APPTG Annual Conference 2017

#APPTG
Peter MacCallum - Declarations

• Honoraria – Bayer, Boehringer-Ingelheim, Daiichi-Sankyo
• Advisory committees – Daiichi-Sankyo
• Sponsorship to attend meetings – Boehringer-Ingelheim, Daiichi-Sankyo
Aims of GARFIELD-VTE

• To provide insights into the evolving global patterns of treatment for VTE

• To inform the study of aspects of the natural history of VTE:
  • Rate of early and late VTE recurrence
  • Incidence of complications of VTE of importance to patients including
    • Post Thrombotic Syndrome (PTS)
    • Chronic Thromboembolic Pulmonary Hypertension (CTEPH)

• To provide information on:
  • Adherence to national and international guidelines
  • Identify good practice as well as treatment deficiencies
  • Relate patient outcomes to clinical management

• To define economic and societal impact of VTE at a regional and global level
Participating countries

10,878 patients in 28 countries

AMERICA
- Argentina
- Brazil
- Canada
- Mexico
- United States of America

EUROPE
- Belgium
- Czech Republic
- Denmark
- France
- Germany
- Italy
- The Netherlands
- Russia
- Spain
- Switzerland
- United Kingdom

ASIA & OCEANIA
- Australia
- China
- Hong Kong
- Japan
- Malaysia
- South Korea
- Taiwan
- Thailand
- Turkey
- United Arab Emirates

AFRICA
- Egypt
- South Africa

www.garfieldregistry.org
The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG
Study Design

### Design
- Independent academic research initiative
- 10000 newly diagnosed VTE patients in 28 countries
- Randomised selection of sites representative of national VTE care settings
- Unselected prospective patients enrolled consecutively
- Long-term follow-up (minimum of 3 yrs)
- Two sequential cohorts of 5000 patients

### Audit requirements
- 5% of all CRFs monitored against source documentation
- Electronic audit trail for all data modifications
- Critical variables subjected to additional audit
- Compliant with Declaration of Helsinki

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**Minimum Patient Follow-up Period (36 Months)**

- **Cohort 1**
  - Recruitment Period
  - N=5000
  - Year 1
  - Year 2
  - Year 3

- **Cohort 2**
  - Recruitment Period
  - N=5000
  - Year 1
  - Year 2
  - Year 3

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**TRI Thrombosis Research Institute**

**www.garfieldregistry.org**

The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG
GARFIELD-VTE journey – a review of how far we have come

- First patient in 2014
- Recruitment complete 2016
- Methods paper published
- First GARFIELD-VTE abstracts presented at ISTH 2017

www.garfieldregistry.org
The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG
GARFIELD-VTE represents a broad cross-section of VTE patients

<table>
<thead>
<tr>
<th>Variable</th>
<th>N=10 677</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>5300 (49.6)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>60.2 (46.1 to 71.7)</td>
</tr>
<tr>
<td>Race/Ethnicity(^1), n (%)</td>
<td></td>
</tr>
<tr>
<td>White</td>
<td>6946 (69.1)</td>
</tr>
<tr>
<td>Asian</td>
<td>1969 (19.6)</td>
</tr>
<tr>
<td>Black</td>
<td>465 (4.6)</td>
</tr>
<tr>
<td>Multi-racial</td>
<td>57 (0.6)</td>
</tr>
<tr>
<td>Other / Unknown</td>
<td>429 (4.3) / 192 (1.9)</td>
</tr>
<tr>
<td>Prior episode of VTE, n (%)</td>
<td>1604 (15.0)</td>
</tr>
<tr>
<td>Active Cancer, n (%)</td>
<td>981 (9.2)</td>
</tr>
<tr>
<td>History of cancer, n (%)</td>
<td>662 (6.2)</td>
</tr>
<tr>
<td>Family history of VTE, n (%)</td>
<td>636 (6.0)</td>
</tr>
<tr>
<td>Known thrombophilia, n (%)</td>
<td>306 (2.9)</td>
</tr>
</tbody>
</table>

\(^1\)Missing n=619

Date of analyses: April 2017
GARFIELD-VTE is revealing country differences in characteristics of patients with VTE

