Risk assessment grid

This risk assessment grid accompanies the NPSA's *Risk assessment of anticoagulant therapy* report. In the report, 66 individual risks associated with the current systems for using anticoagulants were identified. This grid details these risks and their scores.

The risks are scored using a risk assessment matrix. For a full explanation of the risk assessment matrix, see page 33 of *Risk assessment of anticoagulant therapy.* The possible safer practice solutions for anticoagulant use that are referred to in the grid are explained on page 3 of *Risk assessment of anticoagulant therapy.*

The grid is separated into the following stages of the anticoagulant process:

- Decision to treat
- Document and communicate diagnosis and treatment plan
- Arrange monitoring
- Prescribe
- Prepare/dispense/supply
- Administer dose
- Monitor treatment
- Discontinue treatment
- Communication with patient: use of yellow book/patient held information

Decision to treat

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Clinical thrombotic event, e.g. stroke, PE, DVT. Failure to initiate anticoagulant therapy where indicated.	**Secondary care** Surgical thromboprophylaxis. Inadequate consideration of thrombosis in pre-operative assessment.	Therapeutic guidelines.	6	C	H	No change.	6	C	H
	Secondary care Thromboprophylaxis of non-surgical patient. Inadequate consideration of thrombosis in medical assessment.		6	C	H	No change.	5	C	H
	Primary and secondary care Misdiagnosis. Failure to check the requirement for anticoagulant therapy in higher risk patients. Service capacity issue – reluctance to increase patient numbers on anticoagulants – continue to use aspirin when patient may benefit from warfarin therapy. Lack of knowledge and use of treatment guidelines when therapy should be initiated. Conflicting treatment guidelines. Inadequate review of previous medical history. Absent or incomplete medical and medication history available. Wrong information or lack of information. Fear/reluctance to prescribe due to risk of bleeding/stroke – especially in elderly.	National Service Framework (NSF) guidelines for atrial fibrillation (AF) – although reviews to date have focused upon the costs of prescribing rather than audit patient outcomes. Education and training.	5	D	H	No change.	5	C	H
	Failure of patient to seek treatment.		6	D	H	No change	6	D	H

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Decision to treat

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleed. Anticoagulant prescribed for patient with contra-indication.	**Primary and secondary care** Absent or incomplete medical and medication history available. Wrong information or lack of information. Difficult to find information in notes. Failure to consider risk versus benefit. Delegated to individual with inappropriate knowledge or skills (e.g. junior doctors). Lack of time. Failure to fully consider medical and medication history prior to prescribing anticoagulants. Case notes unavailable in clinic – absence of records. Failure to do pre-treatment INR. Consideration of complementary therapy, e.g. St John's Wort.	Information is collected from any/all available sources including GP pre-admission letter, GP notes, patient-held repeat prescription, previous hospital records, and verbal information of patient or carer.	5	B	M	Proposed safer practice solutions 1, 2 and 5.	4	B	L
Bleed. Inappropriate initiation of anticoagulant treatment.	Treated for suspected DVT. Baker cyst – reason for swollen leg. No need for treatment. Doppler test delayed or not done. For AF in primary care assumption made that the anticoagulant service will confirm diagnosis and assess suitability for treatment.	In some places doppler on same day. Minimise time between starting therapy and confirming diagnosis.	5	A	L	No change	5	A	L

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Document and communicate diagnosis and treatment plan

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Increased risk of overdose – bleeds, underdose – thrombotic events. Lack of information and possible confusion over treatment plan, increasing risk of wrong or delayed treatment, dose or duration of therapy. • Warfarin risks.	**Secondary care** Failure/incomplete/unclear record indicating reason for treatment, target INR, duration of therapy/planned cessation date and medication history. Failure to record and communicate plan to nurses, pharmacists, receptionist, anticoagulant clinic/GP. Discharge/handover information incomplete. Pre-screening information/treatment cessation plan missing. Lack of clarity over which member of the medical team is responsible for recording this information and when this information should be recorded: at the same time the anticoagulant is prescribed; before or at the same time the patient is discharged from hospital? NHS pressures of discharge. Lack of time, lack of knowledge, inability to find template referral forms or poor documentation system, or assumption that some other member of the team is responsible, or failure to understand the importance of recording this information for safe and effective anticoagulant treatment. No treatment plan. Discussions/decisions not recorded. Failure to understand the importance of this information for the work of the other members of the hospital multidisciplinary team e.g., nurses, pharmacists, ward clerks, therapists and social care.	A minority of specialist anticoagulant nurses and clinical pharmacists may help ensure that the treatment plan is recorded and complete. However, the majority of specialist anticoagulant nurses focus exclusively on providing services for hospital outpatients. Anticoagulant services and GPs providing ongoing care request complete information before accepting clinical responsibility. (Template forms can be used for the inpatient record and copies sent to the anticoagulant clinic/GP). GPs accepting repeat prescribing responsibilities request complete information prior to accepting clinical responsibility. In some cases the GP is given access to treatment plan from anticoagulation service. Shared care guidelines. None – failure to plan treatment, or reliance upon yellow booklet (or local similar record). Template/pro forma to collect information to share with all disciplines.	6 +	B	H	Proposed safer practice solutions 1, 2 and 5.	4	B	M
• Heparin risks.	Heparin – less of an issue – less frequent continuation into the community – patient keen to stop injections as soon as possible.		4	A	L	Proposed safer practice solutions 1, 2, 3, 5 and 12.	4	A	L

