

Guideline Number & Full Title:	2782 - Guidelines for the management of adult patients taking Direct Oral Anticoagulants (DOACs) who require elective, non-cardiac non-neurosurgical interventional procedures
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Division & Speciality:	CAS (Haematology)
Version:	2
Ratified by:	DTC
Scope (Target audience, state if Trust wide):	Medical staff involved in the perioperative management of patients who are prescribed direct oral anticoagulant drugs.
Review date (when this version goes out of date):	December 2025
Explicit definition of patient group to which it applies (e.g. inclusion and exclusion criteria, diagnosis):	 Adult patients taking Direct Oral Anticoagulants (DOACs) who require elective, non-cardiac interventional procedures Exclusions Patients receiving a vitamin K antagonist (e.g. warfarin) Patients taking DOACs who require emergency surgery (separate guidelines available) or invasive procedures Patients undergoing neurosurgical intervention Patients undergoing cardiac surgery or implantable cardiac devices Patients with mechanical heart valves Patients in the critical care unit Paediatric patients
Summary of evidence base this guideline has been created from:	BSH Guidelines on the Peri-Operative Management of Anticoagulation and Antiplatelet Therapy (2016) Review of the available literature (January 2020)

This guideline has been registered with the trust. However, clinical guidelines are guidelines only. The interpretation and application of clinical guidelines will remain the responsibility of the individual clinician. If in doubt contact a senior colleague or expert. Caution is advised when using guidelines after the review date or outside of the Trust.

Guidelines for the management of patients taking Direct Oral Anticoagulants (DOACs) who require elective surgical intervention

Scope

The purpose of this document is to provide guidance for the management of periprocedural anticoagulation for adult patients taking the direct oral anticoagulants (DOACs) rivaroxaban, apixaban, edoxaban and dabigatran who require elective surgery or invasive procedures.

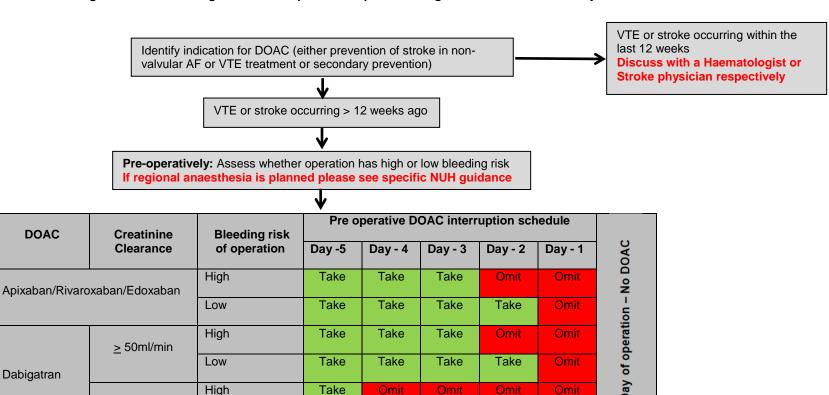
If regional analgesia/anaesthesia is planned, care should be taken to ensure the correct timing of DOAC administration around siting and removal of epidural catheters or spinal injections. See NUH Anaesthetic epidural (non obstetric) guideline at <a href="http://nuhnet/nuh_documents/Lists/Clinical%20A%20to%20Z/AK5.aspx?RootFolder=http://nuhnet/nuh_documents/Lists/Clinical%20A%20to%20Z/AK5.aspx?RootFolder=http://nuhnet/%2fnuhnet%2fnuh%5fdocuments%2fLists%2fClinical%20A%20to%20Z%2fAnaesthesia&FolderCTID=0x0120000A04A8C608278A4C87397FA7D0D7D31E

This document provides general guidance only and is not a substitute for clinical judgment of an individual patient. Complex patients or patients in whom there are specific concerns regarding thrombosis or bleeding risk should always be discussed with a haematologist, cardiologist or stroke physician when making a preoperative anticoagulation plan.

