LETTERS

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Children and clinical trials

The representativeness of children entered into clinical trials is indeed an important issue, as raised by Bain.[1] Recruitment of all children seen by the participating doctors will always remain an utopian ideal. However, this does not imply that results cannot be extrapolated to the population from which the participants of the trial were taken. Bain mentioned that our trial did not report on how representative the children entered into the trial were.[2] This is simply not true. Baseline characteristics of the included children were presented and compared with the characteristics of children with acute otitis media from a large and well executed registration study in Dutch general practice.[3] It was also recorded that 27 of the 425 registered children were not entered into the trial since the general practitioner was of the opinion that the child was too sick to be treated without antibiotics. Therefore I can agree with Bain's conclusion that treating children presenting with severe disease with antibiotics is still justified. This conclusion can be drawn simply by reading the trial report and there is no lack of information as is suggested by Bain. By raising the question of whether children entered into clinical trials on acute otitis media are representative, Bain tackled an important issue. However, his answer is disappointing and suggests that well executed trials are not suitable for day-to-day practice. Our conclusion that watchful waiting is justified for the majority of these children is still important for daily practice and has been recently confirmed.[4] The decision on whether or not to prescribe an antibiotic should be guided by good clinical reasoning, not by fear. By ignoring the minimal effect of antibiotics for acute otitis media, Bain seems willing to go back to the antibiotic era with ensuing increasing resistance of microbes.

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Screening for alcohol abuse

The optimal screening test for alcohol abuse or dependence should be brief and acceptable to both physicians and patients. Only the CAGE questionnaire,[1] the AUDIT-C questionnaire,[2] and the Five-Shot questionnaire[3] are useful in this respect. Nevertheless, the CAGE questionnaire is not sensitive enough and does not distinguish between active and past alcohol problems. Both the AUDIT-C questionnaire and the Five-shot questionnaire were recently introduced into alcohol research as possible alternatives (Box 1).

The AUDIT-C questionnaire, introduced by Bush and colleagues, was performed on a predominantly white, male, veteran population (mean age = 67 years) with multiple medical prob-

Five-shot questionnaire (maximum score = 7, cut-off = 2.5).

1. How often do you have a drink containing alcohol?
   (0.0) Never
   (0.5) Monthly or less
   (1.0) Two to four times a month
   (1.5) Two to three times a week
   (2.0) Four or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
   (0.0) 1 or 2
   (0.5) 3 or 4
   (1.0) 5 or 6
   (1.5) 7 to 9
   (2.0) 10 or more
3. Have people annoyed you by criticizing your drinking?
   (0.0) No
   (1.0) Yes
4. Have you ever felt bad or guilty about your drinking?
   (0.0) No
   (1.0) Yes
5. Have you ever had a drink first thing in the morning to steady your nerves or get rid of a hang-over?
   (0.0) No
   (1.0) Yes

AUDIT-C (maximum score = 12, cut-off = 5).

1. How often do you have a drink containing alcohol?
   (0) Never
   (1) Monthly or less
   (2) Two to four times a month
   (3) Two to three times a week
   (4) Four or more times a week
2. How many drinks containing alcohol do you have on a typical day when you are drinking?
   (0) 1 or 2
   (1) 3 or 4
   (2) 5 or 6
   (3) 7 to 9
   (4) 10 or more
3. How often do you have six or more drinks on one occasion?
   (0) Never
   (1) Less than monthly
   (2) Monthly
   (3) Weekly
   (4) Daily or almost daily

Box 1. Screening questionnaires for alcohol consumption.

lems. Analyses were also restricted to drinkers who responded to a mailed questionnaire. A cut-off of four or more identified 86% of patients with alcohol abuse or dependence, with a specificity of 72%.

Seppa *et al* developed a new questionnaire (the Five-shot), which combined two questions from AUDIT and three from CAGE. Subjects consisted of 40-year-old men who had been invited to a health screening in Finland. A cut-off score of ⩾2.5 gives a sensitivity of 96% and a specificity of 76%, using a reference standard of a daily alcohol intake of >40 g.

