 2020

Financial Year	14/15	15/16	16/17	17/18	18/19	19/20
Simple ablation targets only						
Complete AV nodal	1,218	1,460	1,498	1,599	1,634	1,559
AV nodal re-entry	2,686	3,141	3,348	3,508	3,222	2,845
Accessory Pathway	1,418	1,632	1,656	1,548	1,458	1,520
CTI ("typical atrial flutter")	3,378	3,832	3,945	4,082	3,914	3,337
Total simple ablations	**7,934**	**9,190**	**9,534**	**9,769**	**9,247**	**8,702**
(>1 simple target)	45	40	54	45	45	43
Complex atrial ablations						
AF ablation ± other	6,477	7,331	8,197	8,807	9,153	8,679
Other complex atrial	865	1,063	1,237	1,137	1,099	1,089
Total complex atrial ablations	**7,342**	**8,394**	**9,434**	**9,944**	**10,252**	**9,768**
Ventricular ablations						
PVCs, focal VT only	711	666	815	839	844	760
VT – Scar ±	315	457	530	529	522	550
Total ventricular ablations	**1,026**	**1,123**	**1,345**	**1,368**	**1,366**	**1,310**
Total complex ablations	**8,355**	**9,510**	**10,764**	**11,297**	**11,606**	**11,068**
Total ablations	**16,289**	**18,700**	**20,298**	**21,066**	**20,853**	**19,770**
Ablation in congenital heart disease	203	276	311	291	314	313
No ablation/unknown target	3,230	3,388	3,177	3,036	2,726	2,641

Note: complex procedure totals include those combined with additional simple targets. 'Total simple procedures' excludes these, and counts procedures with >1 simple target singly.

Figure 1.6: Summary of longer-term trends in catheter ablation, 2007 – 2020



Data provided over the last 13 years, grouped by procedure type (data have been analysed by financial year since 2014). Grey indicates estimated totals of ablations at non-submitting centres in the last two years (see Section 1.6.2).

1.9 Adoption of New Technologies

Cardiac rhythm management is dependent 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.

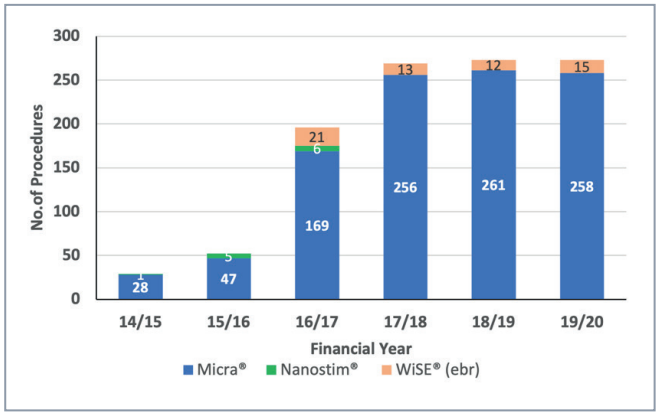
1.9.1 Leadless pacemakers

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.

A recent innovation is a pacemaker sufficiently small to be directly attached to the inside of the right ventricle. At present Leadless Cardiac Pacemakers (LCPs) lack the advantages of atrial based pacing and cardiac resynchronisation. However, they avoid the need for leads and appear to have a significantly lower risk of infection. NICE published interventional procedure guidance in 2018.[2] Two models of LCP have been implanted, Micra® (Medtronic) and Nanostim® (St Jude): market release of the latter was suspended in 2018 but is expected to resume along with a third manufacturer in the near future.

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.

Figure 1.7: Leadless cardiac pacemaker implants, 2007 – 2020



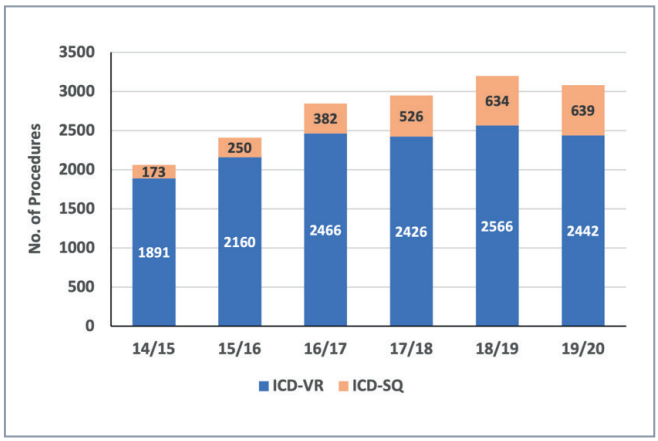
LCPs implants in significant numbers started in the UK in 2016/17, but implant rates remain low compared to many other countries. This may be due to unfamiliarity, the need for special training, manufacturers' stipulations for implanting centres, and a significantly higher cost compared to conventional devices. The WiSE® system is still investigational and implanted at a limited number of centres.

1.9.2 Subcutaneous defibrillators

Conventional ICDs can be affected by the same limitations of leads in the heart, and defibrillation leads can be both more prone to failure and more difficult to extract than pacing leads. The subcutaneous implantable defibrillator (SQID) was introduced to address this limitation for that proportion of patients whose need is solely for defibrillation shocks (i.e. no need for pacing). All components of this device are under the skin but outside the ribcage. At present only one manufacturer of SQID is available (SICD, Boston Scientific). NICE published interventional procedure guidance in 2017.[3]

Most patients receiving a subcutaneous ICD would otherwise receive a transvenous single chamber ICD: relative implant rates for these two types are shown in Figure 1.8.

Figure 1.8: Transvenous single chamber and subcutaneous ICD implants, 2007 – 2020



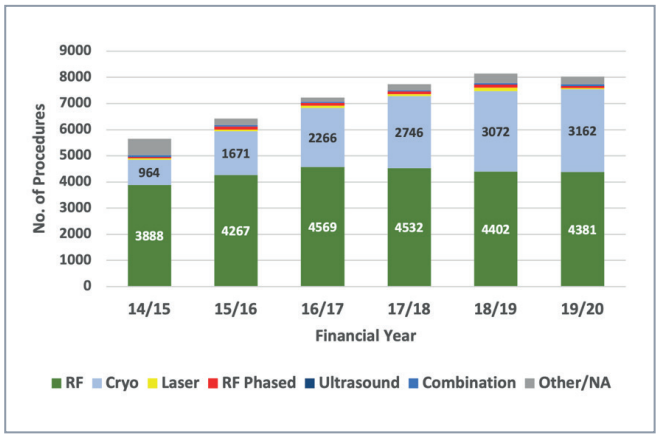
First implants of single chamber transvenous (ICD-VR) and subcutaneous (ICD-SQ) ICDs are shown. In the last three years the latter have accounted for around 20% of cases.

1.9.3 'Single-shot' catheter ablation for AF

AF ablation involves creating a band of scar around the openings of the pulmonary veins into the left atrium, so that the abnormal signals that trigger AF are isolated. Conventionally this 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 'cryoballoon' which produces scar by freezing. This technique has similar effectiveness and safety profiles for first-time AF ablation cases and has the advantage of being quicker.

Figure 1.9 shows the technologies used for AF ablation cases over the last six years. Pulmonary vein isolation by cryoballoon alone now accounts for 39% of cases, with 55% using 'point by point' RF ablation alone.

Figure 1.9: Technologies used for AF ablation, 2007 – 2020



The figure shows procedures where atrial fibrillation was the only ablation target (n = 8679 in 2019/20: a further 645 procedures were for AF and other targets, most commonly atrial flutter).

2 | Quality improvement metrics

For ease of reading, we have grouped analysis of performance against the 14 standards into eight categories (Sections 2.1 to 2.8).

2.1 Centre volumes: the number of hospitals performing small numbers of device and ablation procedures is low and falling

2.1.1 **Overview of QI metric**

QI Metric Description/Name	Hospital Activity Volumes
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: we have compared hospitals' data to those applicable at the time.[5, 6]
QI theme	Safety
What is the standard to be met?	Quality Standard 1 (Device Implants): BHRS Standards (2015)[5] recommend that pacing hospitals undertake a minimum of 80 pacemaker implants per year (this was 60 in the 2013 Standard). Training hospitals should conduct ≥ 105 implants per year. Quality Standard 2 (Complex Device Implants): Hospitals undertaking ICD and CRT implant/upgrades should undertake a minimum of 60 such procedures per year. Quality Standard 3 (Simple Catheter Ablation): BHRS Standards (2016)[6] recommend that ablation hospitals undertake a minimum of 100 ablation procedures per year in total. Quality Standard 4 (AF ablation): Hospitals 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	The number of low volume pacemaker and complex device centres continues to fall slowly but remains high. The number of low volume ablation centres (excluding private and childrens' hospitals) is now very low.
Variance	Apparently low volume centres may partly reflect mis-reporting. Some genuinely low volume centres may be new, or in remote geographies.

