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Proforma for the INITIATION of Direct Oral Anticoagulant (DOAC) therapy in Primary Care

- Each stage of the proforma must be followed and completed during the patient consultation. The appendices (pg. 6 onwards) are for further information.
- A copy of the proforma must be saved on the patient medical record and a copy may be given to the patient.
- The GP must conduct a **follow up appointment with the patient within1 month** of treatment initiation. This review should be conducted using the 'Proforma for the **review** of DOAC therapy in Primary Care' (pg. 4).

PATIENT ELIGIBILITY FOR DOAC THERAPY

Patient has:
Non-valvular atrial fibrillation

If patient has the following, do not initiate a DOAC. Seek specialist advice (via Advice & Guidance) or consider a referral to Cardiology/ Haematology, where appropriate.
Atrial flutter
A continuing risk of arrhythmia recurrence after cardioversion back to sinus rhythm
A mechanical prosthetic valve OR moderate-severe mitral stenosis(require warfarin)

RISK STRATIFICATION

CHA_2DS_2VASc		**Tick**
Congestive Heart Failure	1	
Hypertension A resting blood pressure >140mmHg systolic and/or >90mmHg diastolic on at least 2 occasions or current antihypertensive treatment.	1	
Age ≥75 years	2	
Diabetes Fasting plasma glucose level ≥7.0 mmol/L (126 mg/dL) or treatment with oral hypoglycaemic agent and/or insulin	1	
Prior stroke/TIA	2	
Vascular disease Prior myocardial infarction, angina pectoris, percutaneous coronary intervention or coronary artery bypass surgery.The presence of any the following: intermittent claudication, previous surgery or percutaneous intervention on the abdominal aorta or the lower extremity vessels, abdominal or thoracic surgery, arterial and venous thrombosis.	1	
Age 65-74	1	
Female	1	
TOTAL SCORE		

HASBLED		**Tick**
Uncontrolled hypertension* (systolic >160mmHg)	1	
Abnormal liver function* (bilirubin >2x normal,with AST/ALT/AP >3x normal	1	
Abnormal renal function* (serum Cr>200µmol/L, dialysis, transplant)	1	
Prior stroke	1	
History of major bleed Bleeding history or predisposition (anemia)	1	
Labile INR (on warfarin)* (TTR <60%)	1	
Age ≥65 years	1	
Medication usage predisposing to bleeding(anti-platelets/NSAIDs)*	1 1	
Alcohol (>8units/week)*	1	
TOTAL SCORE		

*Offer methods of modifying and monitoring the bleeding risk factors

A score of 3 or more indicates a higher bleeding risk and requires more regular reviews.

Note:
- A high bleeding risk is not a plausible reason to withhold treatment with a DOAC.
- Do not withhold anticoagulation solely because of a risk of falls.

Seek specialist advice (via Advice & Guidance), where appropriate.

- **Consider** anticoagulation in all **men** with CHA_2DS_2VASc = **1**
- **Offer** anticoagulation to all patients (male or female) with CHA_2DS_2VASc **≥ 2**

Anticoagulation therapy indicated	**YES**	**NO**
Modifiable bleeding risk present	**YES**	**NO**
Actions to modify bleeding risk: e.g. consider gastroprotection if the patient has risks of GI bleeding (e.g. certain drugs) or a HAS-BLED score ≥ 3.		

Recent Parameter	Date of test	In range to anticoagulate		Further information
Clotting screen (INR / APPT)		Yes	No	
FBC (particularly for haemoglobin & platelets)		Yes	No	If NO Further investigations needed,seek specialist advice
LFT		Yes	No	If NO Further investigations needed if :Bilirubin>2x normal, AST/ALT/AP >3x normal Seek specialist advice
Renal function (particularly for serum creatinine)				See below
Weight (kg)				
BP Optimisation				

Assessment of Renal Function

Use Cockcroft-Gault Equation.
https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation
Use Readcode 451A0 to document CrCl value on clinical system.

Note:
Current CrCl calculators embedded within GP IT systems use either actual body weight OR ideal body weight and therefore, may not give a reliable estimate of CrCl for the adjustment of DOAC doses. Ensure the appropriate weight is used.

