

Guideline for managing patients on a factor Xa inhibitor – Apixaban (Eliquis[®]) or Rivaroxaban (Xarelto[®])

1. Purpose

This Guideline provides recommendations regarding best practice for management of patients who are admitted to hospital already taking a factor Xa inhibitor (apixaban or rivaroxaban). It is not intended as a guideline for initiation of treatment with a factor Xa inhibitor. Haematology consultation should be sought in situations which are urgent, complicated or not covered by this Guideline.

2. Scope

This Guideline provides information for all Queensland Health employees (permanent, temporary and casual) and all organisations and individuals acting as its agents (including Visiting Medical Officers and other partners, contractors, consultants and volunteers).

This Guideline takes into account the medication restrictions outlined in the Queensland Health List of Approved Medicines.

Some Hospital and Health Services may have local guidelines where differing medication restrictions are in place. These are beyond the scope of this Guideline.

3. Related documents

Authorising Policy and Standard/s:

- Queensland Health List of Approved Medicines

Procedures, Guidelines and Protocols:

- Guidelines for Anticoagulation Using Warfarin
- Guidelines for Managing Patients on Dabigatran (Pradaxa[®])
- Guideline for Anticoagulation and Prophylaxis Using Low Molecular Weight Heparin (LMWH) in Adult Inpatients

Forms and templates:

- Statewide Heparin Intravenous Infusion Order and Administration – Adult form

4. Guideline

4.1 Indications

The following are oral anticoagulants that act as factor Xa inhibitors. Apixaban is available as 2.5 mg and 5 mg tablets. Rivaroxaban is available as 10 mg, 15 mg and 20 mg tablets.

Table A: Approved indications for apixaban and rivaroxaban*

Factor Xa inhibitor	TGA approved indications	LAM listed	PBS listed
Apixaban	Prevention of venous thromboembolism (VTE) in adult patients who have undergone elective total hip or total knee replacement surgery	Refer to LAM for current restrictions	Yes Refer to PBS for details
	Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and at least one additional risk factor for stroke		
Rivaroxaban	Prevention of VTE in adult patients who have undergone major orthopaedic surgery of the lower limbs (elective total hip, treatment for up to 5 weeks; elective total knee replacement, treatment for up to 2 weeks)		
	Treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE) and for the prevention of recurrent DVT and PE		
	Prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation and at least one additional risk factor for stroke		

TGA = Therapeutic Goods Administration; PBS = Pharmaceutical Benefits Scheme; LAM = Queensland Health List of Approved Medicines

* Information correct as at 15 October 2014. Refer to TGA website, PBS schedule or latest edition of LAM for current indications and restrictions.

TGA: <http://www.tga.gov.au/industry/artg.htm>

PBS: <http://www.pbs.gov.au/pbs/home>

LAM: <http://www.health.qld.gov.au/clinical-practice/guidelines-procedures/medicines/approved-list/default.asp>

Risk factors for adverse events with factor Xa inhibitors include hepatic impairment and renal impairment.

Apixaban is contraindicated with hepatic disease associated with coagulopathy and clinically relevant bleeding risk, including severe hepatic impairment (Child-Pugh C). Rivaroxaban is contraindicated with significant hepatic disease (including moderate to severe hepatic impairment, i.e. Child-Pugh B and C) which is associated with coagulopathy leading to a clinically relevant bleeding risk.

See Tables B and C for dose recommendations for different levels of renal function. Note: Calculation of creatinine clearance (CrCl) should be determined using ideal body weight with the Cockcroft-Gault equation as it is more accurate than eGFR for older patients and those with a low body weight (see online calculators available locally, on QHEPS or eTG Complete).

