Bedfordshire Hospitals NHS Foundation Trust

CLINICAL PROCEDURAL DOCUMENTS				
Document Title: Guideline on the peri-operative management of patients on anticoagulation presenting with neck of femur fractures				
This document is relevant for staff at:	**Luton Hospital site**	**Bedford Hospital site**	**Both Hospital sites** X	
Document Type:	**Clinical Guideline** X	**Standard Operating Procedure**	**PGD**	**Integrated Care Pathway**
Document Author / Responsible Author(s): Dr A. Pradere (Consultant Anaesthetist) Dr V. Nithiyananthan (CT2 Anaesthetics)				
Document Developed in consultation with: Dr M. Kaur (Consultant Haematologist) Laura Watson – Lead Pharmacist Medication Safety & Governance Mr Dan Arvinte (Consultant Trauma and Orthopaedics Bedford Hospital Mr Shobit Verma (Consultant Trauma and Orthopaedics Luton and Dunstable Univ Hospital)				
Is this document new or revised / or has minor amendments? New				
Reason for minor amendments? Please highlight all amendments in your document. N/A				
Document Number CG564T	**Version Number** *(if applicable):* 1			
Target Audience/Scope:	Doctors, nurses, pharmacists			
Associated Trust Documents: *(policies / guidelines which directly impact on this document)*	Policy for the Use of Medicines CG 230: Guidelines on the management of anticoagulation during invasive procedures in patients on warfarin CG 436: Reversal of anticoagulation and management of bleeding in adult patients on either warfarin, non -vitamin K oral anticoagulants (NOACs) or heparin			
Date of Approval: 11th August 2021	**Review Date:** August 2023			
Chief Executive / Chair of Clinical Guidelines Signature:	 Jogesh Kapadia	**Date:** 11th August 2021		

1. Introduction and Purpose

The National Hip Fracture Database (NHFD) annual report 2019 demonstrates that mortality has continued to improve with 564 fewer patients dying in 2018 than 2017.

However, the cost to NHS and social care still represents a considerable figure amounting to £1 billion a year. In the latest report ongoing causes or delays to surgery were highlighted as one of the key factors that impacted on successful patient outcomes with 10% directly attributed to anti-coagulant use and fears surrounding the risk of bleeding.

NICE guidance introduced the Best Practice Tariff to ensure timely management of patients presenting with neck of femur fractures (NOFF). Typically, patients are older, frail with multiple co-morbidities creating higher rates of complications peri and post operatively. Evidence supports that those operated on within 36 hours have improved outcomes, reduced mortality and morbidity and reduced length of stay in hospital.

Although the risk of bleeding in this cohort of patients must always be considered it is often overestimated causing a delay to surgery. The lack of clarity regarding cessation of anti-coagulants is often the culprit effecting post-operative outcome.

Considering this evidence, the following guideline has been developed to provide a safe approach to timing of surgery when managing patients that are anticoagulated.

2. Duties and Responsibilities

This guideline is for use by members of the medical/surgical/anaesthetic team to help aide timing of NOFF surgery in patients who are anticoagulated. It provides a comprehensive overview of the common combination of medications patients may be on that could cause possible delays to surgery. However, the clinical responsibility remains with the primary team looking after the patient and any complex patients, outside of the scope of this document, should be discussed with the relevant teams for further advice where necessary.

3. Background

Generally, blood loss in NOFF surgeries remains low. Where bleeding occurs, it is likely to be of low abundance; is not critical in its location; and in most cases is easily controlled by simple haemostatic mechanisms. However, greater bleeding can be expected during certain surgical procedures for instance dynamic hip screw and intramedullary nailing. Therefore, a multidisciplinary team discussion is recommended prior to arranging surgical timelines for these cases.

This guideline will primarily outline the steps to take to ensure a safe window for surgery in NOFF patients taking apixaban, edoxaban, rivaroxaban, dabigatran, warfarin, antiplatelets and heparin. Throughout this guideline apixaban, edoxaban, rivaroxaban and dabigatran will be referred to as non-vitamin K oral anticoagulants (NOACs). Note in literature NOACs may also be referred to as direct-acting oral anticoagulants (DOACs), these terms (NOACs and DOACs) are interchangeable.