Use the following as a guide:
a) Underweight (BMI <18.5 kg/m2) individuals: estimate CrCl using actual body weight

b) Normal or overweight (BMI ≥18.5 and <30 kg/m2) individuals: estimate CrCl using actual body weight

c) Obese or morbidly obese (BMI ≥ 30 kg/m2) individuals: estimate a CrCl range using IBW and ABW that define the lower and upper boundaries (box 2). If the difference crosses over a DOAC dosing threshold, then assess bleeding and thrombosis risk to decide on suitable dose

If you have concerns about dose adjustments for DOACs based on estimating renal function using Cockcroft-Gault, please contact the anticoagulation team for further advice.
(See appendix 5)

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CONTRAINDICATIONS TO DOAC THERAPY (see SmPC or BNF for full details)

Any contraindication to dabigatran / rivaroxaban / apixaban / edoxaban?	Yes
Hypersensitivity to the active substance or any of the excipients	
Active clinically significant bleeding	
Lesion or condition, if considered to be a significant risk for major bleeding. This may include current or recent gastrointestinal ulceration, presence of malignant neoplasms at high risk of bleeding, recent brain or spinal injury, recent brain, spinal or ophthalmic surgery, recent intracranial haemorrhage, known or suspected oesophageal varices, arteriovenous malformations, vascular aneurysms or major intraspinal or intracerebral vascular abnormalities	
Concomitant treatment with any other anticoagulants e.g. unfractionated heparin (UFH), low molecular weight heparins (e.g. enoxaparin, dalteparin), heparin derivatives (e.g. fondaparinux), oral anticoagulants (warfarin, dabigatran, apixaban, rivaroxaban, edoxaban) except under specific circumstances of switching anticoagulant therapy or when UFH is given at doses necessary to maintain an open central venous or arterial catheter	
Hepatic disease associated with coagulopathy and clinically relevant bleeding risk including cirrhotic patients with Child Pugh B and C	
Uncontrolled severe hypertension (edoxaban)	
Pregnancy or breast feeding	
CrCl< 30ml/min (dabigatran) or CrCl< 15ml/min (rivaroxaban or apixaban or edoxaban)	
Prosthetic heart valve(s)	
Dabigatran: Concomitant treatment with the following strong P-gp inhibitors (systemic ketoconazole, cyclosporine, itraconazole and dronedarone)	
If the answer to any of the above is YES, patient is not suitable for a DOAC	

SmPC: www.medicines.org.uk
BNF: https://bnf.nice.org.uk/

Patient eligibility	Tick relevant option
Patient suitable to start anticoagulation Complete consultation below	
Patient unsuitable to start anticoagulation; document reason anticoagulation unsuitable:	

The MHRA Drug Safety Update

The MHRA issued a drug safety update in June 2019, on DOACs:
Direct-acting oral anticoagulants (DOACs): increased risk of recurrent thrombotic events in patients with antiphospholipid syndrome: https://www.gov.uk/drug-safety-update/direct-acting-oral-anticoagulants-doacs-increased-risk-of-recurrent-thrombotic-events-in-patients-with-antiphospholipid-syndrome

A clinical trial has shown an increased risk of recurrent thrombotic events associated with DOACs, compared with warfarin, in patients with antiphospholipid syndrome and a history of thrombosis.

Advice for healthcare professionals:

- DOACs are not recommended in patients with antiphospholipid syndrome, particularly high-risk patients (those who test positive for all 3 antiphospholipid tests — lupus anticoagulant, anticardiolipin antibodies, and anti-beta 2 glycoprotein I antibodies)
- review whether continued treatment with a DOAC is appropriate for patients diagnosed with antiphospholipid syndrome, particularly high-risk patients, and consider switching to a vitamin K antagonist such as warfarin
- report suspected adverse drug reactions to DOACs on a Yellow Card, including any thromboembolic events suspected to be due to lack of efficacy.

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PATIENT CONSULTATION

The following points must be discussed with the patient and/or their relative/carer prior to starting DOAC therapy:

Discussion point	**Discussion taken place – please tick**
Explanation of atrial fibrillation and risk of stroke given to patient	
Explanation of the purpose of an anticoagulant and intended duration of treatment	
Explanation of how to take the medication and how to manage a missed dose	
Explanation of the risks of bleeding whilst taking anticoagulation therapy; explain the options for management of bleeding whilst on oral anticoagulation (including the lack of specific antidote for rivaroxaban/apixaban/edoxaban)	
Consent	**Yes/No**
Patient/carer gives consent to commencing oral anticoagulant treatment	
Document reason if patient/carer does not consent to oral anticoagulation treatment.	