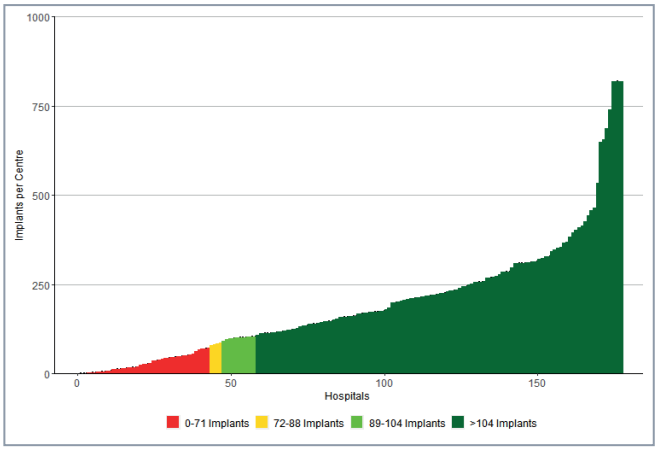
2.1.2 Audit results

Device implants

In 2019/20, 175 centres (including private and children's hospitals) reported pacemaker implants, and 129 reported complex (ICD±CRT) device implants/upgrades. Of these, 131 (75%) met the standard for pacemakers (80 implants) and 72 (56%) met the standard for complex procedures (60 implants/upgrades). Details for each centre are given in Appendix 6.

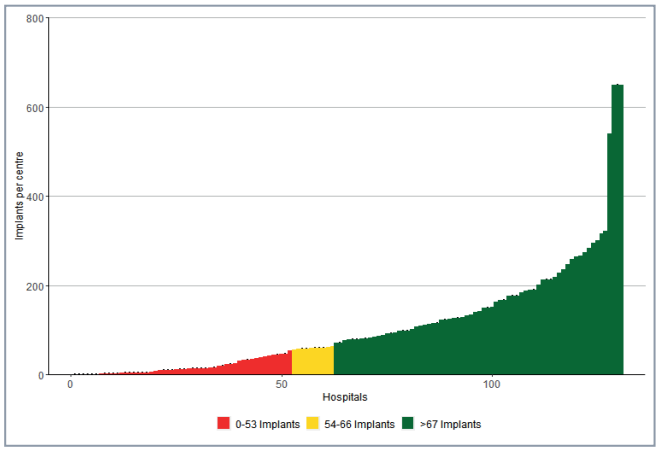
The distributions of centre volumes for pacemakers and complex devices are shown in Figure 2.1 and Figure 2.2.

Figure 2.1: Distribution of centre volumes for pacemaker implants, 2019/20.



Amber indicates centres implanting ± 10% of the recommended minimum (80 procedures). Red and green indicate centres below and above this range. Dark green indicates centres meeting the recommended minimum for training (105 procedures).

Figure 2.2: Distribution of centre volumes for complex implants/upgrades, 2019/20

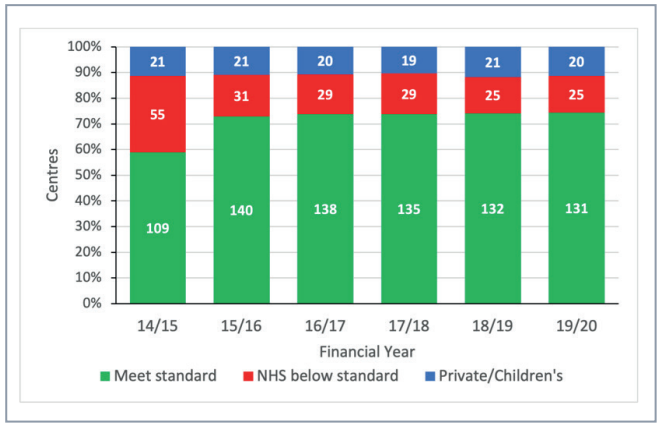


Amber indicates centres implanting ± 10% of the recommended minimum (60 procedures), red and green indicate centres below and above this range.

The number of centres reporting pacemaker implants has diminished somewhat over the last five years, while the number reporting complex implants has remained fairly static [Figure 2.3 and Figure 2.4]. The proportion of NHS adult centres not meeting the standard for pacemaker implantation (80 implants) has decreased to 16%: the proportion for complex procedures has also decreased but remains high at 34%.

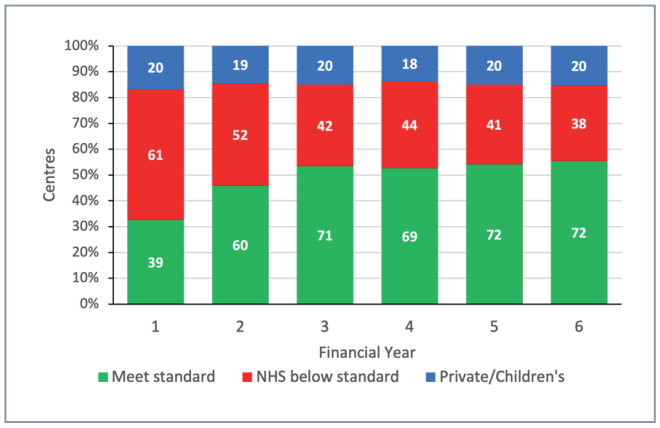
Twenty-two NHS adult hospitals reported fewer than half the standard (<30 procedures). Many of these were private/children's hospitals. Additionally, some NHS adult hospitals may have submitted incorrect data (e.g. under-reporting or non-implanting centres following up patients implanting elsewhere) or be in the process of service transition to larger units.

Figure 2.3: Number of centres meeting standard for pacemaker implants, 2014 – 2020



Actual numbers of centres are within each bar.

Figure 2.4: Number of centres meeting standard for complex implants/upgrades, 2014 – 2020

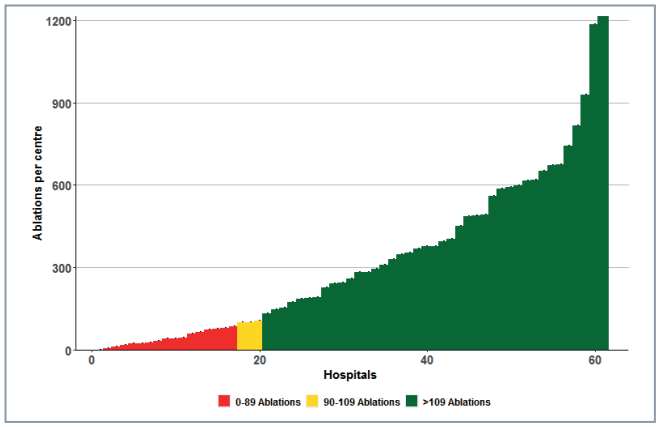


Actual numbers of centres are within each bar.

Catheter ablations

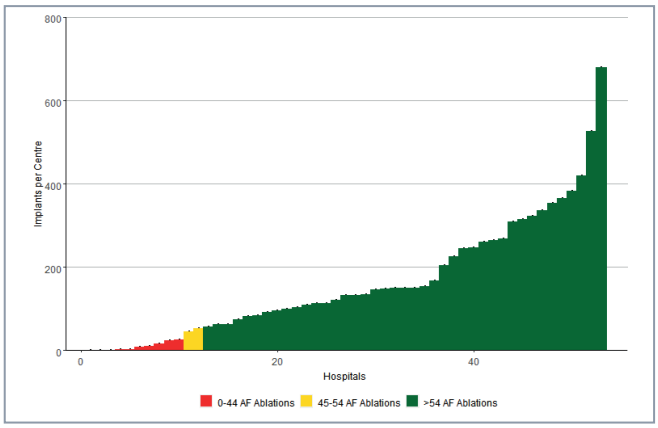
In 2019/20, 61 centres (including private and children's hospitals) reported undertaking simple catheter ablation procedures, and 53 reported AF ablations. Of these, 44 (72%) met the standard (100 ablations in total) for simple ablation and 42 (79%) met the standard for AF ablation (50 procedures). The distributions of centre volumes for simple and AF ablation in 2019/20 are shown in Figure 2.5 and Figure 2.6.

Figure 2.5: Distribution of centre volumes for total ablations, 2019/20



Amber indicates centres undertaking ± 10% of the recommended minimum (100 ablation procedures), red and green indicate centres below and above this range.

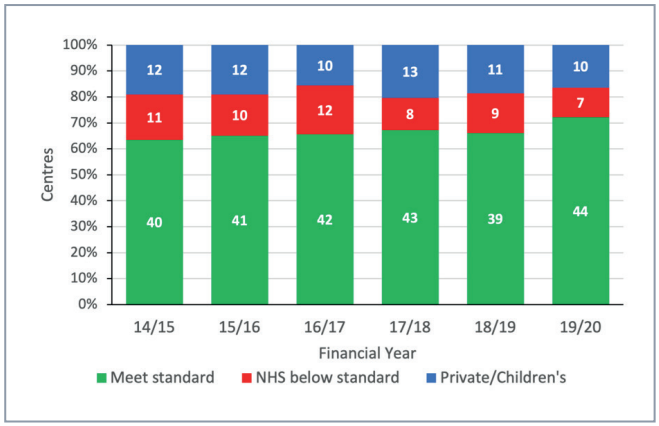
Figure 2.6: Distribution of centre volumes for AF ablation, 2019/20



Amber indicates centres implanting ± 10% of the recommended minimum (50 AF ablations), red and green indicate centres below and above this range.

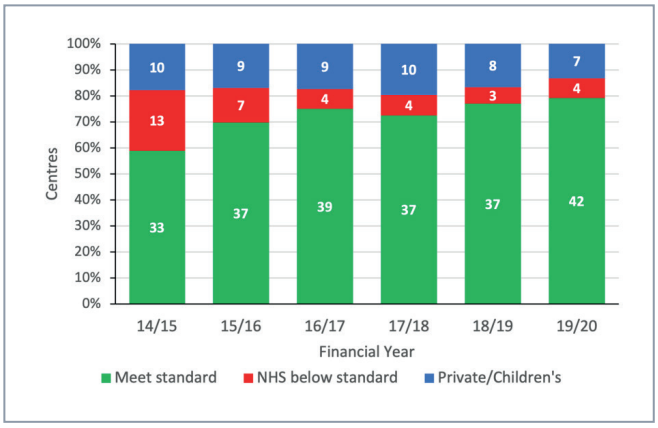
The number of centres reporting catheter ablations has remained fairly static since 2014 [Figure 2.7 and Figure 2.8]. The proportion of NHS adult centres not meeting the standard for simple ablation (100 ablations in total) has fallen and is now 15%, with five NHS adult hospitals reporting very low volumes (fewer than 50 ablations in total). The proportion of NHS Adult centres not meeting the standard for AF ablation (50 cases) remains around 10%: two of the four centres reported very low numbers and may in fact reflect misreporting of simple procedures as AF ablations.

