Blackpool Teaching Hospitals WHS **NHS Foundation Trust Document Type: Unique Identifier: GUIDELINE** CORP/GUID/147 **Version Number:** Title: Warfarin Status: Ratified Target Audience: Divisional and Trust wide **Department:** Pharmacy **Author / Originator and Job Title: Risk Assessment:** Dr Seye Kolade Consultant haematologist Not Applicable Jennifer King Specialist Pharmacist for Haematology / Oncology Replaces: **Description of amendments:** Version 1: Warfarin Loading, Contents page added. Risk assessment, Maintenance, Monitoring, Patient dosing regimen, pharmacy staff responsibility, Education and Discharge of Patients and clinical indications updated. Management CORP/GUID/147 of over anti-coagulation updated. Version 2: Management Of Warfarin Management Of Warfarin Anti-Coagulation Anti-Coagulation Before And After Before and After Elective Invasive **Elective Invasive Procedures** Procedures updated and tables added. PCC CORP/PROC/085 checklist added and info updated. Version 3: Management of Over-Anti-Coagulation CORP/GUID/093 Warfarin Reversal Before An Urgent Or Emergency Operation CORP/PROT/052 Validated (Technical Approval) by: Validation Date: **Which Principles** Quality and Governance Meeting 31/03/2016 of the NHS Constitution Apply? 1 - 4 Ratified (Management Approval) by: **Ratified Date: Issue Date:**

Blackpool Teaching Hospitals NHS Foundation Trust aims to design and implement services, policies and measures that meet the diverse needs of our service, population and workforce, ensuring that they are not placed at a disadvantage over others. The Equality Impact Assessment Tool is designed to help you consider the needs and assess the impact of your policy in the final Appendix.

Review dates and version numbers may alter if any significant

21/04/2016

21/04/2016

01/03/2019

Review Date:

Medicine Management and Safety

Committee

changes are made

CONTENTS

U					
1	Pι	ırpose	.		4
2	Ta	raet /	Audience		4
3		•			
		1 Risk Assessment			
	.2 Clinical Indications, treatment duration and target International Normalised Ra				
Ŭ	(INR) for oral anticoagulation				5
3	.3			care	
	.4				
	 .5			drugs	
Ŭ	.5 3.5			telet Therapy who develop an Indication	
	0.0	•			
	3.5	.2	Management of Patients on Warfar		
	0.0				8
3	.6	Warf	arin Rapid initiation dosing regimen	for patients with VTE / PE	9
	.7	Low	dose, slow initiation of warfarin for A	A.F (in patients NOT for cardioversion).	10
	.8			(pane)	
	.9				
Ū					
	3.9			Anticoagulant Record Books	
3	.10			nts	
3	.15	Mana	agement of Over-Anti-Coagulation		13
	3.1			eases in INR	
	3.1			Associated With Major Bleeding	
	3.1		Guidance	<i>,</i>	
3	.16	Mana	agement of anti-coagulation before	and after invasive procedures / operation	ons
					15
	3.1	6.1		th warfarin prior to an urgent invasive	
			procedure / operation		15
	3.1	6.2	Management of anti-coagulation wi	th warfarin prior to an emergency inva-	sive
	3.1	6.3	Management of anti-coagulation wi	th warfarin prior to an elective invasive	!
			procedure / operation		16
4	At	tachn	nents		19
5	Pr	ocedi	ral Document Storage (Hard and E	lectronic Copies)	19
6				' /	
7	_				_
				Oocuments	
8					
9			G	f, Peers, Patients and the Public	
10			•		
11				pproval	
App	Appendix 1: Warfarin Counselling Record – Obtain VS458 from General Stores2				
, vPF		J. I			20
	Bla	ackpool '	Feaching Hospitals NHS Foundation Trust	ID No. CORP/GUID/147	

Appendix 4: Octaplex Mix2Vial Instructions for Reconstitution	27
Appendix 5: Abbreviated Prescribing Information octaplex	28
Appendix 6: CHADS 2 score	29
Appendix 7: Equality Impact Assessment Form	30

1 PURPOSE

To ensure the safe initiation, maintenance, monitoring and prescribing of Warfarin as per the National Patient Safety Agency (NPSA) alert number 18 March 2007. http://bfwnet/departments/anticoag/NRLS-0440-Anticoagulants-PSA-2007-03-28-v1.pdf.

This guideline will also cover the management of patients who are excessively anticoagulated and the anticoagulation required before and after elective invasive procedures. This policy does not cover the management of children.

2 TARGET AUDIENCE

This guideline applies to all staff employed by Blackpool Teaching Hospitals NHS Foundation Trust that are involved in the prescribing (loading and maintenance doses), administration, monitoring, dispensing, patient education and discharge of patients.

Patients who are unable to tolerate warfarin should be considered for alternative treatments.

3 GUIDELINE

3.1 Risk Assessment

It is the prescribers' responsibility to perform a risk assessment on each individual patient before initiating warfarin and documenting this in the notes. Warfarin therapy is not advisable if the risk of harm is likely to outweigh the benefits of treatment. Oral anticoagulants prescribed in pregnancy should be in consultation with an obstetrician. Based on the bleeding score HAS-BLED for Atrial Fibrillation (AF) the following risk factors should be taken into consideration.

- Is the patient over 65 years?
- Does the patient have a history of uncontrolled hypertension?
- Does the patient have renal disease?
- Is there any evidence of liver disease? Are the Liver Function Tests (LFT's) abnormal?
- Does the patient have a history of stroke?
- Does the patient have any history of a major bleed?
- Is there any evidence of alcohol excess?
- Is there any history of previous falls?
- Does the patient take any Non-steroidal anti-inflammatory drugs (NSAIDS), long term antibiotics or antiplatelets?
- Is the patient being investigated or receiving treatment for cancer?
- Patient compliance / Psychological issues.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

3.2 Clinical Indications, treatment duration and target International Normalised Ratio (INR) for oral anticoagulation

Reason for treatment	Target INR	Duration of Therapy		
Treatment of Venous Thromboembolism				
Calf Vein Thrombosis	2.5	6 weeks		
Proximal Deep Vein Thrombosis (DVT) or Pulmonary Embolism (PE) (associated with temporary risk factors)	2.5	3 months		
Idiopathic proximal DVT / PE	2.5	3-6 months		
Recurrence of spontaneous venous thromboembolism when not on warfarin	2.5	Indefinite		
Recurrence of venous thromboembolism when on warfarin	3.5	Indefinite		
Mechanical Heart Valves				
Aortic Bileaflet	2.5	Indefinite		
Aortic Tilting Disc	2.5	Indefinite		
Mitral Bileaflet	3.0	Indefinite		
Mitral Tilting Disc	3.0	Indefinite		
Caged Ball Aortic	2.5	Indefinite		
Caged Ball Mitral	3.0	Indefinite		
Aortic valve (type not specified)	2.5	Indefinite		
Mitral Valve (type not specified)	3.0	Indefinite		
On X-aortic	2.0	Indefinite		
Other reason not listed above	Please indicate range	Please indicate duration		
Other Reasons				
Cardiomyopathy/ mural thrombus or akinetic segment	2.5	Indefinite		
Atrial Fibrillation or other high risk arrhythmias	2.5	Indefinite		
Other reason not listed above	Please indicate range	Please indicate duration		

Blackpool Teaching Hos	pitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

Information provided by Anticoagulant Dosing Advisory Service (ADAS) and British Committee for Standards in Haematology (BCSH).