Exclusions

- Patients receiving Vitamin K antagonists or antiplatelet agents; see NUH guidelines for management of patients taking vitamin K antagonists and anti-platelet agents http://nuhnet/nuh_documents/Guidelines/Cancer%20and%20Associated%20Specialties/Clinical%20Haematology/2841.pdf
- Patients taking DOACs who require an emergency operation or are bleeding see
 - Guideline for patients receiving Apixaban, Edoxaban or Rivaroxaban requiring Emergency Surgery or treatment for Haemorrhage http://nuhnet/nuh_documents/Guidelines/Cancer%20and%20Associated%20Specialties/Clinical%20Haematology/2805.pdf
 - Guideline for patients receiving Dabigatran requiring Emergency Surgery or treatment for Haemorrhage http://nuhnet/nuh_documents/Guidelines/Trust%20Wide/Trust%20Wide/2173.pdf
- Patients undergoing neurosurgical intervention
- Patients undergoing cardiac surgery or implantable cardiac devices; patients should be discussed with cardiology or cardiothoracic teams
- Patients with mechanical heart valves; DOACS are not licensed for this indication
- Patients in the critical care unit
- Paediatric patients

Perioperative guideline for patients receiving Direct Oral Anticoagulants who require interruption for surgical intervention: Summary



All patients

- If the patient is NBM or expected to have reduced oral absorption, continue enoxaparin at a prophylactic dose until oral treatment can be resumed
- If renal function has deteriorated, the DOAC dose should be adjusted appropriately
- Ensure that the patient has not been started on any drug which could interact with a DOAC (see appendix 4)
- Always ensure attention to hydration, mobilisation and use of anti-embolic stockings (if indicated) as for routine thromboprophylaxis
- If a patient has been prescribed a DOAC, routine low molecular weight heparin prophylaxis should <u>not</u> be prescribed concurrently

Post-operatively: Assess the risk of bleeding and risk of VTE

Take

Take

Take

Do not restart any anticoagulants until a Doctor has assessed the patient as being safe to anticoagulate

Omit

Omit

If Minor Bleeding Risk Surgery, no plans for further surgery and haemostasis achieved

Low

< 50 ml/min

- If high risk for VTE consider single dose of prophylactic enoxaparin s/c 40mg given 6-8 hours after surgery
- Restart DOAC 24 hours after surgery at the patient's usual dose
- If the patient has a low bleeding risk, consideration can be given to restarting the DOAC at 12 hours post operatively

Major Bleeding Risk Surgery or Ongoing Bleeding Risk

- Once it is safe to start anticoagulation, consider enoxaparin at a prophylactic dose
- A DOAC should not be restarted until at least 48 hours post procedure
- Assess the patient at 48 hours postoperatively
 - If haemostasis is secure and no plans to return to theatre, restart DOAC at the patient's usual dose 12-24 hours after the last dose of enoxaparin
 - If ongoing bleeding risk, do not restart DOAC and reassess the patient every 24 hours

Introduction

Several direct oral anticoagulants (DOACs) are now licensed for use in the UK and within NUH. Rivaroxaban (Xarelto®), apixaban (Eliquis®), edoxaban (Lixiana®) and dabigatran (Pradaxa®) are all available on formulary. Rivaroxaban, apixaban and edoxaban are direct factor Xa inhibitors whereas dabigatran is a direct thrombin inhibitor. These agents offer several benefits over traditional warfarin therapy, particularly in that there is no need for therapeutic monitoring. Stable levels of anticoagulation are achieved with a once or twice daily dosing regimen depending on the choice of drug.

Although several of the clinical trials suggested a reduced bleeding risk in specific groups of patients and in particular a reduced incidence of intracranial haemorrhage this was outside of the surgical setting. The approach to perioperative management of patients taking DOACs is based on an approximate calculation of the half-life of the drug, taking into account renal function. This is combined with consideration of the bleeding risk of the proposed procedure and a clinical evaluation of the patient's individual risk factor for thrombosis and bleeding (Keeling at al 2012)

In 2019 the PAUSE protocol was published (Spyrolopolous et al, 2019). This study investigated the hypothesis that a standardized perioperative management approach could be safely used in patients taking Rivaroxaban, Apixaban and Dabigatran. Edoxaban was not routinely available within the timeframe of the study but results are expected to be equally applicable in this patient group.

