The National Patient Safety Agency (NPSA) has identified oral anticoagulants and heparin as major causes of adverse events and hospital admission. According to its research, anticoagulants are implicated in 8-10 per cent of preventable drug-related admissions and are increasingly associated with adverse incidents, including some fatalities, reported to medical defence agencies (see Figure 2).

The NPSA lists 15 high-risk steps in the use of anticoagulants, reflecting shortcomings in all aspects of management (see Table 1). Its response is a new patient safety alert (see Figure 1), backed up by a comprehensive range of support materials.

The deadline for agreeing an action plan and starting implementation is 2 July 2007; all actions should be completed by 31 March 2008.

What is a patient safety alert?

There are three formats by which the NPSA disseminates its advice and recommendations for solving problems:

- **Patient safety information** suggests issues or effective techniques that healthcare staff might consider to enhance safety
- **Safer practice notices** strongly advise implementing particular recommendations or solutions
- **Patient safety alerts** require prompt action to address high-risk safety problems.

A patient safety alert includes concise and detailed summaries of the action the NPSA recommends to tackle a particular risk. It is addressed to the relevant bodies in the NHS and independent health sectors, eg acute trusts or all organisations, and identifies which personnel should take action and which other staff should be informed.

The anticoagulant alert is for action by the chief pharmacist or pharmaceutical adviser in England and Wales and response by all NHS and independent sector organisations.

Alerts are published in full on the NPSA’s web site (www.npsa.nhs.uk) and form part of the DoH’s Safety Alert Broadcast System. There are four categories of alert (see Table 2); the anticoagulant alert calls for ‘action’.
Making anticoagulants safer

The anticoagulant alert includes a large number of documents for downloading from the NPSA website. These include: the patient safety alert itself, a briefing for patients, educational modules for health professionals, detailed work competencies for different aspects of using anticoagulants and a summary of the NPSA’s consultations.

An additional section contains standards and guidelines of the British Society of Haematology (BSH), and information for patients and carers includes an alert card, a treatment record form and a treatment record booklet.

Actions to improve safety

The patient safety alert lists nine action points covering staff training, clinical protocols, anticoagulation services, patient information, monitoring standards, standardising prescribing and improving safe practice in social care settings (see Table 3).

Staff competency

Training in the use of anticoagulants should be provided to staff. This includes not only doctors and nurses but also medical students, pharmacists and biomedical scientists.

The NPSA has developed six work competencies for initiating treatment, maintaining treatment, management in patients needing dental surgery, dispensing oral anticoagulants, preparing and administering heparin, and reviewing the safety and effectiveness of services. This is supported by two e-modules on the BMJ e-learning website covering the initiation and maintenance of treatment. The competencies do not include the use of anticoagulants in children.

The competencies are intended for adaptation to local practice but at the same time the NPSA wants to ensure that skills are transferable between organisations and healthcare sectors.

Revised competencies will be developed by Skills for Health (www.skillsforhealth.org.uk) following consultation with stakeholders.

Updating procedures

All organisations should have written procedures on the use of oral and injectable anticoagulants, based on standards set out by the BSH (www.bshguidelines.com). These should cover risk assessment of treatment, providing patient information, initiating, adjusting and monitoring treatment, safe documentation, communication, annual review and treatment discontinuation.

Audit

The NPSA and the BSH have jointly developed safety indicators with which to audit the initiation and maintenance of treatment; these are provided as part of the alert. For example, indicators for patients established on treatment include the percentages with INR (international normalised ratio) >5.0 or >8.0, and the percentage suffering adverse outcomes such as a major bleed.

Indicators to audit the safe use of heparin are not included and should be developed locally.

The audit results should be used to improve services as part of clinical governance but also to aid performance management by commissioners. A template audit form is available online.

Patient information

Patients should be given verbal and written information about their treatment before the first dose of anticoagulant is administered; this should be recorded in the notes. The messages should be reinforced on discharge from hospital, at the first clinic appointment, and when necessary thereafter.

The BSH has revised the yellow booklet for patients, which is
now titled *Oral Anticoagulant Therapy: Important Information for Patients*. It has three sections: a credit card-sized alert card to be carried by the patient, general information about anticoagulant treatment and a record of INR results, doses and clinic appointments. These records should be maintained even when patients are in hospital.

The booklets are available in a range of languages and can be downloaded from the NPSA website. NHS trusts and others can order hard copies from NHS suppliers.

### Checking INR

A repeat prescription should not be issued unless the patient is regularly attending the clinic, the INR is within safe limits, and the patient understands what dose to take. This information should be added to the patient-held record.

Responsibility for ensuring that it is safe to issue or dispense a repeat prescription lies with the prescriber and the pharmacist. Prescribers should check the patient-held record and obtain any missing data that are needed. Pharmacists should not assume this has been done and should check the record for themselves.

