

National enhanced service

Anti-coagulation monitoring

Introduction

1. All practices are expected to provide essential and those additional services they are contracted to provide to all their patients. This enhanced service specification for the provision of anti-coagulant monitoring outlines the more specialised services to be provided. The specification of this service is designed to cover the enhanced aspects of clinical care of the patient, all of which are beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

Background

2. Warfarin is being used in the management of increasing numbers of patients and conditions including patients post-myocardial infarction, atrial fibrillation, DVTs and other disorders. While it is a very effective drug in these conditions, it can also have serious side effects, eg severe haemorrhage. These side effects are related to the International Normalised Ratio (INR) level, which measures the delay in the clotting of the blood caused by the warfarin. While the "normal" INR is 1, the specific range of INR values depends on the disease and the clinical conditions. Warfarin monitoring aims to stabilise the INR within set limits to help prevent serious side-effects while maximising effective treatment.

Aims

3. An anti-coagulation monitoring service is designed to be one in which:
 - (i) therapy should normally initiated in secondary care, for recognised indications for specified lengths of time
 - (ii) maintenance of patients should be properly controlled
 - (iii) the service to the patient is convenient
 - (iv) the need for continuation of therapy is reviewed regularly
 - (v) the therapy is discontinued when appropriate.

Definitions

4. 'Doser' means any person who is suitably trained and qualified who, upon receipt of relevant information from laboratories or near-patient testing equipment or otherwise, with or without computer-assisted decision-making equipment, determines as the relevant service may require, the anti-coagulant dosage for patients of practitioners in a practice.

Service outline

5. This national enhanced service will fund:
 - (i) **the development and maintenance of a register.** Practices should be able to produce an up-to-date register of all anti-coagulation monitoring service patients, indicating patient name, date of birth, the indication for, and length of, treatment, including the target INR

- (ii) **call and recall.** To ensure that systematic call and recall of patients on this register is taking place either in a hospital or general practice setting
- (iii) **professional links.** To work together with other professionals when appropriate. Any health professionals involved in the care of patients in the programme should be appropriately trained
- (iv) **referral policies.** When appropriate to refer patients promptly to other necessary services and to the relevant support agencies using locally agreed guidelines where these exist
- (v) **education and newly diagnosed patients.** To ensure that all newly diagnosed patients (and/or their carers and support staff when appropriate) receive appropriate management of, and prevention of, secondary complications of their condition including the provision of a patient-held booklet.
- (vi) **individual management plan.** To prepare with the patient an individual management plan, which gives the diagnosis, planned duration and therapeutic range to be obtained
- (vii) **clinical procedures.** To ensure that at initial diagnosis and at least annually an appropriate review of the patient's health is carried out including checks for potential complications and, as necessary, a review of the patient's own monitoring records. To ensure that all clinical information related to the NES is recorded in the patient's own GP held lifelong record, including the completion of the "significant event" record that the patient is on warfarin
- (viii) **record-keeping.** To maintain adequate records of the performance and result of the service provided, incorporating appropriate known information, as appropriate. This may include the number of bleeding episodes requiring hospital admission and deaths caused by anti-coagulants
- (ix) **audit.** To carry out clinical audit of the care of patients against the above criteria, including untoward incidents. This should also review the success of the practice in maintaining its patients within the designated INR range as part of quality assurance
- (x) **training.** Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so
- (xi) **review.** All practices involved in the scheme should perform an annual review which could include:
 - (a) information on the number of patients being monitored, the indications of anticoagulation, ie DVT etc, and the duration of treatment
 - (b) brief details as to arrangements for each of the aspects highlighted above
 - (c) details of any computer-assisted decision-making equipment used and arrangements for internal and external quality assurance
 - (d) details of any near-patient testing equipment used and arrangements for internal and external quality assurance
 - (e) details of training and education relevant to the anti-coagulation monitoring service received by practitioners and staff
 - (f) details of the standards used for the control of anti-coagulation.

Untoward events

6. It is a condition of participation in this NES that practitioners will give notification to the PCO clinical governance lead of all emergency admissions or deaths of any patient covered under this service, where such admission or death is or may be due to usage of the drug(s) in question or attributable to the relevant underlying medical condition. This must be reported within 72 hours of the information becoming known to the practitioner. This is in addition to a practitioner's statutory obligations.

