This report presents the official record of invasive cardiology procedures for cardiac rhythm management (CRM) between 1st April 2016 and 31st March 2017. As such, it is the 12th report relating to CRM devices and the 10th report relating to catheter ablation procedures.

Recommendations are made based on these findings. The report covers centres in England, Scotland, Northern Ireland and Wales. The report is aimed at a wide range of people and institutions with an interest in CRM device and catheter ablation services. This includes those who need a factual record of procedure numbers: by hospital, area and nation within the UK.

This is also the first year of a planned programme to increase the focus on quality improvement (QI) and outcomes (clinical and technical) of CRM device procedures, which links more closely with the wider National Cardiac Audit Programme (NCAP) and related national initiatives. It will therefore be of interest to:

- Patients, carers and the public;
- Doctors and allied health professionals involved in CRM;
- Hospital managers and clinical governance leads;
- Commissioners and government agencies including the National Institute for Health and Care Excellence (NICE), Care Quality Commission (CQC), the “Getting it Right First Time” (GIRFT) initiative, and the Medicines and Healthcare Products Regulatory Authority (MHRA);
- Private healthcare providers and insurers (PHIN).

In 2011, the Audit moved from being part of the NHS Information Centre, to being one of six audits brought together under the National Institute for Cardiovascular Outcomes Research (NICOR), now hosted at Barts Health NHS Trust. In 2017, the National Audit of Cardiac Rhythm Management (NACRM) became a domain within the National Cardiac Audit Programme (NCAP).

This current report is a supplement to the broader NCAP aggregate report that provides highlighted aspects of safety, clinical effectiveness and patient outcomes across all other domains of the NCAP programme.
FOREWORD

From Trudie Lobban

The 2016/17 CRM report has made great strides in improving the data captured. It has investigated in more detail the types of procedures used and is increasingly looking at not just centres, but individual operators. Ensuring that adherence to both NICE & British Heart Rhythm Society (BHRS) guidance is analysed will help identify both good and poor centres, including those that are only poor at entering data. We welcome the return of reporting of catheter ablations after a two year gap – it is very important to be able to measure standards and outcomes of these procedures that greatly improve quality of life for patients.

The report is delving deeper and able to produce more accurate and detailed data, which can only be positive, leading to improved outcomes and benefitting patients. However, any report is only of value if used to improve services and access by patients to available treatments. We must ensure that we disseminate the report to all centres, policy makers and those involved in the care of arrhythmia patients. Arrhythmia Alliance will highlight the report at all opportunities – especially during its numerous medical conferences and patient day events as well as events hosted in Westminster, bringing it to the attention of politicians, who in turn have a responsibility to ensure their constituents are receiving the best possible care from the National Health Service (NHS).

TRUDIE LOBBAN MBE FRCP Edin, FOUNDER & CEO ARRHYTHMIA ALLIANCE
www.heartrhythmalliance.org
The national CRM annual report details clinical activity in the fields of:

- Permanent pacemakers (PPMs - for the treatment of blackouts and other symptoms);
- Implantable cardioverter defibrillators (ICDs - for the prevention of sudden cardiac death);
- Cardiac resynchronisation therapy (CRT - for the treatment of heart failure, cardiac resynchronisation therapy with defibrillation (CRT-D) or pacing (CRT-P)); and
- Catheter ablation (for the treatment of simple, complex atrial, and ventricular arrhythmias).

Implant rates and recent trends in these rates are presented for the UK as a whole, by Country and by Region using Clinical Commissioning Groups (CCGs) to demarcate regional provision. For each implant and ablation centre, clinical activity is reported, along with a variety of quality measures including data completeness, standards set by the British Heart Rhythm Society (BHRS) and NICE, and re-intervention rates. The centre data and maps of implant rates and visualisation of geographical provision are presented as online appendices. The report is based on data derived entirely from the new CRM device and ablation datasets, which were adopted during 2014/15. The new datasets will permit us to report clinically relevant quality improvement measures in increasing detail.

The report not only describes recent activity from the audit, but presents information around three key quality improvement themes, which align with those presented in the wider NCAP programme report. These are:

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

The key findings of the 2016/17 report are:

**NATIONAL TRENDS**

1. The overall pacemaker implant rate in the UK has gradually increased over the last decade, in line with an ageing population, though this trend was not seen in the last year.

2. The overall implant rate for defibrillators (ICD and CRT-D) rose substantially following NICE guidance in 2014, but has levelled off in the last year. An increasing proportion of implants are of CRT-D rather than ICD devices. The rate of implantation of CRT-P devices is also increasing.

3. Nationally, rates vary considerably between the UK nations. Scotland reports considerably fewer ICDs and CRT devices per head of population compared to England, Wales and Northern Ireland.

   - Regionally, the maps detail the rate of treatment with CRM devices and three classes of catheter ablation, according to where patients reside (within CCG and Health Board boundaries) across England and Wales for financial years 2014/15, 2015/16 and 2016/17. These show considerable variation in implant rates, which has not improved in the last two years.

   - Variation is particularly marked for ICD and CRT devices and catheter ablation. This geographical variance is greater than one might expect regarding the need for treatment and could suggest other factors responsible for the extent to which current evidence is applied. A better understanding of the causes of variation is needed.

4. Annual growth in catheter ablation procedures has slowed from 20% (2007/08-2011/12) to 4% (2012/13-2016/17). Recent growth has been entirely in Atrial Fibrillation (AF) ablation and related procedures.

**SAFETY – PROCEDURE VOLUMES**

5. Following a fall in the previous year, the number of adult NHS hospitals implanting small numbers of pacemakers (below the recommended minimum) has increased slightly (from 24 to 30). The number of adult NHS hospitals implanting small numbers of complex devices (below the recommended minimum) has fallen from 47 to 39, but this still represents 36% of such hospitals.

6. A third of centres undertaking catheter ablation procedures do not reach the minimum recommended overall procedure volume, though half of these are private/children’s hospitals.

7. The number of NHS adult hospitals failing to reach the minimum recommended volume for AF ablation has fallen from 13 to 4 over two years.

8. A small minority of patients are treated in low volume centres (including private and children’s hospitals) – this ranges from 3.2% for AF ablation to 7.4% for complex devices.

**EFFECTIVENESS**

9. Data completeness is variable between centres, especially for operator General Medical Council (GMC) Number and some clinical variables. Low completeness is more common in small volume centres. Considerable improvement in data submission will be essential to pursue plans to report clinical outcomes and quality indicators in the future.

10. Approximately 90% of centres achieve the target of ≥80% compliance with NICE guidance for pacemaker type, and over 90% of patients receive the recommended type of pacemaker.

11. However, only around 50% of centres document ≥80% compliance with NICE guidance for ICD implantation. Approximately 80% of ICD implants are documented to meet NICE guidance.

**OUTCOMES**

1. One-year re-intervention rates are reported for the first time. These are dependent on submission of NHS Number, so some centres were excluded from analysis. Should event rates be higher in those excluded, these figures would represent a low estimate.