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Document and communicate diagnosis and treatment plan

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Increased risk of overdose – bleeds, underdose – thrombotic events. Lack of information and possible confusion over treatment plan, increasing risk of wrong or delayed treatment, dose or duration of therapy.	**Primary care** Failure/incomplete/unclear record indicating reason for treatment, target INR, duration of therapy/planned cessation date and medication history. Less complex, less urgent need for treatment group of patients being referred to anticoagulant service. Usually diagnosis AF. Sometimes referral forms used, at other times letters. Patients can arrive to anticoagulant service with no forms due to GP error or patient error. Diagnostic information but no drug details provided. Electronic record keeping better than paper records but GP systems have different layouts – (standard pro forma would improve record keeping). Consider standard pro forma.	Anticoagulant service ensures full information before taking responsibility for patient (possible delay in treatment). Assess to GP records. Clinic in GP surgery. Involvement of patient.	6	A	M	Proposed safer practice solutions 1, 2, 3 and 5.	5	A	M

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Arrange monitoring

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Failure to arrange blood test monitoring in hospital.	**Secondary care** Lack of time or poor documentation system; assumption that some other member of the team is responsible; or failure to understand the importance of communicating to the team for safe and effective anticoagulant treatment.	Specific referral form – for use within hospital which may be transmitted/shared with GP.	5	B	M	Proposed safer practice solutions 1, 2 and 5.	4	B	M
Bleeding, overdose, underdose. Failure to arrange blood test monitoring.	**Primary care – where the GP is responsible for providing anticoagulant monitoring** Lack of time or poor documentation system; assumption that some other member of the team is responsible; or failure to understand the importance of communicating to the team for the safe and effective anticoagulant treatment. Ad hoc vs anticoagulant service.	Standard Operating Procedure (SOP). GP computer system. Arrangement for anticoagulant service within GP practice.	4	B	M	Proposed safer practice solutions 1, 2, 5, 6, 8,9 and 10.	3	B	M
Bleeding, overdose, underdose. Failure to arrange blood test monitoring.	**Primary care – where the GP is responsible for providing anticoagulant monitoring and the patient is housebound or in a care setting and requires a visit from a district nurse to get sample.** Failure of GP to arrange/communication errors. Failure of district nurse to arrange/turn up. Repeat visits to obtain sample.	Good system/ co-ordination. Community phlebotomy services.	5	B	M	Proposed safer practice solutions 1 and 2.	4	B	M

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Arrange monitoring

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Failure to arrange appointment with the outpatient anticoagulant service.	**Secondary care** Standardisation of systems/referral form is lacking – causes confusion. Lack of clarity over when referral form should be completed. When the anticoagulant is prescribed, sometime during the inpatient stay, immediately prior to discharge from hospital. If it is not completed at the same time as the initial prescription then a different practitioner who was not involved in the initial treatment decision may be asked to complete information about diagnosis, target INR, and duration of therapy that is not recorded in the patient's care record. Lack of orientation; systems exist but juniors not aware/informed of systems. Date for next (first) appointment is sent direct to patient. Patient fails to attend first clinic appointment as unaware of need; either not communicated prior to discharge or method of communication post-discharge fails. Confirmation that GP has taken over responsibility not transferred back, i.e. one way communication route. Unclear handover – who has 'ownership' of patient care? Difference between weekday 'normal hours' service and weekend out of hours.	Secondary referral form to GPs which is separate to hospital system. Team sees patient and first clinic appointment is agreed/communicated prior to discharge. Audit of completion of information provision and follow up of patients to confirm understanding and awareness of clinic attendance. DAWN® system may alert hospital/clinic to DNA patients; default system to chase patient. Dosing managed by hospital actively during period between discharge and first clinic appointment/ handover to GP. May be conducted via a stabilisation clinic or on the ward. Daily clinics?	6	A	M	Proposed safer practice solutions 1,2,5 and 6.	5	A	M

