

Patient safety alert



Alert

28 March 2007

Immediate action

Action

Update

Information request

Ref: NPSA/2007/18

Actions that can make anticoagulant therapy safer

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital.¹⁻³ Managing the risks associated with anticoagulants can reduce the chance of patients being harmed in the future.

This patient safety alert has been developed in collaboration with the British Society for Haematology (BSH) and a broad range of other clinical organisations and individual clinicians, patients and patient groups.

Action for the NHS and the independent sector

The National Patient Safety Agency (NPSA) is recommending that NHS and independent sector organisations in England and Wales take the following steps:

- 1 Ensure all staff caring for patients on anticoagulant therapy have the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff may undertake their duties safely.
- 2 Review and, where necessary, update written procedures and clinical protocols for anticoagulant services to ensure they reflect safe practice, and that staff are trained in these procedures.
- 3 Audit anticoagulant services using BSH/NPSA safety indicators as part of the annual medicines management audit programme. The audit results should inform local actions to improve the safe use of anticoagulants, and should be communicated to clinical governance, and drugs and therapeutics committees (or equivalent). This information should be used by commissioners and external organisations as part of the commissioning and performance management process.
- 4 Ensure that patients prescribed anticoagulants receive appropriate verbal and written information at the start of therapy, at hospital discharge, on the first anticoagulant clinic appointment, and when necessary throughout the course of their treatment. The BSH and the NPSA have updated the patient-held information (yellow) booklet.
- 5 Promote safe practice with prescribers and pharmacists to check that patients' blood clotting (International Normalised Ratio, INR) is being monitored regularly and that the INR level is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.

For response by:

- All NHS and independent sector organisations in England and Wales

For action by:

- The chief pharmacist/pharmaceutical advisor should lead the response to this alert, supported by the chief executive, medical director, nursing director and clinical governance lead/risk manager

We recommend you also inform:

- Medical staff
- Nursing staff
- Pharmacy staff
- General practitioners
- Community pharmacists
- Dental surgeons
- Patient advice and liaison service staff in England
- Community health councils in Wales
- Medical laboratory scientists

The NPSA has informed:

- Chief executives of acute trusts, primary care organisations, ambulance trusts, mental health trusts and local health boards in England and Wales
- Chief executives/regional directors and clinical governance leads of strategic health authorities (England) and regional offices (Wales)
- Healthcare Commission
- Healthcare Inspectorate Wales
- Commission for Social Care Inspection

- Medicines and Healthcare products Regulatory Agency
- Welsh Health Supplies
- Royal colleges and societies
- NHS Direct
- Relevant patient organisations and community health councils in Wales
- Independent Healthcare Forum
- Business Services Centre (Wales)
- Independent Healthcare Advisory Services

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- 6 Promote safe practice for prescribers co-prescribing one or more clinically significant interacting medicines for patients already on oral anticoagulants; to make arrangements for additional INR blood tests, and to inform the anticoagulant service that an interacting medicine has been prescribed. Ensure that those dispensing clinically significant interacting medicines for these patients check that these additional safety precautions have been taken.
- 7 Ensure that dental practitioners manage patients on anticoagulants according to evidence-based therapeutic guidelines. In most cases, dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.
- 8 Amend local policies to standardise the range of anticoagulant products used, incorporating characteristics identified by patients as promoting safer use.
- 9 Promote the use of written safe practice procedures for the administration of anticoagulants in social care settings. It is safe practice for all dose changes to be confirmed in writing by the prescriber. A risk assessment should be undertaken on the use of Monitored Dosage Systems for anticoagulants for individual patients. The general use of Monitored Dosage Systems for anticoagulants should be minimised as dosage changes using these systems are more difficult.

Action deadlines for the Safety Alert Broadcast System (SABS)

Deadline (action underway): 2 July 2007

Action plan to be agreed and actions started

Deadline (action complete): 31 March 2008

All actions to be completed

Further information about SABS can be found at:

www.info.doh.gov.uk/sar2/cmopatie.nsf

Further information on the action points

- 1 **Ensure all staff caring for patients on anticoagulant therapy have the necessary work competences. Any gaps in competence must be addressed through training to ensure that all staff may undertake their duties safely.**

Healthcare organisations must ensure that staff who prescribe, adjust the dosage, dispense, prepare, administer, monitor and discharge patients on anticoagulant therapy have received adequate training to ensure they have the necessary work competences to undertake their duties safely. Particular attention should be given to ensuring that systems are in place for foundation year doctors to receive training and to attain the necessary work competences.

