
NHS
National Patient Safety Agency
Improving the safe use of anticoagulant therapy
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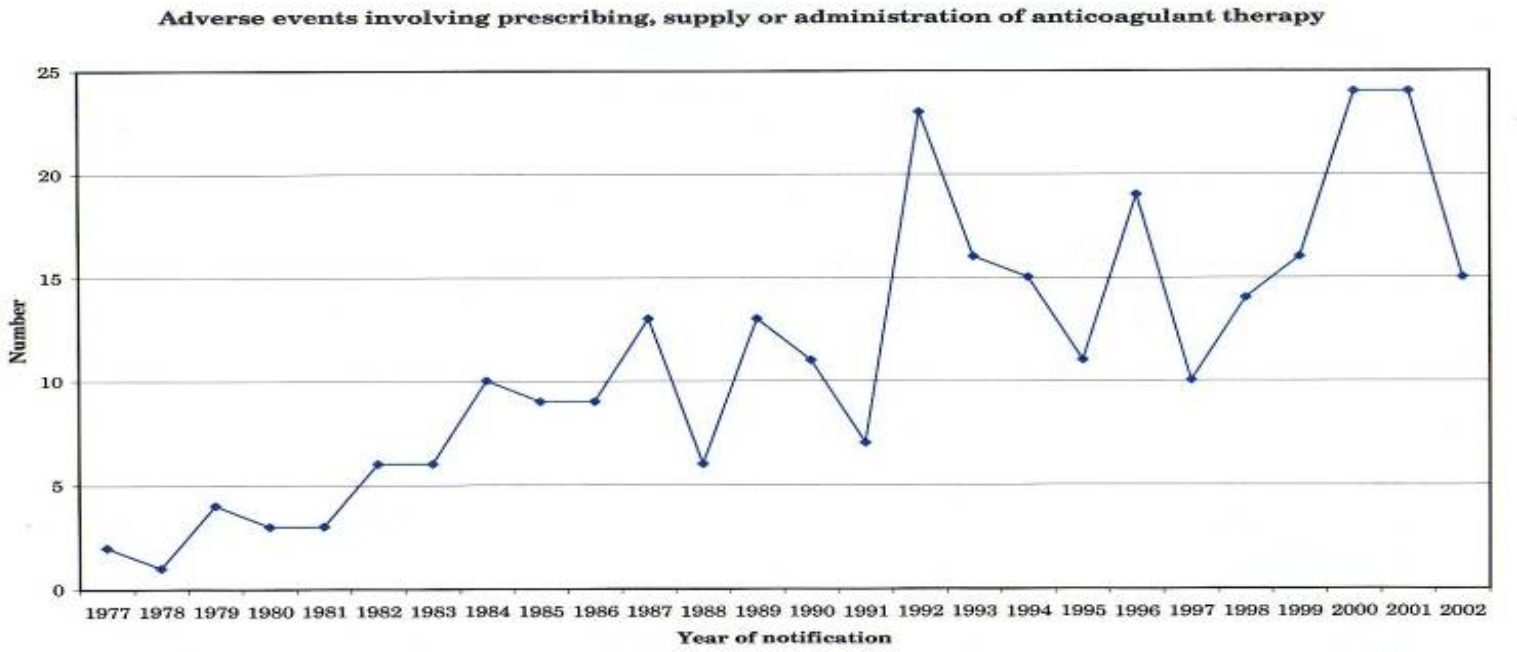
Risk Assessment
Anticoagulant Treatment Process

- The NPSA contacted the medical and pharmacy defence organisations as well as the NHS Litigation Authority.
- There have been 480 reported cases of harm or near harm from the use of anticoagulants in the UK from 1990-2002.
- In addition there have been 120 deaths reported over the same time period.
- Deaths from the use of warfarin is responsible for 77% (92 reports) and heparin is responsible 23% (28 reports).

