

Policy dilemmas for oral anticoagulation management

ATRIAL fibrillation is a major independent risk factor for stroke, with the risk increasing with age, particularly over the age of 65 years.¹ The efficacy of oral anticoagulation therapy (OAT) for stroke prevention in non-rheumatic atrial fibrillation represents a major medical advance,² reducing the risk of stroke by up to 68%.³ Technological developments are enabling near-patient international normalised ratio (INR) monitoring and management in ways that may culminate in patient self-monitoring. The benefits of OAT are only realisable, however, if its therapeutic use is well controlled.

Oral anticoagulation therapy services, traditionally hospital-based, are under increasing strain.⁴ As much as 2% of the population may be eligible for treatment, similar in scale to diabetes.⁵ No accurate United Kingdom (UK) data are available on the number of patients currently being treated.

Monitoring of OAT developed in hospitals owing to the need for a blood test (INR), interpretation, and dose adjustment. Hospital anticoagulation clinics have historically achieved relatively poor results, with less than 50% of patients achieving therapeutic INRs and increasing patient numbers experiencing worsening congestion and waiting times.⁶ New technologies, however, are changing the organisation of OAT services. Reliable near-patient testing is now available for INR measurement.⁷ Computerised decision support software enable test results to be interpreted by non-medical staff.⁸ Clinics can be located in primary care⁹ or, as in Germany, in patients' homes.¹⁰ Trials, completed and continuing, show that these alternatives achieve at least as good INR control as traditional hospital clinics. Patients can now expect to achieve therapeutic INRs at least 60% of the time — a substantial improvement on traditional hospital care (which, however, is improving all the time).^{9,10}

These promising developments raise issues about quality assessment, patient preferences, cost, and long-term outcomes. Quality assessment, strong in hospital contexts, is almost entirely lacking elsewhere.¹¹ Equipment needs to be regularly checked and recalibrated. In the UK, it is left to the discretion of primary care clinics to arrange for quality assessment, either through the local haematology laboratory or the national voluntary scheme. Quality assurance for patients testing at home remains undeveloped, similar perhaps to diabetes.¹¹

Patient preferences, which ought to inform decisions on initiating OAT and on choice of therapy, have not been well researched, despite indications from modelling exercises that results are highly sensitive to such preferences.¹² The advent of patient self-monitoring represents a major shift in the nature and organisation of care delivery. Some patients will see this as an opportunity to regain some control over their lives and will enjoy the reduced level of contact with health professionals. However, others may experience increased anxiety associated with the responsibility for monitoring their condition. Given the need for long-term (sometimes lifelong) therapy in many patients requiring OAT, it is appropriate that patient and carer preferences concerning alternative organisational arrangements for delivering care are taken into account. Thus, measurement of the strength of such preferences should constitute a research priority.

What about the cost? Overall, these new approaches seem to be more costly than hospital clinics. A Birmingham study costed a hospital-based clinic at around £90 per patient per year and a

primary care clinic using computerised decision support software and near-patient testing at around £160 per patient per year,¹³ less in larger practices. The optimum number of patients appears to be around 45, with numbers above this requiring more than one clinic per week and numbers below pushing up the cost per patient.

Improved therapeutic control in primary care clinics, combined with lower patient costs in larger clinics, has implications for primary care groups (PCGs). The benefits of primary care clinics in the Birmingham model may depend on the holistic, continuous care of practice nurses rather than the technology of near-patient testing and computerised decision support software. These benefits could be lost if PCGs create large-scale clinics catering for multiple practices. Under current regulations any general practitioner or PCG can set up anticoagulation clinics by simply buying the relevant technology. No evidence of competence is required and no routine monitoring of outcomes is carried out.

