Note to authors of letters: Letters submitted for publication should not exceed 400 words. All letters are subject to editing and may be shortened. Letters may be sent either by post (please use *double spacing* and, if possible, include a Word for Windows or plain text version on an IBM PC-formatted disk), or by e-mail (addressed to journal@rcgp.org.uk; please include your postal address). All letters are acknowledged on receipt, but we regret that we cannot notify authors regarding publication.

Acute sinusitis and antibiotic treatment

Sir,

Stalman *et al* presented an interesting study (December *Journal*)[1] that found no significant differences between 10 days' treatment of doxycycline and placebo in adults with acute sinusitis-like complaints.

We performed a similar trial comparing penicillin V and amoxycillin treatment in patients with acute sinusitis.[2] Our reference standard was computed tomography (CT), with fluid level or total opacification as criteria of acute sinusitis. In this study, 10 days' antibiotic treatment gave significantly faster response than placebo, evaluated by four outcome measures.

In addition, we performed a study on 63 patients with mucosal thickening of 5 mm or more without fluid level or total opacification. We found no significant differences between the antibiotic group and the placebo group with regard to subjective status, clinical status, and duration of illness (to be published elsewhere).

Our study also included a group of 40 patients with no CT findings who did not get any medication. To compare our studies with that of Stalman, the results in the sinusitis group was summated with those with only mucosal thickening or no CT findings, comprising a total of 230 patients. The difference in proportion of patients feeling restored after 10 days diminished between the antibiotic groups (88/151; 58%) and the placebo group (32/79; 41%), the difference still being significant ($P = 0.01$).

In our BMJ study we had a high probability of bacterial sinusitis.[3] In the Stalman study, only clinical symptoms and signs without any objective visualization were used to include patients. This is the main difference between the two studies and can explain the different results. As the authors state, virus may be the causing agent of many of their patients' illnesses. Thus, we do not agree with the authors that supportive treatment could explain the different results, as our patients also got decongestants.

The authors do not raise the question whether subgroups among patients with a clinical diagnosis of acute sinusitis benefit from antibiotic treatment. Our study has demonstrated that patients with a CT-confirmed acute sinusitis, as a group, benefit from antibiotics. All patients in general practice cannot and should not be investigated by CT or X-ray. The real challenge is clinically to single out patients with a bacterial sinusitis. In another article we demonstrated that patients with at least three out of four clinical symptoms and signs (purulent rhinorrhoea, two phases in the disease history, purulent nasal secretion, and erythrocyte sedimentation rate >10 mm) had a positive predictive value of 0.86 of having a CT-confirmed acute sinusitis.[4] In addition, Gwaltney has underlined the importance of at least seven days' duration before diagnosing bacterial sinusitis.[5]

MORTON LINDBÆK
PER HJORTDAHL

Department of General Practice
University of Oslo, Norway

ULF L-H JOHNSON

Department of Neuroradiology
Ullevål Hospital
University of Oslo, Norway

References

1. Stalman W, van Essen GA, van der Graaf Y, de Melker RA. The end of antibiotic treatment in adults with acute sinusitis-like complaints in general practice? A placebo-controlled double-blind randomized doxycycline trial. *Br J Gen Pract* 1997; **47:** 794-799.
2. Lindbæk M, Hjortdahl P, Johnson U L-H. Randomized, double-blind, placebo-controlled trial of penicillin V and amoxycillin in treatment of acute sinusitis infection in adults. *BMJ* 1996; **313:** 325-329.
3. Willett LR. Commentary on 'Penicillin V and amoxycillin improved health status in sinusitis.' *ACP J Club* 1997; **126:** 10.
4. Lindbæk M, Hjortdahl P, Johnson U L-H. Use of symptoms, signs and blood tests to diagnose acute sinus infections in primary care: comparison with computed tomography. *Fam Med* 1996; **28:** 181-186.
5. Gwaltney JM Jr. Acute community-acquired sinusitis. *Clin Inf Dis* 1996; **23:** 1209-1225.

Counselling in primary care

Sir,

The two recent studies concerning counselling in primary care (March *Journal*)[1,2] add valuable information to the debate about the effectiveness of counselling in this setting. Unfortunately, their results appear conflicting and the debate unresolved.

Counsellors are new to primary care, and how patients of GPs have become clients of counsellors has not been described. In the study by Harvey *et al*, any adult with emotional or relationship problems was eligible for inclusion.[1] The authors were unable to determine the number of potential recruits and, unfortunately, we are not told the practice populations or consultation rates. From the information given, the population from which the study group was drawn was probably in excess of 50 000, so, over the two years of the project, 100 000 adult consultations would have taken place, of whom 30 000 would be expected to have some degree of psychosocial distress. How then were the 162 recruits selected?

Baker *et al* specified more stringent referral criteria but even less information about the population from which they were drawn.[2] There are worries also about their attrition rate, as only 117 clients were included in the analysis from the 583 referred to the service. We are unable to determine whether the different outcomes of the two studies were the result of bias arising from the absence of a control group or arising from patient selection. To make sense of the results, we need to know much more about the process of patient selection and recruitment.

While both studies are to be congratulated on their pragmatic approach, the ill-defined patient entry data criteria and heterogeneity of study groups limits their interpretation and generalizability. I would suggest that the results should inform a future research agenda rather than purchasing policy.[1]

MICHAEL MOORE

Three Swans Surgery
Rollestone Street
Salisbury
Wilts SP1 1DX

References

1. Harvey I, Nelson S, Lyons R, *et al.* A randomized controlled trial and economic evaluation of generic counselling in primary care. *Br J Gen Pract* 1998; **48:** 1043-1048.
2. Baker R, Allen H, Gibson S, *et al.* Evaluation of a primary care counselling service in Dorset. *Br J Gen Pract* 1998; **48:** 1049-1053.