Figure 2.7: Number of centres meeting standard for simple ablations, 2014 – 2020



Actual numbers of centres are within each bar.

Figure 2.8: Number of centres meeting the standard for AF ablation, 2014 -2020



Actual numbers of centres are within each bar.

2.1.3 Recommendations for those not achieving the standards

Data submission: centres with apparently very low volumes should engage with the validation process to ensure they are not misrepresented. Device clinics should not submit records of follow-up patients they have 'inherited' from other implanting centres.

The appropriateness and sustainability of centres with low volumes should be discussed locally and at network level.

2.2 Operator volumes: most cardiology specialists undertaking ICD and CRT implants are doing too few, while most performing ablation are doing sufficient numbers

2.2.1 **Overview of QI metric**

QI Metric Description/Name	Operator volumes for Device and Ablation procedures
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 (2015) and ablation procedures (2016) in adults.[5,6] The standards documents are regularly reviewed: we have compared hospitals' data to those applicable at the time.
QI theme	Safety
What is the standard to be met?	Quality Standard 5 (Pacemaker Implantation): The minimum volume for an implanting specialist is 35 total new devices per year. Quality Standard 6 (Defibrillator/Cardiac Resynchronization Therapy): For those undertaking complex implants/upgrades the recommendation is at least 30 such procedures within a total of 60 device implants per year. Quality Standard 7 (Catheter ablation): Interventional electrophysiologists undertaking catheter ablation should perform at least 50 procedures per year. Quality Standard 8 (Complex ablation): For those undertaking complex procedures (generally AF ablations) the recommendation is at least 25 such procedures within a total of at least 50 ablations per year; while ≥50 complex procedures is desirable.
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	The proportion of cardiologists documented to achieve the quality standards for devices is falling, while that for complex ablations is rising.
Variance	There is wide variation in operator volumes in 2019/20, with 62% of pacing consultants documented to meet the standard and only 39% of complex implanting consultants. 77% of ablating cardiologists were documented to meet the standard for simple ablation, and 85% of those undertaking complex ablation met the standard.

2.2.2 Audit results

Procedure volumes for all operators (identified by GMC Number) are given in Appendix 8 (Devices) and Appendix 9 (Ablation). For the first time, this report gives three-year as well as one-year volumes, as BHRS recognises that a 'rolling average' may be appropriate in some circumstances.

Operators on the specialist register for adult cardiology have been rated red, amber, or green according to whether they have been documented to meet the minimum recommended procedure numbers. A large number have very small numbers (1 or 2 procedures) reported, but inspection of these indicates that they are almost all in error (e.g. admitting cardiologist).

2.2.2.1 Devices

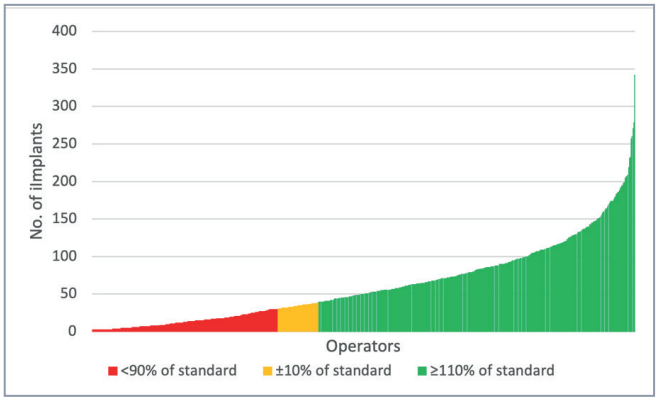
In 2019/20, 1460 doctors identified by valid GMC numbers were reported as having performed device implants/upgrades as scrubbed operator and/or supervising consultant. Of these, 863 were on the specialist register for cardiology, 22 for paediatric specialties, and 353 were trainees. The remaining 222 were a mixture of cardiac surgeons, other specialties (some clearly erroneous entries) and 154 with no registered specialty – these are thought largely to have been non-training fellows, staff grades etc.

The distribution of operator volumes for device and complex (ICD/CRT) device implants is shown in Figure 2.9 and Figure 2.10. 62% of cardiology specialists undertaking device implants met the standard of ≥35 implants, and only 39% undertaking complex implants met the standard of ≥30 such procedures.

These low values are, if anything, worsening [Figure 2.11].

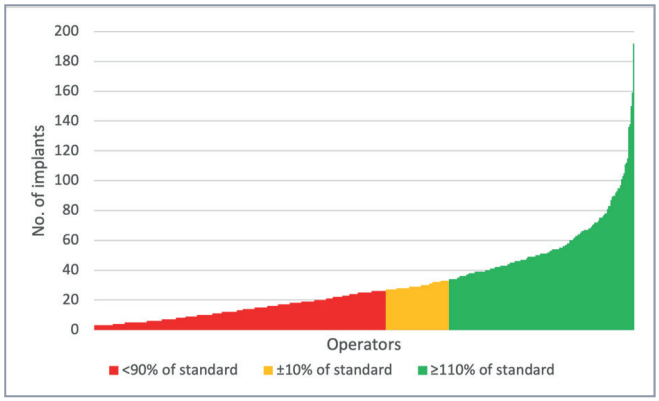
While under-reporting may account for some apparently low implant volumes, it is unlikely to have affected the adverse trend, as GMC Number submission completion is improving (see Section 2.3).

Figure 2.9: Distribution of operator volumes: all device implants, 2019/20



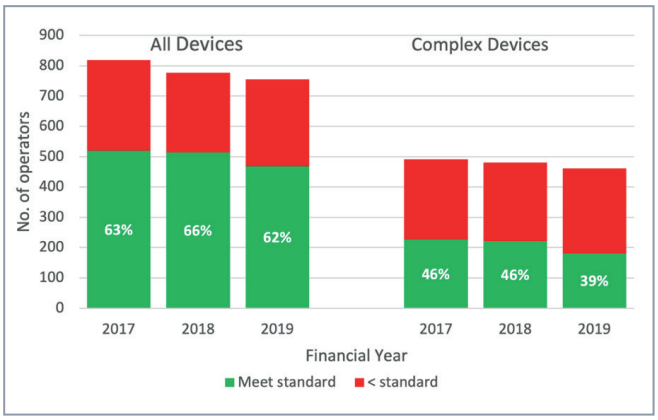
Only cardiology specialists with >2 procedures shown (see text above).

Figure 2.10: Distribution of operator volumes: complex devices, 2019/20



Only cardiology specialists with >2 procedures shown (see text above).

Figure 2.11: Number and proportion of cardiologists achieving recommended minimum procedure numbers for device implants, 2017 – 2020



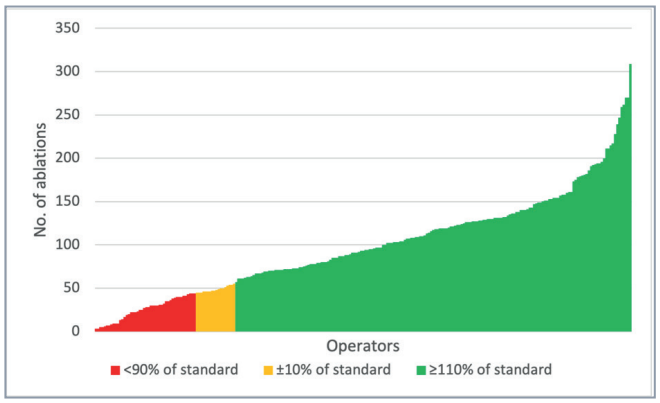
Only cardiology specialists with >2 procedures shown (see text above).

Ablations

In 2019/20, 429 doctors identified by valid GMC numbers were reported as performing device implants/upgrades as scrubbed operator and/or supervising consultant. Of these, 275 were on the specialist register for cardiology, 15 for paediatric specialties, and 100 were trainees. Of the remaining 39, 34 had no registered specialty.

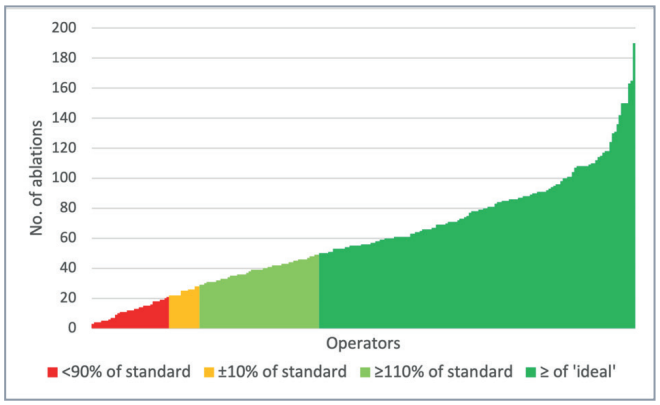
The distributions of operator volumes for ablations and complex (largely AF) ablations are shown in Figure 2.12 and Figure 2.13. 77% of cardiology specialists undertaking ablation met the standard of ≥50 procedures. This has not changed significantly in the last three years. 85% of those undertaking complex ablations met the standard of ≥25 such procedures, an improvement over the last three years [Figure 2.14].

