

An Organisation-Wide Clinical Guideline for the initiation of oral anticoagulants

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Equality statement

This document demonstrates commitment to create a positive culture of respect for all individuals, including staff, patients, their families and carers as well as community partners. The intention is, as required by the Equality Act 2010, to identify, remove or minimise discriminatory practice in the nine named protected characteristics of age, disability, sex, gender reassignment, pregnancy and maternity, race, sexual orientation, religion or belief, and marriage and civil partnership. It is also intended to use the Human Rights Act 1998 to promote positive practice and value the diversity of all individuals and communities. This document is available in different languages and formats upon request to the Trust Procedural Documents Coordinator and the Equality and Diversity Lead.

Please do not delete the Equality Statement. It's presence in your Guideline helps the Trust to demonstrate its Equality Obligations.

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When completing the Contents Page, please:

- 1) Provide your main guideline content in chapter 1. Give this chapter a relevant title.
- 2) List any subsections on the contents page (do not use more than one decimal point).
- 3) As required, add extra lines for additional subsections to chapter 1
- 4) Add page numbers to the final draft
- 5) Delete this explanatory text box.

How to add extra lines to the Contents Page (chapter 3 only):

- 1) Position the cursor to the left of the table
- 2) Left-click the mouse to highlight a line in the table
- 3) Right-click the mouse and choose 'insert rows'
- 4) A new row will be inserted above the line that you highlighted
- 5) To delete a row that you have created, repeat steps 1 to 3 above and choose 'delete rows'*.

*Please only add or delete rows within chapter 1 – all other chapters in the template are

1 Clinical Guideline for the initiation of oral anticoagulants

1.1 Introduction

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm. The risks are greatest in the initial period of anticoagulation. Managing the risks associated with anticoagulation can reduce untoward events and increase the safety of patients. The NPSA Patient Safety Alert 18 (March 2007) identifies areas where improved competencies and documentation can help to ensure safe practice. Whilst warfarin has existed for many years, more recently novel oral anticoagulants such as rivaroxaban, dabigatran and apixaban have been licensed for the management of non-valvular atrial fibrillation and acute as well as extended management of VTE

1.2 Pre-prescription instructions

Before starting oral anticoagulant therapy, review the indication for anticoagulation together with any contra-indications, including co-morbidities, potential drug interactions and likely patient compliance (e.g. can patient understand, have physical ability and willingness to comply with taking warfarin and the necessary blood monitoring). Check baseline INR, FBC and LFTs. If abnormal, discuss with the haematology consultant before starting (see appendix 1 for further information).

If there are relative contra-indications or potential drug interactions, discuss with the Consultant in charge of patient

Document in patient's notes:

- Drug name
- Dosage regime (see appendix 3)
- Indication for oral anticoagulation therapy (see appendix 4)
- Target INR (see appendix 4)
- Planned duration of treatment and review criteria, if applicable (see appendix 5)
- Monitoring plan:

1.3 Initiating warfarin

- Give patient verbal and written information (yellow book) concerning their warfarin therapy.
- Prescribe initial dose(s) of warfarin on the relevant page of the inpatient medication chart according to dosage regime (see appendix 3). Write legibly in block capitals stating the dose and indicate when the INR is to be checked.
- Please note that warfarin is the usual first line vitamin K antagonist (coumarin) anticoagulant used. Alternatives may be necessary in rare cases of warfarin allergy/ intolerance. All such cases must be discussed with the haematology consultant.

- Write subsequent doses on the inpatient medication chart in the light of the INR results, response to treatment and any changes in the patient's clinical state or other drug therapy (see appendix 3)

1.4 Planning for discharge/ transfer of care of patients on warfarin

- Check the INR the day before or on the morning of discharge
- Inform the Anticoagulation Team of planned discharge
- Complete referral form & send to laboratory (if patient to be followed by SaSH anticoagulation clinic)
- Communicate with GP surgery regarding OAT and follow up (if patient to be monitored via GP). If patient is too immobile to attend hospital or GP surgery for a blood test, the GP surgery must be informed that they need to arrange a District Nurse to take blood sample.
- Ensure patient understands their therapy, has yellow book (fully completed) and is aware of follow up arrangements
- Ensure the electronic discharge letter has the following information:
 - Latest INR result
 - Dose of anticoagulant to be taken until next INR test done
 - Date of next INR test

1.5 Initiation of novel oral anticoagulant drugs

NOACS have been licensed for treatment of DVT and PE and prevention of VTE recurrence (rivaroxaban) as well as long treatment of non-valvular AF.