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Arrange monitoring

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose or failure to take dose. Patient has appointment but long time period between discharge and clinic appointment.	**Secondary care** Risk to patient that dosing is incorrect due to delay between clinical review during anticoagulant induction therapy. Patient may be required to return to hospital ward for blood test and dosing – ad hoc arrangement 'on duty' staff who may not know or expect the patient are required to manage care on an interim basis. Patient's care record may no longer be on the ward. Patient may not attend due to confusion over arrangements.	Frequent anticoagulant clinics to minimise the time between discharge from hospital and clinical review.	6	B	H	Proposed safer practice solutions 1, 2, 5, 6, and 8.	4	B	M
Bleeding, overdose, underdose or failure to take dose. Failure to arrange appointment with the outpatient anticoagulant service.	**Primary care** Failure/incomplete/unclear record indicating reason for treatment, target INR, duration of therapy/planned cessation date and medication history. Less complex, less urgent need for treatment group of patients being referred to anticoagulant service. Usually diagnosis AF. Sometimes referral forms used, at other times letters. Patients can arrive to anticoagulant service with no forms due to GP error or patient error. Diagnostic information but no drug details provided. Electronic record keeping better than paper records but GP systems have different layouts – (standard pro forma would improve record keeping). Consider standard pro forma. Lack of orientation; systems exist but juniors not aware/ informed of systems. Date for next (first) appointment is sent direct to patient. Patient fails to attend first clinic appointment as unaware of need; either not communicated prior to discharge or method of communication post-discharge fails.	Anticoagulant service ensures full information before taking responsibility for patient (possible delay in treatment). Assess to GP records. Clinic in GP surgery. Involvement of patient.	4	A	L	Proposed safer practice solutions 1, 2, 5 and 6.	3	A	L

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Prescribe wrong dose or no dose of anticoagulant.	**Secondary care - inpatients** Mis-communication of intended dose of anticoagulant. Prescribing in tablets rather than mg. Dose does not appear on prescription but held separately e.g. back of prescription or other form.		6	B	H	Proposed safer practice solutions 1, 2, 11 and 14.	5	B	M
	Poor dosing decisions based on INR and other factors. Lab results matched to incorrect patient. Omission of doses as written up on a daily basis.		6	B	H	Proposed safer practice solutions 1, 2, 3, 4, 5 and 14.	5	B	M
	No tests – induction doses (higher) initiated – baseline? Lack of standardisation for use of loading dose vs build up from low dose.	Daily dosing and testing local policy (Fennerty). Lack of adverse incidents linked to induction prescriptions.	5	B	M	Proposed safer practice solutions 1, 2, 3, 4 and 5.	4	B	M
Bleeding, overdose, underdose. Prescribe wrong dose or no dose of anticoagulant.	Unfractioned heparin prescribed in units/hour administered in ml/hour. (Prescribed by junior medical staff). Issues over test results and dosing for sodium heparin. Low molecular weight (LMW) heparin mg/kg or unit/kg or ml – and the weight may not be available and incorrectly estimated. Sometimes prescribed total dose per patient. Sometimes prescribed as mg/kg. Many different types of LMW heparin – wrong dose. Different dose/frequency of some LMW heparin for different indications. Units misinterpreted as dose zeros causing dose errors of factors of 10.	Heparin and warfarin prescriptions generated/held together for therapeutic review. Inspection of prescription by pharmacy. Local dosing guidelines. Dose in more than one location; preventative or causal factor? Use British Society of Haematology/hospital guidelines. Standardisation within individual hospitals/ units cardiology vs rest. Special prescribing forms for heparin products in some hospitals .	6	B	H	Proposed safer practice solutions 1, 2, 3, 4, 5, 11, 12 and 14.	4	B	M

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Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Repeat prescribe anticoagulant. Inappropriate prescription for supply.	Failure to check the following: • continued appropriateness; • recent INR; • safe INR; • recent or planned appointment with anticoagulant; • are the tablets to be prescribed appropriate for the dose? • appropriate quantity requested. Locality standard for using 0.5mg, 1mg, 3mg, 5mg tablets. Part of the normal repeat prescription requests for other medicines.	Six monthly medication review. GP managed service where results from hospital. Near-patient system.	5	B	M	Proposed safer practice solutions 2, 9, 10 and 11.	4	B	M
Bleeding, overdose, underdose. Dosing.	**Primary care – where patient managed by GP anticoagulant service results from hospital** Telephone service – instruct patient on new dose. Patient updates dose in yellow book. Repeat prescriptions causes and process as above.		5	B	M	Proposed safer practice solutions 1, 2, 9 and 10.	5	B	M
Bleeding, overdose. Patient is discharged on loading dose.	**Secondary care** Loading dose may be continued in error. Poor inpatient documentation. Unclear, incomplete or wrong completion of yellow book, e.g. loading doses recorded in yellow book, delay in appointment for anticoagulant clinic, no further doses recorded in yellow book, patient assumes that they are to continue with previous dose until seen in the anticoagulant clinic. Lack of awareness of regime by junior doctor.	No formal preventative measures. Relies on individual members of the multidisciplinary team checking that yellow book has been completed fully and accurately and that dosing instruction are appropriate until seen in anticoagulant clinic.	6	B	H	Proposed safer practice solutions 1, 2, 5, 6 and 8.	5	B	M

