

# NATIONAL AUDIT OF CARDIAC RHYTHM MANAGEMENT DEVICES

APRIL 2015 – MARCH 2016



**National Institute of Cardiovascular Outcomes Research (NICOR)** is a partnership of clinicians, IT experts, statisticians, academics and managers which manages six cardiovascular clinical audits and three clinical registers. NICOR analyses and disseminates information about clinical practice in order to drive up the quality of care and outcomes for patients.



**The British Cardiovascular Society** promotes education, training and research in cardiovascular health and upholds clinical and professional standards.



**The British Heart Rhythm Society** is an affiliated group of the British Cardiovascular Society and the Arrhythmia Alliance, and is dedicated to improving all aspects of cardiac arrhythmia care and electrical device based therapies. It provides an essential link between professionals working within pacing, devices and electrophysiology in the UK.



**The Healthcare Quality Improvement Partnership (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, and in particular to increase the impact of clinical audit in England and Wales. HQIP hosts the contract to manage and develop the National Clinical Audit and Patient Outcomes Programme (NCAPOP). The programme comprises 40 clinical audits that cover care provided to people with a wide range of medical, surgical and mental health conditions.



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## Authors

This report was produced by written and compiled by David Cunningham, Morag Cunningham, Akosua Donkor, Nick Linker and Francis Murgatroyd with input from the CRM Steering Group (see Appendix 9 for the 2015/16 membership and attendee list). Data extraction and cleaning were carried

out by David Cunningham. Data Analysis was performed by Adél de Lange and David Cunningham. Andrew Hughes (seconded from NHS England) developed all the interactive geographical analyses for NICOR.

## Acknowledgments

The National Audit of Cardiac Rhythm Management Devices is managed by NICOR, which is part of NCAPOP based at UCL.

Clinical leadership for the audit is provided by the British Heart Rhythm Society (BHRS) and the audits clinical lead Francis Murgatroyd. The strategic direction and development of the audit is determined by the audit Steering Group. This includes representatives of major stakeholders in the audit including cardiologists, BHRS, other professionals groups, commissioners and NHS agencies, patient group representatives and HQIP. We would especially like to thank the contribution of all NHS Trusts, centres, cardiac physiologists, other healthcare professionals and all the individuals across the UK who collect the data and participate in the CRM audit. Without their input the audit could not continue to produce credible analysis or to effectively monitor and assess the rates of implantation in the UK.

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This report is available online at [www.bhrs.com/audit](http://www.bhrs.com/audit) and [www.ucl.ac.uk/nicor/audits/cardiacrhythmmanagement/publicreports](http://www.ucl.ac.uk/nicor/audits/cardiacrhythmmanagement/publicreports)

## Cardiac Rhythm Management Audit

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# National Cardiac Rhythm Management Audit

April 2015 – March 2016

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The 11th annual report for the National Cardiac Rhythm Management (CRM) Device Audit presents the official record of CRM device procedures and quality issues related to the provision of CRM devices between 1st April 2015 and 31st March 2016. 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 services. This includes those who need a factual record of procedure numbers: by hospital, area, nation within the UK. It also details the UK's performance in the context of the European Union and its near neighbours. This is also the first year of a planned programme to increase the focus on quality and outcomes (clinical and technical) of CRM device procedures. It will therefore be of interest to patients, doctors and allied health professionals involved in CRM, hospital managers, clinical governance leads, commissioners, and government agencies including National Institute for Health and Care Excellence (NICE) and the Medicines and Healthcare Products Regulatory Authority (MHRA).

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# 1 Foreword

I am pleased to welcome publication of the 11th Cardiac Rhythm Management (CRM) Device Audit Report, covering the implantation of cardiac pacemakers, implantable defibrillators (ICDs) and cardiac resynchronisation therapy (CRT) during the period April 2015 to March 2016.



The new device dataset introduced in April 2014 has now achieved stability, permitting a process of more detailed reporting of quality measures to commence this year. This includes identification of operators and responsible consultants by their General Medical Council (GMC) number. Future reports will give detailed activity statistics and eventually long term outcomes at operator level, as well as by centre.

As ever, I would like to acknowledge the hard work of clinical physiologists, nurses and clinicians at the device implanting centres. The time taken to submit data is often unfunded, yet freely given, and all concerned deserve our recognition and thanks.

The results for 2015-16 show a rise in implant rates for all types of device in England and Wales, which is encouraging. As in previous years, optimism must be tempered by the observation that UK device implant rates, particularly for pacemakers and ICDs, remain below those of most comparable European countries. The report highlights these continuing differences. Clinicians and commissioners are always encouraged to follow best practice guidelines, such as those published by the National Institute for Health & Care Excellence (NICE), and be alert to any inequity in provision of these devices. The CRM Device Audit provides information which will hopefully assist the real time monitoring of clinical practice.

The national CRM device audit continues to provide valuable data for understanding current practice, and how we might best plan for future improvement. It is of interest to patients, clinicians and commissioners alike and I warmly commend it to all who commission and deliver cardiac device therapy.

## Professor Huon Gray

National Clinical Director (Cardiac)  
NHS England

Year on year this report gathers more data to demonstrate the amount of work centres are undertaking to serve arrhythmia patients. Whilst we applaud their endeavours it is still disappointing to see the low implant numbers compared to many of our European partners.



Access to available treatments vary from one area to another which is unacceptable.

Sudden cardiac death is the number one killer. Despite this we still see low implant of life-saving devices such as ICDs and pacemakers.

I congratulate this report and the data it provides. We must now use this data to improve and increase access to care to save more lives and to improve the quality of life for all arrhythmia patients.

Going forward we should share this data with politicians and policy makers on a national level as well as local services and MPs to drive improvement and change

Arrhythmia Alliance will ensure we reach out to all concerned and especially patients whose lives hang in the balance subject to access and availability.

## Trudie Lobban MBE FRCP (Edin)

Founder & CEO  
Arrhythmia Alliance  
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## 2 Introduction

### 2.1 What are cardiac rhythm management devices?

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. The term 'CRM' is conventionally 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 threaded down a vein to connect to the heart. The implant procedure usually requires only local anaesthesia and can take less than an hour for the simplest devices or >2 hours for the most complex cases.

- **Pacemaker (PM):** These are the most common type of CRM device and have been implanted since 1958. Pacemakers are used to treat slow heart rates or episodes when the heart stops altogether, causing dizzy spells, blackouts, or death. When necessary they give tiny electrical impulses to trigger the heartbeat.
- **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. 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. This improves symptoms, hospitalisations, and mortality. CRT can be a feature of both pacemakers (CRT-P) and defibrillators (CRT-D).

### 2.2 What is covered in the report?

This report serves a number of functions:

- It provides the official record of CRM device procedures in the United Kingdom, demonstrating trends in the use of this therapy. In collaboration with similar reports from more than 40 other nations, this permits meaningful comparison of CRM device activity across the wider Europe.
- The online appendices detail the CRM device activity at each of the 196 implanting centres in the UK. They also detail geographical variation in the provision of CRM device therapy across England and Wales,

- In this report a number of quality measures are reported for each centre, relating to data completeness, meeting standards set by the British Heart Rhythm Society, and adherence to NICE guidance on pacemaker and defibrillator therapy.

### 2.3 Plans for the future

The data collected for the CRM audit reflects the needs and interests of many stakeholders, and is 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.

The plan for next year is to:

- Provide more detailed reporting on adherence to the NICE guidance, including cardiac resynchronisation therapy. This will be of interest to patients, professionals and commissioners who will be closely examining the findings.
- Start reporting one year reintervention rates for first-time pacemaker and complex implants at each centre. This will be an important index of major complications.
- Publish pacemaker and complex procedure numbers by implanter and by responsible consultant. One year reintervention rates will follow in subsequent reports. This 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, 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.



**Francis Murgatroyd**

Audit lead, British Heart Rhythm Society

Chair, National CRM Audit Steering Committee



**Nick Linker**

President, British Heart Rhythm Society

## 3 Executive summary

The national CRM device annual report details clinical activity in the fields of pacemakers (for the treatment of blackouts and other symptoms), implantable defibrillators (for the prevention of sudden cardiac death), and cardiac resynchronisation therapy (for the treatment of heart failure). Implant rates and recent trends in these rates are presented for the UK as a whole (alongside other European nations), for the constituent nations in the UK, and for each Clinical Commissioning Group in England.

