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**Novel Oral Anticoagulants (NOACs) in Atrial Fibrillation – dabigatran / rivaroxaban
 Screening Checklist and Notification of Initiation to GP**

The checklist must be completed and returned to pharmacy dept **prior** to the initiation of dabigatran/rivaroxaban for the above indication

Hospital clinicians should be aware that, if a NOAC is prescribed for patients / indications that do not meet the agreed criteria, prescribing responsibility will remain with the initiating team

- **The completed checklist (pages 1-2) should be sent to the GP when NOAC therapy is initiated**
- **Following a 3 month period, care may be transferred to the GP. The transfer of care document (page 3) should be completed and sent directly to the GP for agreement**

Important information for GPs:

This is notification that NOAC therapy has been started. Please ensure that warfarin or other anticoagulant therapy is stopped. If appropriate, after 3 months of NOAC therapy, we will send a transfer of care document requesting that you take over prescribing responsibility.

Patient Details		GP Details
Surname		Name
Forename		Address
Address		
		Tel
Postcode		Fax
NHS No:		NHS.net email
DOB:	SEX: Male / Female	

Eligibility criteria

NICE ^{1,2} /SLCSN ³ criteria for dabigatran/rivaroxaban use	Yes	No
<i>Note: all three criteria below must be met to be within license for use</i> (Refer to the SPC for full details of licensed indications)		
Nonvalvular atrial fibrillation (AF)		
eGFR⁴ ≥ 30ml/min (dabigatran) or eGFR ≥ 15ml/min (rivaroxaban)		
CHADS₂ ≥ 1		
One or more of following criteria must also be met;		
Patient has a warfarin allergy, warfarin specific-contraindication or is unable to tolerate warfarin therapy due to severe adverse effects (e.g. intolerable rash, significant alopecia, skin necrosis)		
Patient is unable to achieve a satisfactory INR after an adequate trial of warfarin (usually at least 3 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		
Patient has had an ischaemic stroke whilst stable on warfarin therapy – this must be discussed and agreed with haematology prior to initiation		
Patients is unable to comply with the specific monitoring requirements of warfarin (e.g. 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 NOAC is initiated

Contraindications (Refer to the SPC for full details of drug interactions)

Tick all boxes (all answers must be No to proceed)	Yes	No
Any contraindication to dabigatran/rivaroxaban (as listed below)?		
Major bleeding potential or tendency (e.g. severe haemophilia)		
Active peptic ulcer, oesophageal varices, aneurysm, proliferative retinopathy		
Recent organ biopsy		
Lesion or condition at risk of significant major bleed e.g. recent trauma or surgery to the head, eyes, orbit or spine		
Recent stroke (usually < 4 weeks)		

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Contraindications Continued

Tick all boxes (all answers must be No to proceed)	Yes	No
Confirmed intracranial or intraspinal bleed (usually within last 4 weeks)		
Uncontrolled hypertension (>160mmHg systolic BP)		
Infective endocarditis		
Pregnancy or breast feeding		
FBC: platelets < 70 x 10 ⁹ /L		
eGFR ⁴ < 30ml/min (dabigatran) or eGFR < 15ml/min (rivaroxaban)		
LFT: liver enzymes (AST & ALT) elevated by > 2x ULN (i.e.>100IU/L)		
Coagulation screen: APTT > 1.5xnormal; INR > 1.4		
Contraindicated concomitant medications: ketoconazole, itraconazole, dronedarone ⁵ , other anticoagulant agents (except when switching therapy or unfractionated heparin for maintaining venous or arterial catheter patency) ⁶ Rivaroxaban only ⁶ – posaconazole, voriconazole Dabigatran only ⁷ - tacrolimus, ciclosporin,		

Patient Information (circle yes or no as appropriate)*:	Yes	No
Patient 1) is aware of the benefits and risks of NOAC therapy 2) is aware there is no effective antidote to NOAC therapy and 3) has consented to therapy *NOTE: Must be yes for all 3 statements for transfer to primary care		

DABIGATRAN - Dosing recommendations⁴ (Please tick selection)

