disease management in terms of organisation, governance, and incentives. It will also provide recommendations for adoption, application, and dissemination of disease management models in daily practice. The challenge is to identify which patients will benefit from disease management and which outcomes will be improved.[15] [16] The study should also yield a method of evaluating disease management models that can be accomplished quickly and take advantage of emerging databases and information systems.[17]

Conclusions

The shift from shared care to a disease management model in Maastricht came about partly through the demand from general practitioners for the diabetes nurses to expand their care from stable type 2 diabetic patients to other diabetic patients. This demand was supported by evidence that the shared care model was beneficial. Similar changes have taken place in the management of patients with chronic obstructive pulmonary disease in the region of Maastricht.

Although the evidence obtained through health technology assessment should help increase the use of disease management models, the technique is itself faced with barriers to implementation.[15] These barriers may be placed by policymakers (differing perspectives, timeliness and accessibility of health technology assessment findings, reliability of study findings, incentives, and uncertainties), healthcare professionals (practice environment, knowledge and beliefs, lack of consensus, autonomy, and uncertainty), and the general public (financial barriers, information asymmetry, attitudes, and behaviour).[15]

Although evidence is essential to increase dissemination of disease management models, legal, ethical, and organisational aspects as well as the social implications of switching to disease management also have a role.[4] [14] [17] The applied strategy of health technology assessment contains many elements for successful implementation, but it remains to be seen whether its findings will be put into practice.

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Recommendations for patients undertaking self management of oral anticoagulation

D A Fitzmaurice, S J Machin on behalf of the British Society of Haematology Task Force for Haemostasis and Thrombosis

This paper aims to provide guidance for clinicians, based on the evidence available regarding the clinical effectiveness and health economics of the self management of oral anticoagulation therapy by patients. The paper focuses on self management, in which patients measure their own international normalised ratio and interpret the result themselves, as opposed to self testing, in which patients measure their own international normalised ratio but have to contact a health professional for interpretation of the results. The need to provide guidance and recommendations has been driven by patients' demand for self management at primary and secondary care levels. This demand has been fuelled partly by a national media advertising campaign promoting self management by patients using a particular near patient device (CoaguChek, Roche Diagnostics, Mannheim) to test their inter-

Summary points

Data on clinical utility and cost effectiveness to support routine adoption of self management of oral anticoagulation by patients are limited

Patients undertaking self management must be trained by a competent healthcare professional and must remain in contact with a named clinician

The device used for self management must have been evaluated and found acceptable

Quality control of the delivery device and its use is essential

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national normalised ratios. This paper follows on from evidence based guidelines for the therapeutic management of warfarin that were published by the British Committee for Standards in Haematology.[1]

The scale of the problem

The expansion of clinical indications for warfarin,[2 3] particularly non-rheumatic atrial fibrillation,[4 5] has raised concerns about how warfarin monitoring should be undertaken.[6 7] The importance of this issue for all healthcare systems with ageing populations can be estimated from data showing that only one third of patients with identified atrial fibrillation receive anticoagulation.[8] In the absence of screening programmes, probably 60% of patients with atrial fibrillation remain unidentified.[7] On the basis of these data, the introduction of screening could increase the number of patients requiring oral anticoagulation for anticoagulation monitoring by a factor of five. Although national data are not routinely collected, we estimate that around 470 000 people in the United Kingdom currently take warfarin.[9–11]

Our recommendations are based on the concept that successful therapeutic control of the international normalised ratio leads to a reduction in the incidence of major adverse events, particularly thrombotic and haemorrhagic episodes. There is good evidence that there are exponential increases in the risk of thrombosis when international normalised ratio values fall below 2.0 and in the risk of haemorrhage when values rise above 4.5.[12]

Current models of service provision

In the traditional model of care for patients receiving oral anticoagulation therapy, patients attend a hospital outpatient clinic, where their international normalised ratio is estimated from either capillary or venous citrated blood samples, with the result available either immediately or later. Although the clinic has traditionally been led by a consultant haematologist, alternative arrangements have used cardiologists, surgeons, specialist nurses,[13] laboratory staff, and pharmacists.[14] Computerised decision support software has improved therapeutic control in secondary and primary care settings.[15 16] Although there are methodological problems with determining the proportion of time that the internationalised normalised ratio is within the normal range (because it is measured at distinct time points),[12]

on the basis of data from the United Kingdom, patients should expect to be within their own therapeutic range for at least 60% of the time. This is the standard that any alternative model needs to achieve.[10 16]

When international normalised ratios are available with the patient still present, dosing recommendations are made, and the patient is given a date for their next appointment (up to 12 weeks in a stable patient[1]). When the results are not immediately available, patients leave their hand held record (usually yellow national record booklets in the United Kingdom) at the hospital. The result and the dose of warfarin to be taken are written into the book, which is then returned to the patient by post. Less frequently, patients keep their record booklet and make a note of the result and dose following a telephone call from the hospital. This model has been widely used throughout the United Kingdom.