For each implanting centre clinical activity in the CRM device field is reported, along with a variety of quality measures including data completeness and satisfying standards set by BHRS and NICE. Starting this year, the centre data and maps of implant rates are presented as online appendices.

This is the first time the report is based on data derived entirely from the new CRM device dataset, which was launched in 2014. The new dataset will permit us to report clinically relevant quality measures in increasing detail.

### 3.1 Findings

The key findings of the 2015-16 report are:

1. The overall pacemaker implant rate in the UK is gradually increasing, in line with an ageing population. However, the UK implant rate remains low compared to most countries in Western Europe.
2. The overall defibrillator (ICD and CRTD) implant rate in UK is gradually increasing, but remains one of the lowest in Europe.
3. In contrast, the overall implant rate for cardiac resynchronisation devices (CRT-P and CRT-D) is increasing steadily, and is currently just above the Western European average; the UK has the third highest CRT implant rate in Europe.
4. Implant rates vary considerably between the UK nations. Scotland implants approximately half the number of ICDs and CRT devices per head compared to England, Wales and Northern Ireland.
5. Maps detailing the rate of treatment with CRM devices, according to where patients live (missing from recent annual reports), have been restored for England & Wales. These show considerable variation in implant rates (postcode prescribing), which has not improved in the last two years. Variation is particularly marked for ICD and CRT devices.
6. The number of adult NHS hospitals implanting small numbers of pacemakers (below the recommended minimum) has approximately halved in the last year.

7. However, the proportion of adult NHS hospitals implanting small numbers of complex devices (below the recommended minimum) is nearly 50% and has not fallen significantly.
8. The number of centres failing to use the NICE recommended type of pacing for sinus node disease in the majority of patients has fallen from 16 to 10.
9. Most centres are documenting good adherence to NICE guidance for ICD implantation in patients who have suffered life-threatening arrhythmias (secondary prevention). However, in cases where they are implanted purely because of the risk of such arrhythmias (primary prevention), documented adherence to these guidance not as good.
10. Data completeness is variable and poor for some important new items. Considerable improvement in data submission will be essential to pursue our plans to report clinical outcomes and quality indicators in the future.

### 3.2 Recommendations

#### 3.2.1 Commissioners and Chief Executives

*We recommend that you:*

1. Consider whether pacemaker and ICD/CRT implant 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 compliance with NICE guidance TA881, TA3242, TA3143, CG1804, CG1085 and CG1876).
3. Ensure there are sufficient resources allocated to support national clinical audit activity.

#### 3.2.2 Medical Directors and Clinical Leads

*The reports for your centre are available online in the Appendices. There are three domains: (i) data completeness, (ii) activity, and (iii) quality measures. We recommend that you:*

1. Review your data completeness as this affects all quality measures. Please pay particular attention to the recommendations in Section 7 of this report where they affect your centre.
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 uploaded in an incorrect format. Next year procedure data will be reported for individual operators and 1 year outcome reporting will commence thereafter, for centres and operators.

3. Ensure all operators regularly review their data in NICOR to improve timeliness and accuracy (see recommendation 3.2.3, point 3).
4. Provide appropriate clinical support to the clinical audit teams. Our data shows 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 four quality standards: (i) pacemaker implant volume >80 (BHRS 2015 standard7), (ii) complex device implant/upgrade volume > 60 (BHRS 2015 standard7), (iii) atrial based pacing for sinus node disease (NICE TA88/TA324) and (iv) fulfilling NICE indications for ICD implantation (NICE TA314).

### 3.2.3 Clinicians Performing CRM Device Procedures

*This year we have reported only the names of clinicians recorded (by valid GMC number) as having undertaken or supervised procedures. Next year, procedure numbers will be reported at individual clinician level. We recommend that you:*

1. Liaise with your hospital's audit staff to see whether your procedures for the current audit 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 authorized audit lead can modify data). An individual report for your activity (at all centres where you operate) will become available to you for appraisal and revalidation purposes during 2017 (see recommendation 3.2.2, point 3).

### 3.2.4 Clinical Audit Teams

*We recommend that you:*

1. Review the entry for your centre in Appendix 1, which will give an indication of the extent to which your data submissions are complete and valid. Check that the data submitted to NICOR shows what you expect it to be; this is especially relevant to those hospitals that use third party software to submit their data.
2. Consider resubmission for the 2015-16 data in certain circumstances (especially if complete records or critical fields such as NHS Number are missing) – discuss with NICOR helpdesk if necessary.

3. Submit data as soon as possible after device 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.

### 3.2.5 Patients and Public

*What does this mean for me?*

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. Not all hospitals implant all of the types of device.
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.

## 4 Aims and objectives of the audit

The CRM devices audit started as a registry of device implants and this continues to be an essential function. Virtually all pacemaker and complex device implanted in the UK (over a million procedures) has been recorded, and this information is vital for monitoring the technical performance of devices over many years. We hope to expand the analysis of the data held, to look at long term battery life of devices, and the provision of early warning signs of rare faults that might not be picked up by other methods.

The clinical audit element of the annual report has in the past been somewhat limited compared to its registry function, and this is the first year of a planned significant expansion. The immediate goals are to examine adherence to national guidance (from BHRS and NICE) for centres implanting CRM devices. Later it is intended to expand on this and report long-term complication rates.

In this year's report there is a detailed focus on data completeness and quality. This is because some types of data are completed poorly or not at all, impacting on the analyses that are possible. The detailed reporting of data completeness this year should drive a sufficient improvement to permit better and more interesting analyses in future.

The specific quality measures in this year's report are:

- Data completeness across four domains: demographics, clinical variables (what was wrong with the patient), implant details (who performed the implant, what type of device was implanted, etc), and technical details (model and serial number of device, for tracking purposes).
- BHRS 2015 standards for pacemakers and complex implants: the BHRS standard, updated every two years, includes recommendations on the minimum number of implant procedures for each centre and by each doctor. This is because there is strong evidence of a link between low procedure numbers and the risk of complications.
- NICE guidance for type of pacemaker in patients with sinus node disease.
- NICE guidance regarding which patients should receive ICDs.

### 4.1 Structure of the report

In the main body of the 2015-16 CRM devices annual report, the key areas of focus are:

- Implant rates for different types of CRM device in the UK as a whole, in the constituent nations, and changes in these over recent years.
- Comparisons of the UK implant rates with those of other countries in Europe.
- An overview of the findings regarding our quality indicators (meeting BHRS standards and NICE guidance) in the UK.

For the first time, details of the activity and quality indicators for each centre will not be part of this publication but will be available as a set of appendices available online (see Section 8 for Appendices). This will greatly shorten the body of the report itself and allow readers to find and search for specific data more easily.

In addition, interactive maps showing provision of CRM device implants across England and Wales will be made available online and will permit the user to 'zoom in' on an area (defined by Clinical Commissioning Group) to look at the number of implants, corrected for demographic variables determining need (such as age), and to visualise changes within that area in recent years.

## 5 Methodology

### 5.1 Governance of the National CRM Device Audits

The National Cardiac Rhythm Management Device audit has evolved from the British Pacing and Electrophysiology Group national registry, and at 40 years is the oldest such registry in the world. Data are submitted to NICOR by hospitals that undertake pacemaker and defibrillator procedures. Clinical leadership is provided by the British Heart Rhythm Society. The NICOR Steering Group sets the strategy and provides oversight of the audit. It is chaired by the BHRS audit lead and meets four times a year. The Steering Group includes NICOR staff, the BHRS President, representation from all professional groups involved with CRM device management (doctors, physiologists, and nurses), from HQIP, and from patients. Other stakeholders regularly represented include the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Authority (MHRA), NHS England, and the Association of British Healthcare Industries. Other stakeholders are invited to Steering Group meetings on an ad hoc basis.

Data submitted to NICOR for all the cardiac audits are by their nature patient-identifiable (and need to be to permit centres to check and update records), they are therefore held on a highly secure server. This means that identified centre audit leads are able to use secure logins to see and check their own centre's data at a patient level. However, these data are not released in a patient identifiable form to any other parties; only aggregated data can be used for analysis or publication.

### 5.2 Participating hospitals

All NHS hospitals in England are contractually required to submit data to the national cardiac audits held by NICOR. Hospitals in Scotland, Wales and Northern Ireland also submit their data, though not all centres in Scotland are routinely submitting their pacemaker data at this time.