There is evidence that providing nurses, pharmacists and biomedical scientists with these competences, in addition to medical staff, can help deliver inpatient and ambulatory care more safely.¹

The NPSA has commissioned e-learning modules on initiating and maintaining anticoagulant therapy which can help practitioners assess their current level of competence and provide training covering knowledge and understanding to promote safe practice. The e-learning modules are available at www.npsa.nhs.uk/health/alerts

A competence is an expectation of work performance. The process of preparing competences has been established by Skills for Health (www.skillsforhealth.org.uk). Work competences are intended to be multi-disciplinary and outline safe practice for all staff undertaking these responsibilities, including medical staff.

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The NPSA has developed six work competences for anticoagulant therapy:

- initiating anticoagulant therapy;
- maintaining anticoagulant therapy;
- managing anticoagulants in patients requiring dental surgery;
- dispensing oral anticoagulants;
- preparing and administering heparin therapy;
- reviewing the safety and effectiveness of an anticoagulant service.

Details of these work competences are available at:

www.npsa.nhs.uk/health/alerts

There are additional competences required when using anticoagulants in children, such as dose calculation and use of liquid formulations, which are outside the scope of this alert.

These work competences can be adapted and developed for local use. Local policies and procedures for the use of anticoagulants should reflect work competences. The use of these work competences will help to ensure consistency and transferability of anticoagulant skills of practitioners between organisations and healthcare sectors.

Local organisations are responsible for systems of clinical supervision where senior staff oversee and assess work competences of less-experienced staff.

Skills for Health are working with stakeholders to develop a competency framework for anticoagulant therapy. A revised set of competences will be issued in the future.

2 Review and, where necessary, update written procedures and clinical protocols for anticoagulant services to ensure they reflect safe practice, and that staff are trained in these procedures.

Healthcare organisations should have written procedures and clinical protocols for the safe use of oral and injectable anticoagulant therapy. These documents should be based on guidelines for anticoagulant therapy that have been published by the BSH Standards Taskforce.⁴⁻⁶ Details of how this guidance is to be delivered locally should be included in the local procedures and protocols. They should include:

- how to risk assess the benefits and risks of anticoagulant therapy for individual patients;
- information for the patient before anticoagulant therapy is commenced, prior to hospital discharge and on their first visit to the anticoagulant clinic;
- how to safely initiate anticoagulant loading doses, including the use of low dose loading for patients with atrial fibrillation;
- how to monitor anticoagulation and adjust dosage to achieve target INR range;
- safe systems for documenting results and treatment;
- effective communication systems when clinical responsibility for anticoagulant therapy is being transferred, for example, on discharge from hospital;
- an annual clinical review of patients on oral anticoagulants;
- how to safely discontinue anticoagulant therapy.



3 Audit anticoagulant services using BSH/NPSA safety indicators as part of the annual medicines management audit programme. The audit results should inform local actions to improve the safe use of anticoagulants, and should be communicated to clinical governance, and drugs and therapeutics committees (or equivalent). This information should be used by commissioners and external organisations as part of the commissioning and performance management process.

Audit of anticoagulant services using safety indicators should be included as part of the annual medicines management audit programme.

The BSH Standards Task Force, in collaboration with the NPSA, has developed a set of safety indicators for the use of oral anticoagulants for inpatients and ambulatory care patients that include laboratory, documentation and clinical indicators⁷ (see Appendix on page 10).

Additional safety indicators should also be developed locally to audit the use of fractionated and unfractionated heparin products.

There is evidence that anticoagulant dosing software helps to maintain the INR levels within the therapeutic range, extend the time between INR tests and effectively manage anticoagulant records facilitating service audit.⁸⁻¹¹

The NPSA has developed a template audit form that can be adapted and used for annual audit of both inpatient and ambulatory care anticoagulant services. The audit form is available at www.npsa.nhs.uk/health/alerts

The audit results should inform local actions to improve the safe use of anticoagulants, and should be communicated to clinical governance, and drugs and therapeutics committees (or equivalent). This information should also be used as part of the performance management process by commissioners and external organisations.

4 Ensure that patients prescribed anticoagulants receive appropriate verbal and written information at the start of therapy, at hospital discharge, on the first anticoagulant clinic appointment, and when necessary throughout the course of their treatment. The BSH and the NPSA have updated the patient-held information (yellow) booklet.