Figure 2.12: Distribution of operator volumes: all ablations, 2019/20



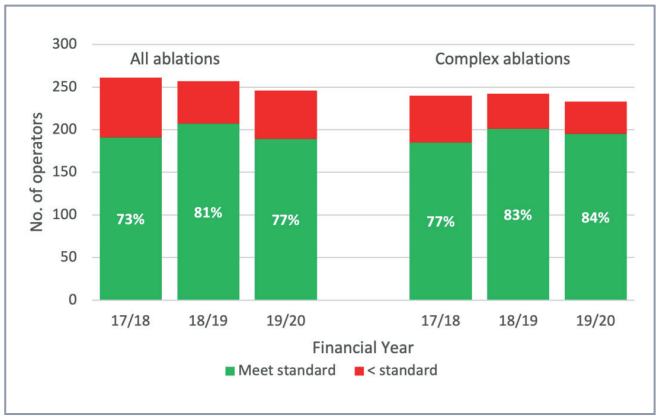
Operators with <3 reported procedures omitted (see text).

Figure 2.13: Distribution of operator volumes: complex ablations, 2019/20



Operators with <3 reported procedures omitted (see text).

Figure 2.14: Proportion of specialists achieving minimum procedure numbers for ablation procedures, 2017 – 2020



Operators with <3 reported procedures omitted (see text).

2.2.3 Recommendations for those not achieving the standard

Consultants are reminded that submission of correct and complete data for procedures is their responsibility.

Clinical directors should investigate whether low operator volumes are the result of poor data submission, or genuinely low activity. Genuinely low volume operators should be subject to close local audit for complications etc, and the sustainability of their practice should be examined.

2.3 Data completeness: improving at NHS hospitals, but many are still failing to submit adequate data

2.3.1 Overview of QI metric

QI Metric Description/Name	Data completeness
Why is this important?	A key indicator of an effective service with good governance is compliance with audit. This means complete and accurate data entry.
QI theme	Effectiveness
What is the standard to be met?	Quality Standard 9: Hospitals should achieve ≥90% completeness in each of 6 data domains for device and ablation procedures
Key references to support the metric	N/A
Numerator	For each data domain, average of fields completed
Denominator	Number of records
Trend	Submissions for demographics and GMC Numbers are improving but remain inadequate at some hospitals, while clinical and procedural data completeness is not improving sufficiently.
Variance	Wide variation exists between hospitals, with some consistently achieving 100% completeness in all domains, others much lower. Completeness from private hospitals and those in Scotland is low, especially in demographics

2.3.2 Audit results

Data completeness has been calculated for a 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 6 domains:

- Demographics: the average completeness of NHS Number and Postcode, (essential for analyses of re-intervention rates and maps of geographic provision). Other demographic fields are technically mandatory and therefore 100% by definition.
- Clinical (basic): average completeness over four fields describing the clinical indications for pacemakers.
- Clinical (complex): average completeness over fields describing the clinical indications for complex devices, or for AF ablations (not required for simple devices and other ablations).
- GMC: mean completion of GMC Registration Number for both first operator and responsible consultant.
- Procedure: mean completion of two fields key to all other analyses: intervention (what procedure was done) and system type (pacemaker, defibrillator, etc.).
- Generator (device procedures only): mean completion of generator model.

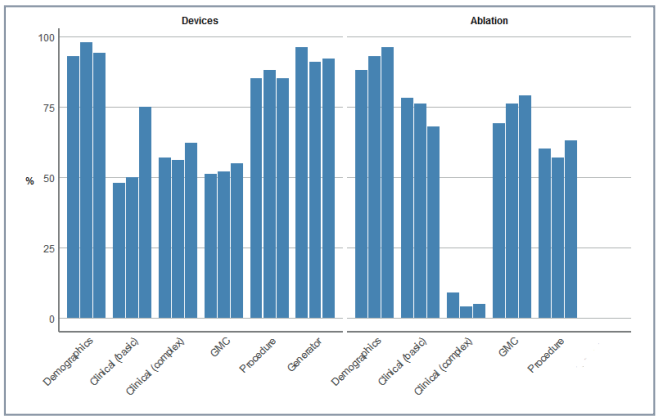
Full details of data completeness are given in each hospital's individual reports (Appendix 4 and Appendix 5). Trends for the last four years are shown.

The results are presented at hospital level [Figure 2.15] and patient level [Figure 2.16]. While around 90% of centres achieve the standard for demographics, this figure is distorted by low submission from private hospitals and some in Scotland: 97% of adult NHS hospitals in England and Wales achieve the standard.

The findings are less good for clinical and procedural details, though these are slowly improving for device procedures. Low GMC number submission remains an issue for many hospitals.

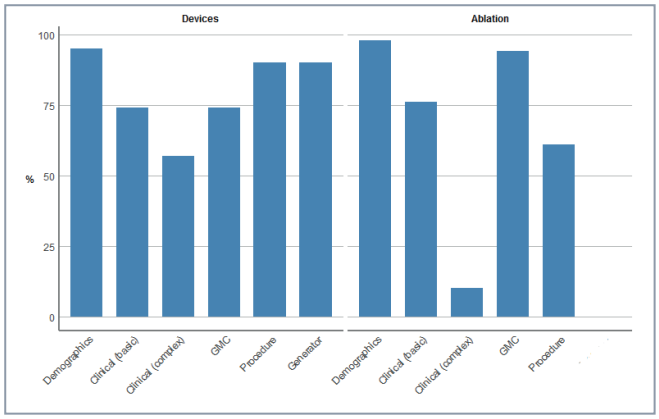
At a patient level (i.e. the proportion of records overall with complete data in each domain) there remain significant problems with recording the indications for device procedures and ablations, and for certain procedural details, especially those relating to complex procedures.

Figure 2.15: *Proportion of hospitals achieving 90% completeness in each domain for device and ablation procedures, 2017 – 2020*



Each set of three bars represents results from 2017/18, 2018/19, and 2019/20.

Figure 2.16: Proportion of individual records nationally in which data were complete, 2019/20



For device and ablation procedures, the proportion of records nationally with complete data submission in each domain is given.

2.3.3 Recommendations for those not achieving the standard

Hospitals with poor data compliance should ensure all members of the local CRM team comply with the requirements of the national audit dataset. Local training on the importance of each data field may be required. Centres failing to achieve the 90% goals (identified as red in their individual hospital reports) should require the clinical leads to analyse their poor performance.

Complete data submission for audit is the hallmark of a centre with good governance. It also results in underestimates of clinical activity for the centre and the doctors working there. Although most submissions are done by allied health professionals, they are the responsibility of the consultants.

2.3.4 Case study – Addenbrooke's Hospital

Addenbrooke's hospital has consistently provided outstanding data quality for its device service in recent years, scoring 100% in all domains.

Kate Sanders, Cardiac Clinical Scientist, was asked how they achieved this:

"Our electronic medical record system was built to allow export of a file with all the implant data required for NICOR. We've used this since 2014 and it made a significant improvement in terms of time taken to complete our NICOR submissions. However, it still requires the team to complete the data correctly and this is where the culture comes through; all of our team understand the importance of accurate data completion during implants and we regularly feedback to them the results of data quality checks. At the end of each implant procedure, the physiologist exports the file to a shared network folder.

From this point, a dedicated individual takes responsibility for uploading the files to NICOR via the web portal and checking them for data quality and completeness; this was myself for several years and now my colleague Anitha GnanaSekar is doing a great job. We cross-check against our implant procedure records to ensure all files are uploaded and review each case for completeness. Although uploading and checking is the responsibility of an individual, this task is not onerous because of the diligence of the team in creating accurate files at each implant.

As a team we've seen the CRM reports and Addenbrooke's good performance and have taken pride each year in trying to maintain this."

2.4 Data validity: Internal validity of key data fields is improving, facilitating better audit

2.4.1 Overview of QI metric

QI Metric Description/Name	Data validity
Why is this important?	A key indicator of an effective service with good governance is compliance with audit. This means valid data entry.
QI theme	Effectiveness
What is the standard to be met?	Quality Standard 10: Hospitals should achieve ≥90% validity in key data domains for device and ablation procedures.
Key references to support the metric	N/A
Numerator	Devices: records in which stated system type matches capability of generator model Ablation: records in which 'ablation attempted' matches other related entries
Denominator	Devices: all pacemaker and complex device implants Ablation: all records
Trend	The proportion of valid records remains around 90% nationally, but is not improving
Variance	The proportion of hospitals not achieving the 90% standard has increased, though very few fall far below this standard

Most analyses in this report are critically dependent on a small number of key fields, which have in the past been unreliably entered. For devices, it is essential to know whether the stated type of system (e.g. single chamber pacemaker, dual chamber defibrillator) is correct, so we have checked that this is consistent with the generator model.