There has been a sharp increase in the licensed indications for DOAC use since publication of our previous guideline (2017) It is therefore important to check what dose of DOAC the patient is taking, particularly when prescribing in the post operative period. It is also important to note that none of the drugs are licensed for use in patients with mechanical cardiac valves and therefore should not be prescribed for this indication.

Laboratory testing

Routine monitoring of the DOACs is not indicated due to the predictable pharmacokinetics of the drugs. As a result, the standard coagulation screens such as the PT, APTT and TT are not validated for use with the DOACS. In an emergency setting, coagulation testing and laboratory investigation of drug levels can be used along with clinical parameters to assess the relative degree of anticoagulation in an individual patient; see NUH guidelines for the management of emergency surgery and bleeding in patients taking DOACS. Further advice in the emergency setting can be sought from a haematologist.

If a clotting screen has been taken for another reason, it is important to note that all DOAC drugs will affect the results; see appendix 1.

Guidance

Whenever an anticoagulant is stopped to allow an operative intervention or an invasive procedure, there is a risk of thrombosis for the patient. Depending on the reason for anticoagulation, this risk will vary with each individual patient and needs to be balanced carefully with the indication and necessity of the procedure.

All patients should be counselled regarding their individual risk of thrombosis when an anticoagulant is omitted by the treating team at the time the operation or intervention is planned.

If there are concerns that a patient is very high risk for thrombosis such as patients who have had a VTE or stroke within the last 3 months, the case should be discussed with a haematologist or stroke physician by a Doctor from the treating team. Similarly if patients are very high risk for bleeding, further advice should be sought. This should be done at the earliest available opportunity to allow advanced planning for operation and to avoid delay to a procedure. Otherwise the general guidance below should be followed.

1. Pre-operatively

As the half-life of DOAC drugs is short (in comparison with warfarin and other vitamin K antagonists), pre-operative bridging anticoagulation is **not** required. Clearance of these drugs has a variable renal component and creatinine clearance is important in assessment of how soon prior to intervention the drug should be stopped. In all cases a formal Cockroft Gault creatinine clearance should be used; eGFR is **not** a suitable alternative. (see Appendix 2 for information on calculation http://nuhnet/diagnostics_clinical_support/antibiotics/Pages/Calculators/Calc.aspx).

The risk of bleeding for the planned operative intervention should be assessed when deciding on when to stop the drug preoperatively. The drugs should be omitted for longer periods for surgery where there is a high risk of bleeding or when the consequences of bleeding would have a severely detrimental effect in the patient.

In addition to standard of care at the pre-operative assessment clinic:

- All patient should have a routine FBC performed
 - If there is thrombocytopenia which would increase the risk of bleeding, the patient should be discussed with a haematologist in advance of surgery
- All patients should have U and E checked within 6 weeks of planned surgical intervention.
- All patients should have a formal Cockroft Gault creatinine clearance calculated to guide perioperative anticoagulation management (see appendix 2)
- Advice should be given to the patient regarding the times of stopping their DOAC drug
 - Preoperatively anticoagulation should be stopped as directed in the tables below (Adapted from) Keeling e al 2016

Rivaroxaban/Apixaban/Edoxaban

Bleeding risk of operation*		
High bleeding risk (minimum interval since last dose)	Low bleeding risk (minimum interval since last dose)	
48 hours	24 hours	

Table 2: Minimum stopping times for direct Xa inhibitors based on renal function and risk of operation

Dabigatran

	Bleeding risk	Bleeding risk of operation*	
Creatinine clearance	High bleeding risk (minimum interval since last dose)	Low bleeding risk (minimum interval since last dose)	
<50 ml/min	96 hours	48 hours	
≥50 ml/min	48 hours	24 hours	

Table 3: Minimum stopping times for Dabigatran based on renal function and risk of operation

2. Postoperatively

It is important to bear in mind that peak concentration of the drug are quickly reached; a patient can be therapeutically re-anticoagulated within 2-4 hours of restarting the DOAC dose postoperatively, depending on the drug used. This needs to be borne in mind when considering timing of restarting DOAC anticoagulation postoperatively.