12. First pacemaker implants: the average re-intervention rate was 4.2%, with 5% of centres having a high rate.

13. First complex device implants: the average re-intervention rate was 6.3%, with 4% of centres having a high rate.

14. Simple ablations: the average re-intervention rate was 3.0% with no centres having a high rate.

15. AF ablations: the average re-intervention rate was 10.3%, with four centres having a high rate.

16. Ventricular ablations: the average re-intervention rate was
10.2%, with one centre having a high rate.

We have provided a list of key recommendations based on our findings, aimed at key stakeholders, which we hope will serve to improve compliance with audit guidance and guidelines in an effort to improve data quality, data completeness and an ability to show quality improvements that benefit both patient outcomes and clinical practice.

Many of the recommendations are similar to those in previous reports, suggesting that there is still a significant task to understand and reduce unwarranted variation. Action undertaken through site inspection by the GIRFT and, where necessary, CQC teams may help with this process.

**RECOMMENDATIONS**

Commissioners and Chief Executives
The report is to help ensure compliance with national standards, including the participation in the national audit and to inform local decision-making.

We recommend that you:

1. Consider whether pacemaker and ICD/CRT implant activity, and the total and complex ablation activity at the hospital level is in line with BHRS guidelines to ensure the skill of performing the procedure is maintained. If activity is below the guideline levels, particular vigilance for the appropriateness of procedures and their complications is recommended, and the sustainability of the service should be considered.

2. Ensure each hospital demonstrates compliance with NICE guidance for device implantation.

3. Ensure there are sufficient resources allocated to support national clinical audit activity.

Medical Directors and Clinical Leads
The reports for your centre are available online in Appendices 2 & 3. There are three domains: (i) safety – measured as procedure volumes, (ii) effectiveness - measured as data completeness and validity, and compliance with NICE guidance, and (iii) outcomes – measured as re-intervention rates at 1 year.

We recommend that you:

1. Review your data completeness as this affects all quality measures (hospitals with poor data completeness will be highlighted in future reports). Patient NHS Number and Operator GMC Number reporting are particularly important deficiencies.

2. Review your activity. If the figures in the report disagree with your local data, then either they are not being reported or they are being incorrectly uploaded.

3. Ensure all operators regularly review their data in the audit to improve timeliness and accuracy. This should be incorporated into the annual appraisal process.

4. Provide appropriate clinical support to the clinical audit teams. Our data show that higher level of clinical engagement with the clinical audit team is associated with better data completeness and data quality of the audit data. Each clinical audit should have an identified clinical lead assigned to support this activity.

5. Evaluate your centre’s performance against this year’s quality standards, compare yourself with (and draw learning from) other hospitals with better performance and institute quality improvement measures where necessary.

Clinicians Performing CRM Device Procedures
For the first time we are reporting activity (simple and complex devices, simple and complex ablations) for each operator, identified by GMC number submitted.

We recommend that you:

1. Liaise with your hospital’s audit staff to see whether your procedures are being correctly recorded.

2. Oversee the entry of data for all your procedures into the national audit, to ensure completeness and correctness. You are clinically responsible!

3. Be aware that NICOR is developing web-based tools that you and your audit staff can use to check on submission completeness (though only the authorised audit lead can modify data). Your activity (at all centres where you operate) is available in Appendices 7 & 8.

Clinical Audit Teams
The online appendices linked to this summary shows hospital level activity and outcomes as well as comparisons with other centres across a variety of metrics.

We recommend that you:

1. Review the entries for your centre in Appendices 2 & 3, which will give an indication of the extent to which your data submissions are complete and valid. Check that the data submitted to NICOR show what you expect; this is especially relevant to those hospitals that use third party software to submit their data.

2. Consider resubmission for the 2016/17 data in certain circumstances (especially if complete records or critical fields such as NHS Number are missing) – discuss with the NICOR helpdesk if necessary. This will not change the current report but will be important for future retrospective analyses.

3. Submit data as soon as possible after device and ablation procedures and on a quarterly basis at the very least. You
are reminded that the NICOR standard for data submission is that each quarter's data should be submitted by the end of the following quarter at the latest. Up to date data are associated with higher completeness and accuracy. Timely feedback will be provided to improve performance.

4. Ensure complications data are completed for all patients.

5. Engage with all local and national reports to check case ascertainment rates and data completeness.

6. Ensure that accurate and specific device procedure data are available to physiologists and implanters to facilitate audit, clinical governance, appraisal and revalidation.

Patients and Public - What does this mean for me?
The centre level data and summary report will provide you with information and guidance to help inform the decisions you make about your care/treatment and/or that of others.

1. If you have symptoms due to a slow heart rate (bradycardia) or pauses in the heart beat, due to a problem with your "natural" pacemaker (sinus node), and your doctor thinks that a dual-chamber pacemaker (with leads in the upper and lower chambers of the heart) is the right treatment, you should be able to have the treatment on the NHS as recommended by NICE.

2. If you are at increased risk of a serious heart rhythm abnormality or have heart failure, and your doctor thinks that an implantable cardioverter defibrillator (ICD) or cardiac resynchronisation therapy with defibrillation (CRT-D) or pacing (CRT-P) is the right treatment, you should be able to have the treatment on the NHS as recommended by NICE.

3. The report allows you to see which hospitals in your region perform implants of the different types of heart rhythm devices, and different types of catheter ablation procedure.

4. The report details the numbers of implant procedures reported by each hospital, as less experienced centres may have higher complication rates. The report also gives indications of the quality of service at each hospital, including whether it meets certain national guidelines, and submits complete data for this audit.

5. The report indicates the proportion of patients at each hospital having a repeat procedure within one year of a device implant or ablation.
1 INTRODUCTION

1.1 THE NACRM AS PART OF THE NATIONAL CARDIAC AUDIT PROGRAMME

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. This report is a supplement to the original NCAP report.

1.2 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.

1.2.1 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 mins 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).

**Margaret’s Story**

“When I was 48 years old, I was very unwell and had recurring fluid congestion due to severe heart failure and a leaking valve. The medication wasn’t working any more, and I was even too breathless to eat. My GP fought to get me seen at a heart hospital in south London as he had seen another patient who did well with a special pacemaker, one with 3 leads. By the time I got there, I was so unwell my kidneys were failing, and skin was breaking down. I and my family knew I was going to die so we did not hesitate when the doctors suggested that a resynchronisation pacemaker might improve my situation.

I felt a bit better almost immediately after the pacemaker was fitted. I had more energy, was less breathless and even enjoyed a small amount of solid food later that same day.
1.2.2 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 the concept of a curative treatment, but necessitated open-chest and usually open-heart surgery. 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 an electrical current into the tissue (radiofrequency – RF), but sometimes by using freezing 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 improve the efficacy of CRT. Accessory Pathway (AP) and Slow Pathway (SP) ablation (also known as AV node modification) can be 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. The vast majority of 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 radiofrequency energy.

