NATIONAL AUDIT OF CARDIAC RHYTHM MANAGEMENT (NACRM)

CRM DEVICES AND ABLATION

2020 SUMMARY REPORT
(2017/18 & 2018/19 DATA)

NICOR

BHRS
British Heart Rhythm Society

CONTENTS

REPORT AT A GLANCE

The NACRM report details activity in cardiac rhythm management device and ablation procedures for England and Wales, and where possible in Scotland and Northern Ireland. Analysis has been performed for 2017/18 and 2018/19.

Procedures

Following a number of years of increased activity, overall levels for CRM device and ablation procedures have not changed significantly since 2016, although there has been an increase in Wales.

Consultants

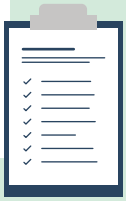
There appears to be a large number of consultants who perform low volumes (below recommended minimum levels) of device implants and ablation procedures. This is partly due to poor submissions of GMC numbers by some centres.

New Technology

There is a small increase in the use of leadless pacemakers, but a larger take-up of subcutaneous ICD devices. 'Single shot' pulmonary vein ablation devices are increasingly used for patients with AF, especially the cryoballoon.

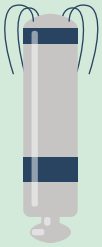
NICE Guidelines

Compliance with NICE guidelines remains good for pacemakers and is now good for ICDs.



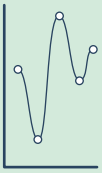
Device Procedures

The number of NHS centres reporting low volume device implants has fallen, but 28 NHS and 38 hospitals fail to reach the minimum recommended level for pacemaker and complex device implants, respectively.



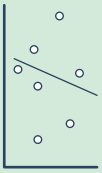
Data Submission

Data submission in some key fields is improving but remains inadequate.



Re-Intervention

The UK has acceptably low re-intervention rates for devices and ablation but there is considerable variability between hospitals.



For a summary of the key findings in the report, click here

EXECUTIVE SUMMARY

The NACRM report details activity in cardiac rhythm management (CRM) device and ablation procedures for England & Wales, and where possible Scotland and Northern Ireland, in 2018/19. Hospitals are measured against standards in the domains of safety, effectiveness, and outcomes. Detailed information for each hospital is given in the appendices, along with identical analyses for 2017/18 (as there was no separate report for that year). The principal findings are as follows.

DATA SUBMISSION

Nearly all hospitals in England & Wales have submitted their CRM device and ablation procedures on a regular basis and are participating in the validation process. However, a small number of hospitals that are thought to be doing these procedures failed to submit any records. A further issue is that data protection concerns 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 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 (AND DOCTORS) 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. However, a substantial proportion does not reach these recommended minimum numbers (18% for pacemakers and 35% for complex devices). The picture is better for ablation, with only three NHS hospitals reporting low numbers of AF ablations.

EFFECTIVENESS – ARE HOSPITALS SENDING COMPLETE AND HIGH QUALITY DATA TO NICOR?

Data completeness for key fields ("what procedure was done, to whom?") is good overall, but less good for clinical details ("why, and exactly how, was the procedure done"). This limits our ability to undertake more detailed audit. Importantly there was great variation between hospitals in data completeness.

EFFECTIVENESS – ARE HOSPITALS FOLLOWING NICE GUIDANCE?

Documented compliance with NICE recommendations for pacemakers remains good, and is improving for implantable defibrillators. Overall, 93% of patients receive the recommended pacemaker type (100% is not the target as not all patients will benefit from more sophisticated pacing systems). 84% of patients are documented to meet NICE criteria for defibrillator implantation. However, there is considerable variation between hospitals with a proportion having low compliance for both types of device, or poor documentation thereof.

OUTCOMES – WHAT PROPORTION OF PATIENTS REQUIRE ANOTHER PROCEDURE?

A second device procedure within 12 months usually reflects a complication from the original procedure. Overall, the frequency of such re-interventions in the UK is good by international standards, (4% for pacemakers and 6% for complex devices). However, there is considerable variation in re-intervention rates between hospitals, which may reflect high complication rates at some.

Likewise, following catheter ablation re-intervention rates are low by international standards (for example, 18% within two years following ablation for atrial fibrillation). This suggests good case selection and effective procedures. Again, however, there is considerable variation between hospitals, though less than for devices.

1. INTRODUCTION/BACKGROUND

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 report.

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 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 2.3).

- **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. This facilitates planning by 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 there have been issues around permission to send data that had been collected).

- 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).

- For the first time, we are also reporting total procedure volumes for every operator in the country identified by the General Medical Council 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 outcomes and complication rates for device implants, and of outcomes for ablation procedures.

1.3 STRUCTURE OF 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 we do to improve patient outcomes?

1.4 METHODOLOGY

The audit reports on data collected from (in 2018/19) 181 implanting hospitals and 53 ablating hospitals from across the UK. Detailed figures are given in the Appendices, which also include data from 2017/18 (as there was no report for that year), and some longer trends are also shown using data from prior reports.

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. As with other NCAP audits, at the end of the data collection, the data are extracted, validated and analysed before reporting. Details of the audit methodology are given in Appendix 1.

2. NATIONAL STATISTICS/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 & Wales can be seen using interactive maps in Appendices 2&3.

2.1 CHANGES TO HOSPITALS REPORTING DEVICE AND ABLATION PROCEDURES

Why does this matter?
Interpretation of the data on procedure volumes depends on an understanding of "missing" data, chiefly from nations and hospitals that ceased to submit to NICOR while continuing clinical activity. Additionally, some small hospitals have genuinely stopped undertaking procedures while a few new hospitals have opened or started submitting. Unfortunately, this year's report has been significantly affected by the cessation of submissions from Northern Ireland, some hospitals in Scotland (related to issues around permission to send data), and some large private sector providers. This section enumerates these data losses and gives estimates of the impact on our national statistics.

1.1.3 DEVICE HOSPITALS

180 hospitals in the UK reported device implants in 2018/19, five fewer than in 2016/17 (our last report). The following 17 hospitals did not report device implants in 2018/19, but had in 2016/17. Hospitals in bold are larger (previously reporting >50 implants/year) hospitals, those asterisked are thought still to be implanting but not submitting to NICOR.

- *England:* **Derriford (Plymouth)***, Lewisham, **Maidstone***, Pilgrim (Boston), **Royal Free (London)***, **Royal United** (Bath)*, Trafford (Manchester), Weston General (Bristol).
- *Northern Ireland:* **Belfast City***, Craigavon Area (Portadown), **Royal Hospitals*** (Belfast)
- *Scotland:* Dumfries & Galloway, **Edinburgh Royal***
- *Wales:* Nevill Hall (Abergavenny), **Royal Gwent*** (Newport).
- *Private:* Leeds Nuffield, Spire Leeds*

12 hospitals reported implants in 2018/19 but had not previously:

- *England:* Alder Hey Childrens' (Liverpool), Evelina Children's Hospital (London), Gloucestershire Royal, Grantham, **Sunderland**, **West Suffolk**
- *Scotland:* **Wishaw** (Lanarkshire)
- *Wales:* Bronglais (Aberystwyth), **Maelor** (Wrexham)
- *Private:* Exeter Heart, Spire Nottingham, The Alexandra (Manchester)

Between them, these hospitals have submitted 332 new pacemaker and 26 new complex implants.

What is the impact of "missing" device submissions?
The impact of these missing submissions is relatively small in England and Wales, but major in Scotland and Northern Ireland.

Table 1: *Breakdown of cases estimated to be "missing" due to implanting hospitals ceasing to submit data to NICOR in 2018/19 compared to 2016/17*

	Pacemakers (n)	Pacemakers %	Complex (n)	Complex %
England NHS	1160	3.0%	111	0.8%
N.I.	692	100%	334	100%
Scotland	561	53.1%	120	38.8%
Wales	117	7.3%	0	0%
Private	4	<1%	3	<1%
UK TOTAL	2534	6.5%	568	4.2%

Ignoring hospitals that appear to have genuinely stopped procedures, assuming constant activity in "missing" hospitals, and including data from new hospitals, we estimate that cessation of reporting has resulted in a lowering of 2018/19 UK submissions by 2198 pacemaker implants and 542 missing complex implants.

Finally, it should be noted that a number of pacemaker hospitals in Scotland have not submitted to NICOR at all in recent years.

1.1.4 ABLATION HOSPITALS

The following 16 hospitals did not report ablations in 2018/19 that had previously.

Hospitals in bold are larger (previously reporting >50 implants/year), those asterisked are thought still to be implanting but not submitting to NICOR.

- *England:* Conquest (Hastings), **Maidstone***, **Northern General*** (Sheffield), Queen Elizabeth (Gateshead)
- *Northern Ireland:* **Belfast City***, **Royal Victoria***
- *Scotland:* **Edinburgh Royal***, **Royal Infirmary*** (Aberdeen)
- *Children's:* Alder Hey, Bristol Royal Children's
- *Private:* **Harley St Clinic***, KIMS*, **London Bridge***, Spire Leeds*, **Spire Southampton***, **Wellington***

Between them, these hospitals had reported 2152 ablations in 2016/17. The biggest loss to reporting is from the private sector (774 ablations), Northern Ireland (552) and Scotland (448). We therefore estimate that the impact on reporting in NHS hospitals in England & Wales was only 378 cases. In addition, Golden Jubilee Hospital (Glasgow), a high-volume hospital, has historically not submitted to NICOR.

Three hospitals reported ablations in 2018/19 that had not in 2016/17: Bristol Royal Infirmary (545 cases), Exeter Heart (Private, 65 cases), Spire Nottingham (Private, 8 cases).

From these figures (ignoring hospitals that have genuinely stopped procedures, assuming constant activity in others), we estimate that cessation of reporting has resulted in a lowering of 2018/19 submissions by 1534 "missing" cases. This is reflected in an extra data point in Figure 2.6.

1.1 DEVICE IMPLANT RATES

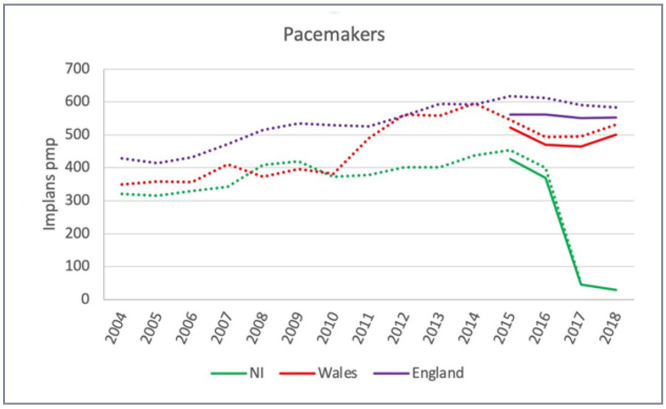
Total reported implants and implant rates per million population (pmp) for hospitals in the four UK nations in financial years 2017/18 and 2018/19 are shown below.

