Induction and Follow up:
The Novel Oral Anticoagulants

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Overview

- Recap on context
- NICE guidance
- Key features of oral anticoagulants
- Baseline tests
- Prescribing
- Communication
- Follow up monitoring
Context

- Underprescribing of warfarin
- Shift in antithrombotic management of Atrial Fibrillation
- QOF, QIPP, NICE recommendations
- Growth of SPAF anticoagulation ‘market’
- Investment in development of anticoagulation monitoring services and in novel agents

Risk Assessment
- CHADS\textsubscript{2} / CHA\textsubscript{2}DS\textsubscript{2}VASC
- HASBLED
- Opportunity to deliver real Stroke prevention benefits
When dabigatran etexilate is used for the prevention of stroke and systemic embolism in people with nonvalvular AF, at least one of the following risk factors should apply:

- previous stroke, transient ischaemic attack or systemic embolism
- left ventricular ejection fraction below 40%
- systematic heart failure of New York Heart Association (NYHA) class 2 or above
- age 75 years or older
- age 65 years or older with one of the following: diabetes mellitus, coronary artery disease or hypertension.
Rivaroxaban is recommended as an option for the prevention of stroke and systemic embolism within its licensed indication, that is, in people with nonvalvular AF with one or more risk factors such as:

- congestive heart failure,
- hypertension
- age 75 years or older
- diabetes mellitus,
- prior stroke or transient ischaemic attack.
Before treatment with dabigatran etexilate / rivaroxaban is started, there should be a discussion between the clinician and the person about the risks and benefits of the drug compared with warfarin.

For people who are taking warfarin, the potential risks and benefits of switching to dabigatran etexilate / rivaroxaban should be considered in light of their level of international normalised ratio (INR) control.
Efficacy

Primary efficacy outcome SSE

- Dabigatran 150mg superior to warfarin
  - NNT = 167
- Dabigatran 110mg non-inferior to warfarin
- Rivaroxaban 20mg (safety on-treatment analyses) superior to warfarin
  - NNT 200
  - No benefit in ischaemic stroke
Safety

- **Dabigatran 150mg** - equivalent rate of major bleed
  - Significantly less ICH – NNT 227
  - Significantly more GI haemorrhage – NNH 204

- **Dabigatran 110mg** - significantly less major bleed
  - Significantly less ICH – NNT 189

- **Rivaroxaban** - equivalent rate of major bleed
  - Significantly less ICH – NNT 400
  - Significantly more GI haemorrhage – NNH 101
Key features

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Initiation of warfarin anticoagulation

Days

Protein C

INR

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## Pharmacokinetic metabolism interactions