- **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.

**Peter’s story**

“I was 54 when I developed atrial fibrillation. I remember the first attack when suddenly my heart started to race and was beating all over the place. I thought my heart would come out of my chest. I had never experienced anything like it and thought I was having a heart attack. I went to accident and emergency and was started on medication to slow down my heart, but my heartbeat remained irregular and I needed a shock to my chest to get my heart back to a normal rhythm. I felt much better after this, but one month later I went back into atrial fibrillation again and felt terrible. I was referred to a specialist and had tests which showed that my heart was normal, but I had an electrical problem and my atrial fibrillation was not going to go away. I hated taking beta-blockers, they just made me feel tired, and I couldn’t do the things that I wanted to do. I spoke to my specialist about other treatments and was told about ablation. It seemed the best chance of regaining my normal life and I had the surgery a year ago. It was amazing that it was done whilst I was awake. My doctor used a balloon to freeze the abnormal electrical areas inside my heart and after an hour the procedure was done, and I went home on the same day. I have remained in a normal rhythm since. My life has been transformed. I am back to my usual self, doing what I want to do, all the exercise that I need to do, and I don’t have to take medication apart from a blood thinner. I am very happy that I was fortunate enough to receive this treatment and the team looking after me were amazing. I am so glad I got my life back.”

I recovered slowly but surely, I was soon able to get out of bed as my blood pressure improved, lost a huge amount of weight (fluid) and was able to restart my heart medication and my kidneys recovered. That was over 15 years ago and now I walk 4-5 miles every day, we can go abroad on holiday every year, and I also swim most days now. I have never needed to stay in hospital again other than for one day to get the pacemaker battery replaced, and I see them for checks and medication reviews. I slowly built up my strength and regained the confidence to live life again and continue to thank God and the hospital team for my miracle pacemaker.”
1.3 WHAT IS COVERED IN THIS REPORT?

This report serves a number of 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 centres and 75 ablation centres 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).
- A number of quality measures are reported for each centre, relating to data completeness, standards set by the British Heart Rhythm Society, and adherence to NICE guidance on pacemaker and defibrillator therapy.
- For the first time, we are also reporting total procedure volumes for every operator in the country identified by General Medical Council registration number.
- For the first time within the National Cardiac Audit Programme, re-intervention rates at one year are reported, tracking patients within and between centres. This provides an index of outcomes and complication rates for device implants, and of outcomes for ablation procedures.

1.4 STRUCTURE OF REPORT

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

These are:

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

1.5 METHODOLOGY

The audit reports on data collected from 187 implanting centres and 75 ablation centres from across the UK. Data collection is now by financial year, with the aim of analysing and reporting in the following year. Participating centres 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: OVERVIEW OF NATIONAL ACTIVITY

2.1 NATIONAL ACTIVITY: DEVICES

2.1.1 INTRODUCTION

Implant rates per million population (pmp) for the four UK nations in financial years, 2015/16 and 2016/17 are shown in Tables 2.1-5, and longer term trends are shown in Figures 2.1-5. Implant rates are also shown according to the areas where patients reside, using interactive maps (Appendix 4).

The new dataset, adopted by centres between 2014 and 2016, improves the distinction between different types of device procedure. In particular, it is now possible to be more selective, distinguishing between first implants and other procedures (such as replacements and upgrades), some of which were grouped together in the past. The ‘new’ and ‘old’ datasets and their related methodologies therefore yield somewhat different results. The tables show results using the new methodology.

The figures show results using the old methods since 2004 (dotted lines), and the new methods (solid lines) for 2015/16 and 2016/17. Note that early data were reported by calendar year but from 2014/15 reporting has been by financial year. In the Figures ‘2016’ indicates financial year 2016/17. Adjudicated data have been used throughout (for details of methods see Appendix 1).

When comparing these trends between nations, it is important to bear three factors in mind:

1. The populations of the UK Nations differ greatly (England 55.6m, Scotland 5.4m, Wales 3.1m and Northern Ireland 1.9m in 2016). The effect of year on year changes in local factors is magnified in the smaller nations.

2. The figures below are based on the centres undertaking procedures, rather than where patients live. Patients may cross borders for treatment (this holds especially for North Wales). For this reason, we have conducted a separate analysis of device and ablation treatments based on postcodes (Appendix 7).

3. Unlike those in England & Wales, Scottish hospitals have not been contractually required to submit data to the national audit. Consequently, data from Scotland have historically been incomplete - in particular, regarding pacemaker implants.

2.1.2 PACEMAKERS

Findings: reported first pacemaker implant rates appear to vary greatly between the nations: in England it remains fairly static at approximately 560pmp; in Wales it has dropped to 450pmp, and in Northern Ireland it remains approximately 400pmp (Table 2.1, Fig 2.1).

Table 2.1: Annual reported first pacemaker implant rate per million population

<table>
<thead>
<tr>
<th></th>
<th>2015/16</th>
<th>2016/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>England</td>
<td>555</td>
<td>555</td>
</tr>
<tr>
<td>Wales</td>
<td>523</td>
<td>456</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>430</td>
<td>372</td>
</tr>
<tr>
<td>Scotland</td>
<td>(incomplete data)</td>
<td>(incomplete data)</td>
</tr>
</tbody>
</table>

Figure 2.1: Pacemaker implant rate trend 2004-2016/17. Dotted lines are estimated using old method (all procedures except battery changes), solid lines using new method (only first implants, hence somewhat lower).

Click here to see how PM implantation rates vary and have changed over time in areas within England and Wales.

2.1.3 IMPLANTABLE DEFIBRILLATORS (ICDs)

We report procedures that are the first time each patient has been implanted with an ICD; some patients will have previously had pacemakers. Therefore, we include ICD procedures classed as ‘first implant’ and those as ‘upgrade’.

Findings: reported ICD implant rates grew rapidly following NICE guidance in 2014 but have reduced slightly between 2015/16 and 2016/17; they appear to vary greatly between the UK nations from around 120pmp in Northern Ireland to around 50pmp in Scotland (where under-reporting is possible) (Table 2.2, Fig 2.2).
Table 2.2: Annual reported ICD implant rate (first implants + upgrades) per million population.

<table>
<thead>
<tr>
<th></th>
<th>2015/16</th>
<th>2016/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>England</td>
<td>97</td>
<td>97</td>
</tr>
<tr>
<td>Wales</td>
<td>75</td>
<td>72</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>124</td>
<td>111</td>
</tr>
<tr>
<td>Scotland</td>
<td>52</td>
<td>44</td>
</tr>
</tbody>
</table>

Figure 2.2: ICD implant rate trend 2004-2016/17. Dotted lines are estimated using old methods (all procedures except battery changes), solid lines using new method (only first implants + upgrades).

Click here to see how ICD implantation rates vary and have changed over time in areas within England & Wales.