Due to ease of administration and monitoring an increasing number of patients are being prescribed NOACs as a preference to warfarin. These drugs work by inhibiting key factors in the coagulation cascade: either by direct thrombin inhibition, in the case of dabigatran, or by the inhibition of factor Xa (FXa) (apixaban, rivaroxaban and edoxaban). Unlike for warfarin, in which antidotes and reversal agents remain readily available, the only commercialised antidote (Idarucizumab) for this group of drugs, is for Dabigatran. Others are on trial and expected to be on the market shortly. Regardless, the pharmacokinetics of NOACs in patients with normal or mildly impaired renal function, primarily its short half-life, allows a safe window for surgery to take place without the need for reversal. At the moment, reversal agents are only indicated for life-threatening bleeding and not for use in surgery.

In comparison, warfarin is a well-established anticoagulant, which has been on the market for many years. It is the most used vitamin K antagonist which inhibits the production of vitamin-K-dependent clotting factors: II, VII, IX and X. Warfarin, unlike the NOACs, takes a long time to have effect and has a long half-life. However, its effect can be readily reversed by the administration of vitamin K or Octaplex. Both of which are widely available.

In the table below there is a comparison of the pharmacokinetics of the different NOACs agents and warfarin.

	Apixaban	**Rivaroxaban**	**Edoxaban**	**Dabigatran**	**Warfarin**
Mechanism of action	Selective Xa inhibitor	Selective Xa inhibitor	Selective Xa inhibitor	Selective thrombin inhibitor	Vit-K epoxide inhibitor
Oral bioavailability (%)	50	80-100 (with food) 66% fasting	62	6.5	79-100
Half-life (h)	8-15	5-13	10-14	12-17	45
Renal elimination (%)	27	33	50	85	92
Time to maximal inhibition (h)	1-4	1-4	1-2	0.5-2	69

Novel antiplatelet use has also been rising with the increasing burden of cardiovascular disease. There is clear guidance on surgery in the presence of monotherapy with clopidogrel or aspirin, which will be revisited here. However, the risks need to be reconsidered when patients are on different agents such as ticagrelor or dual antiplatelet therapy (DAPT). Guidance on the above will be discussed later.

Low molecular weight heparins (LMWH) and unfractionated heparin (UFH) are other examples of commonly used anti-coagulants. They can be used for prophylaxis and treatment of VTEs; for bridging between anticoagulants and in the case of UFH to bridge high risk patients on mechanical valves for example where other anticoagulants like LMWH are not licensed.

UFH potentiates the action of anti-thrombin, inhibiting thrombin activation, catalysing the inhibition of several activated blood coagulation factors. Given IV it has a rapid onset and offset of action

unlike LMWH. It can be reversed by protamine and continuous infusion requires regular APTT monitoring.

LMWH conversely, are given subcutaneously once or twice daily as they have a longer half-life compared to UFH. The uses of both for bridging and VTE prophylaxis will be discussed later in the guideline.

4. Guidelines and recommendations

It is important to determine which anticoagulant drug these patients are on and when it was last taken or administered.

4.1. NOACs

Following last administration, the anticoagulant effects of NOACs drop rapidly after 12-24 hours. In patients taking apixaban, rivaroxaban or edoxaban with creatinine clearance over 30 ml/min, surgery can be undertaken 24 hours after the last dose. Given the short period of time between the dose and surgery, bridging is usually not needed unless there is an unanticipated delay in surgery, or the patient is at high risk of thrombosis. Please refer to 'Bridging' part of the guideline for more information. Dabigatran mainly undergoes renal excretion and therefore its elimination is more dependent on the patient's creatinine clearance. As a result, a more conservative approach has been proposed. In most cases procedures will preferentially be undertaken with a general anaesthetic. In these cases, the flowchart in Appendix 1 can be used to ascertain the safe time for surgery. This can be printed, completed, and filed in the patient's notes.