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding or other adverse drug reaction as a consequence of a drug-drug interaction. Co-prescribing in absence of knowledge of prescription of warfarin or other drugs.	**Secondary care – inpatients** Two separate hospital inpatient prescription forms for anticoagulants and other drugs being prescribed, i.e. prescription information in two or more places, not together. Hospital prescribers have to remember to prescribe the anticoagulant(s) on the main inpatient prescription form without including details of dose and prescribe the anticoagulant(s) a second and subsequent times on an anticoagulant chart where details of the daily dose are included. More than one prescriber not aware of warfarin prescription. **Primary care** Less of an issue – GP prescribing systems alert prescriber. Out-of-hours /house calls where no GP system available.	Less of an issue during induction but risk increased later; although dose depends upon other drugs concurrently prescribed with warfarin. Ward pharmacy services. Education of prescribers. Local documentation/ software systems. Decisions recorded so prescribing actions understood as intentional. Use of IT prescriptions systems to alert to contraindications. Community pharmacy system alert to interaction if they go to the same community pharmacy.	6	A	M	Proposed safer practice solutions 1, 2, 5 and14.	5	A	L
"As directed" directions applied.	**Primary care and hospital outpatients** Prescription for discharge and repeat supplies of warfarin 'as directed'. A dosage check made by the doctor writing prescription. Separation of responsibilities – those prescribing 'supply' of anticoagulants to those 'dosing' anticoagulants. Once discharged from hospital the yellow book is the only information source that provides information about the dosage. The yellow book is not regarded as a prescription but rather 'supplementary clinical information'. The information in the yellow book is not checked by a pharmacist or nurse – as it is not regarded as a prescription. Lack of source of other information to confirm dose for patient or professionals.	Use of other information source to check dose. Use "as directed" within yellow book to direct patient to information. In some cases yellow book checked at time of repeat prescription.	6	B	H	Proposed safer practice solutions 1, 2, 5, 6 and 10.	5	B	M

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Miscommunicating dose (does not include near-patient testing).	**Anticoagulant service, GP services, pharmacy services** Blood sample – telephone or postal dose service. Many steps involved. Communication to and from non-healthcare staff. Information not sent or miscommunication – lost in post. Telephone a message to an intermediary and the message not passed on. Do not receive information. Wrong selection of patient. For telephone service – patients expected to record new dose in yellow book. For postal service – updated yellow book sent and not received. Urgent modification required – telephone.		5	B	M	Proposed safer practice solutions 8 and 10.	4	B	M
Miscommunicating dose (does not include near-patient testing).	Postal issues Lost in post. Delay in receiving letter. Internal distribution delay in care settings. Understanding of written information. Legibility. Failure to read and change dosing practice. Unqualified care staff may not able to change doses.		6	A	M	Proposed safer practice solutions 8 and 10.	5	A	M
	Telephone issues Telephone after hours. Difficulty in reaching patient. For telephone service – patients expected to record new dose in yellow book.		6	A	M	Proposed safer practice solutions 8 and 10.	5	A	M
	Face-to-face Poor communication and understanding of instructions and failure to record new dose in yellow book by health professional.		4	A	L	Proposed safer practice solutions 1and 2.	4	A	L

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Miscommunicating dose – near-patient testing.	**Primary and secondary care** Face-to-face. New record made in yellow book by health professional/check understanding. Near-patient testing may involve district nurse in patient home – dose delayed after test.		4	A	L	No change.	4	A	L
Bleeding or thrombosis. Incorrect dose induction.	**Secondary care** Inexperienced staff. Senior staff using their own protocols. Different guidelines – confusing. Poor compliance with guidelines. No measurement of baseline INR. Patients are discharged before they have completed induction dose – must come back to hospital for INR	Education and training audit.	6	A	M	Proposed safer practice solutions 1, 2, 3, 5 and 14.	5	A	L
Bleeding or thrombosis. Incorrect dose induction.	**Primary care** GP sends patient to hospital anticoagulant service with request to please start this patient on warfarin as per induction guideline on AF.		4	A	L	No change.	4	A	L
Inappropriate maintenance dose calculation/adjustment.	**Primary and secondary care** Empirical dosing method. Algorithms not used appropriately. Multi-tasking/inexperience. No standard method – different styles.		6	B	H	Proposed safer practice solutions 1, 2, 3, 4, 5 and 14.	5	B	M