Hospital outpatient clinics have not always performed well in terms of control of the international normalised ratio, adverse events, and patient satisfaction.[10] Data from clinics using manual systems for dosing show a point prevalence for patients achieving therapeutic international normalised ratios of 43-55%,[10] this value is up to 65% in other clinic models.[13] These figures are comparable with those from general practice clinics that use similar methods and treat a similar population; they achieved 54% based on the same criteria.[17] Routine performance within anticoagulation clinics in the United Kingdom compares favourably with that in other countries, particularly the United States and Germany, where rates of 40% have been seen.[18 19] These data have important consequences for the implementation of alternative models of care that involve the patient attending a clinic, because most data focus on primary care or pharmacy based models[20 21] facilitated by near patient testing for international normalised ratios.

Reliability of near patient testing for self management

The use of near patient testing for estimating international normalised ratios makes it possible for suitable patients to undertake self management.[22 23] Reliable, portable machines that have been subjected to rigorous laboratory evaluation are available.[24–26] Three portable, battery driven, prothrombin time coagulometers have been evaluated by the United

Table 1 Characteristics of coagulometers evaluated by Medical Devices Agency

Characteristic	CoaguChek* (Roche Diagnostics)	TAS/Rapidpoint Coag (Bayer Diagnostics)	Protime (International Technidyne Corporation)
Specimen collection	Test strip plus iron oxide particles plus thromboplastin	Test card plus magnetic strip plus iron oxide particles plus thromboplastin	Test cuvette plus Tenderlett lancet plus cuvette containing thromboplastin
Quantity of blood	10 µl	30-35 µl	65 µl
Detection principle	Iron oxide particles plus photoreflection	Iron oxide particles plus photoreflection	Photoptic detection of decreased blood flow
Type of blood	Whole blood—venous or capillary	Citrated whole venous blood or plasma	Whole blood—venous or capillary
Source of thromboplastin (international sensitivity index)	Rabbit brain	Human placenta	Recombinant
Memory store	30 test results	1000 test results	39 test results
Internal quality control	Supplied by manufacturer	Integral to machine and supplied by manufacturer	Integral to test cuvette
Calibration	Lot specific code chip New test strips	Integral to magnetic strip on test card	Instrument and cuvettes pre-calibrated

*CoaguChek Plus, which also performs activated partial thromboplastin time testing, is also available.

Table 2 Levels of evidence defined in British Society for Haematology guidelines on oral anticoagulation[1]

Grade	Level of evidence	Recommendations
A	Ia and Ib	Requires at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B	IIa, IIb, and III	Requires availability of well conducted clinical studies but no randomised controlled trials on the topic of recommendation
C	IV	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities: indicates absence of directly applicable studies of good quality
	Ia	Meta-analysis of randomised controlled trials
	Ib	At least one randomised controlled trial
	IIa	At least one well designed study without randomisation
	IIb	At least one well designed quasi-experimental study
	III	Well designed non-experimental descriptive studies
	IV	Expert committee reports or opinions and/or clinical experience of respected authorities

Ia=meta-analysis of randomised controlled trials

Kingdom Medical Devices Agency Coagulation Centre, and all three devices have shown acceptable and comparable international normalised ratio values across the therapeutic range (table 1).[27] Commercially available international normalised ratio monitors were reliable in terms of accuracy and reproducibility of results and long term use by selected patients.[28]

Training for self management

Britain currently has few formal training programmes for patients. However, preliminary data suggest that a programme involving two sessions of three hours that covers the practical and theoretical aspects of self management (including quality assurance) is sufficient for the majority of patients (DA Fitzmaurice et al, British Society of Haematology Annual Meeting, Bournemouth, 2000).