<table>
<thead>
<tr>
<th>CYP2C9 inducer</th>
<th>CYP2C9 inhibitor</th>
<th>CYP3A4 inducer</th>
<th>CYP3A4 inhibitor</th>
<th>CYP1A2 inducer</th>
<th>CYP1A2 inhibitor</th>
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</thead>
<tbody>
<tr>
<td>Ritonavir</td>
<td>Atazanavir (ATZ)</td>
<td>Nevirapine (NVP)</td>
<td>Ritonavir</td>
<td>Ritonavir</td>
<td>amiodarone</td>
</tr>
<tr>
<td>adefovir</td>
<td></td>
<td>Efavirenz (EFV)</td>
<td>Delavirdine (DLV)</td>
<td>car bamazepine</td>
<td>cimetidine</td>
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<tr>
<td>car bamazepine</td>
<td>amiodarone</td>
<td>aminoglutethimide</td>
<td>Efavirenz (EFV)</td>
<td>char broiled food</td>
<td>cipro floxacin</td>
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<td>phenobarbital</td>
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<td>Saquinavir (SQV)</td>
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<tr>
<td>phenytoin</td>
<td>cimetidine</td>
<td>adefovir</td>
<td>Indinavir (IDV)</td>
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<td>clarithromycin</td>
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<td>primidone</td>
<td>clopidogrel</td>
<td>adefovir</td>
<td>Nelfinavir (NFV)</td>
<td>phenobar bital</td>
<td>diltiazem</td>
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<tr>
<td>rifampin</td>
<td>cotrimoxazole</td>
<td>adefovir</td>
<td>Amprenavir (APV)</td>
<td>phenytoin</td>
<td>erythromycin</td>
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<tr>
<td>rifapentine</td>
<td>delavirdine</td>
<td>adefovir</td>
<td>Atazanavir (ATZ)</td>
<td>rafampine</td>
<td>ethinyl estradiol</td>
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<td>disulfiram</td>
<td>adefovir</td>
<td>Fosamprenavir (FPV)</td>
<td>raxonavir</td>
<td>flu oxamine</td>
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<td>efavirenz</td>
<td>adefovir</td>
<td>acitretin</td>
<td>smoking</td>
<td>isoniazid</td>
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<td>amiodarone</td>
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<td>ketoconazole</td>
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<td>adefovir</td>
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<td>methox salen</td>
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<td>cyclo sporine</td>
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<td>adefovir</td>
<td>danazol</td>
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<td>delavirdine</td>
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<td>diltiazem</td>
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<td>troleandomycin</td>
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<td>adefovir</td>
<td>erythromycin</td>
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<td>meldonidazole</td>
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<td>ethinyl estradiol</td>
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<td>adefovir</td>
<td>fluoxetine</td>
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<td>adefovir</td>
<td>fluvoxamine</td>
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<td></td>
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<td>adefovir</td>
<td>gestodene</td>
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<tr>
<td></td>
<td>sertraline</td>
<td>adefovir</td>
<td>grapefruit</td>
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<tr>
<td></td>
<td>sulfonamides</td>
<td>adefovir</td>
<td>indinavir</td>
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<td>ticlo pidine</td>
<td>adefovir</td>
<td>imatinib</td>
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<tr>
<td></td>
<td>voriconazole</td>
<td>adefovir</td>
<td>isoniazid</td>
<td></td>
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<tr>
<td></td>
<td>zafirlukast</td>
<td>adefovir</td>
<td>itraconazole</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Narrow therapeutic range with VKA

Stroke

Intracranial bleed

International Normalized Ratio (INR)

Odds ratio


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- **Over-anticoagulation**

- **Replace Vitamin K**
- **Replace clotting factors II, VII, IX, X** (prothrombin complex concentrate)
<table>
<thead>
<tr>
<th>Drug</th>
<th>Dabigatran Etxilate</th>
<th><strong>Rivaroxaban</strong></th>
<th>Apixaban</th>
<th>Edoxaban</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mechanism of Action</strong></td>
<td>Direct thrombin inhibitor</td>
<td>Factor Xa inhibitor</td>
<td>Factor Xa inhibitor</td>
<td>Factor Xa inhibitor</td>
</tr>
<tr>
<td>Prodrug</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td><strong>Pharmacokinetics</strong></td>
<td>Predictable</td>
<td><strong>Predictable</strong></td>
<td>Predictable</td>
<td>Predictable</td>
</tr>
<tr>
<td>Bioavailability</td>
<td>~6.5%</td>
<td>&gt;80%</td>
<td>&gt;50%</td>
<td>~50%</td>
</tr>
<tr>
<td><strong>Half life</strong></td>
<td>12-17 hours</td>
<td><strong>9 -13 hours</strong></td>
<td>8 – 15 hours</td>
<td>~ 6 – 11 hours</td>
</tr>
<tr>
<td>Max plasma concentrations</td>
<td>2 hours</td>
<td>2.5 – 4 hours</td>
<td>1-3 hours</td>
<td>1- 2 hours</td>
</tr>
<tr>
<td><strong>Onset of action</strong></td>
<td>Rapid</td>
<td>Rapid</td>
<td>Rapid</td>
<td>Rapid</td>
</tr>
<tr>
<td>Dosing frequency</td>
<td>Fixed twice daily</td>
<td><strong>Fixed once daily</strong></td>
<td>Fixed twice daily</td>
<td>Fixed once daily</td>
</tr>
<tr>
<td>Blood clotting monitoring</td>
<td>Not required</td>
<td>Not required</td>
<td>Not required</td>
<td>Not required</td>
</tr>
<tr>
<td>Protein Binding</td>
<td>35%</td>
<td>90%</td>
<td>87%</td>
<td>~40-59%</td>
</tr>
<tr>
<td>Renal excretion</td>
<td>85%</td>
<td>66%</td>
<td>25%</td>
<td>~35-39%</td>
</tr>
<tr>
<td>Interactions</td>
<td>P-glycoprotein pump inhibitors /inducers</td>
<td>CYP3A4</td>
<td>P-glycoprotein pump inhibitors /inducers</td>
<td>CYP3A4</td>
</tr>
<tr>
<td>Antidote</td>
<td>No specific antidote</td>
<td>No specific antidote</td>
<td>No specific antidote</td>
<td>No specific antidote</td>
</tr>
</tbody>
</table>

