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APPLIES TO	NATIONAL		
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#### 1. Rationale

The purpose of this Clinical Protocol is to provide a guiding framework for Hospital at the Home service Medical Practitioners and clinical staff.

- Anticoagulation for Atrial Fibrillation (AF) typically involves introduction of a direct oral
  anticoagulant (DOAC) or warfarin +/- bridging with parenteral anticoagulation, typically
  low molecular weight heparin (LMWH). The most commonly used LMWH is Enoxaparin,
  and subsequent information in this protocol is specific to Enoxaparin. (Please reference
  local guidelines for other types of LMWH)
- The decision to anticoagulate is guided by the CHA<sub>2</sub>DS<sub>2</sub>-VA score (Appendix A) in a shared decision making approach with the client.
- The choice between a DOAC and warfarin will depend on a number of factors including valvular vs non- valvular AF, renal impairment and cognitive status etc.
- DOACs achieve maximum anticoagulant effect within 3 hours of the first dose so there is
  usually no requirement for bridging with Enoxaparin at the time of initiation. DOACs do
  require dose adjustment for renal impairment, weight and age. Please see section 6.2
- Patients with valvular AF (mechanical heart valves or moderate to severe mitral stenosis) are NOT suitable for a DOAC and should be treated with warfarin.
- Warfarin takes a number of days to achieve therapeutic anticoagulation and causes an initial increase in prothrombotic potential. Consequently, when immediate anticoagulation is required (e.g. AF with recent stroke, high thrombosis risk), warfarin MUST be started/bridged with concurrent parenteral anticoagulant therapy (usually Enoxaparin). When immediate anticoagulation is not required (e.g. stroke prevention for patients with chronic atrial fibrillation with low thrombosis risk), warfarin may be started without concurrent parenteral therapy. This decision will depend on the estimated risk of thromboembolism and should be discussed with the referrer. Please refer to Appendix C for guidance.
- The use of warfarin is limited by its narrow therapeutic index, interactions with other drugs and food, and the necessity to perform regular blood tests to monitor anticoagulation. Warfarin can be used in patients with severe kidney disease.

• Be aware of the uncommon risk of heparin induced thrombocytopenia (HIT) when bridging with LMWH. Measure platelet count at baseline and during therapy as per Section 6.3 and Section 7.

# 2. Scope

The Clinical Protocol applies Nationally for HATH clients commencing on anticoagulants for the management of atrial fibrillation.

## 3. Acceptance to HATH Criteria and Pathway

RED	Co-existing medical conditions requiring hospital
Unsuitable for	admission
community admission to HATH	Known or suspected hypersensitivity to warfarin or Heparins (unless under the governance of Haematology
(May become suitable	Consultant or Thrombosis Clinic)
for HATH after initial stabilisation in a supervised acute setting)	• Severe thrombocytopaenia: platelets ≤ 50 x10 <sup>9</sup> /L
ORANGE	Over 13 years, suitable for adult dosing and under the
Requires discussion	care of a specialist team
with Medical Governance prior to	• Thrombocytopenia, where platelets are >50 x10 <sup>9</sup> /L
acceptance.	<ul> <li>Obesity (weight &gt;150kg): Enoxaparin dosing needs confirmation with Haematology/specialist</li> </ul>
	<ul> <li>Weight &lt; 50kg: Enoxaparin dosing needs confirmation with Haematology/specialist</li> </ul>
	Renal impairment, eGFR (CG) < 30ml/min
	<ul> <li>Pregnancy (Warfarin is contraindicated so for</li> </ul>
	Enoxaparin only- dosing needs confirmation with
	specialist referrer (e.g. Haematology, O&G,
	Cardiothoracic)
GREEN	Confirmed diagnosis of Atrial Fibrillation (including
Accepted for HATH	valvular or non-valvular)
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- Clear documentation of INR target
- Client's medical condition has been assessed as stable, has a clear diagnosis, management plan, prognosis and is at low risk of deterioration

### 4. Initial Pathology Work Up

Verify and review the required pathology (via referral documentation or referral source):

- Full blood count (FBC) for baseline platelet count
- Urea & electrolytes to assess renal function
- Coagulation profile (INR, APTT, fibrinogen)
- Liver function tests