<table>
<thead>
<tr>
<th>Variable</th>
<th>South Africa (N=416)</th>
<th>GLOBAL (N=10677)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female, n (%)</td>
<td>266 (63.9)</td>
<td>5300 (49.6)</td>
</tr>
<tr>
<td>Age, years, median (IQR)</td>
<td>49.0 (36.0 to 63.0)</td>
<td>60.2 (46.1 to 71.7)</td>
</tr>
<tr>
<td>Age range, n (%) &lt; 35 yrs</td>
<td>93 (22.3)</td>
<td>1345 (12.6)</td>
</tr>
<tr>
<td></td>
<td>96 (23.1)</td>
<td>1379 (12.9)</td>
</tr>
<tr>
<td>36 to 45 yrs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>46 to 55 yrs</td>
<td>59 (14.2)</td>
<td>1822 (17.1)</td>
</tr>
<tr>
<td>56 to 65 yrs</td>
<td>77 (18.5)</td>
<td>2263 (21.2)</td>
</tr>
<tr>
<td>66 to 75 yrs</td>
<td>65 (15.6)</td>
<td>2222 (20.8)</td>
</tr>
<tr>
<td>76 to 85 yrs</td>
<td>20 (4.8)</td>
<td>1371 (12.8)</td>
</tr>
<tr>
<td>86+ yrs</td>
<td>6 (1.4)</td>
<td>255 (2.6)</td>
</tr>
<tr>
<td>Acute medical illness</td>
<td>102 (24.5)</td>
<td>594 (5.6)</td>
</tr>
</tbody>
</table>

Date of analyses: April 2017

www.garfieldregistry.org

The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG
37.5% of patients have at least 1 transient provoking risk factor\(^1\) (within the last 3 months before enrolment)

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>N=10 677</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>1333 (12.5)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>1277 (12.0)</td>
</tr>
<tr>
<td>Trauma of the limb</td>
<td>829 (7.8)</td>
</tr>
<tr>
<td>Acute medical illness</td>
<td>594 (5.6)</td>
</tr>
<tr>
<td>Long-haul travel</td>
<td>520 (4.9)</td>
</tr>
<tr>
<td>Pregnancy(^2)</td>
<td>189 (3.6)</td>
</tr>
<tr>
<td>Oral contraception(^2)</td>
<td>527 (9.9)</td>
</tr>
<tr>
<td>Hormone replacement therapy(^2)</td>
<td>143 (2.7)</td>
</tr>
</tbody>
</table>


\(^2\) Calculated as a percentage of women (n=5300)
61.7% of VTE patients present with DVT only

DVT includes arm and leg thrombosis, vena cava and atypical sites.

Date of analyses: 24th April 2017

Proportion of patients, %

<table>
<thead>
<tr>
<th>Condition</th>
<th>Proportion</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT only (n=6589)</td>
<td>61.7%</td>
<td>10,677</td>
</tr>
<tr>
<td>PE +/- DVT (n=4088)</td>
<td>38.3%</td>
<td></td>
</tr>
</tbody>
</table>

DVT includes arm and leg thrombosis, vena cava and atypical sites.
CT, Computed tomography; MRV, magnetic resonance venography;

Patients may have received more than one test and so the values are not mutually exclusive

Date of analyses: 24th April 2017
Diagnostic Investigation / Assessment for PE

MRA, magnetic resonance angiography; *Transthoracic and/or Transoesophageal

Patients may have received more than one test and so the values are not mutually exclusive

Date of analyses: 24th April 2017

Any CT: 91.8%
Ventilation perfusion scan: 10.4%
MRA: 0.2%
Biomarkers including D-dimer: 16.3%
D- Echocardiography*: 14.2%

Confirmatory diagnostic
Other investigation
AC treatment patterns – by geographic region

Date of analyses: 24th April 2017

1 Other is defined as: Argentina, Australia, Brazil, Egypt, Mexico, South Africa and United Arab Emirates
## Geographic variations in AC prescribing, e.g. Australia

<table>
<thead>
<tr>
<th></th>
<th>North America (n=852)</th>
<th>Europe (n=5333)</th>
<th>Australia (n=356)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Parenteral AC Only</td>
<td>12.7</td>
<td>14.2</td>
<td>10.5</td>
</tr>
<tr>
<td>VKA + Parenteral AC</td>
<td>31.6</td>
<td>28.2</td>
<td>9.2</td>
</tr>
<tr>
<td>VKA Only</td>
<td>2.5</td>
<td>3.4</td>
<td>1.3</td>
</tr>
<tr>
<td>DOACS Only</td>
<td>16.8</td>
<td>26.3</td>
<td>43.1</td>
</tr>
<tr>
<td>DOACS + Parenteral</td>
<td>36.5</td>
<td>27.9</td>
<td>35.9</td>
</tr>
</tbody>
</table>