It is essential for the safe use of anticoagulants that patients and carers receive adequate verbal and written information about their treatment. This information should be provided before the first dose of anticoagulant is administered, and reinforced at hospital discharge, at the first anticoagulant clinic appointment, and when necessary throughout the course of their treatment. It is important that the healthcare practitioner who first provides this information records in the patient's healthcare record that this information has been supplied.

The BSH Standards Task Force and the NPSA have revised the patient-held yellow booklet and it has been re-named *Oral Anticoagulant Therapy: Important information for patients*.

The new booklet has three sections:

I Anticoagulant alert card

This is the size of a credit card and is designed to be carried by the patient at all times. It informs health professionals that the patient is taking oral anticoagulants, and provides a contact telephone number.

II General information about the safe use of oral anticoagulants

This reinforces the information that the prescribers and other healthcare professionals gave to the patient before the first dose of anticoagulant was administered, at hospital discharge, on the first anticoagulant clinic appointment, and when necessary throughout



the course of treatment. It is a concise guide on practical issues to consider when taking anticoagulants. This information is in a larger format than before and is intended to remain with the patient and be readily available for reference. The booklet is not intended to be carried by the patient at all times.

III Blood test results and dosage information

This section has space for a written record of the latest INR test results, dosage information and the next clinic appointment. These may be hand-written records made by a healthcare professional or the patient, or a computer-generated record sent to the patient by the anticoagulant clinic.

It is essential that a written record is always made following an INR blood test or dose adjustment. It is safe practice for these patient-held records to be maintained, even when the patient is admitted to hospital as an inpatient, to enable continuity of care.

The new booklet also has space for information concerning the local anticoagulant service and clinic contact details.

Electronic copies of the yellow booklet in English and a range of languages are available at **www.npsa.nhs.uk/health/alerts**

Supplies of these new items will be available from April 2007, from the current NHS Non-Secure Contract held by Astron. Trusts will be able to pre-order from 28 March 2007. Orders should be sent to Astron, NHS Team, Causeway Distribution Centre, The Causeway, Oldham Broadway Business Park, Chadderton, Oldham OL9 9XD or email **lisa.teefey@astron.co.uk**

If you have access to the electronic ordering system 'Astroweb', you can place your orders this way. This contract is managed by Kay Ellermeyer, National Programme Manager, NHS Non-Secure Forms. You can contact her on 01244 650458 or email **kay.ellermeyer@wcheshirepct.nhs.uk**

5 Promote safe practice with prescribers and pharmacists to check that patients' blood clotting (INR) is being monitored regularly and that the INR level is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.

In many cases, the healthcare professional who issues repeat prescriptions for anticoagulants, for example the general practitioner, is not the same practitioner who monitors and adjusts the dosage of the therapy, for example the anticoagulant clinic practitioner. It is for the prescriber supplying the repeat prescription to ensure that it is safe to do so. Repeat prescriptions of anticoagulants should only be issued if the prescriber has checked that the patient is regularly attending the anticoagulant clinic, that the INR test result is within safe limits, and that the patient understands what dose to administer. Reviewing the patient-held record when the repeat prescription is requested, and discussing the anticoagulant treatment at this time, is one method of doing this.

It is safe practice for the practitioner who dispenses repeat prescriptions for an anticoagulant, for example the pharmacist, to also ensure it is safe to dispense. There may have been some delay between the prescription being written and it being dispensed. It should not be assumed that the prescriber has undertaken the safety checks in all cases. Reviewing the patient-held record, which includes the date of the last clinic appointment, the latest INR test result and current dose, and confirming this information with the patient, is recommended as safe practice.

If the patient is unable to request or collect the oral anticoagulant prescription in person and instead sends a representative, this person should provide the patient-held information instead. The patient or carer should be contacted if any of the information is unavailable.

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The NPSA recommends that prescribing and dispensing software should include functionality to enable the date of the last clinic appointment, the latest INR test result and current dose to be recorded when this information is being checked prior to issuing or dispensing a repeat prescription for an oral anticoagulant.

6 Promote safe practice for prescribers co-prescribing one or more clinically significant interacting medicines for patients already on oral anticoagulants; to make arrangements for additional INR blood tests, and to inform the anticoagulant service that an interacting medicine has been prescribed. Ensure that those dispensing clinically significant interacting medicines for these patients check that these additional safety precautions have been taken.

