offered the benefits of this treatment as younger subjects are.

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GPs not prepared for monitoring anticoagulation

EDITOR,—Philip M W Bath and colleagues suggest that, with the expected increase in patients taking warfarin for non-rheumatic atrial fibrillation, the management of long term anticoagulant treatment could be devolved into the community.[1] The haematology audit committee in North West Thames region is auditing the management of such treatment. As part of this audit we surveyed the general practitioners of 10 consecutive patients referred to each of 13 anticoagulant clinics throughout the region. We excluded three doctors from the same practices as others already recruited, and so a postal questionnaire was sent to general practitioners from 127 practices; 99 (78%) responded.

The 99 practices had a total of 1431 patients receiving anticoagulant treatment on their lists, with a median of 21 (range 1-50) patients per practice. The general practitioners reported that they were responsible for regulating the dose of warfarin for only 121 of the patients, and only 149 of the patients had blood specimens taken in the surgery. Eighty four of the general practitioners were satisfied with the service received from the hospital anticoagulant clinic. When asked about taking more control of their patients receiving anticoagulant treatment, 93 of the general practitioners did not want to run their own anticoagulant clinic—reasons given included insufficient time, knowledge, and training; lack of facilities; and a need for more finance. Although only three of the general practitioners had written guidelines on anticoagulation, 63 said that they would find such guidelines useful.

Our findings show that few patients receiving anticoagulant treatment in our region are managed by their general practitioner and few general practitioners are keen to take on this extra task. Before the management of anticoagulant treatment is devolved to primary care a substantial programme of education and guidance for general practitioners is probably required. In addition, the initiation and early management of warfarin treatment, during the period when patients are most at risk from bleeding,[2] may need to remain the responsibility of hospitals. We agree with Bath and colleagues that more resources are required to prevent strokes in patients with non-rheumatic atrial fibrillation. Prevention of the embolic complications of atrial fibrillation should release such resources,[3] and flexible approaches to the management of anticoagulation in primary and secondary care need to be evaluated.

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No consensus among doctors

EDITOR,—Philip M W Bath and colleagues state that "many patients with atrial fibrillation are not prescribed warfarin despite the absence of contraindications."[1]

Their finding from a retrospective study that there continues to be a low rate of introducing anticoagulation is not new. Our recent prospective survey of patients admitted as emergencies with atrial fibrillation to a district general hospital also showed a surprisingly low rate of introducing antithrombotic treatment.[2] Over six months only 20 of the 102 patients who had had atrial fibrillation were taking warfarin; 17 were taking aspirin.[2] Anticoagulation was given to only seven of the 150 patients who had not previously been given warfarin.[2] Consensus on treatment therefore continues to be lacking among physicians for the introduction of anticoagulant treatment, despite evidence from five randomised controlled trials.[2]

Despite the suggestion that warfarin should be used even in patients with paroxysmal atrial fibrillation[1] the risk-benefit profile for warfarin treatment has not been established in such patients (and the profile may be quite different from that in patients with chronic atrial fibrillation).[3] Therefore warfarin should be reserved for patients with paroxysmal atrial fibrillation who are at highest thromboembolic risk—including those with the sick sinus syndrome, frequent paroxysms of the arrhythmia, a previous thromboembolic event, or structural heart disease.[3] Aspirin, by contrast, has less potential for major adverse reactions and should provide sufficient prophylaxis for most other patients with paroxysmal atrial fibrillation.[3] Many patients with paroxysmal atrial fibrillation also have concomitant underlying ischaemic heart disease, which may benefit from the use of aspirin.

Although aspirin has been advocated as prophylaxis against thromboembolic events, in some patients with chronic atrial fibrillation its use has not been fully substantiated by the recent large studies. Aspirin would be preferable to warfarin if it were equally effective, if only for its ease of administration. The results, however, remain inconsistent. For example, the Copenhagen atrial fibrillation aspirin anticoagulation study showed no benefit from aspirin 75 mg daily, but this study was in an older population.[4] The stroke prevention in atrial fibrillation study reported that aspirin 325 mg daily had some beneficial effect, but not in patients over 75; it also did not prevent severe strokes.[5] Sadly, the use of aspirin remains controversial.