Table B: Dosage of **apixaban** for different levels of renal function

Indication →	VTE prevention in total hip replacement (THR) and total knee replacement (TKR)	Stroke prevention in atrial fibrillation
Creatinine clearance ↓		
Greater than or equal to 30 mL/min	2.5 mg twice a day <ul style="list-style-type: none"> • 32–38 days for THR • 10–14 days for TKR 	5 mg twice a day OR 2.5 mg twice a day in patients with at least two of the following characteristics: <ul style="list-style-type: none"> • greater than or equal to 80 years • body weight less than or equal to 60 kg • serum creatinine greater than or equal to 133 micromol/L
Less than 30 mL/min	Apixaban is contraindicated	

Table C: Dosage of **rivaroxaban** for different levels of renal function

Indication →	VTE prevention in total hip replacement (THR) and total knee replacement (TKR)	Stroke prevention in atrial fibrillation	Treatment of DVT and PE and prevention of recurrent DVT and PE
Creatinine clearance ↓			
Greater than or equal to 50 mL/min	10 mg once daily <ul style="list-style-type: none"> • Five weeks for THR • Two weeks for TKR 	20 mg once daily	15 mg twice daily for three weeks, followed by 20 mg once daily
30–49 mL/min	10 mg once daily <ul style="list-style-type: none"> • Five weeks for THR • Two weeks for TKR 	15 mg once daily	15 mg twice daily for three weeks, followed by 20 mg once daily
15–29 mL/min	10 mg once daily Use with caution	Rivaroxaban is contraindicated	
Less than 15 mL/min	Rivaroxaban is contraindicated		

4.2 Monitoring / Pathology testing

There is variable and limited ability to measure factor Xa inhibitor levels in Queensland Health facilities. This is a rapidly changing area and local advice should be sought on availability of relevant coagulation tests and their sensitivity to the effect of the specific factor Xa inhibitor being taken. Monitoring with International Normalised Ratio (INR) cannot be used. Activated partial thromboplastin time (APTT) is prolonged, dose-dependent; however, because of reagent insensitivity or nonlinearity it is not recommended to assess the effect of factor Xa inhibitors. A normal thrombin clot time is expected with the presence of factor Xa inhibitors.

The Prothrombin Time (PT) cannot be used to completely exclude the presence of a factor Xa inhibitor and is not useful for monitoring or dose adjustment. Usually, a normal PT (12–15 seconds) excludes the presence of **therapeutic** factor Xa inhibitor levels. However, the PT can also be influenced by concomitant use of other anticoagulants and vitamin K deficiency.

Factor Xa inhibitors can be assayed using **anti-factor Xa** testing if set up correctly for the specific medication. Consult with Haematology Service to confirm if anti-factor Xa tests specific for the factor Xa inhibitor taken by the patient are available at your facility.

Routine testing for the effect of factor Xa inhibitors is generally not conducted during treatment because they have predictable pharmacokinetic profiles, enabling fixed-dose regimens. In the following situations laboratory testing may be helpful in assessing patients on factor Xa inhibitors; however, there is limited evidence to guide interpretation of these concentrations:

- the peri-operative setting
- acute coronary syndrome (ACS)
- in the event of bleeding or recurrent thrombosis
- elderly patients due to a higher risk of bleeding
- when hepatic or renal function is deteriorating or if renal impairment with CrCl less than 30 mL/min
- when parenteral anticoagulants are being considered for a patient taking a factor Xa inhibitor
- patients with extremes of body weight because low body weight has a high bleeding risk and obesity may have poor efficacy
- patients on potentially interacting medications (i.e. concomitant administration of strong inducers or inhibitors of CYP3A4 or P-glycoprotein)
- in case of overdose or if there are concerns about compliance.

4.3 Drug interactions

Thrombolytic agents or antiplatelet agents (e.g. aspirin, clopidogrel, prasugrel, ticagrelor, ticlopidine): Concomitant administration of these agents with factor Xa inhibitors is not recommended unless there are specific cardiac or clinical reasons (see section 4.8) because dual therapy is associated with higher risks of bleeding and anaemia, especially if there are other risk factors (see section 4.1).

Other anticoagulants: Concomitant administration is not recommended with other factor Xa inhibitors, dabigatran, warfarin, heparin or low molecular weight heparin.

Non-steroidal anti-inflammatory drugs (NSAIDs): Monitor for risks of bleeding if a factor Xa inhibitor is used with NSAIDs, especially those with half-lives greater than 12 hours (e.g. naproxen, piroxicam). NSAIDs with short half-lives less than 12 hours (e.g. ibuprofen) have not been shown to be associated with increased bleeding risk.

