Medicines Optimisation Update

Novel Oral Anticoagulants (NOACs)

Partners in improving local health

NHS Cumbria Clinical Commissioning Group

What this includes:

Ensuring that Novel Oral Anticoagulants (NOACs) are prescribed and reviewed appropriately.

Identifying the problem:

NICE decision aid Atrial Fibrillation: medicines to help reduce your risk of a stroke – what are the options?
Patient UK Atrial Fibrillation Shared decision aid.

Suggested actions:

Factors to be considered for patients needing anticoagulation for atrial fibrillation (AF):

Efficacy: To date no study has demonstrated superiority of a NOAC vs warfarin treatment. A patient with Atrial Fibrillation has a 96.9% chance of not having an embolic event on a NOAC drug and a 96.2% chance of not having one on warfarin. From the meta-analysis of trials, 141 of 142 patients treated with a NOAC drug received no benefit over warfarin.

Bleeding Risks: Intracranial Haemorrhage (ICH) - Absolute risk reduction difference between NOACs and warfarin was 0.65%. There is a 99.4% chance of *not having* an ICH on a NOAC drug and a 98.8% chance of *not having* one on warfarin. From the meta-analysis of trials, for 151 of 152 patients treated, there was no difference between NOAC drugs and warfarin.

Gastrointestinal Bleed – The risk of major bleeding was not significantly different, but the risk of gastrointestinal bleeding was higher for NOAC drugs by a factor of 0.5%.

Control: INR (International Normalized Ratio) can be measured regularly to demonstrate anticoagulation, however no such test exists for NOACs.

Compliance: Studies demonstrate that non-compliance is as prevalent with NOACs as with other therapies. Reasons that contribute to non-compliance should be considered and addressed. Patients must be compliant every day with their tablets in order to be protected against a stroke. The NOACs have short half-lives, so there is no benefit to be gained from switching from warfarin if poor control is due to the patients not taking their tablets.

Shared Decision Making: Patients should be involved in treatment choice, with the main points discussed recoded in the patient notes. Practices may wish to use the read code 8Cl,"shared decision making". Patients need to be aware of the risks and benefits of anticoagulation for AF: only then can they make the decision as to whether warfarin or a NOAC is more appropriate.

Limited antidote: Currently there is only an antidote for dabigatran - idarucizumab. This costs around £2000 and is stocked in hospitals only . No antidotes are currently available for the other 3 NOACs on the market.

Use with antiplatelets: there is an increased bleeding risk when on dual therapy. This decision is for the Cardiologist, but GP takes responsibility for the dual prescribing in primary care and needs to agree with the risk/benefit decision.

Conversion from warfarin: Do not automatically change patients who have time in therapeutic INR range (TTR) <65% after 6 months. First, assess the factors which contribute to poor control and see if these can be improved. If poor control is due to cognitive function or adherence, then a this is unlikely to improve with a NOAC and the patient will still not be protected. If the decision is made to change to a NOAC, further information on this switch is detailed in the local prescribing guidelines.

In the majority of cases NOAC prescribing is about convenience NOT benefit.

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Suggested actions:

Suggested actions for patients currently being prescribed a NOAC:

Check patient compliance: NOACs have a short half-life. This is an advantage if a patient is bleeding, but a disadvantage if the patient misses a dose. Patient must be compliant every day in order to have protection against a stroke. NOACs which are not taken regularly will have equivalent effects of patients on warfarin with TTR< 65%. Non-adherence must be identified, reasons for non-compliance explored and the patient counselled. If patient is non-compliant then there is no place for anticoagulant therapy.

Check licensed indications: Do NOT use for valvular AF. The NOAC have slightly different licensed indications for the prevention of stroke in non-valvular AF and so need to be aware patients are appropriate for NOAC.

Make sure patients are being monitored: Renal function must be checked before starting NOACs and every 12 months thereafter, or 6 monthly if patient has renal impairment. Edobaxan requires annual liver function tests. All patients require annual reviews of their anticoagulation treatment.

Adjust the dose if the patient has renal impairment: All NOACs require a dose adjustment in renal impairment and it is vital to check if dose is correct or if contraindicated depending on renal function.

Resources:

Cumbria Anticoagulant Decision Support Tool July 2016
http://medicines.necsu.nhs.uk/guidelines/cumbria-guidelines/

NICE decision aid Atrial Fibrillation: medicines to help reduce your risk of a stroke – what are the options
https://www.nice.org.uk/guidance/cg180/resources/patient-decision-aid-243734797

CHADS2VAS and HASBLED scores – NICE recommends American College of Cardiology AF Toolkit
http://www.acc.org/tools-and-practice-support/clinical-toolkits/atrial-fibrillation-afib

Patient AF Shared decision aid
http://patient.info/decision-aids/atrial-fibrillation-medication-options

NICE Pathway Preventing stroke in atrial fibrillation patients
http://pathways.nice.org.uk/pathways/atrial-fibrillation#path=view%3A/pathways/atrial-fibrillation/preventing-stroke-in-people-with-atrial-fibrillation.xml&content=view-node%3Anodes-anticoagulation-treatment

NICE CKS on oral anticoagulants http://cks.nice.org.uk/anticoagulation-oral

NICE CKS on atrial fibrillation http://cks.nice.org.uk/atrialfibrillation#!scenario

References:

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http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4301757/

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National Institute for Health and Care Excellence (NICE). Clinical Guideline 180. Atrial Fibrillation: management. June 2014. Available at
https://www.nice.org.uk/guidance/cg180

LMMG Prescribing Guidance for NOAC in patients with non-valvular atrial fibrillation. March 2016. Available at
http://medicines.necsu.nhs.uk/download/noacs-in-af-prescribing-guide-cumbria-apc-approves-the-lmmg-pathway-which-cumbrian-clinicians-may-wish-to-follow/