Postoperative anticoagulation should not be re-started until the patient has been assessed by a doctor, haemostasis is secure and it is deemed safe to restart an anticoagulant

General recommendations (See also summary flow chart);

^{*}Dabigatran is contraindicated if creatinine clearance is <30ml/min, Rivaroxaban Apixaban and Edoxaban are contraindicated if creatinine clearance is <15ml/min or if the patient is on dialysis. If these drugs have been prescribed in this circumstance, advice should be sought from a haematologist with regards to stopping preoperatively.

a) For major or high risk bleeding surgery or where there is ongoing bleeding risk

- Once the patient has been assessed by a doctor, haemostasis is secure and it is deemed safe to restart an anticoagulant, commence enoxaparin at a (weight and renal function appropriate) prophylactic dose
- DOACS should not be restarted until at least 48-72 hours post procedure
- Assess bleeding risk at 48 hours postoperatively
 - If no bleeding concerns, convert to full anticoagulation with the DOAC at patient's normal dose
 - If there are bleeding concerns, delay restarting the DOAC and review the patient every 24 hours
 - Consider whether enoxaparin prophylaxis can safely be given if full therapeutic anticoagulation is being witheld
 - the first dose of the DOAC should be given 12-24 hours after the last dose of prophylactic enoxaparin

b) For minor or low risk bleeding surgery and low further bleeding risk

- Once the patient has been assessed by a doctor, haemostasis is secure and it is deemed safe to restart an anticoagulant, restart the DOAC 24 hours postoperatively at the patient's normal dose.
 - If indicated consider prescribing enoxaparin at a (weight appropriate) prophylactic dose in the evening on the day of surgery (ensuring at least 6 hours post op) and then restarting their DOAC the next day.
- If the patient has a very low bleeding risk, consideration can be given to restarting the DOAC at 12 hours post operatively

c) For all patients

- If surgery necessitates the patient to be nil by mouth or a patient is expected to have reduced absorption of oral medication postoperatively, treatment should be continued with enoxaparin until oral medication can be resumed.
 - The dose of enoxaparin can be increased from prophylaxis to treatment dose when the treating team are happy that it is safe to resume full therapeutic anticoagulation, taking into account the timing advice above
 - Once oral administration is possible, the patient should be switched to their usual DOAC dose
- If renal function has deteriorated, the DOAC dose should be reviewed by the ward team and adjusted appropriately
- Ensure that the patient has not been started on any drug which could interact with a DOAC (See appendix 4)
- Always ensure attention to hydration, mobilisation and use of anti-embolic stockings (if indicated) as for routine thromboprophylaxis
- If a patient has been prescribed a DOAC, routine low molecular weight heparin prophylaxis should <u>not</u> be prescribed concurrently

d) If unexpected bleeding occurs

All anticoagulation should be stopped and the patient reassessed

- For management of bleeding on DOAC medication, NUH guidance on emergency surgery and bleeding in patients receiving apixaban, rivaroxaban, edoxaban and dabigatran should be followed.
- Further advice can be sought from the haematology on call teams

Further Information for the interested reader

Assessing thrombotic risk

1. Patients with venous thrombosis (VTE)

It takes approximately 3 months to treat an acute venous thrombotic event and the risk of recurrent thrombosis is higher if anticoagulation treatment is discontinued during this time (Kearon 2014). Risk of recurrence is also higher in patients in whom the initial VTE event was unprovoked, patients with recurrent events or persistent risk factors for thrombosis and in patients with antiphospholipid syndrome. The severity of the initial event also needs to be borne in mind; for example patients with a severe PE associated with pulmonary hypertension (even if >12 months ago) are at higher risk.