PATIENT DECISION AID

If there is no distinguishing clinical feature to warrant the choice of one oral anticoagulant over another, the patient should be provided with information about the options available in order to make an informed decision about the treatment option they wish to pursue.

Factor	**Options**	**Suitable DOAC**
Frequency of tablets/capsules	One tablet once a day	Rivaroxaban/edoxaban
	One tablet/capsule twice a day	Apixaban/dabigatran
The need for blood tests	Before you start treatment; then periodically (at least once a year) to check kidney and liver function	Any DOAC
Use of a compliance aid (dosett^{T}box)	Suitable to go into existing compliance aid	Apixaban/rivaroxaban/ edoxaban
	Separate compliance aid(provided by manufacturer as capsules need to be kept in foil wrapper)	Dabigatran
	I am good at remembering to take my medicines	Any DOAC
With/without food	Take with / without food	Dabigatran, edoxaban, apixaban
	Take **WITH** food	Rivaroxaban
Swallowing difficulties/feeding tube	CAN be crushed	Rivaroxaban, edoxaban, apixaban
	CANNOT be crushed	Dabigatran
The availability of a direct antidote	I want to take a medicine with an established direct antidote. I understand the limitations of the available direct antidotes	Dabigatran
	I understand that general measures can be used to control bleeding which may be successful. I am happy with this option.	Apixaban, edoxaban, rivaroxaban

ANTI-COAGULANT CARD

Provide an anticoagulant alert card. These can be ordered using the NHS order portal from Xerox (UK) Ltd, using the order code 'OATALERTCARD'. For organisations not registered with Xerox (UK) Ltd, visit www.nhsforms.co.uk website and complete the appropriate registration form.
Alternatively, call the help desk on 0300 123 0849.

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Proforma for the REVIEW of DOAC therapy in Primary Care

- This proforma is for use in patients being reviewed (within 1 month of treatment initiation) and/or at the annual review.
- Each stage of the proforma must be followed and completed during the patient consultation.
- A copy of the proforma must be saved on the patient medical record and a copy may be given to the patient.

Patients taking DOACs do not need routine monitoring of INR/anticoagulation, but require periodic review of haemoglobin, renal function and liver function, at least annually or more frequently, where clinically indicated. In addition, adherence and tolerance should also be checked at every opportunity.

Ensure that the baseline creatinine clearance (calculated using Cockcroft-Gault formula) is correct and verify dosage.

Renal function:

- For patients with CrCl< 15ml/min: DOACs are contraindicated.
- For patients with CrCl 15-29ml/min:
  -dabigatran is contraindicated;
  - apixaban / edoxaban / rivaroxaban should be used with CAUTION (no effectiveness or safety data for this patient cohort) especially if renal function is not stable.

Questions to ask the patient:

- ✓ Assess compliance.
- ✓ Check for alert card.
- ✓ Any changes in medication and lifestyle.
- ✓ Missed doses?
  - If yes, explore why.
- ✓ Bleeding and bruising.
  - When?
  - How much and how often?
  - How severe?
  - Ant other triggering factors?
  - Action taken
- ✓ Other side effects.
- ✓ Outline what happens next.

Monitoring

Blood sampling[1]	Yearly	Haemoglobin, renal and liver function
	6 monthly	Renal function if: ≥75 years frail[a]
	x-monthly	If impaired renal function (CrCl<60ml/min) Recheck frequency (months) = CrCl/10e.g. CrCl 30ml/min = 3 monthly
	On indication	If intercurrent condition that may impact on renal or hepatic function

[a] Frailty is defined as three or more criteria of unintentional weight loss, self-reported exhaustion, weakness assessed by handgrip test, slow walking speed, or low physical activity.