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Dose adjustment for surgery/dentistry.	Different guidelines. BDA endorsed guidelines unknown or unused. Dentists require different INR before operating. Unclear guidelines/requirements for surgery. Major/minor/ investigations/ cardioversion/endoscopy. Operations are delayed and cancelled. Attend hospital for blood test. If INR level okay, proceed; if not, surgery delayed.		6	B	H	Proposed safer practice solutions 1, 2 and 3.	5	B	M
Bleeding or other adverse drug reaction as a consequence. Unconsidered co-prescribing of non-steroidal anti-inflammatory agents (NSAI).	**Primary and secondary care** Lack of knowledge, time, professional judgement. Lack of use of cytoprotective. Lack of awareness. Patients self prescribing/taking over the counter supplies of nonsteroidals.	No system safeguards. Clinical experience. GP computer system alerts – too sensitive – not always effective.	6	B	H	Proposed safer practice solutions 1, 2, 5 and 7.	5	B	M
Bleeding or other adverse drug reaction as a consequence. Unconsidered co-prescribing of aspirin/antiplatelets.	**Primary and secondary care** Lack of knowledge, time, professional judgement. Lack of use of cytoprotective. Lack of awareness. Failure to stop aspirin as intended when warfarin started.	No system safeguards. Clinical experience. Treatment plan stating use of aspirin. GP computer system alerts – too sensitive – not always effective. Pharmacist review of prescription.	4	B	M	Proposed safer practice solutions 1, 2, 5 and 7.	4	B	M

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Prescribing/dosing

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding or other adverse drug reaction as a consequence. Unconsidered co-prescribing of other interactive drugs.	**Primary and secondary care** Lack of knowledge, time, professional judgement. Lack of awareness. Assumption that the anticoagulant service will adjust warfarin dose to cope with the interacting drug. Failure of the prescriber to inform the anticoagulant service of the interaction when new drug started and also when interacting drug is stopped, e.g. amiodarone. Irregular consumption by patient of co-prescribed medicines.	GP computer system alerts – too sensitive – not always effective. Pharmacist review of prescription.	4	B	M	Proposed safer practice solutions 1, 2, 5 and 7.	4	B	M
Over or underdosing. Patient managed care home monitoring.	**Primary care** Self testing with dose advice from health professional. Self determined dose. Incorrect dose used. Appropriate and convenient for some patients. May be costly if overused. Patients have to buy their own test machine	Appropriate patient selection.	4	A	L	No change.	4	A	L
Over or underdosing. Anticoagulant service provided by community pharmacy.	**Primary care** Referral from GP. Temporary residents. No requirement to dispense all prescriptions for patients. Rely on information from GP, patient and other community pharmacies.	Dedicated time. Dedicated staff. Dedicated community pharmacy for all dispensing and anticoagulant services. Share info via NHS spine.	4	A	L	Proposed safer practice solutions 1and 2.	4	A	L

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Prepare/dispense/supply

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Supply of wrong strength of anticoagulant by health professional.	**Secondary care** Doses written as number of colour of tablets. Product of previous dose choice [error]. Misinterpretation of dose on the prescription – dispensing error. Unrestricted access to supplies of anticoagulants as ward stock; no check of product used by a pharmacist. Supply of wrong strength from pharmacy for ward stock (selection error by pharmacy staff). Use or supply to patient of wrong strength anticoagulant (selection error by nursing staff). Confusing labelling and packaging of medicine products, poor storage, poor procedures.	Local standardisation on one strength of tablet. Use of differentiated labelling and packaging. Risk assess storage area.	3	B	M	Proposed safer practice solutions 2 and 11.	3	B	M
Overdose/underdose during preparation.	**Secondary care** Heparin – supplied as concentrate that required dilution 5,000units/ml, 10,000units/ml, 20,000units/ml. LMW heparin based on weight. Miscalculation error. Use of wrong body weight measurement. Incorrect physical syringe measurement of dose. Incorrect dilution / volume of dilutent.		6	B	H	Proposed safer practice solutions 2 and 12.	4	B	M

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Prepare/dispense/supply

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Failure to reinforce counselling.	**Secondary care** Prescribed as "use as directed"; failure to check yellow book; yellow book not available at point of supply. Lack of linkage between supply and review of dose; pharmacy dose not seen; yellow book induction dose may be maintained. Absence of INR results /out-of-hours service provision; supply made before dose agreed. Change in working practices may result in patients being discharged before INR is available; discharge medication supplied but patient must contact ward to find out dose once at home – may not be undertaken/may not understand/carers not aware System inflexibility to meet patient needs safely; who is responsible for dosing information?	Move towards supply from ward stock where yellow book information is available.	5	B	M	Proposed safer practice solutions 1, 2, 5, 6 and 8.	4	B	M
Bleeding, overdose, underdose. Supply of wrong drug/ strength of anticoagulant by health professional.	**Primary care** Hand written prescription – legibility. Selection errors. Problems confusion with 0.5mg and 5mg.	National standard for warfarin strengths. Use of colour and design of labelling and packaging.	3	A	L	Proposed safer practice solutions 2 and 11.	3	A	L

