Appendix 1: Methodology

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

The Expert Group (formerly Steering Committee)

More recently, clinical leadership has been provided by the British Heart Rhythm Society (BHRS, the successor to BPEG, and an affiliated group of the British Cardiovascular Society). The NICOR/BHRS Expert Group sets the strategy and provides oversight of the audit. It is chaired by the BHRS audit lead and meets regularly. The Expert Group includes NICOR staff, the BHRS President and Audit Lead, representation from all professional groups involved with CRM device management (doctors, physiologists, and nurses). Twice a year larger meetings are held with representation invited from HQIP, patients, and other stakeholders regularly including 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.

Confidentiality

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

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.

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. Completely

revised datasets were announced in 2013 and due to be implemented in 2014, but adoption by centres was not complete until 2015. The 2015-16 report was the first to be based entirely on the new dataset. There was no report on ablations in 2014/5 or 2015/6: this is therefore the first report using the new ablation dataset, and for this reason details of submissions in the "missing" years are given.

Definitions

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

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

- S**imple:** single or dual chamber pacemakers, for the treatment of bradycardia. These are commissioned locally (in England by Clinical Commissioning Groups)
- **Complex:** implantable defibrillators (ICDs, for patients who have suffered from, or are at high risk of, cardiac arrest) and cardiac resynchronization therapy pacemakers (**CRTP**) or defibrillators (**CRTD**), for the treatment of heart failure and risk of cardiac arrest). Complex devices are subject to Specialised Commissioning (e.g. by the Local Area Teams of NHS England).

Device procedures types: "first implant" and others

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

- **First implant**: the first time a patient has received any form of pacemaker or defibrillator. Some analyses (e.g. reintervention rates, Section 5) have looked only at first implants to achieve a uniform expectation of complication rates.
- **Replacement**: replacement of the generator, usually due to battery depletion.
- **Upgrade**: from a simple device to a complex device, (e.g. pacemaker to ICD) or from an ICD or CRT pacemaker to a CRT defibrillator. This is therefore the first time the patient has received this level of therapy. Most analyses have combined new + upgrade procedures as they represent the first time the patient has received this level of therapy. This is made explicit in each section.

