terms of a salaried service, were not lost on the audience many of whom practised on an item-for-service basis. Controversy over such matters highlights the importance of the medical care system for the content and quality of general practice in different countries. These comparisons were emphasized by papers looking at the nature of primary care in Scotland, Denmark, Holland, Norway and Yugoslavia. The last day focused on the problems of minority communities and produced some fascinating papers on migrant workers in Germany, gypsies in Hungary and a study of morbidity patterns amongst immigrants in the UK by Dr Laurence Pike.

In addition to the formal presentations there were workshops on teaching and research, which included one on the use of audiovisual methods given by Dr de Buda from Toronto and another on the appreciation of research publications given by Dr Chavannes from Holland.

### Informal contacts

As is usual at such meetings, the informal contacts were just as important as the formal proceedings. These provided opportunities to get to know general practitioners and their families from many different countries. Problems shared and compared broaden horizons and raise perspectives. The facility with which many European doctors converse in several languages is humbling, but British general practice is well represented on the board of

SIMG by Dr Lotte Newman and Dr Peter Frank, who are bilingual with English in German and Hungarian respectively.

Klagenfurt is well placed as a meeting place where family doctors from all over Europe, both East and West, can exchange ideas. If anything the contributions from central Europe tended to be more philosophical, with hard data on general practice coming more from the UK, the Netherlands and Scandinavia, as well as some from Eastern Europe. But we have much to learn as well as much to give in this renaissance of primary care. The SIMG international congress provides a well organized, enjoyable and stimulating forum for any general practitioner, to which many return with profit and pleasure.

## **CONTROVERSY**

# Change the rules for clinical trials in general practice

G. T. LEWITH

Director, Centre for the Study of Alternative Therapies, Southampton

### D. MACHIN

Senior Lecturer in Community Medicine, University of Southampton

Clinical decisions in general practice involve many variables. Before prescribing a particular therapy, factors such as age, current drug regime and the likelihood and severity of adverse effects must all be taken into account. It is likely that the drug considered by the general practitioner was evaluated by a randomized controlled trial in which its desired therapeutic effect achieved the accepted level of statistical significance.

WHEN evaluating a comparative drug trial with a statistical test, we assume the results are not random if the probability of the observed result of the test occurring by chance is 1 in 20 or less. This arbitrary probability, p=0.05, has come to be the usually accepted level of statistical significance. Why has this figure been generally applied? Why not probabilities of p=0.1 or 0.01? The reason may be historical in that p=0.05 fits almost exactly into the normal distribution curve, and describes the proportion in excess of two standard deviations from the mean. Nevertheless this probability figure is arbitrary and not always appropriate. For instance, when dealing with a rare disease it may be difficult to obtain adequate numbers of patients for a clinical trial, and p=0.1 may be an acceptable level particularly if the disease is life-threatening.

Too often studies are published comparing two treatments, in which the authors conclude that both treatments are equally effective, but have studied insufficient numbers of patients to justify such a conclusion. For example, if a researcher wished to evaluate two different treatments, one 50 per cent effective and the other 70 per cent effective, approximately 90 patients would be needed in each treatment group for an 80 per cent chance (often referred to as power) of demonstrating a difference between the two groups with a probability value of p=0.05. In clinical terms a 20 per cent treatment advantage may be very important, but it is often impossible to execute clinical trials with enough subjects to demonstrate such differences if the present statistical standard is accepted.

The general practitioner often has to deal with vague problems and evaluates both diagnosis and therapy in terms of probabilities. General practitioners may be prepared to prescribe a relatively safe therapy that may only have a moderate chance of being effective. Statistical and clinical techniques for evaluating the efficacy of a treatment generally have been developed for the requirements of hospital specialists. It may be inappropriate to take results obtained in the hospital ward and transfer them to the general practitioner's surgery, without taking into account differences in the severity and type of problems encountered in these two environments.

It would be logical to assume that a life-threatening disease for which there is no available effective treatment should have a low threshold for the acceptance of new therapy, whatever the possible adverse effects. For minor self-limiting illnesses, a low threshold of acceptance might also be reasonable, providing the therapy has few or no adverse effects.

Statistics, when applied to biological systems, must assume a series of rules. However, as Professor Howie pointed out, 'Statistical significance does not automatically imply clinical significance'. It is also necessary to point out that statistical insignificance does not automatically imply clinical insignificance.

#### References

- Altman DG. Statistics and ethics in medical research, III: How large a sample? Br Med J 1980; 281: 1336-1338.
- Howie JGR. Research in general practice. Croom Helm, London, 1979.