Where should oral anticoagulation monitoring

THE principal objectives of oral anticoagulation monitoring are to minimize the risks of haemorrhagic side effects and to maximize the avoidance of stroke.[1] By measuring the induced clotting deficit, the oral anticoagulant dose (predominantly warfarin) can be titrated to achieve therapeutic levels.

The reorganization of the provision of therapeutic oral anticoagulation monitoring in the United Kingdom (UK) continues to have controversial implications.[2] Change has been driven by an increased number of patients receiving anticoagulant therapy, primarily following evidence for the effectiveness of warfarin in stroke prevention for patients with atrial fibrillation,[3] together with the trend towards decentralized hospital services.[4] However, to ensure optimum patient benefit, potential innovations require formal evaluation.

Existing models of care

There are essentially three options for the management of patients receiving oral anticoagulation therapy: complete hospital management, complete general practice management, or a combination of the two. Traditionally, oral anticoagulant management has been a hospital outpatient service because of the need for testing blood for an international normalized ratio (INR) and the need for a specialist interpretation of the result. The INR measures the ratio of the prothrombin time for a warfarinized patient versus that of a non-anticoagulated control sample, standardized for the reagent used. The need for patient education regarding warfarin therapy and the monitoring of adverse events has also been identified as a reason for specialist supervision.[5]

Taylor et al[6] described hospital-based moves away from medical review at every visit made by the patient, with regular attenders being managed primarily by health care assistants. This model of care has been relatively unsuccessful in terms of INR control and also involves long waiting times and travelling problems for patients, particularly patients requiring hospital transport.[7,8] The increase in the number of patients receiving oral anticoagulant therapy (principally as a result of studies highlighting its effectiveness in preventing stroke in patients with non-rheumatic atrial fibrillation) has led to increasing efforts to rationalize care, with primary care workers being asked to undertake a significant proportion of the increased management.[5]

Primary care responsibility for warfarin monitoring has previously been dependent upon local outpatient provision and the enthusiasm of the general practitioners.[7] The simplest and most widespread form of general practice involvement is blood sampling, with INR testing and interpretation taking place within the local hospital. This form of management has been shown to be as efficient as traditional outpatient management in terms of INR control,[7] but it does have the disadvantage of an inherent delay between phlebotomy and patients receiving dosing advice.[9,10]

The development of reliable near-patient testing (NPT) for INR estimation could facilitate devolution of testing to general practice.[11] Reliable machines are available for this purpose, which have been subject to rigorous laboratory evaluation.[12,13,14] However, for such technology to be effectively employed in general practice, formal training and quality assurance procedures must be ensured. There are inherent similarities between INR estimation and blood glucose estimations, and there is no reason why practice-based anticoagulation clinics cannot become as routine as practice-based diabetic clinics. The advantages for the patients are ease of access, shorter waiting times, continuity of care, and an overall holistic approach, as practice-based staff are more likely to be aware of treatment changes than hospital-based staff.[15]

Several computerized decision support software systems (DSSs) are available for providing advice on anticoagulant dosing.[16] These have been shown to be at least as effective as specialist advice in terms of INR control.[15,17] There are, however, no commercially available DSSs designed specifically for general practice, although one system evaluated in primary care practice nurse-run clinics has been shown to be safe and effective.[9,15] By combining NPT with DSSs, a complete devolution of care to general practice may be available for the majority of patients requiring therapeutic warfarin monitoring. However, one North American study suggests that patient outcomes are worse in small, low-volume clinics.[18] These findings need to be explored in the UK, especially given recent technological advances, before widespread devolution of anticoagulation services can be undertaken.

Other models of anticoagulation monitoring outside hospitals are expanding, with recent evaluations of nurse-led[9] and pharmacy-led[19] care. Future UK developments could include patient self-management. This model of care has been shown to be feasible in a highly selected population in the United States.[20,21] Unfortunately, it remains difficult to compare these care options because of the lack of a standard format for presentating the degree of INR control.

Clinical efficacy should be measured as the degree of INR control within the therapeutic reference range for the clinical indication for therapy.[22] For example, the pharmacy evaluation quoted total within-range parameters of the British Society of Haematology guidelines plus or minus 10%,[19] thus preventing comparison with other studies and providing potentially poor control. We have recommended that all trials report three statistics as a standardized dataset for any evaluation of an oral anticoagulant clinic: the point prevalence figures reporting the percentage of patients within range, the percentage of total INR tests within range, and the percentage of time spent in range.[23,24] We also advocate the estimation of mean INR plus or minus one standard deviation for each therapeutic range as a further measure of the degree of control for any specific clinic.[15]

Economic analysis of primary care-based clinics provides some data to show that they represent the most cost-minimizing method of anticoagulant service provision.[9,15] However, more data are needed before widespread purchasing decisions are taken.