**The final decision about the duration of anticoagulation can be complex and must be done in consultation with the patient - e.g. there will be certain patients with idiopathic Venous Thromboembolism (VTE) who it would be reasonable to consider indefinite anticoagulation.

Cancer associated thromboembolism is generally treated with a Low Molecular Weight Heparin (LMWH) as there is evidence that this is more effective at preventing recurrence than warfarin (CLOT trial).

3.3 Prescribing Anticoagulants in secondary care

 Oral anticoagulants must be prescribed in accordance with the Trust's Medicines Prescribing Policy:

http://fcsharepoint/trustdocuments/Documents/CORP-PROC-301.docx

- Perform risk Vs benefit analysis of patient.
- Inform patient of decision to start warfarin.
- Document reason for initiating warfarin therapy and the intended duration of therapy in the patient's notes.
- Counsel the patient using the 'Warfarin Counselling Record checklist' (Appendix 1). Counselling can be conducted by a Nurse, Pharmacist or Doctor.
- Prescribe warfarin on the regular section of the in-patient prescription chart at 18:00. The dose should not be specified but the words "See INR" should be used.
- Initiate anticoagulant loading doses (see section 3.6)
- Arrange monitoring and electronic referral to ADAS.
- Complete the 'Anticoagulant Treatment Section' on the reverse of the prescription chart. Details to be completed;
- Name of anticoagulant Target INR e.g. 2.5.
- Indication as to whether newly commenced or continuation therapy dose.
- If continuation therapy, the usual maintenance dose.
- Indication for use / diagnosis.
- Intended duration of treatment.
- The INR on a specified date.
- The daily dose in milligrams.

Before prescribing warfarin for an in-patient always:

Review bleeding history.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

- Review and document baseline INR, creatinine, LFTs, Activated Partial Thromboplastin Time (APTT) and Full Blood Count (FBC) within one week prior to commencement of treatment.
- review previous results and the trend in INR.
- Review drug chart for new interacting treatment starting or stopping.

3.4 Co-prescribing interacting medicines

Many drugs can interact with warfarin. A full list can be found in the British National Formulary (BNF) online via the trust internet. https://www.medicinescomplete.com/mc/bnf/current/bnf_int220-coumarins.htm

When prescribing, a non-interacting drug should be chosen wherever possible.

For short courses of a new drug, warfarin dose adjustment is not essential.

When starting a new interacting medicine for more than 7 days an INR test should be performed after 3–7 days so the warfarin dose can be adjusted if necessary.

The prescriber who initiated or discontinues an interacting medicine is responsible for informing the patient of the change in therapy, informing the anticoagulant clinic and ensuring that an INR check is performed.

Special considerations:

- Concomitant use of certain antibiotics e.g. Quinolones.
- Concomitant use of amiodarone.
- The dose of oral anticoagulant may need to be reduced by up to one third if amiodarone is added to anticoagulant therapy. Weekly INR monitoring for up to 4 weeks after initiating or discontinuing amiodarone is advised.
- Avoid Cranberry Juice.

3.5 Guidance on co-prescribing antiplatelet drugs

For full guidance follow the link below to the BSCH guidelines

http://www.bcshquidelines.com/documents/warfarin 4th ed.pdf

Caution: The combination of warfarin, clopidogrel and a non-steroidal anti-inflammatory drug (NSAID) may result in a significant Gastro Intestinal (GI) bleed.

Blackpool Teaching Hos	spitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

3.5.1 Management of Patients on Antiplatelet Therapy who develop an Indication for Warfarin

• Single agent Aspirin should be continued until 12 months post Acute Coronary Syndrome (ACS), unless increased bleeding risk.

Antiplatelet therapy should be stopped in the following cases when warfarin is initiated;

- Primary prophylaxis for cardiovascular disease.
- Peripheral artery disease or previous ischaemic stroke
- Secondary prophylaxis for stable ischaemic heart disease (>12 months following Myocardial infarction (MI)).

Antiplatelet therapy should be reviewed and discussed with a cardiologist in the following cases

- Dual treatment with aspirin and clopidogrel following a stent placement or ACS should be carefully assessed before warfarin added.
- When combined warfarin and single antiplatelet agent are indicated, consideration should be given to use of aspirin given the higher bleeding risk associated with clopidogrel

3.5.2 Management of Patients on Warfarin Who Develop an Indication for Antiplatelet Agents

The need for warfarin should be reviewed. If there is a clear indication for warfarin to be continued, then an attempt should be made to reduce the length of time on dual or single antiplatelet therapy. The exact duration of dual or single agent antiplatelet therapy should be guided by the perceived bleeding risk.

- Patients requiring a coronary artery stent, should be considered for bare metal stent (rather than drug eluting stent) which would only necessitate triple therapy for 4 weeks, followed by aspirin and warfarin for 12 months.
- Patients who do not undergo Percutaneous Coronary Intervention (PCI) should be considered for 4 weeks triple therapy, after which clopidogrel should be stopped, and aspirin continued for a further 11 months.

3.6 Warfarin Rapid initiation dosing regimen for patients with VTE / PE

This regimen is recommended where oral anticoagulation is desired within 3 to 4 days. Target INR 2-3. Baseline INR must be less than 1.4 to use this algorithm.

Day 1 - 4

Measure baseline creatinine, LFT's, INR and FBC. Perform risk assessment.

Prescribe Warfarin 5mg for 4 days (3mg if risk factors)* Prescribe therapeutic LMWH until INR > 2 for 48 hours

^{*} Risk factors: age>70yrs, weight<60kg, liver impairment, severe cardiac failure, low albumin, interacting drug therapy



Day 5

INR to be checked day 5 and warfarin dosed accordingly. (See below)

Only follow the dosing algorithm below if the patient has taken 5mg for 4 days.