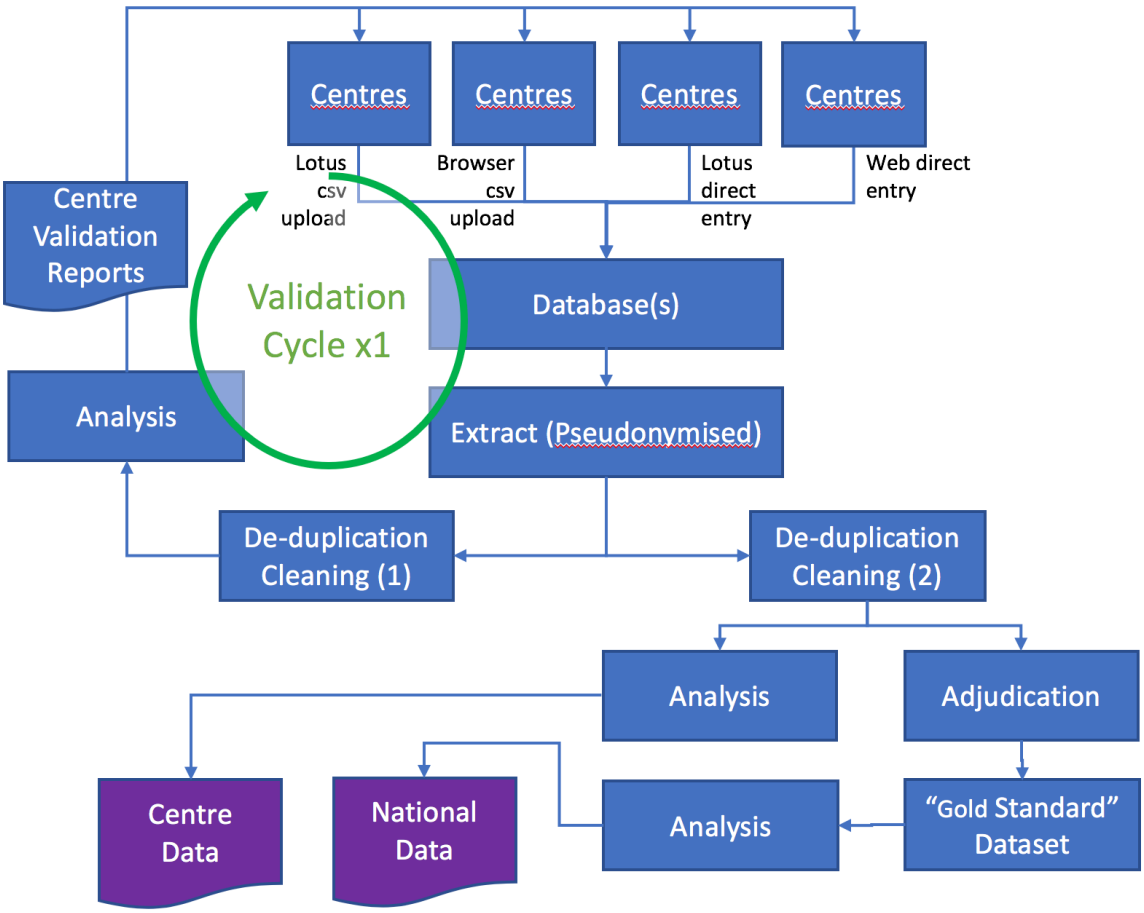
Ablation procedures

As described in Section 1 of the report, ablation procedures have been divided into

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

Data processing

The flow for data processing is shown below



1. Data Submission centres submit their records either by typing directly into the NICOR portal, or by uploading using comma-separated variable (.csv) files generated from local IT systems.
2. First extract: this is prepared containing all relevant fields; any patient-identifiable data are pseudonymised (see "confidentiality", earlier in this Appendix)
3. De-duplication: identified duplicate records are removed (the number of these is shown at the beginning of each individual centre report in Appendices 2 & 3).
4. Cleaning. Data quality among the ~100,000 records submitted each year is variable, and minor errors of syntax are common, while a small number of submissions have still followed prior dataset definitions. Corrections are made, where this can be done without ambiguity or risk of error.
5. Validation analysis. The analytic process for individual centre reports run to produce a first draft.
6. Validation. Each centre is sent the validation report, showing how its data would look once analysed; a month is allowed for centres to correct their data.
7. Final extract: a second, final extract is prepared, de-duplicated, and cleaned using identical methods.
8. Adjudication: as detailed in Section 4 of the report, some key fields have been noted to be incomplete or clearly incorrect in a minority of records. Adjudicated versions of these fields are generated as follows:
    a. *Device system type*. Where the stated device system type is clearly incompatible with the stated generator model (e.g. the system type is stated to be a dual chamber pacemaker, but the generator model is a dual chamber

defibrillator), the record is adjudicated where possible using other fields, such as the number and types of leads.

b. *Device procedure type*: where this is missing or clearly incorrect, based on compatibility with other fields, the record is adjudicated where possible with confidence.
c. *"Ablation performed?"* this field is intended to distinguish procedures in which an ablation was performed from those that were purely diagnostic or where ablation was not attempted for various reasons. In a proportion of cases (enumerated for each centre in its report) this field was incomplete or clearly incorrect based on other data. Adjudication is performed where possible with confidence.

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

9. Final analysis: the analytic code is run to produce the final centre reports and the national report with its Appendices. Note that unadjudicated data was used for all reporting relating to centres (so that their analyses reflect their data quality/completeness). However, the results for the national trends (Section 2) and the maps of implant and ablation rates across England and Wales (Appendix 4) have used adjudicated data.

Generation of interactive maps

The maps linked to in Appendix 4 show the rates of various categories of device and ablation procedures for England and Wales, according to the submitted postcode of residence of each patient. To preserve confidentiality, the postcode is converted to geographic indicators when generating the final data extract.

In order to make comparisons procedures across geographical areas, numbers are aggregated by Clinical Commissioning Groups (England) or Local Health Boards (Wales), based on the residence of the patient. Procedures were aggregated by year and geography for defined device types.

For devices (but not ablations), rates are age and sex adjusted using the indirect standardisation method. Expected deaths were calculated by multiplying the England & Wales age-specific implant rates (in 5-year age-bands) by the corresponding age-specific population for the corresponding year in each geography. The indirectly standardised rates are calculated by dividing the observed numbers of device implants by the expected numbers to create a standardised incidence ratio and the ratio is then multiplied by the England and Wales crude device implant rate to create the rates.

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

Caveats: Estimates for geographical areas are based on the patient's postcode of residence. Postcode assignment to a valid health area was over 97% complete for patient details treated at England or Wales hospitals in the CRM audit, so there are a small number of records that have not been mapped to a geographic location.

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

*Breslow NE, Day NE. Statistical methods in cancer research, volume II: The design and analysis of cohort studies. Lyon: International Agency for Research on Cancer, World Health Organization; 1987:69