Sir,

Harvey *et al* (March *Journal*) undertook a randomized controlled trial and health economic evaluation of counselling in primary care. They found no difference in functional or mental health outcome at four months between subjects referred to counselling or those given usual care by their GP. They also found no clear difference in the cost effectiveness of the two interventions.[1] However, the emphasis given by the authors on functional and mental health outcomes may hide some of the other benefits of counselling identified within the study.

Table 6 of the paper identifies that patients in the counselling group made substantially lower demands on GP time, were prescribed fewer drugs, and were less likely to be referred to specialist mental health services.

These are benefits in themselves, but are not highlighted in the conclusions of the report. They are also outcomes that are directly sought from counselling.[2,3] This trial shows that it is possible to achieve these benefits, which are improvements in the quality of care, through counselling, while maintaining the same outcome as traditional care and within a broadly similar cost envelope.

In conclusion, it appears that this trial should be seen as being broadly supportive to counselling, given that it offers quality improvements with no effect on outcomes and no significant evidence of increase in costs.

MAX KAMMERLING

Somerset Health Authority
Wellsprings Road
Taunton
Somerset TA2 7PQ

References

1. Harvey I, Nelson S, Lyons R, *et al.* A randomized controlled trial and economic evaluation of generic counselling in primary care. *Br J Gen Pract* 1998; **48:** 1043-1048.
2. Fletcher J, Fahey T, McWilliam J. The relationship between the provision of counselling and the prescribing if antidepressants, hypnotics, and anxiolytics in general practice. *Br J Gen Pract* 1995; **45:** 467-469.
3. Scott A, Vale L. Increased general practice workload due to a primary care led National Health Service: the need for evidence to support rhetoric. *Br J Gen Pract* 1998; **48:** 1085-1088.

Cluster randomization

Sir,

We agree with Underwood *et al* (March *Journal*)[1] that researchers are often unaware of the effect of cluster randomization on the power of the study. This is understandable as it is largely ignored in texts on medical statistics, even including specialists books on sample size calculations. The standard work on sample size for clinical trials[2] only included cluster randomization in the second edition.[3] We have written a series of articles for clinicians demonstrating the dangers of an incorrect analysis[4,5] and describing appropriate sample size calculations.[6,7] We have used examples from a range of general practice situations but we have not encountered a design effect as large as 24.5, as Underwood *et al* have quoted. The reported calculations contain an error either in the design effect or in the intracluster correlation coefficient (ICC).

Applying the formula $1+(\bar{n}-1)r$, where r is the ICC, gives an inflation factor of 4.58 where $\bar{n}$ is 200 and r is 0.018, not 24.5 as the authors state. This would result in a total sample size of 6074 patients, which could be obtained from 36 practices. Although greater than the original 24 the authors had planned to use, it would be far more realistic and practicable to recruit another 12 practices than the 162 required to satisfy the design effect of 24.5.

A design effect of 24.5 could result from an ICC of 0.118. In our experience, values of ICC in general practice trials are likely to be between 0.001 and 0.05. This is in agreement with the authors' own report. A value of 0.118 would seem unusually high, particularly as HbIAC is an outcome measured on the patient directly, and is affected by many patient factors as well as GP care. High values of ICC, greater than 0.01, are more likely to be found for outcomes such as prescribing, which measure doctor behaviour directly.[6]

Cluster randomization may indeed be a trap for the unwary, but not as deep as the authors suggest.

SALLY KERRY
MARTIN BLAND

Division of General Practice and Primary Care
St George's Hospital Medical School
Hunter Wing
Cranmer Terrace
London SW17 0RE

References

1. Underwood M, Barnett A, Hajioff S. Cluster randomization: a trap for the unwary. *Br J Gen Pract* 1998; **48:** 1089-1090.
2. Machin D, Campbell MJ. *Statistical tables for the design of clinical trials.* London: Blackwell Scientific Publications, 1987.
3. Machin D, Campbell MJ. *Statistical tables for the design of clinical trials.* 2nd edition. London: Blackwell Scientific Publications, 1997.
4. Kerry SM, Bland JM. Statistics notes. Analysis of a trial randomised in clusters. *BMJ* 1998; **316:** 54.
5. Kerry SM, Bland JM. Trials which randomise practices I: how should they be analysed. *Fam Pract* 1998; **15:** 80-83.
6. Kerry SM, Bland JM. Statistics notes. Sample size in cluster randomisation. *BMJ* 1998; **316:** 549.
7. Kerry SM, Bland JM. Trials which randomise practices II: sample size. *Fam Pract* 1998; **15:** 84-87.

Urine sample collection

Sir,

The article by Giddens and Morrison (February *Journal*)[1] highlighted the importance of accurate diagnosis of urinary tract infection in small children and the difficulties of accurate urine collection.

In our study (May *Journal*),[2] we discussed GPs' problems with urine collection. We found that GPs collected more satisfactory urine samples from infants than from older children. This may be the result of the widespread introduction of urine collection pads in the geographical area studied.

The high cost and inpractibility of adhesive urine collection bags (frequently commented on by GPs) has been resolved by the introduction of urine collection pads (UCPs),[2-9] which are cheap, easy to use, and available from National Health Service (NHS) supplies (order no. CFQ 152), with savings of about £114 000 since their introduction. Cost estimates in