Date of analyses: 24\textsuperscript{th} April 2017

www.garfieldregistry.org

The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG
From initial anticoagulation to secondary prevention and beyond AC treatment within ± 30 days and on day 90 and day 180

N=9111

Date of analyses: 24th April 2017
Global Enrolment: By Country

Total Enrolled = 10,878

www.garfieldregistry.org

The GARFIELD-VTE registry is funded by an unrestricted research grant from Bayer AG.
GARFIELD-VTE - 20 sites in the UK

- 16 sites in England
- 2 sites in Scotland
- 1 site in Northern Ireland
- 1 site in Wales
Patient Population from UK

Assessed for eligibility, n=1084
- Declined to participate
- Not meeting protocol-defined inclusion/exclusion criteria
- Deceased before consent

Excluded after screening, n=200

Enrolled, n=884

Patients with objectively confirmed diagnosis of VTE, n=865

1 As defined by Bates et al Chest 2012; 141(Suppl): e351S–e418S

Date of analyses: 24th April 2017
Site of VTE

DVT includes arm and leg thrombosis, vena cava and atypical sites

Date of analyses: 24th April 2017

Proportion of patients, %

<table>
<thead>
<tr>
<th></th>
<th>Europe</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVT only</td>
<td>59</td>
<td>64.2</td>
</tr>
<tr>
<td>PE +/- DVT</td>
<td>41</td>
<td>35.8</td>
</tr>
</tbody>
</table>

DVT includes arm and leg thrombosis, vena cava and atypical sites
Site of DVT

Date of analyses: 24th April 2017
**Baseline Demographics**

<table>
<thead>
<tr>
<th>Variable</th>
<th>UK (N=865)</th>
<th>Europe (N=5123)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Tobacco use, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Current or ex-smoker</td>
<td>365 (47.4)</td>
<td>2063 (41.8)</td>
</tr>
<tr>
<td><strong>Body mass index, median (IQR)</strong></td>
<td>29.1 (25.3 to 33.4)</td>
<td>27.4 (24.5 to 31.2)</td>
</tr>
<tr>
<td><strong>Body mass index, n (%)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Underweight</td>
<td>3 (0.5)</td>
<td>57 (1.2)</td>
</tr>
<tr>
<td>Normal</td>
<td>122 (22.1)</td>
<td>1307 (27.3)</td>
</tr>
<tr>
<td>Overweight</td>
<td>175 (31.8)</td>
<td>1919 (40.2)</td>
</tr>
<tr>
<td>Obese I (30.0-34.9 kg/cm²)</td>
<td>137 (24.9)</td>
<td>962 (20.1)</td>
</tr>
<tr>
<td>Obese II (35.0 to 39.9 kg/cm²)</td>
<td>65 (11.8)</td>
<td>372 (7.8)</td>
</tr>
<tr>
<td>Obese III (40 kg/cm² or greater)</td>
<td>49 (8.9)</td>
<td>162 (3.4)</td>
</tr>
</tbody>
</table>

Date of analyses: April 2017
## Transient provoking risk factor\(^1\) (within the last 3 months before enrolment)

<table>
<thead>
<tr>
<th>Variable, n (%)</th>
<th>UK (N=865)</th>
<th>Europe (N=5123)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td>100 (11.6)</td>
<td>565 (10.9)</td>
</tr>
<tr>
<td>Hospitalization</td>
<td>72 (8.3)</td>
<td>529 (10.2)</td>
</tr>
<tr>
<td>Trauma of the limb</td>
<td>80 (9.2)</td>
<td>425 (8.2)</td>
</tr>
<tr>
<td>Acute medical illness</td>
<td>39 (4.5)</td>
<td>267 (5.2)</td>
</tr>
<tr>
<td>Long-haul travel</td>
<td>88 (10.2)</td>
<td>251 (4.8)</td>
</tr>
<tr>
<td>Pregnancy(^2)</td>
<td>8 (0.9)</td>
<td>72 (1.4)</td>
</tr>
<tr>
<td>Oral contraception(^2)</td>
<td>22 (2.5)</td>
<td>300 (5.8)</td>
</tr>
<tr>
<td>Hormone replacement therapy(^2)</td>
<td>12 (1.4)</td>
<td>86 (1.7)</td>
</tr>
</tbody>
</table>


