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Direct Oral Anti-Coagulants (DOACs) in Patients Undergoing Elective Surgery or Procedures Procedure

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1.0			Completed	Thrombosis Committee	04/03/2016	04/03/2019

Brief Summary of Document:	The aim of this procedure is to ensure that anti-coagulated patients do not develop preventable complications peri-, intra- or post-operatively.
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To be read in conjunction with:	Local endoscopy written control documents Reversal of Dabigatran Guideline
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Classification:	Clinical	Category:	Procedure	Freedom Of Information Status	Open
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Authorised by:	Phil Kloer	Job Title	Medical Director & Director of Clinical Strategy	Signature:	A signed copy of this document is stored with corporate services
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	Medical & Dental	<input checked="" type="checkbox"/>	Nursing	<input checked="" type="checkbox"/>	Scientific & Professional	<input type="checkbox"/>	Other	<input type="checkbox"/>

CONSULTATION	Please indicate the name of the individual(s)/group(s) or committee(s) involved in the consultation process and state date agreement obtained.			
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RATIFYING AUTHORITY <small>(In accordance with the Schedule of Delegation)</small>	KEY		COMMENTS/ POINTS TO NOTE
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MMG	A	23.3.16	

Date Equality Impact Assessment Undertaken		Group completing Equality impact assessment	To be undertaken as part of main Thrombosis Policy
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Please enter any keywords to be used in the policy search system to enable staff to locate this policy	DOAC, elective procedure, elective surgery, direct oral anticoagulant, anticoagulation, dabigatran, edoxaban, apixaban, rivaroxaban
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Document Implementation Plan			
How Will This Policy Be Implemented?			
Who Should Use The Document?			
What (if any) Training/Financial Implications are Associated with this document?			
What are the Action Plan/Timescales for implementing this policy?	Action	By Whom	By When

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CONTENTS

1. INTRODUCTION	5
2. SCOPE	5
3. AIM	5
4. OBJECTIVES	5
5. TRAINING	5
6. MONITORING AND COMPLIANCE.....	5
7. EVIDENCE BASE AND RELATED POLICIES	6
8. PROCEDURE.....	6
9. APPENDIX 1: ENDOSCOPIC PROCEDURES AND ASSOCIATED BLEEDING RISK.....	9
10. APPENDIX 2: SURGICAL PROCEDURES AND ASSOCIATED BLEEDING RISK	10

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1. INTRODUCTION

Dabigatran, edoxaban, apixaban and rivaroxaban are direct oral anticoagulants (DOACs) which are used as alternatives to coumarins (e.g. warfarin) in selected groups of patients for certain indications.

Dabigatran is a direct thrombin inhibitor.

Rivaroxaban, edoxaban and apixaban are direct inhibitors of factor Xa.

All 4 agents are licensed for:

- prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation
- prophylaxis of venous thromboembolism following total hip and knee replacement
- treatment and secondary prevention of venous thromboembolism.

Note that the dose is different depending on the indication.

2. SCOPE

This procedure applies to adult patients who are prescribed dabigatran, edoxaban, rivaroxaban or apixaban for prevention of stroke or thrombosis and who are due to undergo elective surgery or an elective procedure.

Staff to whom the procedure is directed include doctors, anticoagulation specialist nurses and pre-assessment nurses involved in the prescribing of dabigatran, edoxaban, rivaroxaban or apixaban.

A separate procedure covers emergency surgery, bleeding and overdose.

3. AIM

The aim of this procedure is to ensure that anti-coagulated patients do not develop preventable complications peri-, intra- or post-operatively.

4. OBJECTIVES

The procedure outlines the steps to be taken in patients who are taking dabigatran, rivaroxaban, edoxaban or apixaban and are due to undergo elective surgery or an elective procedure.

5. TRAINING

All clinical staff are responsible for ensuring they are up to date with knowledge of the procedure included in this guidance for thromboprophylaxis, acute thrombosis management, and safe use of anticoagulation. All medical staff are expected to be able to follow the pathway as they are competent in history taking, clinical examination and are able to prescribe the required medications.

6. MONITORING AND COMPLIANCE

Audit should be undertaken on patients prescribed dabigatran, edoxaban, rivaroxaban or apixaban undergoing elective surgery or procedures. Incident reporting should be undertaken through the Health Board Datix system and in accordance with the MHRA Yellow Card reporting system.

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7. EVIDENCE BASE AND RELATED POLICIES

- European Heart Rhythm Association Practical Guideline on use of DOACs in patients with non-valvular atrial fibrillation. Hein Heidebuchel et al. Eurospace 2013 15 625-651
- Systemic review: the New Oral Anticoagulants. Practical Management for Patients Attending for Endoscopic Procedures. Woodhouse et al. Frontline Gastroenterology 2013; 4(3): 213-218
- Association of Anaesthetists of Great Britain and Ireland, Obstetric Anaesthetists Association and Regional Anaesthesia UK. Regional anaesthesia and patients with abnormalities of coagulation. Anaesthesia 2013; 68 966-72.

8. PROCEDURE

Patients on direct oral anticoagulants who are to undergo elective surgery or procedure must have the DOAC stopped in sufficient time before the elective surgery or procedure to allow the drug to clear from the body. The table below gives timings (see 8.2.1).