When compared to standard of care NOACs have several distinct advantages. They have a predictable response to fixed doses; therefore, do not require frequent dose adjustments or routine monitoring. There are reduced food and drug interactions. They also represent a single-drug approach to management and do not require any overlap with parenteral anticoagulation.

However, in deciding whether a NOAC is appropriate for your patient a number of considerations should be taken into account and discussed with the patient

1. Renal impairment (see specific drug below)
2. Compliance (the importance and reason of taking these medications needs to be clear to the patient as well as the risk of missing doses)
3. No specific antidote available if severe bleeding

Prior to starting NOACs renal function and liver function must be checked. Patients should be reviewed at 3 months by an expert in initiating anticoagulation to ensure compliance to medication. Renal function and liver function should also be checked at this stage too and a decision on whether to stop anticoagulation or continue needs to be made

Ongoing compliance and renal function should then be done on at least an annual basis or sooner (i.e. every 3 months) if patients clinical state changes or patients have reduced eGFR

1.6 Initiating Rivaroxaban

Prevention of stroke and systemic embolism in patients with non-valvular AF

The recommended dose is 20 mg once daily, which is also the recommended maximum dose.

Therapy with rivaroxaban should be continued long term provided the benefit of prevention of stroke and systemic embolism outweighs the risk of bleeding

If a dose is missed the patient should take rivaroxaban immediately and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.

Treatment of DVT, treatment of PE and prevention of recurrent DVT and PE

The recommended dose for the initial treatment of acute DVT or PE is 15 mg twice daily for the first three weeks followed by 20 mg once daily for the continued treatment and prevention of recurrent DVT and PE, as indicated in the table below.

	Dosing schedule	Maximum daily dose
Day 1-21	15 mg twice daily	30 mg
Day 22 and onwards	20 mg once daily	20 mg

Missed doses

If a dose is missed during the 15 mg twice daily treatment phase (day 1 - 21), the patient should take rivaroxaban immediately to ensure intake of 30 mg rivaroxaban per day. In this case two 15 mg tablets may be taken at once. The patient should continue with the regular 15 mg twice daily intake as recommended on the following day.

If a dose is missed during the once daily treatment phase (day 22 and onwards), the patient should take rivaroxaban immediately, and continue on the following day with the once daily intake as recommended. The dose should not be doubled within the same day to make up for a missed dose.

Renal impairment

If creatinine clearance 15-29 ml/min, rivaroxaban should be used with caution.
If creatinine clearance <15 ml/min, rivaroxaban is not recommended.

1.7 Initiating Dabigatran

Prevention of stroke and systemic embolism in patients with non-valvular AF

The recommended daily dose of dabigatran is 300mg taken as one 150mg capsule twice daily. Therapy should be continued long term.

For the following two groups the recommended daily dose of dabigatran is 220mg taken as one 110mg capsule twice daily:

- Patients aged 80 years or above
- Patients who receive concomitant verapamil

For the following groups, the daily dose of dabigatran of 300 mg or 220 mg should be selected based on an individual assessment of the thromboembolic risk and the risk of bleeding:

- Patients between 75-80 years
- Patients with moderate renal impairment
- Patients with gastritis, oesophagitis or gastro-oesophageal reflux
- Other patients at increased risk of bleeding

Missed doses

A forgotten dabigatran dose may still be taken up to 6 hours prior to the next scheduled dose. From 6 hours prior to the next scheduled dose on, the missed dose should be omitted.

Renal Impairment

Dabigatran is not recommended in patients with severe renal impairment (creatinine clearance < 30 ml/min)

1.8 Initiating Apixaban

Prevention of stroke and systemic embolism in patients with non-valvular AF

The recommended dose of apixaban is 5 mg taken orally twice daily.

Dose reduction

The recommended dose of apixaban is 2.5 mg taken orally twice daily in patients with NVAf and at least two of the following characteristics: age \geq 80 years, body weight \leq 60 kg, or serum creatinine \geq 133 micromol/l.