[1]Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with NVAF, 2015

Enter diary date for next review, on clinical system

Appendix 1: Counselling Check-list

FOR FURTHER INFORMATION ONLY

Counselling Point	Guidance
Reason for DOAC	Atrial fibrillation – irregular heart beat = inefficient blood flow = clots = stroke/TIA
Mode of action	Anticoagulants 'thin the blood' or 'reduce the ability of blood to form clots'
Duration	Lifelong
How to take	Apixaban: TWICE a day, with or without food – can be crushed Dabigatran: TWICE a day, with or without food – do not open or chew capsules, do not put in usual compliance aid; separate compliance aid available from manufacturer. Edoxaban: ONCE a day, with or without food – can be crushed Rivaroxaban: ONCE a day **WITH** food– can be crushed
Adherence	Importance of taking as prescribed – if a dose/day of medicine is missed, the medicine will not work on that day putting the patient at risk of a stroke Advise on adherence aids e.g. reminders.
Missed dose	**ONCE daily** DOACs (rivaroxaban and edoxaban – from SmPC): The dose should be taken immediately and then be continued the following day with the once-daily intake as recommended. The patient should **not take double** the prescribed dose on the same day to make up for a missed dose. *The patient can take a forgotten dose up until 12 hours after the scheduled time. If that is not possible anymore, the dose should be skipped and the next scheduled dose should be taken[1].* **TWICE** daily DOACs(from SmPC): Dabigatran – forgotten dose may still be taken up to 6 hours prior to the next scheduled dose. From 6 hours prior to the next scheduled dose on, the missed dose should be omitted. Double dose should not be taken to make up for the missed dose. Apixaban- if a dose is missed, the patient should take apixaban immediately and then continue with twice daily intake as before. *The patient can take a forgotten dose up until 6 hours after the schedules intake. For patients with a high stroke risk and low bleeding risk, this can be extended up till the next scheduled dose[1].* [1]Updated European Heart Rhythm Association Practical Guide on the use of non-vitamin K antagonist anticoagulants in patients with NVAF, 2015
Informing healthcare professionals	ESSENTIAL in an emergency situation, planning surgery, planning pregnancy, dentist, pharmacist (interactions), practice nurse (immunisations)
Side-effects	Signs of bleeding and bruising (seek emergency help if severe) – epistaxis (if lasts >10min seek medical assistance), haematuria, haemotypsis, haematemesis, melaena, abnormal genitourinary bleeding See individual patient packs for drug specific side effects e.g. fainting with rivaroxaban (counsel on safety with driving/operating machinery)
How to manage a major bleed	Apixaban, edoxaban, rivaroxaban – counsel on lack of specific antidote but that general measures (e.g. PCC) have been used successfully Dabigatran – direct reversal agent licensed
Interactions	Check with pharmacist if buying herbal or OTC medication e.g. NSAIDs, aspirin not recommended
Food and alcohol	No known food interactions No interaction with alcohol but staying within the recommended national guidelines is advised (≤14 units/week) (NB: risk of falls with excessive alcohol consumption)
Women of child bearing age	Use reliable contraception whilst taking a DOAC Discuss with doctor if planning pregnancy or as soon as possible if they discover they are pregnant May experience heavier menstruation
Alert card	Carry anticoagulant alert card at ALL times

Appendix 2: Dosing guidance for patients on DOACs (correct as of August 2019):
(See latest BNF or Summary of Product Characteristics for full details and most up-to-date information)

Doses are as per current SPCs. Please check SPC for any further dose information.

<table>
<tr><th>DOAC</th><th>Standard dose</th><th>When to reduce</th><th>Reduced dose</th><th>Not recommended</th></tr>
<tr><td>Apixaban</td><td>5mg TWICE daily</td><td>• CrCl 15-29ml/min
• Any two of the following:
<table><tr><th>Age</th><th>Weight</th><th>Serum Cr</th></tr><tr><td>≥ 80 years</td><td>≤ 60kg</td><td>≥ 133mmol/L</td></tr></table></td><td>2.5mg TWICE daily</td><td>CrCl<15 ml/min</td></tr>
<tr><td>Dabigatran</td><td>150mg TWICE daily</td><td>Dose reduction recommended:
• Age ≥ 80 years
• Concomitant treatment with verapamil