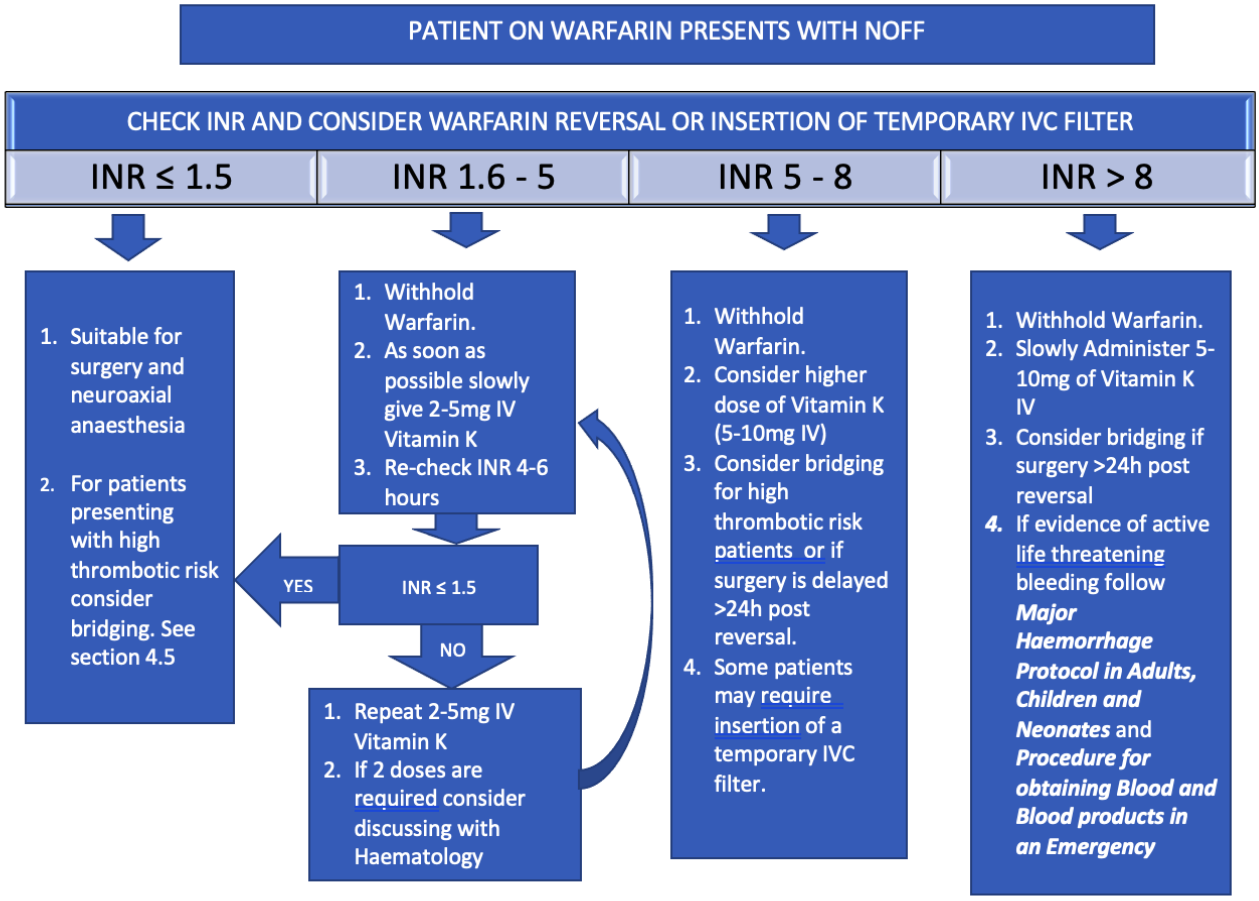
The European and Scandinavian Societies of Anaesthesiologists' 2010 guidelines recommend neuroaxial blockade after two half-lives from the last intake, after which, 25% of the drug will remain in the system if renal function is normal. The group of patients these recommendations were based on include young and relatively healthy individuals, unlike the common population group who present with NOFF. The reduced 36-48-hour window stated on those recommendations may be appropriate in elective cases or in those with a high thrombotic risk. However, this guideline recommends waiting 72 hours to ensure a 4-6 half-life interval between last-dose and neuroaxial injection, to ensure adequate clearance of the anticoagulant/antithrombotic drug.