In Germany, around 50 000 patients currently manage their own anticoagulation therapy, and there is a nationally approved, formalised training programme for patients. It is similar in concept to the National Asthma and Respiratory Training Centre in Britain, which provides training for health professionals, who then train patients.[29]

The Association of Self Management of Anticoagulation has established a series of training centres across Germany. The association organises seminars to train the trainers—doctors and nurses who will train their patients on how to perform self monitoring—and the patients. The courses cover theoretical and pharmaceutical aspects of anticoagulation, a demonstration of the equipment to be used by the patients, and a practical session using the near patient testing systems (box).

It is difficult to know whether training of a similar intensity is necessary in the United Kingdom, whether it could be provided within the British NHS, or whether private medical insurance companies would accept the costs of such an approach. Further points to consider within the NHS are the need for patient consent and the formulation of a contract between the trainer and patient.

Summary statement of evidence

This summary uses the levels of evidence defined in British Society for Haematology guidelines (table 2), the evidence discussed above and our review of the literature (see appendix on *BMJ*'s website).[1]

- Grade B (level IIa) evidence shows the effectiveness of self management by patients[19 30]; however, the effectiveness depends on the criteria used to select patients and on the training given to the selected patients.
- Given the nature of the training, only patients with indications for long term (greater than one year) warfarin therapy should be considered for self management.
- There is no additional evidence to guide the selection of patients or the intensity of the training and support for patients being offered the opportunity for self management.
- Grade B (level II) evidence shows the cost effectiveness of self management within the American and German healthcare systems.[31 32] This evidence is based on improved therapeutic control compared with that from routine care; however, the results from routine care are poor compared with data reported from British clinics. We did not identify any published evidence about cost effectiveness within the British healthcare system.
- We did not identify any data that consider the nature of patients' interpretations of the international normalised ratio, and no formal dosing algorithms have been published.

Association of Self Management of Anticoagulation training course for patients

Theoretical session
- Theoretical aspects of anticoagulation management
- Indications for anticoagulation
- How to monitor the blood
- Frequency of coagulation monitoring
- Problems with monitoring
- Interaction between anticoagulants and other drugs
- The influence of nutrition, alcohol, intercurrent illness, and travel on the efficacy of anticoagulants
- How to record the test results
- How to recognise and treat complications
- Overlapping heparin therapy
- Vaccinations
- Endocarditis prophylaxis

Practical session
- Operating the coagulation monitor
- Practising a coagulation test
- Practising an internal quality control test
- Correct fingerstick procedure
- Possible sources of error
- Recording test results

Implications for self monitoring of oral anticoagulation by patients in Britain

Although evidence from outside Britain suggests that management of anticoagulation by patients is a valuable model of care for the long term management of anticoagulation in terms of reliability, convenience, and reduced risks, further multicentre, randomised trials in Britain are required. This is particularly true since therapeutic control found within other healthcare systems where testing in the physician's office remains routine practice is poor, and anticoagulation hospital clinics are not as well established or widespread as they are in Britain.[18 19]

We are currently aware of four ongoing clinical trials in Britain. These are being undertaken within primary care (DA Fitzmaurice, unpublished data), in paediatric practice (JRL Hamilton et al, Society of Cardiothoracic Surgeons of Great Britain and Ireland Annual Meeting, Nottingham, 1999), following heart valve surgery (H O'Kane, P Sidhu, Society of Cardiothoracic Surgeons Annual Meeting, Nottingham, 1999), and through an anticoagulation clinic based in a haematology department (J Parker-Williams, personal communication, 2000). Current and future research should focus on the practicalities of the model for self management of anticoagulation by patients within the NHS, with particular emphasis being given to training and costs. In Britain, at the time of writing, there is no reimbursement for monitors or test strips, and unless test strips can be obtained on prescription in a similar way to glucose monitor strips, home monitoring will be available only to the minority of patients who can afford to pay for monitors and strips themselves.

Quality control

While quality control is deemed essential for hospital laboratories and primary care clinics measuring international normalised ratios, the issue of quality control for patients measuring their own international normalised ratios does not seem to have been addressed. Massicotte's paper includes data on the comparative results obtained using near patient testing and laboratory technology, but it does not address the issue of quality control.[33] One approach would be for the patients, instruments, and processes to be assessed every 6-12 months at the clinic responsible for the patients' care, and for an external quality control exercise to be performed under supervision.

The most widespread British quality control scheme for anticoagulation (the National External Quality Assessment Scheme) sends freeze dried samples of blood to laboratories every three months. The laboratories reconstitute the freeze dried samples and estimate the international normalised ratio, which is unknown to them. The results are collated for all participants, and the performance is expressed as being within or outside a predetermined range around the median international normalised ratio value obtained by the participants. This process is costly and time consuming for patients, without even taking into consideration the potential difficulties that the patients encounter in reconstituting freeze dried samples. Until data from British trials regarding quality control are available, recommendations can only be based on consensus.