Arguably, all anticoagulation clinics should be required to perform to minimum competence criteria. All personnel involved should have received adequate training and local haematology departments might 'accredit' training courses. All centres undertaking anticoagulation management should adhere to quality control procedures and be registered with a recognised external quality assurance scheme (as for pathology laboratories). Clinics should be audited regularly to ensure optimum therapeutic control. The idea of accreditation or a 'provider certification programme' for centres providing anticoagulation services is more advanced but remains at the theoretical stage in the United States of America.¹⁴

These concerns are amplified when patient self-monitoring is considered. Patient-held devices cost around £500 per device plus running costs. Although patient-based monitoring has yet to be formally explored in the UK, some 40 000 use it in Germany. Adherence to the basic principles of quality assurance applies, particularly to patient self-monitoring. In Germany, there is a strong training component, driven by the funding insurance companies, but little in the way of follow-up outside evidence that patients are achieving optimum control. Although trial data suggest improved patient outcomes in terms of INR control, the degree to which this translates into improved clinical outcomes in routine practice remains unclear.¹⁵ The UK could learn from the German experience and from experience with diabetic patients to ensure optimal patient self-management of OAT.

The efficacy of INR control in reducing adverse events has been assumed to translate into greater effectiveness in practice. If the gains demonstrated in trials are to be realised in practice, then quality control, training, and long-term follow up of patients are necessary. Improved collection of routine data (an OAT register) offers one option worth exploring.

Perhaps the real challenge lies in ensuring that policy on the development of anticoagulation services is based on research evidence rather than driven by technology, costs or, potentially, patient populism. Current policy is incoherent. The research agenda is replete with questions regarding optimum models of care, optimum frequency of testing, the measurement of patient utilities, the role of new technologies, and the scope for routine data collection. Given the devastating effects of poorly managed

anticoagulation care it is perhaps time these issues were formally addressed.

D A FITZMAURICE

Department of Primary Care and General Practice, The Medical School, University of Birmingham

J P RAFTERY

S BRYAN

Health Services Management Centre, Birmingham

References

1. Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation as an independent risk factor for stroke: the Framingham Study. *Stroke* 1991; **22**: 983-988.
2. Stroke Prevention in Atrial Fibrillation Investigators. Stroke Prevention in Atrial Fibrillation Study: final results. *Circulation* 1991; **84**: 527-539.
3. Stroke Prevention in Atrial Fibrillation Investigators. Risk factors for stroke and efficacy of antithrombotic therapy in atrial fibrillation; analysis of pooled data from five randomised controlled trials. *Arch Intern Med* 1994; **154**: 1449-1457.
4. Rodgers H, Sudlow M, Dobson R, *et al*. Warfarin anticoagulation in primary care: a regional survey of present practice and clinicians' views. *Br J Gen Pract* 1997; **47**: 309-310.
5. Rose P. Audit of anticoagulant therapy. *J Clin Pathol* 1996; **49**: 5-9.
6. Pell JP, McIver B, Stuart P, *et al*. Comparison of anticoagulant control among patients attending general practice and a hospital anticoagulant clinic. *Br J Gen Pract* 1993; **43**: 152-154.
7. Machin SJ, Mackie IJ, Chitolie A, Lawrie AS. Near patient testing (NPT) in haemostasis — a synoptic review. *Clin Lab Haematol* 1996; **18**: 69-74.
8. Fitzmaurice DA, Hobbs FDR, Delaney BC, *et al*. Review of computerised decision support systems for oral anticoagulation management. *Br J Haematol* 1998; **102**: 907-909.
9. Fitzmaurice DA, Hobbs FDR, Murray ET. Primary care anticoagulant clinic management using computerized decision support and near patient International Normalized Ratio (INR) testing: routine data from a practice nurse-led clinic. *Fam Pract* 1998; **15**: 144-146.
10. Bernado A. Experience with patient self management of oral anticoagulation. *J Thromb Thrombol* 1996; **2**: 1886.
11. Murray ET, Fitzmaurice DA. An evaluation of quality control activity for near patient testing in primary care. *Br J Gen Pract* 1998; **48**: 1853-1854.
12. Greenberg ML, Malenka DJ, Disch DL. Therapeutic strategies for atrial fibrillation. The value of decision analysis. *Cardiol Clin* 1996; **14**: 623-640.
13. Fitzmaurice DA, Hobbs FDR, Rose PE, Murray ET. A randomised controlled trial comparing anticoagulant management utilising computerised decision support (CDSS) and near patient testing (NPT) versus routine care: final results. *Br J Haematol* 1997; **97**: S79.
14. Vanscoy GJ, Rock W. Workshop: Credentialing of anticoagulation providers. A proposed model. *J Thromb Thrombol* 1998; **5**: S53-S61.
15. Jacobson AK. Patient self management of oral anticoagulant therapy: an international update. *J Thromb Thrombol* 1998; **5**: S25-S28.