Our recommendation is based on a recent publication by ASRA endorsed by the European Society of Anaesthesia which advice that in all patients on NOACs, neuroaxial anaesthesia and peri neuroaxial blocks should be delayed for at least 72 hours after the last intake. This time increases in patients on dabigatran, who do not have normal renal function. If the anaesthetic team have decided that a patient is unsuitable for a general anaesthesia, and they plan for a neuroaxial block (e.g., spinal/epidural, CSE), then the algorithm in Appendix 2 can be used in deciding the time for surgery. This can be printed, completed, and filed in the patient's notes.

The NOACs can be restarted the day after surgery if haemostasis is achieved. Some patients may need prophylactic dose LMWH 6 hours post operatively to bridge them until this time. Please refer to the 'Bridging' section of this guideline for more information.

4.2. Warfarin

NOFF surgery can safely be conducted with INR≤ 1.5. As NOFF are not classified as emergency surgery there is a limited role for octaplex which can work within 10 minutes. As an alternative vitamin K can be used to reverse warfarin within 4-6 hours. Some patients may require the insertion of a temporary IVC filter when anticoagulation is interrupted. Please follow the algorithm for warfarin reversal.



While Octaplex may not be indicated in all cases it is appropriate where there is life, limb or sight threatening bleeding. It may also be used for emergency surgery, where rapid reversal of INR is needed. Please discuss with Haematology if Octaplex is deemed necessary.

Indications for bridging with LMWH/UFH is discussed later in this guideline. Please discuss with Haematology or relevant team for any complex patients.

4.3. Antiplatelets

The British Society of Haematology have made recommendations for peri-operative management of anticoagulation and anti-platelet therapy. Regarding NOFF patients it is recommended that aspirin or clopidogrel monotherapy is continued as normal, if platelet count is above 80, which is the generally agreed consensus for surgery. While there is extensive evidence supporting the safe continuation of clopidogrel monotherapy in NOFF surgery, where a general anaesthetic approach is taken, the evidence for the use of other novel antiplatelets is limited. This is likely due to the fact that these drugs are not commonly used as monotherapeutic agents. In cases where they are seen, particularly with ticagrelor and prasugrel which work similarly to clopidogrel, we propose the continuation of these drugs when on monotherapy. Given the benefit to mortality and morbidity with timely surgical procedures, we suggest proceeding with caution and ensuring the patient is optimised to mitigate the potential increased risk of bleeding.

The length of time anti-platelets drugs is in-effect in the body can be seen in the table below. The recommended waiting time following last administration of each anti-platelet agent prior to neuroaxial, or deep regional blocks is highlighted in column four of the table. Such procedures should only be carried out after this time.

For patients on anti-platelet agents there is limited evidence to support the transfusion of platelets when urgent low risk surgery is required. However, this could be beneficial in those cases where platelet count falls beneath the recommended values or the risk of bleeding is very high, despite tranexamic acid. It is important to note that anti-platelet agents can also have an effect on transfused donor platelets. Therefore, administration of platelets must be carefully timed in concordance with last dose of the anti-platelet agent. For guidance, please refer to column six in the table below.

Antiplatelet Agent **(Mono-therapy only)**	**Onset of action after oral administration**	**Plasma half-life of active metabolite**	**Amount of time to wait for surgery if undergoing neuraxial blockade**	**Amount of time to wait for surgery if undergoing general anaesthetic**	**Length of time after administration donor platelets can be transfused**
Aspirin	<1hr	15-20min	None	None	2hrs
Clopidogrel	4-8hrs	30min	5-7days	None	12hrs
Prasugrel	2-4hrs	7hrs	7-10days	None	16-18hrs
Ticagrelor	1-5hrs	8-12hrs	3-5days	None	18-26hrs
Ibuprofen	45min-2hrs	2hrs	None	None	6hrs
Ebtifibatide	N/A	2-5hrs	4-8hrs	4-8hrs	4hrs

Patients on DAPT, however, are at increased risk of bleeding and this will need to be balanced with their risk of thrombosis. Those with recent (within 4 weeks) PCI and stent insertion are at higher risk from adverse cardiac events. Cessation of one of the agents (e.g. clopidogrel/ticagrelor) will need to be discussed with Cardiology.