Table 2: *Total reported implants of pacemakers and complex devices for UK and devolved nations 2017/18 and 2018/19 (Implants per million population in parentheses)*

	2017/18					2018/19				
	England	N.I.	Scotland	Wales	UK	England	N.I.	Scotland	Wales	UK
Pacemakers *first implants*	30,833 (551)	86 (46)	964 (-)	1,455 (464)	33,338	31,048 (552)	- (29)	279 (-)	1,575 (500)	32,902
ICDs *new + upgrade*	5,307 (95)	34 (18)	233 (43)	243 (77)	5,817	5,596 (99)	- (-)	137 (25)	296 (94)	6,029
ICD + CRTD *new + upgrade*	9,451 (169)	47 (25)	325 (60)	422 (134)	10,245	9,570 (170)	- (-)	213 (39)	492 (156)	10,275
CRTP + CRTD *new + upgrade*	8,271 (148)	22 (12)	282 (52)	284 (90)	8,859	8,043 (143)	- (-)	184 (34)	369 (117)	8,596

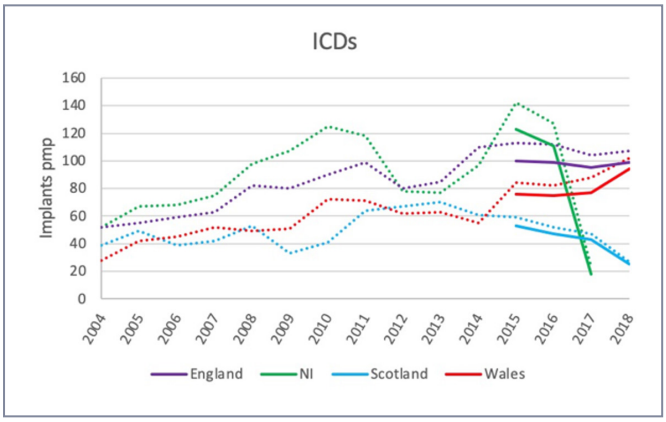
Longer term trends for device implant rates per million population are shown in Figures 2.1-2.5. The dotted lines use old counting methods that included device replacements, etc. Solid lines represent first implants (for pacemakers), or first implants of the type (i.e. including upgrades) for complex 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 2.1: *Pacemaker implants per million population*



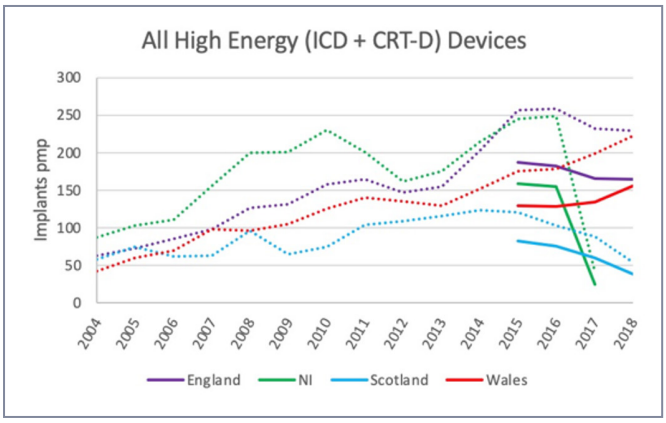
These rose between 2004 and 2014 but have since been fairly stable. This mirrors a halt in increasing life expectancy.[1] Scottish implants are not shown as a number of pacing hospitals have never participated in the audit.

Figure 2.2: *Implantable defibrillator (non CRT) implants*



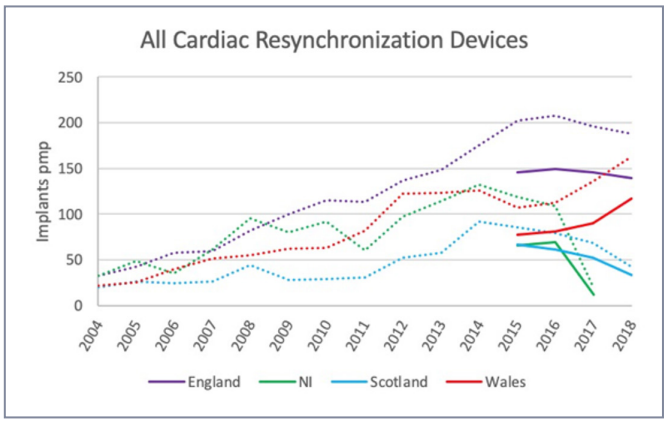
Following a steady rise in response to NICE guidance in 2006, implant rates have not changed significantly in England over the last five years. Implants in Wales have continued to increase and now match those in England.

Figure 2.3: *All high energy (ICD + CRTD) implants*



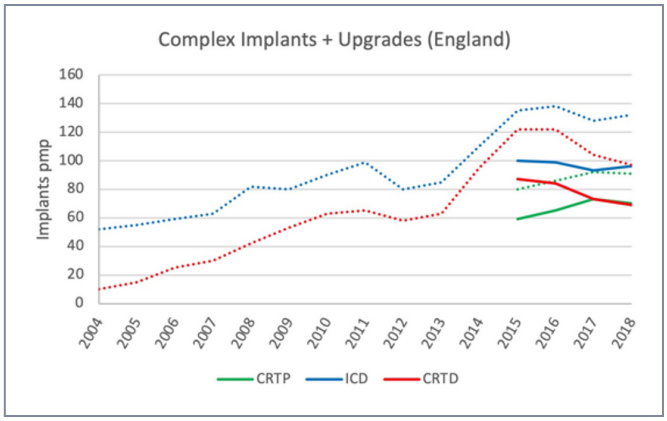
Again, in England these increased steadily in the decade to 2015 but have not changed significantly since, while those in Wales have recently caught up.

Figure 2.4: *All cardiac resynchronization (CRTP+CRTD) implants*



These increased five-fold over the decade to 2015 but have been steady since, other than in Wales where they are nearing levels in England.

Figure 2.5: *Case-mix for complex device implants (England only)*



Reliable historic data are not available for CRTP. These were dominated by ICDs in 2004, but the ratio of ICD:CRTD:CRTP is currently 40%:30%:30%.

Notes:

- 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 5.4m, Wales 3.1m and Northern Ireland 1.9m, compared to England 55.6m, in 2016). 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 in Northern Ireland.
- Interactive maps of device implant rates by patients' area of residence (rather than site of treatment) can be seen in Appendix 2.

1.2 CATHETER ABLATION VOLUMES

The breakdown of ablation procedures reported in the UK over the last five years is given in Table 3. Longer-term trends in ablations, grouped by the category of target, are shown in Figure 2.6. The estimated "missing" data in 2018/19 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, before levelling off since 2016.

Over this 12-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.

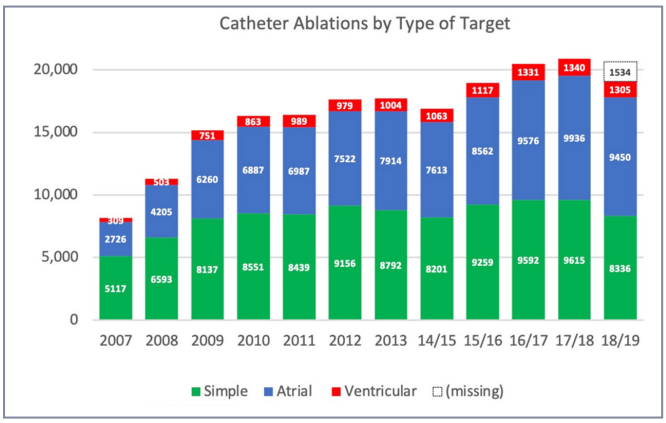
Procedure rates based on the residence (postcode) of patients in England & Wales can be seen using interactive maps in Appendix 3.

Table 3: *Reported ablation procedures in the UK for each target (2014/15 to 2018/19)*

	14/15	15/16	16/17	17/18	18/19
Simple ablation targets only					
Complete AV nodal	1232	1455	1486	1562	1496
AV nodal re-entry	2847	3242	3477	3536	2863
Accessory pathway	1455	1637	1641	1514	1285
CTI (typical flutter)	3436	3794	3882	3947	3640
Total simple procedures	**8201**	**9259**	**9592**	**9615**	**8336**
"Complex" atrial ablations					
Atrial fibrillation ±	6736	7502	8365	8846	8443
Other complex atrial	877	1060	1211	1090	1007
Total complex atrial procedures	**7613**	**8562**	**9576**	**9936**	**9450**
Ventricular ablations					
PVCs, focal VT	734	664	802	815	798
VT-scar ±	329	453	529	525	507
Total complex ventricular procedures	**1063**	**1117**	**1331**	**1340**	**1305**
No ablation/ unknown target	**2327**	**2594**	**2476**	**2330**	**2581**

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 2.6: *Longer-term trends in UK ablation volumes*



Data provided over the last 12 years, grouped by procedure type (data have been analysed by financial year since 2014).

2.2 ADOPTION OF NEW TECHNOLOGIES

For the first time, we report on the adoption of some specific newer device and ablation technologies.

Why does this matter?

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

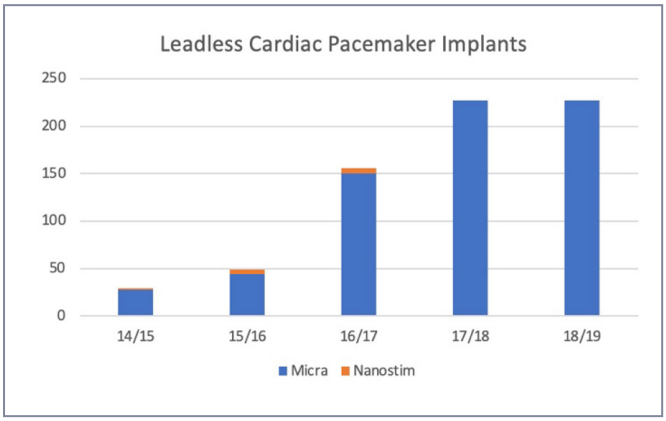
1.2.1 LEADLESS CARDIAC PACEMAKERS

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 chambers of the heart. Rarely, these can become damaged or infected, necessitating their replacement. Removal of existing leads can be difficult and risky because they become 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 devices 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]

Figure 2.7: *Leadless cardiac pacemaker implants in the last five years*



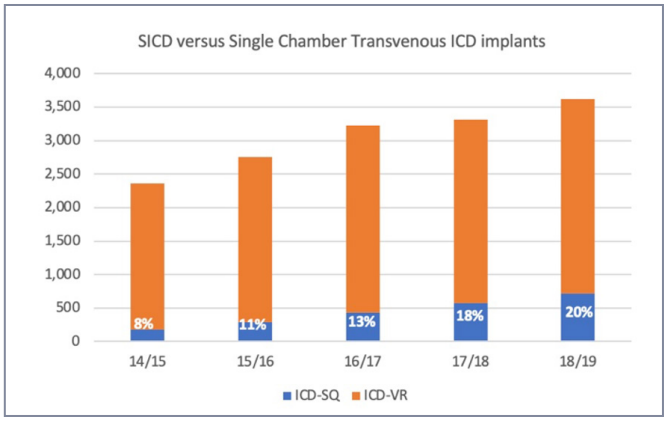
These devices started to be implanted in significant numbers in the UK in 2016/17, but at present there remain less than 250 implants/year. This may be due to unfamiliarity, the need for special training, manufacturers' constraints on hospitals, and significantly increased cost compared to conventional devices. The majority of devices have been the Micra™ (Medtronic): a limited number of Nanostim™ (St Jude Medical) devices were implanted before the original model was suspended from the market.