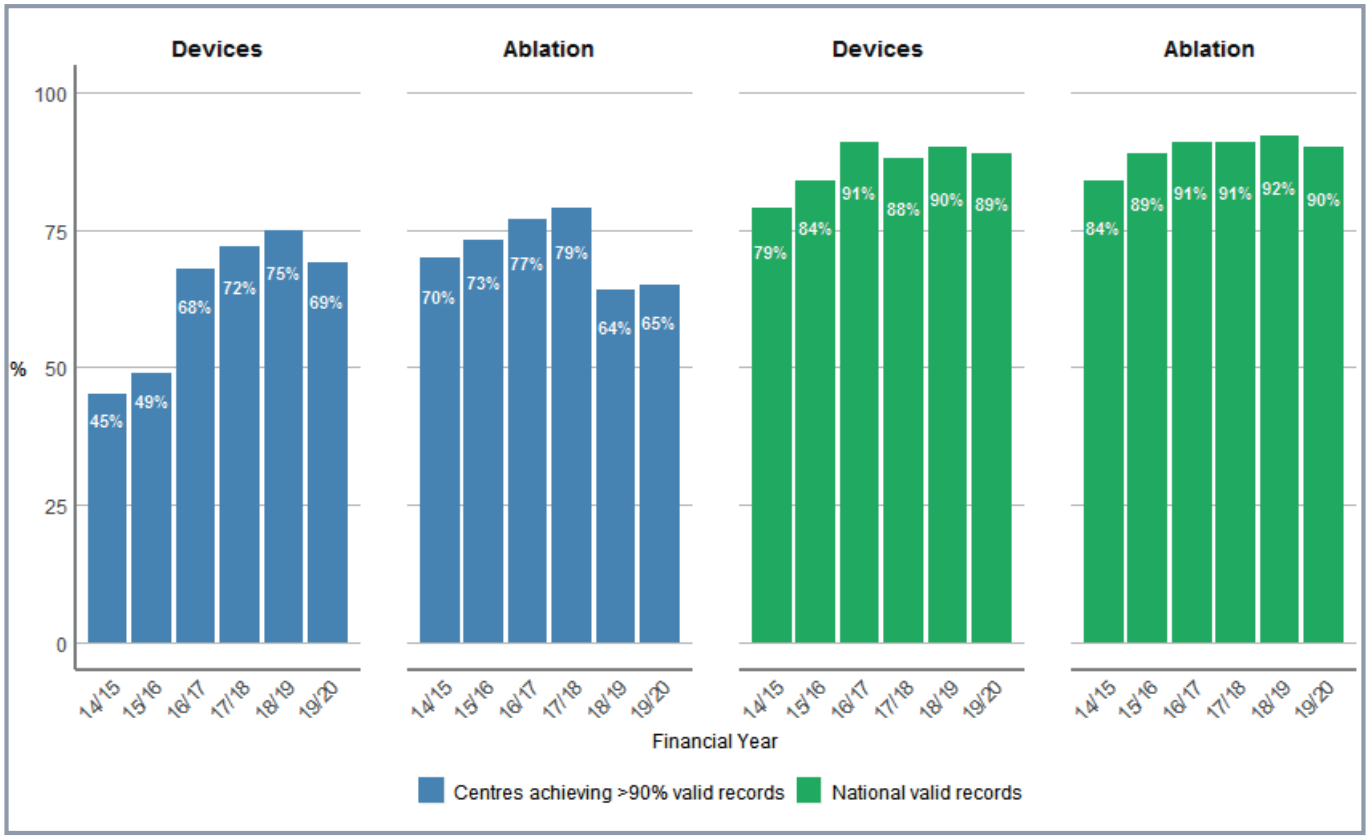
For ablation, we have checked that the entry for 'ablation attempted?' is consistent with other entries. For example, if 'ablation attempted?' is "yes" but there is no stated target for ablation or the outcome is not given, this is considered invalid. Conversely, if 'ablation attempted?' is "no" or blank, but elsewhere it is stated that there was a target, an energy type, and an outcome, then that record is invalid.

2.4.2 Audit results

A small number of hospitals are submitting lower quality data than in previous years. This is of particular concern with regard to ablation records, with a drop from 79% to 65% achieving the 90% validity standard, for reasons that are unclear [Figure 2.17]. On the other hand, many of the poor performers were private hospitals, and only 8 centres (10%) had very poor quality (<80% valid records). Individual hospital performance is given in Appendix 10 and Appendix 11.

Larger volume centres tended to have high data quality so that the results nationally were better, with around 90% of both device and EP/ablation records being valid, as in recent years.

Figure 2.17: Proportion of hospitals reaching ≥90% valid submissions, and proportion of valid records nationally, 2014 – 2020



2.4.3 Recommendations for those not achieving the standard

Centres with low scores on data validity for devices and ablation should undertake an urgent root cause analysis.

Low validity often reflects simple data entry errors and can have serious effects on a centre's performance throughout this report. Misunderstanding of the key fields appears to be a common problem and can be dealt with by training of those completing records.

2.5 NICE guidance for pacemaker type: the overwhelming majority of patients receive an appropriate device

2.5.1 Overview of QI metric

QI Metric Description/Name	Adherence to NICE guidance for pacemakers
Why is this important?	NICE Technology Appraisals make recommendations for the type of pacemaker to be used for the treatment of slow heart rates.[7, 8]
QI theme	Effectiveness
What is the standard to be met?	Quality Standard 11 (pacing for sinus node disease in the absence of atrial fibrillation): 90% of pacemaker implants should be dual chamber. Quality Standard 12 (pacing for atrioventricular block in the absence of atrial fibrillation): 90% of pacemaker implants should be dual chamber
Key references to support the metric	References as above are in reference list at end of report.
Numerator	Patients implanted with dual chamber pacemakers
Denominators	Patients without atrial fibrillation receiving first pacemaker implants for (i) sinus node disease, and (ii) atrioventricular block
Trend	Nationally , the proportion of patients receiving the recommended pacemaker type is high and stable
Variance	23% of hospitals do not achieve standard for implanting the recommended pacemaker type for sinus node disease, and 32% for atrioventricular block.

The standard is 90% to allow for patient specific factors described in the NICE guidance for the fact that dual chamber pacing is inappropriate for some patients due to frailty or anatomical constraints.

2.5.2 Audit results

Audit is reported against the 90% standard both at a hospital level (what proportion of hospitals achieves the quality standard?) and on a national level (did pacemaker implants in the UK overall meet the standard?). Performance against the previous, more lenient 80% standard is also shown. Results for each hospital are detailed in Appendix 6.

The proportion of hospitals documenting that ≥90% of their pacemaker implants are consistent with NICE recommendations remains level at approximately 77% in sinus node disease, and 70% in atrioventricular block [Figure 2.18]. Performance against the previous standard (80% consistency with NICE) remains high at 95% and 88%, respectively.

The national picture remains excellent, with 94% of patients paced for sinus node disease and 92% of those paced for atrioventricular block receiving dual chamber pacemakers [Figure 2.19]. The disparity between individual hospital performance and the national picture is probably because most implants are undertaken at larger centres with high rates of dual chamber pacemaker implantation.

Figure 2.18: Documented hospital compliance with NICE guidance on pacemaker prescription, 2016 – 2020

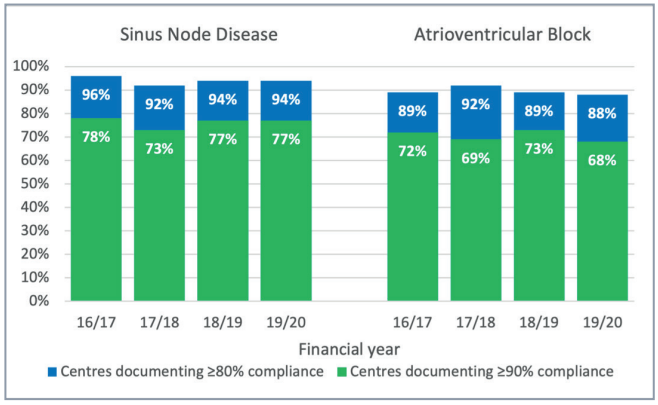
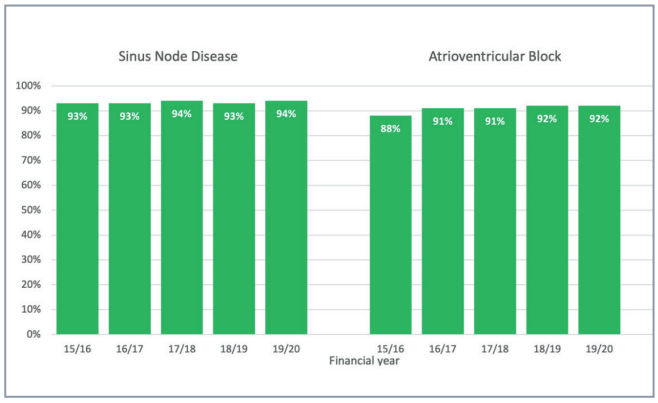


Figure 2.19: Documented national compliance with NICE guidance on pacemaker prescription, 2015 – 2020



2.5.3 Recommendations for those not achieving the standard

Centres achieving <90% compliance with NICE guidance for pacemaker prescription (in particular those achieving <80% compliance) should consider carefully whether some operators are less confident with dual chamber implants and may be prioritizing expediency over the best treatment for their patients.

2.5.4 Case study – Kingston Hospital

Kingston Hospital had consistently low rates of dual chamber pacing implants, but now performs extremely well in adherence to the NICE guidance.

Roy Jogiya, Consultant Cardiologist:

"When I joined Kingston, it had been repeatedly identified by NICOR reports as an outlying trust with very low rates of dual chamber pacing for sinus node disease and heart block. We undertook a gap analysis and risk assessment at Trust level. This raised local awareness of the issue. The feedback was very useful and we reflected on this within our own clinical governance structure and we were able to review practice. We used the results in an open and positive light and were successful in appointing another devices specialist as well as setting up formalised multidisciplinary team meetings. The net result is that we now successfully comply with the recommended standards to enhance patient care, and Kingston is now one of the best performers in the UK in this metric."