DAY 5 INR	WARFARIN DOSAGE
=/< 1.4	8mg for 3 DAYS
1.5-1.7	6mg for 3 DAYS
1.8-2.2	4mg for 3 DAYS
2.3-2.7	3mg for 3 DAYS
2.8-3.2	2mg for 3 DAYS
3.3-3.7	1mg for 3 DAYS
>3.7	MISS 1 DAY AND RETEST

After day 5, repeat INR on day 8, then repeat frequently until two consecutive INR's within therapeutic range, with variation of < 0.3 INR.

There are no dosing guidelines for patients with a baseline INR of >1.4.

Consideration should be given to the safety of initiating therapy in patients who have a raised baseline INR and deranged LFT's. Further assessment is required; refer back to a consultant/senior member of the team.

Blackpool Teaching Hos	spitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

3.7 Low dose, slow initiation of warfarin for A.F (in patients NOT for cardioversion)

The treatment of A.F for patients not requiring rapid anticoagulation can be safely managed using a slow loading regimen. This can be initiated through the ADAS system on the online referral system.

Day 1-4

Measure baseline creatinine, LFT's, INR and FBC. Prescribe Warfarin 3mg for 4 days. Check INR day 5

3.8 Monitoring oral anticoagulants

Monitoring of warfarin should be based on an inpatient's clinical state. A daily INR check may not always be clinically indicated. The dose of warfarin does not need to be adjusted for minor changes in INR.

Once a stable warfarin dose is obtained, the warfarin dose should not be increased or decreased by > 20 % in the absence of abnormal LFT's, interacting drugs, or hypersensitivity to warfarin.

To prevent the 'ping pong' effect of frequent dose alteration, it is recommended that trends are followed. Alteration of warfarin dose is generally reflected by a change in INR result in 2 - 3 days i.e. don't react to the INR result the day following a dose change, unless markedly different.

In the outpatient setting maintenance dose adjustment is the responsibility of community clinics. For a full list of clinics available follow the link below. http://bfwnet/departments/anticoag/guidance.htm

See sections 3.15.1 and 3.15.2 for more information on managing raises in INR.

3.9 Patient Education

3.9.1 Inpatient Counselling

All new patients prescribed warfarin must have a counselling checklist (Appendix 1) completed to ensure that all the appropriate information has been provided. This includes;

- The name of the drug and current dose.
- The reason they are taking the drug.
- Therapeutic goal.
- The anticipated length of treatment.
- What to do in the event of a missed dose.
- Symptoms of under / over anticoagulation and action to take if these occur i.e. major bleeds, unexplained bruising.

Blackpool Teaching Hos	spitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

- Drug / drug and drug / food interactions (including alcohol).
- Clinic arrangements and how to obtain further medicine supplies.
- What to do if dental treatment/surgery is required.
- What to do if a surgical procedure is required / indicated.
- Who to contact regarding any worries or concerns relating to their anticoagulation management.
- Attendance at the clinic for monitoring is essential and compulsory.
- The patient must be given the opportunity to ask questions.

Counselling can be conducted by the discharging doctor, staff nurse or pharmacist on the ward. The patient or carer must sign and date the counselling form which must then be filed in the patient's notes.

3.9.2 Anticoagulant Education Packs and Anticoagulant Record Books

Anticoagulant Education Packs and Anticoagulant Record books can be obtained from Pathology. Wards should keep a small supply. The pack includes a record book, alert card and information book.

- The record book must be completed with the following information.
 - Page 1 Patients, name address and hospital number. A hospital addressograph label is sufficient.
 - Page 2 The staff at the anticoagulation clinic will complete this page.
 - Page 3 GP name only.
 - Page 4 Referring consultant's name, reason for anticoagulation, target INR and duration of treatment.
 - Anticoagulant treatment record Warfarin should be dosed at the time of discharge until the first appointment.
- The patient should be informed to take the warfarin record booklet to every anticoagulant appointment. This will remind them of their daily dosage and appointment date.
- Inform the patient to take the warfarin education folder, the Anticoagulant Therapy Record Book and alert card with them to Anticoagulant Clinic (ADAS) on their first visit. ADAS will re-enforce the warfarin counselling and complete the alert card.
- The prescriber must ensure that the patient has read and understood this information.

Blackpool Teaching Hos	spitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

3.10 Discharging patients on oral anticoagulants

- The prescriber must fully complete the Anticoagulant Therapy Record Book.
- It is mandatory for the prescriber to complete the online referral form via the Nexus Suite Portal app ADAS.
- All patients should be given an appointment date / time at the anticoagulant clinic as soon as possible after discharge.
- **E-Discharge prescriptions** -should state why the anticoagulant has been started, duration of therapy and what follow up arrangements have been made.

3.11 Discontinuing oral anticoagulants

If anticoagulation is no longer required it is safe to stop warfarin abruptly. There is no need to taper the dose.

Discontinuation of warfarin therapy must be reported to ADAS and the general practitioner

3.12 Nursing staff responsibility

- Ensure that the patient takes the anticoagulant safely.
- If not already done, on discharge the nurse will provide an Anticoagulant Education Folder to all newly started warfarin patients.
- If not already done, on discharge, the nurse will counsel patients on warfarin therapy.

3.13 Pharmacy staff responsibility

- Ensure the prescription chart is filled in correctly.
- Ensure that INR is being monitored correctly and that dose adjustments are made if required.
- Monitor and check for interactions when new medication is started.
- Check the appropriateness of co-prescribing other anti-platelet medication.
- If not already done, on discharge, the pharmacist will counsel patients on warfarin therapy.
- Ensure that new patients receive an anticoagulant education pack and booklet.
- 28 x 1mg tablets and 28 x 3mg tablets should be supplied on discharge.
- The tablets will be labelled "Take as directed in the Anticoagulant Booklet".
- Ensure on discharge that the anticoagulant booklet is completed and the patient has a clinic appointment confirmed.

Blackpool Teaching Hos	spitals NHS Foundation Trust	ID No. CORP/GUID/147	
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

3.14 **Audit**

ADAS will conduct an annual audit of patients on oral anticoagulants. The annual anticoagulant audit will monitor the % of new referrals with incomplete information; % of patients that were not issued with patient-held information and written dosage instructions; % of patients who were discharged from hospital without an appointment for the next INR measurement or for consultation with an appropriate healthcare professional to review and discuss treatment plans, benefits, risks and patient education.