1.2.2 SUBCUTANEOUS ICDS

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. The concept of 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]

The number of SQID implants has increased from 183 to 715 over the last five years. They are now 20% of single chamber ICDs, and 11% of non-CRT defibrillators overall (dual chamber implants are declining as more patients with a pacing indication receive CRTD devices).

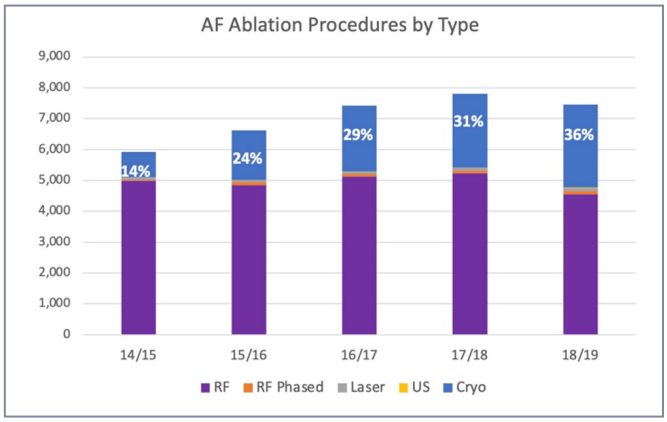
Figure 2.8: *Subcutaneous implantable defibrillators (SQID) implants in the last 5 years*



1.2.3 "SINGLE SHOT" CATHETER ABLATION OF 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.[4]

Figure 2.9: *Technologies used for AF ablation over the last five years*



While the majority of cases continue to use point-by-point radiofrequency ablation (RF), cryoballoon (cryo) accounts for an increasing proportion, and was used in over 1/3 of cases in 2018/19. Other methods (phased radiofrequency, laser, ultrasound) are used in very small numbers. It is thought that the use of the cryoballoon has so far been largely limited to first-time procedures in patients with paroxysmal AF, but this pattern may change.

2.3 NATIONAL STATISTICS AND TRENDS: SUMMARY AND DISCUSSION

Complete reporting of CRM device and ablation activity in the UK has been severely affected by the cessation of reporting from NHS hospitals in Scotland and Northern Ireland, and by some of the larger hospitals in the private sector. It is strongly hoped that contractual arrangements can be agreed to permit resumption of submissions, and indeed to encourage the very small number of hospitals that have not previously submitted. Reporting by the private sector should be particularly important for future reports due to its contribution to NHS work in the COVID-19 recovery phase.

Despite this setback, some clear patterns emerge:

- Implant rates in all nations increased over the decade to 2016/17 for all categories of CRM device. Subsequently, those in England for all categories of CRM devices have not risen significantly and are now approached by those in Wales; it is not possible to comment on activity in Scotland and Northern Ireland.
- Cardiac resynchronization therapy has been widely adopted, and the proportions of complex device types are approximately ICD 40%, CRTD 30%, and CRTP 30%.
- As with devices, there was rapid growth in catheter ablation procedures in the decade from 2007, largely driven by AF ablation. This growth has now ceased.
- The subcutaneous ICD now has an established place in the UK, and now accounts for 20% of single chamber implants (the usual type for primary prevention of sudden arrhythmic death).
- Leadless pacemakers are being implanted in small numbers. This is expected to grow as functionality increases.
- Cryoballoon ablation is increasingly widely adopted, and now accounts for more than a third of AF ablation procedures.
- All of the above new technologies are currently provided by unique suppliers. Their use may increase as competitors bring new functionality to the market and drive prices down.

3. QUALITY MEASURES

Individual reports have been created for each reporting hospital, detailing their activity in 2017/18 and in 2018/19, for device procedures (Appendices 4 & 5) and catheter ablation procedure (Appendix 6 & 7).

Hospital and individual operator performance against quality measures have been tabulated, for 2017/18 and 2018/29 in Appendices 8-19.

3.1 SAFETY

3.1.1 ARE HOSPITALS PERFORMING SUFFICIENT NUMBERS?

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, which include minimum recommended procedure volumes, which are fairly stringent by international standards.[5,6] The standards documents are regularly reviewed: we have compared hospitals' data to those applicable at the time.

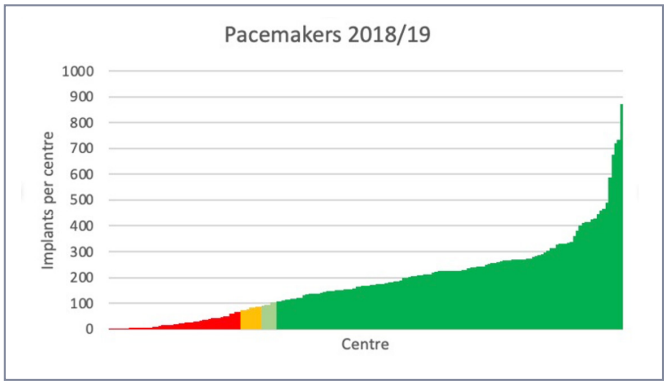
Procedure volumes for pacemaker and complex devices for each hospital are tabulated in Appendix 8 (2017/18) and 9 (2018/19).

Procedure volumes for simple and complex ablation procedure volumes are given for individual hospitals in Appendix 10 (2017/18) and 11 (2018/19).

Quality Standard 1 (Pacemaker Implants): BHRS Standards (2015) 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.

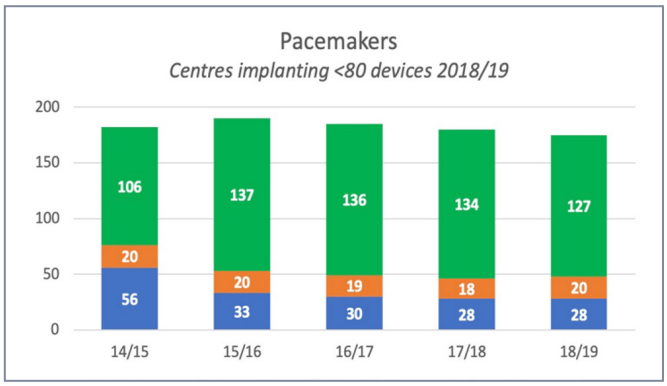
Audit findings
In 2018/19, 175 hospitals in the UK reported at least one pacemaker implant. This includes 5 children's and 18 private hospitals. 48 hospitals failed to meet the standard of 80 implants, of which 28 were NHS adult hospitals (half the number in 2014/15). 4% of pacemakers were implanted in low volume hospitals, (2.4% were in NHS adult hospitals).

Figure 3.1: *Number of pacemaker implants reported by each hospital in the UK*



Amber indicates hospitals that are ± 10% of the standard of 80 implants, red is below this level, and green above. Dark green indicates hospitals performing >105 implants per year.

Figure 3.2: *Number of hospitals meeting the standard of 80 pacemaker implants/ year, over a 5-year period*



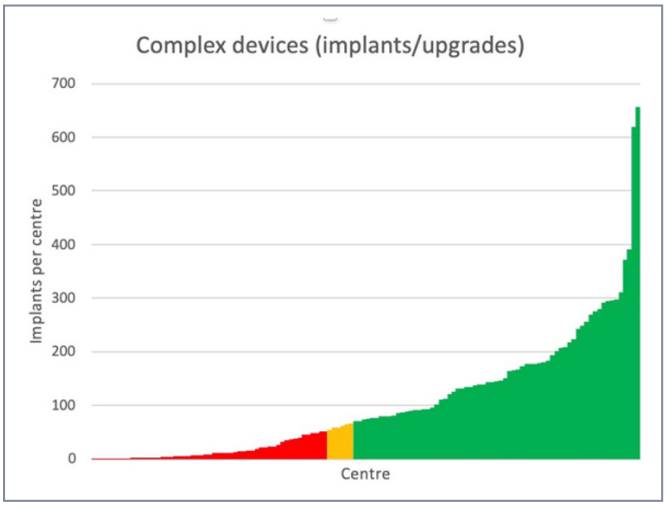
NHS hospitals not meeting the standard halved between 2014/15 and 2016/17 and have remained static since then.

Quality Standard 2 (Complex device Implants) BHRS Standards (2015) recommend that complex device hospitals undertake a minimum of 60 such procedures (ICD and CRT implant/ upgrades) per year.

Audit findings
In 2018/19, 128 hospitals in the UK reported at least one complex device implant (or upgrade from pacemaker). This includes 5 children's and 15 private hospitals. 58 hospitals failed to meet the standard of 60 implants/upgrades, of which 38 were NHS adult hospitals (this was 60 in 2014/15). 7.7% of complex implants/

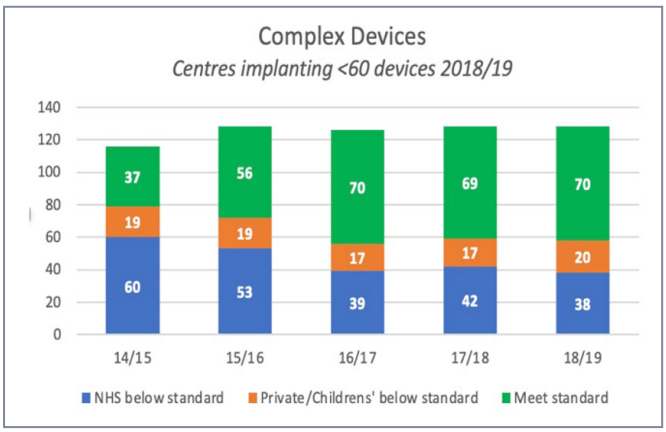
upgrades were performed in low volume hospitals (6.3% were in NHS adult hospitals).

Figure 3.3: *Number of complex device implants/upgrades implants reported by each hospital in the UK*



Amber indicates hospitals that are ± 10% of the standard of 60 implants, red is below this level, and green above.

Figure 3.4: *Number of hospitals meeting the standard for complex devices over a 5-year period*



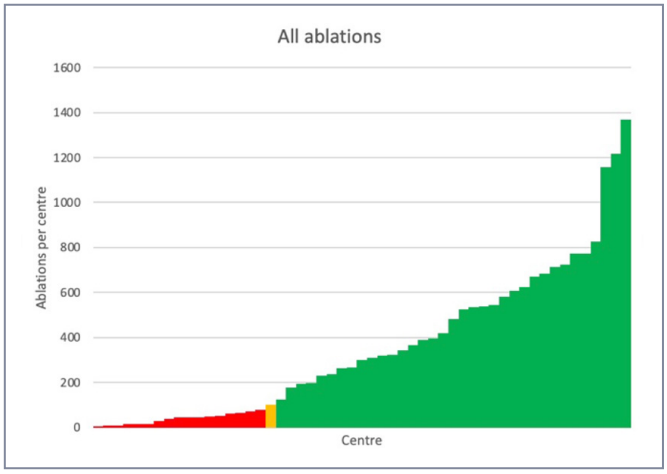
NHS hospitals not meeting the standard fell by 1/3 between 2014/15 and 2016/17 and have remained static since then.