Frequency of testing

One striking feature of all the papers that we reviewed was the frequency of testing encouraged by the self management model. Testing is recommended every three to seven days, and more often if control of the international normalised ratio starts to fluctuate. This frequency of testing would be extremely costly, and it is not clear why it is required. In contrast, stable patients in the clinic setting may be tested at intervals of only 10-13 weeks.

Cost

Cost is an extremely important element in the model of self management by patients. The German and American health systems are influenced by insurance companies, and insurers seem to be convinced that this model is therapeutically effective and are willing to fund it once the competence of an individual patient is established. This is due, in part, to the improved therapeutic control seen in patients who self manage compared with those receiving routine care in these countries. It is not clear whether this level of improvement, which is enough to reduce major adverse events, is possible in the United Kingdom. If it is not, the increased capital costs associated with each patient having their own coagulometer, increased frequency of testing, and the cost of training need to be offset against the reduced costs that are due to reduced contact between patients and health professionals.

Recommendations

Given the relative lack of evidence, the following recommendations are necessarily consensual (evidence level C).

(1) Only patients with indications for long term warfarin therapy should be considered for self management. In exceptional circumstances, patients with short term indications—for example, first occurrence of a deep vein thrombosis—may be considered for self testing; however, it should be noted that it can take 2-3 months before a patient becomes fully accustomed to managing their own treatment (H O'Kane, P Sidhu, Society of Cardiothoracic Surgeons Annual Meeting, Nottingham, 1999).

(2) Only portable coagulometers that have undergone acceptable evaluations by an expert body—for example, the United Kingdom Medical Devices Agency—should be used for self testing.[27]

(3) Patients (or their carers) must be willing and able to perform self management.

(4) Patients (or their carers) must give informed consent to undertake self management; this will include an agreement to regularly attend clinics and record the results accurately.

(5) Competence to test international normalised ratio must be assessed by a trained healthcare professional before home testing is allowed.

(6) Competence to correctly interpret an international normalised ratio result must be assessed by a healthcare professional before self management is allowed. This assessment must be based on an individualised patient strategy (figure).

(7) Previous stability of international normalised ratio is not a prerequisite to home testing because unstable patients may benefit from increased autonomy and the possibility of performing the test more frequently.

Betty Smith			
Indication for warfarin	**Therapeutic range**		**Current warfarin dose**
Atrial fibrillation	2-3		3 mg
Date	**INR result**	**Warfarin dose**	**Next test due**
1/11/98	<1		Contact nurse
	1-1.5	4 mg	1 week
	1.5-2	3.5 mg	1 week
	2-3	3 mg	2 weeks
	3-4	2.5 mg	1 week
	4-5	2 mg	1 week
	>5	Stop warfarin	Contact nurse

Strategy for treatment of an individual patient

(8) Patients being considered for self management must have a stated target for international normalised ratio in line with accepted guidelines and clinical practice.[1]

(9) Contraindications for self management by patients will include previous non-compliance in terms of attendance at clinic or taking of medication. This may include evidence of alcohol misuse.

(10) Patients undertaking self management must remain in contact with a named clinician who will be clinically responsible for them—in most cases, this will be a consultant haematologist. In all cases, the patient's general practitioner and the clinician who initiated the warfarin therapy must be informed.

(11) Patients undertaking self management must be reviewed at least every six months by the responsible clinician.

(12) Electronic quality control of the coagulometer should be performed every time the machine is used (if possible).

(13) Some form of regular external quality control must be performed. This may take the form of sending a contemporaneous venous sample for laboratory testing. Alternatively, patients may be regularly assessed—for example, every six months—in a clinic that participates satisfactorily in a formal external quality assessment scheme. The patient would check their international normalised ratio on their own and the clinic's coagulometers. If the results from both coagulometers are within 0.5 of each other, assessment would be considered satisfactory.

(14) If the external quality control procedure is unsatisfactory on more than one occasion, the patient's technique and device must be assessed by the training centre. If performance in the external quality control procedure is persistently poor, the patient should be withdrawn from the self management programme.

(15) Internal quality control of the device must be performed at least once a month or, if testing is less frequent than this, every time the machine is used.

(16) All quality control results must be recorded, and they should be available for review at clinic visits.

The recommendations should be revised in April 2002.

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