

Cardiac Rhythm Management Audit Project Device Procedure Report

NICOR Report for Forth Valley Royal
2019-20

This report is based on data extracted on **6 April, 2021**.
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1 Data Quality/Completeness

Number of records in 2019-20 = **132**

Number of records after cleaning and removal of duplicates = **100**

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	2018-19	2019-20	Percentage change	Definitions
Pacemaker	30	40	33.3	3.12 = AAIR,VVIR,DDDR
ICD	13	10	-23.1	3.12 = ICD-VR,ICD-DR,ICD-SQ
CRT P+D	7	9	28.6	3.12 = CRT-P, CRT-D

In accordance with ONS guidance, exact data have been suppressed where case numbers are less than 3 and approximate values provided- if applicable- when suppressed values could be derived, to ensure anonymity of patient data.

The analysis include all 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 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 apparently “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)	53	81.5
Invalid 3.12 (max system capability) does not match 3.20 (generator model)	7	10.8
Invalid 3.20 (generator model) blank or uninterpretable	0	0
Invalid 3.12 (max system capability) blank or uninterpretable	5	7.7
Invalid 3.12 and 3.10 blank or uninterpretable	0	0
Total	65	100

Exact data have been suppressed where case numbers are less than 3 and approximate values provided- if applicable- when suppressed values could be derived, to ensure anonymity of patient data.

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 due to multiple ways the generator is typed by centres.

1.3 Data completeness

The tables in this section show the percentages of records 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. GMC number entries that are not seven digits are regarded as invalid and are not counted. 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. In future, validity checks on other fields (e.g. permissible values for NYHA class and QRSd) will be introduced.

>=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	87	100	100	100	100	75

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

	2.02	2.03	2.04	2.05	2.06*	2.07*	2.09*	2.10*	2.08 ^a
Clinical Details	Aetiology	Symptom	ECG indic.	Atr rhyt	NYHA	LV function	QRSd	QRS morph	ICD indic
	75	93.2	84.1	75	92.3	100	69.2	100	100

* only required for ICD and CRT procedures.

^a only required for ICD procedures

Table 5: Data completeness of procedure details

	3.03*	3.09*	3.11	3.12	3.13 ^a	5.01	3.19 ^b	3.20 ^b	3.21 ^b
Procedure Details	First Op GMC	Cons. GMC	Interven	System type	Fluoro	Acute comp.	Manuf	Model	Serial No
	0	0	94	90	0	100	96.9	100	98.5

* exclude monitor procedures

^a Records in which fields 3.11 = 1,3,4

^b Records in which fields 3.11= 1-5

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 (total) (including LCP)	28 (0)	12 (0)	0 (0)	0 (0)	< 3 (0)	< 44 (0)
ICD-TV	6	3	< 3	0	< 3	< 13
ICD-subcutaneous	0	0	0	0	0	0
CRT-P	4	< 3	< 3	< 3	0	< 9
CRT-D	< 3	< 3	0	0	< 3	< 5
Other/blank	< 3	3	0	0	< 3	< 8
ILR	-	-	-	-	-	24

Exact data have been suppressed where case numbers are less than 3 and approximate values provided- if applicable- when suppressed values could be derived, to ensure anonymity of patient data.

Pacemaker = AAIR, VVIR, DDDR, VDDR; ICD-TV = ICD-VR, ICD-DR, ICD-VDDR. LCP = leadless cardiac pacemakers, identified by 3.20 generator model. 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 common 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 (2017) 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.

There is no table presented here because this hospital either did not submit information on GMC numbers or did not perform relevant procedures.

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 (2017) for centres implanting bradycardia pacemakers

For centres implanting bradycardia pacemakers, BHRS standards (2017) recommend an annual minimum of 80 new implants (100 for training centres). In the table below, amber is 10% below or above this threshold.

Table 7: Number of implanted bradycardia pacemakers

n	
Total new pacemakers procedures	28

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data. Data are derived from fields 3.11 and 3.12 as in previous tables

4.2 BHRS standard (2017) for centres implanting ICD/CRT devices

For centres undertaking complex (ICD/CRT) device procedures, BHRS standards (2017) recommend an annual minimum of 60 (total implants + upgrades will be reported). In the table below, amber is 10% below or above this threshold.

Table 8: Number of implanted ICD/CRT devices

n	
Total new/upgrade ICD/CRT	13

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data. 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 9: Pacing in sinus node disease

Eligible PPM Implants	No. meeting guidance	% meeting guidance	% not meeting guidance	% indeterminate
< 3	-	-	-	-

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data.

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 10: Pacing in AV block

Eligible PPM Implants	No. meeting guidance	% meeting guidance	% not meeting guidance	% indeterminate
11	10	90.9	9.1	0

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data.

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 11: Primary prevention ICD implants

Eligible ICD Implants	No. meeting guidance	% meeting guidance	% not meeting guidance	% indeterminate
4	4	100	0	0

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data.

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 12: Secondary prevention ICD implants

Eligible ICD Implants	No. meeting guidance	% meeting guidance	% not meeting guidance	% indeterminate
< 3	-	-	-	-

Exact data have been suppressed where case numbers are less than 3, to ensure anonymity of patient data.

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 re-intervention

As an index of late complications, we will be reporting all-cause re-intervention within 12 months of a first device implant. This will be ascribed to the original implanting centre, not the centre undertaking the re-intervention where the re-intervention was at a different centre. In this analysis, patients have been tracked by both NHS No. and Hospital/Hospital No. However, because under-reporting of NHS No. may lead to re-interventions being under-identified, the national report will only include centres with $\geq 90\%$ completeness of NHS No. in both years (2018-19 and 2019-20) used for analysis; the data deficiency will be highlighted for other centres.

It is understood that re-intervention 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.

The NHS numbers for one or both years (2018-19 and 2019-20) necessary for reintervention analysis had less than 90% completeness, therefore reinterventions are likely to be underestimated.

Table 13: Re-interventions within a year

	No. of first implants in 2018/19*	Re-interventions within 1 year†
Simple devices	21	< 3 (< 7%)
Complex devices	7	0 (0%)

Exact data have been suppressed where case numbers are less than 3 and approximate values provided- if applicable- when suppressed values could be derived, to ensure anonymity of patient data.

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

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