Accreditation

7. Those doctors who have previously provided services similar to this enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

Costs

8. In 2003/04 each practice contracted to provide this service will receive:

Level 1 – laboratory outreach sampling, test and dose	£6 - £10
Level 2 – HA, Trust or other externally funded phlebotomist or pharmacist etc., practice sample, laboratory test, practice dosing	£75 - £100
Level 3 – Practice-funded phlebotomist or pharmacist etc, practice sample, laboratory test, practice dosing	£80 - £110
Level 4 – Practice-funded phlebotomist or pharmacist etc, practice sample, practice test, practice dosing	£85 - £120
In addition to the above fees, where the sampling requires a domiciliary visit to a housebound patient on or behalf of the practice, and not by a member of staff employed by an NHS body to provide community health services, an additional fee would be paid for each separate address visited on that day	£3 - £5

These prices will be uprated by 3.225 per cent in 2004/05 and again in 2005/06.

Annex

Warfarin prescribing guidelines

General guidance

1. This protocol sets out details for the care of patients taking warfarin. The patient should also have received advice and written information on anticoagulant therapy, normally in the form of an anticoagulant booklet.

Background

2. Warfarin use is increasing as new indications for its efficacy have been recently identified. Nevertheless, its use is associated with adverse effects, particularly bleeding, and optimum management can be achieved by shared care between hospital and general practitioner. The present indications for warfarin, together with the presently agreed degree of anticoagulation for that indication are shown in the attached Tables 1 and 2.

Table 1

Therapeutic recommended uses and International Normalised Ratios (INRs) for those uses (British Society of Haematology)

Prophylaxis of postoperative deep vein thrombosis (general surgery)	2.0-2.5
Prophylaxis of postoperative deep vein thrombosis in hip surgery and fractures	2.0-3.0
Myocardial infarction: prevention of venous thromboembolism	2.0-3.0
Treatment of venous thrombosis (DVT)	2.0-3.0
Treatment of pulmonary embolism (PE)	2.0-3.0
Transient ischaemic attacks	2.0-3.0
Tissue heart valves	2.0-3.0
Atrial fibrillation	2.0-3.0
Valvular heart disease	2.0-3.0
Recurrent deep vein thrombosis and pulmonary embolism	3.0-4.5
Arterial disease including myocardial infarction	3.0-4.5
Mechanical prosthetic valves (see table 2)	
Recurrent systemic embolism	3.0-4.5
Intravascular stent	2.5-3.5

Table 2

Recommended INR for prosthetic valves		
	Sinus rhythm normal left atrial size (i.e. most aortic valve replacement patients)	Atrial fibrillation enlarged left atrium (i.e. most mitral valve replacement patients)
Low thrombogenicity prosthesis	2.0 - 3.0	2.5 - 3.5
Other prostheses	3.5 - 4.5	3.5 - 4.5

Dosage regimens

- The average dose of warfarin required daily is around 5 mg (range 1-9 mg) but may vary markedly because of several factors. Warfarin should be given once daily (5-6 pm is an ideal time) and is given as a tablet for oral administration. [Tablet strengths are 1 mg (brown), 3 mg (blue), 5 mg (pink).]

Duration of therapy

- After a single episode of venous thromboembolism, it is likely that three months' therapy is necessary. The duration of therapy needed after a second episode of DVT or PE is uncertain but 6-12 months' therapy is normally advocated. Patients with repeated episodes or in whom risk factors persist may require long-term (even life-long) therapy. In other indications long-term therapy may be necessary.
- For patients in whom no new factor has arisen, the frequency of monitoring can be determined by the criteria shown in Table 3.

Table 3

Warfarin therapy: maximum recall periods during maintenance therapy*	
*(not initiation)	
One INR high:	recall in 7-14 days (stop treatment for 1-3 days) (maximum 1 week in prosthetic valve patients)
One INR low:	recall in 7-14 days
One INR therapeutic:	recall in 4 weeks
Two INRs therapeutic:	recall in 6 weeks (maximum for prosthetic valve patients)
Three INRs therapeutic:	recall in 8 weeks, apart from prosthetic valve patients
Four INRs therapeutic:	recall in 10 weeks, apart from prosthetic valve patients
Five INRs therapeutic:	recall in 12 weeks, apart from prosthetic valve patients
NB Patients seen after discharge from hospital with prosthetic valves may need more frequent INRs in the first few weeks.	
(Based on data from Ryan et al (1989) British Medical Journal 299, 1207-1209)	

6. When a condition known to cause alteration in the dose requirement of warfarin occurs (eg a potentially interacting drug), or the patient has an acute intercurrent illness, frequency of monitoring should be increased.
7. The following conditions cause warfarin sensitivity (ie need for reduced dose):
 - (i) liver dysfunction
 - (ii) heart failure
 - (iii) hyperthyroidism
 - (iv) some drugs
 - (v) acute pyrexial episode.
8. Some conditions cause warfarin requirements to be increased (ie need for greater than normal dose):
 - (i) hypothyroidism
 - (ii) vitamin K containing remedies, eg some herbal remedies and enteral feeds
 - (iii) some drugs.