Pre-operative use of IV tranexamic acid should be considered if risk of thrombosis is not precluded.

4.4. Heparin

Please see the following table for a comprehensive view of how long to stop UFH/LMWH prior to surgery and when to restart it. This was adapted from the European Society of Anaesthesiology's recommendation for neuraxial puncture/catheter removal. It has been modified to include surgery for NOFF within the same timeframe. This table is for use in those with normal renal function (CrCl >30 for LMWH, CrCl >50 for fondaparinux), any impairment will need prolonged time intervals – this will need discussion with Haematology.
For guidance on use of UFH and monitoring please discuss with Haematology.

	Time before surgery/ neuro-axial puncture	**Time after procedure to restart medication**
UFH (Prophylactic dose - <15000 units/d)	4-6h	1h
UFH (Treatment dose)	IV 4-6h SC 8-12h	4-6h 4-6h
LMWH (Prophylactic dose)	12h	6h
LMWH (Treatment dose)	24h	6h
Fondaparinux (Prophylactic dose – 2.5mg/d)	36-42h	6-12h

4.5. Bridging

In most cases bridging will not be required pre-procedurally as the time between stopping the anti-coagulant/anti-platelet agent should not exceed 24 hours. Patients with a greater time delay due to renal impairment and use of Dabigatran, also do not need to be bridged because of a residual anticoagulation activity at the time of surgery. Bridging should be considered on patients at high risk of thrombosis and on those whose surgical procedures are delayed beyond a 24h period. The CHA_2DS_2-VASC score is being increasingly used to stratify risk for non-valvular atrial fibrillation (AF) and is particularly useful in those in the lower risk categories. The score, table and algorithm shown below can be used to decide whether bridging is necessary.

For the small subset of patients who are deemed to have a very high risk of thrombosis, and may be either on warfarin (e.g., for metal valves) or on NOACs (e.g., high-risk genetic predisposition), the time between stopping the anticoagulant and surgery, which could be a minimum of 24 hours may still be too great. In these cases IV, or SC UFH, should be considered for bridging. Furthermore, some patients, especially those who have recently had a DVT may benefit from an

Inferior Vena Cava filter in the perioperative period. Such specific cases will need discussing with the relevant teams, Haematology or Cardiology.

CHA_2DS_2-VASC on non-valvular AF patients

Definition	Stroke risk-stratification
Congestive Heart Failure	1
Hypertension	1
Age >/=75	2
Diabetes Mellitus	1
Stroke/TIA/Thrombo-embolism	2
Vascular Disease	1
Age 65-74	1
Female Gender	1
Total	/9

Risk stratification and Decision for Bridging

	Risk Stratification	Bridging Needed?
AF with CHA_2DS_2VASC score **0-4** without prior stroke/TIA	Low	No
VTE >12m ago and no other risks	Low	No
Bi-leaflet aortic valve prosthesis and no other risks	Low	No
AF with CHA_2DS_2VASC score **5-6** without prior stroke/TIA	Moderate	Likely No
Bi-leaflet aortic valve prosthesis and other risks including AF/stroke/TIA/HTN/DM/CCF/Age>75	Moderate	Consider
VTE in last 3-12m Non-severe thrombophilia	Moderate	Consider
Factor V Leiden Heterozygous	Moderate	Consider
Recurrent VTE	Moderate	Consider
Active cancer	Moderate	Consider
AF with CHA_2DS_2VASC score **7-9**	High	Yes
Rheumatic heart disease	High	Yes
AF with stroke in last 3m	High	Yes
Mitral valve prosthesis (any type)	High	Yes
Cage and ball aortic valve prosthesis	High	Yes
Any aortic valve prosthesis and stroke/TIA in last 6m	High	Yes
Severe thrombophilia	High	Yes
Protein C/S deficiency	High	Yes