Strong inhibitors of CYP3A4 or P-glycoprotein: Apixaban and rivaroxaban are metabolised by the CYP450 enzyme, CYP3A4. Apixaban is eliminated by renal and non-renal pathways, including metabolism and biliary excretion, and is a substrate of P-glycoprotein / breast cancer resistance protein transport systems. Renal excretion of rivaroxaban as the unchanged drug involves the P-glycoprotein / breast cancer resistance protein transporter systems.

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Factor Xa inhibitors are contraindicated with drugs that are strong inhibitors of **both** of these pathways.

- azoles except fluconazole (i.e. ketoconazole, itraconazole, voriconazole, posaconazole)
- protease inhibitors (e.g. ritonavir).

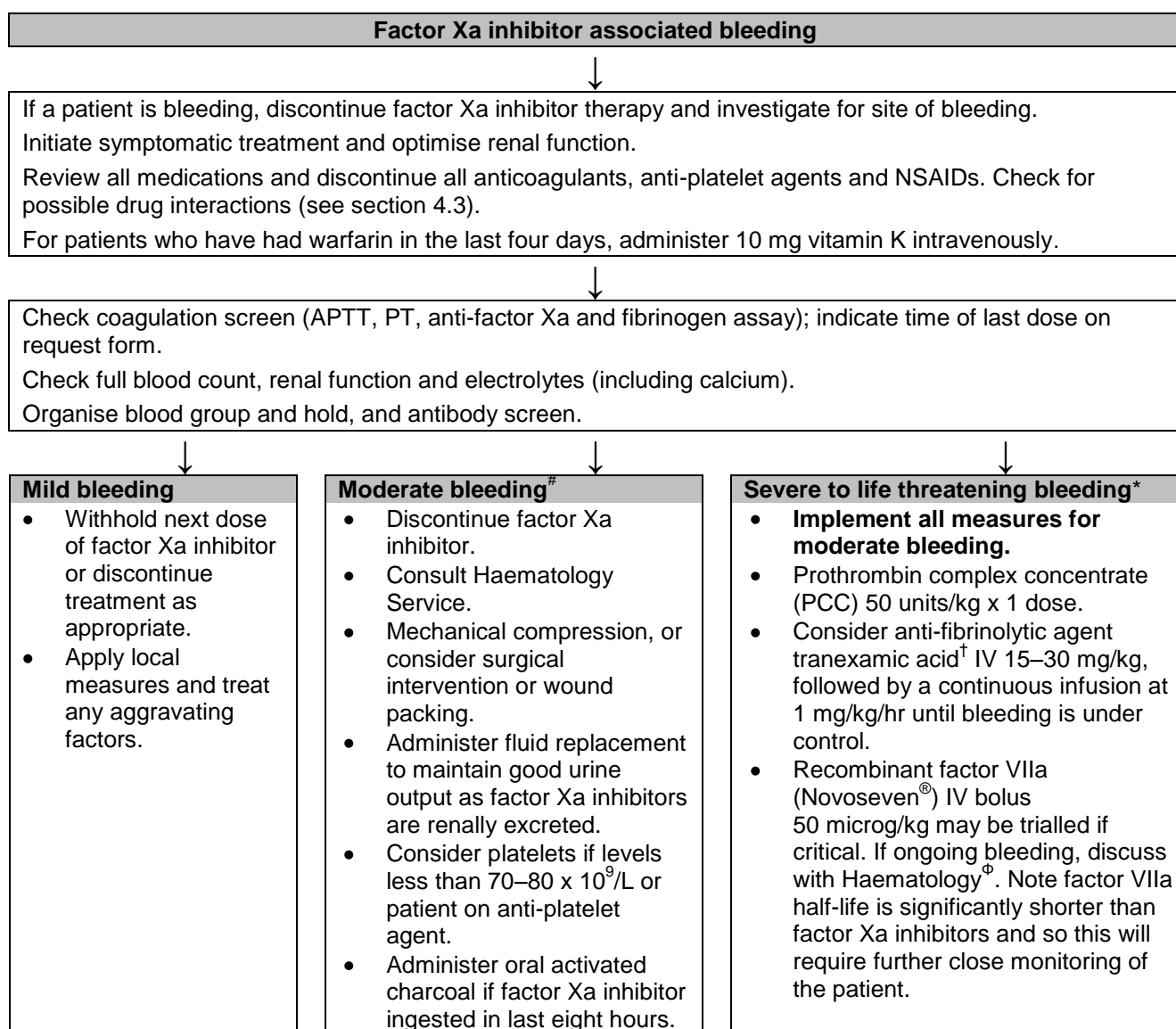
The following less potent inhibitors or drugs inhibiting only one of these two pathways may significantly contribute to increased bleeding risk if administered with a factor Xa inhibitor when there are other risk factors (see section 4.1); however, they are not currently contraindicated.