Incidence of Patient Safety Incidents with Anticoagulants 1977 - 2002



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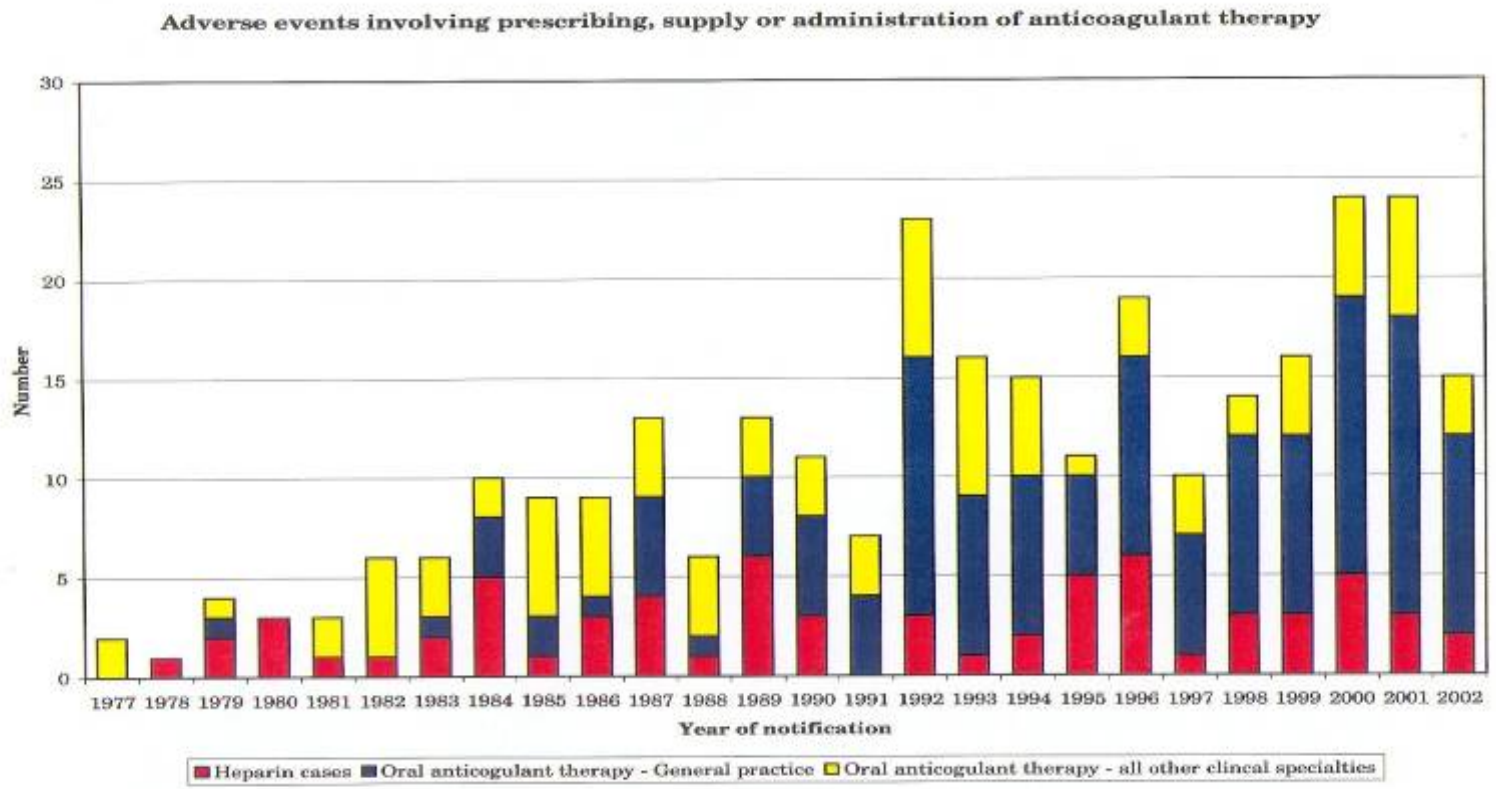

Risks Of Anticoagulant Services 1

- Not all staff who prescribe and monitor anticoagulants have received the necessary training and have the required work competences
- Inadequate clinical audit of anticoagulant service and/or failure to act on audit results to improve the service.
- Failure to initiate anticoagulant therapy (including thromboprophylaxis) where indicated.
- Poor documentation of the clinical indication and treatment plan at commencement of therapy.
- Prescribed wrong dose or no dose of anticoagulant (especially loading doses).
- Unconsidered co-prescribing and monitoring of non-steroidal anti-inflammatories and other interacting medicines.
- Incorrect selection, preparation and administration of heparin products.