### 5.3 Data Collection and IT

As the CRM audit database largely relates to procedures performed, most hospitals collect data at the time of these procedures. Data can either be submitted directly to NICOR via a web portal, or collected by hospital information systems and uploaded in batches. As a variety of information systems are used, with at least six major third party IT providers, changes to the dataset can pose a challenge, and adherence can be delayed. The 2015-16 report is the first to be based entirely on a new dataset, announced in 2013, introduced in 2014 and used exclusively from 2015.

### 5.4 Definitions: 'simple' and 'complex'; 'new' and 'total' implants

There are three classes of device considered in this report:

- **Pacemakers (PM):** For treatment of symptomatic bradycardia.
- **Implantable cardiac defibrillators (ICD):** For treatment of cardiac arrest and patients suffering from, or at risk of, life threatening ventricular arrhythmias.
- **Cardiac resynchronisation therapy devices (CRT):** For treatment of heart failure. Cardiac resynchronisation pacemakers (CRT-P) and defibrillators (CRT-D) are grouped together in most parts of this report.

In line with NHS commissioning structures and other professional bodies in the world, BHRS classifies CRM device procedures as 'simple' and 'complex'. Pacemaker implants are **'simple'** procedures, and are commissioned locally (in England by Clinical Commissioning Groups).

All CRT and ICD implants are classified as **'complex'** CRM procedures and are subject to Specialised Commissioning, e.g. by the Local Area Teams of NHS England.

The first time a patient receives a device, the procedure is classed as a **'new implant'**. If that device is replaced with another of the same class, usually due to battery depletion, then that procedure is classed as a **'replacement'**.

If a patient's device type is changed to upgrade its functionality, then for the purpose of overall statistics this will be counted in this report as a 'new implant'. For example, if a pacemaker is upgraded to a CRT-P device (this involves both changing the device itself and inserting one or more new leads in the heart) then this will count as a new CRT implant in the statistics.\*

For the purposes of this report, the word **'total'** is defined as 'new plus replacement' implants. Where data are combined for different modes e.g. single plus dual chamber, CRT-P plus CRT-D, this is made clear in the text, or the word 'all' is used.

*\*In future, report outcomes (reinterventions) at one year for each centres' implants will be published, but this will be based on first implants only (not upgrades, etc). The one-year analysis will subsequently to individual operator level.*

## 5.5 Notes on comparisons with information in previous reports

- **Reporting by financial year**

This report is based on data provided by hospitals for the financial year April 2015 to March 2016.

- **Reporting at hospital level**

This report analyses data by the hospital performing the implantation. Up until 2011, CRM audit reports analysed data at the level of Primary Care Trusts (PCTs) and Cardiac Networks. From 2012 onwards the data has been analysed on the basis of Clinical Commissioning Groups (CCGs) and Local Area Teams (LATs).

- This report analyses data by the hospital performing the implantation. Reports are being developed at Clinical Commissioning Groups (CCGs) and Local Area Teams (LATs) levels which will be available on the NICOR web portal at <https://nicor4.nicor.org.uk>.

- **Reporting at individual clinician level**

In line with other national audits (e.g. Adult Cardiac Surgery, Percutaneous Coronary Intervention), data for individual operators are to be published. For this introductory year, only a simple list of clinicians (identified by GMC no.) reported by each centre to have undertaken device procedures, or to have been the consultant responsible for those procedures undertaken by others (principally trainees), has been published. The 2016-17 audit will detail the numbers of each type of procedure undertaken by each clinician, with the view to publish 1 year outcomes for first implants thereafter.

## 6 Findings

### 6.1 Overview of CRM device implants in the UK – national implant rate trends

Implant rates per million for the UK nations in 2014 and 2015 are shown in Tables 1-4, and trends over the last decade are shown in Figures 1-4. (Pacemaker data for Scotland are known to be incomplete and are therefore not shown, however we are confident in the complex device data). The data for ICDs and CRT devices include both new implants and replacements.

*Pacemakers:* there has been a gradual increase with implant rates in England and Wales now just over 600pmp; the rate in Northern Ireland appears to be much lower at 432pmp.

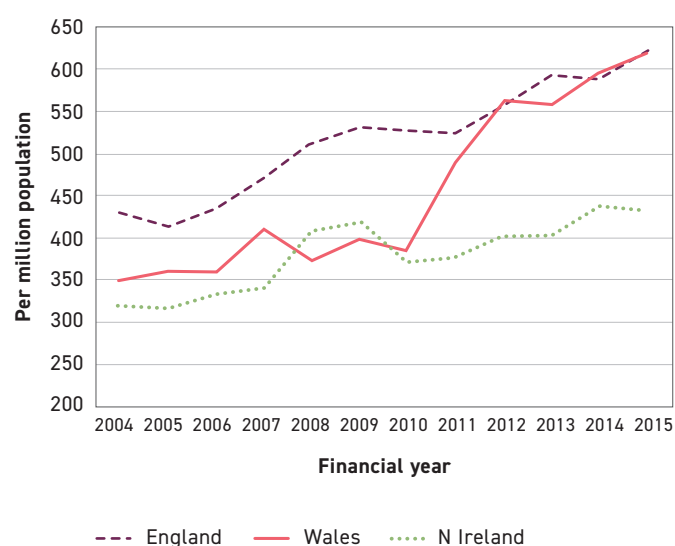
*Implantable Defibrillators:* the implant rates in England, Wales, and Northern Ireland have gradually increased in recent years and are now around 100pmp. The rate in Scotland is significantly lower at 49pmp and reported activity has actually declined in the last two years.

*Cardiac Resynchronisation Therapy:* uptake of this treatment for heart failure has been steadily increasing for several years in all parts of the UK, with England having the highest rate around 200pmp, Wales and Northern Ireland around 1/3 lower, and Scotland implanting only 90pmp.

**Table 1: Annual new pacemaker implant rate per million population**

	2014/15 rate	2015/16 rate
ENGLAND	592	621
WALES	596	619
N IRELAND	438	432
SCOTLAND	incomplete data	incomplete data

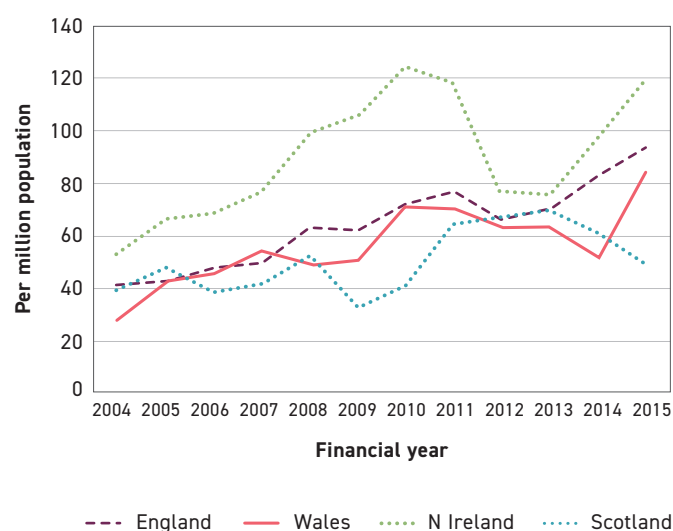
**Figure 1: New pacemaker implant rate trend 2004-15**



**Table 2: Annual New ICD Implant Rate per million population**

	2014/15 rate	2015/16 rate
ENGLAND	83	94
WALES	55	85
N IRELAND	97	119
SCOTLAND	61	49

**Figure 2: New ICD implant rate trend 2004-2014**



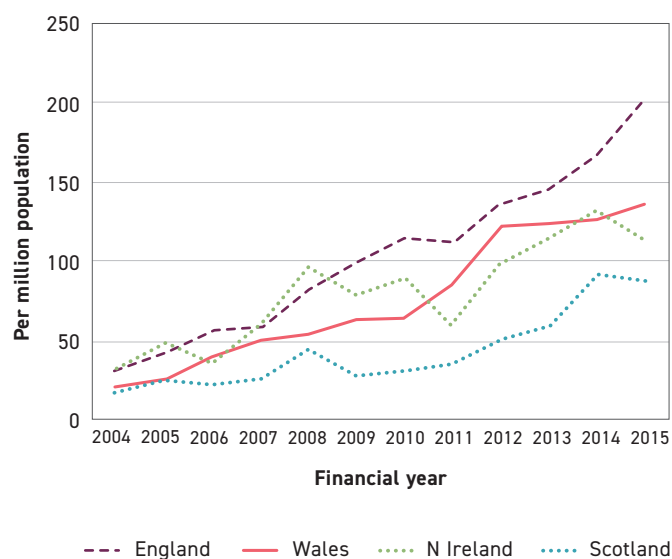
**Table 3: Annual Total CRT Implant Rate per million population**

Including both new and replacement CRT-P and CRT-D

	2014/15 rate	2015/16 rate
ENGLAND	166	201
WALES	128	137
N IRELAND	131	114
SCOTLAND	91	89

The Implant rate has risen significantly in England and slightly in Wales. N Ireland shows an apparent drop in CRT rate, mirroring their increase in ICD rate.