Many medicines interact with oral anticoagulant therapy. Often, the healthcare professional prescribing other medicines, for example the general practitioner, might not be the same person monitoring and adjusting the dosage of the therapy, who could be the anticoagulant clinic practitioner.

If possible, medicines should be selected that do not produce clinically significant interactions. If this is not possible, the prescriber who initiates or discontinues a prescription for an interacting medicine is responsible for ensuring that the patient is informed that an interacting medicine has been commenced or discontinued. They should also tell the patient to arrange an INR test within four to seven days of the start or discontinuation of the interacting medicine. The patient should be instructed to provide details of the change in therapy when the blood sample is taken. This information can then be recorded on the test request form to inform the anticoagulant clinic. Once notified in this way, the anticoagulant clinic may require additional INR tests and may need to adjust the dose of the oral anticoagulant accordingly.

In the same way, healthcare professionals dispensing other medicines for patients maintained on anticoagulants must not assume that additional INR tests have been arranged and the anticoagulant clinic informed. When dispensing or noting the discontinuation of an interacting medicine, it is safe practice for healthcare professionals to check that these additional safety precautions have been taken. Where no additional precautions have been taken, they must inform the patient and the prescriber, where necessary, that an additional INR test may be required. The anticoagulant clinic needs to be informed of the change.

The NPSA recommends that prescribing and dispensing software should include functionality to enable details of the interacting medicines and the request for the patient to arrange additional INR tests to be recorded.

7 Ensure that dental practitioners manage patients on anticoagulants according to evidence-based therapeutic guidelines. In most cases, dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.

In some cases, patients on anticoagulant therapy have had their dental treatment delayed or cancelled, their anticoagulant therapy temporarily discontinued or their dose reduced. This has, in part, been due to a lack of understanding of evidence-based practice guidelines. In most cases, dental treatment can proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.

The NPSA has been working with the British Dental Association and the BSH to produce a poster outlining safe practice guidelines for patients on anticoagulants requiring dental therapy. The NPSA is arranging to send a copy of this poster to every dental practice in England and Wales. A copy of this poster is available at www.npsa.nhs.uk/health/alerts



A leaflet providing advice for patients on oral anticoagulants receiving dental treatment is available at www.npsa.nhs.uk/health/alerts. The leaflet is available in a range of languages.

8 Amend local policies to standardise the range of anticoagulant products used, incorporating characteristics identified by patients as promoting safer use.

Warfarin

Across NHS organisations, there is wide variation in the supply and dosing methods used for warfarin tablets. This can be complex and confusing for patients and carers, as well as healthcare professionals.

Patient and carer groups have informed the NPSA that warfarin regimens with the following characteristics would promote safer use:

- use the least number of tablets each day;
- use constant daily dosing and not alternate day dosing;
- not require the use of half tablets – patients find it difficult to break tablets in half and instead, when necessary, would rather use 0.5mg tablets.

The NPSA recommends that NHS organisations should review their local practice to incorporate these characteristics. All strengths of warfarin tablets should be used to best meet the needs of individual patients. Not all patients will need all strengths of tablets.

It is recommended that oral anticoagulant doses should be expressed in mg and not as the number of tablets.

Intravenous sodium heparin

The use of intravenous sodium heparin infusions has reduced significantly in recent years following the introduction of low molecular weight heparin products. However, there is still some use of intravenous sodium heparin infusions, requiring the dilution of concentrated heparin products in clinical areas. It is recommended that the NHS adopt a standardised ready-to-administer infusion of sodium heparin (1,000 units presented in 1ml ampoule, vial or prefilled syringe), and minimise the use of concentrated heparin products. Changes in daily dose should be made by adjusting the rate of administration; the standardised sodium infusion concentration should remain unchanged.

When prescribing injectable heparin the word 'units' should always be used to express doses. Symbols or abbreviations such as 'U' should not be used as these can be misread and cause dosage errors.

9 Promote the use of written safe practice procedures for the administration of anticoagulants in social care settings. It is safe practice for all dose changes to be confirmed in writing by the prescriber. A risk assessment should be undertaken on the use of Monitored Dosage Systems for anticoagulants for individual patients. The general use of Monitored Dosage Systems for anticoagulants should be minimised as dosage changes using these systems are more difficult.

The safe use of oral anticoagulants in social care settings requires particular mention. This includes care homes and when home care workers support patients in their own homes. National Minimum Standards for care homes and domiciliary care agencies require providers to have written policies and procedures for medicines. This is supported by the Royal Pharmaceutical Society's publication, *The administration and control of medicines in care homes and children's services*.¹² The NPSA recommends that local policies should incorporate a specific section on oral anticoagulants.