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Use of warfarin dependent on local services

EDITOR,—The observation of Philip M W Bath and colleagues that many patients with atrial fibrillation were not given long term warfarin or aspirin as prophylaxis against stroke is not surprising.[1] Previous studies have shown that despite the proved efficacy of warfarin in primary stroke prevention in atrial fibrillation, doctors remain reluctant to prescribe oral anticoagulant treatment for their elderly patients.[2]

The Veterans Affairs stroke prevention in non-rheumatic atrial fibrillation study was a randomised study of 228 patients aged over 70, 88 of them being over 75.[3] It confirmed that the benefits of warfarin applied to people over 70, with a 79% reduction in the risk of first stroke, and that the rate of bleeding complications was not increased in older people.

The use of anticoagulation in atrial fibrillation is dependent on local clinical services achieving complication rates comparable with those in the published trials. If warfarin is to be widely used in older patients, in whom there is clear and proved benefit, local anticoagulation services must be able to deliver care to them. If, as Bath and colleagues suggest, the unpublished results of the European atrial fibrillation trial show a beneficial effect for warfarin in secondary stroke prevention the matter is further complicated. Patients with atrial fibrillation and recurrent stroke are likely to be more frail; to have coexistent disease; to be receiving concomitant drug treatment, which increases the risk of interaction with anticoagulants; and to be less able to attend hospital outpatient clinics.

Physicians have understandable concerns about prescribing warfarin for elderly patients because of fears about haemorrhage or drug compliance. The usual contraindications to anticoagulant treatment apply to elderly patients, just as to younger people, and dose requirements for warfarin decrease with age.[4] Studies have shown, however, that when prothrombin time is monitored regularly haemorrhagic complications from warfarin treatment can be avoided in elderly people.[5]

If government firmly believes that it can achieve the targets stated in *The Health of the Nation* there should be a case for introducing anticoagulation in atrial fibrillation as a health promotion strategy in general practice.

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Don't deny treatment to elderly people

EDITOR,—In the paper surveying the use of anticoagulation in patients with atrial fibrillation, Philip M W Bath and colleagues recommended that patients over the age of 80 should not be given anticoagulant drugs because the risks are high.[1] This statement is unsupported by evidence. The benefits of anticoagulation are now well accepted.[2,3] Since a stroke at any age is catastrophic, any therapy which reduces the incidence

is commendable. Since the over 80s are a heterogeneous group, such a blanket statement as the above must be intolerable.

In terms of the risk of bleeding, the Boston area anticoagulation trial, which included subjects aged over 80, reported two deaths from fatal haemorrhage out of 212 patients treated with warfarin.[2] At the same time the risk reduction for stroke was 86%. In a study of spontaneous intracranial haemorrhage Schutz *et al* reported only two cases out of 42 as being due to treatment with warfarin.[4] Tabibian, in an evaluation of acute gastrointestinal bleeding in patients aged 40-89 given anticoagulant drugs, reported that age, duration of anticoagulation, degree of prolongation of prothrombin time, and presence or absence of gastrointestinal symptoms were of no value in predicting the risk of bleeding.[5]

Thus the decision about anticoagulation should be based on a holistic evaluation of the patient and not on age alone.

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Doctors reluctant despite evidence

EDITOR,—Despite the fact that recent randomised controlled trials as surveyed by Philip M W Bath and colleagues[1] have shown the efficacy of warfarin in reducing the risk of stroke in patients with atrial fibrillation there is still a reluctance to treat patients, particularly elderly patients, with anticoagulant drugs.

We have recently completed a questionnaire survey of the attitudes of consultant geriatricians and consultant cardiologists to giving anticoagulants to otherwise healthy elderly (>70 years of age) patients with atrial fibrillation in the primary prevention of stroke. Cardiologists were more likely to prescribe warfarin in atrial fibrillation associated with dilated cardiomyopathy (132/153 *v* 73/141, $p<0{\cdot}01$). Geriatricians were more likely to give anticoagulants to those with aortic valve disease and atrial fibrillation (52/141 *v* 36/153, $p<0{\cdot}05$), although this constituted the minority in each group. Most doctors surveyed (86% geriatricians and 89% of cardiologists) would use anticoagulants in atrial fibrillation associated with mitral stenosis. Aspirin was favoured for atrial fibrillation alone. Cardiologists were more likely to give anticoagulants to young patients (<40 years of age) with similar conditions associated with atrial fibrillation.