- calcium channel blockers (e.g. diltiazem, verapamil)
- fluconazole
- immunosuppressants (e.g. cyclosporine)
- macrolides (e.g. clarithromycin, erythromycin)
- others (e.g. amiodarone, dipyridamole, tamoxifen).

Strong inducers of CYP3A4: Concomitant use of a factor Xa inhibitor with strong CYP3A4 inducers (e.g. rifampicin, phenytoin, carbamazepine, phenobarbitone or St John's Wort) may lead to reduced plasma levels of the factor Xa inhibitor (up to 50% reduction in the case of apixaban). Caution should be exercised if using factor Xa inhibitors in these situations.

4.4 Management of bleeding

Currently, there is no available antidote for factor Xa inhibitors. Prothrombin complex concentrates have been shown in studies to reverse the abnormalities in laboratory markers due to rivaroxaban specifically; however, there is no clinical data available to show the effects on factor Xa inhibitor-associated bleeding. Vitamin K and plasma infusion have not been shown to be effective. The effect of factor VIIa (Novoseven[®]) is currently uncertain. Factor Xa inhibitors are highly protein-bound and cannot be removed by dialysis.



[#] **Moderate bleeding:** non-trivial bleeding with a reduction in haemoglobin of less than 20 g/L, or requiring transfusion of less than two units of red blood cells.

^{*} **Severe to life-threatening bleeding:** bleeding with a reduction in haemoglobin of greater than or equal to 20 g/L, or requiring transfusion of greater than or equal to two units of red blood cells, or involving a critical site.

[†] There is limited evidence of the clinical benefit for tranexamic acid in this setting and treatment should not delay resuscitation and adequate factor replacement.

[Ⓞ] NB: Individual Patient Approval should be obtained as per Hospital and Health Service or local procedure for recombinant factor VIIa 'For the management of life-threatening bleeding and coagulopathy in non-haemophilic patients who have failed to respond to conventional therapy.' (See Appendix 9 of the LAM)

4.5 Management peri-operatively of patients admitted to hospital on a factor Xa inhibitor

Semi-acute or elective surgery

- **Assess the risk of bleeding against the risk of thrombosis** as factor Xa inhibitors may not need to be discontinued for minor procedures.
- If the factor Xa inhibitor needs to be withheld, plan ahead as there is no known treatment available for immediate reversal.
- Factor Xa inhibitors have predictable pharmacokinetics, a relatively short half-life and a rapid onset of action after oral administration so bridging with another anticoagulant is not required when discontinued before or initiated after surgery.

As factor Xa inhibitors undergo both hepatic and renal excretion, hepatic function and renal function will determine the withholding time prior to surgery and this should be checked pre-admission. The patient should be advised when to withhold their medication pre-operatively. **In situations where complete haemostasis is required, APTT, PT and anti-factor Xa should be checked pre-operatively.**

Table D: Discontinuation of factor Xa inhibitor prior to surgery

Renal function (CrCl, mL/min) NB. Use Cockcroft-Gault equation with ideal body weight (see section 4.1)	Half-life (hours)	Minimum time frame to withhold factor Xa inhibitor prior to surgery after last dose	
		Low bleeding risk [‡]	High bleeding risk ^ψ
Greater than or equal to 50 mL/min	Apixaban: 8–15	1 day	3 days
	Rivaroxaban: 5–9 (11–13 if elderly)		
Less than 50 mL/min	Apixaban: unknown	3 days	4 days
	Rivaroxaban: greater than 9		

Hepatic function (Child-Pugh Score)	Half-life (hours)	Minimum time frame to withhold factor Xa inhibitor prior to surgery after last dose	
		Low bleeding risk [‡]	High bleeding risk ^ψ
Mild impairment (Child-Pugh A)	Apixaban: unknown	1 day	2 days
	Rivaroxaban: 8		
Moderate impairment (Child-Pugh B)	Apixaban: unknown	At least 2 days	At least 4 days
	Rivaroxaban: 12–16		
Severe impairment (Child-Pugh C)	Unknown	5 days	At least 7 days

[‡] Examples of surgery associated with low risk of bleeding include electrophysiology procedures, cardiac catheterisations, surgery with no additional patient-specific risk factors.