### Drug interactions

When possible, drugs should be prescribed that do not interact with anticoagulants. When this is not practical, the health professionals who prescribe or dispense other medicines must ensure that patients are aware of the potential effect of their new treatment (or the effects of discontinuing an established drug). They should be instructed to have an INR test within four to seven days and tell the clinic why;

### High risks identified

1. Not all staff who prescribe and monitor anticoagulants have received the necessary training and have the required work competencies.
2. Inadequate clinical audit of anticoagulant services and/or failure to act on audit results to improve the service.
3. Failure to initiate anticoagulant therapy (including thromboprophylaxis) where indicated.
4. Poor documentation of reason and treatment plan at commencement of therapy.
5. Prescribed wrong dose or no dose of anticoagulant (especially loading doses).
6. Unconsidered co-prescribing and monitoring of NSAIDs and other interacting medicines.
8. Unsafe arrangements and communications at discharge from hospital.
9. Insufficient support and monitoring of warfarin therapy for the first 3 months and for vulnerable groups.
10. Inadequate safety checks at repeat prescribing and repeat dispensing in the community.
11. Confusion over anticoagulant management for dentistry, surgery and other procedures.
12. Nonstandardised supply/use of 0.5mg, 1mg, 3mg and 5mg tablets.
13. Yellow book (patient-held information) in need of revision and translation into other languages.
14. Inflexible medicines presentations and arrangements in care homes to implement anticoagulant dose changes.
15. Inadequate Quality Assessment (QA) for near-patient testing equipment.

### Important observations

Failure to implement professional guidelines concerning the prescribing, counselling, monitoring and administering of anticoagulants is an important underlying problem identified by the risk assessment process. It has been perpetuated by local failure to audit anticoagulant services effectively, to act on audit results to improve clinical and process outcomes, and to alert clinical governance structures in NHS organisations to the extent of the risk.

Table 1. High-risk factors in the management of anticoagulants highlighted in the patient safety alert

<table>
<thead>
<tr>
<th>Immediate action: Used in cases where there is a risk of death or serious injury and where the recipient is expected to take immediate action on the advice.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Action:</strong> used where the recipient is expected to take action on the advice, where it is necessary to repeat warnings on long-standing problems, or to support or follow-up manufacturers’ field modifications.</td>
</tr>
<tr>
<td><strong>Update:</strong> used to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device group basis, and where further follow-up safety information is judged to be beneficial.</td>
</tr>
<tr>
<td><strong>Information request:</strong> used to alert users about a specific issue that may become a problem and where feedback is requested. These alerts will be sent out with additional questions to be completed.</td>
</tr>
</tbody>
</table>

Table 2. Patient safety alert category descriptions

Prescribers should check the patient-held record and obtain any missing data that are needed. Pharmacists should not assume this has been done and should check the record for themselves.
subsequent tests and dose adjustments are carried out by the clinic.

**Dental treatment**

In most cases, dental treatment can proceed as normal and no change to anticoagulant therapy is needed.

Every dental practice in England and Wales is to receive a poster, developed by the NPSA, BSH and the British Dental Association, outlining safe practice. A patient leaflet in a range of languages is available from the NPSA website.

**Standardising anticoagulants**

The NPSA has found wide variation between NHS organisations in the supply and dosing methods for warfarin. It recommends standardisation according to principles developed by patients and carer groups:

- use the least number of tablets each day
- use constant daily dosing, not alternate-day dosing
- do not use half tablets.

All strengths of warfarin tablets should be used to implement these principles. Doses should be expressed as mg and not number of tablets.

*Ad hoc* dilution of concentrated heparin solution for intravenous injection should be minimised. The NHS should standardise on a ready-to-administer heparin solution of 1000 units per ml in ampoule, vial or prefilled syringe. When prescribing, doses should be expressed as ‘units’, not ‘U’.

**Social settings**

Written policies for medicines use in care homes should include a specific section on oral anticoagulants. Written confirmation of dosage should be included in the medicine administration record; verbal instructions should be followed only in emergencies and should be confirmed in writing.

Anticoagulants should not be included in monitored dosage systems because they are not sufficiently flexible to accommodate frequent dose changes. Instead, oral anticoagulants should be administered from original packs dispensed for individual patients. Health professionals should ensure that the latest prescribed

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1. Ensure all staff caring for patients on anticoagulant therapy have the necessary work competencies. 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 (INR) is being monitored regularly and that the INR level is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.
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 appropriately.
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.

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**Table 3.** Nine action points listed in the patient safety report for implementation to improve patient safety
dose is provided for patients living in the community who use compliance aids.

Summary
The NPSA's alert on anticoagulants is a comprehensive and detailed package of practical measures to improve safety in clinical practice. It is relevant to everyone in primary and secondary care involved in supplying or monitoring treatment and offers an achievable means of reducing the morbidity and mortality associated with anticoagulants.

References

Steve Chaplin is a pharmacist who specialises in writing on therapeutics.