Quality Standard 3 (Catheter ablation): BHRS Standards (2016) recommend that ablation hospitals undertake a minimum of 100 ablation procedures per year in total.

Audit findings

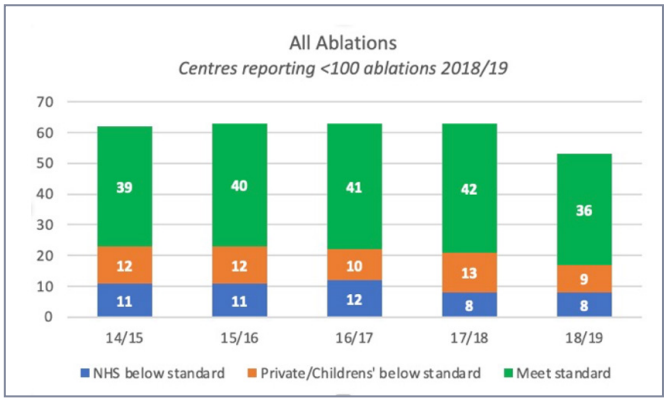
In 2018/19 53 hospitals in the UK reported ablation procedures. This includes 11 children's and private hospitals. 17 hospitals failed to document meeting the standard of 100 ablations/year, of which 8 were NHS adult hospitals. Between them, the latter reported only 301 ablations (1.6% of NHS cases).

Figure 3.5: *Number of ablation procedures reported by each hospital in the UK*



Amber indicates hospitals that are ± 10% of the standard of 100 ablations, red is below this level, and green above.

Figure 3.6: *Number of hospitals meeting the standard for ablations over a 5-year period*



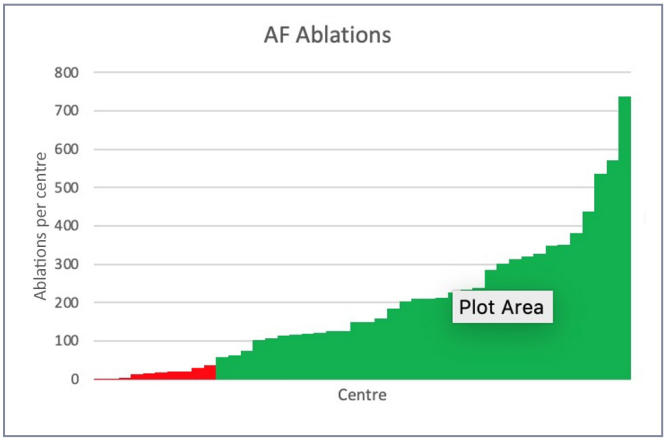
NHS hospitals not meeting the standard fell by 1/3 between 2014/15 and 2016/17 and have remained static since then.

Quality Standard 4 (complex/AF ablation): BHRS Standards (2016) recommend that hospitals undertaking AF ablation should perform a minimum of 50 such cases per year.

Audit findings

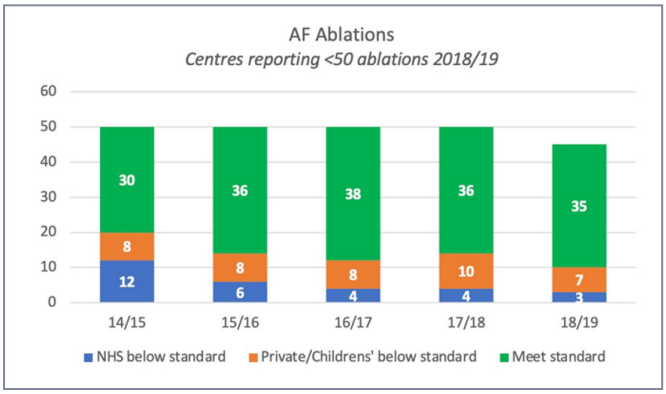
44 hospitals reported AF ablation procedures in 2018/19. Ten of these hospitals reported fewer than 50 cases, of which seven were private hospitals. In total, 159 AF ablations were in low volume hospitals (2.0% of cases), of which only 40 were in NHS hospitals (0.5% of cases). This is in contrast to 258 such procedures (4.6%) on the NHS in 2014/15.

Figure 3.7: *Number of AF ablation procedures reported by each hospital in the UK*



Amber indicates hospitals that are ± 10% of the standard of 50 ablations, red is below this level, and green above.

Figure 3.8: *Number of hospitals meeting the standard over a 5-year period*



NHS hospitals not meeting the standard fell by 2/3 between 2014/15 and 2016/17 and have remained static since.

1.2.4 ARE OPERATORS DOING ENOUGH PROCEDURES?

Background

BHRS has also made recommendations for individual specialists undertaking device (2015) and ablation procedures (2016) in adults.

Quality Standard 5: The minimum volume for an implanting specialist is 35 total new devices per year; for those undertaking complex implants/upgrades the recommendation is at least 30 such procedures within a total of 60 device implants.

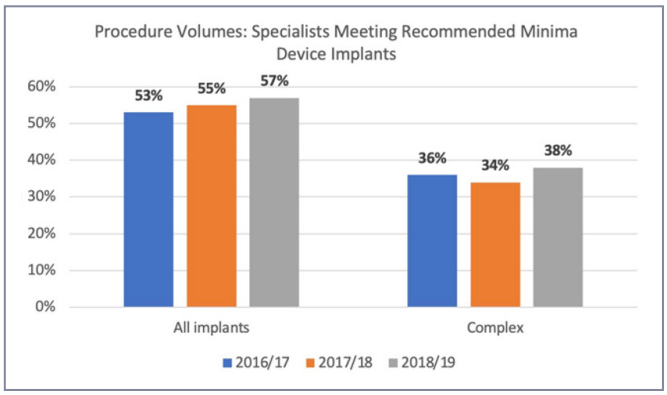
Quality Standard 6: Interventional electrophysiologists undertaking catheter ablation should perform at least 50 procedures per year; for those undertaking complex procedures (generally AF ablations) the recommendation is at least 25 such procedures within this total; while ≥50 complex procedures is desirable.

Reported operator activity is summarised in individual hospital reports (Appendices 4 & 5 for devices & Appendices 6 & 7 for ablations) and aggregated for each operator in Appendices 12-15, where specialty/training status is also indicated. For many operators, numbers will have been underestimated because of inaccurate or missing GMC Numbers. We are publishing individual reported activity in the appendices in order to drive improved reporting. Nevertheless, these figures for individuals should be interpreted with caution and with reference to the notes below.

Audit Findings

1458 doctors were identified by GMC Number as participating in at least one pacemaker/complex device procedure during 2016/17.

Figure 3.9: *Proportion of specialists reported to have undertaken the recommended minimum number of device implants in 2018/19*



All device implants

Of 820 doctors on the specialist register for Cardiology ±General Medicine performing pacemaker implants, 473 (57%) were documented to have met the standard of performing ≥35 device implants in total. This is a slight improvement on the proportion in the 2016/17 report (53%).

Complex implants

Of 529 doctors on the specialist register for Cardiology ±General Medicine participating in complex device implants in 2018/19, 201 (38%) were documented to meet the standard of performing ≥60 total device implants including ≥30 complex device implant/upgrade procedures. This is a marginal improvement on the proportion in the 2016/17 report (36%).

In addition, 48 specialists in cardiothoracic surgery and 23 paediatricians/paediatric cardiologists and 165 others were identified as being involved in device implants. 35 of these "others" met the standard of ≥35 implants, while most of the rest had very low volumes and may have arisen through data entry errors. 362 clinicians identified as trainees during the year were recorded as participating in implants.

Simple ablation

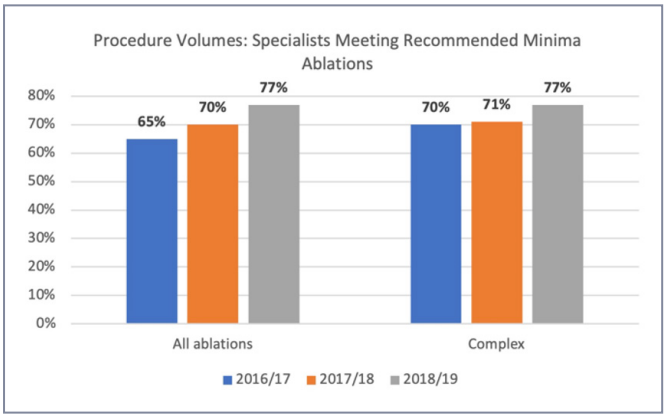
Of 253 doctors on the specialist register for Cardiology ±General Medicine performing catheter ablation in 2018/19, 191 (75%) were

documented to have met the standard of performing ≥50 total ablation procedures that year. This is an improvement on the proportion in the 2016/17 report (65%).

AF ablation

Of 236 doctors on the specialist register for Cardiology General Medicine performing complex ablations (largely for AF) in 2018/19, 180 (76%) were documented to have performed the minimum of 25 such procedures and 50 ablations in total (an improvement on 70% in 2016/17), and 133 (56%) to have performed the "desired" number of 50 complex ablations.

Figure 3.10: *Proportion of specialists reported to have undertaken the recommended minimum number of simple and AF ablations in 2018/19*



In addition, 89 doctors identified by GMC No as trainees were recorded as having participated in ablation procedures.

3.1.2 SUMMARY OF FINDINGS AND DISCUSSION

Pacemaker implants: the number of NHS adult hospitals reporting fewer than the recommended minimum number of pacemaker implants (80/year) has fallen by half since 2014/15, but 28 do not meet the standard. Although this represents 18% of implanting NHS hospitals, only 2.4% of NHS adult patients received pacemakers in these hospitals.

Complex devices: the number of NHS adult hospitals reporting fewer than the recommended minimum number of complex device implants/upgrades (60/year) has fallen by a third since 2014/15, but 38 do not meet the standard. This represents 35% of implanting NHS hospitals, and 6.3% of NHS adult patients.

Catheter ablation: in contrast, low volume catheter ablation hospitals have virtually disappeared in the NHS. Only 8 NHS adult hospitals report fewer than the recommended number of ablations, and only 3 fewer than the recommended number of AF cases. Only 301 ablations (1.6%) were performed in low volume NHS hospitals, and of these only 40 were AF ablations (0.5%). By comparison, a recent study of 54,597 AF ablations in the USA found that 2/3 of cases were performed in hospitals undertaking fewer than 52 procedures, and 1/3 in hospitals undertaking fewer than 21 procedures (in whom readmission rates and complications were significantly higher).[7]

Operators: 58% of operators performing pacemaker implants were documented to have sufficient volume to meet the BHRS standard (35/year) for these procedures; only 38% have documented sufficient volume for complex procedures. These figures are better for catheter ablation (75% and 76% each of those undertaking simple and complex ablations).

The data in this section have been analysed after validation by hospitals but without any adjudication by NICOR. It is possible that some of the apparently low volume hospitals are under-reporting. This is even more the case for the apparently poor results on operator volume, which partly reflect substantial under-reporting of GMC numbers (see Section 3.2.1).