2.1.4 CARDIAC RESYNCHRONISATION THERAPY

As with ICD implants, it is appropriate to combine first implants with upgrade procedures, as the aim is to determine the first time the patient has received CRT therapy.

Findings: After a steady rise since 2012, CRT implant rates were stable or slightly reduced between 2015/16 and 2016/17 (Table 2.3, Fig 2.3).

Table 2.3: Annual reported CRT-pacemaker and CRT-defibrillator implant rate (new + upgrade) per million population

<table>
<thead>
<tr>
<th></th>
<th>2015/16</th>
<th>2016/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>England</td>
<td>143</td>
<td>146</td>
</tr>
<tr>
<td>Wales</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>66</td>
<td>70</td>
</tr>
<tr>
<td>Scotland</td>
<td>63</td>
<td>57</td>
</tr>
</tbody>
</table>

Figure 2.3: CRT implant rate trend 2004-2016/17. Solid lines are estimated using new method (only first implants + upgrades), dotted lines using old methods (all procedures including battery changes, which accounts for the large difference).

Click here to see how CRT implantation rates vary and have changed over time in areas within England & Wales.

2.1.5 ALL ‘HIGH ENERGY’ DEVICES

For some purposes it is useful to look at total ‘high energy’ device implants (ICD and CRT-D) as a group. For example, they are considerably more expensive than simple and CRT pacemakers. Again, we report first implants combined with upgrade procedures.

Findings: High energy implant procedures have stabilised after two years’ rapid growth that followed the publication of NICE TA314 in early 2014 (Table 2.4, Fig 2.4).
Figure 2.4: High Energy device implant rate trend 2004-2016/17. Solid lines are estimated using new method (only first implants + upgrades), dotted lines using old methods (all procedures including battery changes, accounting for the large difference).

Click here to see how High Energy (ICD + CRT) device implantation rates vary and have changed over time in areas within England & Wales.

### 2.1.6 COMPLEX DEVICES – CHANGE IN ‘CASE MIX’

Evidence-based international and NICE indications for different types of complex device have evolved over the last decade, and this is reflected in the pattern of implants. For example, many patients that would have received ICDs in the past are now receiving CRT-D devices, while there are new indications for CRTP devices, including pacing for bradycardia in patients with mild heart failure.

Findings: while new implant rates for each category of complex device has remained stable in the last year, CRT-D devices are now almost as common as ICDs, and >40% of CRT devices are now pacemakers rather than defibrillators (Table 2.5, Fig 2.5).

Table 2.5: Annual reported complex case mix implant rate (new + upgrade) per million population (England only)

<table>
<thead>
<tr>
<th>Device</th>
<th>2015/16</th>
<th>2016/17</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICD</td>
<td>97</td>
<td>97</td>
</tr>
<tr>
<td>CRTD</td>
<td>85</td>
<td>82</td>
</tr>
<tr>
<td>CRTP</td>
<td>58</td>
<td>64</td>
</tr>
</tbody>
</table>

Figure 2.5: Complex implant case-mix trend 2004-2016/17 (England only). Dotted lines are for ICD and CRTD only, estimated using old methods (all procedures including battery changes), solid lines are for ICD, CRTD and CRTP, using new method (only first implants + upgrades).

### 2.2 NATIONAL ACTIVITY - CATHETER ABLATION

As the last national ablation report was in 2013/14, we report summary statistics for financial years 2014/15, 2015/16 and 2016/17, in addition to more detailed quality metrics for 2016/17. The apparent dip in ablations in 2014/15 was probably due to under-reporting rather than a true fall in activity, as centres were not asked to validate their data for that year until 2018.

Note that early data were reported by calendar year but from 2014/15 reporting has been by financial year. In the charts ’2016’ indicates financial year 2016/17.

Adjudicated data have been used throughout (for details of methods see Appendix 1).

Interactive maps showing the rates of simple, complex atrial, and ventricular ablations according to where patients reside, are in Appendix 4.

Findings: following a 20% annual growth in reported ablations between 2007 and 2011, activity has risen little in recent years (average 4%/year between 2011 and 2016/17). The increase in recent years has largely been in AF ablation which has grown by ~6%/yr (Table 2.6, Fig 2.6).
Table 2.6: Breakdown of activity by ablation target

<table>
<thead>
<tr>
<th>Year</th>
<th>2014/15</th>
<th>2015/16</th>
<th>2016/17</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Simple Targets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Complete AV nodal</td>
<td>1227</td>
<td>1456</td>
<td>1477</td>
</tr>
<tr>
<td>AV nodal re-entry</td>
<td>2088</td>
<td>2873</td>
<td>3181</td>
</tr>
<tr>
<td>Accessory Pathway</td>
<td>1294</td>
<td>1550</td>
<td>1550</td>
</tr>
<tr>
<td>CTI (typical flutter)</td>
<td>3334</td>
<td>3774</td>
<td>3808</td>
</tr>
<tr>
<td>(&gt;1 simple target)</td>
<td>(40)</td>
<td>(44)</td>
<td>(59)</td>
</tr>
<tr>
<td><strong>Total simple ablation procedures</strong></td>
<td>7261</td>
<td>8805</td>
<td>9152</td>
</tr>
<tr>
<td><strong>Complex Atrial Targets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Atrial Fibrillation</td>
<td>5686</td>
<td>7082</td>
<td>7937</td>
</tr>
<tr>
<td>Other Complex Atrial</td>
<td>885</td>
<td>1056</td>
<td>1174</td>
</tr>
<tr>
<td><strong>Total complex atrial procedures</strong></td>
<td>6571</td>
<td>8138</td>
<td>9111</td>
</tr>
<tr>
<td><strong>Ventricular Targets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PVCs and focal VT</td>
<td>729</td>
<td>668</td>
<td>761</td>
</tr>
<tr>
<td>VT - scar</td>
<td>326</td>
<td>451</td>
<td>493</td>
</tr>
<tr>
<td><strong>Total complex ventricular procedures</strong></td>
<td>1055</td>
<td>1119</td>
<td>1254</td>
</tr>
</tbody>
</table>

| No ablation/unknown target | 3082 | 3341 | 3100 |

As noted above, the apparent dip in 2014/15 was probably due to under-reporting rather than a true drop in activity.

Figure 2.6 Trends in UK ablation volumes for financial years 2007-2016/17, grouped by procedure type.

Click here to see how ablation rates vary and have changed over time in areas within England & Wales.

3: SAFETY

3.1 ARE IMPLANTING AND ABLATING CENTRES UNDERTAKING SUFFICIENT ACTIVITY?

Published evidence indicates an association between the number of procedures undertaken by a centre and the incidence of complications. In particular, low volume centres are more likely to have high complication rates; the same is thought to hold for individual operators. It must be emphasised that this is only a statistical link: high volumes do not guarantee safety, nor is an individual with low current procedure volumes necessarily expected to have a higher complication rate.