Therapy should be continued long term.

Missed Dose

If a dose is missed, the patient should take apixaban immediately and then continue with twice daily intake as before

Renal impairment

No dose adjustment is necessary in patients with mild or moderate renal impairment

Patients with serum creatinine >133 mmol/l and associated with age ≥ 80 years or body weight ≤ 60 kg should receive the lower dose of apixaban 2.5 mg twice daily.

Patients with exclusive criteria of severe renal impairment (creatinine clearance 15-29 ml/min) should also receive the lower dose of apixaban 2.5 mg twice daily.

Patients with creatinine clearance <15 ml/min apixaban is not recommended

1.9 Discharging patients on novel oral anticoagulant drugs

Ensure patient is aware of indication for rivaroxaban, and implications of missed doses and when a follow up appointment is arranged. They also need to know where to seek medical advice if any complications

Follow up should be arranged at the time of discharge with the consultant responsible for the patient. The patient needs to know where to get any follow up prescriptions or advice i.e GP if a Surrey patient or Comet Ward if West Sussex.

2 Rationale

The aim of this guideline is to standardise the management of patients commenced on oral anticoagulation for both rapid and slow induction indications.

3 Scope

This guideline is designed for all doctors involved in the care of patients that need to be commenced on oral anticoagulation. It should be read prior to commencing oral anticoagulation.

4 Responsibilities

Junior doctors- Responsible for prescribing oral anticoagulation on inpatient prescription charts and ensuring that follow up arrangements have been made.

Consultant Haematologist- They have expertise in giving advice on bleeding and thrombotic conditions and giving advice on oral anticoagulation

Consultant in charge of patient- Responsible for ensuring that patient is follow up in a time appropriate way

Pharmacists. Responsible in ensuring those potential drug interactions that may impact on oral anticoagulation are identified and that patient is prescribed appropriate anticoagulation as per discharge documentation

Nurses: Responsible for ensuring that patient take medications as per prescription chart

5 Compliance monitoring arrangements

Monitoring policy implementation

Monitoring will in done in accordance with the NPSA 18 documentation and will be performed every 3 years. This will be monitored as part of the haematology governance meeting

6 Training to ensure compliance with this guideline

Junior doctor teaching- Patient Safety: Oral anticoagulation and how to use it safely

8 Glossary explanation of terms used in this document

Acronym/ Abbreviation/ Term	Meaning
NPSA	National Patient Safety Agency
INR	International Normal Ratio
FBC	Full Blood Count
LFT	Liver Function Tests
OAT	Oral Anticoagulant Therapy
NOACs	Novel Oral AntiCoagulants
DVT	Deep Vein Thrombosis
PE	Pulmonary Embolism
AF	Atrial Fibrillation
eGFR	estimated Glomerular Filtration Rate
NVAf	Non-Valvular Atrial Fibrillation
SPC	Summary of Product Characteristics
LMWH	Low Molecular Weight Heparin

9 Document Control

This procedural document supports:

Standard(s)/ Key Lines of Enquiry:	Para/ I.D. no.	Standard/title
NHS Litigation Authority (NHSLA)		
Care Quality Commission (CQC)		
NICE Guideline		
Other national guidance (e.g. Royal College Guidance) - please list:		

Consultation record

Relevant service	Speciality, Sponsor or User Group name	Individual's name	Job title	Date consulted	Date feedback received
Pharmacy		Ana Armstrong	Lead medical pharmacist	July 2014	
Radiology	N/A				
Cancer Services	N/A				
Medicine	Acute Medicine	Dr B Mearns	AMU consultant	May 2014	

9 Document Control (continued)

Change History

Version	Date (DD/MM/YYYY)	Author/ Lead	Job title	Details of Change	Ratification body	Archiving location

When revising an existing document update the 'Change History' box accordingly (add details of all known previous versions).

Appendices

Appendix 1 Equality Analysis (EqA)

By completing this document in full you will have gathered evidence to ensure, documentation, service design, delivery and organisational decisions have due regard for the Equality Act 2010. This will also provide evidence to support the Public Sector Equality Duty.