#### 5. General Management

- Daily nursing assessment as per Atrial Fibrillation Assessment tool.
- Collaborate with medical governance doctor if any deterioration in client's condition
- As part of admission on to HATH service, collate the following required information in conjunction with Medical Governance:
  - Review blood results from referral source and collaborate with medical governance doctor regarding any abnormal test results
  - Confirm the nature of atrial fibrillation (valvular vs non- valvular).
    - If valvular: nature of valve condition or type of valve replacement as appropriate
  - Confirm target INR range
  - Obtain last 2-3 INR results and Warfarin doses from referral source if warfarin has already commenced
- Measure creatinine clearance using Cockcroft-Gault (CG) calculation for all clients as below: -
  - Measure the client's height and weight.



- Ascertain the Ideal body weight for the height and gender using the table in Appendix D. CG calculation is based on ideal or actual body weight, whichever is less.
- If the client's weight is at or below the estimated ideal body weight, then use the actual measured body weight in the CG formula to calculate Creatinine clearance.
- If the measured body weight is <u>above</u> the ideal body weight for the height, use the Ideal body weight for the CG calculation of Creatinine clearance.
- Check Enoxaparin orders with Medical Governance.
- Administer Enoxaparin as per medical authority until INR in therapeutic range for 24-48hours. See section 6.3 for further detail.
- If client has been on warfarin before, continue the usual brand the client is familiar with and has been stable on prior (e.g. Coumadin or Marevan). Ensure brand is documented in notes. Please note that brands are NOT interchangeable as there is a lack of data on bioequivalence
- Monitor point of care (POC) INR daily (utilising CoaguChek) and liaise with medical governance doctor for dosing of warfarin
- POC INR result greater than or equal to 3.5 CANNOT be relied upon as an accurate result. A formal blood test is required for confirmation.
- Advise client regarding Warfarin use, including its potential complications and interactions with diet, medications and alcohol as per *Living with Warfarin* booklet.
- For management of bleeding and/or high INR in a patient taking warfarin refer to Appendix E.

#### 6. Medical Management / Treatment Plan

#### 6.1 Warfarin

• The effect of warfarin is measured by a blood test referred to as INR (International Normalised Ratio). The safety and efficacy of warfarin depends on maintaining the INR within the target range. Please see Appendix B for INR target ranges according to indication.



- When commencing warfarin, measure the baseline INR. If baseline INR is 1.4 or above without warfarin, then further patient assessment and specialist advice should be sought regarding the patient's suitability for Warfarin.
- When starting or restarting Warfarin, there is a delay in achieving therapeutic anticoagulation because it takes several days for circulating coagulation factors to decrease. When first initiated, movement in the INR result may only be seen after 5-7 days
- Once the INR has started to respond, changes in INR are often seen approximately
   2-3 days after dose adjustment. This should be kept in mind when adjusting warfarin dosages.
- A patient's response to warfarin is driven mainly through genetic variance in the hepatic clearance, and vitamin K handling. Diet, age, weight changes, dosing and medication interactions also influence the anticoagulant effect.
- The list of medications that interact with warfarin (both prescription and nonprescription) is extensive. Tables detailing these medications may be found on Australian Therapeutic Guidelines, and this should be kept in mind when troubleshooting unexpected changes in INR.
- Several nomograms exist to guide warfarin dosing (e.g. age adjusted, day of therapy based etc). These can be used as a guide as deemed necessary, but do not replace clinical acumen to account for the various patient and situational factors that determine Warfarin dosing.
- When a patient is new to Warfarin, suggest initial dosing of 5mg daily for the first 2 days. Consider smaller starting doses when the patient is elderly, has low body weight, abnormal liver function tests, severe renal impairment or high bleeding risk
- When a patient is recommencing warfarin, a patient's regular dose should be prescribed, unless bleeding risk is high.
- Warfarin is contraindicated in pregnancy