Risks Of Anticoagulant Service 2

- Unsafe arrangements and communications at discharge from hospital.
- Insufficient support and monitoring of warfarin therapy for the first three months and for vulnerable groups.
- Inadequate safety checks at repeat prescribing and repeat dispensing in the community.
- Confusion over anticoagulant management for dentistry, surgery and other procedures.
- Non-standardised supply/use of 0.5mg, 1mg, 3mg and 5mg tablets.
- Yellow book, patient held information – in need of revision – and translation into other languages.
- Inflexible medicines presentations and arrangements in care homes to implement anticoagulant dose changes.
- Inadequate quality assessment of near patient testing equipment.

Proposed Patient Safety Recommendations For Anticoagulants 1

1. Ensure staff who prescribe, adjust the dosage and monitor anticoagulant therapy have received adequate training and have the necessary work competences to undertake their duties safely. There is evidence that including nurses and pharmacists with these competences, in addition to medical staff, can help deliver inpatient and ambulatory care more safely.
2. Undertake regular audit of safety indicators for anticoagulant services.. These indicators should inform local actions to improve the safe use of anticoagulants. There is evidence that using computer dosing software for decision support and audit can improve practice.
3. Update systems for ensuring patients prescribed anticoagulants receive appropriate verbal and written information concerning their anticoagulant therapy at the start of therapy and again on discharge from hospital. The new template for patient held information developed by British Society of Haematolgy should be adapted for local use.

Proposed Patient Safety Recommendations For Anticoagulants 2

4. Implement local policies for prescribers and pharmacists to check that the patients' INR is being monitored regularly and is safe before providing repeat prescriptions for oral anticoagulants.
5. Establish procedures for prescribers co-prescribing one or more interacting medicine for patients already on oral anticoagulants to make arrangements for additional INR blood tests and inform the anticoagulant service that an interacting medicine has been prescribed.
6. Ensure that dental practitioners manage patients on anticoagulants according to evidenced based therapeutic guidelines. In most cases dental treatment should proceed as normal and oral anticoagulant treatment should not stopped or the dosage decreased inappropriately.
7. Amend local policies to standardise and simplify the anticoagulant products used.
8. Promote the use of written safe practice procedures for the use of anticoagulants in care homes, including the requirement for written confirmation of dose changes from prescribers and not to use monitored dosage systems.

1. Training and work competences

- NHS organisations must ensure that staff who prescribe, adjust the dosage and monitor anticoagulant therapy have received adequate training and have the necessary work competences to undertake their duties safely.
- There is evidence that including nurses and pharmacists with these competences, in addition to medical staff, can help deliver inpatient and ambulatory care more safely.
- A competence is an expectation of work performance. The process of preparing competences has been established by Skills for Health (www.skillsforhealth.org.uk).

1. Training and work competences

- The NPSA has developed six draft work competences for anticoagulant therapy:
  - Initiating anticoagulant therapy.
  - Maintaining anticoagulant therapy.
  - Managing anticoagulants in patients requiring dental surgery
  - Dispensing anticoagulants.
  - Preparing and administering heparin therapy.
  - Reviewing the safety and effectiveness of an anticoagulant service
- Details of these draft work competences will be available in the *anticoagulant discussion group in the medication practice section at* www.saferhealthcare.org.uk/ihi/forums
- These work competences can be adapted and developed for local use. The NPSA recommends that Skills for Health working with other stakeholders develop the competency framework for anticoagulant therapy.

1. Training and work competences

- In order to assist practitioners assess their current level of competence and to provide training materials covering the defined knowledge and understanding, the NPSA has commissioned e-learning modules from Professor David Fitzmaurice and the Department of General Practice, University of Birmingham.
- These e-learning materials will be available at www.saferhealthcare.org.uk at the same time the NPSA publishes final recommendations.

