Table 1—Data available from trial comparing short term (five years) treatment with adjuvant tamoxifen with longer term treatment (eight years and seven months) for breast cancer. Figures are numbers of women except where otherwise stated

	Short term treatment	Long term treatment
Survival (%)	96	94 (P = 0.11)
Event free survival (%)	92	86 (P = 0.016)
Recurrence	10	23
Death	13	23
Cancer in contralateral breast	5	6
Second primaries	16	24

unpublished data. Table 1 gives the data, which are available under the American Freedom of Information Act.

Baum and Cuzick believe that the statistical analysis is highly unreliable and that the National Surgical Adjuvant Breast and Bowel Project, the National Cancer Institute and its independent data safety monitoring committee, and the Food and Drug Administration met "to influence policy on the European side of the Atlantic." A more charitable view might be that they issued their clinical announcement for the benefit of patients.

There will be consternation among the Californian panel on carcinogenesis and a second group of experts who met recently at the International Agency against Cancer in Lyons. Their conclusion, that tamoxifen is a carcinogen,^{3,4} is dismissed as "absurd" by Baum and Cuzick. Newbold *et al* have recently shown that tamoxifen induces proliferative changes in the oviduct and uterus of mice treated with tamoxifen (100%) and at 12 months of age there is an increased incidence of endometrial cancer.⁵ They might be well advised to withdraw their abstract before Baum and Cuzick take them to task.

Sasco and Gendre point out that drugs other than tamoxifen are also carcinogenic.⁶ This does not stop such compounds being used, but they must be used with care rather than handed out like sweets, and the recipients should be informed of the risks involved.

Helena Earl and colleagues' letter about the aTTom trial states that there is "an ethical and scientific imperative to determine the optimum duration of treatment."¹ The design of their trial, however, does not seem to address the problem that some volunteers will not benefit from treatment and that the prognosis in others is so favourable that they also are not appropriate candidates for adjuvant treatment. Nor will the trial determine the costs of the treatment in terms of side effects, which Baum and Cuzick believe to be "anecdotal," since the end point is the number of dead in each arm.

R D BULBROOK

Former head, clinical endocrinology laboratory, Imperial Cancer Research Fund

Clachan,
Dunlichity,
Inverness IV1 2AN

- 1 Adjuvant treatment with tamoxifen [letters]. *BMJ* 1996;312:1036-7. (20 April.)
- 2 Bulbrook RD. Long term adjuvant therapy for primary breast cancer. *BMJ* 1996;312:389-90. (17 February.)
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Informed consent and follow up in aTTom trial are inadequate

EDITOR,—The fact that women will be given adjuvant tamoxifen for more than five years despite the National Cancer Institute's warning that longer term treatment may do more harm than good is not the only reason why doctors and the public should reject the controversial aTTom (adjuvant tamoxifen treatment—offer more?) trial in breast cancer and its international counterpart, ATLAS (adjuvant tamoxifen—longer against shorter).^{1,2}

The megatrial was designed to "impose no extra workload on collaborators, other than randomizing and treating their patients, so that even the busiest clinicians can participate. There are no forms at all to complete, and no regular follow-up information is required—survival information will be obtained from national registries." There will be "no extra investigations, no extra clinic visits, infrequent follow-up, and no requirements for detailed documentation of initial status, toxicity, treatment compliance, health economic aspects, quality of life, and so on."³ Although patients are randomised "to at least 5 years of tamoxifen while some may be rerandomized after 5 years to lifetime tamoxifen,"⁴ the designers believe that it is not necessary to ensure that the 20 000 women are closely and uniformly monitored for gynaecological conditions associated with tamoxifen, including endometrial cancer. Nor will clinicians be required to monitor the women routinely and report other second tumours, liver toxicity, thromboembolism, ocular toxicity, depression, or bone loss in premenopausal women—conditions associated with longer term tamoxifen in clinical trials.