2.6 NICE guidance for ICD indications: more than 80% of patients have a documented indication, but many hospitals do not record this

2.6.1 **Overview of QI metric**

QI Metric Description/Name	NICE Guidance for ICDs
Why is this important?	NICE has made a technology appraisal for the appropriate implantation of ICDs to prevent sudden arrhythmia death.[9]
QI theme	Effectiveness
What is the standard to be met?	Quality standard 13 (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 14 (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 ICD implants for primary, and secondary prevention
Trend	Nationally, reported compliance with NICE guidance is steadily improving, though this is largely due to better reporting.
Variance	Less than half UK centres document that ≥90% of their ICD implants are indicated according to NICE guidance.

2.6.2 **Audit results**

Only 41% of hospitals meet the standard documenting a primary prevention indication for new ICDs implants, and only 36% for secondary prevention indications [Figure 2.20]. This has not improved in recent years.

However, the proportion of patients nationally that are documented to have a NICE indication for ICD implants has steadily improved and is now 81% for primary prevention, and 84% for secondary prevention. This improvement is largely due to better documentation at larger centres: the proportion of ICD implants documented not to meet NICE criteria remains at 15-20% [Figure 2.21].

Figure 2.20: Documented hospital compliance with NICE guidance on ICD implantation, 2016 – 2020

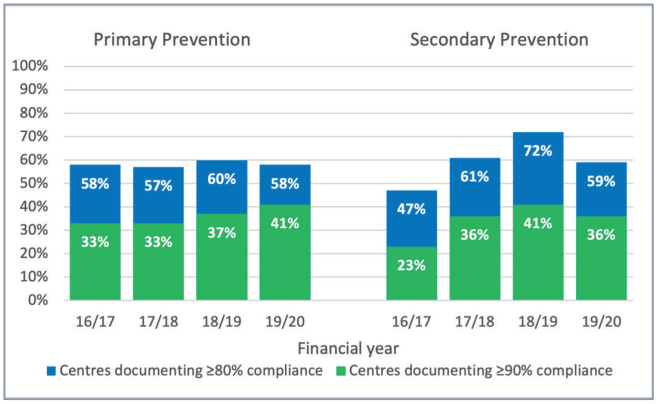
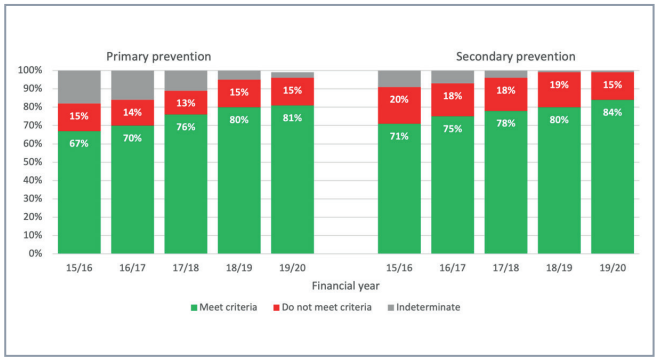


Figure 2.21: ICD implants in UK documented to meet NICE guidance, 2015 – 2020



2.6.3 Recommendations for those not achieving the standard

Centres not achieving the standard for appropriate use of ICDs should consider whether this is an issue of poor documentation or whether their threshold for ICD implantation is unduly low.

Low volume centres in particular should examine their case selection and documentation. It is not expected that 100% of patients receiving ICDs will meet NICE indications, however at least 90% documented compliance is expected.

2.7 Re-intervention following device implants: a number of high volume centres appear to have high complication rates

2.7.1 Overview of QI metric

QI Metric Description/Name	Re-interventions within the first year following pacemaker and complex device implants
Why is this important?	Inpatient complication rates are not an ideal quality measure as many implant related complications present at a later stage. However, re-interventions in the first year following implants are usually the result of procedural complications and can be used as an index thereof.
QI theme	Outcomes
What is the standard to be met?	Quality Standard 15 (Pacemaker re-interventions): 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 16 (Complex device re-interventions): The rate of re-interventions within a year of a first ICD or CRT implant should be below the 95% upper control limit (national mean + 2 standard errors).
Key references to support the metric	Internal reference (funnel plot to distinguish centres with statistically high/low re-intervention rates).
Numerator	All re-interventions in the year following an index procedure, at the implanting hospital or elsewhere.
Denominator	All first pacemaker and complex (ICD±CRT) implants
Trend	Re-intervention rates have been broadly stable in the last three years.
Variance	There is considerable variance in re-intervention rates, with high rates in a small number of centres, some of which have high procedure volumes.

Mortality is the principal (and sometimes only) safety outcome for most procedural audits in the National Cardiac Audit Programme, but is not a helpful indicator of safety for CRM device procedures. Expected procedure-related mortality is of the order of 0.1-0.3%, while that due to age-related conditions, heart failure, etc., is up to 10% per year.

Complications would theoretically be a more relevant measure of a hospital's safety performance. However, reliance on self-reported complications is impractical, as (i) it relies on a governance culture and level of dedication that is likely to be poor at the centres of concern; and (ii) many complications present weeks after the procedure, often at another hospital.

However, certain key procedure-related complications almost always require a second intervention. These include lead displacement, infection, and sometimes haematoma. Re-interventions within the first year of an implant are largely due to these complications and can generally be ascribed to the implant procedure.

We therefore report re-interventions performed within 12 months of a first device implant. This provides a level playing field as patients are broadly similar between low and high volume centres (whereas higher risk procedures such as upgrades are undertaken more frequently at some than others).

This is the first national audit to examine re-intervention rates in this way. We believe that re-interventions are a useful index of procedure safety, but the results must be interpreted with caution:

- most re-interventions result from procedural complications, but occasionally there are other reasons (e.g. change in clinical status requiring a different type of device, manufacturer advisory notices)
- some complications do not result in a device re-intervention: (e.g. some displaced leads are not replaced, and pneumothorax is not treated by a device re-intervention)

Detection of re-interventions requires an NHS number for both the implant record and that of the re-intervention. For each analysis, we have assigned hospitals to two Tiers. 'Tier 1' consists of hospitals reporting NHS numbers in ≥90% of procedures, over both the implant year and the 12 months' follow-up. Our most robust estimates, along with national means and control limits, come from this group, shown as filled blue markers in the figures.

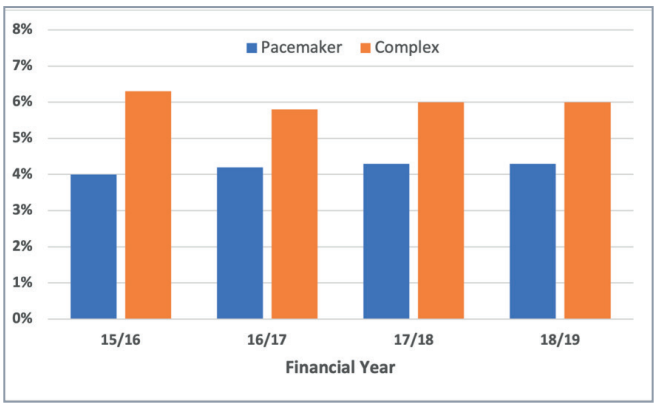
Hospitals with lower submission rates of NHS numbers have been termed 'Tier 2', analysed separately and shown as open red markers. Low NHS submission inevitably introduces systematic bias toward the under-detection of re-interventions, which complicates efforts to reduce the apparent re-intervention rate. This bias is confirmed by the fact that in every analysis, we found the mean rate of detected re-interventions was lower in Tier 2 hospitals than Tier 1 hospitals, by a factor of 25-50%.

2.7.2 Audit results

2.7.2.1 The national picture

In the last four years, one-year re-intervention rates have been stable at around 4% following pacemaker implants and 6% following complex device implants [Figure 2.22].

Figure 2.22: Mean 1-year re-intervention rates following simple and complex device implants, 2015 – 2020



Years refer to date of index procedure.

2.7.2.2 Variance between hospitals – use of 'funnel plots'

As this type of analysis is new, there is insufficient evidence to determine a fixed standard for re-interventions. The data are therefore represented using 'funnel plots' in which each centre's re-intervention rate is plotted against its overall volume. With increasing volume the effect of chance is less, so confidence increases as to whether a centre has a low, normal, or high re-intervention rate.

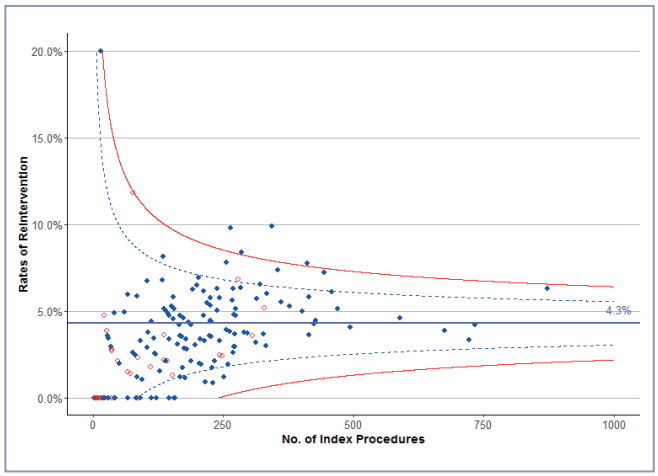
2.7.2.3 Variance between hospitals – Pacemakers

The mean re-intervention rate following pacemaker implants was 4.3%, the distribution between centres is shown in Figure 2.23. Individual hospital results are given in Appendix 12.