3.15 Management of Over-Anti-Coagulation

3.15.1 Management of Asymptomatic Increases in INR

- The risk factors for excessive anticoagulation need to be considered. These include;
 - Age >70 years
 - Cognitive impairment
 - Poor hearing / eyesight
 - Multiple other medications, especially anti-platelet and anti-inflammatory agents
 - Thrombocytopenia / liver dysfunction / alcohol excess
 - Previous bleeding episodes
- Need to consider why the INR is high. These include;
 - Not taking the correct dose, i.e. unintentional overdose
 - Altered metabolism
 - Liver disease including alcohol binges
 - New drug(s) recently started?
 - Intercurrent illness
- Action depends on INR

INR between	1. Decrease maintenance dose by 25 %.
3.0 to < 5.0	
(target INR 2.5)	
INR between	Stop warfarin for 1-2 doses
5.0 – 8.0	2. The cause of elevated INR should be investigated
no bleeding	3. The maintenance dose should be reduced
	4. Check INR next day
	5. Restart when INR <5

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

INR >8.0	Stop warfarin
no bleeding	2. Give 2 mg of vitamin K (phytomenadione) orally. ∯
	3. Recheck INR next day
	4. Repeat dose of vitamin K (phytomenadione) orally if INR still high after 24 hours
	5. The cause of elevated INR should be investigated
	6. The maintenance dose should be reduced
	7. Restart warfarin when INR < 5
INR between	Stop warfarin
5.0 - 8.0	2. Give vitamin K 1-3mg by slow intravenous injection
minor bleeding	3. Restart warfarin when INR < 5.0

- ∯ For Vitamin K (phytomenadione) orally use Konakion®MM paediatric injections used orally. Draw up 2mg in 0.2ml using the oral dispenser provided and drop onto the tongue.
- There is good evidence that the intravenous preparation of vitamin K, administered orally, is a simple, safe and effective means of reversing asymptomatic overanticoagulation. The anti-coagulant department at Blackpool Teaching Hospitals gives 2mg orally vitamin K to patients in the community who have an INR >8 at a clinic visit. This avoids the need to have intravenous access, as well as avoiding potential risk of anaphylaxis from the Intravenous (IV) formulation.
 - Re-start warfarin when INR <5

3.15.2 Management of an Increased INR Associated With Major Bleeding

Please Note: The use of fresh frozen plasma (FFP) in the reversal of warfarin anticoagulation is not used within the trust. The preferred agent is Octaplex a 4 factor prothrombin complex concentrate (PCC) – it should be noted that this is contra-indicated in patients with a known allergy to heparin or history of heparin induced thrombocytopenia (HIT). This contains active clotting factors whose levels have been depleted by warfarin, namely factors II (prothrombin), VII, IX and X.

PCC has the following advantages over FFP:

- No need for a blood group
- No need to thaw
- Reduced Volume
- Reduced risk of FFP-associated side-effects such as transfusion-related acute lung injury (TRALI)

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

3.15.3 Guidance

- Stop warfarin
- Give intravenous vitamin K 5mg. Haematology On-call can give advice on the actual dose to be given. The administration of vitamin K is vital to allow normal clotting factor production in 6-12 hours by the liver. If it is not given, then the effects of PCC will soon wear off, and the INR will rise back to presentation levels.
- Requests for PCC must have been discussed with and agreed by a doctor of registrar grade or above. It is their responsibility to calculate the dose and request it accordingly from the blood bank. The issuing of PCC does NOT have to be authorised by a Haematologist, and the Haematologist should only be contacted for clinical advice – not for authorisation.
- Each vial of PCC contains 500 units. The dose is dependent upon the initial INR:
 - INR 1.4 or less PCC is not required.
 - INR 1.5-4.9 give 15 units/kg. Round to the nearest 500unit vial.
 - INR 5 and above give 30 units/ kg. (Max 3000units). Round to the nearest 500unit vial
 - More PCC may be required dependant on repeat INR.
- The PCC should be collected immediately from the blood bank. For intravenous administration start infusion at a slow speed: Initially 1ml per minute test dose, then no faster than 2-3 ml per minute. (For additional information on dosage and administration of PCC refer to Appendix 4)
- Repeat INR 30mins post PCC.
- The decision when to re-start warfarin following a major bleed can be very difficult. It is very much about the risk: benefit ratio of continuing with anticoagulation or not. The decision when to re-start warfarin in a patient with a metallic mitral valve requires discussion between the haematologist and cardiologist to assess the risk of recurrent bleeding versus the risk of valve thrombosis. A short, initial period of no anticoagulation immediately after the bleed may be appropriate.

3.16 Management of anti-coagulation before and after invasive procedures / operations

3.16.1 Management of anti-coagulation with warfarin prior to an urgent invasive procedure / operation

- An urgent procedure or operation is defined as one that needs to be performed within 24-48 hours but not immediately. A good example of this would be a hip replacement for a fractured neck of femur.
- Stop the Warfarin, check the INR and give 2.5mg-5mg Vitamin K intravenous (This
 will generally allow full reversal in 6-12 hours).
- The INR must be checked to ensure adequate correction prior to the procedure / operation.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

• For management post-operatively see elective schedules below.

3.16.2 Management of anti-coagulation with warfarin prior to an emergency invasive procedure / operation

 An emergency operation / procedure is defined as one that needs to be performed immediately and cannot wait 6-12 hours for vitamin K to take its effect. A good example of this would be operative intervention for perforated bowel.

Stop the Warfarin, check the INR, give 2.5mg-5mg Vitamin K intravenous and PCC.

The dose is dependent upon the initial INR:

- INR <5 15 units/ kg. Round to the nearest 500unit vial.
- INR >5 30 units/ kg. Round to the nearest 500unit vial.
- Repeat INR 30mins post PCC, and certainly before operation / procedure.
- More PCC may be required dependant on repeat INR
- For instruction guidance on reconstitution of PCC refer to Appendix 3
- For management post-operatively see elective schedules below

3.16.3 Management of anti-coagulation with warfarin prior to an elective invasive procedure / operation

- Decisions on management of patients prior to an elective invasive procedure / operation will depend on balancing the likely thrombotic risk during the interruption of anticoagulation versus the bleeding risk of the procedure/operation and individual patient comorbidities that may increase bleeding risk.
- Some procedures do not require interruption of anticoagulation e.g. Cataract surgery; Dental procedures; Cardiac procedures – cardiac implantable devices, catheter ablation.
- The table below highlights patients at high risk of thromboembolic events and should be offered bridging with heparin pre and post operatively to minimise the time off anticoagulation as detailed in schedule 1.
- The low risk group should not be offered pre- operative bridging with heparin as the risk of perioperative bleeding generally outweighs the small risk of thromboembolic events without anticoagulation.
- There will be a group of patients who neither fall into the high or low risk categories detailed below. e.g. Atrial fibrillation with CHADS₂ 3/4. (Appendix 6).
- Recent evidence from the BRIDGE study suggests that patients in this category who
 were bridged preoperatively have a higher risk of postoperative bleeding with similar
 risks of thromboembolic events as those that were not bridged. Therefore in general
 these patients should not have preoperative bridging. However decisions should
 be made on a case by case basis.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

