Development, Implementation and Audit of Locally Agreed Standards for Permanent Pacemaker Follow-Up

Presenting Author: E. Beaney, Highly Specialised Cardiac Physiologist
The James Cook University Hospital, Middlesbrough, UK

Outline

• Why is the quality assurance (QA) process needed?
• QA standards
• Data collection
• Results
• Conclusions
Why is QA needed?

- QA identifies variation in clinical practice
- No comprehensive standards
  - HRS/EHRA\(^1\)
  - BHRS\(^2\)
- BHRS recommend a formal QA process
- Suboptimal programming common\(^3\)

1) Wilkoff et al. Europace 2008
2) BHRS Council, 2015
3) Ziacchi et al. Europace 2017
QA Standards

• Patient symptoms documented?
  - Symptoms potentially ppm-related thoroughly investigated?
  - If heart failure symptoms reported, has appropriate referral been made or investigation been performed?
  - Appropriate advice given if non-pacemaker related?

• Wound check documented?
  - If abnormal clinical features, has further advice been sought?

• Presenting ECG rhythm and rate, and EGM markers recorded?
  - If inappropriate device function seen, have settings been adjusted?

• Underlying rhythm recorded?
  - If AV conduction seen, is algorithm programmed on to minimise V pacing (or justification of why not)?
  - If previous AV node ablation, has CHB been confirmed?
  - Programmed mode appropriate for current pacing indication?

• Battery status recorded (Longevity / voltage / magnet rate / impedance)?
  - If discrepancy between battery parameters, has further advice been sought from manufacturer?
  - At 6/12 remaining has assessment of need for device, or a referral to the CRM nurses been made?
  - Changes made to maximise longevity where box change is less desirable?

• Threshold measurements recorded?
  - Measurements verified?
  - Pulse width / unipolar threshold performed if high?
  - Appropriate output programmed / automatic capture management algorithm programmed on?

• Sensing measurements recorded?
  - Measurements verified?
  - Appropriate sensitivity programmed?

• Impedance measurements recorded?
  - Measurements verified?
  - If significant change in impedance, have further investigations been performed (arm movements, chest X-ray)?

• % Atrial and ventricular pacing recorded?

• Heart rate histograms assessed and documented?
  - If inadequate heart rate variation, have settings been adjusted (or justification given if not)?
  - If high ventricular rates in AF seen, has letter been sent to GP / Consultant?
  - If increased proportion at max tracking rate, have settings been adjusted?
**QA Standards**

- Appropriate lower rate limit programmed?
  - Is AMS base rate appropriate?

- Appropriate upper tracking rate programmed?

- Appropriate upper sensor rate programmed?

- Atrial high rate episodes documented?
  - EGM correctly interpreted?
    - If noise, have further investigations been performed (arm movements / impedance trends assessed / chest X-ray)?
  - If oversensing, have settings been adjusted?
  - Longest / fastest episode noted?
  - If symptomatic, has this been escalated?

- PMTs documented?
  - Is PMT prevention / termination algorithm on?
  - If no algorithm available, or algorithm ineffective, has VA conduction been evaluated and PVARP adjusted?

- Rate drop response / CLS programmed on for cardio-inhibitory patients?
  - If MHRA advisory on device / lead, has it been adhered to?

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- Changes to device programming documented?

- Next required follow-up documented?
  - Is the time period appropriate?

- Are reports printed?

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**AHRE**

- EGM correctly interpreted?
  - Anticoagulation confirmed / GP letter sent?
  - If MHRA advisory on device / lead, has it been adhered to?

- VHRE
  - If oversensing, have settings been adjusted?
  - If symptomatic, has this been escalated?

- If symptomatic SVT, has letter been sent to GP or Consultant?

- Is rate response programmed on during mode switch?