The DOAC should be restarted when the risk of surgical or procedural related bleeding is low. If indicated, a prophylactic dose of LMWH can be given during the interval starting at the time of the elective surgery/procedure and ending when the DOAC is restarted (see 8.2.2).

8.1. Monitoring

Monitoring of these drugs is normally not required, but this should be considered if the patient has renal impairment or is at the extremes of body mass. Advice from the consultant haematologist must be sought if this applies to the patient.

Tests designed to accurately assess the anticoagulant activity of these drugs are not available within the Health Board but through the specialist laboratory at University Hospital of Wales (UHW).

The APTT and PT can be used to assess whether there is significant drug effect but should not be used on their own to decide whether it is safe to proceed with the elective surgery or procedure.

No reversal agents exist for anti Xa inhibitors. See guidance for Reversal of Dabigatran (HB 477).

8.2. Procedure

Before determining the correct management of the patient, the following must be checked:

- the proposed elective operation/procedure and the associated risk of bleeding
- whether neuraxial anaesthesia is proposed
- the indication for anticoagulation, the DOAC the patient is taking and the dose
- the patient's FBC and U+E
- that consultant haematologists are available for advice

If neuraxial anaesthesia is proposed the case MUST be discussed with a consultant anaesthetist.

8.2.1 Stopping of DOACs before elective surgery or procedure

HYWEL DDA UNIVERSITY HEALTH BOARD

If the risk of bleeding is very low, for example some dental procedures, it is possible to perform the procedure 18-24 hours after the last DOAC dose and resume the DOAC dose 6 hours later.

In all other cases the DOAC should be stopped before the elective surgery/procedure for a period of time as shown in the table below:

	Dabigatran		Rivaroxaban, Edoxaban or Apixaban	
	Low risk of bleeding	High risk of bleeding	Low risk of bleeding	High risk of bleeding
Creatinine clearance > 80ml/min	24 hours	48 hours	24 hours	48 hours
50-80	36 hours	72 hours	24 hours	48 hours
30-50	48 hours	96 hours	24 hours	48 hours
15-30	NA	NA	36 hours	96 hours
<15	NA	NA	NA	NA

NA = drug contraindicated at this creatinine clearance.

It should not be necessary to give LMWH before the procedure unless the patient's DOAC is stopped for longer than shown in the above table.

8.2.2 Re-starting of DOACs following elective surgery/procedure

If the patient is having an endoscopic procedure:

The DOAC should be restarted after the procedure, taking into account any biopsy performed and the consequent risk of bleeding (see Appendix 1), in accordance with the following:

- if the risk of bleeding is low the DOAC can be restarted 6-8 hours post procedure
- if the risk of bleeding is high the DOAC can be restarted 48 hours post procedure
- if the endoscopist advises the risk of bleeding is particularly high they may recommend a further delay. However, a prophylactic dose LMWH could be considered, according to the local endoscopy unit written control documents, if the patient is at high risk of thrombosis and restarting the DOAC is delayed.

If the patients is having any other elective surgery or procedure:

If there is no complication the DOAC can be restarted 24 hours after minor procedures, 48 hours after major procedures (see Appendix 2). If there is concern with regard to bleeding risk, drug absorption or renal function, restarting the DOAC must be delayed until this is resolved.

A prophylactic dose LMWH should be considered after the procedure especially if the patient's DOAC is not to be restarted more than 24 hours after elective surgery or procedure.

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If a prophylactic dose LMWH is given it should not be given together with the DOAC.
Restarting the DOAC should be at least 12 hours after the prophylactic dose of LMWH.

If the patient is to have neuraxial anaesthesia:

A consultant anaesthetist must be consulted about the case before proceeding.

The DOAC must be stopped prior to the procedure, using the table above, but applying the high risk column in all cases.

The DOAC must not be restarted whilst the spinal / epidural catheter is in place post surgery or procedure.

The DOAC can be restarted 6 hours post spinal/epidural catheter removal, but extending this time interval must be considered if there has been any trauma.

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9. APPENDIX 1: ENDOSCOPIC PROCEDURES AND ASSOCIATED BLEEDING RISK

Low risk group:

- Diagnostic OGD +/- biopsy
- Diagnostic colonoscopy +/- biopsy
- Biliary stenting
- Pancreatic stenting
- Diagnostic EUS.

High risk group:

- Polypectomy
- ERCP + sphincterotomy
- Endoscopic mucosal resection
- EUS with FNA
- PEG insertion
- Variceal banding
- Stricture dilatation.

* Patients having bowel screening colonoscopy should stop their DOAC pre-procedure as if they are all high risk. Post procedure they should be assigned to the low or high risk group according to the actual procedure performed.

Reference: *Systemic review: the New Oral Anticoagulants. Practical Management for Patients Attending for Endoscopic Procedures. Woodhouse et al. Frontline Gastroenterology 2013; 4(3): 213-218*

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10. APPENDIX 2: SURGICAL PROCEDURES AND ASSOCIATED BLEEDING RISK

This is a guideline only. Always check with the surgeon/person performing the procedure if possible.

Very low:

Dental extraction. Maximum 3 teeth.

Low:

Prostate or bladder biopsy

Pacemaker insertion

Angiography

High:

Any major general or orthopaedic surgical operation

TURP

Renal or liver biopsy

Reference: *Rhythm Association Practical Guideline on use of DOACS in patients with non valvular atrial fibrillation. Hein Heidebuchel et al. Eurospace 2013 15 625-651.*