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Prepare/dispense/supply

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Inappropriate supply of anticoagulant.	Routine check of INR, dose or clinic attendance may not be a part of the repeat prescription process. Failure to check the following: • continued appropriateness; • recent INR; • safe INR; • recent or planned appointment with anticoagulant; • are the tablets to be prescribed appropriate for the dose? • appropriate quantity requested. Locality standard for using 0.5mg, 1mg, 3mg, 5mg tablets. Part of the normal repeat prescription requests for other medicines.		6	B	H	Proposed safer practice solutions 2, 9 and 11.	5	B	M
Dispensing anticoagulants in monitored dosing systems.	Single product card. Problems of dose adjustment in monitored dose system. Preparation weeks or a month in advance in the pharmacy. Returned box from care home for re-dispensing. Delay or omission of doses. Multiple product dosette. Problems of dose adjustment in multiple product dosette. Delay or omission dose changes.		5	A	M	Proposed safer practice solutions 2 and 13.	4	A	L

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Administer dose

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, dose duplication underdose – thrombosis. Administer the wrong dose of anticoagulant.	**Secondary care** Lack of effective systems to check administration problems – includes information on administration chart. Patient receives wrong drug.	SOPs. Training of clinical staff, carers and patients. Standard prescription form. Missing information highlighted/obtained by nursing staff. Pharmacy surveillance. Local decisions to use one form of LMWH. Minimise use of sodium heparin. Syringes specific to doses /heparins. Skill base reduced due to decrease use of unfractionated heparin products.	5	A	M	Proposed safer practice solutions 1, 2 and 5.	4	A	L
	Primary care Warfarin. Poor communication to patients by health professionals. Confusion over dose to be taken – not on medicine label – verbal or yellow book information. Confusion over mg/tablet dosing. Poor record keeping in yellow book. Record keeping – possibility of dose omission or dose duplication. Human error – administer wrong drug. Lack of specialist medicines training for staff.	Training. SOPs. Medication review. Training.	5	B	M	Proposed safer practice solutions 2, 8, 9, 10 and 11.	4	B	M
	Care home Pharmacy/home generated drug administration chart – transcription error from yellow book. Poorly designed inflexible system. High potential for confusion and error. Charts may say "as directed" – care staff have to check with the yellow book or some other record for the dose. Dose advice sent to home by fax. Over mg/tablet dosing. Poor record keeping in yellow book.	SOPs. Medication review. Poorly designed inflexible system.	5	B	M	Proposed safer practice solutions 2, 8, 10, 11 and13.	4	B	M

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Administer dose

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose – thrombosis – during preparation. Administer the wrong dose of heparin.	**Primary and secondary care** Heparin. Sodium calculation errors. Dosing by units per hour or mls per hour. Infusion pump programming error, canula block. Failure to monitor results in wrong dose administration. Poorly designed system. High potential for confusion and error.	Not available as ward stock in some hospitals. Standardise products and strengths available as ward stock. Pharmacist review of prescription. Double checks on preparation of infusion.	5	B	M	Proposed safer practice solutions 1, 2, 12 and 14.	3	B	M
Misselection and use of LMW heparin.	**Community nurses** LMWH; select correct dose for body weight. Prophylaxis and treatment doses confused. Different heparins for different indications. Confused mg/kilo prescribed. No double check on pre-filled syringe.	Standardise products and strengths available.	5	B	M	Proposed safer practice solutions 2 and 14.	4	B	M
Misselection and use of LMW heparin.	Incorrect selection, volume calculation, dose measurement.	Standardise products and strengths used. SOP. Training.	1	B	L	Proposed safer practice solutions 2 and 14.	1	B	L
Dose omitted.	**Secondary care** The daily dose not prescribed and so dose administration omitted. Due to : Lack of availability of INR result to adjust dose before administration. Blood samples taken in hospital during morning – results sent back to ward in the afternoon. INR result available but failure of junior medical staff to prescribe new dose. Due to oversight, time pressures, lack of clarity over responsibility. The anticoagulant prescription is overlooked by nursing staff responsible for administering medicines due to oversight, time pressures, lack of clarity over responsibility for this role. Warfarin dose not prominently displayed on regular drug chart, separate chart.The anticoagulant dose cannot be administered as the medicine/drug chart is not available on the ward.	Nursing and pharmacists ensuring dose prescribed. Pharmacy review of omission on drug chart.	5	A	M	Proposed safer practice solutions 1, 2, 5 and 14.	3	A	L