\(^2\) Calculated as a percentage of women

Date of analyses: April 2017
# Planned Treatment Strategy

<table>
<thead>
<tr>
<th></th>
<th>UK (n=865)</th>
<th>Europe (n=5123)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Anticoagulant therapy</strong></td>
<td>863 (99.8%)</td>
<td>4689 (91.5%)</td>
</tr>
<tr>
<td><strong>Thrombolytic/Fibrinolytic Therapy</strong></td>
<td>10 (1.2%)</td>
<td>219 (4.3%)</td>
</tr>
<tr>
<td><strong>Surgical/Mechanical Interventions</strong></td>
<td>4 (0.5%)</td>
<td>77 (1.5%)</td>
</tr>
<tr>
<td><strong>Compression Therapy</strong></td>
<td>119 (13.8%)</td>
<td>2824 (55.1%)</td>
</tr>
</tbody>
</table>

**Thrombolytic**: Systemic or catheter-directed

**Surgical Mechanical**: IVC filter, pulmonary embolectomy, thrombectomy

**Compression**: Bandages or stockings

Date of analyses: April 2017
Conclusions

• GARFIELD VTE is providing a contemporary global picture of the patient characteristics and management of VTE

• Global profile demonstrates differences between countries in baseline characteristics and management practices

• Longer-term follow-up than in clinical trials enables capture of outcomes of particular importance to patients
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#APPTG
Overview of current patient safety initiatives in VTE

Graeme Kirkpatrick
Head of Patient Safety – Advice & Guidance
National Patient Safety Team

Primarily aimed at identifying new and under-recognised patient safety issues.

For example –

An 85 year old male patient attended [hospital] for a routine pacemaker check follow up appointment on Friday [date]. An incidental finding of atrial fibrillation was discovered. The cardiac physiologist referred the patient to the anticoagulation clinic on the same day, referring the patient electronically. The following day the patient unfortunately suffered a stroke on Saturday [date + 1 day] and was subsequently admitted to [hospital’s] Hyper Acute Stroke Unit. The patient passed away on [date + 11 weeks]. The referral for the anticoagulation clinic was picked up on Monday [date + 2 days], an appointment letter was sent for a clinic appointment on [date + 6 weeks]. This was approximately 6 weeks after the patient was referred.

Whilst outcome may not have been different, we are considering if incidental findings and need to start anticoagulation timely in these clinical settings is a new issue.

NCD contacted for comment
VTE Risk Assessment

• From April 2017 NHSI took on responsibility as the publisher of official statistics for VTE from NHS England.
• The official statistics for VTE risk assessment in England for Q1 2017/18 were released on 1 September 2017
• Key findings:
  – 95% of all adult IP admissions to NHS-funded acute care received a VTE risk assessment
  – 96% from Q3 2015/16 to Q4 2016/17 but has decreased to 95% in Q1 2017/18
  – Percentage receiving a VTE risk assessment was slightly lower for NHS acute care providers (95%) compared to independent sector providers (98%).

Deaths from VTE related events within 90 days post discharge from hospital

- a slowly improving trend for this indicator, although it can be subject to fluctuations between individual years.
- 2015/16: 64.3 deaths per 100,000 hospital admissions, which equates to a decrease of 5.9 percent compared to the previous year.
- over the whole time series, the indicator has decreased by 10.8 percent.
- rise in 2012/13 due to changes in ICD10 coding
NICE Guidance

- Consultation just closed on updated NICE Guidance - **Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism**
- Expected publication date: **21 March 2018**
- The current national data collection guidance added definitions and clarifications over and above the 2010 NICE VTE guidance, in order to make the national data collection consistent.
- NHSI is working with NICE to **ensure guidance is clear and specific** on which patients need risk assessment, and how soon it should be done.
- However, NHSI is keen that NICE produces the **standalone version of guidance** so that the national data collection guidance echoes rather than expands on the updated NICE guideline.
National Clinical Audit

Healthcare Quality Improvement Partnership (HQIP) commissioned the Health Innovation Network, hosted by Guys and St Thomas, to test both the feasibility and the likely impact, of a National Clinical Audit for VTE Prevention by identifying:

- what would be its specific improvement aims;
- the patient group(s) and services that it should include;
- the quality indicators and outcome measures that would best support the improvement aims;
- the methodology that would deliver its required outcomes most efficiently and effectively in terms of local burden and central costs; and
- the roles, groups and/or professions who would need to be influenced to realise and drive any required change locally and their needs in terms of reporting and other outputs.

The project is contracted to run until December 2017.
A full NCA will become major driver of further improvement.
Growing shift to the newer anticoagulants (DOACs or NOACs), with associated increase in expenditure - cost of DOACs as a percentage of total anticoagulation costs:
- 2014/15 was 27%, 2015/16 it was 46% and 2016/17 it was 59%.