3.16.3.1 Table 1 -Risk stratification for perioperative thromboembolism

Risk Category	MHV	Atrial Fibrillation	VTE
High	Any mitral valve prosthesis	CHADS ₂ score of 5 or 6	Recent (<3months) VTE Or previous VTE during interruption of anticoagulation
	Aortic valve and any additional stroke risk factors	Recent (<3months) stroke / TIA	Severe / multiple thrombophilias e.g. Deficiency of protein C, Protein S or antithrombin; antiphospholipid antibodies; multiple abnormalities.
		Rheumatic Valvular heart disease	
		1	<u> </u>
Low	Bileaflet AVR without major	CHADS ₂ score of 0-2	VTE > 12 months

Low	Bileaflet AVR without major risk factors for stroke	(and no prior stroke	ago & no other risk
		or TIA)	factors

^{*}TIA indicates transient ischemic attack; AVR, aortic valve replacement; ATE, arterial thromboembolism; VTE, venous thromboembolism; and MHV, mechanical heart valve. **See appendix 6 for CHADS₂ score**

3.16.3.2 Schedule 1 – High risk bridging protocol

Day	Intervention
-6	Check INR
-5	Stop warfarin
-3	Start LMWH at therapeutic dose
-1	Last pre -procedural dose of LMWH administered no less than 24 h before procedure
	Check INR (consider Vitamin K if not in range)
Day of procedural Intervention	Check INR

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

Day	Intervention
0 or +1	Resume maintenance dose of warfarin on evening after procedure Consider prophylactic doses of LMWH if adequate haemostasis.
Post-procedural Intervention	
+1	
	Continue prophylactic dose if high risk of bleeding
	Consider treatment dose LMWH administration if low risk of bleeding;
	Resume warfarin therapy
+2 or +3	
	Restart LMWH at treatment dose
+4	
	INR testing (discontinue LMWH if INR > 2)

3.16.3.3 Schedule 2 - Low risk Bridging protocol

Day	Intervention
-6	Check INR
-5	Stop Warfarin
-1	Check INR – (consider vitamin K if not in range)
Day of procedural intervention	Check INR
0 or +1	Resume maintenance dose of warfarin on evening of or morning after procedure. Consider prophylactic doses of LMWH if adequate haemostasis.
Post-procedural intervention	
+1	Restart LMWH at prophylactic dose; resume warfarin therapy
+4	INR testing (discontinue LMWH if INR > 2)

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

4 ATTACHMENTS		
Appendix Number	Title	
1	Warfarin Counselling Form – Sample do not print. Obtain from	
	stores.	
2	Oral vitamin K	
3	PCC checklist	
4	Octaplex® Mix2vial™ Instructions for reconstitution	
5	Abbreviated Prescribing Information octaplex	
6	CHADS score	
7	Equality Impact Assessment Tool	

	5 PROCEDURAL DOCUMENT STORAGE (HARD AND ELECTRONIC COPIES)
Γ	Electronic Database for Procedural Documents
Γ	Held by Procedural Document and Leaflet Coordinator

6 LOCATIONS THIS DOCUMENT ISSUED TO			
Copy No	Copy No Location Date Issued		
1	Intranet	21/04/2016	
2	Wards, Departments and Service	21/04/2016	

7 OTHER RELEVANT / ASSOCIATED DOCUMENTS			
Unique Identifier	Title and web links from the document library		
CORP/PROT/008	Administration Of Intravenous Heparin For The Treatment Of		
	Venous Thrombo-Embolic Disease		
	http://fcsharepoint/trustdocuments/Documents/CORP-PROT-		
	008.docx		
CORP/PROC/301	Prescribing - A Zero Tolerance Approach To Safe Prescribing		
	http://fcsharepoint/trustdocuments/Documents/CORP-PROC-		
	301.docx		

8 SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS

References In Full

NHS National Patient Safety Agency. (March 2007). Actions that can make anticoagulant therapy safer: Alert and other information, NPSA/2007/18. Available:

http://www.nrls.npsa.nhs.uk/resources/?entryid45=59814 . Last accessed 23/05/2016.

National Patient Safety Agency Rapid Response Report 14. Reducing Treatment Dose Errors with Low Molecular Weight Heparins, July 2010. Available at www.npsa.nhs.uk

National Patient Safety Rapid Response Report- 18 Loading Dose Errors November 2010. Available at www.npsa.nhs.uk

4th Edition version in British Journal of Haematology (2011). <u>BCSH Oral Warfarin</u> <u>Guidelines 2011</u>

Safe Introduction of warfarin for thrombotic prophylaxis in atrial fibrillation requiring only a weekly INR. S.Janes et al. Clin. Lab. Haem. 2004, 26, 43-47.

A comparison of a low-dose warfarin induction regimen with the modified Fennerty regimen in elderly inpatients. J.Gedge et al. Age and Ageing 2000; 29: 31-34

Perioperative Management of Antithrombotic Therapy. Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. J. Douketis et al, Chest. 2012 Feb; 141

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

8 SUPPORTING REFERENCES / EVIDENCE BASED DOCUMENTS

References In Full

How I treat anticoagulated patients undergoing an elective procedure or surgery - Alex C. Spyropoulos, James D. Douketis – Blood 2012

9 CONSULTATION / ACKNOWLEDGEMENTS WITH STAFF, PEERS, PATIENTS AND THE PUBLIC

AND THE TODEIO		
Name	Designation	Date Response
		Received
Dr Cahalin	Consultant Haematologist	16/7/2015
Dr Macheta	Consultant Haematologist	13/10/2015
Dr Grey	Consultant Haematologist	16/7/2015
Dr Paracha	Consultant Respiratory Physician &	16/7/2015
	Thrombosis Lead Consultant	
Lisa Jones	ADAS Anticoagulation Manager	4/8/2015

10 DEFINITIONS / GL	OSSARY OF TERMS	
ACS	Acute Coronary Syndrome	
ADAS	Anticoagulant Dosing Advisory Service	
AF	Atrial Fibrillation	
APTT	Activated Partial Thromboplastin Time	
ATE	Arterial thromboembolism	
BCSH	British Committee for Standards in Haematology	
BNF	British National Formulary	
CVD	Cardiovascular disease	
DVT	Deep Vein Thrombosis	
FBC	Full Blood Count	
FFP	fresh frozen plasma	
GI	Gastro Intestinal	
HIT	heparin induced thrombocytopenia	
INR	International Normalised Ratio	
IV	Intravenous	
LFT's	Liver Function Tests	
LMWH	Low Molecular Weight Heparin	
MHV	Mechanical Heart Valve	
MI	Myocardial infarction	
PCC	prothrombin complex concentrate	
PCI	Percutaneous Coronary Intervention	
PE	Pulmonary Embolism	
TIA	Transient Ischaemic Attack	
TRALI	transfusion-related acute lung injury	
VTE	Venous Thromboembolism	