**Figure 3: Total CRT Implant Rate per million population**

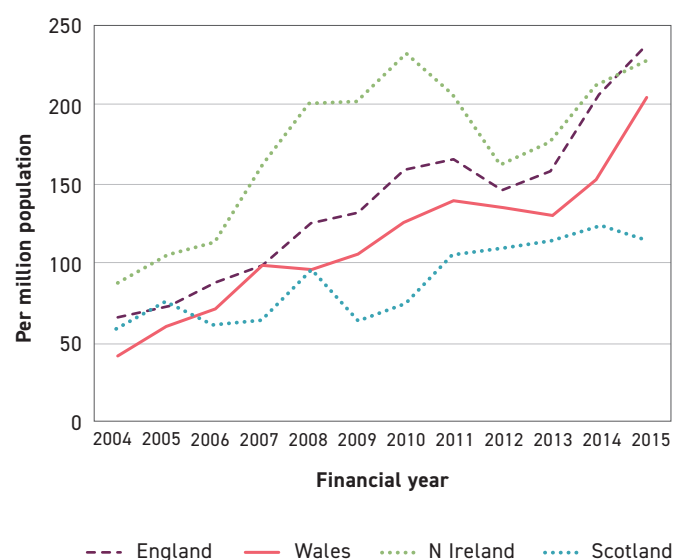


**Table 4: Total High Energy Implant Rate per million population All ICD + CRT-D implants**

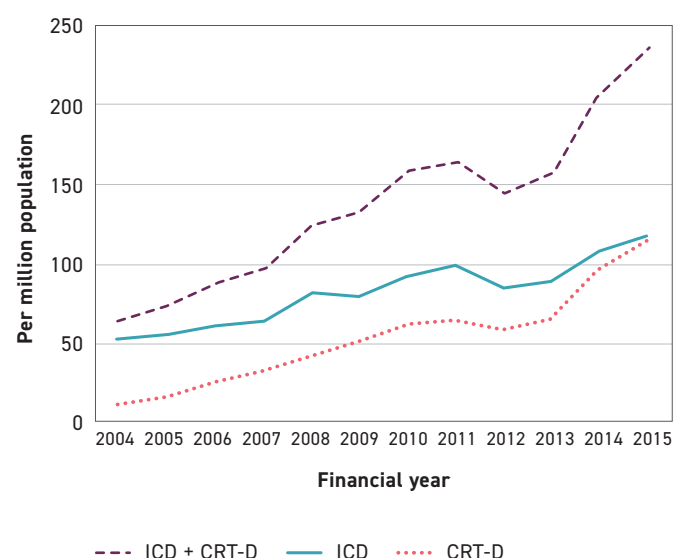
Including both new and replacement ICD and CRT-D

	2014/15 rate	2015/16 rate
ENGLAND	206	238
WALES	154	203
N IRELAND	212	228
SCOTLAND	123	115

**Figure 4: All High Energy Implant Rate trend per million population**



**Figure 5: High Energy Implant Rate trend per million population in England: ICD vs CRT-D**



As last year, CRT-D implants continue to rise faster than ICD. This may be in part a reflection of the shorter battery life of CRT-D units, and the consequent greater need for replacements.

## 6.2 Regional variation in implant rates across the UK

Up to 2012 the annual reports included maps of most of the UK, detailing implant rates for simple and complex devices, corrected for demographics. These maps highlighted great regional variation in provision of device services and acted as a driver to reduce 'postcode prescription'. These were recently omitted due to lack of funding for the analysis. Thanks to input from Public Health England (PHE), it has been possible to include these maps again for England and Wales. Maps have been created using the CCG covering each patient's postcode, and using PHE methods for standardizing according to local demographics. Rather than appearing in 'paper' maps, local implant rates can now be viewed in the online appendices, which permits a more detailed and interactive view over the last three financial years.

The analysis shows that there is considerable variation in local implant rates for both simple and complex CRM devices. This has not changed significantly between 2013/14 and 2015/16. This variation is sometimes called "postcode prescription" though it probably reflects a number of factors, from availability of diagnostic tests to the training of professionals and provision of specialist services. The measure of variation (coefficient of variation) is 25-30% for pacemakers, with some areas implanting more than 100 devices per 100,000 and others less than 50. The coefficient of variation is even higher (30-45% over the period studied) for complex devices.

### 6.3 How do UK implant rates compare with those in the rest of Europe?

Over the last decade the UK has lagged behind most other European countries in pacemaker and ICD implants. This remains the case in 2015 despite the gradual increases seen in recent years. The implant rates per million for countries in wider Europe are shown in Figures 6-9. The UK implants more devices than most countries in Eastern Europe and the Eastern Mediterranean, but UK implant rates are well below the European average and at or near the lowest of the Western European countries. This situation has not changed over the years.

**Pacemakers (Fig.6):** The UK implant rate (615 per million) remains well below the Western European average (739 per million), and is ranked 13th of the countries reported. There is no clinical reason why this should be, and the implication is that UK patients in need of pacemakers are not being diagnosed or treated adequately.

**Defibrillators (Fig 7) and total high energy devices (ICD + CRT-D Fig 9):** the UK new implant rate (83/million) is much lower than the Western European average (141 per million). The UK has fallen further behind other countries and is now 19th in Europe for new ICDs, and 18th for all high energy devices (ICDs + CRTDs). Again, there is no clinical reason why this should be, and the implication is that UK patients in need of ICDs are not being diagnosed or treated adequately, and many preventable deaths are occurring as a result.

**Cardiac resynchronisation therapy devices (CRT-P + CRT-D, Fig 8):** in this regard, the UK is performing well, implanting 186 per million, slightly above the Western European average (164/million). This is partly because there is a greater tendency to implant CRT pacemakers (as opposed to CRT-D) in the UK than elsewhere, but possibly also because there is good integration between heart failure and CRM device services.

#### Note on sources of data

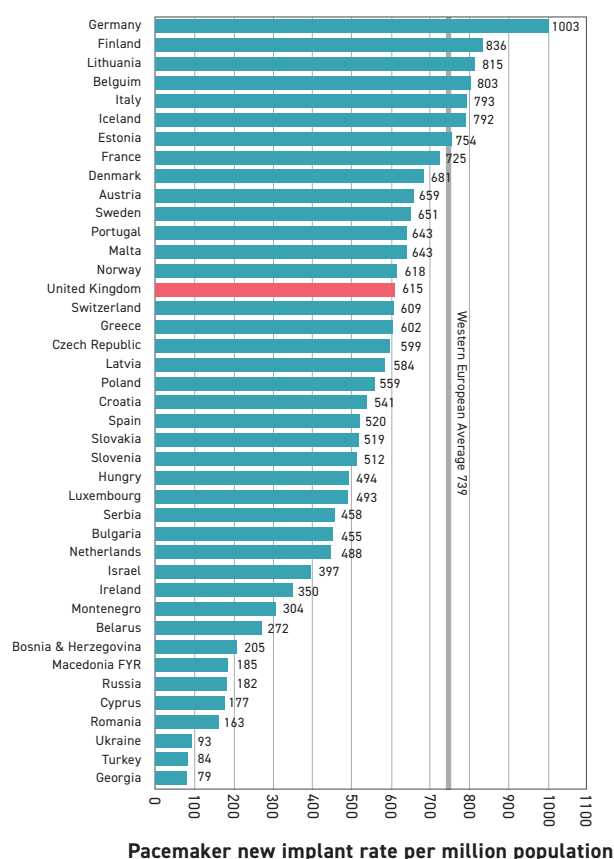
Data was abstracted from European Heart Rhythm Association White Book for 2015 (calendar year) and available at [http://www.escardio.org/The-ESC/Communities/European-Heart-Rhythm-Association-\(EHRA\)/Publications/The-EHRA-White-Books](http://www.escardio.org/The-ESC/Communities/European-Heart-Rhythm-Association-(EHRA)/Publications/The-EHRA-White-Books).