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<th>Rivaroxaban</th>
<th>Apixaban</th>
</tr>
</thead>
<tbody>
<tr>
<td>P-GP substrate?</td>
<td>YES</td>
<td>YES</td>
<td>NO</td>
</tr>
<tr>
<td>P-GP inhibitor</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>CYP-3A4 substrate</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
<tr>
<td>CYP-3A4 inhibitor</td>
<td>NO</td>
<td>YES</td>
<td>YES</td>
</tr>
</tbody>
</table>

### Interactions

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dabigatran Etexilate</th>
<th>Rivaroxaban</th>
<th>Apixaban</th>
</tr>
</thead>
<tbody>
<tr>
<td>p-GP inhibitor</td>
<td><strong>Amiodarone:</strong> ↑ AUC 58%&lt;br&gt;Ketoconazole: ↑ AUC 153%&lt;br&gt;Quinidine: ↑ AUC 53%&lt;br&gt;Verapamil 1 hr before dabigatran: ↑ AUC 2.4-fold (but negligible if 2 hr after dabigatran)</td>
<td><strong>Ketoconazole:</strong> ↑ AUC 100%&lt;br&gt;Ritonavir: ↑ AUC 100%&lt;br&gt;Clarithromycin: ↑ AUC 50%&lt;br&gt;Erythromycin: ↑ AUC 30%</td>
<td>N/A - Not reported</td>
</tr>
<tr>
<td>p-GP inducer</td>
<td>Rifampin: ↓ AUC 66% carbamazepine, Phenytoin</td>
<td>Rifampin: ↓ AUC 50% carbamazepine, Phenytoin</td>
<td>N/A - Not reported&lt;br&gt;Not reported</td>
</tr>
<tr>
<td>CYP-3A4 inhibitor</td>
<td>N/A</td>
<td>Ketoconazole: ↑ AUC 100%&lt;br&gt;Ritonavir: ↑ AUC 100%&lt;br&gt;Clarithromycin: ↑ AUC 50%&lt;br&gt;Erythromycin: ↑ AUC 30%</td>
<td>Ketoconazole: ↑ AUC 2 fold</td>
</tr>
<tr>
<td>CYP-3A4 inducer</td>
<td>N/A</td>
<td>Rifampin: ↓ AUC 50%</td>
<td>Rifampin: ↓ AUC 54%</td>
</tr>
<tr>
<td>C/Is</td>
<td>ketoconazole, cyclosporin,itraconazole and tacrolimus</td>
<td>ketoconazole, itraconazole, voriconazole and posaconazole or HIV protease inhibitors</td>
<td>ketoconazole, itraconazole, voriconazole and posaconazole and HIV protease inhibitors (e.g., ritonavir)</td>
</tr>
</tbody>
</table>
## Renal impairment

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Dabigatran</th>
<th>Rivaroxaban</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild renal impairment (CrCL 50-80 ml/min)</td>
<td>no dose adjustment</td>
<td>no dose adjustment</td>
</tr>
<tr>
<td>Moderate renal impairment (CrCL 30-50 ml/min)</td>
<td>no dose adjustment however, for patients with high risk of bleeding, consider dose reduction (↑age, ↓weight)</td>
<td>Reduced dose – 15mg</td>
</tr>
<tr>
<td>Severe renal impairment (CrCL &lt; 30 ml/min)</td>
<td>contraindicated</td>
<td>CrCl 15-29 ml/min – 15mg CrCl&lt;15 - contraindicated</td>
</tr>
</tbody>
</table>