Antiphospholipid syndrome	High	Yes

4.6. Re-initiation of anticoagulation

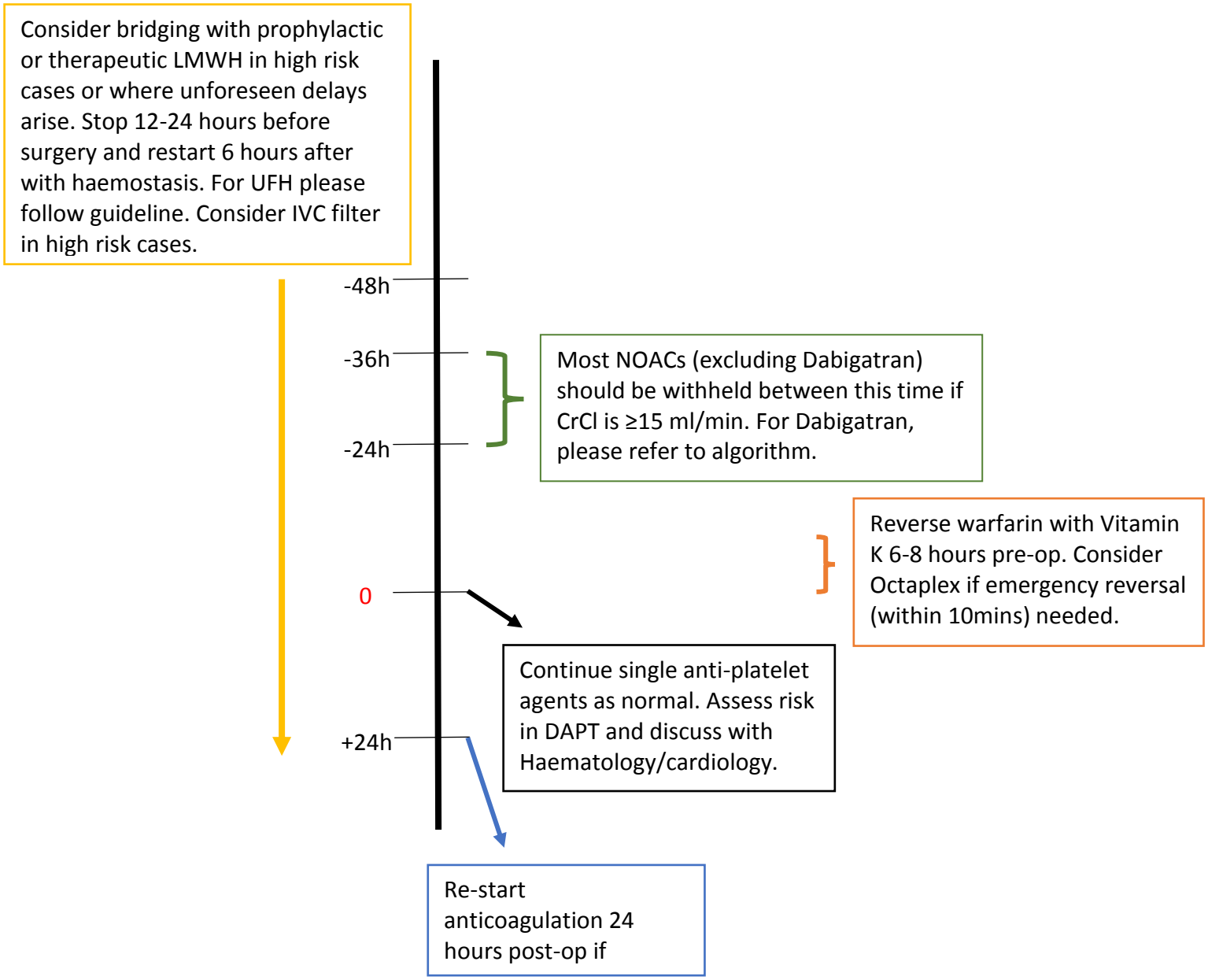
Anticoagulation should be restarted 24 hours post-surgery provided there are no bleeding complications and where appropriate, oral intake has been established. Patients on low and moderate thrombotic risk should be started on prophylactic dose LMWH 6-12h post-operatively to bridge between surgery and the restarting of usual anticoagulation, provided haemostasis has been achieved. If the recommencing of anticoagulation is delayed for any reason other than haemostasis, bridging with prophylactic/treatment dose LMWH is recommended depending on thrombotic and bleeding risk. Again, UFH can be used on very high-risk patients up to an hour after surgery. Please discuss with Haematology or Cardiology as appropriate.