Re-intervention rates were high at Barts, Southampton, Plymouth, Musgrove Park, Blackpool, Brompton, Wellington North, Poole and Great Ormond St Hospitals; they were very high (above the 99.9% control limit) at Basildon, Wolverhampton, St Thomas', and QE Birmingham Hospitals; none of these centres, save Great Ormond St, implant less than 80 pacemakers.

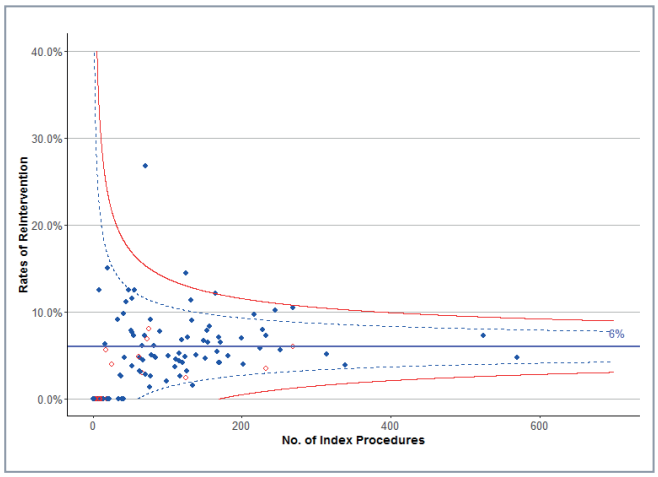
Re-intervention rates appeared low at Pinderfields, Darlington, Telford, Hartlepool, Royal Glamorgan, Kingston, Harlow, Yeovil and Prince Charles Hospitals. None were very below the lower 99.9% control limit. A number of centres reported that no re-interventions occurred. This is plausible due to chance at lower volume centres, but unlikely for higher volume centres.

Figure 2.23: Funnel plot of re-interventions within a year of first pacemaker implants in 2018/19



Filled blue markers: 'Tier 1" centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

Figure 2.24: Funnel plot of re-interventions within a year of first ICD/CRT implants in 2018/19



Filled blue markers: 'Tier 1" centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

2.7.2.4 Variance between hospitals – complex (ICD±CRT) devices

For complex devices, the mean re-intervention rate was 6%, and the distribution between centres is shown in Figure 2.24. Individual hospital results are given in Appendix 12. Re-intervention rates were high at St George's, Good Hope, Freeman, Bath and Dorset County Hospitals, and very high (above the 99.9% control limit) at Queen Elizabeth Birmingham, Exeter, and Torbay; Torbay is a low-volume centre. The re-intervention rate was low at Derby.

2.7.3 Recommendations for those with outlier re-intervention rates

Hospitals with reported re-intervention rates that remain high year-on-year, and those above the 97.5% control limit, should examine the reasons for re-interventions. In most cases, these will chiefly be complications, and centres should look at procedure times, protocols, operator procedure volumes, and whether juniors are adequately supervised.

'Tier 2' centres must improve reporting of NHS Number for each case: their true re-intervention rates are likely to be higher than reported.

2.7.4 Case study – Valerie

Valerie had a rare problem with her pacemaker, requiring a second operation and almost requiring a third

"Last year I suddenly became short of breath and started having dizzy spells, almost blacking out. At the hospital they quickly found that this was because I had heart block, making my heart too slow. Lots of blood tests and scans were done to see if there was a cause (I was only 57, and there is sarcoid in my family) and then I had a pacemaker implanted. It was a difficult procedure but afterwards I felt fine.

Six weeks later, I came for my first check-up and they told me that the measurements for one of the pacemaker wires were not good, and my pacemaker might not work reliably. I had to come into hospital where the consultant did another operation and replaced the wire. The same thing happened again soon after, though again the X-ray was fine. This time they gave me a course of steroids, which did the trick. After several months of close monitoring while the steroids were tailed off, everything is back to normal now and I'm so glad I didn't need a third operation on my pacemaker."

2.8 Re-intervention rates following catheter ablation are acceptable nationally, but there is wide variation between hospitals, especially for AF ablation

2.8.1 Overview of QI metric

QI Metric Description/Name	Re-interventions in the first two years following ablations (simple, complex atrial, and ventricular)
Why is this important?	Re-interventions following catheter ablations are largely a reflection of case selection and procedural efficacy.
QI theme	Effectiveness
What is the standard to be met?	Quality Standard 17: the frequency of repeat interventions within a year of catheter ablation procedures (simple, complex atrial, and ventricular) should be below the 95% upper control limit (national mean + 2 standard errors). Quality Standard 18: the frequency of repeat interventions within a year of catheter ablation procedures (simple, complex atrial, and ventricular) should be below the 95% upper control limit (national mean + 2 standard errors).
Key references to support the metric	Internal reference (funnel plot to distinguish centres with statistically high/low re-intervention rates).
Numerator	Repeat ablations in the year following an index procedure, at the implanting hospital or elsewhere.
Denominator	All catheter ablations, divided into simple, complex atrial, and ventricular targets
Trend	Re-intervention rates have been broadly stable in the last three years.
Variance	Re-intervention rates vary considerably between centres, especially for AF ablation.

A repeat ablation is not undertaken because the first procedure caused a complication, but because it was unsuccessful. A hospital's re-intervention rate reflects initial case selection, the quality of the first procedure, and the enthusiasm (of the doctor and patient) to undertake a repeat procedure where the first has not been entirely successful.

As with devices, we have divided centres into 'Tier 1', in which ≥90% of records had NHS Numbers submitted, for index and follow-up years, and 'Tier 2' who did not submit NHS Numbers to this.

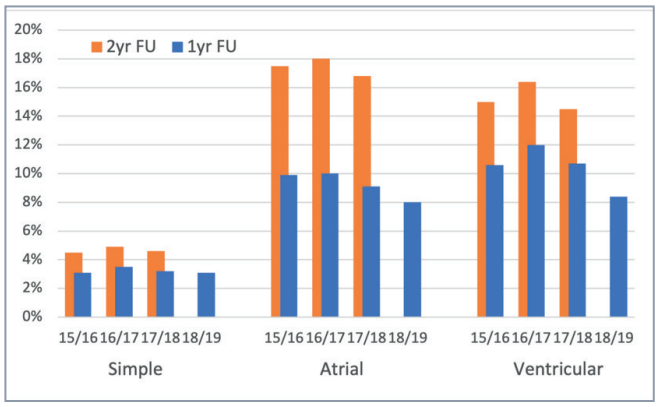
2.8.2 Audit results

2.8.2.1 The national picture

Annual trends for mean re-intervention rates at Tier 1 centres are shown in Figure 2.25. Only re-interventions with the same target have been counted.

The one-year re-intervention rate following 'simple' ablations (for supraventricular tachycardia, typical flutter, and AV node ablation) is stable at 3%, increasing by 1% after a second follow-up year. This is consistent with an expected permanent cure rate of 90-95% following such procedures.

Figure 2.25: Mean 1- and 2-year re-intervention rates following simple, complex atrial, and ventricular ablations, 2015 – 2020



Years refer to date of index procedure. 2-year re-interventions from 2018/19 are not yet available.

The overwhelming majority of index complex atrial ablations are for atrial fibrillation, and redo procedures may be classed as 'AF ablation' or other targets such as left atrial tachycardia or atypical flutter. For this reason, all atrial ablations other than typical flutter have been grouped.

The one-year re-intervention rate has fallen from 10% to 8%, but almost as many patients have a second procedure in the second follow-up year. This probably reflects a combination of factors: late arrhythmia recurrence, delay in deciding to undertake a repeat procedure (e.g. waiting to see whether recurrences are repeated, re-trying drug treatment), and long waiting lists. It should be noted that a very low re-intervention rate does not necessarily reflect good practice, if some patients with recurrent arrhythmia are denied the benefit of a second procedure.

These re-intervention rates for AF ablation are low by international standards: most studies report the need for a second AF ablation in 20-40% of cases (depending on clinical characteristics) to achieve a good success rate.[10, 11, 12]

Ventricular ablations constitute only 5% of procedures, and are a heterogeneous group ranging from foci responsible for premature ventricular complexes to extensive scar substrates responsible for recurrent ventricular tachycardia. Initial failure may be because of difficulty in inducing the arrhythmia, inaccessibility of the target, instability of a sick patient undergoing a procedure that can last several hours.

One-year re-intervention rates appear to have fallen from 12% to 8%, with a consistent additional 4% after a second year of follow-up. Year-on-year trends should be interpreted with caution because total procedure numbers are small.

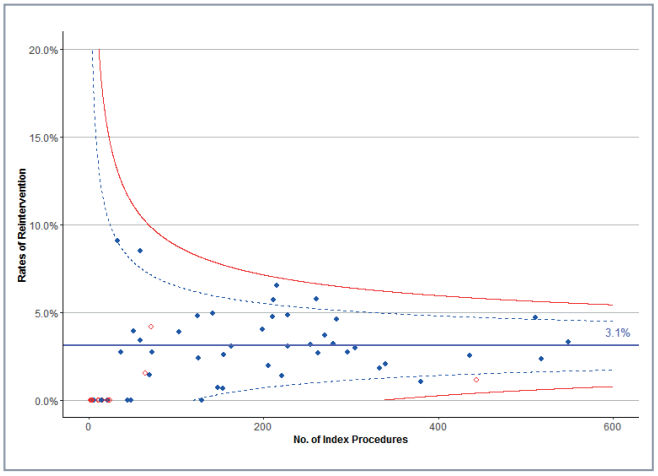
2.8.2.2 Variance between hospitals

Each hospital's 1- and 2- year re-intervention rates for simple, complex atrial and ventricular ablations are shown in funnel plots (these are explained in Section 2.7.2.2).