11 AUTHOR / DIVISIONAL / DIRECTORATE MANAGER APPROVAL			
Issued By	Dr Seye Kolade	Checked By	Jennifer King
Job Title	Consultant	Job Title	Specialist
	Haematologist		Pharmacist
Date	30th March 2016	Date	31st March 2016

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 1: WARFARIN COUNSELLING RECORD – OBTAIN VS458 FROM GENERAL STORES

FILE IN SECTION 3

Blackpool Teaching Hospitals NHS Foundation Trust

WARFARIN COUNSELLING RECORD

Abbreviations used in this document to be listed here with the full description:

OTC medicines: - Over the Counter medicines

Patient's Signature:

Write	patient	detai	ils oı	affix
le	dentifica	ation	labe	Ĭ

Date:

VS458

Hospital Number:

Name: Address:

Date of Birth: NHS Number:

This patient has been given verbal and written information on warfarin therapy, by a Doctor, Pharmacist or Nurse in accordance with the guidance overleaf.

The anticoagulant book MUST be fully completed prior to discharge including information regarding recent inpatient dosing, discharge dose and follow-up appointment details.

	Counselling point	Signature	Comments
	The use of the Oral Anticoagulant Therapy Record book.		
	Standard dispensing labels (i.e. 'take as directed')		
	Basic mode of action of warfarin		
Ĺ	Indication for therapy		75 N/
ě	Expected duration of therapy		Specify duration if known
	Tablet identification – colour of the different tablet strengths		
7	Dose: Varied dosing Time of day to take warfarin How to use the different tablet strengths to make up intended dose Action to take if dose missed; NOT to take extra doses		
3	Compliance and ways of remembering to take the tablets e.g. using a calendar		
)	Monitoring: Target INR Outpatient monitoring clinics (importance of attendance)		
)	Acute illness		
1	Side effects of warfarin and poor control of anticoagulation (and what to do if experienced) • Signs/symptoms of excess anticoagulation: bleeding or bruising • Recurrence of thromboembolism		
2	Potential for drug interactions: aspirin, ibuprofen (paracetamol is the preferred analgesic), antibiotics, herbal remedies, glucosamine and other supplements, OTC medicines, alternative therapies. Seek advice.		
3	Diet (vitamin K containing foods, importance of avoiding major fluctuations in dietary intake; cranberry juice/capsule interaction)		
4	Alcohol intake		
5	Contraception, pregnancy, and hormone replacement therapy (if relevant)		
5	Surgical procedures (inc. day surgery /dental treatment) & hospital admission)		
1	Hobbies and leisure activities (including flying)		
1	Injections (including immunisation)		
)	How to obtain further supplies of warfarin		
)	Who to contact for advice/ further information		

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

Approved by the Health Records Committee 23/6/08

APPENDIX 1: WARFARIN COUNSELLING RECORD - OBTAIN VS458 FROM **GENERAL STORES**

Warfarin Counselling Guidelines

- Use of the Anticoagulant Therapy Record book (yellow book). Go through the yellow book with them. Tell them that it is the
 only record of dosing information available for the patient, since (2) the dispensing labels on the warfarin boxes will be labelled as 'Take as directed in the Anticoagulant Book". Therefore it is important to keep it up to date at all times and to understand the dosing instructions. Explain to the patient that they will receive an additional wallet containing more information and an Alert Card when they go for their first clinic appointment with the Anticoagulant Dosing & Advisory
- See above
 Basic mode of action of warfarin 'thins the blood' or 'reduces the bloods ability to form clots'
- Indication for therapy explain why the patient is taking warfarin. Common examples and patient explanations include:
 DVT/PE 'to prevent clot getting bigger or returning'
 AF 'when the heart is not beating regularly, the blood will not flow smoothly. Therefore, there is a risk of getting a clot, which may float through the body and cause damage e.g. stroke'

 - Pre & post DC cardioversion for AF Heart valves 'there is a risk of getting clots around the valve, which may float through the body and cause damage; also to prevent valve damage
 - Some cancer patients who are receiving thalidomide in combination with chemotherapy and dexamethasone 'to reduce the risk of getting a clot which is sometimes associated with this group of patients'.
- Expected duration of therapy (if known) if unsure, check with Doctor. Do not assume or guess.
 DVT/PE may be a short course (3-6 months) or lifelong if recurrent

 - AF/ heart valves treatment will be lifelong
 - $DC\ cardioversion-e.g.\ at\ least\ 4\ weeks\ before\ and\ 4\ weeks\ after,\ the\ latter\ depending\ on\ success\ of\ DC\ cardioversion$
 - Cancer patients receiving thalidomide in combination with chemotherapy and dexamethasone until end of treatment
- Tablet identification
 - Explain colour of the different tablet strengths and that they will always be the same colour for each strength even if the
 supplier is different. White 500microgram(0.5mg)/ Brown 1mg tablets / Blue 3mg tablets / Pink 5mg tablets. It is unusual to
- 7. Dose
 - Varied dosing according to blood result / INR
 - Warfarin should be taken at same time of day every day (which is often around teatime / 6-7pm). If patient decides to take it in the morning, tell patient to inform hospital staff if (s)he is ever admitted, to reduce the risk of getting a double dose (since many hospitals prescribe in-patient warfarin at 6pm).

 - How to use the different tablets strengths to make up the dose intended If a dose is missed, OK to take on the same day within 6 hours of when dose was due. NEVER double up on a dose but carry on as normal on next day if dose is missed. Make a note of the date the dose was missed in the yellow book and let
- anticoagulant clinic/doctor know. If unsure, then it is better to miss the dose rather than risk taking a double dose Compliance and ways of remembering to take the tablets e.g. using a calendar to mark off whether a dose has been taken
- - INR is monitored regularly initially (every few days) and gradually less often once dose and INR settles (monthly to 12 weekly)
 - Outpatient monitoring clinics (and importance of attendance)
- 10. Any Change in Medical Condition Inform treating Doctor (e.g. GP) of acute illness, as more regular INR check may become
- 11. Side effects of warfarin and poor control of anticoagulation (and what to do if experienced)

 - Recurrence of thromboembolism: contact doctor if original symptoms recur Signs/symptoms of excess dosing: severe bleeding or multiple bruising with or without high INR is the most common side
 - effect: contact doctor immediately if unusual or severe
 Contact clinic/ GP/ hospital if these occur: bloody stools or urine, nose bleeds (if lasting for > 5mins or if pt does not usually suffer from nose bleeds), blood shot eye, coughing or vomiting blood, excessive vaginal bleeding, cuts that take longer
- than 5 minutes to stop bleeding. Bleeding from gums (use a soft toothbrush)

 Any other side-effects: discuss with GP or anticoagulant clinic

 12. Potential for drug interactions: may be affected by many medicines, therefore:

 - Patient should always let doctor/dentist/pharmacist know that s/he on warfarin.