Patients should not be on 2 anticoagulants simultaneously except for LMWH and warfarin, when the INR is subtherapeutic.

Refer to bridging guidance.

Summary Timeline

Hours around surgery (0 = Time of surgery)



Please discuss with Haematology/Cardiology for any complex cases.

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Appendix 1. Flowchart to calculate safe timescale for surgery following NOAC discontinuation

Management of patients with NOF fractures on non Vit-K oral anticoagulants (NOACs)
FOR ALL PATIENTS ANAESTHETISED UNDER GENERAL ANAESTHESIA + REGIONAL BLOCK (1st choice)

$$CrCl = \frac{N \times (140 - Age) \times weight\ (kg)}{Serum\ Creatinine\ (mmol/l)}$$

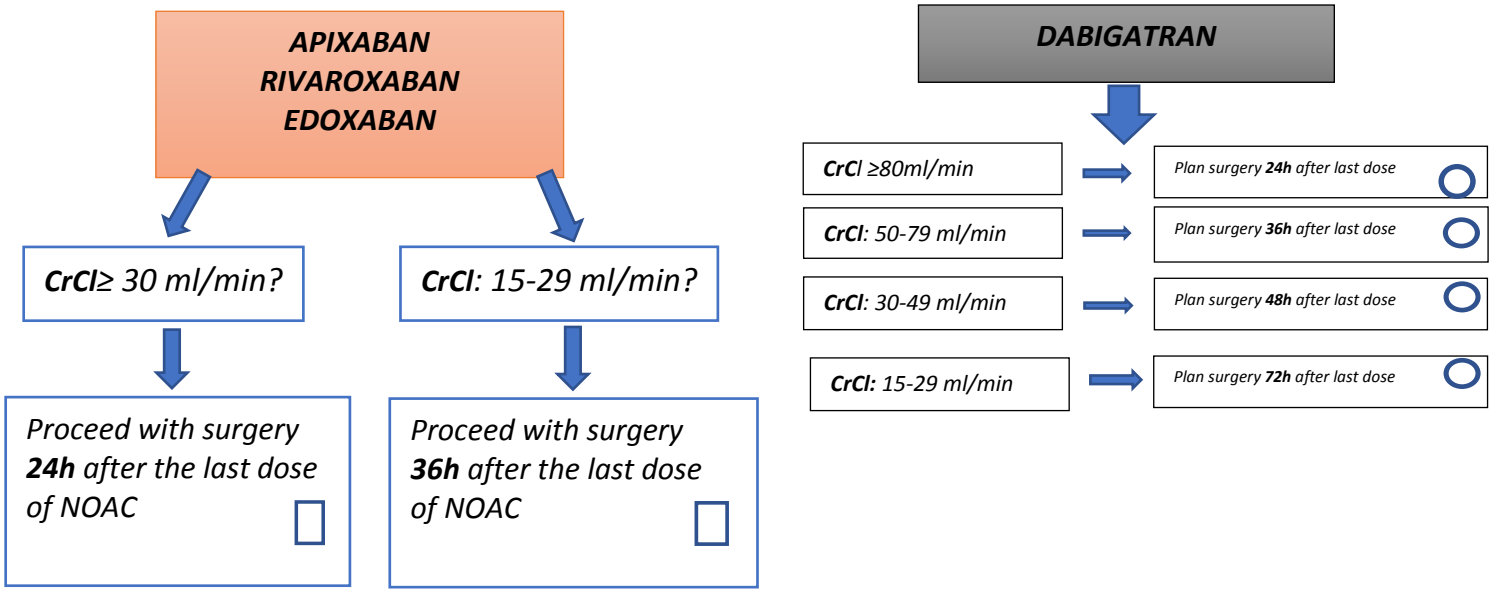
N=1.23 for males
N= 1.04 for females

1) ***To establish the drug, dose and frequency, indication and the date and time of the last dose taken.***
2) ***Discontinue the NOAC administration***
3) ***Assess the thrombotic risk: See Bridging (Pg 13-14)***
4) ***Calculate the CrCl using the Cockcroft-Gault formula provided.***
5) ***Plan NOF surgery following the algorithm and discuss with the surgical team.***
6) ***Group and Save (G&S) for all patients on NOACs.***