Increase is likely to be due to a number of factors
- existence of NICE guidance,
- GPs being incentivised to find and treat AF
- national push on DOAC prescribing as a measure of the NHS's ability to adopt innovation.

Significant variation in use of DOACs - 16% to 74% between CCGs, as a proportion of all prescribed anticoagulant items.

National average DOAC use is approximately 34%, which sits within an expected normal distribution.

As an initial step to addressing this challenge, NHS England has commissioned the Evidence for Policy and Practice Information and Co-ordinating (EPPI) Centre to carry out a literature review to assess the clinical evidence published since the NICE guidance. The review will include both national and international peer reviewed research and specifically focus on efficacy, safety and patient experience.
WHO Global Challenge

- WHO 3rd Global Patient Safety Challenge *Medication Without Harm* launched March 2017 - aim to reduce severe avoidable medication-related harm by 50% globally in the next 5 years

- The Strategic Framework for this Challenge based on four fundamental problems:
  - **Patients and the public** are not always medication-wise.
  - **Medicines** are sometimes complex and can be puzzling in their names, or packaging and sometimes lack sufficient or clear information.
  - **Health care professionals** sometimes prescribe and administer medicines in ways and circumstances that increase the risk of harm to patients.
  - **Systems and practices of medication** are complex and often dysfunctional, and can be made more resilient to risk and harm if they are well understood and designed.
WHO Global Challenge

- **Early priority actions** – the challenge asks countries and key stakeholders to make strong commitments, prioritize and take early action, and effectively manage three key areas to protect patients from harm, namely:
  - high-risk situations
  - polypharmacy
  - transitions of care

- SoS (Health) fully supports the WHO challenge and has established an initiative focused on reducing prescribing and medication errors led by Keith Ridge – Chief Pharmaceutical Officer
WHO Stocktake

– Pan-London approach
  ➢ **Increasing uptake** of anticoagulants in people with AF via the provision of localised infographics, developing resources to support healthcare practitioners and patients and provision of virtual clinics in primary care to enhance uptake


– **CCG Campaign** to optimise the use of oral anticoagulation in people with atrial fibrillation.
  ➢ 1\(^{st}\) year using the **GRASP AF tool** in practices to identify patients at high risk of stroke who were sub-optimally treated.
  ➢ 2\(^{nd}\) year using the **PRIMIS Warfarin Patient Safety Audit Tool** in all practices.
  ➢ 3\(^{rd}\) year focusing on reviewing patients who are taking a DOAC to check that the dose is correct for the patient and clinical indication.
New Work

- The WHO challenge will initiate new work in the area of anticoagulants and VTE management
  - NHSI and Specialist Pharmacy Service developing closer links to relook at anticoagulant management as a key safety theme and especially during the peri-operative period

- Currently at the concept stage, NHSI is looking to link relevant datasets with the aim to:
  - Understand which patients are at greatest risk of dying from a VTE related cause within 90 days of admission to hospital so that the patient group of highest risk of mortality can be targeted for interventions.
  - The analysis will be undertaken by linking Hospital Episodes Statistics and ONS Mortality records dataset. The planned analysis will use case-control methodology and an adjusted regression model.
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#APPTG
EXCELLENCE IN ANTICOAGULANT CARE

Helen Williams  FFRPS, FRPharmS, IPresc
Consultant Pharmacist for CV Disease, South London
Clinical Associate for CVD, Southwark CCG
Clinical Director for AF, Health Innovation Network
National Clinical Adviser for AF, AHSN Network
Anticoagulation from Old to New

What we had… Where we are now…

- Warfarin or other vitamin K antagonists
- LMWH or aspirin as an alternative
- Anticoagulant services focused on INR monitoring
- Limited opportunity for primary care management under LES

- Multiple treatment options
- Clear guidance from NICE for AF and VTE that all should be available
- Anticoagulant services to support drug selection and safe initiation, and ongoing monitoring where necessary?
- Greater opportunity for primary care management
Ischaemic strokes in patients with known AF (Charing Cross)

1265 ischaemic strokes

266 (21%) had **known** AF prior to stroke

- **Anticoagulation**
  - 115 on anticoagulation
    - 103 on warfarin
      - 88 had INR < 2
      - 15 had INR > 2
    - 12 on DOAC
      - In 8, evidence of suboptimal dose or intake
- **Aspirin only**
  - 82 (31%)
- **Nothing**
  - 69 (26%)

96 / 115 (83%) had inadequate anticoagulation control prior to stroke
PERFECT
Excellence in anticoagulant care

Key components of a high quality anticoagulation service include:

- Patient education about the benefits and risks of anticoagulation treatment and the importance of medication adherence
- Support for patients and carers in the choice of treatment options
- Support for patients to self monitor and self manage their anticoagulation therapy
- Staff education to improve skills for supporting self-monitoring and improve adherence
- Robust mechanisms in place to assess “time in therapeutic range” (TTR) information, with clear protocols to optimise the quality of anticoagulation control
- Key performance indicators (e.g. referral to treatment time, TTR, adverse events, number of patients self-monitoring/managing warfarin)
- Annual review of the service
Delivering Excellence 2017/18 (1)

1. Anticoagulant services should be offered in a convenient ‘one-stop’ clinic offering patient education, discussions, blood tests and drug / dose changes in the same consultation.

2. Anticoagulant services should be able to demonstrate that time from referral to assessment for treatment for people with AF is less than one week.

3. Anticoagulant pathways should offer people access to all anticoagulant options in line with licensed indications.
DOAC Uptake across England

CCG uptake ranges from 16% to 75%

Medicines Optimisation Dashboard 2017
4. Anticoagulant services should offer appropriate patients the opportunity to self-monitor or self-manage their vitamin K antagonist
Both coagulometers are recommended for use by people taking long-term anti-blood clotting therapy who have atrial fibrillation or heart valve disease, if they prefer and are able to effectively use this type of monitoring.

People (and their carers) who will be using 1 of these devices should be given training, and their doctor should regularly assess self-monitoring.

October 2016: NICE is aware that the INRatio2 PT/INR monitor (Alere Ltd) has been withdrawn from the market and is not currently available to the NHS.
AntiCoagulation services and patient access to INR self-monitoring in the NHS in England

A report by the AntiCoagulation Self-Monitoring Alliance

July 2014

178 of 211 (84%) CCGs responded to FOI request

34% of CCGs allowed self-testing

28% of CCGs allowed self-monitoring

7% of CCGs had formal guidelines

A report by the AntiCoagulation Self-Monitoring Alliance

July 2014

Process for initiation of patients on INR self-monitoring

Coagulometer provided in line with local commissioning arrangements

Patient assessed as suitable against selection criteria

Patient signs agreement to participate in the INR self-monitoring programme (See appendix 1)

Patient trained by anticoagulant service provider on use of coagulometer; training record completed (See appendix 2)

Patient initiated on programme and GP informed

Patient returns to anticoagulant service provider for quality control check every six months

Annual anticoagulation review held to include suitability for continued inclusion in programme

As the evidence is unclear and it is not cost effective. Although not specifically approved by NICE, those receiving long term (indefinite) secondary prevention of VTE with VKAs may be suitable for a self-monitoring programme.
4. Anticoagulant services should offer appropriate patients the opportunity to self-monitor or self-manage their vitamin k antagonist.

5. Anticoagulant services should ensure that all patients are issued and advised to carry an anticoagulant alert card, regardless of drug choice.

6. Anticoagulation services should communicate to both the patient and their GP individual patient International Normalized Ratio (INR), to ensure safe prescribing, and time in therapeutic range (TTR), to inform discussions about ongoing management.
PRADAXA®
PATIENT ALERT CARD

I am under anticoagulant therapy with Xarelto® in combination with warfarin.

Please contact your medical professional if:

- you experience any of the following:
  - pain
  - tenderness or discomfort
  - leg pain or swelling

- you are allergic to Xarelto® or any Xarelto® component

- you are unable to take Xarelto® for any other reason

- you have any of the following conditions:
  - bleeding
  - high blood pressure
  - diabetes

- you have any of the following factors that may increase your risk of bleeding:
  - advanced age
  - liver disease
  - kidney disease
  - surgery

Please remember:

- Xarelto® is prescribed with warfarin
- Xarelto® is not used for stroke prevention
- Xarelto® is not used for deep vein thrombosis prevention

Follow your doctor’s instructions when taking Pradaxa®

- Pradaxa® prevents clots by making your blood less “sticky”. However, this may increase the risk of bleeding
- In case of a bleeding event which does not stop spontaneously, immediately inform your doctor
- As Pradaxa® acts on the blood clotting system, most side effects are related to signs of bruising or bleeding. Signs and symptoms of bleeding events might be: haematoma of the skin, tar stools, blood in urine, nose bleed, etc.
- If surgical or invasive procedures need to be performed, inform the treating physician about your intake of Pradaxa®
- Do not stop the intake of Pradaxa® without talking to your doctor, as you are at risk of suffering from a stroke or other complications due to blood clot formation.
- In the case of bleeding, please contact your doctor before stopping the intake of Pradaxa®

- If you have questions about Xarelto®, please refer to the Patient Information Leaflet or the Physician’s Information Guide.
- If you have questions about Pradaxa®, please refer to the Patient Information Leaflet or the Physician’s Information Guide.