^ψ Examples of surgery associated with high risk of bleeding include surgery involving a major organ, procedures requiring complete haemostasis (e.g. spinal anaesthesia) or when additional risk factors for bleeding are present (e.g. advancing age, co-morbidities such as major cardiac, respiratory or liver disease, and concomitant use of anti-platelet therapy).

Urgent surgery

- Stop factor Xa inhibitor.
- Check full blood count, electrolytes (including calcium), renal function and coagulation screen (APTT, PT, anti-factor Xa and fibrinogen assay); indicate time of last factor Xa inhibitor dose on request form.
- Consider delaying surgery, if appropriate, until coagulation screen is normal or until sufficient time for drug clearance (see Table D).
- Where urgent life-saving surgery cannot be delayed, consult with Haematology Service over measures to control bleeding perioperatively.
- Epidural and spinal anaesthesia are contraindicated.
- Cross-match blood.

Recommendations regarding epidural and spinal catheter

- Epidural and spinal anaesthesia are contraindicated unless factor Xa inhibitors have been eliminated as indicated by the absence of anti-factor Xa activity (i.e. anti-factor Xa level of zero) or sufficient time for drug clearance (see Table D as high bleeding risk).
- Factor Xa inhibitors should not be recommenced in patients who have an epidural or spinal catheter in place.
- Factor Xa inhibitors should not be restarted within 24 hours of removal of spinal or epidural catheter; a longer delay should be considered if there are multiple punctures or traumatic insertion of spinal or epidural catheter.

Restarting factor Xa inhibitors after surgery

- The timing of recommencement of therapy is based on the nature of surgery, haemostatic state and urgency of restarting anticoagulant therapy. In complicated cases, seek specialist advice.
- Do not restart a factor Xa inhibitor in severe renal impairment (i.e. CrCl equal to or less than 30 mL/min).
- Do not restart a factor Xa inhibitor in severe hepatic impairment (i.e. Child-Pugh C).
- In general, Table E provides a guide to the timing for restarting factor Xa inhibitors after surgery.
- If haemostasis is not satisfactory and clinically significant bleeding is present, a delay in restarting a factor Xa inhibitor is appropriate.
- Consider using an alternative short acting and reversible anticoagulant (e.g. unfractionated heparin) if the risk of thrombosis is greater than the risk of wound bleeding.

Table E: Restarting factor Xa inhibitors after surgery

Factor Xa inhibitor	Suggested timing for restarting factor Xa inhibitor after surgery	
	Low bleeding risk surgery [‡]	High bleeding risk surgery [‡]
Apixaban	Resume 24 hours after surgery	Resume 48–72 hours after surgery
Rivaroxaban		

[‡] Examples of surgery associated with low risk of bleeding include electrophysiology procedures, cardiac catheterisations, surgery with no additional patient-specific risk factors.

[‡] Examples of surgery associated with high risk of bleeding include surgery involving a major organ, procedures requiring complete haemostasis (e.g. spinal anaesthesia) or when additional risk factors for bleeding are present (e.g. advancing age, co-morbidities such as major cardiac, respiratory or liver disease, and concomitant use of anti-platelet therapy).

4.6 Bridging or switching to or from other anticoagulants

Conversion from a factor Xa inhibitor to a parenteral anticoagulant

Table F: Converting factor Xa inhibitors to parenteral anticoagulants

Creatinine clearance (CrCl)	Instructions
Greater than or equal to 30 mL/min	Start treatment dose of low molecular weight heparin (LMWH) when next dose of factor Xa inhibitor would have been due OR Start unfractionated heparin (UFH)* intravenous infusion without a bolus 12 hours after last factor Xa inhibitor dose
Less than 30 mL/min [#]	Start UFH* intravenous infusion when the next dose of factor Xa inhibitor would have been due. Consider measuring anti-factor Xa levels

* Note: Loading doses of UFH should not be given. The *Queensland Health Heparin Intravenous Infusion Order and Administration – Adult* form should only be used as a guide for dose adjustment.