#### 6.2 Direct acting oral anticoagulants (DOACs)

- DOACs (e.g. Apixaban, Rivaroxaban, Dabigatran) are widely used in Australia for Stroke prevention in patients with Atrial Fibrillation, and for treatment and prophylaxis of Deep Venous Thrombosis (DVT) and Pulmonary Embolism (PE)
- Patients with valvular AF (mechanical heart valves or moderate to severe mitral stenosis) are NOT suitable for a DOAC and should be treated with warfarin.
- DOAC dosing depends on the indication.
- DOACs do not need anticoagulation monitoring.
- DOACs achieve maximum anticoagulant effect within 3 hours of the first dose so
  there is <u>usually</u> no requirement for bridging anticoagulation at the time of
  initiation or peri-procedurally. Specific clinical scenarios may arise contrary to this,
  and in these situations, the case details require review with the referrer and in
  conjunction with the Silver Chain peri-procedural bridging protocol.
- DOACs are contraindicated in pregnancy

#### 6.3 Enoxaparin

- Bridging involves the practice of prescribing Heparin (usually Enoxaparin)
   concurrently with Warfarin to cover the pro-coagulant phase of Warfarin therapy
   and to prevent thrombosis in high-risk patients whilst the INR is sub-therapeutic.
- Bridging with Enoxaparin is not always needed when Warfarin is initiated in patients with Atrial Fibrillation. This decision will depend on the risk of thromboembolism as per Appendix C.
- Please refer to the Pre- and Post-surgical bridging protocol for further information on estimating thromboembolic risk and the need for bridging in this clinical situation, in patients with AF.
- If bridging with Enoxaparin is recommended at the time of Warfarin initiation in Atrial Fibrillation, it is usually continued for 48 hours once a therapeutic INR is reached.
  - There may be certain clinical scenarios (e.g. High bleeding risk, large jump in INR)
     where it may be decided to cease Enoxaparin after 24hours of therapeutic INR.



- Twice daily dosing of Enoxaparin is generally preferred for patients at high risk of bleeding, high risk of thrombosis, patients who are older, obese or have a malignancy.
- If the Enoxaparin dose required is greater than 150mg, dose must be given as a twice daily dose.
- The minimum time interval between twice daily Enoxaparin dosing is 10 hours. The maximum time interval between twice daily Enoxaparin dosing is 14 hours.
- If the patient weighs less than 50kg or more than 150kg, dosage of Enoxaparin should be confirmed with Haematologist.

#### Recommended Enoxaparin dose if weight range 50-150kg and not pregnant

Renal function	Treatment dose
Normal renal function	1.5 mg/kg SC daily** or
CrCl > 30mL/min	1 mg/kg SC BD*
Severe renal impairment	1 mg/kg SC daily, organise Anti-Xa levels
CrCl < 30mL/min	and adjust dose accordingly.

<sup>\*</sup> Twice daily dosing of enoxaparin is preferred in patients with high risk of bleeding, high risk of thrombosis, elderly, post acute coronary syndrome, malignancy.

- Patients with a weight of 120-150kg may be referred with a different lower starting dose to the above calculation based on emerging guidelines around this weight range. Clarify the dose with the referrer if needed. They should have anti-Xa testing to check if dose needs adjusting.
- If the patient is pregnant, weighs ≥150kg or <50kg or has renal impairment (CrCl < 30ml/min), use of anti-Xa monitoring is also recommended.
  - consult with haematology or referrer for starting dose
  - Blood test for Anti-Xa should be performed 4 hours post dosing, and ideally performed on 3<sup>rd</sup> or 4<sup>th</sup> dose post commencement of enoxaparin
  - Review results with haematologist for advice re dosage adjustment
  - Anti-Xa levels may also be used to guide dosing in patients with very high bleeding risk, recurrent or ongoing bleeding/bruising.

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<sup>\*\*</sup> If the dose required is greater than 150mg, dose must be given as a twice daily dose.