BHRS publishes indicative standards for centres and operators undertaking device and ablation procedures. These standards are revised every 2-3 years. We have used standards applicable during 2016/17.

Quality Standards for Centres

Quality Standard 1: BHRS Standard (2015) recommended that pacing centres undertake a minimum of 80 of pacemaker implants per year (this was 60 in the 2013 Standard). Training centres should conduct > 105 implants per year. This should include a minimum of 60 complex procedures.

Quality Standard 2: BHRS Standard (2015) recommended that complex device centres undertake a minimum of 60 such procedures (ICD and CRT implant/upgrades) per year.

Quality Standard 3: BHRS Standard (2016) recommended that ablation centres undertake a minimum of 100 ablation procedures per year in total.
Quality Standard 4: BHRS Standard (2016) recommended that centres undertaking AF ablation should perform a minimum of 50 such cases per year.

Reported device and ablation procedure volumes for each centre are detailed in individual centre reports (Appendices 2 & 3) and tabulated in Appendices 5 & 6.

Summary of Findings

- **Pacemakers**: In 2016/17, 30 out of 165 (18%) NHS adult hospitals reporting pacemaker implants did not meet the BHRS standard for procedure volume. This number has fallen from 56 centres over two years. In 2016/17, only 1,242/33,117 (3.8%) of pacemaker implants were undertaken in low volume centres.

- **Complex Devices**: In 2016/17, 39 out of 109 (36%) of NHS adult hospitals reporting complex implants/upgrades did not meet the BHRS standard. This number has fallen from 60 centres over two years. In 2016/17, only 787/12,735 (6%) of complex implants/upgrades were undertaken in low volume centres.

- **The above statistics exclude 3 children’s and 17 private hospitals**: In 2016/17 only one private hospital met the recommended minimum procedure volume for pacemaker implants, and none met the standard for complex device implants.

- **Catheter ablation**: In 2016/17, 22/63 hospitals (35%) undertaking catheter ablation procedures did not meet the BHRS standard for procedure volume. Half of these were children’s or private hospitals. This pattern has not changed over two years.

- **AF ablation**: In 2016/17, 12/50 hospitals (24%) undertaking AF ablation procedures did not meet the BHRS standard for procedure volume. Over two years, this figure has dropped from 20/50 (40%) entirely due to improved procedure volumes in NHS adult hospitals.

### 3.1.1 Detailed Findings – Pacemaker Implants

In 2016/17, 184 UK hospitals reported pacemaker implants; of these 17 were private and 4 were children’s hospitals. Forty-nine hospitals (27%) failed to meet the standard of 80 implants. Among NHS adult hospitals, the number failing to meet the standard has fallen by 1/3 over two years, while it has changed little among children’s and private hospitals. The number of hospitals reporting very low volumes (<20 implants) has fallen from 34 to 17 over two years; this drop has largely been among NHS adult hospitals (Fig 3.1).

### 3.1.2 Detailed Findings – Complex (ICD and CRT) Implants

In 2016/17, 126 UK hospitals reported complex implants (including upgrades from simpler devices); of these, 15 were private and 2 were children’s hospitals. 56 hospitals (44%) failed to meet the standard of 60 implants. Among NHS adult hospitals, this number has fallen by 21% over two years, while it has changed little among children’s and private hospitals. Thirty seven hospitals (30%) reported very low volumes (<20 implants): this number has not changed significantly (Fig 3.2).

### 3.1.3 Detailed Findings – Catheter Ablation (Total)

In 2016/17, 63 UK hospitals reported catheter ablation procedures; of these, 12 were private and 3 were children’s hospitals. Twenty two hospitals (35%, of whom 10 were private/children’s) failed to meet the standard of 100 ablations. Two NHS and 3 private/children’s hospitals reported fewer than 25 ablation procedures. This pattern has not changed over three years (Fig 3.3).
NATIONAL AUDIT OF CARDIAC RHYTHM MANAGEMENT DEVICES AND ABLATION APRIL 2016 – MARCH 2017

3.1.4 DETAILED FINDINGS – CATHETER ABLATION FOR ATRIAL FIBRILLATION

In 2016/17, 50 UK hospitals reported AF ablation procedures, including 1 children’s and 12 private hospitals. Twelve hospitals (24%, of whom 8 were private/children’s) failed to meet the standard of 50 AF ablations. Two NHS and 4 private/children’s hospitals reported fewer than 25 ablation procedures. The number of NHS private hospitals reporting substandard and low numbers of AF ablation has fallen by three quarters over three years, while the numbers of private/children’s hospitals has changed little (Fig 3.4).

Figure 3.4: No of centres reporting very low (<25) and below standard (<50) numbers of AF ablation procedures. Empty bars represent centres with higher volumes.

3.1.5 HOW MANY PATIENTS HAVE PROCEDURES IN LOW VOLUME CENTRES?

Although a substantial proportion of device and ablation centres do not meet the standards for procedure volume, this does not translate to a high proportion of procedures (Fig 3.5, 3.6). In 2016/17:

- **Pacemakers**: 1,702 out of 33,659 (5.1%) pacemaker implants were conducted in the 27% of centres that did not meet the standard of ≥80 procedures/year, and only 163 (0.5%) were conducted in very low volume (mostly children’s & private) hospitals.

- **Complex devices**: 953 out of 12,936 (7.6%) complex implants were conducted in the 44% of centres that did not meet the standard of ≥80 procedures/year, and 239 (1.9%) were conducted in very low volume centres.

- **Total Ablations**: 1,035 out of 19,319 (5.4%) ablations were conducted in the 35% of centres that did not meet the standard of ≥100 ablations/year, and 57 (0.3%) in very low volume centres.

- **AF ablations**: 250 out of 7,875 (3.2%) AF ablations were conducted in the 24% of centres that did not meet the standard of ≥50 AF ablations/year, and 47 (0.6%) in very low volume centres.

3.2 PROCEDURE VOLUMES FOR INDIVIDUAL OPERATORS

BHRS recommendations for individual specialists undertaking device (2015) and ablation (2016) procedures are as follows:
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.

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 centre reports (Appendices 2 & 3) and aggregated for each operator in Appendices 7 & 8 where specialty/training status is also indicated.

This is the first year that procedure numbers for individual operators are being reported. For some operators, numbers will have been underestimated because of inaccurate or missing GMC Numbers (see Section 4.1). For these reasons, this year we have not explicitly measured each individual against the published standards. However, we are publishing individual reported activity in the Appendices, in order to drive improved reporting. These should be interpreted with caution and with reference to the notes below.

### FINDINGS

#### 3.2.1 DEVICE PROCEDURES

1447 doctors identified by GMC Number had been involved with at least one pacemaker/complex device procedure during 2016/17.