- Has the device been reprogrammed to VVIR if permanent AF (≥1 year)?
Data Collection

- Retrospective audit of pacemaker follow-ups

First audit cycle (100 patients)

- Results disseminated
- Changes implemented

Second audit cycle (100 patients)
Demographics

• 200 patients

<table>
<thead>
<tr>
<th></th>
<th>Audit One</th>
<th>Audit Two</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean Age (±SD)</strong></td>
<td>75 (±13)</td>
<td>77 (±10)</td>
</tr>
<tr>
<td><strong>Mean Device Age (±SD)</strong></td>
<td>3.5 (±3)</td>
<td>3.6 (±3)</td>
</tr>
<tr>
<td><strong>% Male</strong></td>
<td>59</td>
<td>56</td>
</tr>
<tr>
<td><strong>% Dual chamber</strong></td>
<td>72</td>
<td>69</td>
</tr>
</tbody>
</table>

• p = NS between groups
• Abbott (69), Boston (64), Medtronic (55), Sorin (10), Vitatron (2)
## Pacing Indications

<table>
<thead>
<tr>
<th>Condition</th>
<th>Audit One</th>
<th>Audit Two</th>
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<tbody>
<tr>
<td>CHB</td>
<td>30</td>
<td>37</td>
</tr>
<tr>
<td>SND</td>
<td>26</td>
<td>25</td>
</tr>
<tr>
<td>AF + Brady</td>
<td>10</td>
<td>13</td>
</tr>
<tr>
<td>AF + AVNA</td>
<td>9</td>
<td>10</td>
</tr>
<tr>
<td>2:1 AVB</td>
<td>4</td>
<td>7</td>
</tr>
<tr>
<td>Mobitz I</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>Mobitz II</td>
<td>7</td>
<td>1</td>
</tr>
<tr>
<td>Trifascicular Block</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Bifascicular Block</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>First Degree AVB</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td>Cardioinhibitory VVS</td>
<td>1</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>
Changes Implemented

• **Areas for improvement**
  - Documenting heart rate histograms (36% compliance) PMTs (8%) & ULR (78%)
  - MHRA advisories (81%)
  - HF symptoms (67%)
  - Symptomatic SVT (50%)

• **Changes implemented following result feedback**
  - Follow-up form adapted
  - Advisories listed
  - HF referral letter
  - Symptomatic SVT protocol
  - Anticoagulation status for permanent AF / VVIR devices
Results

Overall QA Compliance

92% vs 98% (p < 0.001)

<table>
<thead>
<tr>
<th>Audit One</th>
<th>Audit Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
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</table>
QA Compliance by Subgroup - Episodes

<table>
<thead>
<tr>
<th>QA Standard</th>
<th>Audit One</th>
<th>Audit Two</th>
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</thead>
<tbody>
<tr>
<td>AHRE</td>
<td>90</td>
<td>90</td>
</tr>
<tr>
<td>VHRE</td>
<td>70</td>
<td>70</td>
</tr>
<tr>
<td>PMT Documented</td>
<td>5</td>
<td>25</td>
</tr>
<tr>
<td>Anticoagulation</td>
<td>90</td>
<td>90</td>
</tr>
</tbody>
</table>

p = NS  p = 0.008  p = 0.009  p = NS
QA Compliance by Subgroup

<table>
<thead>
<tr>
<th>QA Standard</th>
<th>Audit One</th>
<th>Audit Two</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maximising Longevity</td>
<td>p = NS</td>
<td>p = NS</td>
</tr>
<tr>
<td>MHRA Advisory</td>
<td>p = NS</td>
<td>p = NS</td>
</tr>
<tr>
<td>Follow-up</td>
<td>p = NS</td>
<td>p = NS</td>
</tr>
<tr>
<td>Changes Documented</td>
<td>p = NS</td>
<td>p = NS</td>
</tr>
</tbody>
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% Compliance
Conclusions

• National guidance for follow-up is lacking
• Local implementation has improved quality of care
• Highlighted areas of ambiguity
• QA standards do not replace clinical judgement
• Ongoing process - extended to ICD / CRT follow-up
• Robust QA process should be implemented across all follow-up centres
Any Questions?

Email – emma.beaney@nhs.net