Name of the policy / function / service development being assessed		
Date last reviewed or created & version number		
Briefly describe its aims and objectives:		
Directorate lead		
Target audience (including staff or patients affected)		
Screening completed by (please include everyone's name)	Organisation	Date

Clinical Guideline Title

Equality Group (Or protected characteristic):	What evidence has been used for this assessment?	What engagement and consultation has been used	Identify positive and negative impacts	How are you going to address issues identified?	Lead and Timeframe
Age					
Disability					
Gender reassignment					
Marriage & Civil partnership					
Pregnancy & maternity					
Race					
Religion & Belief					
Sex					
Sexual orientation					
Carers					

When answering the questions across the top of this page, cells can be merged where the same answer applies to several equality groups or protected characteristics (in column 1). To do this, highlight the blank cells to be merged, right click on the mouse and choose 'merge cells'. Then add your answer.

Appendix 2: Cautions, contra-indications and other factors to consider when initiating warfarin

Absolute contra-indications

Known hypersensitivity to warfarin or to any of its excipients
Haemorrhagic stroke
Clinically significant haemorrhage
Within 72 hours of major surgery with risk of severe bleeding
Severe hepatic impairments, especially if prothrombin time is already prolonged
Severe renal impairment
Within 48 hours postpartum
Pregnancy (1st trimester)

Cautions

Any condition in which risk of bleeding is increased
Oesophageal/gastric varices
History of gastro-intestinal bleeding
Peptic ulcer
Recent surgery
Recent ischaemic stroke
Postpartum (avoid until risk of haemorrhage is low)
Bacterial endocarditis (unless otherwise indicated)
Uncontrolled hypertension
Concomitant use of drugs that increase risk of bleeding.
Any reason to suspect that the patient will have poor compliance or poor attendance for regular blood tests

Other factors that may affect warfarin handling/ metabolism

Hepatic impairment
Hypo or Hyperthyroidism

Drug interactions

Please refer to the British National Formulary (BNF) appendix 1 for a full risk of interactions. It is worth noting that aspirin does not interact with warfarin, but potentiates the bleeding risk by its anti-platelet effect.

Remember to consider interactions with herbal and vitamin supplements.

Appendix 3: Loading doses and maintenance doses of warfarin

Patients requiring rapid anticoagulation (for treatment of venous thromboembolism).

Patients with VTE will commence treatment with (LMW) heparin. Warfarin can be started as soon as the diagnosis is confirmed. Heparin should be continued until the INR has been ≥ 2 for at least two consecutive days or for five days whichever is the longer.

10mg warfarin can be given on day 1 and day 2 unless:

- Patient is > 65 years old
- Relative contraindications
- Low body mass (< 50kg)
- Concomitantly starting amiodarone, statin, antibiotic or other drug known to potentiate warfarin

When 5mg warfarin should be given on day 1 and 2

If baseline INR >1.4, please discuss with haematologist

Day	INR	Warfarin dose (mg) at 6pm
1st	<1.4	10 5 (if >65 years old- see above)
2nd	<1.8 1.8 >1.8	10 5 (if >65 years old- see above) 1 none
3rd	<2.0 2.0-2.1 2.2-2.5 2.6-2.9 3.0-3.3 3.4-3.6 >3.6	10 5 4 3 2 1 none
4th	<1.4 1.4-1.5 1.6-1.8 1.9-2.1 2.2-2.6 2.7-3.0 3.1-4.0 4.1-4.5 >4.5	>8 8 7 6 5 4 3 miss 1 dose, then 2mg miss 2 doses, then 1mg

Slow induction of warfarin for out-patient management of atrial fibrillation

The following induction regime has been shown to be safe and effective. If baseline INR > 1.4 discuss with haematologist. If patient has taken warfarin in the past then their previous dosing schedule should be taken into consideration. Please be aware that early tests may overestimate dose.

	INR	Warfarin Dose
Day 1-7		3mg daily and check INR on day 8
Day 8	<1.4	Increase to 6mg and check in 1 week (and see Day 15 below)
	1.4-1.5	Increase to 5mg and check in 1 week
	1.6-1.8	Increase to 4mg and check in 1 week
	1.9-2.1	Maintain 3mg and check in 1 week
	2.2-2.5	Reduce to 2mg/3mg on alternate days and check in 1 week
	2.6-2.7	Reduce to 2mg and check in 1 week
	2.8-3.0	Omit 1 day, reduce to 1mg and check in 1 week
	>3.0	Stop, check INR in 3-5 days. Restart at 1mg when INR <3.0 (+ give 1mg vitamin K if INR >8.0)

For those patients that have received 3mg daily for the first week and 6mg daily for the second week.