The process of gaining informed consent for the aTTom and ATLAS trials also leaves much to be desired, as is evident from a flyer issued by Wandsworth Health Authority's local research ethics committee in 1995:

Tamoxifen does cause some minor side effects in a few women, which either lessen if the treatment is continued or cease when the treatment is stopped. There is some evidence that there may be a small risk of an increase in diseases of the liver and womb if tamoxifen is taken for many years. Nobody knows for sure....

It is unclear if the invitation's wording is the product of a single research ethics committee's interpretation of the world literature or stems from a model developed by the national trialists, who have argued that "the recent trends towards extensive informed consent, careful quality of life assessment and measurements of economic costs of treatments in trials are often seriously inappropriate."⁵ The *BMJ* is to be commended for publishing an editorial questioning the ethics of such extended trials of tamoxifen.¹

HAZEL CUNNINGHAM

Former assistant specialist, University of Hawaii School of Public Health

166 L. Waialae Beach Road,
Wailuku, HI 95793,
USA

- 1 Bulbrook RD. Long term adjuvant therapy for primary breast cancer. *BMJ* 1996;312:389-90. (17 February.)
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Specialist surgeons and survival in breast cancer

Observational studies are essential

EDITOR,—Several letters¹ have criticised the methods used and the conclusions drawn in

Charles R Gillis and David J Hole's study, which showed substantial improvements in survival from breast cancer among women referred to specialist surgeons.² The study used observational data from the West of Scotland Cancer Registry. It is argued that such data can never be appropriately controlled for differences in case mix and that only data from randomised controlled trials can be used to provide reliable evidence. We believe that this objection is invalid and negates the underlying importance of observational studies in health services research, which Nick Black has highlighted.³

We do not deny the obligatory role of randomised controlled trials in evaluations of alternative treatments. Specialist care, for which specialist surgeons were a marker in the Scottish study, is not simply about improved surgical technique or the optimum deployment of adjuvant treatment but includes treatment by a multidisciplinary team with access to all oncological and nursing facilities. This overall context can rarely, if ever, be evaluated by randomised controlled trials.

The evidence review prepared for the National Clinical Outcomes Subgroup on Breast Cancer Guidance (chaired by one of us (RAH)) identified 27 observational studies relating case volume and process to outcome, of which nine dealt with breast cancer. Five further studies dealt with the effect of specialisation on survival or mortality of patients with breast cancer. While a few studies were relatively small (under 1000 patients), four had over 5000 patients, of which two had over 10 000 patients. Controlling for case mix and patients' characteristics is a major problem, although in our analysis of survival in breast cancer among 13 000 women in Yorkshire, adjustment using crude but consistent indicators of prognosis had no impact on the results.⁴ This may be because potential biases that may operate with smaller numbers are minimised when large numbers are studied in a population context.

Population based research that uses data from sources such as cancer registries can quantitatively assess the experience of an entire community and compare it with that of another community. Such communities may live in different areas and be served by different hospitals or may live in the same area but follow different referral pathways from their general practitioners. Observed differences require explanation and in some cases may be artefactual. The observations need to be made, however, as a necessary component of rigorous evaluative research. This is not just a plea from academic research workers but also an increasing demand from patient and community groups.

R A HAWARD

Professor of cancer studies

D FORMAN

Professor of cancer epidemiology

Centre for Cancer Research,
University of Leeds,
Cookridge Hospital,
Leeds LS16 6QB

- 1 Specialist surgeons and survival in breast cancer [letters]. *BMJ* 1996;312:1155-6. (4 May.)
- 2 Gillis CR, Hole DJ. Survival outcome of care by specialist surgeons in breast cancer: a study of 3786 patients in the west of Scotland. *BMJ* 1996;312:145-8. (20 January.)
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Treating a specified number of patients is no guarantee of quality

EDITOR,—The NHS Executive has recently written to trust executives about the development of

cancer units in district general hospitals.¹ It refers to the number of patients with common cancers whom surgeons need to treat to ensure adequate skill and suggests that figures regarded as adequate now will be revised upwards in the future.