The dose of oral anticoagulants is likely to change from time to time and it is safe practice that anticoagulant clinics provide clear written dosing instructions for care workers. It is safe practice to attach the written confirmation of the oral anticoagulant dosage, supplied by the anticoagulant clinic, to the medicine administration record (MAR) used by the care provider. Verbal dose changes should only be used in emergencies, and always confirmed in writing as soon as possible.

There is widespread use of Monitored Dosage Systems in care homes and in the community at large. Although the use of these systems may be beneficial for other types of medicines, where dose changes are infrequent, the use of anticoagulants in these dosage systems is not recommended. These systems are usually not flexible enough to facilitate frequent dose changes. It is recommended that oral anticoagulants are administered from the original packs dispensed for individual patients.

There may be some patients in the community, outside of care home settings, that use compliance aids to help them manage their medicines. Oral anticoagulants may still be used with these compliance aids provided that, if they require filling, whoever fills these aids ensures that the tablets in the compliance aid match the latest prescribed dose.

Cost implications of implementing NPSA advice

The new patient information booklet, *Oral Anticoagulant Therapy: Important information for patients*, will cost more than the current yellow book. However, it will only need to be issued once because it uses A4 continuation sheets or separate record books each time the record section is completed.

Purchasing ready-to-use sodium heparin infusions may have an additional cost of less than £1,000 per year for average trusts.

None of the other action points are likely to incur significant additional costs.

Further details

For further information about the NPSA's work on anticoagulants, please contact:

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For more information about how you can improve patient safety, visit www.saferhealthcare.org.uk – one stop for knowledge and innovation for safer healthcare.



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Appendix – Safety indicators for anticoagulant services

The NPSA and the British Committee for Standards in Haematology have identified safety indicators for inpatient and ambulatory anticoagulant services.⁷ Indicators have been developed for starting and maintaining anticoagulant therapy. Monitoring these indicators will help to identify risks and promote the appropriate action to minimise them.

Safety indicators for patients starting oral anticoagulant treatment

- 1 Percentage of patients following loading protocol.
- 2 Percentage of patients developing INR > 5.0.
- 3 Percentage of patients in therapeutic range at discharge.
- 4 Percentage (incidence) of patients suffering a major bleed in first month of therapy, and percentage suffering major bleed with INR above therapeutic range.
- 5 Percentage of new referrals to anticoagulant service (hospital or community-based) with incomplete information, for example, diagnosis, target INR, stop date for anticoagulant therapy, dose of warfarin on discharge and list of other drugs on discharge.
- 6 Percentage of patients that were not issued with patient-held information and written dosage instructions at start of therapy.
- 7 Percentage of patients that were discharged from hospital without an appointment for the next INR measurement or for consultation with appropriate healthcare professional to review and discuss treatment plan, benefits, risks and patient education.
- 8 Percentage of patients with subtherapeutic INR when heparin stopped.

Safety indicators for patients established on oral anticoagulant treatment

- 1 Proportion of patient-time in range (if this is not measurable because of inadequate decision/support software then secondary measure of percentage of INRs in range should be used).
- 2 Percentage of INRs > 5.0.
- 3 Percentage of INRs > 8.0.
- 4 Percentage of INRs > 1.0 INR unit below target (e.g. percentage of INRs < 1.5 for patients with target INR of 2.5).
- 5 Percentage of patients suffering adverse outcomes, categorised by type, such as a major bleed.
- 6 Percentage of patients lost to follow-up (and risk assessment of process management for identifying patients lost to follow-up).
- 7 Percentage of patients with unknown diagnosis, target INR or stop date.
- 8 Percentage of patients with inappropriate target INR for diagnosis, high and low.
- 9 Percentage of patients without written patient education information.
- 10 Percentage of patients without appropriate clinical information, e.g. diagnosis, target INR, last dosing record.

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A patient safety alert requires prompt action to address high risk safety problems.

This patient safety alert was written in the following context:

It represents the view of the National Patient Safety Agency, which was arrived at after consideration of the evidence available. It is anticipated that healthcare staff will take it into account when designing services and delivering patient care. This does not, however, override the individual responsibility of healthcare staff to make decisions appropriate to local circumstances and the needs of patients and to take appropriate professional advice where necessary.

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