Dose reduction for consideration[#]:
• Age 75 – 80 years
• CrCl 30-50ml/min
• Patients with gastritis, esophagitis or gastroesophageal reflux
• Increased risk of bleeding</td><td>110mg TWICE daily</td><td>CrCl<30 ml/min</td></tr>
<tr><td>Edoxaban</td><td>60mg ONCE daily</td><td>• CrCl15-50ml/min
• ≤ 60kg
• Concomitant treatment with ciclosporin, dronedarone, erythromycin, ketoconazole</td><td>30mg ONCE daily</td><td>CrCl<15 ml/min</td></tr>
<tr><td>Rivaroxaban</td><td>20mg ONCE daily</td><td>• CrCl 15-49ml/min</td><td>15mg ONCE daily</td><td>CrCl<15 ml/min</td></tr>
</table>

[#]Seek specialist advice (via Advice & Guidance)

Appendix 3: Checklist for FOLLOW UP:

Review	Interval	Guidance
1. Adherence	Each visit	• Remind patient to bring DOAC card and remaining medication to assess average adherence (if patient is using adherence support technology – review recorded data) • Re-educate on importance of strict intake schedule • Inform about adherence aids (including compliance aids such as blister packs, smartphone applications)
2. Thromboembolism	Each visit	• Are there are new signs or symptoms the patient has experienced?
3. Bleeding	Each visit	• Assess frequency, severity and onset of any bleeding. • 'Nuisance' bleeding (minor or clinically non-relevant bleeding) e.g. epitaxis: are preventative measures possible? e.g. PPI, haemorrhoidectomy. Encourage patient to diligently continue with anticoagulation; do not stop treatment or adjust dose – seek specialist advice if concerned • Bleeding with impact on quality of life or with risk: are preventative measures possible? (also consider the onset of headaches carefully and send for review if concerned); particularly if combined with other symptoms such as weakness, nausea, confusion, slurred speech) • If major bleeding refer for emergency care. • If preventative measures not possible, contact AF anticoagulation service for advice OR refer immediately.
4. Other side effects	Each visit	• Carefully assess relation of new side effects to DOAC therapy: - Is it attributable to DOAC? - Is side effect likely to be transient? - can it be managed with symptomatic relief e.g. antihistamines, PPI • Encourage patient to diligently continue with anticoagulation • If side-effect persistent and/or impacting on patient's quality of life, switch the DOAC or seek specialist advice. • Common side effects seen in real-life clinical practice are: - rash or fainting with rivaroxaban - dyspepsia with dabigatran - nose bleeds with all DOACs
5. Other medications for interactions	Each visit	• Prescription drugs • Over the counter drugs (especially aspirin and NSAIDs) and herbal remedies See DOAC interaction checker (appendix 5)
6. Monitoring		See Review Proforma(pg.4)

Appendix 4: **Interaction checker**:
Some drugs can be used concomitantly, with caution, some may require dosage adjustments - See current BNF or SmPC for full details

Apixaban	Edoxaban	Dabigatran	Rivaroxaban
Amiodarone	Antiplatelet agents	Amiodarone	Carbamazepine
Carbamazepine	Carbamazepine	Antiplatelet agents	Dronaderone
Clarithromycin	Ciclosporin	Carbamezapine	HIV protease inhibitors, ritonavir
Clopidogrel	Dronedarone	Ciclosporin	Itraconazole
Diltiazem	Erythromycin	Clarithromycin	Ketoconazole
Dipyridamole	Ketoconazole	Dronedarone	Phenobarbital
HIV protease inhibitors, ritonavir	NSAIDs	HIV protease inhibitors, ritonavir	Phenytoin
Itraconazole	Phenobarbital	Itraconazole	Posaconazole
Ketoconazole	Phenytoin	Ketoconazole	Rifampicin
Naproxen	Rifampicin	NSAIDs	St. John's wort
NSAIDs	St. John’s wort	Phenytoin	Voriconazole
Phenobarbital		Posaconazole	
Phenytoin		Quinidine	
Posaconazole		Rifampicin	
Quinidine		St. John's wort	
Rifampicin		Tacrolimus	
St. John’s wort		Verapamil	
Verapamil			
Voriconazole			

Drugs that increase bleeding risk:

- NSAIDs
- SSRIs
- Antiplatelet agents
- Systemic steroid treatment
- Drugs associated with thrombocytopenia (e.g. chemotherapeutic agents)

Appendix 5:

South London Calculating Creatinine Clearance for DOACs

Cockcroft-Gault equation is the standard method for estimating creatinine clearance (CrCl) and drug dose adjustment in adults. It is recommended by the manufacturers of all Direct Oral Anticoagulants (DOACs - apixaban, dabigatran, edoxaban and rivaroxaban) for determining kidney function of patients when prescribing these agents. Studies have demonstrated that use of the Cockcroft-Gault equation allows appropriate dosing of DOACs and minimises the risk of over anticoagulation. Estimated glomerular filtration rate (eGFR) should not be used, as data suggests this can lead to inappropriate dosing in up to 50% of patients.