Finally, some apparently low volume hospitals/operators may appear simply due to data entry errors (e.g. miscoding of a single simple procedure may result in a hospital being misclassified as a low volume complex hospital). We have counted all the doctors involved in a procedure, whether as first or second scrubbed operator or as supervising consultant. Many patients will have had procedures with low volume operators (trainees, visiting fellows, etc.) involved, assisting, or supervised by experienced consultants.

Recommendations for those not achieving the standards

Regions with low volume hospitals should ensure that these hospitals comply fully with the data entry requirements of the audit. Reasons for the low level of activity should be understood and decisions made about how hospitals can reach the desired standards. In some cases, it may be appropriate to decommission a low volume hospital.

Hospitals with low volume operators should ensure accurate documentation of who performs procedures and ensure job plans and decisions about sub-specialisation are reviewed.

Low volume hospitals (reporting fewer than 80 pacemakers/year, fewer than 60 complex implants/upgrades, fewer than 100 ablations/year, or fewer than 50 AF ablations/year) should ensure that their submissions to NICOR are complete and accurate (low numbers may result from incomplete reporting or misclassification of device types).

Hospitals and commissioners/inspection bodies (GIRFT, CQC) should take note of low volume hospitals and question approaches to ensure standards are reached. There may be good reasons for a low volume hospital to continue, such as:

- Remote geography, especially for pacing which is dominated by elderly patients, often with limited mobility. However, it may be less valid for catheter ablation procedures.
- New hospitals in underserved areas, supported by a long-term plan agreed with local commissioners.

Low volume does not necessarily equate with low standards: many smaller hospitals offer excellent services delivered by experienced consultants. However, they should ensure that robust and timely audit, especially of complications and appropriate indications, is regularly conducted – preferably with peer review by an impartial third party supported by BHRS.

Low volume operators (undertaking fewer than the recommended minimum numbers of procedures) should ensure careful documentation of all procedures they undertake.

Cardiac rhythm management services should:

- Determine which of their operators are low volume (across all sites where they work), whether this is a documentation issue, and whether this is a "one-off" year. This will apply particularly to future reports where activity will have been affected by the COVID-19 pandemic.
- Ensure all their procedures are correctly submitted to the national audit. This includes procedures performed as visitors to other hospitals. They should exert pressure on private hospitals to participate in the audit, so that their private cases are counted towards their totals and are audited.
- Ensure the correct assignation of doctors to procedures. In particular the "supervising consultant" should be the doctor directly responsible for the procedure, not for the hospital spell (which may be under a different specialty).
- Should identify whether low volume activity may compromise patient safety (e.g. if a low volume operator undertakes procedures without assistance from a more experienced colleague). The appropriateness of low volume practice should be questioned. If continuation is agreed, the operator concerned should be subject to ongoing audit of outcomes and complications, over more than one year if necessary, and retraining may be necessary as per BHRS guidance.

Larger hospitals with multiple low volume operators should ensure that standards are maintained by local audit. They should consider whether subspecialisation might be appropriate to ensure that all patients are treated by experienced consultants. This may mean some consultants giving up part of their practice.

Commissioners and inspection bodies (CQC, GIRFT) should hold hospitals to account to ensure the above steps are taken. The professional bodies (BHRS, BCS) should support this by providing independent peer review where necessary. Operator performance as reported to NICOR should become a standard (possibly mandatory) part of annual appraisal and revalidation. This will become easier with the advent of "live" reporting on the NICOR website.

3.2 EFFECTIVENESS

1.2.5 DATA COMPLETENESS AND VALIDITY

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.

Quality Standard 7: Hospitals should achieve ≥90% completeness in each of 6 data domains for device and ablation procedures

Individual hospital reports (Appendices 4-7) detail completeness for a large number of fields (24 for device procedures and 30 for ablations), in order to help hospitals identify their data deficiencies. Full details of data completeness are given in each hospital's individual report.

These fields have been distilled into 6 domains:

1. Demographics: the average completeness of NHS Number and Postcode, essential for analyses of re-intervention rates and maps of geographic provision. The other four demographic fields are technically mandatory and therefore 100% by definition.
2. Clinical (basic): the average completeness over four fields that describe the clinical indication for simple device therapy.
3. Clinical (complex): the average completeness over fields that describe the clinical indications for complex devices, or for AF ablations. These fields are not required for simple devices and other ablations.

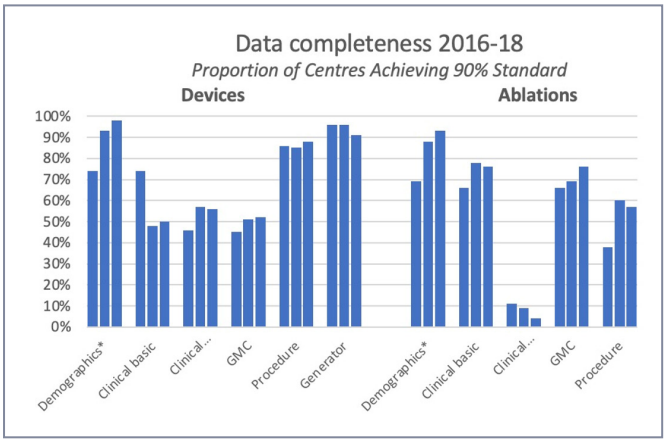
4. GMC: the mean completion rate of GMC Registration Number for first operator and responsible consultant.

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

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

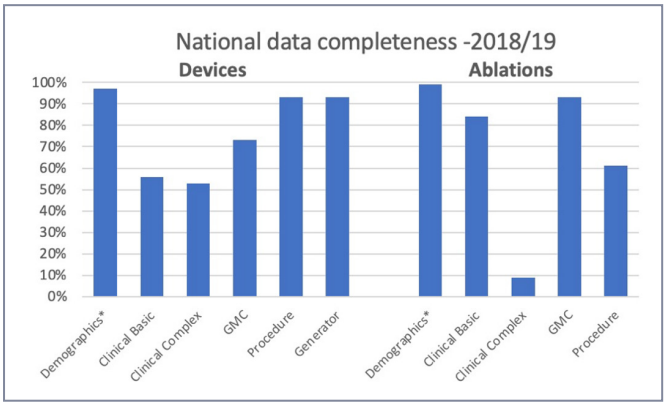
Data completeness and validity in each of these domains for 2017/18 and 2018/19 are tabulated in Appendices 16 & 17 (Devices) and Appendices 18 & 19 (Ablations).

Figure 3.11: *Proportion of hospitals achieving the standard (90% completeness) in each of the six data domains for device procedures*



For each domain, three columns represent 2016/17 (data from last report), 2017/18, and 2018/19. There have been great improvements in reporting of demographics, and lesser improvements in other domains. Private hospitals were excluded from the demographics metric which is dominated by NHS No.

Figure 3.12: *Proportion of individual records nationally in which data were complete*



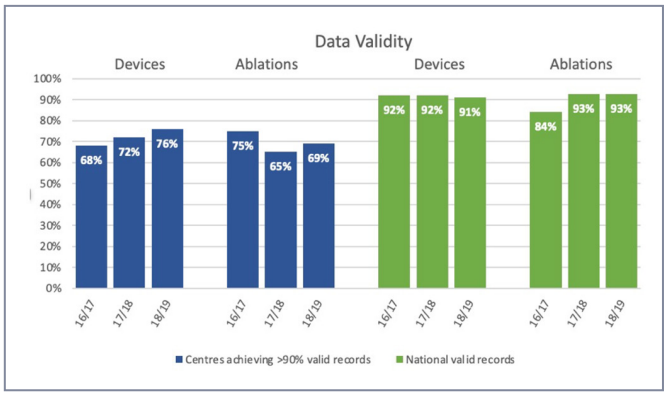
Quality Standard 8: Hospitals should achieve ≥90% validity in each of 2 data domains for device and ablation procedures.

Two further measures have been derived to test the validity of key fields, which are essential to most of the analyses in this report:

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

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

Figure 3.13: *Proportion of hospitals and records reaching device and ablation validity measures*



On the left, the proportion of hospitals achieving the standard (90% validity) for device and ablation validity measures over the last three years is shown. This has shown some improvement for devices but not for ablations. On the right are the proportions of records nationally that are valid (now >90%).

2.2.1 COMPLIANCE WITH NICE GUIDANCE

Why is this important?

NICE Technology Appraisals make recommendations for the type of pacemaker to be used for the treatment of slow heart rates,[8,9] and for appropriate indications for the implantation of ICDs to prevent sudden arrhythmia death.[10]

Separate guidance has been issued for the use of complex devices in the treatment of patients with heart failure.

NICE Guidance for pacemaker therapy (NICE TA88 & TA324)

"Dual-chamber pacing is recommended for the management of symptomatic bradycardia due to sick sinus syndrome, atrioventricular block, or a combination thereof (except in patients with continuous atrial fibrillation of where the presence of patient specific factors, such as frailty or comorbidities influence the risk/benefit balance in favour of single chamber ventricular pacing)."

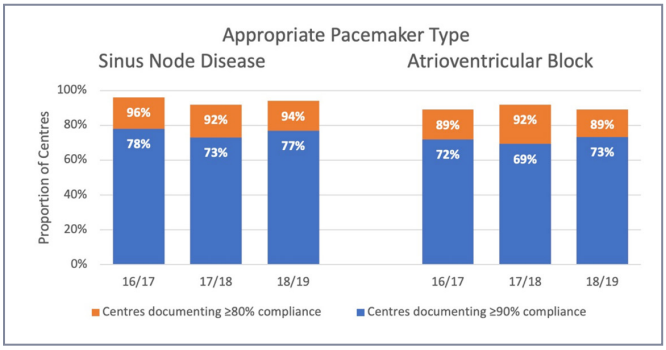
Quality Standard 9 (pacing for sinus node disease in the absence of atrial fibrillation): 90% of pacemaker implants should be dual chamber.

Quality Standard 10 (pacing for atrioventricular block in the absence of atrial fibrillation): 90% of pacemaker implants should be dual chamber.

* The standard is 90% to allow for patient specific factors described in the guidance. Audit is reported against this standard both on a national level (did pacemaker implants in the UK overall meet the standard?), and by hospital (what proportion of hospitals achieve the quality standard?).

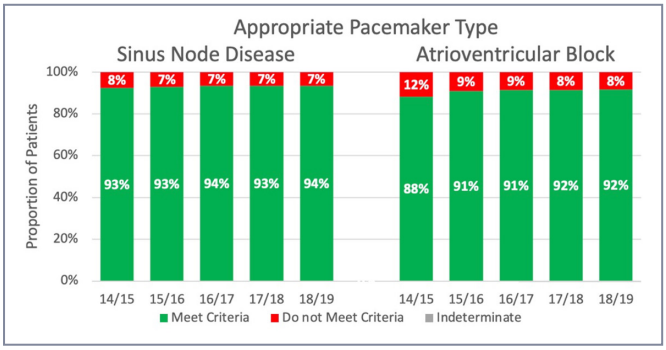
Each hospital's performance against these standards in 2017/18 and 2018/19 is tabulated in Appendices 8 and 9, respectively.

