

Cardiac Rhythm Management Audit Project Device Procedure Report

NICOR Report for Leeds General Infirmary
2016-17

Data extracted on **05 July, 2018**.
Period extracted: **1 April 2015 - 31 March 2018**.
Document prepared on **December 11, 2018**.
NICOR, Barts Health NHS Trust

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1 Data Quality/Completeness

Number of records in 2016-17 = **1223**

Number of records after cleaning and removal of duplicates = **1219**

1.1 Year on year change in total reported activity

This calculation is intended to highlight major changes in reported activity, especially due to missing submissions, according to the implanted system type (field 3.12, “maximum system capability”).

Table 1: Number of implanted system

| System | 2015-16 | 2016-17 | Percentage change | Definitions |
|-----------|---------|---------|-------------------|-----------------------------|
| Pacemaker | 578 | 530 | -8.3 | 3.12 = AAIR,VVIR,DDDR |
| ICD | 155 | 144 | -7.1 | 3.12 = ICD-VR,ICD-DR,ICD-SQ |
| CRT P+D | 234 | 196 | -16.2 | 3.12 = CRT-P, CRT-D |

The analysis include procedures where field 3.11 (“Intervention Category”) = new system (first implant), generator change, upgrade, generator + lead, or downgrade.

1.2 Implanted system type validation against generator

This calculation is intended to highlight errors in the reported implanted system type. This is obviously a key field used in most of the analyses. Field 3.12 (“maximum system capability”) has been compared to the make and model of generator (fields 3.19 and 3.20) as entered. An “invalid” entry may occasionally be correct if, for example a CRTD generator is implanted with no LV lead so the max system capability is ICD-DR. This table only summarises system type validation for patients with options 1 to 5 in field 3.11 (“Intervention Category”).

Table 2: Validation of maximum system capability against generator

| | n | % |
|--|-----|-------|
| Valid 3.12 (max system capability) matches 3.20 (generator model) | 863 | 99.2 |
| Invalid 3.12 (max system capability) does not match 3.20 (generator model) | 7 | 0.8 |
| Invalid 3.20 (generator model) blank or uninterpretable | 0 | 0.0 |
| Invalid 3.12 (max system capability) blank or uninterpretable | 0 | 0.0 |
| Invalid 3.12 and 3.10 blank or uninterpretable | 0 | 0.0 |
| Total | 870 | 100.0 |

Rarely, mismatches may be appropriate (e.g. a CRT-D generator with no LV lead), but most commonly field 3.12 is blank or incorrect, e.g. where VVIR is reported instead of ICD-VR. Field 3.20 is difficult to interpret: the 150 generator models used over the year were typed in using 13,000 different spellings!

1.3 Data completeness

The tables in this section show the percentages of records that are non-blank for a number of important fields. Please note that the red/amber/green boundaries defined below do not indicate that achieving >95% in each field (green) is considered adequate. For obviously important fields such as GMC, NHS No, Intervention category, Maximum system capability, generator model (where applicable), centres should aim for 100% completeness and the boundaries in future years will become more stringent to reflect this.

A “non-blank” entry does not imply that data are valid, let alone correct. For example, a GMC number that is not 7 digits will count in this analysis, but is not valid (and of course an incorrect 7-digit GMC number may have been entered). For this reason, the activity data for a centre or operator later in the report may be smaller than the expected figures in Tables 3-6 might suggest.

| |
|--------|
| >=95% |
| 90-95% |
| <90% |

Table 3: Data completeness of demographics

| | NHS No. | 1.04 Surname | 1.05 Forename | 1.06 DOB | 1.07 Sex | 1.08 Postcode |
|--------------|---------|--------------|---------------|----------|----------|---------------|
| Demographics | 99.9 | 100 | 100 | 100 | 100 | 99.6 |

Table 4: Data completeness of clinical details for patients requiring new implants and upgrades only

| | 2.02 Aetiology | 2.03 Symptom | 2.04 ECG indic. | 2.05 Atr rhyt | 2.06* NYHA | 2.07* LV function | 2.09* QRSd | 2.10* QRS morph | 2.08 ^a ICD indic |
|------------------|-------------------|-----------------|--------------------|------------------|---------------|----------------------|---------------|--------------------|--------------------------------|
| Clinical Details | 99.5 | 100 | 100 | 99.4 | 95.2 | 94.8 | 61.9 | 100 | 100 |

* only required for ICD and CRT procedures.

^a only required for ICD procedures

Table 5: Data completeness of procedure details

| | 3.03* First Op GMC | 3.09* Cons. GMC | 3.11 Interven | 3.12 System type | 3.13 Fluoro | 5.01 Acute comp. | 3.19 Manuf | 3.20 Model | 3.21 Serial No |
|-------------------|-----------------------|--------------------|------------------|---------------------|----------------|---------------------|---------------|---------------|-------------------|
| Procedure Details | 86.7 | 99 | 99.9 | 84.7 | 70 | 100 | 100 | 88 | 87.8 |

* exclude monitor procedures

2 Centre Activity

The table shows the reported interventions for the centre based on field 3.11 (“Intervention Category”) and 3.12 “Max. system capability”).