Ireland did not split their pacemaker (PM) and ICD data into new and replacement numbers so these were inferred from historical data.

#### Western European Average

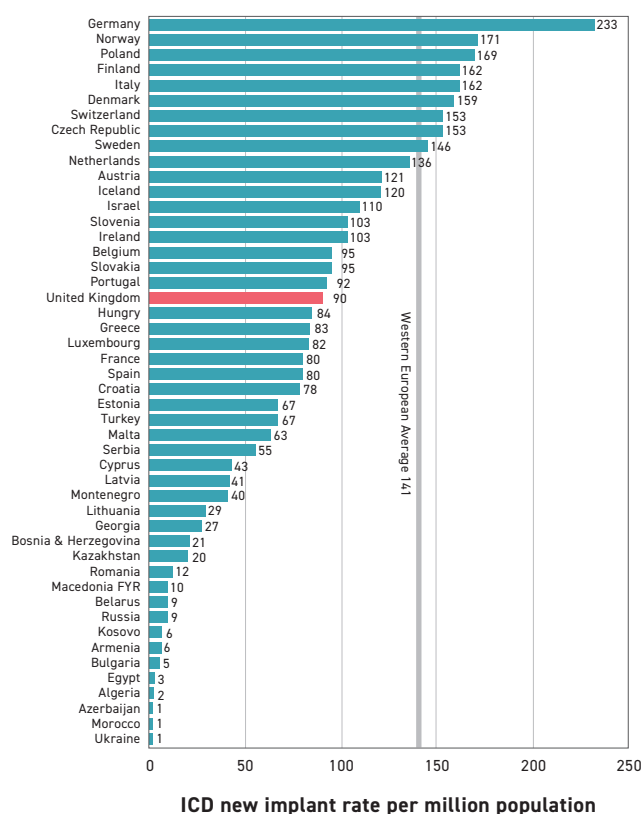
The Western European average is a population-weighted average of the data from the following countries: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Netherlands, Norway, Portugal, Spain, Sweden, and Switzerland.

**Figure 6: Pacemaker New Implant Rate 2015**



UK new ICD implantation data from 2015 (highlighted in red) are compared to data from other Western European countries in the EHRA White Book. The European average new ICD implant rate in 2015 was 141 per million population and is indicated by a grey line.

**Figure 7: ICD New Implant Rate 2015**



UK total CRT (CRT-P + CRT-D) implantation data from 2015-16 (highlighted in red) are compared to data from other Western European countries for 2015 in the EHRA White Book. The European average total CRT implant rate in 2015 was 164 per million population and is indicated by a grey line. The UK rate is higher than the European average.

**Figure 8: CRT Total Implant Rate 2014**

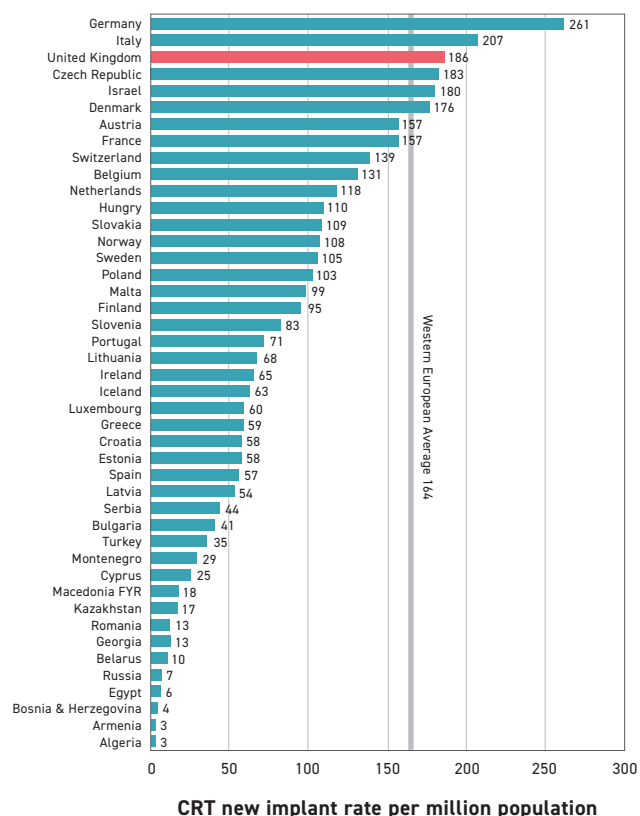
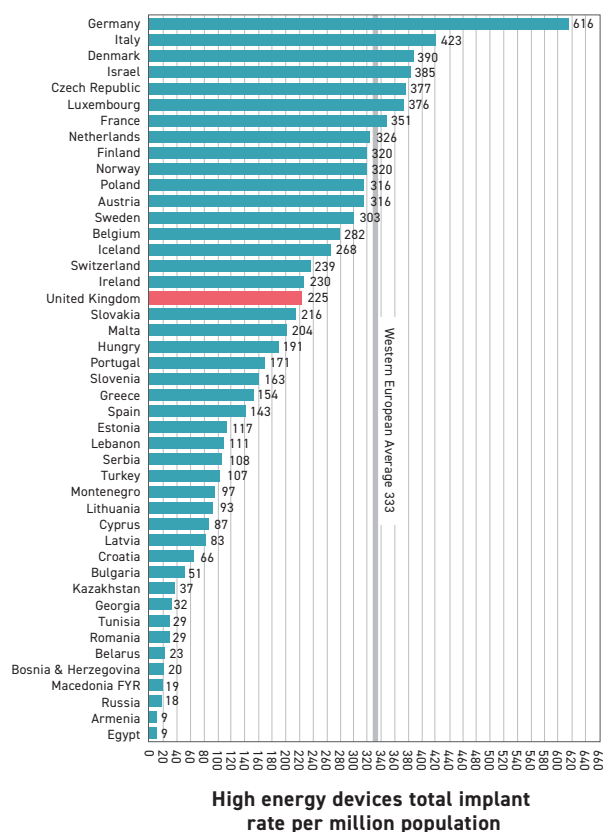


Figure 9 shows Western European average total high energy implant rate (2015) = 333 per million population. UK data is from financial year 2015-16 registrations. The data presented for all other countries is derived from the EHRA White Book for calendar year 2015.

**Figure 9: High Energy Devices Total Implant Rate 2015**  
(total ICD + total CRT-D)



## 7 Quality measures at UK implanting centres

### 7.1 Data completeness (online Appendix 1)

In this and future reports, the performance of individual centres and operators will be analysed in increasing detail (Appendix 2 and 3). This analysis is entirely dependent on receiving accurate and complete data. For example, in order to give breakdowns of the clinical activity of each operator, it will be necessary for the 'GMC Number' fields, the 'Intervention Category (i.e. what kind of procedure)' field and the 'Maximum System Capability' (i.e. what type of CRM device) field to have been correctly completed. Likewise, in order for reinterventions (a critical measure of patient outcomes) to be analysed, NHS number is critical to track patients both within and between centres. Some of these data have not been analysed and presented before, so their importance may not have been appreciated. To highlight deficiencies in data submission, data completeness at each centre is reported in some detail, in three domains:

#### 1. Demographics (patient identifiers, inc. NHS No.)

88 out of 192 centres (46%) are to be congratulated for >98% completeness in all fields, and 131 (68%) achieved >90% completeness in all fields. Unfortunately, overall completeness for NHS number remains only 92%. Private hospitals are particularly poor at recording NHS numbers (<10% in most cases), even though most of their patients are UK citizens.

**Recommendation: centres should resubmit their current returns if the recording of NHS numbers is incomplete. Even though this will not affect the current report, this step is vital to enable:**

- **Prospective accurate and complete follow-up of patients and devices used.**
- **The tracking of late complications (even where treated at other centres), and the reporting of long term issues such as device reliability and longevity.**

#### 2. Clinical data

We congratulate Addenbrooke's, the Royal Brompton, and Whipps Cross hospitals for achieving >98% data completeness in all fields, and James Cook, the Freeman, Spire Hull & East Riding, Airedale, Broomfield, Glenfield, Wycombe, Poole, and Princess Royal Hospitals for achieving >90% completeness in all fields.