Figure 3.14: *Hospital compliance with NICE guidance on pacemaker type*



In 2018/19, 77% of hospitals reporting pacemaker implants for sinus node disease achieved the quality standard of 90% documented compliance with NICE guidance. 73% of hospitals reporting pacemaker implants for atrioventricular block achieved this target. These proportions have not changed significantly over three years.

Figure 3.15: *National compliance with NICE guidance on pacemaker type*



In 2018/19, 94% of patients in the UK receiving first pacemaker implants for sinus node disease, and 92% of those implanted for atrioventricular block, met NICE guidance.These figures have gradually improved from 93% and 88% in 2014/15, and the 90% standard has been consistently met since 2015/16.

NICE guidance for appropriate implantation of implantable cardioverter-defibrillator therapy for primary and secondary prevention of sudden cardiac death (NICE TA314).

NICE recommends ICD implantation as an option for the prevention of sudden arrhythmic death in two categories of patients:

- Primary prevention (patients who are considered at high risk but who have not hitherto suffered a malignant arrhythmia).
- Secondary prevention (patients who have survived a malignant arrhythmia).

Quality standard 11: 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.

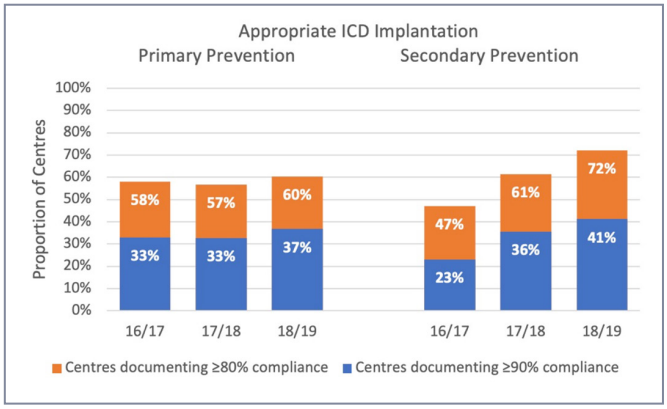
Quality standard 12: 80% of ICD implants for secondary prevention should be documented to meet at least one of the NICE criteria:

- 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%.

The standard for 2018/19 remains 80% compliance, to allow for patient specific factors in prescribing ICDs and because this is a relatively new measure (the last audit was only published during the years that are currently reporting). We are also reporting against a future target of 90% compliance, to permit monitoring of performance over time.

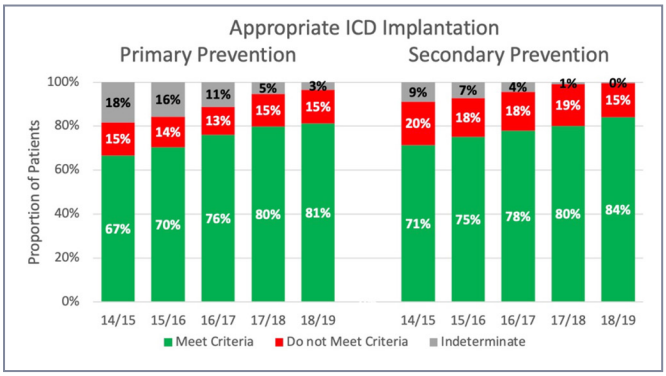
Each hospital's performance against these standards in 2017/18 and 2018/19 is tabulated in Appendices 8 and 9, respectively. Again, audit is reported against these standards both on a national level (did pacemaker implants in the UK overall meet the standard?), and by hospital (what proportion of hospitals achieve the quality standard?).

Figure 3.16: *Hospital compliance with NICE guidance on ICD implantation*



In 2018/19, only 60% of hospitals achieved the standard of documenting compliance with NICE guidance for primary prevention implants, and 72% for secondary implants. The former has remained static, while the latter has improved significantly over three years. The disparity between these low figures and the national figures arises because of a large number of poorly compliant hospitals that are also low volume.

Figure 3.17: *National compliance with NICE guidance on ICD implantation*



In 2018/19 81% of ICDs implanted for primary prevention and 84% of those implanted for secondary prevention were documented to be appropriate per NICE guidance.The 80% quality standard was met for the first time nationally in 2017/18. These figures have improved significantly since 2014/15 when they were 67% and 71% respectively. However, the proportion of "indeterminate" cases (not classified because of insufficient information) fell greatly during these five years. Much of the improvement may therefore reflect better documentation as well as improved clinical practice.

3.2.1 SUMMARY OF FINDINGS AND DISCUSSION

NICOR's ability to embark on increasingly direct and clinically relevant audit in the future is dependent on data completeness and validity. We report these parameters nationally and by hospital to drive improvement in submissions. That this can be effective is illustrated by the improvement in documented compliance to NICE guidance for ICDs:

- Data completeness: this is improving, and for some key data domains (demographics, device procedure details) is approaching 100%. However, some data domains are very poorly reported, especially clinical details (indications for procedures) and operator identification by GMC No. This can create a poor picture of clinical performance that may be false.

- Data validity: our checks on the validity of key fields shows improvement, with >90% validity nationally in both device and ablation records. However, only ~70% of hospitals are achieving the target of 90% validity, and we intend to raise this bar to 95%.

- Adjudication of the data using other fields permits NICOR to correct invalid submissions in order to obtain an accurate picture of national activity. However, this step should not be necessary.

- Pacemaker type. NICOR has audited this for over a decade and achieved considerable improvement, meeting the 90% target nationally over each of the last four years. For sinus node disease and atrioventricular block, 94% and 92% of patients respectively receive dual chamber devices as recommended by NICE. For clinical reasons explained earlier, a 100% target would be inappropriate. However, 5-10% of hospitals continue failing to meet NICE guidance in at least 20% of their cases.

- ICD indication: since NICOR started to audit this three years ago, documented compliance with NICE guidance has improved from 67% to 81% of all primary prevention and from 71% to 84% of all secondary prevention implants. Nationally therefore, the 80% target is met. This largely reflects improved documentation by many larger hospitals (the proportion of cases in which NICE adherence cannot be determined is now nearly zero). Unfortunately, approximately one third of hospitals still do not meet the audit target – this is improving, but slowly.

Recommendations for those not achieving the standards

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.

Poor data completeness and validity implies a low level of clinical governance. It usually results in a hospital's clinical performance appearing worse than is the case (e.g. low volume for the hospital and its clinicians, low adherence to guidance):

- Medical directors in hospitals undertaking CRM device and ablation procedures should examine their hospital's performance in the "league tables" (Appendices) and identify where improvements are needed. The validation reports sent out to each hospital give a final opportunity to improve submissions and should not be ignored.

- Even if data submissions are performed by allied professionals and juniors, each consultant should take personal responsibility for ensuring that the procedures he/she undertakes are correctly recorded and submitted.

- BHRS and the Domain Expert Group should review the dataset and determine whether certain fields (e.g. some of the clinical data for AF ablations) should be dropped, or whether their importance to future audit is sufficient to warrant a sustained drive with hospitals. BHRS should engage more with hospitals to help encourage better data submission.

- NICOR should use the opportunity of the new IT platform to provide tools permitting instant feedback to hospitals on their data completeness and (where possible) validity. NICOR should proactively reach out more to poorly performing hospitals to motivate better data submission. This should be done on an ongoing basis rather than during a hasty validation period.

- Again, commissioners and inspection bodies (CQC, GIRFT) should hold hospitals to account to ensure the above steps are taken.

3.3 | OUTCOMES

Background: why is this important?
Mortality is the principal 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 up to 10% of patients with devices are expected to die each year due to age-related conditions, heart failure, etc.

Complications might be a more relevant measure of a hospital's safety performance. However, reliance on self-reported outcomes requires a consistent approach to data definition. Furthermore, many important complications do not become apparent for weeks, and may present away from the implanting entre. It is therefore virtually impossible to assure systematic detection and recording of nonfatal complications.

This issue can be addressed by using data that are probably more reliable. Certain key procedure-related complications almost always require a second intervention. These include:

- Displacement of or damage to a pacemaker/defibrillator lead (requiring repositioning/replacement);

- Infection (requiring system explant);

- Sometimes, haematoma (collection of blood) or generator displacement (requiring revision of a pacemaker wound or pocket).

These problems do not always present within 30 days, but where such re-interventions occur within 12 months it is fair to ascribe them to implant complications. Other possible reasons for early re-interventions include a change in a patient's clinical condition or device malfunction/recall.

As an index of complications, therefore, we report re-interventions performed within 12 months of a device implant. Submission of Hospital Number is mandatory but cannot be used to track patients treated at more than one hospital. Therefore, NHS Numbers (we use this term to include their equivalent in Scotland/NI) were also used to detect re-interventions. Both Hospital Nos. and NHS Nos. are securely encrypted prior to analysis to preserve anonymity.

The risk of complications is higher for complex devices than pacemakers, and considerably higher following re-interventions (battery changes, upgrades, etc). To create an even playing field between hospitals with different case-mixes, we have therefore only included first implants as the 'index' procedure, and we have analysed first pacemaker and first complex (ICD/CRT) device implants separately.

This is the first national audit to track re-intervention rates over this period. We believe that re-interventions are a useful index of procedure safety, but the results must be interpreted with caution for a number of reasons:

- While the overwhelming majority of re-interventions result from procedural complications, occasionally there are other reasons, such as:
  - a change in a patient's clinical status that requires a different type of implanted device.
  - a failed first implant, requiring a second attempt even though no actual complication has occurred (this applies especially to CRT implants).

- Not all complications result in a device re-intervention: some displaced leads are not replaced, and certain complications such as pneumothorax (collapsed lung) are not treated by another device intervention, so are not captured by the audit.

- Detection of a re-intervention requires entry of the correct NHS Number for the index procedure and re-intervention.

For each analysis, we have assigned hospitals to two Tiers. 'Tier 1' consists of hospitals reporting NHS Nos 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.

- Hospitals with lower submission rates of NHS Nos have been termed 'Tier 2' and analysed separately. Low NHS submission inevitably introduces systematic bias toward the under-detection of complications, making the performance of Tier 2 hospitals appear better than reality. 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%.

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.

- Filled and open markers are centres with adequate and inadequate reporting of NHS No, respectively (Tier 1 and Tier 2, see below).
- The mean re-intervention rate for all procedures is shown as a solid line.
- Dashed lines show control limits (±1.96 x standard error from mean): the probability is 2.5% of being above this range due to chance.
- Thin dotted lines show a 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.