[#] Note: Apixaban is contraindicated if CrCl is less than 30 mL/min—do not restart. Rivaroxaban is contraindicated for orthopaedic surgical prophylaxis if CrCl is less than 15 mL/min and for all other indications if CrCl is less than 30 mL/min—do not restart.

Conversion from a parenteral anticoagulant to a factor Xa inhibitor

Check renal function prior to re-starting a factor Xa inhibitor. If renal impairment, the factor Xa inhibitor may require dose adjustment or should not be used, depending on its indication.

- For conversion from an UFH infusion to a factor Xa inhibitor, discontinue UFH when the first dose of the factor Xa inhibitor is administered.
- For conversion from enoxaparin or other LMWH to a factor Xa inhibitor, start the factor Xa inhibitor when the next dose of LMWH would have been due.

Conversion from factor Xa inhibitors to warfarin

- Treatment options during conversion are shown in Table G. Consider the risk of stroke and embolism.
- A baseline INR is recommended and should be taken when the next dose of factor Xa inhibitor would have been due.
- Start dosing as per the *Queensland Health Guidelines for Anticoagulation Using Warfarin – Adult* or, if the patient has previously been on warfarin, restart on usual maintenance dose.

Table G: Converting factor Xa inhibitors to warfarin

Creatinine clearance (CrCl)	Options for conversion	
	Low risk of thrombosis	High risk of thrombosis
Greater than or equal to 30 mL/min	Stop factor Xa inhibitor and start warfarin at the next standard administration time	Stop factor Xa inhibitor and start treatment dose of low molecular weight heparin (LMWH) when next dose of factor Xa inhibitor is due. Then start warfarin at the next standard administration time. Continue parenteral anticoagulant for a minimum of five days and until INR has been in target range for at least two consecutive days OR Stop factor Xa inhibitor and start unfractionated heparin (UFH)* intravenous infusion without a bolus 12 hours after last factor Xa inhibitor dose. Then start warfarin at the next standard administration time. Continue parenteral anticoagulant for a minimum of five days and until INR has been in target range for at least two consecutive days
Less than or equal to 30 mL/min [#]	Stop factor Xa inhibitor and start warfarin at the next standard administration time	Stop factor Xa inhibitor and start UFH* intravenous infusion without a bolus when the next dose of factor Xa inhibitor is due. Then start warfarin at the next standard administration time. Continue parenteral anticoagulant for a minimum of five days and until INR has been in target range for at least two consecutive days

* Note: Loading doses of UFH should not be given. The *Queensland Health Heparin Intravenous Infusion Order and Administration – Adult* form should only be used as a guide for dose adjustment.

[#] Note: Apixaban is contraindicated if CrCl is less than 30 mL/min—do not restart. Rivaroxaban is contraindicated for orthopaedic surgical prophylaxis if CrCl is less than 15 mL/min and for all other indications if CrCl is less than 30 mL/min—do not restart.

Conversion from warfarin to a factor Xa inhibitor

Check renal function prior to re-starting a factor Xa inhibitor. If renal impairment, the factor Xa inhibitor may require dose adjustment or should not be used, depending on its indication.

- For conversion from warfarin to a factor Xa inhibitor, discontinue warfarin and start the factor Xa inhibitor when INR is below two.

4.7 Venous Thromboembolism (VTE) prophylaxis

Do not commence pharmacological VTE prophylaxis (e.g. heparin, dalteparin, enoxaparin) if patient is taking a factor Xa inhibitor. If a factor Xa inhibitor is ceased, and VTE prophylaxis is indicated, start pharmacological prophylaxis when coagulation screen is normal or sufficient time has elapsed for drug clearance (see Table D, section 4.5).

4.8 Acute coronary syndrome (ACS)

There is currently no published literature available for ACS management in patients who are on factor Xa inhibitors. The following information is suggested guidance only and it may be modified in the future depending on accumulating clinical experience. Further advice should be sought from a cardiologist.