At present no firm recommendations exist about the critical number of patients who are required to ensure adequate clinical skill, though 50-80 per specialist has been suggested by the British Association of Surgical Oncology and the British Breast Group. The only evidence currently available suggests that outcome is better when the annual caseload per consultant exceeds 30 compared with under 10.² Evidence from the same source showed a slightly worse (though not significant) outcome, with fewer patients receiving adjuvant treatments, when the caseload exceeded 50, but this has received no attention. The study concluded that improved survival could be explained by the introduction of a multidisciplinary approach to treatment and that the effect of patient numbers was probably a function of this and of clinical organisation.

A recent paper suggested that the prognosis of patients with breast cancer is improved by specialist care.³ A specialist interest was defined on the basis of four criteria: having a dedicated breast clinic; having a defined association with pathologists and oncologists, organising and facilitating clinical trials, and maintaining a separate record of all patients. The paper received some criticism (though general support for specialist care),^{4,5} but, interestingly, the number of patients treated was not a criterion.

It is nonsense to assume that the quality of a clinical service bears a linear relation to the number of patients treated. Just as a minimum number of patients is necessary to maintain skill, there is probably a maximum number (still to be determined) above which the service becomes overwhelmed. For every new patient seen with breast cancer, up to 15 are now referred with benign disease, implying a total of 1000-1500 new referrals in a practice seeing 60-100 new cancers a year; this is quite enough to ensure continuing skill in a district general hospital committed to subspecialisation.

The management of cancer is not simply a matter of number crunching: 200 patients can be treated just as badly as 20. The quality of a cancer unit should be measured chiefly by the commitment of its staff to subspecialisation; multidisciplinary consensus management; and participation in continuing medical education, audit, and clinical trials—and ultimately by its results.

ADRIAN BALL
Consultant surgeon

Breast Service,
Department of Surgery,
Crawley Horsham NHS Trust,
Crawley Hospital,
Crawley,
West Sussex RH11 7DH

- 1 Langlands A, Calman K. *A policy framework for commissioning cancer services*. Leeds: NHS Executive, 1996. (EL(96)15.)
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Authors' reply

EDITOR,—We wish to respond to several points raised in the previously published letters¹ and the above letters about our paper.² None of Ian Campbell's points¹ change our results or their interpretation. We considered selective bias by

analysing our data on the basis of hospital catchment areas. Specialists and non-specialists worked in the same hospital serving the same catchment areas. There was a 4.6% advantage in five year survival for those catchment areas where the specialists saw 44% of patients compared with those where the specialists saw only 9% of patients. As both analyses showed an advantage for specialist care, selection bias is an unlikely explanation of the differences seen.

We relied heavily on tumour size as the main prognostic factor because of our stated concerns about the accuracy of nodal assessment. Using actual tumour size, or six rather than three categories, as a covariate in the survival analysis leaves the hazard ratio for specialists relative to non-specialists unaltered at 0.83.

Our data fit the proportional hazards model well. Analysis of the data in two separate periods of follow up (0-5 and 5-10 years) produced ratios of 0.81 (95% confidence interval 0.70 to 0.93) and 0.89 (0.71 to 1.11) respectively for specialists compared with non-specialists.

To say that our study was biased because we did not take all prognostic factors into account is to say that all non-randomised studies of disease are biased. While randomised controlled trials give an indication of efficacy in a selected population, observational studies show how effective findings are in the general population. Also, when there are difficulties in carrying out a randomised trial, observational studies are the only means of proceeding.

We agree with Michael Baum¹ that the maximum difference that could be attributed to the application of optimal adjuvant treatment is 4%, compared with the 11% advantage that we observed for specialists in patients aged 50-64. We present no evidence to explain this observation. We believe that the only way to test the validity of our findings is to extend the period of the study to the present, with the cooperation of the specialists. This is now being done.