A similar study has shown the reluctance of physicians to treat elderly patients with anticoagulant drugs.[2] Indeed, Bath and colleagues state that one of the exceptions for anticoagulation should be if "the patient is older than 80 years." Although elderly patients are more likely to have multiple pathology precluding them from taking anticoagulants (for example, peptic ulcers or dementia), this is not universal. An eight year follow up study of patients taking warfarin has shown that there is no association of age with minor or major bleeding complications.[3] As atrial fibrillation is a considerable contributor to stroke in older people[4] it is precisely these patients who require anticoagulant drugs. Age alone should not be an exclusion for treatment with warfarin, and an otherwise "fit" elderly patient with atrial fibrillation should not be deprived of its benefits.

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Atrial fibrillation associated with aging

EDITOR,—The survey of use of anticoagulation in patients with atrial fibrillation by Philip M W Bath and colleagues adds to the evidence that the results of high quality research are not in themselves enough to change clinical practice.[1] The data that Bath and colleagues present on the use of anticoagulants in their hospital are not, however, inconsistent with the treatment guidelines they propose in their comment. In their sample the median age was 79, and about half the patients who did not have a comorbid condition contraindicating anticoagulation received either warfarin or aspirin. As they recommend that patients over the age of 80 should not receive anticoagulants this proportion seems about right.

The fact that half of this sample were over the age of 80 emphasises the extent to which atrial fibrillation is, overwhelmingly, associated with aging. In the Framingham study 36·2% of strokes in patients aged 80-89 were attributable to atrial fibrillation compared with 8·1% in those aged 60-69 and 21·3% in those aged 70-79.[2] In public health terms the impact of giving anticoagulants on the incidence of stroke is likely to be small if patients over 80 are not offered treatment. The randomised trials of anticoagulation in atrial fibrillation did not exclude older patients, and if these trials are to be the standard by which clinical practice is judged there seems little justification for such a policy. There are, of course, problems in generalising results from clinical trials with their controlled conditions, and clinical judgment must be used to assess the ratio of benefit to risk in individual patients. Recommending against the use of anticoagulation on the basis of age alone, however, is outdated and inappropriate.

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Informed consent in clinical trials

Should be comprehensive . . .

EDITOR,—We were surprised to witness the selective attention given by two "committed trialists" to existing work on the subject they were addressing—namely, fully informed consent.[1] Many studies have shown not only that patients want more detailed information about what is happening to them[2] but that this information may help in their psychological management of the experience of treatment. Contrary to Jeffrey S Tobias and Robert L Souhami's argument, Fallowfield *et al* showed that women with breast cancer who participated in randomised trials experienced no more psychological, sexual, or social problems than women who decided about their treatment themselves.[3] In a different setting, but using more reliable methods, Kerrigan *et al* showed that detailed information on possible adverse outcomes fails to increase anxiety in patients about to undergo repair of an inguinal hernia.[4] In sum, the case for offering patients more detailed information on the treatment recommended and why it is being recommended is incontrovertible despite the anecdotal tale offered as evidence by the authors.

The authors use the argument that seeking normal consent to treatment results in confusion and distress to defend their position challenging the need to fully inform candidates recruited into a clinical trial. This is surely unacceptable. One can sympathise with the dilemma faced by researchers who find it difficult to recruit subjects. But to pretend that the solution to the issue lies in not informing at all, because of the need to reduce the distress that may be caused by offering details of treatment, is spurious.

The authors chose not to address other reasons why recruiting informed patients into trials may be difficult. Might informed patients withdraw from trials because, having received information, they are able to contemplate various outcomes of treatment and may decide to accept an outcome that is different from that being treated? Truly informed consent enables the patient to make his or her own judgment about the impact of the various treatment options offered.[5] An informed patient may choose a non-interventional treatment in the hope of benefiting from an enhanced quality of life even if longevity may be reduced. Risk is seen differently when it is your own. Doctors must not forget this.

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. . . it's the law

EDITOR,—Jeffrey S Tobias and Robert L Souhami argue that informed consent should be obtained "in the manner considered best for the individual patient" in clinical trials.[1] They also acknowledge the counterargument that they could be accused of advocating a paternalistic, "doctor knows best" approach.

I sympathise with their plight, but these discussions are taking place too late. The difficulty of adopting fully informed consent, which has its origins in the culture of the United States, in Europe has been discussed for many years. The directive of the European Commission implemented in the United Kingdom on 29 November essentially embraces all the elements of good clinical practices for clinical research in the United States.[2]

Whether we like it or not, obtaining fully informed consent—preferably in writing—is the