- Of 894 doctors on the specialist register for Cardiology/General Medicine performing pacemaker implants, 475 (53%) were documented to meet the standard of performing >35 device procedures in total.
- Of 557 doctors on the specialist register for Cardiology/General Medicine performing complex device implants, 200 (36%) were documented to meet the standard of performing >60 total device implants including >30 complex device implant/upgrade procedures.
- In addition, a total of 321 trainees and 57 specialists in cardiothoracic surgery or paediatric cardiology/paediatrics, and 158 others were identified by their involvement in device procedures.

#### 3.2.2 ABLATIONS

389 doctors were identified by GMC Number as being involved with at least one ablation procedure during 2016/17.

- Of 268 doctors on the specialist register for Cardiology (or General Medicine) performing ablations, 173 (65%) were documented to perform >50 ablations in total (the recommended minimum).
- Of 237 Cardiology/General Medicine doctors performing complex ablations, 173 (73%) were documented to perform >25 procedures (‘minimum’), and 116 (49%) were documented to perform >50 of these procedures (‘desirable’). These were nearly all AF ablations.
- In addition, a total of 74 trainees and 17 specialists in paediatric cardiology/paediatrics were identified by their involvement in ablation procedures.

### NOTES:

- Each doctor is attributed to a case if his/her GMC Number appears as 1st/2nd scrubbed operator or responsible consultant. It therefore does not follow that the doctor personally performed each procedure in its entirety; furthermore, some procedures will count towards the volume of more than one doctor.
- This is the first time that procedure numbers have been reported by operator. For many, their volume will be underestimated due to poor GMC number reporting by centres. Publication of these procedure numbers by doctor is expected to improve this figure.
- For a few doctors, status as trainee or specialist may be incorrect as linkage was made to the GMC registry some time after 2016/17.
- Apparently low procedure counts do not necessarily indicate that a patient has been treated by a doctor with insufficient experience. Explanations may include:
  - Correct GMC Number not entered for a number of cases
  - Paediatric cases (BHRS standards are for adult patients)
  - The doctor was a trainee or specialist working under supervision of a more experienced colleague, or a surgeon.
4: EFFECTIVENESS

4.1 DATA COMPLETENESS AND VALIDITY

A key indicator of an effective service is compliance with audit. This means complete and accurate data entry.

Data Completeness: individual centre reports ([Appendices 2 & 3]) detail completeness for a large number of fields (24 for device procedures and 30 for ablations), in order to help centres identify their data deficiencies.

These have been distilled into 6 domains:

1. Demographics (6 fields in centre reports): the average of NHS Number and Postcode, which are essential for analyses of re-intervention rates and maps of geographic provision. Other fields are technically mandatory and therefore 100% by definition.
2. Clinical (basic): 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: 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): the mean completion rate for the model and serial number for pacemaker and ICD generators.

Data Validity: further measures have been derived to test the validity of key fields.

7. 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).
8. Ablation validity (ablation procedures): consistency and completeness of the fields ‘ablation performed?’

FINDINGS:

The averages of data completeness within each of the six domains above, and of the two validity measures are tabulated for each centre in [Appendix 9]. Each has been rated Green ≥95%, Amber ≥90%, Red <90%.

Most centres achieved 90% data completeness in device domains apart from clinical (complex) and GMC Numbers. Seventeen centres achieved 95% data completeness in all device domains. The number of centres achieving good data completeness for ablation procedures was lower (Table 4.1 and 4.2, Fig 4.1).

Overall data completeness is more impressive than might appear from the centre data. This is because centres with poor completeness tended to be smaller, while most (though by no means all) large volume centres had very high completeness in most fields. Thus, although only ~58% of centres (including private & children’s) achieved the goal of >95% NHS Number submission for device procedures, 79 (mostly high volume) centres reported NHS Number in 99-100% of procedures. As a result, NHS Number was submitted in 84% of procedures overall nationally (89% of those in NHS adult hospitals). The same effect is seen in other analyses in this report. Figure 4.2 shows the proportion of procedures nationally with complete data in each domain.
Table 4.1: Data completeness. Proportion of centres achieving at least 95% and 90% completeness in each domain, along with overall data completeness (per procedure, nationally).

<table>
<thead>
<tr>
<th>Devices</th>
<th>Ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre completeness</td>
<td>National data completeness</td>
</tr>
<tr>
<td>≥95%</td>
<td>≥90%</td>
</tr>
<tr>
<td>Demographics*</td>
<td>64%</td>
</tr>
<tr>
<td>Clinical (basic)</td>
<td>65%</td>
</tr>
<tr>
<td>Clinical (complex)</td>
<td>34%</td>
</tr>
<tr>
<td>GMC Numbers.</td>
<td>35%</td>
</tr>
<tr>
<td>Procedure</td>
<td>75%</td>
</tr>
<tr>
<td>Generator</td>
<td>84%</td>
</tr>
</tbody>
</table>

*17 private hospitals excluded

Table 4.2: Data Validity. Proportion of centres achieving at least 95% and 90% validity in key fields (device system type, ablation), along with overall data validity (per procedure, nationally).

<table>
<thead>
<tr>
<th>Devices</th>
<th>Ablation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Centre data validity</td>
<td>National data validity</td>
</tr>
<tr>
<td>≥95%</td>
<td>≥90%</td>
</tr>
<tr>
<td>Proportion of centres</td>
<td>49%</td>
</tr>
</tbody>
</table>

4.2 APPROPRIATE USE OF DEVICE THERAPY (NICE GUIDANCE)

4.2.1 QUALITY STANDARDS

PACING IN SINUS NODE DISEASE AND ATRIOVENTRICULAR BLOCK (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: 90% of pacemaker implants should be documented to meet NICE criteria.

* the standard is 90% to allow for these patient specific factors.
ICD IMPLANTATION FOR PRIMARY AND SECONDARY PREVENTION OF SUDDEN CARDIAC DEATH (NICE TA314)

Primary prevention: ICD implantation is recommended as an option for:

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

Secondary prevention: ICD implantation is recommended as an option for the following (in the absence of reversible causes):

- patients who have suffered cardiac arrest caused by ventricular tachycardia (VT) or fibrillation.
- patients with sustained VT causing syncope or significant haemodynamic compromise.
- patients with sustained VT and left ventricular ejection fraction ≤35%.

Quality standard: 80% of ICD implants should be documented to meet NICE criteria.

This year the standard is 80%, to allow for patient specific factors in prescribing ICDs and because this is a new measure. In future the standard will be raised.

FINDINGS

- Around half of individual centres do not meet the standard for ICD implantation (58% for primary prevention, and 47% for secondary prevention implants).
- A smaller proportion of individual centres do not meet the standard for pacemaker implants (22% for sinus node disease and 28% for atrioventricular block).

Many poorly performing centres are relatively small, so that:

- Nationally, the quality standard for pacemaker implantation is met (>90% of patients eligible for dual chamber pacemakers receive them).
- Nationally, the quality standard for ICD implantation is not quite met (just under 80% of ICD implants are documented to be indicated according to NICE guidance).