Elsewhere the picture is very poor, with 166 centres achieving <80% completeness in at least one field. The fields with the poorest completion were (all devices) aetiology and atrial rhythm, and (complex devices) QRS duration and morphology. The worst performing 17 hospitals failed to achieve 80% completeness in any fields: these were Craigavon, BMI Alexandra, Trafford General, Queen Elizabeth Birmingham,

Russells Hall, Princess Alexandra Harlow, Milton Keynes, Yeovil District, Kent Institute of Medicine and Surgery, The Royal Surrey County Hospital, Spire Southampton, Ealing, London Independent, St Anthony's, Dumfries & Galloway, Golden Jubilee, and Aberdeen Royal Infirmary.

**Recommendation: Audit committees at each centre to examine their data completeness in the report tables. The clinical data fields will be used to derive quality indicators, such as compliance with NICE guidance, and every missing or incorrect entry may affect the centre's reported quality. The 17 named centres with low completeness in all clinical fields should agree and implement plans to improve future data completeness.**

#### 3. Procedure

This domain includes operator and consultant GMC numbers, type of procedure and device, fluoroscopy and complications, as well as device details. Again, the completeness is disappointing, with only the Luton and Dunstable Hospitals achieving >98% completeness in all fields, and Princess of Wales Hospital achieving >90% completeness in all fields. Intervention category (what type of procedure: new implant, battery change, etc) was completed in 98.3% of cases, and maximum system capability (what type of device) in 99.2%. Unfortunately the first operator the GMC number was completed in only 65% of cases, and for the consultant, in only 60%. More than 50% of procedures had invalid device models recorded, though serial numbers were completed in >99% of cases.

**Recommendation: audit committees at each centre to examine the reported completeness for the procedure details, and if necessary put in measures place to assure the completeness, integrity, and validation of procedure data. In particular, it is important to ensure complete and accurate entry of:**

- **GMC number for the first operator and the Consultant responsible for the procedure.**
- **Valid device and lead model and serial numbers.**

**These data will in future be used for operator-based reports such as procedure numbers and complications; and for tracking device reliability and longevity.**

**NICOR urges centres to make strenuous efforts to improve the quality and completeness of clinical and procedure data entry. Quality measures (e.g. performance against NICE guidance) will make increasing use of these data in future, and will be of increasing interest to both commissioners and patients. Next year's report will list procedure numbers by operator using submitted valid GMC numbers (in line with other cardiac audits), and outcomes by operator will follow.**

## Summary of Findings

- *Demographic data:* Overall these were submitted to high levels of completion (99.6%). However, a valid NHS number was submitted in only 90.0% of cases.
- *Clinical data:* there is huge variation between centres in the completeness of data. Incomplete data submission will reflect poorly in future years when increasingly detailed analyses of parameters such as NICE compliance and 1-year outcomes are reported.
- *Procedure data:* The 'Intervention category' and 'Maximum system capability' fields have been completed (though not necessarily correctly) in >99% of cases, as were device nos. serial identification of the first operator and responsible consultant by valid GMC numbers were very poor in many centres. This means that the record of procedure activity for those clinicians will appear correspondingly low.

## 7.2 Are implanting centres of sufficient volume? (Appendices 2, 3, and 4)

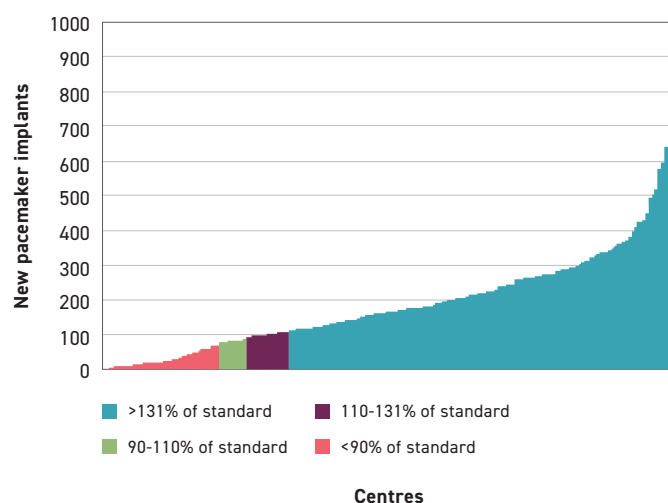
There is clear evidence in the research literature of the relationship between the number of procedures performed in its centre and its complication rates. As part of its biennial standards document, BHRS makes recommendations for minimum numbers of procedure implants ([www.BHRS.com/standards](http://www.BHRS.com/standards)).

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

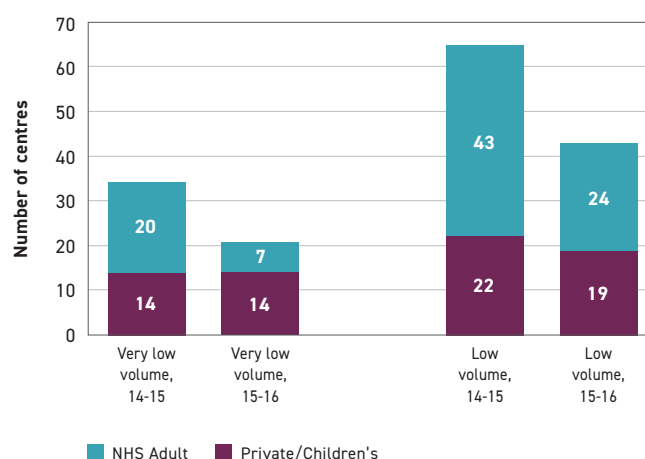
### Detailed findings:

Figure 10 is a histogram showing the number of new pacemakers implanted by centre. Individual centre data are detailed in online Appendix 2, along with the names of operators identified by GMC number as having implanted pacemakers. Those implanting <73 (90% of the standard) are in red, and those implanting 73-89 (10% above or below the standard) in yellow. Centres implanting 90-105 are in green, and those implanting >105 (sufficient to train) in blue. Individual centre data are given in the online appendix.

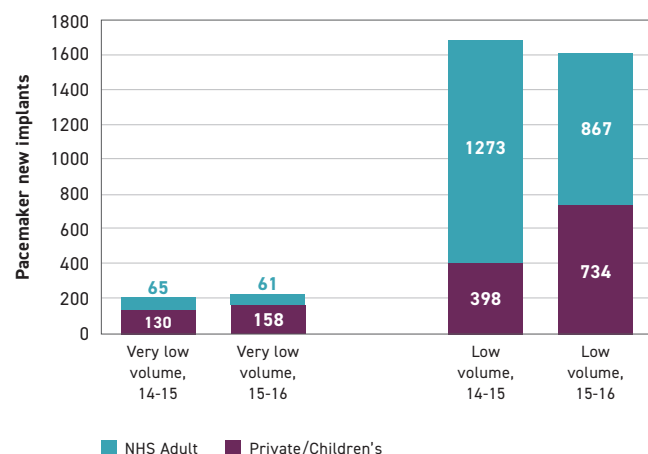
**Figure 10:** Histogram showing the number of new pacemakers implanted by centre



**Figure 11:** Comparison of the number of centres implanting low (<80), and very low (<20) numbers of pacemakers in 2014-15 and 2015-16



**Figure 12:** The numbers of implants undertaken in low volume and very low volume centres in 2014-15 and 2015-16. Individual centre data are given in the online appendices



## Summary of Findings

- A quarter of centres did not meet the BHRS standard, but many of these were private or children's hospitals (see below).
- The number of private and children's hospitals with low pacing volumes has not changed, but the number of NHS adult hospitals with low volumes has decreased by nearly half.
- Only 5% of patients underwent pacemaker implants in low volume centres (<80 implants), and less than 1% in very low volume centres (<20 implants). The procedures in low volume private hospitals increased significantly, but the procedures in low volume NHS centres decreased by a third.

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

## Detailed Findings

Figure 13 shows the number of complex procedures (ICD, CRT-P and CRT-D implants and upgrades) by centre. Those with <54 procedures are in red, those with 54-66 procedures (within 10% of the standard) in yellow, and those with >66 procedures in green." 64 out of 134 (48%) of centres reported fewer than 60 complex procedures. Individual centre data are detailed in online appendix, along with the names of operators identified by GMC number as having undertaken complex device procedures.