Address for correspondence

D A Fitzmaurice, Department of Primary Care and General Practice, The Medical School, University of Birmingham, Edgbaston B15 2TT.

Taking another look at the acute sore throat

THE acute sore throat is, generally speaking, a benign self-limiting illness. However, as it presents in general practice, this seemingly straight-forward problem manages to throw up many of the challenges that are characteristic of our discipline and is one of the most common clinical scenarios causing discomfort in our prescribing decisions.¹ Its diagnosis and management require us to deploy all our skills of handling uncertainty, risk management, clinical judgement, managing potential clashes of perspective between ourselves and our patients, applying evidence from clinical studies to the management of individuals, and exploring and agreeing mutually acceptable solutions to achieve an outcome that is clinically, economically, and socially acceptable to our patients and ourselves.

Research and, more recently, the application of evidence-based medicine techniques have managed to chip away at some of the uncertainties surrounding this condition. In particular, the Cochrane review by Del Mar *et al* has severely challenged the previously held assumption that patients with acute streptococcal sore throat would benefit unequivocally — in terms of reductions in symptoms and in reduction of suppurative (e.g. quinsy) and non-suppurative (e.g. rheumatic fever and glomerulonephritis) complications — from the administration of an antibiotic such as penicillin.² This evidence has exposed this justification for antibiotic prescribing for what it is: an example of the surrogate outcome fallacy.³

Del Mar *et al* have taken this empirically focused, evidence-based approach to management one step further and looked at the evidence for other approaches to management.⁴ The evidence they have uncovered, it must be said, is limited in both quantity and quality but a few useful pointers do emerge for both clinical practice and future research. First, analgesics, specifically ibuprofen, in regular and adequate doses seem to be effective in providing symptom relief in adults. I concur with Del Mar *et al*'s

suggestion that it is reasonable to incorporate this finding into our clinical practice in terms of advising regular analgesia in adequate doses to our sore throat patients as of now. More research, though, is required to compare different analgesics, particularly in terms of relative safety and efficacy, and possibly to investigate modes of administration. In particular, I was disappointed to find that my own standard advice of aspirin gargles appears not to have been adequately evaluated. Secondly, they highlight the potential role of preventive strategies and found that both influenza and pneumococcal vaccination show promise. Other preventive strategies may be worth evaluating, too, and the possible impact of smoking cessation on recurrence rates of sore throat would seem particularly worthy of study.

Given the reasonably convincing evidence we now have to support a decision to not prescribe antibiotics, however, we should not rush to alternative prescription-based treatment options. The options of not treating the condition at all, offering deferred treatment, and advising and informing self-care — including the use of home remedies and/or the recommendation of over-the-counter medicines — should all be considered as alternatives to prescribing.^{5,6} These approaches have the particular benefits of reducing the risk of medicalising the problem and encouraging patient self-reliance. In this regard, Del Mar *et al* also highlight the intriguing finding that the quality of the communication in consultations for sore throat can also impact positively on outcomes such as symptom relief. This finding points to the important possibility that how we manage this clinical condition is about much more than the presence or absence of particular micro-organisms or the choices between different medicines.

The core of this problem, and possibly many others in general practice, may be clashes in perspective or misunderstandings between doctors and patients.^{7,8} Doctors, at least historically, have come from a perspective that the acute sore throat is a physical

manifestation of an infective condition of the upper respiratory tract and the required minimum management is one that will eliminate the causative organism, if possible, and relieve symptoms. General practitioners, though, have other goals and one of these is to please or satisfy their patients. They are also sensitive to the potential impact on patients' lives of this troublesome symptom. A classical study by Howie showed how patients' social situation had more impact on decisions about prescribing antibiotics for sore throats than clinical features of the case.⁹ Doctors are aware that many patients expect to be prescribed an antibiotic for a sore throat; however, their awareness of who has the expectation and the nature of the expectation (i.e. whether it is something the patient hopes for or anticipates from past experience but is neutral about whether or not it happens) seems perfunctory. They also seem to assume that any such expectation is immutable and disappointment will follow if it is thwarted. Their response seems to be to prescribe antibiotics quite often on the basis of these assumptions and live with any ensuing discomfort arising from their realisation that the benefits of antibiotics may be small and that such prescribing is the subject of opprobrium from other quarters.¹