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## Features Comparison

<table>
<thead>
<tr>
<th>Feature</th>
<th>Warfarin</th>
<th>NOAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Onset / offset of action</td>
<td>Slow</td>
<td><strong>Rapid</strong> (dabigatran twice daily dosing)</td>
</tr>
<tr>
<td>Predictability of patient response</td>
<td>Low (narrow therapeutic window), variable dosing required</td>
<td>High, therefore <strong>fixed daily dosing</strong></td>
</tr>
<tr>
<td>Food and drink interactions</td>
<td>Vitamin K containing foods, alcohol, cranberry juice(?)</td>
<td><strong>No dietary interactions reported</strong></td>
</tr>
<tr>
<td>Drug interactions</td>
<td>Numerous drugs affect INR</td>
<td><strong>Less drug interactions compared with warfarin;</strong> Pgp inhibitors and inducers additionally for Xa inhibitors CYP 3A4 inhibitors, inducers, substrates)</td>
</tr>
<tr>
<td>Coagulation monitoring requirements</td>
<td>Routine monitoring required</td>
<td><strong>Routine monitoring not required. Routine monitoring not widely available, potential cause for concern particularly in emergency circumstances where quick decision required (e.g. thrombolysis)</strong></td>
</tr>
<tr>
<td>Bleeding profile</td>
<td>Overall rate of intracranial haemorrhages low</td>
<td><strong>Lower rates of intracranial haemorrhages than warfarin, higher rate of gastrointestinal bleed</strong></td>
</tr>
<tr>
<td>Reversal agents</td>
<td>Vitamin K, prothrombin concentrate complex</td>
<td><strong>No specific agent available for reversal, cause for concern, particularly in profuse bleeding and emergency surgery</strong></td>
</tr>
<tr>
<td>Non-bleed Side effects</td>
<td>Rash, alopecia, GI disturbances</td>
<td>GI disturbances, anaemia</td>
</tr>
<tr>
<td>Renal function</td>
<td>More frequent monitoring may be required in renal impairment</td>
<td>Requires dose adjustment. <strong>Caution required in renal impairment</strong></td>
</tr>
<tr>
<td>Experience</td>
<td>Real-world experience is extensive</td>
<td>Experience growing, still lots to learn</td>
</tr>
</tbody>
</table>

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Adherence

- Joint decision making process – partnership
- Patient should have a clear understanding of:
  - Necessity of therapy
  - Pros and cons of different agents
- Address patient concerns
- Consider follow up arrangements
Assessment of bleeding risk

- HAS-BLED
  - Hypertension, abnormal renal/hepatic, previous stroke, prior bleed/predisposition to bleed, labile INR, ≥65 years, medication predisposing to bleeding, alcohol

- Score ≥ 3 high risk bleed
  - Still need to balance risks of bleed and thrombosis
  - Manage modifiable risk factors
  - Take with food
  - More frequent follow-up
  - Role of gastroprotection
Baseline tests

- Renal function
- FBC (anaemia / thrombocytopenia)
- Clotting screen
- Liver function
- Willingness / ability to adhere
  - Short half life
  - Rebound thrombosis with missed doses??
Whose role is this?

- GPs first line clinicians.
- Currently play key role in diagnosis and treatment of AF.
- GPs should be able to make decisions to commence new oral anticoagulants OR switch from warfarin to new oral anticoagulants.
- Pharmacist / nurse prescribers.
The recommended dose of dabigatran is:
- 150mg twice daily,
- 110mg twice daily for patients ≥80 years or on concomitant verapamil

In addition, 110mg twice daily can be considered for patients:
- Aged 75-80 years with an increased risk of bleeding
- With gastritis, oesophagitis or gastro-oesophageal reflux, active ulcerative gastrointestinal (GI) disease or recent GI bleeding
- With moderate renal impairment (CrCl 30-50ml/min), plus an increased risk of bleeding
- Close surveillance is required for patients with low body weight and those taking concomitant Pgp inhibitors.
What dose to give?

- 83 year old man with CrCl >80ml/min, weight 75kg
  - Dose of dabigatran?
    - 110mg twice daily
  - Dose of rivaroxaban?
    - 20mg once a day

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What dose to give?