**Figure 13:** Number of complex procedures (ICD, CRT-P and CRT-D implants and upgrades) by centre

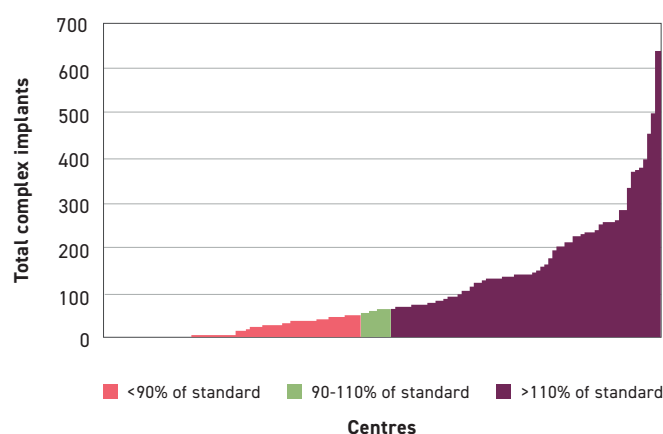


Figure 14 compares the number of centres undertaking low (<60), and very low (<20) numbers of complex procedures in 2014-15 and 2015-16. There has been very little change, other than that the number of NHS Adult hospitals undertaking very few procedures has fallen from 24 to 17.

**Figure 14:** Comparison of the number of centres undertaking low (<60), and very low (<20) numbers of complex procedures in 2014-15 and 2015-16

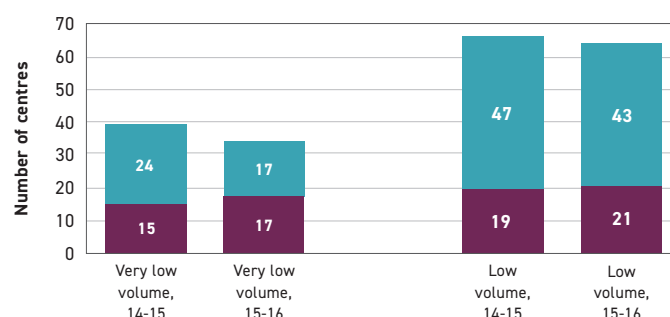
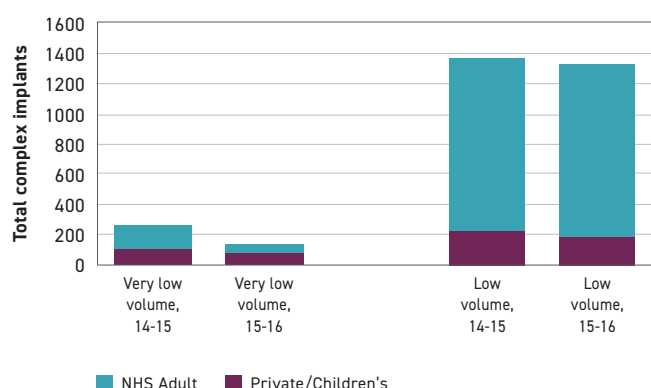


Figure 15 compares the number of complex device procedures undertaken in low volume centres during 2014-15 and 2015-16. The picture has changed very little, with 9.6% of procedures undertaken in low volume centres. However, less than 1% of complex device procedures were undertaken in very low volume centres in 2015-16.

**Figure 15:** Complex Device Procedures in Low Volume Centres



### Summary of Findings

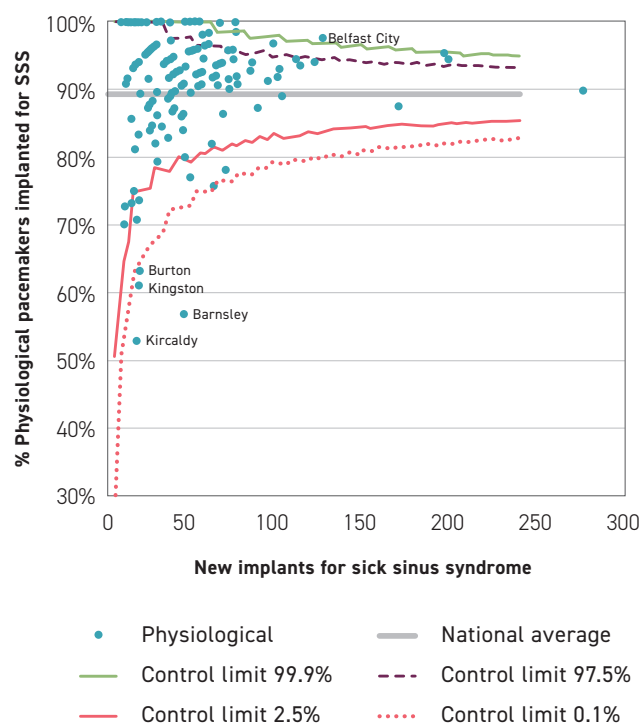
- Almost half of the UK centres undertaking complex device procedures did not meet the BHRS standard; this has changed very little in the last year.
- However, the number of UK NHS adult hospitals reporting very low activity (fewer than 20 implants/upgrades) has fallen by a third in the last year.

## 7.3 Are implanting centres following NICE guidance?

*Quality Standard 3: physiological (atrial based) pacing is preferred in patients with sinus node disease, not in permanent atrial fibrillation (NICE TA88/TA324).*

Figure 16 is a funnel plot of the percentage of patients reported as receiving physiological pacing at each centre against the total number implanted for sinus node disease in 2015-16. Control limits of 99.9%, 97.5%, 2.5% and 0.1% are plotted, along with the national average. Only centres reporting at least 10 implants for sinus node disease are included. Individual centre data are shown in Appendix 2.

**Figure 16:** Funnel plot showing percentage of patients reported as receiving physiological pacing at each centre against the total number implanted for sinus node disease in 2015-16



### Summary of Findings

- The average rate of physiological pacing remains 89.5%, but the number of centres with very low rates of physiological pacing (below the 2.5% control limit) has decreased from 16 in 2014-15 to 10 in 2015-16.

*Quality Standard 4: Adherence to NICE guidance for Implantable Cardioverter Defibrillators (NICE TA314)*

The 2014 dataset includes new fields that document the indications for ICD implantation in sufficient detail for adherence to the NICE guidance to be examined. In brief:

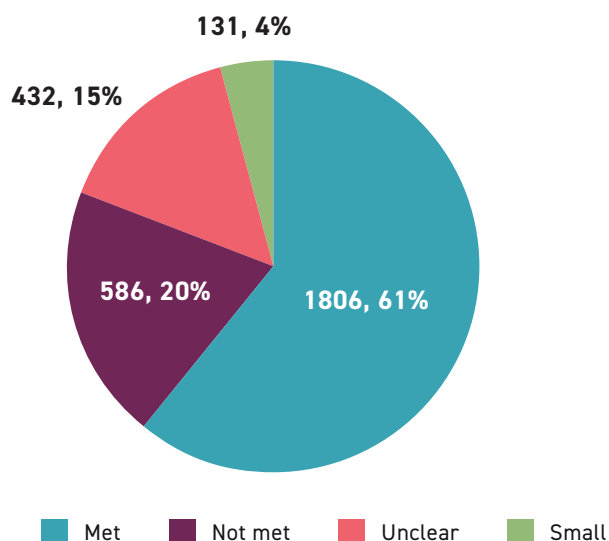
- Secondary prevention:** ICD implantation is recommended in patients who have suffered cardiac arrest, or life-threatening heart rhythms (ventricular tachycardia with collapse/loss of consciousness or ventricular tachycardia with left ventricular ejection fraction <35%), in the absence of reversible causes.

- *Primary prevention:* ICD implantation is recommended in patients who are at high risk of cardiac arrest due to a weak heart (left ventricular ejection fraction <35%) after optimization of medical therapy, or certain inherited conditions (or after surgery for certain congenital heart disease).

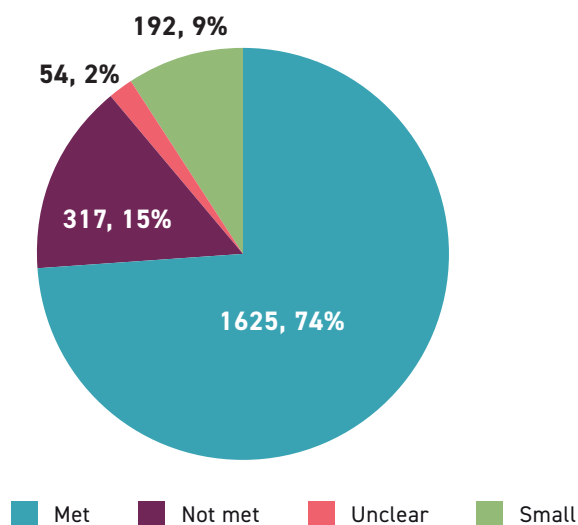
Centre based data are presented in Online Appendix 5. This analysis is dependent on centres completing a number of fields for each patients. Some of these fields are new and most have not been analysed hitherto, and data completeness has been variable. As a result, for a significant proportion of patients it has not been possible to determine whether the NICE guidance was followed.