A high proportion of patients do, indeed, come expecting to receive a prescription for an antibiotic. Some have a great deal of faith in the power of antibiotics to relieve their symptoms and have experience that they interpret as evidence of the effectiveness of this form of treatment. This, of course, may be an example of another fallacy, one of false association of cause and effect.³ However, not all patients may be so fixed in their ideas as we suppose. Many are seeking other outcomes too, such as reassurance and explanation; or possibly just recognition of their suffering and some empathic understanding.^{7,10}

In the light of this sort of evidence, a wholly different set of strategies suggest themselves. First, when set in this context of different world views the problem is identified as a cultural one and more complex and sophisticated solutions are required. Secondly, the overall conduct of the consultation takes centre stage rather than just the microbiological diagnosis or the pharmacotherapeutic management. These considerations pitch this problem into the realm of on-going debates about making general practice consultations more patient-centred, involving patients in shared decision-making, striving for concordance in doctor-patient relationships, and building therapeutic alliances.¹¹⁻¹³ Having better and clearer empiric evidence is undoubtedly very helpful but it is by no means the whole answer to what is a surprisingly complex but quintessential general practice problem.

COLIN P BRADLEY

Professor of General Practice, University College Cork, Ireland

References

- Bradley CP. Uncomfortable prescribing decisions: a critical incident study. *BMJ* 1992; **304**: 294-296.
- Del Mar CB, Glasziou PP, Spinks AB. Antibiotics for sore throat. In: Cochrane Collaboration. *Cochrane Library*. Issue 3. Oxford: Update Software, 2000.
- Skrabnek P, McCormick J. *Follies and Fallacies in Medicine*. Glasgow: Tarragon Press, 1989.
- Thomas M, Del Mar C, Glasziou P. How effective are treatments other than antibiotics for acute sore throat? *Br J Gen Pract* 2000; **50**: 817-820.
- Little P, Gould B, Williamson I, et al. Reattendance and complications in a randomised trial of prescribing strategies for sore throat: the medicalising effect of prescribing antibiotics. *BMJ* 1997; **315**: 350-352.
- Bradley CP, Bond C. Increasing the number of drugs available over-the-counter: arguments for and against. *Br J Gen Pract* 1995; **45**: 553-556.
- Butler CC, Rollnick S, Pill R, et al. Understanding the culture of prescribing: qualitative study of general practitioners' and patients' perceptions of antibiotics for sore throats. *BMJ* 1988; **317**: 637-642.
- Britten N, Stevenson FA, Barry CA, et al. Misunderstandings in prescribing decisions in general practice: qualitative study. *BMJ* 2000; **320**: 484-488.
- Howie JGR. Clinical judgement and antibiotic use in general practice. *BMJ* 1976; **2**: 1061-1064.
- Barry CA, Bradley CP, Britten N, et al. Patients' unvoiced agendas in general practice consultations: qualitative study. *BMJ* 2000; **320**: 1246-1250.
- Bradley CP, Crowley M, Barry C, et al. Patient-centredness and outcomes in primary care. [Letter.] *Br J Gen Pract* 2000; **50**: 149.
- Stevenson FA, Barry CA, Britten N, et al. Doctor-patient communication about drugs: the evidence for shared decision making. *Soc Sci Med* 2000; **50**: 829-840.
- Royal Pharmaceutical Society of Great Britain. *From Compliance to Concordance: Achieving Shared Goals in Medicine Taking*. London: Royal Pharmaceutical Society of Great Britain, 1997.

Address for correspondence

Professor Colin P Bradley, Department of General Practice, University College Cork, Distillery House, North Mall, Cork, Ireland.