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Administer dose

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Thrombosis. Dose omitted.	**Primary care** Warfarin doses are administered in the evening in hospitals for logistic reasons. This convention is continued when the patient is in the community – and this time for drug administration may not be suitable for the patient at home or for carer use. Patient forgets. Patient wishes to drink alcohol, Out of supplies – availability of heparin products.		6	A	M	Proposed safer practice solutions 2, 10 and 11.	4	A	L
Thrombosis. Dose omitted.	**Residential care** Warfarin doses are administered in the evening in hospitals for logistic reasons. This convention is continued when the patient is in the community – and this time for drug administration may not be suitable for the patient at home or for carer use. Patient forgets. Patient wishes to drink alcohol, Out of supplies – availability of heparin products.		4	A	L	Proposed safer practice solutions 2 and 10.	4	A	L
Bleeding or thrombosis. Wrong/previous dose administered.	**Secondary care** Dose restarted post operatively but administration not linked to previous records. Lack of reference to, or access to, historical information to re-introduce anticoagulation therapy.	Picked up by ward staff before discharge by everyday checks or GP, patient, carer.	5	A	M	Proposed safer practice solutions 1, 2, 3 and 14.	4	A	L

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Monitor treatment

Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose. Failure to attend INR clinic.	**Primary and secondary care** Poor communication to patients by health professionals, confusion over need/frequency to attend for regular INR testing. Inconvenience of attending anticoagulant clinic /inability to attend (transport/willingness/still in hospital/treatment stopped)/lack of understanding for attendance. Failure to audit and follow-up DNA's. GP services may not have a automated systems for DNA's.	Community phlebotomy services. Near-patient testing services. Rely on anticoagulant service to follow-up. Escalate letters to patient – then to GP if multiple DNA's.	6	A	M	Proposed safer practice solutions 1, 2, 6, 8 and 10.	5	A	L
Bleeding, overdose, underdose – dose omission. Sampling problems; phlebotomist takes blood from wrong patient, wrongly labelled, sample lost, label lost or defaced.	**Primary and secondary care** Wrong anticoagulant administered to patient. Dose omitted due to no INR result. Wrong test is requested. Underfilled sample bottle. Haemolysed sample.	SOPs. Training. Bar coding and other technologies. Audit. Undertake near-patient testing.	5	A	M	Proposed safer practice solutions 1 and 2.	4	A	L
Blood tests for domicillary patients. Delays or no INR test.	**Primary care** Inability to get venus blood – weekend problems. Inexperienced staff – ill patients.	Capillary blood sample used.	5	B	M	Proposed safer practice solutions 1 and 2.	4	B	M

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Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdose, underdose – dose omission. Problems and errors with laboratory measurement. Calibration/quality assurance (QA) of equipment and results.	**Primary and secondary care** Wrongly calibrated machine. Problems with analyser equipment and reagents. Failure to maintain laboratory equipment. Use of out of date reagents. Failure to enrol and act on quality control system.	Up-to-date SOPs. Education and training of laboratory staff. Internal and external quality assurance systems.	2	B	L	No change.	2	B	L
Bleeding, overdose, underdose – dose omission. Problems and errors with near patient testing equipment.	**Primary and secondary care** Inadequate education and training of staff and patients using this equipment. Inadequate SOP's. Wrongly calibrated machine. Problems with equipment and reagents. Failure to maintain near-patient testing equipment. Use of out-of-date reagents. Failure to enrol and act on quality control system. (Significant numbers of users not enrolled with external QA systems). More problems with district nurse measurement in patients homes. Small number of patients and poor training. Testing of individual patients in GP clinic or community pharmacies, clinics. Small batches of patients in clinics.	SOPs. Education and training of laboratory staff. Internal and external quality assurance systems. Immediate repeat test.	5	A	L	Proposed safer practice solutions 2 and 3.	4	A	L

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			F	C	R		F	C	R
Bleeding, overdose, underdose – dose omission. Problems with test reporting system.	**Primary and secondary care** Transcription errors/poor hand writing. Patient identity errors. From autoanalyser to laboratory reporting system. From laboratory reporting system to GP system. From autoanalyser to anticoagulant dosing system to yellow book. From autoanalyser to anticoagulant dosing system to yellow book. From laboratory reporting system to care record. Delays in reporting results from laboratory to clinician.	Clinical/admin staff identify problem and send for retest.	6	A	M	Proposed safer practice solutions 2 and 10.	4	A	L
Bleeding, overdose, underdose. Failure to modify dose, monitoring and counsel patient.	Poor systems of communication between anticoagulant clinic and patient – poor use of telephone, postal communication. Patients/carer not at home. Telephone communication to the confused patient where the carer supervises medication. Incorrect telephone number. Staff unable to make contact. Language difficulties. Access to staff easier in residential care. Patient fails to carry out communicated action and update yellow book accurately. Social care carers are not permitted to adjust dosage.	Education and training of patients and carers. Suitable patient selection – able to use telephone communication. Get patient to say the new dose back. Send yellow book back to patient. Postal service. Telephone service. Six month check as a safeguard.	5	B	M	Proposed safer practice solutions 1, 2, 8, 9, 10 and 11.	4	B	L