Keep this card in your wallet at all times.

Present this card to every physician or dentist prior to treatment.

National Patient Safety Agency

Oral Anticoagulant Therapy
Important information for patients
7. Anticoagulation pathways should clearly define follow-up arrangements for all patients on anticoagulant therapy either within the anticoagulant services or via primary care.

8. Anticoagulant pathways should be able to demonstrate how patients newly initiated on anticoagulant therapy are formally referred into the community pharmacy New Medicine Service for adherence support, where appropriate.

9. Anticoagulant pathways should be able to demonstrate how they can provide for patients with complex needs
Adherence to new medication

Table 2  Adherence to new medication

<table>
<thead>
<tr>
<th></th>
<th>Still taking medication at 10 days (n = 226/239)</th>
<th>Still taking medication at 4 weeks (n = 171/197)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adherent</td>
<td>159 (70%)</td>
<td>128 (75%)</td>
</tr>
<tr>
<td>Non-adherent</td>
<td>67 (30%)</td>
<td>43 (25%)</td>
</tr>
<tr>
<td>Partial non-adherence</td>
<td>49</td>
<td>26</td>
</tr>
<tr>
<td>Complete non-adherence</td>
<td>18</td>
<td>17</td>
</tr>
</tbody>
</table>

Table 3  Examples of problems caused by medicines

<table>
<thead>
<tr>
<th>Nature of problem</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects</td>
<td>Numbness, oral thrush, nausea, vomiting, giddiness</td>
</tr>
<tr>
<td></td>
<td>Stopped taking new medicine because of side effects</td>
</tr>
<tr>
<td>Concerns</td>
<td>Not keen – don’t believe in taking pills</td>
</tr>
<tr>
<td></td>
<td>Worried about taking new medicine, for example because of previous side</td>
</tr>
<tr>
<td></td>
<td>effects, allergy, potential interactions</td>
</tr>
<tr>
<td>Practical aspects</td>
<td>Tablets difficult to swallow</td>
</tr>
<tr>
<td></td>
<td>Hard to remember complicated regime</td>
</tr>
<tr>
<td></td>
<td>Have to take half a tablet and hard to break accurately</td>
</tr>
</tbody>
</table>


BEHAVIOUR

Practitioner – prescribing

Patient – adherence

Effective treatments

Optimum outcomes
Promoting adherence during anticoagulant therapy

Here is a roadmap of the different points that adherence support can be provided during a patient’s journey following initiation of anticoagulation and during long term management. Adherence to treatment can be checked at each of these points and support offered to address any issues. All treatment decisions are a partnership between the clinician and the patient.

THE INITIATION AND STABILISATION PHASE

1. Medically necessary treatment must not be delayed even if a conversation between an appropriately qualified professional and the person is not possible at that point.
2. Evidence has shown it takes on average 30 minutes to discuss treatment options in enough depth to allow an informed decision, counselling, and follow up, all factors that influence adherence.
3. Relevant if initiation is in secondary care. Letter sent to patient and GP.
4. Could be by telephone or face to face e.g., by referral to New Medicines Service. Adherence to treatment can decline as early as 10 days after initiation. Patients on warfarin will also have been followed up by the initiating service after 3 days.

THE LONG TERM MANAGEMENT PHASE

5. Studies show that there is a tail-off in necessity beliefs at 3 months following initiation of treatment.
6. Maintaining positive relationships between clinicians and patients is key, and should continue e.g., if a patient moves from warfarin to direct oral anticoagulants (DOACs) and so has had regular contact with a pharmacy. *A specific review of house bound patients will be required.

Blood tests for renal function or blood pressure checks in primary or secondary care

District nursing or home visits*

3 months – 1 year Opportunities to review adherence include:

Clinic appointments (all locations)

Medicines collection or medicines use review (MUR)

Any hospital admissions
New Medicine Service (NMS)

Referral to community pharmacist for NMS

Engagement

Patient identified by community pharmacist for NMS

7-14 days

Intervention

Patient agrees to adhere to new medicine or pharmacist to resolve medicines-related issues

14-21 days

Follow

Refer to GP to resolve medicines-related issues

Refer to GP to resolve medicines-related issues

Improve adherence 10%
10. Feedback from patients and carers should be sought and used to improve the local anticoagulant pathway.