2.2.2 RE-INTERVENTION FOLLOWING FIRST DEVICE IMPLANTS

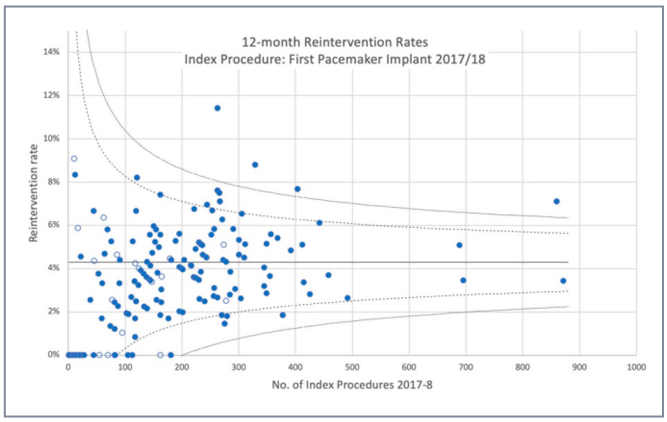
The one year re-intervention rates for each hospital are given in its individual hospital report (Appendices 4 & 5), and in tabular form in Appendices 20 & 21 (for implants in 2016/17 and 2017/18, respectively).

In 2018/19, 143 of 181 hospitals reporting device implants were Tier 1 (>90% NHS No submission in both years analysed). 38 fell into Tier 2 and were excluded from the primary analysis. These are identified in the Appendix table. Tier 2 included all private hospitals, as well as all but one hospital in Scotland and in Northern Ireland.

This is a considerable improvement on the 2015/16 report, when 84 hospitals fell into Tier 2.

Quality Standard 15 (Pacemakers): The rate of re-interventions within a year of a first pacemaker implant should be below the 95% upper control limit (national mean + 2 standard errors).

Figure 3.18: *Funnel plot of re-interventions following first pacemaker implants in 2017/18*



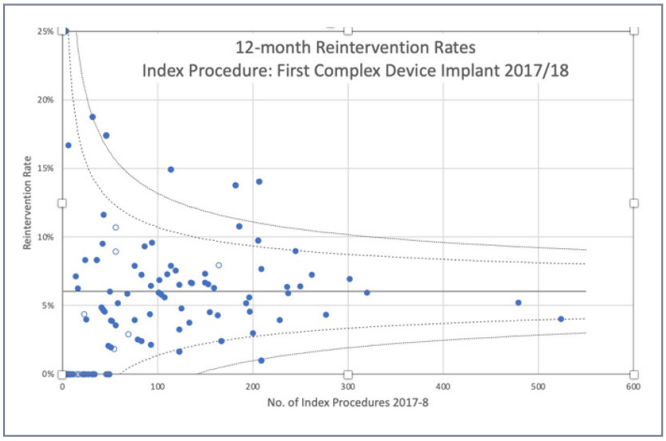
The mean 1-year re-intervention rate (calculated from Tier 1 data, filled markers) was 4.3%. This compares to 4.0% for 2015/16 implants, and 4.2% for 2016/17 implants.

Hospitals with high re-intervention rates Blackpool, Bournemouth, Good Hope, Poole, Wycombe, Morriston, St Bartholomew's*, St Thomas'*, and Southampton*.*
** above the 99% control limit*

Hospitals with apparently low re-intervention rates: Bedford, Hartlepool, Hereford, Kingston, St George's, Wansbeck, Worcester.
Note that a significant proportion of low volume hospitals were in Tier 2 (open markers) so their true re-intervention rates may have been significantly higher.

Quality Standard 16 (Complex Devices): The rate of re-interventions within a year of a first complex device (ICD or CRT) implant should be within the 95% control limit (national mean + 2 standard errors).

Figure 3.19: *Funnel plot of re-interventions following first complex device implants (but not upgrades) in 2017/18*



For first complex device implants in 2017/18, the mean 1-year re-intervention rate (calculated from Tier 1 data) was 6.0% for complex devices. This compares to 5.8% for 2016/17 implants, and 6.3% respectively for 2015/16 implants.

Hospitals with high re-intervention rates Manchester Royal Infirmary, Southampton Duchy (Cornwall), Frimley Park*, Good Hope*, New Cross (Birmingham)*, Queen Elizabeth (Woolwich)* and St Thomas'*.*
** above the 99% control limit*

Hospitals with apparently low re-intervention rates: Bristol Royal Infirmary, Liverpool, St George's, and Worcester.
Note that a significant proportion of low volume hospitals were in Tier 2 (open markers) so their true re-intervention rates may have been significantly higher.

3.3.1.1 SUMMARY OF FINDINGS AND DISCUSSION

Re-intervention rates in the year following first implants in 2017/18 of pacemakers and complex devices were 4.3% and 6.0% respectively. These values are fairly stable and in line with published data on complications from other countries such as Denmark,[11] (though direct comparisons are impossible as the measures are different).

As in previous years, a number of hospitals have high re-intervention rates: some are large hospitals in which this finding is consistent over the years. Some others, with poor reporting of NHS No, may also have high true re-intervention rates that were not detected.

Recommendations

Hospitals with high re-intervention rates following device implants should review their cases to examine the factors involved and to determine means by which these can be lowered.

- Hospitals with a high re-intervention rate (especially if this is consistent from year to year) should examine whether this is largely due to complications (the commonest cause), in which case an in-depth examination of contributory factors should be undertaken. This includes human factors (individual operators, adequate supervision of trainees), patient factors (active infection, diabetes, renal failure especially haemodialysis), protocols (e.g. use of prophylactic antibiotics), and infrastructure (suitability of premises). Where re-interventions are due to failed initial implants, hospitals should examine the availability of a second experienced operator.

- Hospitals with significantly low detected re-intervention rates should confirm that these are genuine (rather than under-reporting of repeat interventions), and if so should be encouraged to identify which factors are responsible and act as champions of good practice nationwide.

- Commissioners should hold to account hospitals with high re-intervention rates, and those in Tier 2 (for whom accurate re-intervention rates cannot be estimated). Explanations should be sought, and plans established to improve reporting and outcomes.

3.3.1 RE-INTERVENTION FOLLOWING CATHETER ABLATIONS

Background
Unlike device procedures, re-intervention is not a treatment for complications and cannot be considered an index thereof.

The need for re-intervention following a catheter ablation reflects the outcome of the original procedure. Whether a patient actually receives a repeat catheter ablation procedure can depend on a number of factors. The cause and pattern of the target arrhythmia can greatly influence the probability of success (this applies particularly to atrial fibrillation and ventricular tachycardia), so patient selection is important. Operative factors include the choice of technology, degree of training and experience of the operator and availability of a colleague. The bias of patient and doctor towards undertaking a further ablation procedure versus using adjuvant drugs (or abandoning the ablation strategy altogether) can have a substantial influence.

Finally, the timing of a repeat procedure can vary greatly, because of doctor/patient preference (e.g. "to wait and see if things improve") and because of waiting times for follow-up appointments and repeat procedures. The previous 12-month horizon for repeat ablations may not be adequate so this year we are also reporting on 2-year follow-up.

Another difference from device procedures is that it may not be clear whether an ablation is the patient's first for that target: surprisingly, this is not always clear if a patient has been treated elsewhere. Every catheter ablation during the period examined has therefore been regarded as an 'index case' and followed for 1 (or 2) years to determine whether that patient has undergone a further ablation of the same (or related) target.

However, each patient can only be counted once as a re-intervention for each target. This is particularly important for AF ablations, when a minority of patients may undergo multiple procedures – this will only count as one patient, to avoid skewing the hospitals' results. As with device implants, the proportion of re-interventions at each hospital has been plotted against the number of index cases in a 'funnel plot', and hospitals reporting NHS Number for <90% of procedures in each of the years analysed have been removed from Tier 1 for the primary analyses.

As previously, three types of procedure have been examined. 'Simple' ablations include those for supraventricular tachycardias, typical atrial flutter, and complete AV nodal ablation. 'Atrial ablation' is dominated by pulmonary vein isolation procedures for atrial fibrillation but includes other atrial tachycardias, often related to prior AF ablations. 'Ventricular ablations' constitute only 5% of procedures: this is a heterogeneous group ranging from including foci responsible for premature ventricular complexes, to extensive scar substrates responsible for ventricular tachycardia.

Quality Standard 17 (Catheter Ablation): The frequency with which patients undergo a repeat procedure (i.e. to the same or related target) within a year of catheter ablation should be within the 95% control limit (national mean + 2 standard errors).

One- and two- year re-intervention rates for each hospital are given in its individual hospital report (Appendices 6 & 7), and in tabular form in Appendices 22-24 (for index procedures in 2015/16, 2016/17 and 2017/18).

The Table shows mean re-intervention rates nationally following catheter ablations (along with control limits for funnel plots), calculated from Tier 1 data (hospitals with adequate NHS No submission):-

Table 3.1: *National re-intervention rates following catheter ablation*

	2015/16		2016/17		2017/18
	1 yr FU	2 yr FU	1 yr FU	2 yr FU	1 yr FU
Simple	3.1%	4.5%	3.5%,	4.9%	3.2%
Atrial	9.9%	17.5%	10.0%,	18.0%	9.1%
Ventricular	10.6%	15.0%	12.0%,	16.4%	10.7%

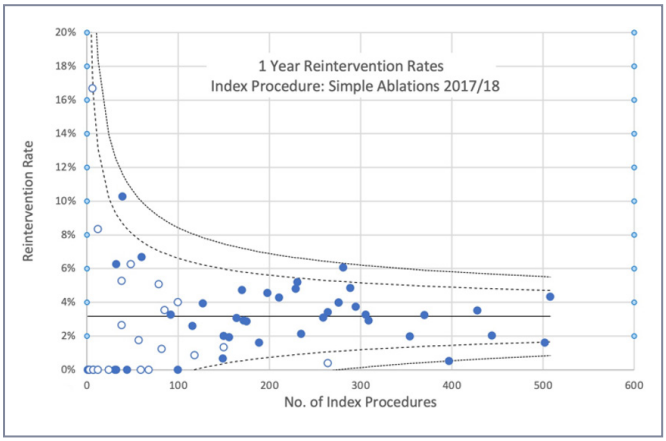
2-year follow-up following procedures undertaken in 2017/18 requires the analysis of data from 2019/20 and is therefore not in this report.

These data have not changed significantly since re-interventions were first reported in 2016/17. Funnel plots for the three categories of procedure are given with 1 year follow-up for index procedures undertaken in 2017/18 and 2 year follow-up for procedures undertaken in 2016/17. Hospitals lying above the 95% upper control limits are listed below each funnel plot (hospitals above the upper 99% control limit are asterisked); hospitals lying below the lower 95% control limit are listed unless they are Tier 2 (as their rates may be considerably underestimated).

Reintervention rates for other years are given in appendices 20-24.

Simple ablation

Figure 3.20: *Funnel plot of 1-year re-intervention rates following simple ablations undertaken in 2017/18*

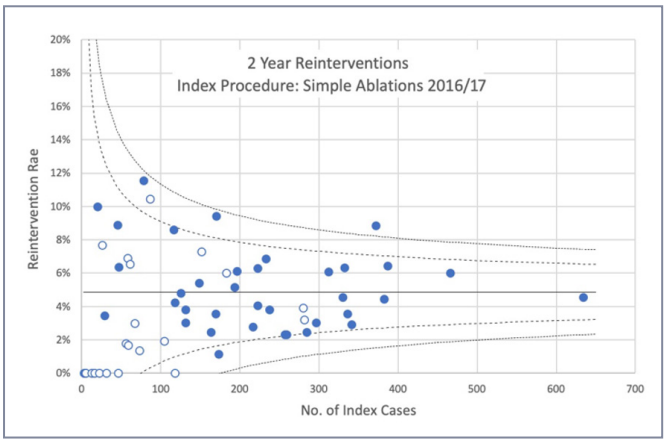


The mean re-intervention rate was 3.2%.