	INR	Warfarin Dose
Day 15	<1.4	Increase to 10mg and check in 1 week (check compliance/meds)
	1.4-1.6	Increase to 8mg and check in 1 week
	1.7-1.8	Increase to 7mg and check in 1 week
	1.9-2.4	Maintain 6mg and check in 1 week
	2.5-2.9	Reduce to 5mg and check in 1 week
	3.0-4.0	Omit 1 day and reduce to 4mg and check in 1 week
	4.1-5.0	Omit 1 day and reduce to 4mg and check in 1 week
	>5.0	Stop, check INR in 3-5 days. Restart at 3mg when INR <3.0 (+ give 1mg vitamin K if INR >8.0)

Appendix 4: Indications and INR targets

Indication	Recommended Target INR
Venous Thromboembolism (VTE)	2.5
Recurrent VTE whilst on an anticoagulant and within therapeutic range	3.5
Antiphospholipid syndrome	2.5
Atrial fibrillation (AF)	2.5
Cardioversion	2.5
Patients with mitral stenosis or regurgitation who have atrial fibrillation, or a history of systemic embolism, or left atrial thrombus, or an enlarged left atrium	2.5
Mechanical heart valve	See table below
Bioprosthetic heart valves	2.5
Acute arterial embolism	2.5
Post myocardial infarction	2.5
Dilated cardiomyopathy	2.5

Recommended target INRs for mechanical heart valve:

Prosthesis Thrombogenicity*	INR target No patient risk factors	INR target Patient-related risk factors†
Low	2.5	3.0
Medium	3.0	3.5
High	3.5	3.5

***Prosthesis thrombogenicity: Low:** Carbomedics (aortic position), Medtronic Hall, St Jude Medical (without silzone); **Medium:** Bjork-Shiley, other bileaflet valves; **High:** Starr-Edwards, Omniscience, Lillehei-Kaster.

†**Patient-related risk factors for thrombosis:** Mitral, tricuspid or pulmonary position; Previous arterial thromboembolism; Atrial fibrillation; Left atrium diameter >50 mm; Mitral stenosis of any degree; Left ventricular ejection fraction <35%; Left atrial dense spontaneous echo contrast.

Appendix 5: Duration of initial anticoagulation

- Patients with proximal DVT or PE should be treated for at least 3 months

At least 3 months of anticoagulant therapy is required to prevent extension of thrombus and recurrence in patients with proximal DVT (i.e. involvement of popliteal vein or above) and/or PE. Two studies have randomized patients with proximal DVT or PE to receive either 3 or 6 months of treatment and there was no difference in recurrence rates. Selected patients may require 6 months

- If a diagnostic strategy that identifies isolated calf vein DVT is employed, treatment of such clots can be restricted to 6 weeks

Many diagnostic strategies will only look for proximal DVT and these strategies that leave isolated calf vein DVT (i.e. no extension into popliteal vein) undiagnosed and untreated are as safe as those in which isolated calf vein DVT is diagnosed and treated. If symptomatic isolated calf vein DVT is diagnosed and treated then 6 weeks of anti-coagulation is sufficient.

- Patients with cancer-associated VTE should initially be treated for 6 months with therapeutic dose LMWH rather than warfarin

Patients with cancer-associated VTE are at high risk of recurrence and LMWH has been shown to be more effective than warfarin for the first 6 months of treatment.

Continued anticoagulation beyond the initial 3 month period

- Long-term anticoagulant therapy is not recommended in patients with VTE provoked by surgery
- Long-term anticoagulant therapy is not recommended in patients with VTE provoked by non-surgical transient trigger factors (e.g. pregnancy, combined oral contraceptive pill, plaster cast)
- Patients with unprovoked proximal DVT or PE should be considered for long-term anticoagulation, taking into account information that may help predict risk of recurrence and risk of bleeding in the individual patient

This is illustrated by a lower annual risk in patients with a normal D-dimer result after completion of initial warfarin therapy compared to those with an elevated D-dimer. Risk of recurrence has also been related to the presence of post-thrombotic syndrome and male sex.