11. Local anticoagulant services should be able to provide data on:
   - Service delivery - such as number of patients seen, number of patients self-monitoring and self-managing warfarin anticoagulation
   - Quality and safety - such as time to first available appointment from referral
   - Patient satisfaction and patient experience surveys
Checklist for Delivering Excellence in Anticoagulant Care

In line with *Excellence in anticoagulant care*¹ this checklist summarises the components of an excellent anticoagulant pathway, regardless of the model of care delivery (primary care, community-based or acute care).

Commissioners and providers should use this list to benchmark current services to identify gaps in service provision.

1. **Excellent anticoagulation services for a local population should be patient-centred and directly involve users and carers**

<table>
<thead>
<tr>
<th></th>
<th>Yes / No</th>
<th>Evidence provided</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Public and patients are actively involved in the design of their local anticoagulant pathway</td>
<td></td>
<td>(for example, involvement of patients in consultations regarding service redesign, local thrombosis committees)</td>
<td></td>
</tr>
<tr>
<td>Patient and carer feedback, including (but not limited to) results of patient satisfaction and experience surveys, is used to improve anticoagulant service pathways</td>
<td></td>
<td>(for example: results of patient satisfaction and experience surveys)</td>
<td></td>
</tr>
<tr>
<td>Services are offered in a convenient ‘one-stop’ clinic offering patient education, discussion and support, blood tests and drug / dose changes and date of next appointment in the same consultation.</td>
<td></td>
<td>(for example, clinic arrangements demonstrate one-stop approach, evidence from patient satisfaction questionnaires)</td>
<td></td>
</tr>
<tr>
<td>Anticoagulant services are located to maximise convenience for the service user, with accessible public transport links and parking facilities.</td>
<td></td>
<td>(for example: Clinic times and locations and facilities available)</td>
<td></td>
</tr>
<tr>
<td>The local anticoagulant pathway offers appointment times to meet the needs of the whole population, including working age adults.</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
EXCELLENCE IN ANTICOAGULANT CARE

Helen Williams  FFRPS, FRPharmS, IPresc
Consultant Pharmacist for CV Disease, South London
Clinical Associate for CVD, Southwark CCG
Clinical Director for AF, Health Innovation Network
National Clinical Adviser for AF, AHSN Network
APPTG Annual Conference 2017

#APPTG
Anticoagulation Europe is now Anticoagulation UK - Brand strategy for Anticoagulation UK

Why have we changed our name?
Focus on our continuing commitment to provide information, education and support to the anticoagulation patient community

Extend our offerings by developing our new Prevention, Provision and Promotion strategy going forward

Launch of new website
New layout and infrastructure delivering an extensible platform for future growth

Responsive design, implementing usability and access from any device

Improved navigation and layout, providing faster and more intuitive recall of content
Anticoagulation UK – Mission and objectives defined by the 3P’s

**Prevention**
- Raising awareness about blood clots
- Outlining the 4 most common conditions

**Provision**
- Providing information, tools and resources for patients and healthcare professionals
- Creating a repository of content

**Promotion**
- Promoting patient choice and independence
- Helping people, healthcare professionals and government departments understand, engage and become involved
Anticoagulation UK – Start spreading the news

News
Improved promotion of relevant news articles
Increased distribution across website and Anticoagulation UK social media platforms
News articles can be shared / sent to multiple platforms and or interested parties by users

Social Media Platforms
Redeveloped Social Media platforms, allowing faster promotion and engagement of content
Creating a ‘360’ connected experience for users and members, pushing and pulling content from both the website and social media engagement
Campaign to raise awareness of Hospital Risk Assessment
Initial digital/print awareness postcard containing key information

The postcard helps promote our “Be Clot Clever” campaign and provides a simple guide for patients who are going into hospital and are worried about developing a blood clot.

Cards can be ordered by emailing: info@anticoagulationuk.org

#beclotclever
Anticoagulation UK – Anticoagulation Achievement Awards (AAA)

Celebrating outstanding practice in the management, education and provision of anticoagulation across the UK

Deployment of bespoke AAA website outlining key objectives and allowing a promotional vehicle for both the awards, hosts and sponsors

Promotional assets developed and deployed across multiple associate sites

News and social media promotion

Turn key online application process for nominations

Awards ceremony hosted by Andrew Gwynne MP at the House of Commons

Deployment of updated website containing winner information, brochure of the days event and online gallery

www.anticoagulationawards.org
APPTG Annual Conference 2017

#APPTG