Cockcroft-Gault Equation
Creatinine Clearance (ml/min) = $\frac{(140 - \text{Age}) \times \text{Weight (kg)}^* \times \text{constant}}{\text{Serum Creatinine (µmol/L)}}$ Constant = 1.23 for male and 1.04 for female

Accuracy of Cockcroft-Gault estimation is influenced by body weight

The Cockcroft-Gault equation estimates CrCl using the patient's age, weight, and gender and serum creatinine. Inaccuracies in estimating CrCl with the equation are noted in extremes of bodyweight, especially in those who are obese.

Current CrCl calculators embedded within GP IT systems do not give a reliable estimate of CrCl for the adjustment of DOAC doses and should not be used.

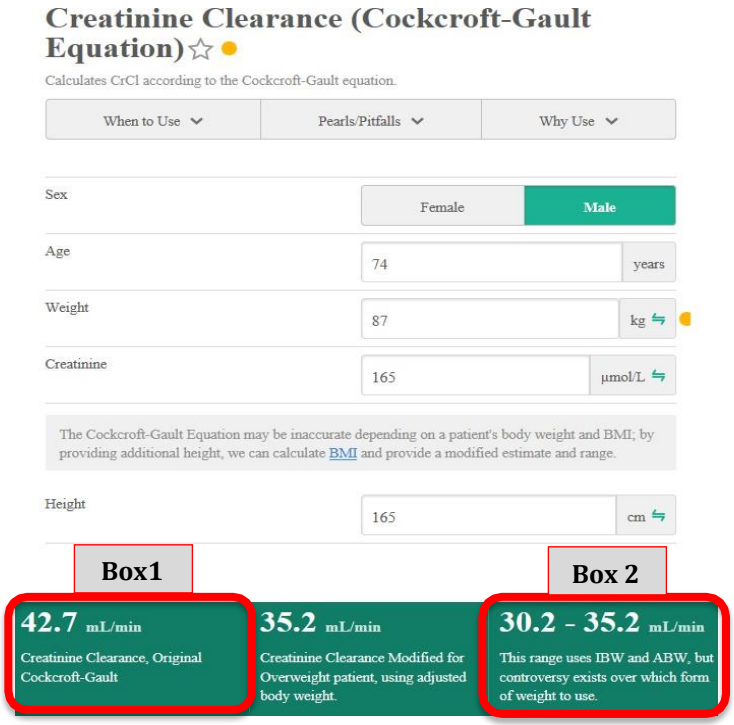
We recommend use of the MD+CALC Cockcroft-Gault equation which recognises the need to adjust for bodyweight in obese individuals and will calculate a modified estimate of CrCl with a range that is based on ideal bodyweight (IBW) and adjusted body weight (ABW). This can be accessed using the link: https://www.mdcalc.com/creatinine-clearance-cockcroft-gault-equation or it can be downloaded as an app to an apple device.

Always check the default units are correct when entering weight, serum creatinine and height. These can be changed using the drop down list if needed.

Use the following as a guide:

a) **Underweight (BMI <18.5 kg/m^2) individuals: estimate CrCl using actual body weight (box 1)**
b) **Normal or overweight (BMI ≥18.5 and <30 kg/m^2) individuals: estimate CrCl using actual body weight (box 1)**
c) **Obese or morbidly obese (BMI ≥ 30 kg/m^2) individuals: estimate a CrCl range using IBW and ABW that define the lower and upper boundaries (box 2). If the difference crosses over a DOAC dosing threshold, then assess bleeding and thrombosis risk to decide on suitable dose**

If you have concerns about dose adjustments for DOACs based on estimating renal function using Cockcroft-Gault, please seek advice from your local anticoagulant service



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Participating Trusts: Epsom and St Helier, Croydon, Kingston, St Georges