Table 4.3 Proportion of centres meeting NICE guidance for pacemaker and ICD implants (our standard in bold), and proportion of cases nationally implanted according to NICE guidance.

<table>
<thead>
<tr>
<th>Centres</th>
<th>Pacing in SND</th>
<th>Pacing in AVB</th>
<th>ICD for 1ary prevention</th>
<th>ICD for 2ary prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documenting &gt;90% compliance</td>
<td>78%</td>
<td>72%</td>
<td>33%</td>
<td>23%</td>
</tr>
<tr>
<td>Documenting &gt;80% compliance</td>
<td>96%</td>
<td>89%</td>
<td>58%</td>
<td>47%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Cases (nationally)</th>
<th>Pacing in SND</th>
<th>Pacing in AVB</th>
<th>ICD for 1ary prevention</th>
<th>ICD for 2ary prevention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases eligible for analysis</td>
<td>7031</td>
<td>7056</td>
<td>2871</td>
<td>1821</td>
</tr>
<tr>
<td>Documented compliance</td>
<td>6566 (94%)</td>
<td>6463 (92%)</td>
<td>2240 (78%)</td>
<td>1440 (79%)</td>
</tr>
</tbody>
</table>
Figure 4.3: Proportion of centres achieving documented levels of compliance with NICE guidance for pacemaker and ICD implants.

Figure 4.4 Proportion of patients nationally receiving pacemaker and ICD implants documented to be compliant with NICE guidance.
5: OUTCOMES - REQUIREMENT FOR RE-INTERVENTION

5.1: NEW PACEMAKER AND COMPLEX DEVICE IMPLANTS – 1-YEAR RE-INTERVENTION RATES

Hospital or 30-day mortality is the principal safety outcome for most procedural audits in the NCAP programme, but is not a helpful indicator of safety for CRM device procedures. 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 are a more relevant measure of a hospital’s safety performance. Reliance on self-reported outcomes requires a completely consistent approach to variable definition and a complete adherence to collecting the relevant data accurately to the relevant time point. This issue can be overcome by utilising 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.

As an index of complications, we are therefore reporting re-interventions performed within 12 months of a device implant. NHS Numbers (or equivalent in Scotland/NI) were used to detect re-interventions, whether these were at the original implanting centre or elsewhere (NHS Numbers are 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 centres 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. The encrypted NHS Number (or equivalent) was used to track patients.

This is the first time that a large-scale cross-site study of re-intervention rates has been conducted within the National Cardiac Audit Programme. We believe that re-interventions will prove to be 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 procedure-related complications, occasionally there are other reasons. These include a change in a patient’s clinical status that requires a different type of implanted device.
- A small proportion of implants (especially CRT devices) are unsuccessful, and require a second attempt, even though no actual complication has occurred.
- Not all complications result in a device re-intervention: some displaced leads are not replaced, and some complications such as pneumothorax (collapsed lung) are not treated by another device procedure, so are not captured by this method.
- Detection of a re-intervention requires entry of the correct NHS Number for the index procedure and re-intervention. We have excluded centres reporting <90% NHS Number in either of the two years required for the analysis, which simplistically should give 81% power to detect re-interventions. The results of this analysis may represent a lower estimate of the re-intervention rate.

As this type of analysis is new, there is insufficient evidence to determine a 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. The mean re-intervention rate for all procedures is shown as a solid line. Thick dotted lines show control limits (±2 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.
### DEVICES: SUMMARY OF FINDINGS

- The mean 1-year re-intervention rate following first pacemaker implants was 4.2% (Fig 5.1).
- Six hospitals had unexpectedly high re-intervention rates (two very high), and five had unexpectedly low re-intervention rates.
- The mean 1-year re-intervention rate following first ICD/CRT implants was 6.3% (Fig 5.2).
- Three hospitals had unexpectedly high re-intervention rates (one very high).

**Comment**

- For device procedures, 1-year re-interventions are regarded as an index of implant-related complications. However, not all complications require a device re-intervention, while some re-interventions are indicated due to a change in the patient’s clinical status.
- Comparisons with published data are difficult, as the latter tend to report singular outcomes such as ‘complications’, while re-intervention is multifactorial. For this reason, we have not set fixed standards, but instead concentrated on variation between centres.
- The clinical impression from the Domain Expert Group was that the mean re-intervention rates following simple and complex device implants are approximately as expected, and that a very small proportion of centres fall outside expected variation.

#### 5.1.2 DEVICES: DETAILED FINDINGS

The re-intervention rate for each centre is given in its individual centre report, and in Appendix 10. Eighty four hospitals reporting device implants were excluded from the analysis because of inadequate NHS Number submission (these are identified in the Appendix): these included all private and children’s hospitals, as well as all but one hospital in Scotland and in Northern Ireland.

**First pacemaker implants:** Seven hospitals (7%) had re-intervention rates lying on or above the 2xSE control limit, the rates for one hospital was above the 3xSE control limit (apparently poor performance). Seven hospitals (7%) had re-intervention rates lying on or below the 2xSE control limits (i.e. very good performance).

**First ICD/CRT implants:** Three hospitals had re-intervention rates above the 2xSE control limits, the rate for one hospital was above the 3xSE limit. None had rates below the control limits.

#### 5.2: ABLATION PROCEDURES – 1-YEAR RE-INTERVENTION RATES

Unlike device procedures, the need for re-intervention following catheter ablations can be regarded as reflecting purely the success or failure of the original procedure: re-intervention is not a treatment for complications.

Another difference from device procedures is that it may not be clear whether an ablation is the patient’s first for that target. Every catheter ablation during 2015/16 (index case) has therefore been regarded as an ‘index case’ and followed for 365 days 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 centres’ results.

As with device implants, the proportion of re-interventions at each centre have been plotted against the number of index cases in a ‘funnel plot’, and centres reporting NHS Number for <90% of procedures have been excluded.

Individual centres have not been named on these plots, but can be identified from the tables in Appendix 10.
**ABLECTION: SUMMARY OF FINDINGS**

- The mean 1-year re-intervention rate following simple ablations was 3.0%. No centres had unexpectedly high rates; one had an unexpectedly low rate (below the 2x SE limit).

- The mean 1-year re-intervention rate following complex atrial ablations was 10.3%. Four centres had unexpectedly high rates (above the 2xSE limit).

- The mean 1-year re-intervention rate following ventricular ablations was 10.2%. One centre had an unexpectedly high rate (above the 2xSE limit).

**Comments:**

- Comparisons with published data are difficult, as the latter tend to report apparently simple outcomes such as ‘success’ or arrhythmia recurrence, while re-intervention is multifactorial. For this reason, we have not set fixed standards, but instead concentrated on variation between centres.

- The clinical impression from the Domain Expert Group was that the mean re-intervention rates for each type of ablation are, if anything, lower than expected, as are the variations between centres.