- 77 year old female, CrCl 45ml/min, 60kg, no additional bleed risk factors
- Dabigatran dose?
  - 150mg twice daily
- Rivaroxaban dose?
  - 15mg once daily
- What if she was 45kg?
  - Might consider dabigatran 110mg twice daily
Patients on warfarin

Additional considerations (ad-hoc analysis cautious interpretation)

- Benefit of dabigatran in SSE may be greater in suboptimal INR control
  - ICH benefit remains

- Rivaroxaban modest benefit over TTR 58%
  - No change in effect observed at different TTRs
Switching from warfarin

- Dabigatran - Warfarin should be stopped and dabigatran initiated when INR < 2.0

- Rivaroxaban - Warfarin should be stopped and rivaroxaban initiated when INR ≤ 3.0

Pathway Practicalities
Counselling

Points for inclusion

- Indication – rationale
- Duration of treatment
- Mechanism of action
- Key side-effects
- Signs of bleeding
  - What to do if bleed / suspected bleeding
- Missed doses
- Drug interactions including OTC
- Need for adherence
- Antidotes / monitoring (current challenges)
- Alert cards
- Pregnancy / breastfeeding

(not exhaustive)
Current pathways

- **Inpatient**
  - Initiation of warfarin and referral into anticoagulation clinic
  - Recommendation of initiation and referral to GP or ac clinic

- **Outpatient**
  - Recommendation of initiation and referral of patients to GP or ac clinic
New pathways

- At which point does discussion / decision take place?
- Referrals into primary care for discussions and decisions
  - GPs as primary prescriber?
- Role of anticoagulation clinics going forward?
- Systematic management of undertreated patients?
- Tracking / follow up management
- Adherence support
  - Role for community pharmacy (e.g. New Medicines Service and Medicines Use Review)?
Follow up

- Traditional anticoagulation management
  - Frequent monitoring at initiation phase
- Novel oral anticoagulants
  - Routine monitoring not required
Follow up

- Monitoring of adherence and adverse events
- How soon?
  - After 1 month?
  - At least within first 3 months
- Appropriate frequency of follow up – consider:
  - Presence of comorbidities
  - Renal function
  - Risk of bleeding
  - Age
  - Previous treatment with VKA
  - Presence of side-effects
Established

- Twice yearly
- Consider Quarterly:
  - >75 years
  - Renal impairment
- At annual review
  - Appropriateness of continued therapy
Reinforce patient education

- Verbal
- Written
- Patient support schemes
- Medicines Use Review
Side-effects

- **Dyspepsia**
  - Take with meals
  - PPI?

- **Bleeding (reversal)**
  - Haematology support
  - No specific antidote
  - Protocols required
When is monitoring required
- Overdose suspected
- A&E major bleeding
- Indication for urgent surgery

Dabigatran: Thrombin Time (TT), Activated Partial Thromboplastin Time (aPTT), Ecarin Clotting Time (ECT), Hemoclot (a diluted TT assay)

Rivaroxaban: aPTT, anti-factor Xa assay; standardised tests of prothrombin time using appropriate thromboplastins

Timing of previous dose relative to blood test important

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Lots to learn about NOACs

- Real-life adherence
- Monitoring
- Reversal
- Perioperative management
- Dual / Triple antithrombotic (AF and ACS / CAD)
  - ATLAS-TIMI 51 Rivaroxaban ACS study
  - What about the NOACs with the newer oral antiplatelets (e.g. prasugrel, ticagrelor)?
- Thrombolysis management

- Need to ensure that the learning is shared
Role for Pharmacy

- How much time currently spent discussing drug therapy and supporting adherence in a 10 minute consultation?

- Important role for pharmacists to promote patient understanding of their condition and appropriate use of medication
  - New Medicines Service
  - Medicines Use Review
Challenges

- Size of patient population (growing)
- Need to address undertreatment
  - Suboptimal INR
  - On antiplatelet therapy
  - Not receiving antithrombotic therapy
    - New oral anticoagulants not necessarily the answer
    - Consider alternative models of anticoagulation monitoring
      - E.g. Domiciliary, self-testing/management
- Change in relationship dynamics
  - Role of anticoagulation clinic
  - Role of GPs
Summary

- Increased role for anticoagulation in management of AF
  - Opportunity to deliver significant stroke benefits nationally
- NICE recommends use of novel oral anticoagulants
  - Compared with warfarin: Modest efficacy benefits, equivalent major bleed rates and reduced rates of intracranial haemorrhages
- The NOACs have important advantages but there are key areas of uncertainty and learning
- Whilst they are cost-effective, affordability continues to be a major issue
- Increased role of primary care in management of AF including patient education
  - Pathway redesign required
  - Anticoagulation clinics continue to have an important role
- Adherence support crucial to delivery of positive patient outcomes
  - Role for pharmacy
Induction and Follow up:

The Novel Oral Anticoagulants

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