It remains essential that, wherever patients receiving oral anticoagulant therapy are monitored, rigorous performance review is regularly undertaken. Furthermore, all sites involved in monitoring must commit themselves to an external quality assurance scheme. If primary care clinics are to become the preferred care option in the UK, then adequate resources to cover the training, capital, labour, and consumable costs will have to be identified.

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References

1. Duxbury BMcD. Therapeutic control of anticoagulant treatment. *BMJ* 1982; **284:** 702-704.
2. Sweeney KG, Gray DP, Steele R, Evans P. Use of warfarin in non-rheumatic atrial fibrillation: a commentary from general practice. *Br J Gen Pract,* 1995; **45:** 153-158.
3. Sudlow CM, Rodgers H, Kenny RA, Thomson RG. Service provision and use of anticoagulants in atrial fibrillation. *BMJ* 1995; **311:** 558-560.
4. Secretaries of State for Social Services, Wales, Northern Ireland and Scotland. *Promoting better health. The government's programme for improving primary health care (Cm 249).* London: HMSO, 1987.
5. Taylor F, Ramsay M, Covell B, *et al.* Management of expanding anticoagulant clinics: a role for general practitioners. *Br J Haematol* 1994; **86:** 68.
6. Taylor FC, Ramsey ME, Renton A, Cohen H. Methods for managing the increased workload in anticoagulant clinics. *BMJ* 1996; **312:** 286.
7. Pell JP, McIver B, Stuart P, *et al.* Comparison of anti-coagulant control among patients attending general practice and a hospital anti-coagulant clinic. *Br J Gen Pract* 1993; **43:** 152-154.
8. Pell JP, Alcock J. Monitoring anticoagulant control in general practice: comparison of management in areas with and without access to hospital anticoagulant. *Br J Gen Pract* 1994; **44:** 357-358.
9. Fitzmaurice DA, Hobbs FDR, Murray ET, Bradley CP. Evaluation of utilizing a computerised decision support system (DSS) in the therapeutic management of oral anticoagulation in general practice. *Fam Pract* 1995; **12:** 505.
10. Rose PE, Brown RM, Gilbert M. *Audit of oral anticoagulant treatment in a region.* [Report from Departments of Haematology and Medical Audit.] Warwick Hospital, 1995.
11. Hobbs FDR. Near patient testing in primary care. *BMJ* 1996; **312:** 263-264.
12. Kapiotis S, Quehenberger P, Speiser W. Evaluation of the new method Coagucheck for the determination of the prothrombin time from capillary blood: comparison with thrombotest on KC-1. *Thrombosis Research* 1995; **77:** 563-567.
13. Sanders KJ, Lewis SM, Cooper S, England JM. *An evaluation of the Nycomed Thrombotrak coagulation system.* London: NHS Procurement Directorate. 1989.
14. Oberhardt BJ, Dermott SC, Taylor M, *et al.* Dry reagent technology for rapid, convenient measurements of blood coagulation and fibrinolysis. *Clin Chem* 1991; **37:** 520-526.
15. Fitzmaurice DA, Hobbs FDR, Murray ET, *et al.* A randomized controlled trial comparing primary care oral anticoagulant management utilising computerized decision support (DSS) and near patient testing (NPT) with traditional management. *Fam Pract* 1995; **12:** 253-254.
16. Poller L, Wright D, Rowlands M. Prospective comparative study of computer programs used for management of warfarin. *J Clin Pathol* 1993; **46:** 299-303.
17. Ryan PJ, Gilbert M, Rose PE. Computer control of anticoagulant dose for therapeutic management. *BMJ* 1989; **299:** 1207-1209.
18. Lundberg GD. Searching for inaccuracy in clinical laboratory testing using Medicare data. *JAMA* 1993; **269:** 1030-1033.
19. Macgregor SH, Hamley JG, Dunbar JA, *et al.* Evaluation of a primary care anticoagulant clinic managed by a pharmacist. *BMJ* 1996; **312:** 560.
20. Ansell JE, Patel N, Ostrovsky D, *et al.* Long term patient self-management of oral anticoagulation. *Arch Int Med* 1995; **155:** 2185-2189.
21. Ansell J, Holden A, Knapic N. Patient self-management of oral anticoagulation guided by capillary (fingerstick) whole blood prothrombin times. *Arch Int Med* 1989; **149:** 2509-2511.
22. British Committee for Standardization in Haematology. Guidelines on oral anti-coagulation. 2nd edition. *J Clin Pathol.* 1990; **43:** 177-183.
23. Van den Besselar AMHP. Recommended method for reporting therapeutic control of oral anticoagulant therapy. *Thrombosis and Haemostasis* 1990; **63:** 316-317.
24. Azar AJ, Deckers JW, Rosendaal FR, *et al.* Assessment of therapeutic quality control in a long term anticoagulant trial in post-myocardial infarction patients. *Thrombosis and Haemostasis* 1994; **72:** 347-351.