Table 6: Number of procedures by intervention category

| | First Implant | Generator Change | Upgrade | Other | Undefined | Total |
|------------------|---------------|------------------|---------|-------|-----------|-------|
| PPM | 384 | 118 | 4 | 36 | 0 | 542 |
| ICD-TV | 88 | 34 | 4 | 12 | 0 | 138 |
| ICD-subcutaneous | 9 | 3 | 0 | 0 | 0 | 12 |
| CRT-P | 54 | 16 | 12 | 7 | 0 | 89 |
| CRT-D | 50 | 39 | 14 | 12 | 0 | 115 |
| Other/blank | 0 | 0 | 0 | 35 | 1 | 36 |
| ILR | - | - | - | - | - | 137 |

Pacemaker = AAIR, VVIR, DDDR, VDDR; ICD-TV = ICD-VR, ICD-DR, ICD-VDDR.
 Records in which fields 3.11 or 3.12 are blank are not reported; for those in which 3.11 = 9 (monitor procedure only) are not broken down by intervention category.

3 Operator Activity

In this year’s and future reports, doctors will be solely identified by the stated seven-digit GMC number, and the name will be identified via the GMC register. This is because of the ubiquitous finding of multiple submitted spellings of names. For records in which the GMC number is not given or invalid, the operator will not be identified. A procedure has been ascribed to a doctor if his/her GMC number appears as first or second (scrubbed) operator, or as responsible consultant (fields 3.03, 3.06, or 3.09). It follows that each procedure may count toward the activity of up to three doctors, but if GMC numbers are missing, it may not be counted at all.

For doctors implanting bradycardia pacemakers only, BHRS standards (2015) recommends a minimum of 35 new implants a year; for those undertaking complex (ICD/CRT) procedures, a minimum of 30 of complex implants/upgrades is recommended, with a minimum of 60 total pacemaker/complex implants.

The table shows annual activity (as either first/second scrubbed operator, or responsible consultant) for each doctor uniquely identified by GMC registration No.

Table 7: Number of fitted devices

| GMC No. | Name | Pacemaker (implant/upgrade) | Pacemaker (other) | ICD/CRT (implant/upgrade) | ICD/CRT (other) |
|---------|----------------------|-----------------------------|-------------------|---------------------------|-----------------|
| 3083961 | Blackburn, Michael | 9 | 21 | 13 | 11 |
| 7026711 | Congiu, Stefano | 3 | 3 | 1 | 0 |
| 6052500 | Cullington, Damien | 1 | 0 | 0 | 0 |
| 4292328 | Graham, Lee | 33 | 9 | 13 | 12 |
| 4621832 | Hares, Dominic | 7 | 15 | 5 | 4 |
| 4713366 | Hogarth, Andrew | 45 | 10 | 29 | 12 |
| 5187461 | Jaber, Osama | 0 | 1 | 0 | 0 |
| 3082788 | O'Regan, David | 0 | 1 | 0 | 0 |
| 4615901 | Page, Stephen | 35 | 12 | 29 | 8 |
| 3309922 | Pepper, Christopher | 68 | 21 | 42 | 32 |
| 3497304 | Sapsford, Robert | 57 | 20 | 1 | 0 |
| 6050846 | Simms, Alexander | 29 | 11 | 11 | 8 |
| 6120728 | Swoboda, Peter | 24 | 8 | 11 | 5 |
| 4504780 | Tayebjee, Muzahir | 59 | 19 | 39 | 26 |
| 3187092 | Van Doorn, Catharina | 1 | 2 | 0 | 0 |
| 4107231 | Witte, Klaus | 45 | 15 | 56 | 15 |

“Pacemaker” and “ICD/CRT” are derived from field 3.12; “implant/upgrade” and “other” are from field 3.11

4 Centre compliance with national guidance

Centres' reported activity is evaluated against contemporary national guidance for bradycardia pacing and ICD implantation. NICE recommendations for CRT are complex and do not cover all indications, so CRT compliance will not be reported this year.

4.1 BHRS standard (2015) for centres implanting bradycardia pacemakers

For centres implanting bradycardia pacemakers, BHRS standards 2015 recommend an annual minimum of 80 new implants (105 for training centres). In the table below, amber is 10% below or above this threshold.

Table 8: Number of implanted bradycardia pacemakers

| n | |
|---|-----|
| Total new/upgrade pacemakers procedures | 388 |

Data are derived from fields 3.11 and 3.12 as in previous tables

4.2 BHRS standard (2015) for centres implanting ICD/CRT devices

For centres undertaking complex (ICD/CRT) device procedures, an annual minimum of 60 of these is recommended (total implants + upgrades will be reported). In the table below, amber is 10% below or above this threshold.