#### 7. Monitoring

- When treating with Enoxaparin, measure the patient's FBC (specifically platelet count) at baseline.
  - If the patient has not previously been treated with heparin, measure the platelet count on Day 5 post commencement, and re check the platelet count every 2-3 days/twice weekly during therapy until Day 14.
  - If the patient has previously been treated with heparin, measure the platelet count on Day 2 after starting Enoxaparin and re check the platelet count every 2-3 days/twice daily during therapy, until Day 14.
  - If platelets drop by more than 30% from baseline or <100x10<sup>9</sup>/L, the 4T's score for HIT can help with assessment and then subsequent discussion with a Haematology consultant for a plan re: enoxaparin and any investigations needed.
- Renal function up to twice weekly until stable especially if moderate to severe renal impairment. Less frequent if stable.
- Consider the need for anti-Xa level if the patient is pregnant, weight >150kg, <50kg, impaired renal function (CG Cr Cl<30ml/min), active bleeding/significant unexplained bruising on treatment.

#### 8. Medical Governance

- The client must have access to medical governance support for 24 hours per day, 7 days per week.
- Primary medical governance can be held by referring medical specialists, credentialed referring GPs or by Silverchain medical officer.
- When governance is retained by a Silverchain medical officer the client will have a medical review within 48 hours of admission and the medical officer will determine when the scheduled follow up and discharge will occur.



- Where the primary medical governor is unavailable the Silverchain medical officer can provide the medical governance.
- Care delivery is planned and provided in consultation with the client, medical officer/specialist holding medical governance and nursing staff.
- In the instance where a client's condition deteriorates the Silverchain medical officer or nursing staff will confer with referring medical officer or an emergency department medical officer as indicated-or escalate immediately if required
- A summary of the episode of care is sent to the referrer or the client's GP at discharge.

#### **Discharge Planning**

- Ensure the client has an appointment arranged with own General Practitioner (GP) prior to discharge to ensure continuity of care. This needs to be in a timely fashion to ensure INR monitoring.
- Fax client discharge summary to GP including Anti-Xa results if done (+/- subsequent haematology advice), other pertinent results, INR and warfarin doses for last 2-3 days to assist GP with ongoing management.
- In addition, nursing team to provide patient with a copy of POC and warfarin dosing chart to take to their GP appointment
- If patient has pathology laboratory led anticoagulation care, contact the lab to find out process for transfer of anti-coagulation care.

#### **Supporting Documents**

Silver Chain Group documents that directly relate to and inform this Clinical Protocol are available with this document in the Policy Document Management System (PDMS).

Other documents that directly relate to and inform this Clinical Protocol are as follows:

- Therapeutic Guidelines. eTG complete: Cardiovascular Anticoagulant Therapy (eTG March 2021 edition) <a href="https://tgldcdp-tg-org-au.silverchain.idm.oclc.org/viewTopic?topicfile=anticoagulant-therapy">https://tgldcdp-tg-org-au.silverchain.idm.oclc.org/viewTopic?topicfile=anticoagulant-therapy</a>
- <a href="https://ww2.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf">https://ww2.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf</a>
- https://www.nps.org.au/australian-prescriber/articles/anti-xa-assays



https://www.heartlungcirc.org/article/S1443-9506(18)31778-5/fulltext

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Silver Chain Group's policies align with relevant legislation and standards and are based on providing a fair, inclusive and safe working environment free from bullying and discrimination and one that enables equal opportunity for all Silver Chain staff. Our policies embody our values of Care, Community, Integrity and Excellence.

# Appendix A: CHADS2-VA score

Score	Points	Definition
С	1	Congestive Heart Failure – recent signs, symptoms or admission for decompensated heart failure. This includes both HFrEF and HFpEF, or moderately to severely reduced systolic ventricular function, whether or not there is a history of heart failure
Н	1	History of <b>Hypertension</b> , whether or not blood pressure is currently elevated
A <sub>2</sub>	2	Age ≥ 75years
D	1	Diabetes
S <sub>2</sub>	2	History of prior Stroke or TIA or Systemic Thromboembolism
V	1	Vascular Disease, defined as prior myocardial infarction or peripheral arterial
		disease or complex aortic atheroma or plaque on imaging (if performed)
Α	1	Age 65-74 years

HRpEF: heart failure with preserved ejection fraction; HFrEF: heart failure with reduced ejection fraction; TIA: transient ischaemic attack