 Not to take aspirin unless prescribed by doctor. Care with OTC painkillers (e.g. ibuprofen/aspirin). Paracetamol is preferred Caution with antibiotics and always check with pharmacist/anticoagulant clinic before taking herbal remedies.
- Inform anticoagulant clinic of any drugs stopped, started or if doses are changed.
 Diet: some foods contain high levels of vitamin K which may interfere with warfarin action (e.g. broccoli, brussel sprouts, cauliflower, cabbage, chickpeas, kale, spinach, turnip greens, liver). Patients may have these foods in moderation, but important to avoid major changes in regular diet or crash diets. Report any major changes in diet to anticoagulant clinic. Cranberry juice may raise INR – avoid or limit intake of cranberry juice whilst on warfarin.

 14. Alcohol intake: check patient's current alcohol intake and baseline LFTs/clotting. If patient a heavy drinker (known alcoholic,
- or drinks > recommended units/wk), discuss with Dr re plan for alcohol reduction and also warfarin implications/suitability. Ideally, keep intake to a minimum. Small to moderate amounts (e.g. 1 glass of wine / ½ pint beer/lager per night or 2-3 x per
- week) shouldn't affect warfarin control in otherwise healthy individuals with no liver problems. Avoid binge drinking.

 15. Contraception, pregnancy, and hormone replacement therapy (if relevant): this will be discussed in detail in the anticoagulant clinic according to separate guidance. Check that there is no possibility of the patient being pregnant at the time of starting warfarin therapy and that she understands the importance of effective contraception. Pregnancy should be planned following discussion with anticoagulant clinic/ GP.
- 16. Surgical procedures (inc. dental treatment) and hospital admission; patient must inform Doctor/dentist that s/he is on
- Hobbies and leisure activities (including flying): avoid contact sports (e.g. boxing) and other higher risk sports (e.g. skiing and horse riding), as increased risk of bruising/bleeding. Inform Dr/anticoagulant clinic if flying in the near future.
- Injections (including immunisations): patient must inform GP/ practice nurse that s/he is on warfarin.
 Further supplies of warfarin are obtained from your GP. The GP and Chemist will ask to see the yellow book before they can prescribe and dispense. Make sure never to run out of warfarin tablets, especially when on holidays
- Further advice/information from anticoagulant clinic on (01253)306719, GP, pharmacy medicines information dept, or in an emergency A&E dept.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147	
Revision No: 2	Next Review Date: 01/03/2019 Title: Warfarin		
Do you have the up to date version? See the intranet for the latest version			

APPENDIX 1: WARFARIN COUNSELLING RECORD – OBTAIN VS458 FROM GENERAL STORES

(to be filed in medical records)

This patient has been given verbal and written information on warfarin therapy, by a Doctor, Pharmacist or Nurse in accordance with the guidance overleaf.

The anticoagulant book MUST be fully completed prior to discharge including information regarding recent inpatient dosing, discharge dose and follow-up appointment details.

For in-patients, it is the responsibility of the discharging doctor to ensure that this occurs

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 2: ORAL VITAMIN K

- The smallest available tablet of vitamin K is 10mg. Therefore to give 1-2mg, need to use liquid vitamin K. The formulation in this Trust is Konakion MM Paediatric 2mg in 0.2ml
- To administer, open the vial. Using a syringe, draw up 0.1ml if need 1mg, or draw up the whole vial contents i.e. 0.2ml if need 2mg.
- Give orally with a glass of water.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147	
Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version			

APPENDIX 3: PCC CHECKLIST			
Name of requester			
Bleep NumberGrade			
Name of Registrar / Consultant authorising F	PCC use		
Name of laboratory scientist issuing the PCC	D:		
Dose of PCC issued			
Signature	Time		

APPENDIX 4: OCTAPLEX MIX2VIAL INSTRUCTIONS FOR RECONSTITUTION bate of preparation: October 2010. octaplex® Mix2Vial" Instructions for reconstitution package. not remove the package. Do Mix2Vial™ top of the Remove the device from the The reconstitution guidelines above have been adapted from octaplex* Summary of product characteristics and reconstitution direction from Mix2Vial** of West Pharmaceutical Services. Follow the hospital's aseptic procedures at all times. Working on a clean flat surface, remove the vials from the outer Step 1 packaging and remove the flip top lids. Disinfect the vial injection sites with an alcohol swab DEC 307 end of the the blister pack water vial, using the stopper and spike penetrates down until the as a holder, Push device on the Seat the blue the device snaps Step 2 (500 IU coagulation factor IX per vial, powder and solvent for infusion, Human Prothrombin Complex) and discard it. to touch the plastic package exposed end of Take care not the device. Remove the Step 3 , pushing down stopper and the octaplex® vial, and insert the vial upside down dear end into until the spike device snaps in penetrates the the powdered Turn the water Step 4 octaplex^o vial. is thoroughly automatically vial to make sure Gently swirl the flow into the the octaplex® The water wil Step 5 to the octaplex® water vial by Remove the Attach a syringe dockwise. turning it anti-Step 6 octaplex* vial octaplex* is turning the dockwise. syringe by Remove the solution into the withdraw the upside down and Turn the now ready for barrel counter syringe. administration **octa**pharma Step 7

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	Next Review Date: 01/03/2019 Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 5: ABBREVIATED PRESCRIBING INFORMATION OCTAPLEX