Drug: _____ Dose_____ Frequency: OD, BD Indication: _____

***Date and time of the last dose**: _____/_____/_____/ at ____: _____*

CrCl: _____ ml/min



Surgery planned for: _____/_____/_____ at _____: _____

Appendix 1. Flowchart to calculate safe timescale for surgery following NOAC discontinuation

Restarting NOACs postoperatively

- *Following NOF surgery is reasonable to resume NOACs on the day after the procedure considering:*
  1. *Oral intake has been established*
  2. *Haemostasis has been achieved.*
- *Postoperative NOAC dosing should reflect the postprocedural renal function*
- *Prescribe one dose of prophylactic tinzaparin 6-12h after surgery if not contraindication. Once NOACs are resumed, discontinue tinzaparin.*
- *Non-pharmacological agents for thromboprophylaxis can be used if appropriate: TEDS, IPC*

Complex cases with multiple drugs affecting the coagulation need multidisciplinary evaluation and careful planning. Discuss with Haematologist.

Appendix 2. Algorithm for safe timescale for SAB and RB

Management of patients with NOF fractures on non Vit-K oral anticoagulants (NOACs)
FOR ALL PATIENTS ANAESTHETISED UNDER SUBARACHNOID BLOCK + REGIONAL BLOCK

$$CrCl = \frac{N\ x\ (140 - Age)\ x\ weight\ (kg)}{Serum\ Creatinine\ (mmol/l)}$$

N=1.23 for males
N= 1.04 for females

1) ***To establish the drug, dose and frequency, indication and the date and time of the last dose taken.***
2) ***Discontinue the NOAC administration***
3) ***Assess the thrombotic risk: See Bridging (Pg 13-14)***
4) ***Calculate the CrCl using the Cockcroft-Gault formula provided.***
5) ***Plan NOF surgery following the algorithm and discuss with the surgical team.***
6) ***Group and Save (G&S) for all patients on NOACs.***

Drug: _____ Dose_____ Frequency: OD, BD Indication: _____

***Date and time of the last dose**: _____/_____/_____/ at ____: _____*

CrCl: _____ ml/min

APIXABAN
RIVAROXABAN
EDOXABAN

↓

CrCl *≥ 30 ml/min?*

↓

Proceed with SAB +RB ***72h*** *after the last dose of NOAC* ☐

DABIGATRAN

↓

CrCl *≥80ml/min*	→	*SAB + RB* ***72h*** *after last dose* ○
CrCl*: 50-79 ml/min*	→	*SAB +RB* ***96h*** *after last dose* ○
CrCl*: 30-49 ml/min*	→	*SAB + RB* ***120h*** *after last dose* ○
CrCl: *15-29 ml/min*	→	*Not advised to proceed with SAB* ○

Surgery planned for: _____/_____/_____ at _____: _____

For patients with CrCl< 30 ml ***ASRA suggests against the performance of any neuroaxial technique.***
These times should also be considered for any patient undergoing perineuroxial, deep plexus, or deep peripheral nerve blocks

Appendix 2. Algorithm for safe timescale for SAB and RB

Restarting NOACs postoperatively

- *Following NOF surgery is reasonable to resume NOACs on the day after the procedure considering:*
  3. *Oral intake has been established*
  4. *Haemostasis has been achieved.*
- *Postoperative NOAC dosing should reflect the post procedural renal function*
- *Prescribe one dose of prophylactic tinzaparin 6-12h after surgery if not contraindication. Once NOACs are resumed, discontinue tinzaparin.*
- *Non-pharmacological agents for thromboprophylaxis can be used if appropriate: TEDS, IPC*

Complex cases with multiple drugs affecting the coagulation need multidisciplinary evaluation and careful planning. Discuss with Hematologist.