- Long-term anticoagulant therapy is not recommended in patients with VTE confined to the calf (i.e. not extending into the popliteal vein)

Temporary pages

(These pages will be deleted by The Corporate Governance Officer immediately prior to publishing on the intranet).

Approval and Ratification Checklists

This checklist is to be used by the Sponsor Group to assess readiness for submission to Management Board for ratification:

Sponsor Group Approval Checklist (Authors can also use this checklist to confirm that the document is ready for approval)		Policy for Procedural Documents (further information)
Administration		
1	Was the document authorised at the correct level and does it avoid duplication with national guidance?	1.1, 1.3 Fig 1
2	Has the most appropriate type of document (strategy/ policy/ guideline) been selected?	1.2, 1.4 Fig 2
3	Has the author checked with Corporate Affairs to determine whether specific NHSLA requirements relate to this document?	2.1
4	Has the correct Sponsor Group been identified?	2.2, 5.1, 5.2 Appendix B
5	Has the correct approved template been used?	3.1
6	Are the document Control pages up to date?	3.4
7	Does the version number follow the recommended format?	3.5
8	Does the version number match the details in the Change History box?	3.4, 3.5
9	Is the review date and review frequency identified on the front of the document?	6.6 Fig 5
Technical detail		
10	Does the 'Rationale' and 'Scope' reflect why a local level document is necessary and how it avoids duplication of national advice?	4.2
11	Strategies: are the objective(s) and intended outcomes of the document clear and unambiguous?	4.3
12	Have all relevant sources and supporting documents been cited in full in the main text and included within 'References'?	4.6
13	Does the Sponsor Group agree that the technical content is correct and up to date?	5.1 to 5.5
Consultation		
14	Have all relevant specialities, Heads of Service and Divisional groups within SASH been consulted?	5.1/ 5.2
15	Have all relevant service users and staff groups for whom the document is intended been consulted?	5.3
16	Has the incorporation of stakeholder comments been discussed by the Sponsor Group?	5.4
Monitoring and training		
17	Are arrangements for monitoring clearly stated?	4.4
18	Are there measurable standards and / or KPIs appropriate and sufficient?	4.4

Clinical Guideline Title

19	Is there an audit tool or plan within the document to review SASH compliance?	4.4
20	Does the plan include the necessary training/ support to ensure compliance?	4.4, 4.5
21	Are the required resources in place to implement the procedure and if not, is there a business plan to accompany it?	1.3, 4.1, 4.4, 4.5
Preparing for approval		
22	Has the final draft been proof read for technical / clinical content?	5.5
23	Has the final draft been proof read for formatting and layout?	5.5
24	Is the Content's page easy to cross-reference with the main text?	-
25	Has the final draft been subject to an equality analysis EqA? (Evidence must be prepared at the planning stage and the analysis completed prior to submission to management board for ratification).	2.5 Appendix C
26	Revised documents: has the agreed pathway for approving key changes and/ or minor amendments been followed?	6.3/ 6.4 Fig 3
27	Is the document being sent to the correct ratifying body?	6.2 Fig 4
28	Is the document due to be published in the correct location?	6.2 Fig 4
Dissemination and Publication		
29	Is there an outline plan to identify how this will be done and by whom?	7.1 to 7.3

This checklist is to be used by Management Board to guide the ratification process:

Management Board Ratification Checklist		Policy for Procedural Documents (further information)
Is Management Board assured that:		
Approval		
1	The correct, approved Sponsor Group has approved the document as suitable for ratification?	Appendix B
2	Consultation on the document has been sufficiently wide?	5.1 to 5.3
3	The correct approval pathway has been followed?	Figures 3 and 4
Content		
4	The document is clear and accessible and the correct approved template has been used?	3.1, 3.2, 3.3
5	Controversial or difficult issues are (a) clearly stated and (b) suitably resolved?	4.7
Monitoring and Training arrangements		
6	Monitoring and training arrangements are clearly stated in the document and have been properly embedded at ward/ office level?	4.4, 4.5
7	The required resources are in place to implement the procedure? If not, has a business plan been submitted?	1.3, 4.1, 4.4, 4.5
Dissemination		
8	The posts that will be responsible for dissemination (and associated timescales) are clearly stated?	7.1