2. Patients with Atrial Fibrillation (AF)

Patients with arterial indications for anticoagulation such as AF are at increased risk of stroke in the absence of anticoagulation. In patients with non-valvular AF the CHADS2 and CHADSVasc scoring systems have been validated to give an estimation of stroke rate per 100 patient years in a non-surgical setting (see appendix 1, tables 3 and 4). Preliminary data suggests that the CHADS2 score can be used to predict stroke risk postoperatively (Spyropoulos 2012). If the annual risk of stroke in untreated AF is 4% per annum, this will translate to approximately 0.5 events per 1000 patients who have 5 days without anticoagulation. For AF with previous stroke, the figures are approximately 12% per annum or approximately 1.6 cases per 1000 patients for 5 days without anticoagulation. However, typical rates of peri-operative arterial thromboembolism that have been reported are much higher than these calculated figures (Keeling 2011). Patients at highest risk for stroke are those with a previous stroke/TIA or rheumatic valvular heart disease

3. Stratifying the risk

A higher thromboembolic risk increases the importance of minimising the interval without anticoagulation. A suggested strategy for assessing baseline thrombotic risk was published by the American College of chest Physicians in 2012 (Douketis and Spyropolous, 2012) and is shown in table 3. This stratified patients into high, moderate or low based on the indication for anticoagulant therapy although this remains

unvalidated. In this suggested risk classification, patients classified as high risk have a 10% annual risk for thromboembolism, moderate risk have a 5-10% annual risk for thromboembolism and low risk have <5% annual risk for thromboembolism whilst off anticoagulation.

Table 4: Risk stratification based on indication for anticoagulation

Risk	AF	VTE
High	 CHADS₂ score of 5 or 6 Recent (within 3 months) stroke or TIA Rheumatic valvular heart disease 	 Recent (within 3 months) VTE High risk thrombophilia (eg, deficiency of protein C, protein S, or antithrombin, antiphospholipid antibodies or multiple abnormalities (eg homozygous factor V leiden, compound heterozygosity)
Moderate	CHADS ₂ score of 3 or 4	 VTE within the past 3-12 months Other thrombophilia (eg, heterozygous factor V Leiden or prothrombin gene mutation) Recurrent VTE Active cancer (treated within 6 months or palliative)
Low	CHADS ₂ score of 0 to 2 (assuming no prior stroke or TIA)	VTE > 12 months previous and no other risk factors

It is also important to consider general risk factors for thrombosis which may increase thrombotic risk. These include:

- Active cancer or cancer treatment
- Age > 60 years
- Critical care admission
- Dehydration
- Known thrombophilia or antiphospholipid syndrome
- Obesity (body mass index [BMI] over 30 kg/m²)
- One or more significant medical comorbidities (for example: heart disease; metabolic, endocrine or respiratory pathologies; acute infectious diseases; inflammatory conditions, nephrotic syndrome, myeloproliferative disorders)
- Personal history or first-degree relative with a history of VTE
- Use of hormone replacement therapy or oestrogen-containing contraceptive therapy
- Varicose veins with phlebitis or leg ulcers
- Immobilisation (>48 hours pre-op, >24 hours post op)
- Non-weight bearing lower limb procedure or plaster cast

Pregnancy or within 2 months of delivery

A limitation of the risk stratification described above is that individual patient factors may increase thrombotic risk, for example some patients will have multiple risks within each category. The type of surgery which a patient is to undergo also needs to be considered as variability exists in the risks of stroke and thrombosis with different surgical procedure.

Assessment of peri-operative thromboembolic risk therefore needs to be individualised, taking into consideration both the estimated baseline risk, the individual factors related to the patient and the surgery or procedure type.

Assessing bleeding risk

Surgery with a low risk of bleeding includes procedures for which if bleeding occurs, will be minor, non-critical in its location and/or easily controlled by simple mechanical haemostasis. Conversely, high risk bleeding surgery includes all procedures for which the probability of clinically significant bleeding cannot be excluded, any surgery that is usually haemorrhagic or for which the consequences of bleeding would be unacceptable.