Re-interventions following simple ablations are shown in Figure 2.26 and Figure 2.27. At one year, the mean re-intervention rate was 3.1%. Rates were high at Papworth, St Thomas', Eastbourne, Stoke, Watford and Alder Hey Hospitals, and very high (above the 99.9% control limit) at none. Re-intervention rates were apparently low at Wythenshawe Hospital and Cardiff.

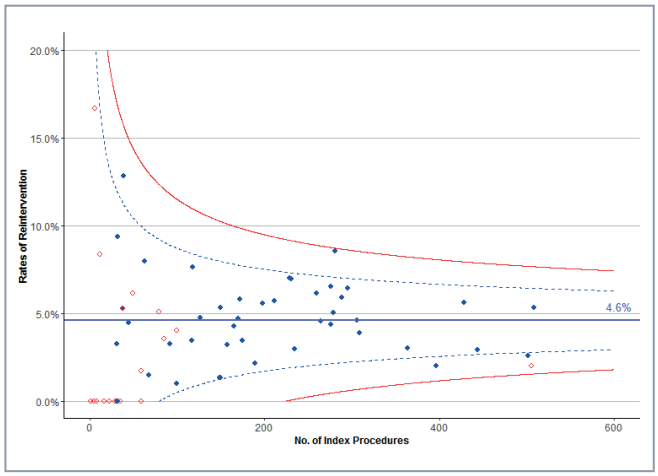
At two years, the mean re-intervention rate was 4.6%. Re-intervention rates were high at the Brompton and Birmingham Children's Hospitals, and very high (above the 99.9% control limit) at none. Re-intervention rates were apparently low at Barts and Wythenshawe.

Figure 2.26: 1-year re-intervention rates following simple ablations undertaken in 2018/19



Filled blue markers: 'Tier 1' centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

Figure 2.27: 2-year re-intervention rates following simple ablation (undertaken in 2017/18)



Filled blue markers: 'Tier 1' centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

Re-interventions following complex atrial ablations (largely for AF) are shown in Figure 2.28 and Figure 2.29.

At one year, the mean re-intervention rate was 8%. The rate was high at Portsmouth, and very high (above the 99.9% control limit) at the Royal Brompton and Middlesbrough Hospitals. Re-intervention rates were apparently low at Wythenshawe and Blackpool, and very low (below the 99.9% control limit) at St George's and Coventry.

At two years, the mean re-intervention rate was 16.8%. The rates were high at Barts, Queen Elizabeth Birmingham, Southampton, and Portsmouth, and very high (above the 99.9% control limit) at Middlesbrough. Re-intervention rates were apparently low at St George's, the Freeman, Brighton and Blackpool, and very low (below the 99.9% control limit) at Coventry and Hull.

Figure 2.28: 1-year re-intervention following complex atrial ablations (undertaken in 2018/19)

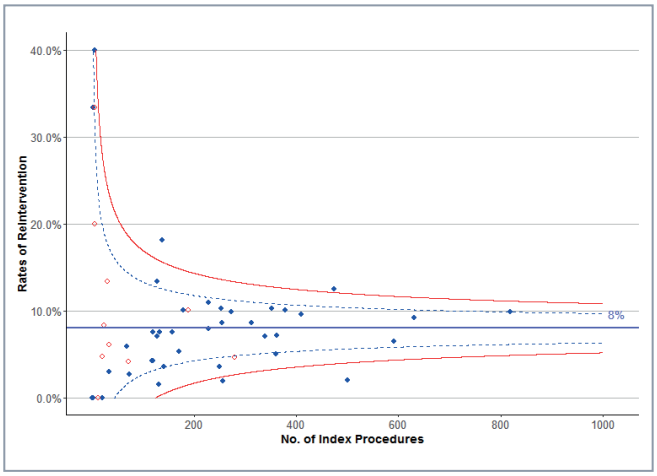
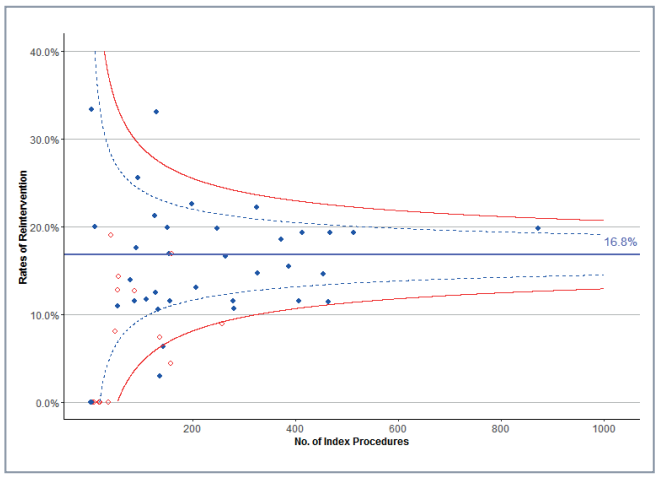


Figure 2.29: *2-year re-interventions following complex atrial ablations (undertaken in 2017/18)*



Filled blue markers: 'Tier 1' centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

Re-interventions following ventricular ablations are shown in Figure 2.30 and Figure 2.31. At one year, the mean re-intervention rate was 8.4%. No hospital showed re-intervention rates outside the control limits. At two years, the mean re-intervention rate was 14.5%. The re-intervention rate was high at Southampton but not very high (above the 99.9% control limit) or statistically low at any hospitals.

Figure 2.30: *1-year re-interventions following ventricular ablations undertaken in 2018/19*

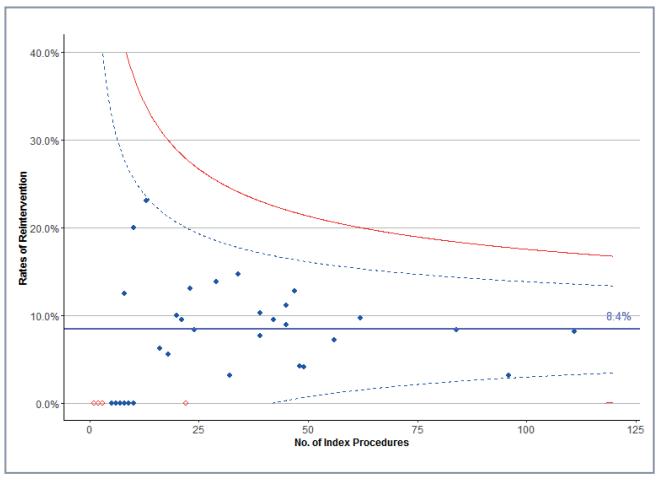
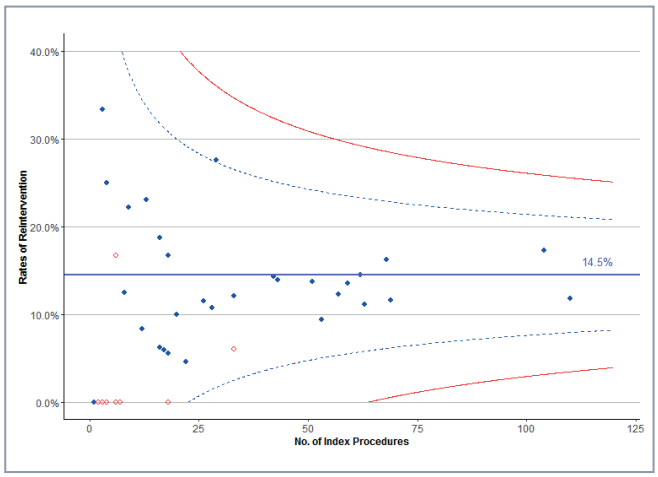


Figure 2.31: 2-year re-interventions following ventricular ablations undertaken in 2017/18



Filled blue markers: 'Tier 1' centres with good submission of NHS No; Empty red markers: 'Tier 2' centres with lower NHS submission rates. Solid blue line: mean re-intervention rate for Tier 1 centres. Dashed blue lines: control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance. Red lines: more stringent control limit: (±3 x standard error from mean): the probability is 0.1% of being outside this range due to chance. Means and control limits are calculated solely from Tier 1 data.

2.8.3 Recommendations for those with outlier re-intervention rates

Hospitals with high re-intervention rates following ablation procedures should examine the techniques and endpoints for their procedures, and in particular case selection. Centres with very low re-intervention rates should consider whether this reflects genuine success or whether some patients with recurrent arrhythmia are being denied the benefit of a second ablation.

3 | Future directions

Our chief concern at present is to improve data submission so that the results for each hospital are a true reflection of its performance and that of its consultants. To this end, NICOR's migration to a new IT platform will permit real-time validation of individual data entries and uploads, and will give CRM centres the ability to benchmark themselves against other centres in real time.

We are working with other cardiac audit domains (in particular those relating to heart failure, myocardial infarction, and paediatric/congenital cardiology) so that our data can be linked. This should permit previously impossible analyses, such as the proportion of eligible patients that receive ICD and CRT therapy. In future, datasets are to be aligned across all domains, in particular for comorbidities and risk factors, (not currently part of the CRM dataset).

A vitally important outcome from some CRM procedures, especially AF ablation, is improvement of symptoms and quality of life. Recording of Patient Reported Outcome Measures is to become mandatory under an NHS England initiative, and these will be reported once available.

Finally, we will include interactive figures so that individual centres can be identified, for example, in the re-intervention funnel plots.

4 | Appendices

5 | References

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