1) 150mg Twice daily PO – standard dose	
2) 110mg Twice daily PO – suitable patients:	
<ul style="list-style-type: none"> All patients aged ≥ 80 years or Selected patients aged ≥ 75 years if high bleeding risk or Other patients with high bleeding risk, especially if moderate renal impairment or those with gastritis, oesophagitis, GORD or concomitant verapamil 	

RIVAROXABAN - Dosing recommendations⁴ (Please tick selection)

1) 20mg OD PO with food – standard dose	
2) 15mg OD PO with food – suitable patients:	
<ul style="list-style-type: none"> CrCl = 30-49ml/min (moderate) / eGFR = 30-45ml/min (CKD stage 3b) CrCl = 15ml-29/min (severe) / eGFR =15-29ml/min (CKD stage 4) 	

AUTHORISATION (medical practitioner undertaking assessment)

Signature:	Print name:
Position:	Contact number:
Date:	

HOSPITAL PHARMACY DEPT

Approved Yes / No / Not applicable (circle as appropriate)
If 'No' include reason :

References

- NICE TA249 (15th March 2012) Dabigatran etexilate for the prevention of stroke and systemic embolism in atrial fibrillation (AF)
- NICE TA256 (15th May 2012) Rivaroxaban for the prevention of stroke and systemic embolism in AF
- SLCSN NOACs in AF Position statement
- MHRA Drug Safety Update Vol 5 Issue 5, Dec 2011: A2
- MHRA Drug Safety Update Vol 5 Issue 12 July 2012 : A1
- SPC Rivaroxaban, Bayer Ltd 18.06.2012
- Summary of product characteristics (SPC) Dabigatran. Boehringer Ingelheim Ltd 23/07/12

Adapted from a document initially prepared by the anticoagulant pharmacists at Kings College Hospital

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**Novel Oral Anticoagulants (NOACs) in Atrial Fibrillation
 Transfer of Care / Prescribing Agreement**

Following a 3 month period, prescribing responsibility may be transferred to the GP (subject to GP agreement). This transfer of care / prescribing agreement should be completed and sent directly to the GP.

Section A: To be completed by the initiating organisation / clinician

Patient Details:

Name..... DOB:/...../.....

GP Practice Details:

Name:
 Address:
 Tel no:
 Fax no:
 NHS.net e-mail:

Consultant Details:

Consultant Name:
 Clinic Name:.....
 Address:
 Tel no:
 Fax no:
 NHS.net email:

Next hospital appointment:/...../.....

Dear Dr.,
 Your patient was seen on/...../.....
 Patient was initiated on:(add drug name, dose and frequency)
 for the above diagnosis on...../...../.....
 I am requesting your agreement to the transfer of the care of this patient from/...../..... in accordance with the
 SLCSN NOACs in AF Position Statement¹ (i.e. after at least 3 months treatment).

The following investigations have been performed on/...../..... and are acceptable for transfer of care.
 Please monitor **Renal function annually** or more frequently if clinically appropriate

Test	Result	Test	Result
Serum Creatinine			
eGFR			

Other relevant information:

- I confirm that I have prescribed in accordance with the SLCSN guidelines
- I confirm that the patient has been made aware of the benefits and risks of NOAC therapy, including risks of bleeding both major and minor and that there is currently no effective reversal agent available
- I confirm the patient has consented to treatment

Signed:..... **Name of Clinician:**..... **Date:**

Section B: To be completed by the GP and returned to the hospital consultant as detailed in Section A above.

Please sign and return your agreement to accept prescribing responsibility within 14 days of receiving this request
 Tick which applies:

- I accept transfer of care of **Rivaroxaban / Dabigatran** (delete as appropriate).
 Primary Clinicians may refer to the SLCSN Rivaroxaban or Dabigatran Guidance on the use of these drugs for stroke prevention for information to support the prescribing in primary care.
- I am not willing to accept the transfer of care for this patient for the following reason:

GP name: **GP signature:** **Date:**/...../.....

(This transfer of care document should be reviewed in-conjunction with the NOAC drug screening checklist sent previously by the initiating clinician - if not received contact consultant named above for details)

INITIATING ORGANISATIONS TO ADD LOCAL CONTACT DETAILS FOR HAEMATOLOGY / ANTICOAGULANT SERVICES (TEL / EMAIL) FOR QUERIES

All SLCSN documents can be found at the following link <http://www.slcsn.nhs.uk/noacs.html#>