We agree with Adrian Ball, in the letter above, that the number of patients treated should never be the sole criterion for designating a service as a specialist service. The ultimate assessment of survival will come from prospective audit. This will give precise meaning to the term "specialist."

CHARLES R GILLIS
Director

DAVID J HOLE
Principal epidemiologist

West of Scotland Cancer Surveillance Unit,
Ruchill Hospital,
Glasgow G20 9NB

- 1 Specialist surgeons and survival in breast cancer [letters]. *BMJ* 1996;312:1155-6. (4 May.)
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Anaesthesia in the United States

Anaesthesia in Britain is as bad as in the United States

EDITOR,—I am a registrar and, like Peter Hambly¹, on an exchange—but from the Groote Schuur Hospital, Cape Town, to a similar post in Kent. In Britain, as in the United States, anaesthesiologists do not warrant the time of day. Surgeons do not inform us of when they are about to make the incision, dilate the cervix, or stretch the anus; nor do they keep us informed of their progression or imminent termination of the operative procedure. Surgeons do not inform us that they are going to inject adrenaline (into patients with heart disease) or pump the abdomen full of carbon dioxide. We are just there to deal with the consequences. Similarly, we are

expected somehow to know which antibiotics are favoured in particular situations by every surgeon.

Surgeons do not discuss with the anaesthetist planned major surgery, changes to their lists, or variations from the scheduled starting times (I can count on one hand the number of operating sessions that have started on time in the past year). They post their out of hours operating list on the board and expect the anaesthetists to assimilate it by osmosis or extrasensory perception. They would not think of telephoning me to discuss preoperative care and preparations; this results in money being wasted on unnecessary investigations, while patients most in need of specialised investigations do not have them, which results in delayed surgery.

Anaesthetists are seen as dispensable technicians, great for looking after central venous lines and for making frequent adjustments to the light but not to be consulted in greater matters of clinical state. I was also astounded to learn that in Britain anaesthetists seem to have a monopoly on the airway and that doctors who spend their entire working lives in accident and emergency medicine either cannot or will not intubate patients.

Surgeons also fail to realise their responsibilities in transferring patients from the bed to the operating table, since they are never in theatre when this takes place. A case heard in Windhoek (Namibia) Supreme Court found that the surgeon and anaesthetist had to be in the operating room when such a transfer was made.

The training that I received in Cape Town could not have been bettered in any way, either in the variety of clinical experiences or in the many skills imparted. The new, seamless modular training proposed by Calman will produce anaesthetists without this wide range of clinical experiences. Hambly misses British surgeons; I miss the Cape Town surgeons for their unfailing courtesy and their communication skills.

ERROL M CORNISH

Specialist registrar in anaesthetics and intensive care

11 Holmbury Park,
Bromley,
Kent

- 1 Hambly P. Visions of anaesthetic hell. *BMJ* 1996;312:1045. (20 April.)

Anaesthesia is an unpopular specialty in the United States

EDITOR,—Peter Hambly's visions of anaesthesia hell accurately describe the relationship between anaesthetists and surgeons in one of the more aggressive surgical institutions in the United States.¹ A more positive professional ambience is normal in private practice and in my own experience at the University of Virginia. The reasons that Hambly gives for this unfortunate relationship echo my own, but recently issued American training statistics for the specialty paint a dismal picture.

Over the past five years the number of residency positions available each year has fallen from over 1300 to 712 for July 1997. Of those 712 positions offered, only 211 (30%) have been filled. These positions were offered across the country by 118 training programmes, only six of which filled all their positions. Last year saw similarly dismal figures, with only 44% of positions being filled.

Hambly's article goes some way towards explaining why the number of people entering the specialty has fallen so dramatically. Discussions in coffee rooms here suggest that the availability of jobs at the end of training and financial reward have a more pivotal role in attracting new residents. It is now well recognised that hospital