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.

T SOLANKI

Selly Oak Hospital,
Birmingham B29 6JD

1 Bath PMW, Prasad A, Brown MM, MacGregor GA. Survey of use of anticoagulation in patients with atrial fibrillation. *BMJ* 1993;307:1045. (23 October.)
2 Petersen P, Boysen G, Godtfredsen J, Andersen ED, Andersen B. Placebo-controlled, randomised trial of warfarin and aspirin for prevention of thromboembolic complications of chronic atrial fibrillaion. *Lancet* 1989;i:175-9.
3 Boston Area Anticoagulation Trial for Atrial Fibrillation Investigators. The effect of low-dose warfarin on the risk of stroke in patients with nonrheumatic atrial fibrillation. *N Engl J Med* 1990;323:1505-11.
4 Schutz H, Bodekar RH, Damian M, Krack BC, Dorndorf W. Age-related spontaneous intracerebral hematoma in a German community. *Stroke* 1990;21:1412-8.
5 Tabibian N. Acute gastrointestinal bleeding in anticoagulated patients: a prospective evaluation. *Am J Gastroenterol* 1989;84: 10-2.

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.

DEBRA KING
KEREN N DAVIES

University Department of Geriatric Medicine,
Royal Liverpool Hospital,
Liverpool L7 8XP

1 Bath PMW, Prasad A, Brown MM, MacGregor GA. Survey of use of anticoagulant in patients with atrial fibrillation. *BMJ* 1993;307:1045. (23 October.)
2 Kufner M, Nixon G, Silverston F. Physicians' attitudes toward oral anticoagulants and antiplatelet agents for stroke prevention in elderly patients with atrial fibrillation. *Arch Intern Med* 1991;151:1950-3.
3 Gurwitz JH, Goldberg RJ, Holdern A, Knapic N, Ansell J. Age-related risks of long-term oral anticoagulant therapy. *Arch Intern Med* 1988;148:1733-5.
4 Wolf PA, Abbot RD, Kannel WB. Atrial fibrillation: a major contributor to stroke in the elderly. *Arch Intern Med* 1987;147: 1561-4.

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.

TIM LANCASTER

General Practice Research Group,
University Department of Public Health and Primary Care,
Radcliffe Infirmary,
Oxford OX2 6HE

1 Bath PMW, Prasad A, Brown MM, MacGregor GA. Survey of use of anticoagulation in patients with atrial fibrillation. *BMJ* 1993;307:1045. (23 October.)
2 Wolf PA, Abbott RD, Kannel WB. Atrial fibrillation: a major contributor to stroke in the elderly. *Arch Intern Med* 1987;147: 1561-4.

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.

MARK EMBERTON
CAROL WOOD
PHIL MEREDITH

Surgical Audit Unit,
Royal College of Surgeons of England,
London WC2A 3PN

1 Tobias J, Souhami R. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201. (6 November.)
2 Cassileth BR, Zupkis RV, Sutton-Smith K, March V. Information and participation preferences among cancer patients. *Ann Intern Med* 1980;92:832-6.
3 Fallowfield L, Hall A, Maguire G, Baum M. Psychological outcomes of different treatment policies in women with early breast cancer outside a clinical trial. *BMJ* 1990;301:575-80.
4 Kerrigan DD, Thevasagayam RS, Woods TO, McWelch I, Thomas WEG, Shorthouse AJ, *et al*. Who's afraid of informed consent? *BMJ* 1993;306:298-300.
5 Scarman, Lord. Consent, communication and responsibility. *J R Soc Med* 1986;79:697-700.

. . . 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