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			F	C	R		F	C	R
Thrombosis. Discontinue too early.	**Prophylaxis** Discontinue too early because of adherence to protocol without clinical assessment e.g. ongoing thrombotic risk. Evidence accumulating for requirement of more prolonged prophylaxis, e.g. one month post THR balance cost/ease of administration. **Treatment** Discontinue too early because of adherence to protocol without clinical assessment. Discontinue too early – therapeutic INR for 24 hours not yet achieved. Infusion pump failure/blocked i.v. access. Failure to discontinue/ recognise patient on anticoagulant when new bleeding event has occurred – unfamiliar patient/on call staff, lack of drug chart.	Awareness of need to overlap heparin with oral anticoagulant for 48 hours after initial attainment of therapeutic range of INR.	6	A	M	Proposed safer practice solutions 1, 2, 3, 5 and 14.	5	A	M
Failure to discontinue warfarin.	Failure to discontinue/recognise patient on anticoagulant when new bleeding event has occurred – unfamiliar patient/on call staff, lack of drug chart.		5	B	M	Proposed safer practice solutions 1, 2, 3 and 5.	4	B	M
Failure to discontinue heparin.	Failure to discontinue heparin.	Finite prescription on drug chart. Medical /nursing staff awareness.	5	B	M	Proposed safer practice solutions 1, 2, 3, 5 and 14.	4	B	M

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Undesired event	Cause	Current preventive and mitigation measures	Current risk			Additional preventative and mitigation measures	Risks with all action		
			F	C	R		F	C	R
Bleeding, overdosage, underdosage, or failure to take dose. Failure to issue yellow book or written information. Incomplete or unclear, or incorrect information in yellow book.	Separation of duties. Prescriber may inform patients of their new treatment at the same time as they prescribe the anticoagulant, and assume some other member of the multidisciplinary team will communicate with the patient and issue a yellow book and advise on attending an anticoagulant clinic. Lack of time, or poor documentation system. Lack of stock of yellow book. Counselling may be disassociated with supply of yellow book. Lack of clarity over when the yellow book should be issued. Some trusts do not use yellow book – use separate information leaflets and individually printed dosage instruction forms from the anticoagulant service. In some trusts the yellow book is used as the referral document for anticoagulant clinic. In this case failure to issue the yellow book may have a greater clinical consequence. Lack of education of staff. Different arrangements in different hospitals/wards. Done less well outside DVT service. Heparin – no yellow book or written information. Heparin and warfarin – mention of heparin may be in yellow book.	No formal prevent measures. Relies on individual members of the multidisciplinary team checking that a yellow book has been issued, written information is complete and accurate. The yellow book provides the minimum information about anticoagulant therapy and current dosage and a written reminder for patients and carers that they must attend anticoagulant clinics regularly, have their blood tested, and dose adjusted. Supply book with drugs – on discharge but not on ward – varies for weekend discharge. Information completed by the anticoagulant service/GP/Community. Start the use of yellow book at time '0' used in some hospitals. Also record inpatient dosing used in some hospitals.	5	A	L	Proposed safer practice solutions 1, 2, 5, 8 and 10.	4	A	L

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Communication with patient: use of yellow book/patient held information

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			F	C	R		F	C	R
Bleeding, overdosage, underdosage, or failure to take dose. Failure to communicate treatment. Patient knowledge incomplete – passive recipients or misunderstanding of why on anticoagulant.	Prescriber may inform patients of their new treatment at the same time as they prescribe the anticoagulant, and assume some other member of the multidisciplinary team will communicate with the patient about their anticoagulant treatment, issue a yellow book and advise the patient concerning attending an anticoagulant clinic or GP clinic. Patient does not recall information. No documentary evidence of counselling or test of patient understanding. Failure to obtain feedback from patient. Patient not aware of symptoms to watch out for. Communication is frequently a one way transfer of information. There is no checking of understanding. The communication needs of carers and social care (when the patient is in residential care) are not usually considered. Lack of time, or poor documentation system. The communication is undertaken without the presence supply of yellow book. Yellow book may be supplied without any verbal counselling. Assumption that nurses/junior medics have knowledge and skills to counsel. Junior medical staff new shift patterns – lack of continuity or availability to counsel patients. Yellow book update needed – accurate and appropriate (incl. language) information for patients needs.	No formal preventative measures. Relies on individual members of the multidisciplinary team checking that patient has been adequately counselled about their therapy. Patients may not retain very much information when being communicated with in hospital. Clinicians refer patient to anticoagulant clinic where patient understanding may be assessed – information provided or re-iterated. What is important is to ensure they know that they must attend anticoagulant clinics regularly, have their blood tested, and dose adjusted. Additional treatment communication can be undertaken as part of the anticoagulant clinic service. GP/practice staff reinforcement of education.	5	A	M	Proposed safer practice solutions 1,2, 5 and 8.	4	A	L

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