excluded - record patient name and product batch number. Appropriate vaccination (hepatitis A and B) is recommended for patients in regular/repeated on INR before treatment and target INR. Prothrombin complex factor correction persists for approximately 6 - 8 hours. Guidance for initial dosage for K dependent coagulation factors II and X when purified specific coagulation factor product is not available. Dosage and Method of Administration M2 1AB. United Kingdom. Date of Preparation: September 2013 OPX/13/1 Further information is available from the Marketing Authorisation Holder: Octapharma Limited, The Zenith Building, 26 Spring Gardens, Manchester, Authorisation Numbers: PL 10673/0027 (UK); PA 521/13/1 (ROI) Package Quantities and Basic NHS Cost: Vial containing 500 IU Factor IX: £245 (UK sudden allergy induced thrombocytopenia may occur. For further information on side effects please refer to SmPC. Legal category: POM Marketing may occur rarely. Replacement therapy may rarely lead to inhibitor formation manifesting as poor clinical response. octaplex® contains heparin therefore be taken into consideration in patients on controlled sodium diet. Only use in pregnancy and lactation if clearly indicated. Undesirable Effects: Risk of peri- or post-operative patients, to neonates, and to patients at risk of thrombosis or DIC. octaplex® contains 75 - 125 mg sodium per vial and this should patients receiving vitamin K antagonists. Repeated dosing in patients with congenital or acquired bleeding defect is associated with a risk of thrombosis or sought. Stop infusion if allergic or anaphylactic reactions occur. Despite measures to prevent infection, possibility of infective transmission cannot be totally induced thrombocytopenia. Special Warnings and Precautions: The advice of a specialist experienced in management of coagulation disorders should be Start infusion rate at 1 ml/min followed by 2 - 3 ml/min. Contraindications: Hypersensitivity to active substance, excipients or heparin. History of heparin congenital deficiency: 1 IU/kg body weight raises the activity of factor II by 0.02 IU/ml and factor X by 0.017 IU/ml. For intravenous administration only (prothrombin time, INR) are needed for dosing. Guidance for bleeding and bleeding prophylaxis during vitamin K antagonist treatment: Dose will depend patient's clinical condition. Regular determination of either individual plasma levels of coagulation factors or global tests of prothrombin complex levels substitution therapy depends on the severity of the coagulation disorder, location and extent of bleeding, half-life of the different coagulation factors and deficiency of prothrombin complex coagulation factors when rapid correction of the deficiency is required and 2) congenital deficiency of the vitamin total protein (260 - 820mg). FIX specific activity ≥ 0.6 IU/mg proteins. Indications: Treatment and perioperative prophylaxis of bleeding in 1) acquired contains coagulation factors II (280 - 760 IU), VII (180 - 480 IU), IX (500 IU) and X (360 - 600 IU), Protein C (260 - 620 IU), Protein S (240 - 640 IU) and Please refer to the Summary of Product Characteristics (SmPC) before prescribing. Presentation: Powder and solvent for solution for infusion. Each vial thromboembolic episodes. Headache, transient rise in liver transaminases, allergic or anaphylactic - type reactions including increase in body temperature disseminated intravascular coagulation (DIC). Closely monitor when administering to patients with a history of coronary heart disease or liver disease, to receipt of human plasma derived prothrombin complex products. Infusion of prothrombin complex may exacerbate underlying hypercoagulable state in Treatment should be initiated under the supervision of a physician experienced in the treatment of coagulation disorders. The dosage and duration of Abbreviated Prescribing Information octaplex® (500 IU coagulation factor IX per vial, powder and solvent for infusion, Human Prothrombin Complex

Adverse events should also be reported to Octapharma on +44 (0)1748 828855 Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or www.imb.ie.

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	No: 2 Next Review Date: 01/03/2019 Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 6: CHADS 2 SCORE

Score	CHADS ₂ Risk Criteria
1 point	Congestive heart failure
1 point	Hypertension
1 point	Age >75 years
1 point	Diabetes mellitus
2 points	Stroke / transient ischemic attack

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2	n No: 2 Next Review Date: 01/03/2019 Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 7: EQUALITY IMPACT ASSESSMENT FORM

 Department
 Organisation Wide
 Service or Policy
 Procedure
 Date Completed:
 March 2016

GROUPS TO BE CONSIDERED

Deprived communities, homeless, substance misusers, people who have a disability, learning disability, older people, children and families, young people, Lesbian Gay Bi-sexual or Transgender, minority ethnic communities, Gypsy/Roma/Travellers, women/men, parents, carers, staff, wider community, offenders.

EQUALITY PROTECTED CHARACTERISTICS TO BE CONSIDERED

Age, gender, disability, race, sexual orientation, gender identity (or reassignment), religion and belief, carers, Human Rights and social economic / deprivation.

question.	RESPONSE		IMPACT	
45-5.15.1	Issue	Action	Positive	Negative
What is the service, leaflet or policy development? What are its aims, who are the target audience?	The Procedural Document is to ensure that all members of staff have clear guidance on processes to be followed. The target audience is all staff across the Organisation who undertakes this process.	Raise awareness of the Organisations format and processes involved in relation to the procedural document.	Yes – Clear processes identified	
Does the service, leaflet or policy/ development impact on community safety Crime Community cohesion	Not applicable to community safety or crime	N/A	N/A	
Is there any evidence that groups who should benefit do not? i.e. equal opportunity monitoring of service users and/or staff. If none/insufficient local or national data available consider what information you need.	No	N/A	N/A	
Does the service, leaflet or development/ policy have a negative impact on any geographical or sub group of the population?	No	N/A	N/A	
How does the service, leaflet or policy/ development promote equality and diversity?	Ensures a cohesive approach across the Organisation in relation to the procedural document.			
Does the service, leaflet or policy/ development explicitly include a commitment to equality and diversity and meeting needs? How does it demonstrate its impact?	The Procedure includes a completed EA which provides the opportunity to highlight any potential for a negative / adverse impact.			
Does the Organisation or service workforce reflect the local population? Do we employ people from disadvantaged groups	Our workforce is reflective of the local population.			
Will the service, leaflet or policy/ development i. Improve economic social conditions in deprived areas ii. Use brown field sites iii. Improve public spaces including creation of green spaces?	N/A			
Does the service, leaflet or policy/ development promote equity of lifelong learning?	N/A			
Does the service, leaflet or policy/ development encourage healthy lifestyles and reduce risks to health?	N/A			
Does the service, leaflet or policy/ development impact on transport? What are the implications of this?	N/A			
Does the service, leaflet or policy/development impact on housing, housing needs, homelessness, or a person's ability to remain at home?	N/A			
Are there any groups for whom this policy/ service/leaflet would have an impact? Is it an adverse/negative impact? Does it or could it (or is the perception that it could exclude disadvantaged or marginalised groups?	N/A			

Blackpool Teaching Hospitals NHS Foundation Trust		ID No. CORP/GUID/147
Revision No: 2 Next Review Date: 01/03/2019		Title: Warfarin
Do you have the up to date version? See the intranet for the latest version		

APPENDIX 7: EQUALITY IMPACT ASSESSMENT FORM						
Does the policy/development promote access to services and facilities for any group in particular?						
Does the service, leaflet or policy/development impact on the environment	N/A					
During development						
At implementation?						
ACTION:						
Please identify if you are now required to carry out a Full Equality Analysis			•			
Name of Author: Signature of Author:	Dr Seye Kolade	Dat	e Signed:	30 th March 2016		
Name of Lead Person:		Dat	e Signed:			
Signature of Lead Person:						
Name of Manager:		Dat	e Signed:			
Signature of Manager						

Blackpool Teaching Hospitals NHS Foundation Trust		pitals NHS Foundation Trust	ID No. CORP/GUID/147	
	Revision No: 2	Next Review Date: 01/03/2019	Title: Warfarin	
Do you have the up to date version? See the intranet for the latest version				