2. Patient safety indicators

- It is essential that safety indicators for anticoagulant services for inpatients and ambulatory care patients are audited to ensure that the system for anticoagulant use is safe and that any system risks are addressed.
- The BSH Standards Task Force are developing anticoagulant service safety indicators that include laboratory, documentation and clinical indicators. The NPSA recommends that these safety indicators are used to ensure anticoagulant services are safe. Further details of these indicators will be available at www.bcshguidelines.com at the same time the NPSA publishes final recommendations.

2. Patient safety indicators

- NHS organisations should audit their anticoagulant services at least annually.
- Audit results and an action plan to improve poorly performing aspects of these services should be communicated to Clinical Governance and Drugs and Therapeutics Committees each year and this information should also be used as part of the performance management process by external organisations.
- 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.

2. Safety indicators for patients starting oral anticoagulant

- Percentage of patients following loading protocol
- Percentage of patients developing INR > 5.0.
- Percentage of patients in therapeutic range at discharge.
- Percentage (incidence) of patients suffering a major bleed in first month of therapy and percentage suffering major bleed with INR above therapeutic range.
- Percentage of new referrals to anticoagulant service (hospital or community based) with incomplete information
- Percentage of patients that were not issued with patient held information and written dosage instructions at start of therapy.
- Percentage of patients that were discharged from hospital without essential information

2. Safety indicators for patients established on anticoagulant

- Proportion of patient-time in range.
- Percentage of INRs > 5.0.
- Percentage of INRs > 8.0.
- Percentage of INRs > 1.0 INR unit below target (e.g. percentage of INRs < 1.5 for patients with target INR of 2.5).
- Percentage of patients suffering adverse outcomes, categorised by type, e.g. major bleed.
- Percentage of patients lost to follow up (and risk assessment of process management for identifying patients lost to follow up).
- Percentage of patients with unknown diagnosis, target INR or stop date.
- Percentage of patients with inappropriate target INR for diagnosis, high and low.
- Percentage of patients without written patient educational information.
- Risk assessment of standard operating procedures

3. Update systems for verbal and written information for patients

- Information should be provided before the first dose of anticoagulant is administered, reinforced at hospital discharge, on the first anticoagulant clinic appointment and when necessary throughout the course of treatment.
- It is important that the healthcare practitioner, who first provides this information, records that this information has been supplied in the patients healthcare record.

3, Update systems for verbal and written information for patients

- The BSH Standards Task Force is revising the template for the patient held anticoagulant record.
- he record consists of two parts 1) General information about the safe and effective use of oral anticoagulants 2) Specific information about the latest INR level, dose and date of next appointment. Part two information should be updated following each clinical appointment/INR test.
- The patient information templates will be available at www.bcshguidelines.com
- It is the responsibility of individual healthcare organisations to develop patient held information from these templates to meet local needs. A two compartment folder presentation is recommended. Central supply of old style anticoagulant therapy yellow books will no longer be available.

3, Update systems for verbal and written information for patients

- It is essential that written confirmation is supplied for all anticoagulant dose changes. Verbal instructions can be used where rapid communication is required, but this must always be confirmed in writing.
- A chronological record of INR test results and anticoagulant doses in the patient held record should be maintained, even when the patient is admitted to hospital as an inpatient, to enable continuity of care.

4. Safe practice on repeat prescribing and dispensing

- It is essential that the prescriber supplying a repeat prescription for anticoagulant ensures that it is safe to continue to prescribe this therapy.
- Repeat prescriptions of anticoagulants should only be issued if the prescriber has checked that the patient is regularly attending the anticoagulant clinic, the INR test result is within safe limits, and the patient understands what dose to administer.
- Reviewing the patient held record at the same time as the repeat prescription is requested is a quick and easy method of checking this information.

4. Safe practice on repeat prescribing and dispensing

- It is also essential that the practitioner who dispenses repeat prescriptions for anticoagulants (e.g. pharmacist) ensures it is safe to dispense. There may have been some delay between the prescription being prescribed and it being dispensed and it cannot be assumed that the prescriber has undertaken the safety checks in all cases.
- The NPSA is working with Connecting for Health to ensure that NHS accreditation standards for software incorporates a requirement for functionality that enables this information to be checked and recorded to ensure safe practice when repeat prescriptions for anticoagulants are requested and processed.