Table 9: Number of implanted ICD/CRT devices

| n | |
|---------------------------|-----|
| Total new/upgrade ICD/CRT | 231 |

Data are derived from fields 3.11 and 3.12 as in previous tables

4.3 NICE TA324: Dual chamber pacing in sinus node disease without AV block

Table 10: Pacing in sinus node disease

| Eligible PPM Implants | No. meeting guidance | % meeting guidance | % not meeting guidance | % indeterminate |
|-----------------------|----------------------|--------------------|------------------------|-----------------|
| 103 | 97 | 94.2 | 5.8 | 0 |

¹ PPM Eligible: Records in which (i) "Intervention" indicates first implant and (ii) "Max system capability" indicates simple pacemaker and (iii) "Atrial rhythm" is not sustained atrial arrhythmia and (iv) "ECG indication" indicates sinus node disease.

² Meeting guidance: No. of records in previous column where recommended type has been implanted (3.12 = AAIR or DDDR)

³ Not Meeting guidance: % of records where other system (i.e. VVIR/VDDR) has been implanted

⁴ Indeterminate: % of records where compliance cannot be adjudicated due to missing/invalid data

4.4 NICE TA88: Dual chamber pacing in AV block

Table 11: Pacing in AV block

| Eligible PPM Implants | No. meeting guidance | % meeting guidance | % not meeting guidance | % indeterminate |
|-----------------------|----------------------|--------------------|------------------------|-----------------|
| 111 | 102 | 91.9 | 8.1 | 0 |

¹ PPM Eligible: Records in which (i) “Intervention” indicates first implant and (ii) “Max system capability” indicates simple pacemaker and (iii) “Atrial rhythm” is not sustained atrial arrhythmia and (iv) “ECG indication” indicates AV block or conduction disease.

² Meeting guidance: No. of records in previous column where recommended type has been implanted (3.12 = DDDR or VDDR)

³ Not Meeting guidance: % of records where other system (i.e. AAIR or VVIR) has been implanted

⁴ Indeterminate: % of records where compliance cannot be adjudicated due to missing/invalid data

4.5 NICE TA314: ICD for primary prevention

Table 12: Primary prevention ICD implants

| Eligible ICD Implants | No. meeting guidance | % meeting guidance | % not meeting guidance | % indeterminate |
|-----------------------|----------------------|--------------------|------------------------|-----------------|
| 45 | 38 | 84.4 | 8.9 | 6.7 |

¹ ICD Eligible: Records in which (i) “Intervention” indicates first implant and (ii) “Max system capability” indicates ICD-VR or ICD-DR or ICD-SQ and (iii) “ICD indication” indicates primary prevention.

² Meeting guidance: No. of records where either (i) “Aetiology” indicates cardiomyopathy other than DCM (HCM, ARVC, amyloid, sarcoid, other), channelopathy or structural congenital HD; or (ii) “LV function” is poor; and “NYHA status” is not IV.

³ Not Meeting guidance: % of records where the above criteria are not met

⁴ Indeterminate: % of records where compliance cannot be adjudicated due to missing/invalid data

4.6 NICE TA314: ICD for secondary prevention

Table 13: Secondary prevention ICD implants

| Eligible ICD Implants | No. meeting guidance | % meeting guidance | % not meeting guidance | % indeterminate |
|-----------------------|----------------------|--------------------|------------------------|-----------------|
| 52 | 45 | 86.5 | 13.5 | 0 |

¹ ICD Eligible: Records in which (i) “Intervention” indicates first implant and (ii) “Max system capability” indicates ICD-VR or ICD-DR or ICD-SQ and (iii) “ICD indication” indicates secondary prevention.

² Meeting guidance: No. of records in previous column where procedures were either (i) “Symptom” includes cardiac arrest or aborted sudden death; or (ii) “Symptom” includes syncope and “ECG indication” includes nonsustained VT/VF or sustained VT/VF or torsade de pointes; or (iii) “ECG Indication” includes sustained VT/VF and LV Function is poor

³ Not Meeting guidance: % of records where the above criteria are not met.

⁴ Indeterminate: % of records where compliance cannot be adjudicated due to missing/invalid data

5 1-year all-cause reintervention

As an index of late complications, we will be reporting all-cause reintervention within 12 months of a first device implant - only in centres with $\geq 90\%$ completeness of NHS No. in both of the two years used for analysis. This will be ascribed to the original implanting centre, not the centre undertaking the reintervention. This year patients will be tracked purely by NHS No, but more sophisticated methods will be used in future.

It is understood that reintervention does not always reflect a complication from the original procedure: it may be due to a manufacturers recall or a change in clinical indication, for example. In future reports, we will take these factors (if appropriately documented in later fields in the dataset) into account.

Table 14: Re-interventions within a year

| | First implants in 2015-16 (n)* | Reinterventions within 1 year (n)† | Reinterventions within 1 year (%) |
|-----------------|--------------------------------|------------------------------------|-----------------------------------|
| Simple devices | 407 | 18 | 4.42 |
| Complex devices | 243 | 12 | 4.94 |

* No. of patients where “Intervention” = first implant and “Max system capability” indicates AAIR/VVIR/DDDR/VDDR (simple) or ICD-VR/ICD-DR/ICD-SQ/CRTP/CRTD (complex)

† Of these, no. of patients identified who have undergone a further intervention (other than ‘monitor procedure only’) within 365 days.

Of first implants performed in 2015-16, 5 patient(s) with simple devices and 1 patient(s) with complex devices had a reintervention within one year in a different hospital.