From: https://www.heartlungcirc.org/article/S1443-9506(18)31778-5/fulltext

## Appendix B: Usual Target INR range based on indication

Target INR	Target INR Range	Indication
2.5	2-3	<ul> <li>Therapy for deep vein thrombosis (DVT) or pulmonary embolism (PE)</li> <li>Preventing DVT: high risk patients eg hip or knee surgery</li> <li>Preventing systemic embolism: atrial fibrillation (AF), valvular heart disease, post myocardial infarction (MI), bioprosthetic heart valves (first 3 months)</li> </ul>
3.0	2.5-3.5	<ul> <li>Starr- Edwards mechanical heart valves</li> <li>Mitral bileaflet mechanical heart valve</li> <li>Aortic heart valve if risk factors for thromboembolic event including AF, previous thromboembolism, left ventricular dysfunction, hypercoagulable condition</li> </ul>
Other	Other	Higher targets/ranges under Haematology consultation only

From: https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf



# Appendix C: When to consider bridging with treatment dose heparin in patients who are initiating warfarin:

Consider bridging with treatment dose heparin in:		
Venous thromboembolism	Patients with a VTE within the previous 3months	
(VTE)	Very high risk patients such as those with a previous VTE whilst on therapeutic anticoagulation who now have a target INR of 3.5	
Atrial fibrillation (AF)	Patients with a previous stroke/TIA in last 3months	
	Patients with a previous stroke/TIA and three or more of the following risk factors:  Congestive cardiac failure Hypertension (> 140/90 mmHg or on medication) Age >75 Diabetes mellitus	
	Patient with AF who have CHADS <sub>2</sub> score of 4 or less and who have not had a stroke or TIA in the last three months should not receive bridging	
Mechanical Heart Valve (MHV)	All patients with MHV, EXCEPT those with a bileaflet aortic valve and NO other risk factors as above.	

From: https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf

# Appendix D: Ideal body weight for height and gender

Height		Ideal body weight in kg	
cm	Feet (') & Inches (")	Female	Male
155	5'	48	53
160	5' 2"	53	57
165	5' 4"	57	62
170	5' 6"	62	66
175	5' 7"	66	71
180	5' 9"	71	75
185	6'	75	80
190	6' 2"	80	84

195	6' 4"	84	89
200	6' 6"	89	93
205	6' 7"	93	98
210	6' 9"	98	102
215	7'	102	107
220	7' 2"	107	111

# Appendix E: Management of Bleeding and/or High INR (Over-anticoagulation) Principles

- INR ≥ 3.5 on Point of Care (POC) machine e.g. CoaguChek mandates laboratory specimen to be taken.
- Laboratory specimen is considered as 'gold standard' and should be utilised in preference to POC machine.

#### **Bleeding Risk Factors:**

Risk of bleeding can be assessed using the HAS-BLED scoring system. A score of ≥ 3
indicates high risk. Assessment is performed to identify modifiable risk factors that may
be managed prior to initiation of warfarin.

HAS	S -BLED clinical characteristics	Points
Н	Hypertension (uncontrolled, > 160mmHg systolic)	
Α	Abnormal renal and liver function (1 point each)	1 or 2
S	Stroke (previous history, particularly lacunar)	1
В	B Bleeding (history or predisposition e.g. anaemia)	
L	Labile INRs (i.e. time in therapeutic range is less than 60%)	
Ε	E   Elderly (age > 65 years)	
D	Drugs (e.g. non steroidal anti inflammatory or antiplatelet drugs, heparin or 1	
	thrombolysis) OR alcohol (1 point each)	
	TOTAL SCORE (maximum 9 points)	

- HAS-BLED scores of 0,1 or 2 correlate to 1.13, 1.02 and 1.88 major bleeds per 100 patient years respectively.
- This risk significantly increases at higher scores with HAS-BLED scores of 3,4 and 5 correlating to 3.74, 8.70 and 12.50 major bleeds per 100 patient-years respectively

From: https://www.health.wa.gov.au/~/media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf



• Treating clinicians may find it helpful to consider these bleeding risk factors in terms of those that are modifiable vs not. Addressing modifiable risks will play a significant role in reducing negative outcomes for patients.