Hospitals with high re-intervention rates:
Birmingham Children's, Royal Brompton.

Hospitals with low re-intervention rates:
1-year re-interventions: Wythenshawe, St Bartholomew's.
The majority of low volume hospitals were in Tier 2 (open markers) and their true re-intervention rates may have been significantly higher.

Figure 3.21: *Funnel plot of 2-year re-intervention rates following simple ablations undertaken in 2016/17*



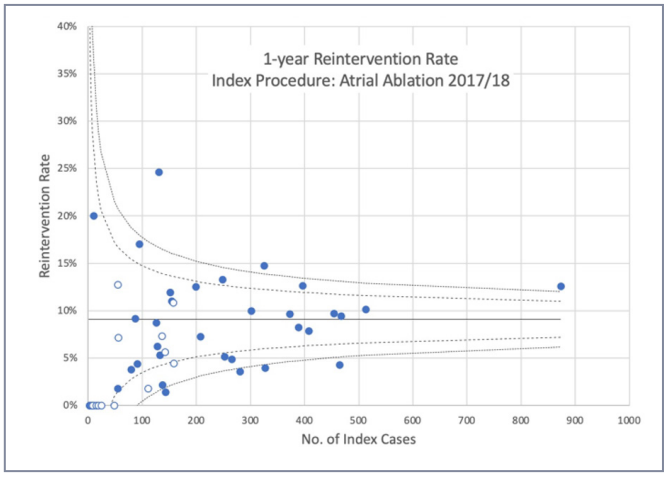
The mean re-intervention rate was 4.9%.

Hospitals with high re-intervention rates:
Frimley Park, Great Ormond St, Manchester Royal, Wythenshawe.*
** above the 99% control limit*

Hospitals with low re-intervention rates: Hull
Again, the majority of low volume hospitals were in Tier 2 (open markers) and their true re-intervention rates may have been significantly higher.

Atrial Ablation

Figure 3.22: *Funnel plot of 1-year re-intervention rates following atrial ablations undertaken in 2017/18*

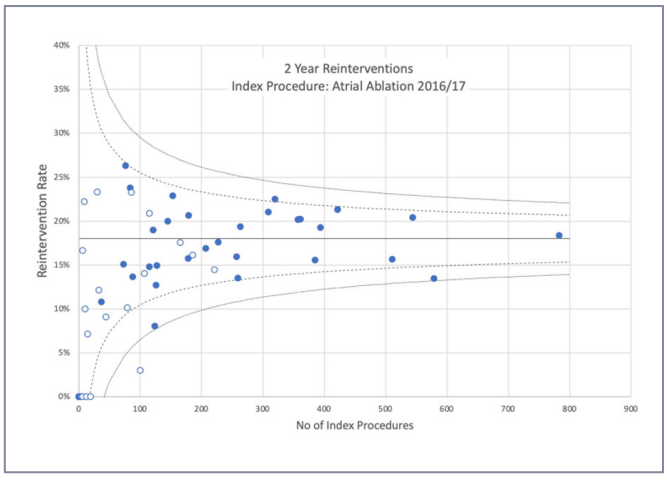


The mean re-intervention rate was 9.1%.

Hospitals with high re-intervention rates
1 year re-interventions: Portsmouth, QE Birmingham and Oxford, James Cook, QE Birmingham*, St Bartholomew's*.*
** above the 99% control limit*

Hospitals with low re-intervention rates: Hull, Coventry, Blackpool, Leicester, Brighton, Wythenshawe, St George's
Again, the majority of low volume hospitals were in Tier 2 (open markers) and their true re-intervention rates may have been significantly higher.

Figure 3.23: *A Funnel plot of 2-year re-intervention rates following atrial ablations undertaken in 2016/17*



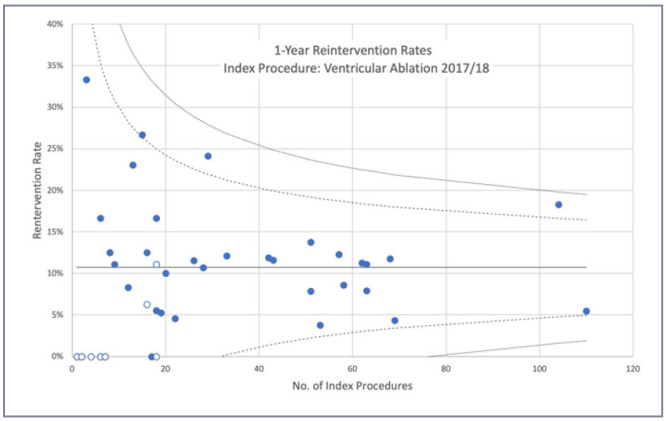
The mean re-intervention rate was 18.0%.

Hospitals with high re-intervention rates: Leeds General Inf.

Hospitals with low re-intervention rates: Hull, Liverpool
Again, the majority of low volume hospitals were in Tier 2 (open markers) and their true re-intervention rates may have been significantly higher.

Ventricular Ablation

Figure 3.24: *Funnel plot of 1-year re-intervention rates following ventricular ablations undertaken in 2017/18*

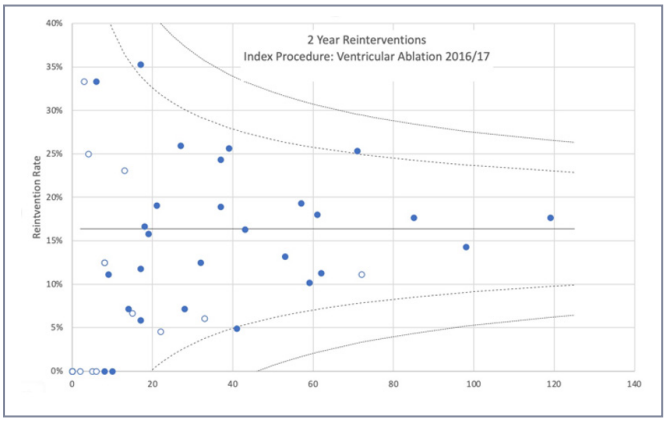


The mean re-intervention rate was 10.7%.

Hospitals with high re-intervention rates: Manchester Royal Inf, Southampton, St Bartholomew's

Hospitals with low re-intervention rates: none

Figure 3.25: *Funnel plot of 2-year re-intervention rates following ventricular ablations undertaken in 2016/17*



The mean re-intervention rate was 16.4%.

Hospitals with high re-intervention rates: Basildon, Royal Brompton

Hospitals with low re-intervention rates: Leicester

3.3.1.1 SUMMARY OF FINDINGS AND DISCUSSION

The majority of patients undergoing simple ablation appear to have had successful initial procedures, 3.3% undergo re-intervention within a year, and that figure is only increased to 4.7% after a further year's follow-up.

The picture is very different for atrial ablations (largely AF ablation), where the re-intervention rate almost doubles between 1 year (9.6%) and 2 years' follow-up (17.7%). In fact, this re-intervention rate is remarkably 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.[12-14]

For ventricular ablations, the picture is intermediate, with re-interventions increasing from 11.1% to 15.8% after a second year of follow-up. As mentioned earlier, these procedures are conducted for very heterogeneous conditions, but the ventricle is the target in only 5% of ablations, so the numbers are too small to permit meaningful subdivision of the data.

As discussed earlier, re-intervention depends on a number of factors, including patient selection and technical issues for the original ablation, and patient and doctor motivation to undertake a further procedure. Nevertheless, the considerable variance in re-intervention rates between hospitals, especially for atrial ablation procedures, should prompt examination of patient selection criteria for initial and repeat procedures.

Recommendations

Hospitals with high re-intervention rates following ablation procedures should review their cases to examine the factors that are involved and to determine whether these can be reduced.

- Hospitals with high re-intervention rates should establish why this is the case: is it a reflection of a poor-quality initial procedure, of case selection ("resistant" patients, especially persistent atrial fibrillation)? Or is it a reflection of an effective hospital that takes an aggressive approach to initial failures. Likewise low re-intervention rates may have very good case selection and effective operators at 'good' hospitals; alternatively the hospitals may simply be abandoning the ablation strategy at an early stage, when for some patients a repeat procedure (locally or at a larger hospital) may be in their interests. Open and multidisciplinary discussion of ablation failures should aim to lessen the large variance identified.

- Commissioners should recognize that on average, re-intervention rates in the UK are quite low by international standards, especially for AF ablation. However, variance between hospitals is high. Engagement with hospitals to understand and lessen this variance

is desirable. While the overall frequency of re-interventions may not need to fall, value can be sought by targeting initial and repeat procedures at those patients most likely to benefit – either because of the severity of their condition, or the likely success of a procedure. This will be aided by the creation of pathways for shared decision making and agreed management plans across formal networks or groups of hospitals.

4. KEY FINDINGS

- The ability of this report to give a complete picture of CRM device and ablation activity in the UK has been severely impacted by the withdrawal of Scotland, Northern Ireland, and some key private hospitals. It is to be hoped that their contributions will be reinstated as a result of ongoing negotiations. Submissions from the private sector will be particularly important over the next two years as it will contribute a substantial proportion of elective NHS work during the COVID recovery phase. It will be important to monitor this work discretely from the work undertaken by the same clinical teams in their normal NHS premises.

- Data submissions from NHS Hospitals in England and Wales have continued and the impact of the above withdrawals has been modelled.

- Following several years of rapid growth, overall activity levels for all CRM device and catheter ablation procedures has not changed significantly since 2016.

- The adoption of cryoballoon ablation for AF has been rapid, while that of leadless pacemakers has been slow. This partly reflects cost and partly caution on the part of the manufacturer in releasing these devices to hospitals. The role of the subcutaneous ICD is established.

- The number of NHS hospitals reporting small volumes of device procedures (especially complex devices) has diminished but remains high. Some of this may reflect data errors, and there may be good reasons for some low volume hospitals to continue, but for others this may be questionable.

- The number of small volume ablation hospitals is very low, and the pattern in the UK is far better than that in other countries such as the USA.

- There appear to be large numbers of low volume implanting and ablating consultants. This is partly due to poor submissions of GMC numbers by some hospitals.

- Nationally, compliance with NICE guidance remains good for pacemakers, and is now also good for ICDs. However, a substantial proportion of low volume are poor at documenting compliance.

- Data submission in some ancillary fields (e.g. clinical data) is improving but remains inadequate.

- As a country, the UK has acceptably low re-intervention rates for devices and ablation. However, there is unexpectedly wide scatter, even amongst hospitals with good NHS number submission. Furthermore, as the latter was poor amongst low volume hospitals, some of these may have high re-intervention rates that are not currently detected.

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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 the Welsh Government and, for four of the domains, from the Scottish Government. Funding has been sought to aid the participation of hospitals in Northern Ireland, the Republic of Ireland and the private sector.
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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 turnover of £1.5 billion and 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, 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/national-programmes