NOVEL ORAL ANTICOAGULANTS (NOACS) FOR STROKE PREVENTION IN ATRIAL FIBRILLATION

Background

Two novel oral anticoagulants were licensed for stroke prevention in atrial fibrillation (SPAF) during 2011/12:

- **Dabigatran**, a direct thrombin inhibitor, which was recommended as an option for treatment in NICE guidance published in March 2012
- **Rivaroxaban,** which was recommended as an option for treatment in NICE guidance published in May 2012

In addition, **apixaban**, a factor Xa inhibitor, is expected to be licensed within the next 12 months.

The introduction of these new agents will require significant pathway redesign and realignment of anticoagulant services in order to offset the additional cost of these drugs. This position statement is intended to support the implementation of NICE guidance for NOACs across South London and identify which patient groups should be prioritised for treatment.

SLCSN position

1. **The focus of AF management should be to identify patients with AF** and undertake stroke risk assessment using the $CHADS_2$ risk assessment tool[1]. Patients with a $CHADS_2$ score ≥ 1 should normally be considered for initiation on oral anti-coagulation therapy.

2. **Warfarin is usually the first line option for the prevention of stroke and systemic embolism in AF.** Patients stable on warfarin therapy should not normally be considered for a switch to NOACs.

3. **NOACs should be considered as an alternative to warfarin for stroke prevention in** AF in patients with $CHADS_2$ ≥ 1 who**:**
   - Have a warfarin allergy, warfarin specific-contraindication or are unable to tolerate warfarin therapy due to severe adverse effects[2]
   - Are unable to comply with the specific monitoring requirements of warfarin[3]
   - Are unable to achieve a satisfactory INR after an adequate trial of warfarin (usually at least three months) despite compliance with drug therapy. Patients at particular risk are those that remain sub-therapeutic (INR persistently <2), those where the INR regularly fluctuates above 4 and those requiring dosages at the extreme ends of the dose range
   - Have had an ischaemic stroke whilst stable on warfarin therapy - this must be discussed and agreed with haematology prior to initiation

[1] Details of $CHADS_2$ may be found in the SLCSN *Atrial Fibrillation Pathway for Primary Care*.
[2] Such as intolerable rash, significant alopecia, skin necrosis
[3] Inability to comply with warfarin monitoring may be due to lack of understanding of the monitoring process or inability to access any local monitoring service (this should be discussed with the patient's own GP, before a NOAC is initiated).

4. **Initiation of NOACs should only be undertaken by clinicians with expertise in initiating anticoagulant therapy for stroke prevention in AF**. The initiating clinician / organisation is responsible for the safe prescribing of NOACs including:
   - Ensuring the patient meets the defined criteria for use, as overleaf
   - Providing at least the first three months of therapy
   - Ensuring adequate follow up during the initiation phase including providing adherence counselling, dealing with side effects and addressing any patient concerns regarding therapy

5. **Following the initial 3 month period**, patients may be considered for transfer to the patient's own GP for long-term management, provided the SLCSN guidance on the transfer of care for these patients is followed and the GP agrees to take on prescribing responsibility. The patient's own GP should only take on the prescribing of NOACs when initiated in line with this position statement. If NOACs are prescribed for patients not covered by this guidance, the responsibility for prescribing will remain with the initiating clinician / organisation.

6. **Aspirin (with or without clopidogrel) is not a suitable alternative to warfarin or NOACs** in patients with atrial fibrillation and a $CHADS_2$ score ≥ 1, as it offers significantly less protection against stroke. Aspirin (with or without clopidogrel) should only be considered for such patients where warfarin and NOACs cannot be used due to allergy or contraindications.[4]

Anticoagulation service provision is a complex issue involving multiple stakeholders from primary and secondary care. The introduction of NOACs into clinical practice in line with NICE guidance requires the input of all stakeholders across the patient pathway, including clinicians, commissioners, medicines management teams and the South London Cardiovascular and Stroke Network.

For more information

Prescribing guidelines for NOACs can be found at www.slcsn.nhs.uk/noacs.html

Details on the commissioning and budget impact issues associated with the introduction of new oral anticoagulants in South London, contact Helen Williams, Consultant Pharmacist for Cardiovascular Disease via email on info@slcsn.nhs.uk.

Information on the work by the SLCSN to improve atrial fibrillation management is available on the website, www.slcsn.nhs.uk/af. Enquiries may also be directed to Sara Nelson, Associate Director, via email on info@slcsn.nhs.uk.

[4] Clopidogrel monotherapy is recommended for secondary prevention following a stroke in patients without AF. See www.slcsn.nhs.uk for more information on this indication.