5. Procedures for co-prescribing one or more interacting medicines

- Many other medicines interact with oral anticoagulant therapy. In many cases the practitioner who prescribes other medicines for a patient on anticoagulants (e.g. General Practitioner) is not the same practitioner who monitors and adjusts the dosage of the therapy (anticoagulant clinic practitioner).
- Where possible, medicines should be selected that do not produce clinically significant interactions.
- Where this is not possible the prescriber who initiates the prescription for an interacting medicine is responsible for ensuring that the patient and anticoagulant clinic is informed that an interacting medicine has commenced and arranging an INR test within 4-7 days of the start of the interacting medicine.

5. Procedures for co-prescribing one or more interaction medicines

- It is also important that when interacting medicines are discontinued for a patient on anticoagulant therapy, that the anticoagulant clinic is informed and additional blood tests are performed. Again it is the responsibility of the prescriber discontinuing the medicines to take action.
- Health 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 interacting medicines for these patients they must check that these additional safety precautions have been taken. Where no additional precautions have been taken they must inform the patient and the prescribe of the interaction in order to help remind them to arrange additional INR tests and possible dosage adjustment.

6. Ensure that dental practitioners manage patients on anticoagulants according to evidenced based therapeutics guidelines.

- In some cases patients on anticoagulant therapy have their dental treatment delayed or cancelled and/or their anticoagulant therapy temporarily discontinued or the dose reduced due to lack of understanding of evidence based practice guidelines. In most cases dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately
- The NPSA has worked with the British Dental Association, and the British Society of Haematology to produce a poster outlining safe practice guidelines for patients on anticoagulants requiring dental therapy.

7. Standardised methods of medicine product supply and dosage adjustment.

- There is wide variation in the supply and dosing methods used for warfarin tablets use in NHS organisations in England and Wales, and this leads to complexity and confusion for patients, carers and healthcare professionals
- Patient and carer groups have informed the NPSA that they would prefer warfarin regimens to have the following characteristics to promote safe 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. Patient find it difficult to break tablets in half. Instead when necessary use 0.5mg tablets.
- The NPSA recommends that NHS organisations should review their local regimens to incorporate these characteristics.

Example regimen

- Less than 5mg daily dose.
  - Supply 1mg and where necessary 0.5mg tablets.
  - Use the same dose each day.
  - Use dose changes of 0.5mg – 1mg.
- Between 5mg – 9mg daily dose
  - Supply 1mg and 3mg tablets.
  - Use the same dose each day.
  - Use dose changes of 1mg.
- 10mg or greater daily dose.
  - Supply 1mg and 5mg tablets.
  - Use the same dose each day.
  - Use dose changes of 1mg.

Supply of sodium heparin infusions

- There is still some use of intravenous sodium heparin infusions, requiring the dilution of concentrated heparin products in clinical areas.
- It is recommended that where-ever possible that the NHS adopt a standardised ready to administer infusion of sodium heparin 1000 units in 1 ml presented as either a 50 ml vial/ampoule or prefilled syringe, and minimises 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.
- Hospital pharmacy departments should source this ready to administer preparation from hospital manufacturing units or commercial specials suppliers.

8. Safe practice procedures for anticoagulants in care homes

- It is essential that there are clear written dosing instructions to guide care home staff.
- It is safe practice to attach the written confirmation of the oral anticoagulant dosage supplied by the anticoagulant service to the medicine administration record (MAR).
- The use of verbal instructions issued by anticoagulant services to change the dose of patients in care homes should only be used in emergencies and always confirmed in writing as soon as possible.

8. Safe practice procedures for anticoagulants in care homes

- There is wide spread use of monitored dosage systems in care homes.
- Although the use of these systems may provide benefits for other types of medicines where there are infrequent dose changes, the use of anticoagulants in these dosage systems is not recommended as 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.

Wide Stake holder Consultation on Proposed NPSA Safer Practice Recommendations Medicine Topics –
Closes 31st March 2006

More information on recommendations and response form – and open discussion forum at

www.saferpractice.org.uk

Communities – medication discussion forums