A higher bleeding risk confers a greater need for perioperative haemostasis and hence a longer period of anticoagulation interruption. Stratification of bleeding risk in the context of perioperative anticoagulation is difficult because the available evidence is based mainly on case series involving selected types of surgery.

All patients should be assessed by the surgical team with regards to the bleeding risk of the planned procedure. Further consideration should be given if the patient is also taking an antiplatelet agent as to whether this needs to be continued or stopped; see NUH Guidelines on perioperative management of vitamin K antagonists and antiplatelet agents.

Appendix 1: Effect of DOAC drugs on routine coagulation parameters

Parameter	Apixaban	Rivaroxaban	Edoxaban	Dabigatran
APTT	Prolonged	Prolonged	Prolonged	Prolonged
		1.5 -1.8 times control		1.4 -1.8 times control
РТ	Prolonged	Prolonged in linear fashion (neoplastin)	Prolonged	No effect
TT	No effect	No effect	No effect	Prolonged
Platelet count	No effect	No effect	No effect	No effect
D-dimer	Suppress levels	Suppress levels	Suppressed levels	Suppress levels
Fibrinogen	No effect	No effect	No effect	May be falsely low
Estimation of Drug levels (must be discussed with a haematologist before testing)	Anti Xa	Anti-Xa	Anti Xa	Haemclot assay ECT

Appendix 2: Calculation of Cockroft Gault creatinine clearance

In assessing renal function for patients considering DOACS, a formal Cockroft Gault creatinine clearance should be calculated according to the following formula. eGFR is NOT a suitable alternative.

(140 – age) x weight (kg) x 1.04 (female) or 1.23 (male) serum creatinine (micromol/l)

Rivaroxaban, apixaban and edoxaban are not recommended if the patient's creatinine clearance is less than 15ml/min or if the patient is on dialysis due to increased risk of drug accumulation. Dabigatran is contraindicated when the creatinine clearance is less than 30ml/min. The drug doses should be reviewed if the patient develops renal impairment peri-operatively

Appendix 3: CHADS₂ Score and Thrombotic Risk

	Condition	Points
С	Congestive cardiac	1
	failure	
Н	Hypertension	1
Α	Age >75 years	1
D	Diabetes Mellitus	1
S	Prior stroke or TIA	2

Table 5: CHADS₂ score

CHADS ₂ score	Stroke Risk (%)	95% confidence interval
0	1.9	1.2-3.0
1	2.8	2.0-3.8
2	4.0	3.1-5.1
3	5.9	4.6-7.3
4	8.5	6.3-11.1
5	12.5	8.2-17.5
6	18.2	10.5-27.4

Table 6: Annual stroke risk with respect to CHADS₂ score

Appendix 4: Drug interactions with new oral anticoagulants

Dabigatran is a substrate for P-glycoprotein (P-gp). **Rivaroxaban, apixaban** and **edoxaban** are metabolised by the cytochrome P450 isoenzyme CYP3A4 and are also substrates for P-glycoprotein (P-gp). Common drug interactions can be found on the NUH guides page at

http://nuhnet/nuh_documents/Guidelines/Cancer%20and%20Associated%20Specialties/Clinical%20Haematology/2730.pdf

Appendix 5: Standard letter for patients regarding stopping anticoagulation

Patient identification label	
Dear	
You are taking a type of medication called a undergo a surgical procedure, it is importar period of time to reduce the risk of you blee procedure.	nt that this medication is stopped for a short
You should therefore take your last dose of Rivaroxaban/Apixaban/Edoxaban/Dabigatra	
Your anticoagulant medication will need to by the Doctors responsible for your care an	be restarted after the operation or procedure at they will tell you when it is safe to do so.
Although we try to avoid cancelling operation anticoagulant medication, occasionally this any reason, you will need to ask the team lead to a speak to you anticoagulation clinic helpline at QMC on 0 specialist nursing team	happens. If your procedure is cancelled for ooking after you when to restart your our Doctor you can also call the
If you have any questions about your antico operative assessment nurse during your cli	·
Signed	
Printed	
Date	

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