- *ICD implants for primary prevention (Fig. 18).* From the data submitted, NICE guidance was met in 1806 of 2935 cases (61.5%), and was not met in 566 cases (19.3%). In 432 cases (14.7%), there were insufficient data to make a determination, and 131 cases were in centres reporting small (<10) numbers, and were not analysed.
- *ICD implants for secondary prevention (Fig. 19).* From the data submitted, NICE guidance was met in 1625 of 2187 cases (74.3%), and was not met in 317 cases (14.5%). In 54 cases (2.5%), there were insufficient data to make a determination, and 192 cases were in centres reporting small (<10) numbers, and were not analysed.

**Figure 17: ICD implants for primary prevention**



**Figure 18: ICD implants for secondary prevention**



### Summary of Findings

- 61% of ICDs implanted for primary prevention of sudden cardiac death were documented to meet NICE guidance for this indication.
- 74% of ICDs implanted for secondary prevention of sudden cardiac death (i.e. in patients who have already suffered a life-threatening arrhythmia) were documented to meet NICE guidance for this indication.
- In the remainder, either NICE guidance appears not to have been followed or there was insufficient information to make a determination.
- Note that these data refer purely to ICD, and not to CRT-D devices (which are implanted for both sudden death prevention and the treatment of heart failure).

## 8 Appendices

Online appendices giving details by centre and by geography of pacemaker, ICD and CRT provision and performance across the UK.

### Appendix 1:

Data completeness for key fields in 3 domains: demographics information, clinical details of patient, procedure details

[Appendix 1 Data completeness 2015-16](#)

### Appendix 2:

Centre activity reports

[Appendix 2 Centre Activity Reports 2015-16](#)

### Appendix 3:

Doctors identified by GMC each centre as having performed or supervised CRM device procedures during 2015-16

[Appendix 3 Registered Operators 2015-16](#)

### Appendix 4:

New simple implants, and complex implant/upgrades by centre. Colour code indicates whether BHRS recommend minimum procedure numbers have been met

[Appendix 4 Simple and Complex Devices by Centre 2015-16](#)

### Appendix 5:

*Documented adherence to NICE indications for ICD implantation at each centre. CRTD implants not included*

[Appendix 5 Document Adherence to Nice 2015-16](#)

## 9 CRM Steering Group membership list

Name	Committee Position	Job title	Organisation
Anthony Bradley		Project Manager (former)	NICOR
David Cunningham	Research Committee	Senior Strategist	NICOR
Morag Cunningham		Project Co-ordinator	NICOR
Nadeem Fazal	National Clinical Audits Service Manager	NICOR Audits Service Manager	NICOR
Akosua Donkor		Project Manager (current)	NICOR
Nick Linker	BHRS representative Co-Chair	Consultant Cardiologist	The James Cook University Hospital
Trudie Lobban	Patient Group representative	Trustee	Arrhythmia Alliance
Francis Murgatroyd	BHRS representative Co-Chair	Consultant Cardiologist	Kings College Hospital/BHRS
Pier Lambiase	Research Lead	Consultant Cardiologist	UCL
Chris Plummer		Consultant Cardiologist	Freeman Hospital
CRM Steering Group attendees			
Heather Cusden	Cardiac Physiology representative	Clinical Cardiac Physiologist	Royal Devon & Exeter Hospital
Roy Gardner	British Society for Heart Failure representative	Consultant Cardiologist	Golden Jubilee Hospital/British Society for Heart Failure
Michael Griffith	BHRS EP/Ablation representative	Consultant Cardiologist	Queen Elizabeth Hospital Birmingham/BHRS
Simon Holmes	MHRA representative	Senior Medical Device Specialist	Medicines & Healthcare Products Regulatory Agency
Mauro Lencioni	EP/Ablation advisor-PROMS lead	Consultant Cardiologist	Queen Elizabeth Hospital Birmingham
Sue Manuel		Developer	NICOR
David Roberts	Industry representative	Marketing Manager Medtronic UK	Association of British Healthcare Industries

## 10 Glossary

Word	Acronym or abbreviation	Definition
Arrhythmia		An abnormal heart rhythm. Many arrhythmias are benign, and some do not even cause symptoms. However, some types of arrhythmia (malignant) are life-threatening.
Bradycardia		A slow heart rate (e.g. less than 40 beats/minute). Bradycardia can cause tiredness, dizzy spells/blackouts, or if the heart stops altogether, can be fatal.
Cardiac Resynchronisation Therapy	CRT	The use of pacing pulses delivered to locations on opposite sides of the left ventricle, to improve its coordination. CRT is used in some patients for the treatment of (or prevention of) heart failure. Some CRT devices only have pacemaker capability (CRT-P) while others also have defibrillation capability (CRT-D).
Complex Implant		Implant of a CRT device or an ICD
Dual Chamber		A PM or ICD with an atrial and (right) ventricular lead
First Implant		The first implant of any kind of pacemaker, ICD, or CRT or ICD in a patient. This definition will be important in future reports, which will publish the frequency of some important complications. To make these comparable between centres only complications of first implants will be reported.
Implantable Cardioverter-Defibrillator	ICD	A device that can, treat a malignant arrhythmia if necessary by delivering a shock to the patient (defibrillation). Most ICDs are also capable of acting as pacemakers
New Implant		For the purposes of the statistics in this report, a first implant of a device, or a procedure upgrading the functionality in a patient, will both be counted as "new". For example, if a patient's pacemaker is upgraded to a CRT-P, this will require an additional lead as well as a change of device, and be counted as a "new" CRT-P device.
Pacemaker (PM)	PM	A device implanted under the skin, with one or more leads connecting it to the heart, able to treat bradycardia by triggering the heartbeat with very small electrical pulses.
Replacement		Replacement of the implanted device alone, with no change to the leads. In laymans' terms, a "battery change". This can be due to the battery running down, or occasionally because of a real or potential fault in the device.
Simple implant		Implant of a single or dual chamber pacemaker
Single Chamber		A PM or ICD with a single lead in the heart (almost always the right ventricle)
Sinus node disease		Disease of the natural 'pacemaker' tissue that initiates the heartbeat. This is most commonly age-related, though it can occur for other reasons. It is one of the two common indications for pacemaker implantation
Tachycardia		A fast heart rate, typically >120 beats per minute. This can be normal (e.g. during exercise) or due to an arrhythmia
Total procedures		The total of all procedures of a type of device (new, replacement, upgrade).

## 11 References

1. NICE guidance on dual chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome and/or atrioventricular block (TA88)  
<https://www.nice.org.uk/guidance/ta88/chapter/3-The-technology>
2. NICE guidance on dual chamber pacemakers for symptomatic bradycardia due to sick sinus syndrome without atrioventricular block (TA324, update of TA88)  
<https://www.nice.org.uk/guidance/ta324>
3. NICE guidance on implantable cardioverter defibrillators and cardiac resynchronisation therapy for arrhythmias and heart failure (TA314, update of TA95)  
<https://www.nice.org.uk/guidance/ta314>
4. NICE guidance on atrial fibrillation: management (CG180)  
<https://www.nice.org.uk/guidance/cg180>
5. NICE guidance on chronic heart failure in adults: management (CG108)  
<https://www.nice.org.uk/guidance/cg108>
6. NICE guidance on acute heart failure: diagnosis and management (CG187)  
<https://www.nice.org.uk/guidance/cg187>
7. BHRS 2015 Standards for Implantation and follow up of cardiac rhythm management devices in adults  
[www.bhrs.com/standards](http://www.bhrs.com/standards)

## 12 Information for Patients about Pacemakers and Defibrillators

British Heart Foundation

<https://www.bhf.org.uk/heart-health/treatments>

Arrhythmia Alliance

<http://www.heartrhythmalliance.org/aa/uk/treatments>



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