Note: For patients with stents requiring dual antiplatelet therapy, factor Xa inhibitors should only be considered by a cardiologist.

Table H: Acute coronary syndrome management in patients on a factor Xa inhibitor

ST Elevation Myocardial Infarction (STEMI)
<ul style="list-style-type: none"> For parenteral anticoagulation for ACS in factor Xa inhibitor treated patients, unfractionated heparin (UFH) is preferred to low molecular weight heparin. For patients receiving a factor Xa inhibitor, primary percutaneous coronary intervention (PCI) is preferred (if available) to thrombolysis. The decision to thrombolysed should be based on an assessment of the perceived benefit (e.g. anterior versus inferior myocardial infarction, time to presentation) versus the perceived risk of a bleeding complication (e.g. elderly, reduced renal function, presence of other relative contraindications). If thrombolysis is administered, do not start UFH within 12 hours of last factor Xa inhibitor dose or longer if impaired renal function (see likely half-lives with renal impairment in Table D, section 4.5). Loading doses of UFH should not be given. See Table F, section 4.6 for information on UFH dosing.

Non-ST Elevation Acute Coronary Syndrome (NSTEMACS) (e.g. Non-ST Elevation Myocardial Infarction (NSTEMI) and Unstable Angina)
<ul style="list-style-type: none"> For parenteral anticoagulation for ACS in factor Xa inhibitor treated patients, UFH is preferred to low molecular weight heparin. Do not start UFH within 12 hours of the last dose of factor Xa inhibitor or longer if impaired renal function (see likely half-lives with renal impairment in Table D, section 4.5). Loading doses of UFH should not be given. See Table F, section 4.6 for information on UFH dosing.

5. Review

This Guideline is due for review on: 1 October 2015

Date of Last Review: 3 October 2014

Supersedes: Guideline for managing patients on a factor Xa inhibitor- Apixaban (Eliquis®) or Rivaroxaban (Xarelto®) Version 1 (QH-GDL-950:2014)

6. Business Area Contact

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7. Definitions of terms used in the policy and supporting documents

Term	Definition / Explanation / Details
ACS	Acute coronary syndrome
APTT	Activated partial thromboplastin time
CrCl	Creatinine clearance, which is an indicator for renal function
DVT	Deep vein thrombosis
INR	International normalised ratio
LAM	Queensland Health List of Approved Medicines
LMWH	Low molecular weight heparin
NSAIDs	Non-steroidal anti-inflammatory drugs
NSTEACS	Non-ST elevation acute coronary syndrome
NSTEMI	Non-ST elevation myocardial infarction
PBS	Pharmaceutical Benefits Scheme
PE	Pulmonary embolism
PT	Prothrombin time
STEMI	ST elevation myocardial infarction
TGA	Therapeutic Goods Administration
THR	Total hip replacement
TKR	Total knee replacement
UFH	Unfractionated heparin
VTE	Venous thromboembolism

8. Approval and Implementation

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Version Control

Version	Date	Prepared by	Comments
1	1 Jul 2014	Justin Lee	
2	1 Nov 2014	Sarah Mathers	Clinician feedback addressed
2	6 Jan 2015	Sarah Mathers	Link to LAM homepage updated

Disclaimer

This guideline has been prepared to promote and facilitate standardisation and consistency of practice, using a multidisciplinary approach.

Information in this guideline is current at time of publication.

The Department of Health, Queensland Government does not accept liability to any person for loss or damage incurred as a result of reliance upon the material contained in this guideline.

Clinical material offered in this guideline does not replace or remove clinical judgement or the professional care and duty necessary for each specific patient case.

Clinical care carried out in accordance with this guideline should be provided within the context of locally available resources and expertise.

This guideline does not address all elements of standard practice and assumes that individual clinicians have the responsibility to:

- Discuss care with consumers in an environment that is culturally appropriate and which enables respectful confidential discussion. This includes the use of interpreter services where necessary.
- Advise consumers of their choice and ensure informed consent is obtained.
- Provide care within scope of practice, meet all legislative requirements and maintain standards of professional conduct.
- Apply standard precautions and additional precautions as necessary, when delivering care.
- Document all care in accordance with mandatory and local requirements.

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