Modifiable bleeding risk factors	Comment
Hypertension (SBP >16)	Blood pressure control reduces the potential risk of
	bleeding
Labile INR (TTR < 60%)	Consider changing to a DOAC if suitable
Concomitant medications including	Minimise duration of double or triple therapy in patients
antiplatelet agents and NSAIDs	with coronary disease and AF
Excess alcohol (> 8 drinks per week)	
Potentially modifiable bleeding risk	
factors	
Anaemia	
Impaired renal function	Monitor, especially in situations where renal function
	may be affected
Impaired liver function	
Frailty and falls	Walking aids, footwear, aged care home review
Non-modifiable bleeding risk factors	
Advanced age	Stroke risk outweighs bleeding risk
History of major bleeding	
Dialysis dependent kidney disease	The role of anticoagulation (warfarin only indicated) in
	this population is controversial
Cirrhotic liver disease	Contraindication to NOACs (these patients were
	excluded from trials), consider advice from hepatologist
Malignancy	Individualise decisions about anticoagulation based on
	risk and benefit
Genetic or racial variation	Subgroup analysis from the DOAC versus warfarin RCTs
	suggest that, when warfarin is used, Asian patients are at
	higher risk of major bleeding and ICH than non-Asians.
	Standard dose DOACs appear to be as effective in Asians
	and non- Asians
	ICH risk is higher in Aboriginal and Torres Strait Islander
	patients on anticoagulation
	Pay careful attention to blood pressure control in these
	populations.
AF: atrial fibrillation; ICH: intracranial haemorrh	age; INR: international normalised ratio; DOAC: direct acting oral

AF: atrial fibrillation; ICH: intracranial haemorrhage; INR: international normalised ratio; DOAC: direct acting oral anticoagulant; NSAIDs: non steroidal anti-inflammatory agents; RCT: randomised controlled trial; SBP: systolic blood pressure; TTR: time in therapeutic range

From: https://www.heartlungcirc.org/article/S1443-9506(18)31778-5/fulltext



# Management of patients on warfarin/enoxaparin/DOAC therapy with bleeding or significant bruising\*

Inform and discuss plan with medical governance in all clinical settings

Clinical setting	Recommendation		
Life threatening bleeding	Basic life support protocol, ring 000 for immediate hospital transfer. Withhold all anticoagulation.		
Clinically significant bleeding	Cease anticoagulation and transfer immediately to hospital (BLS and 000 if clinically indicated)		
Minor bleeding/significant bruising whilst on anticoagulation therapy	Discuss with Medical Governance for tailored plan. Recommendations may include actively managing/ monitoring bleeding or bruising based on clinical judgment, omit/reduced anticoagulation therapy, close monitoring of INR if applicable, anti- Xa tests and transfer to hospital if worsening bleeding/concerns.		

# **Reversing warfarin over-treatment**

REVERSING WARFARIN OVER-TREATMENT (bleeding risk increases exponentially from INR 5 to 9. Monitor closely INR ≥ 6)									
Clinical Setting		Management							
INR	Bleeding	Warfarin	Vitamin K (seek advice if cardiac valve replacement)	Comments					
Greater than therapeutic range but less than <4.5	Absent	Reduce dose or omit next dose		Resume warfarin at reduce dose when INR approaches therapeutic range.  If INR <10% above therapeutic level, dose reduction may not be necessary.					
4.5-10	Absent (Low risk)	Stop		Measure INR within 24 hours. Resume warfarin at reduced dose when INR approaches the therapeutic range.					
	Absent (*High risk)	Stop	Consider 1-2mg (oral) or 0.5-1mg IV	Measure INR within 24 hours. Resume warfarin at reduced dose when INR approaches the therapeutic range.					
>10	Absent (Low risk)	Stop	Consider 3-5mg (oral) or transfer to hospital for IV	Measure INR in 12-24 hours.					



						Resume warfarin at reduced dose when INR approaches the therapeutic range.
	Absent (*High risk)	igh and possible prothrombinex VF.				
*High bleeding risk = one of more of →		Recent surgery/trauma/bleed		Renail failure	Alcohol abuse	Antiplatelet therapy
		Advanced age		Hypertension	Active GI bleed	Other relevant co-morbidity eg severe liver disease

 $From: \underline{https://www.health.wa.gov.au/^{media/Files/Corporate/general-documents/WATAG/Warfarin-guidelines-for-anticoagulation.pdf} \ with modifications$