- Many hospitals (including all private hospitals) reporting ablation were excluded from analysis because of low NHS Number submission. Including these centres would be expected to underestimate their true re-intervention rates. It is hoped that improved reporting of NHS Number will permit a higher proportion of centres to be analysed in future.

- 1-year re-interventions following catheter ablation are not purely a reflection of success. For example, some clinicians and their patients may be more likely to accept a ‘partial’ success, while others are more likely to re-intervene. Furthermore, decision-making times and waiting list durations may affect whether a re-intervention happens within a year or later. For this reason, the 2017/18 analysis will extend re-intervention follow-up for ablation to two years.

**5.2.1 ABLATION: DETAILED FINDINGS**

We have divided ablations into three categories:

**5.2.1.1 Simple ablation targets:** catheter ablation of ‘simple’ targets, when successful, is expected to be a permanent treatment. These targets are complete atrioventricular nodal ablation (AVNA - to produce AV block so a patient is permanently paced), accessory pathways (APs) or the slow pathway (SP) of the AV node (for supraventricular tachycardias), and the cavotricuspid isthmus (CTI) for typical atrial flutter.

Following simple ablations, a re-intervention has only been counted if it was for the same target. Thus, a patient having CTI ablation followed by AP ablation does not count as a re-intervention, while CTI followed by repeat CTI does (see Fig 5.3).

![Figure 5.3: 1-year re-intervention rates following simple ablation procedures. The mean re-intervention rate for patients at the 29 hospitals analysed was 3.0%.

**5.2.1.2 Complex atrial ablation:** 87% of complex atrial ablations include isolation of the pulmonary veins (otherwise known as AF ablation), and this is now the commonest ablation target overall, accounting for 41% of all ablations. Because the procedure requires the creation of uninterrupted lines of scar that block the conduction of abnormal signals, recurrence due to recovery of some tissue is common. Most reports indicate that repeat ablation is required in 20-70% of cases, depending mostly on the pattern of AF. Repeat procedures may be re-isolation of the pulmonary veins or ablation of associated atrial targets.

Following complex atrial ablations, we have tracked every patient for 365 days to see if they have had any further complex atrial ablation. Procedures with simple or ventricular targets were not counted as re-interventions following AF ablation (see Fig 5.4).

![Figure 5.4: 1-year re-intervention rates following complex atrial ablation procedures (mostly AF ablation). The mean re-intervention rate for patients at the 27 hospitals analysed was 10.3%.

**5.2.1.3 Complex ventricular ablation:** only 6% of ablations are for ventricular targets, which can be divided into:

- Focal ventricular arrhythmias (where the object is to locate and eliminate a single focus, usually near the pulmonary
or aortic valves). A successful procedure is usually a permanent cure, but re-intervention may be required because the arrhythmia was difficult to induce and therefore ‘map’ on the day of the first procedure.

- Re-entrant ventricular arrhythmias, the majority of which are related to scar from prior myocardial infarction or inflammatory conditions. Extensive mapping and ablation of the arrhythmia substrate is usually required, and re-intervention may be necessary because the substrate was not completely ablated or subsequently changed, or because an alternative approach (e.g. from the outside of the heart) was required.

Although the outcomes from these two types of ventricular ablation may differ, we have grouped them together as the numbers are too small for separate analysis (see Fig 5.5).

Figure 5.5: 1-year re-intervention rates following ventricular ablation procedures. The mean re-intervention rate for patients at the 26 hospitals analysed was 10.2%.
6. PLANS FOR THE FUTURE

The data collected for the CRM audit reflect the needs and interests of many stakeholders and are under regular review. We aim to adapt to new technologies and question whether some items are no longer important. However, changes to the dataset take a long time to implement across the country, so we try to avoid frequent changes. In the 2017/18 report, we plan to add further details to our analyses:

- **New device technologies**: the dataset introduced in 2014/15 permits the identification of new devices including subcutaneous defibrillators and leadless cardiac pacemakers. The adoption of these will be documented in the 2017/18 report, which will be of interest to patients, professionals and commissioners who will be closely examining the findings, as well as agencies such as the MHRA.

- **New ablation technologies**: An increasing proportion of catheter ablations use cryothermy (freezing) rather than the conventional radiofrequency electrical current. The adoption of this will be reported in 2017/18.

- **Indications for ablation**: the 2017/18 report will detail patterns of arrhythmia in patients undergoing AF ablation.

- As submission of GMC registration number improves, we will look at the feasibility of separating out procedures performed by consultants from those where a consultant is responsible but the procedure is performed by a different member of the team. These data will be of particular relevance to patients, Trusts and Clinical Directors (e.g. for annual appraisal), and professional bodies such as the GMC for revalidation purposes.

- In line with the other cardiac audits, the CRM domain is moving during 2019 to the new IT platform developed at the National Institute for Cardiovascular Outcomes Research (NICOR). Online tools are being developed to enable implanters and Trusts to view their statistics in real time (e.g. implant numbers, data completeness). This is intended to improve timely and complete data submission. Only authorised audit leads/data managers at each centre will be able to view and edit patient-level data for their specific centre.

- Consideration will be made to how the national data audit programme can better understand the variation in numbers and performance that has been identified.
REFERENCES

The British Heart Rhythm Society standards for centres undertaking CRM device procedures and catheter ablation are published on the BHRS website, http://bhrs.com/standards.

The National Institute for Health and Care Excellence technological appraisals relating to pacemaker and ICD therapy (TA88, TA 324, TA314) are published on the NICE website, http://www.nice.org.uk
1. General methodology
2. Individual centre reports – CRM device activity
3. Individual centre reports – catheter ablation procedures
4. Interactive maps of device implant rates and catheter ablation procedures, according to patient residence
5. Compliance with national guidance (BHRS and NICE): device procedures
6. Compliance with national guidance (BHRS): ablation procedures
7. Procedure volumes by operator: devices
8. Procedure volumes by operator: ablations
9. Data completeness and validity: devices and ablations
10. Re-intervention rates for first-time device implants and ablation
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This report is available online here.

2019 Healthcare Quality Improvement Programme (HQIP)

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NICOR (National Institute for Cardiovascular Outcomes Research)
NICOR is a partnership of clinicians, IT experts, statisticians, academics and managers which manages six cardiovascular clinical audits and a growing portfolio of new health technologies, including the TAVI registry. Hosted by Barts Health NHS Trust, NICOR collects, analyses and translates vital cardiovascular data into relevant and meaningful information to drive sustainable improvements in patients well-being, safety and outcomes.

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 centres 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, Barts Health is a leading healthcare provider in Britain, and one of the largest NHS trusts in the country. The Trusts’ five hospitals – St Bartholomew’s Hospital in the City, including the Barts Heart Centre, The Royal London Hospital in Whitechapel, Newham University Hospital in Plaistow, Whipps Cross University Hospital in Leytonstone and Mile End Hospital – deliver high quality compassionate care to the 2.5 million people of East End 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