We validated those two questionnaires in a large general practice population (men and women) with DSM criteria used as reference standard.[4] Recommended cutpoints corresponded remarkably well in this general practice population concerning the Five-Shot intervention. For the AUDIT-C, a cutpoint of ⩾5 was used in our population. Nevertheless, screening properties vary between male and female.[4]

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Risk information in general practice

The article by Misselbrook and Armstrong[1] raises many issues, and there are two in particular that I should like to address.

First, I would be interested to know how many of my colleagues routinely use the kind of 'risk framing' described in the paper in their everyday practice. While the aim of providing valid risk information is a worthy one, I have serious doubts about the approach. Not only are the statistics themselves dubious (derived as they are from one major trial of mild hypertension), but their confidence intervals for any individual are unknown and unknowable. Furthermore, my own experience is that the great majority of patients — even when presented with some estimate of risk — want me to advise them whether they 'should' start treatment. This leads to my second concern.

When I decide that a patient should be 'offered' treatment for their usually symptomless hypertension, I am aware that behind this decision lies a huge propaganda machine operated by the Joint British Societies, The RCGP, the clinical governance lobby, the pharmaceutical industry, and the general body of right-thinking practitioners who feel it their duty to ride into battle against Tudor Hart's infamous 'rule of halves'. Unfortunately the latter does not include the awkward notion — supported by Misselbrook and Armstrong's paper — that 'half of those offered treatment may legitimately refuse it'. I have yet to see an audit of hypertension detection and management that builds this quite reasonable proposition into its standards and targets. And so, like most practitoners running scared these days, I have no doubt that I lean on my patients, however subtly, to accept the party line and take their medicines just like the doctors say they should. Am I alone?

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Risk information study was marred by poor questionnaire design

Misselbrook and Armstrong (April, *Journal)*[1] addressed the important question of how different forms of risk presentation may affect patients' choice about treatment. Unfortunately, their study was marred by major flaws in their questionnaire design. The authors purported to present the same risk information (i.e. reduction of an absolute annual risk of one in 400 to one in 700) by their four risk-framing questions, shown in their Figure 1, but they completely failed to achieve this objective.

First, for question 1 (i.e. 'would you take the pills described above if they reduced your risk of having a stroke by 45%?'), the patients' decisions clearly depend on their baseline risk of having a stroke — the treatment would be more worthwhile for patients with higher baseline risks. In reality, thoughtful patients would refuse to make a decision until they are told their baseline risks (i.e. 1 in 400, per year). However, the responders were forced to make a choice in the study with insufficient information.

Second, the wording at the beginning of the second question ('i.e. what if you were unlikely to have a stroke...') may lead the responders to think that the researcher expects a different answer from the first question. The use of the word 'unlikely' may strongly bias the responders' response.

Third, question 3 (i.e. 'if the doctor had to treat 35 patients for 25 years in order to prevent one stroke, do you think it would be worth taking the treatment for yourself?') is problematic. The number-needed-to-treat (NNT) of 875 implied in this question, differs significantly from the NNT of 933, implied in question 2. More importantly, future risks are often regarded as less important than present risks. The authors should have rephrased the question as '933 patients for one year'.

Finally, the meaning of question 4 (i.e. 'if the tablets had a 3% chance of doing you good by preventing a stroke and a 97% chance of doing no good, or not being needed in your case, would you take them?') is totally unclear, as the time-frame is missing. How long do the patients have to take the tablets for, to achieve a 3% chance of doing them good? From the information in question 2, the chance of the tablets doing the patients some good

in a year is (1 in 400 to 1 in 700) 0.11%. To achieve a 3% chance of the tablets doing the patients some good, they have to take the tablets for 27 years. The authors should have inserted 'for 27 years' into their question.

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Authors' response

Dr Leung is quite right to point out that risk presentations reported in our study can be criticised for their imprecision. Our intention was to present risk information according to the four different methods found in the epidemiological literature, but in the sort of everyday language that a GP might use with a patient. This explains our rounding of numbers and the use of a notional lifetime risk (assuming a patient is on treatment for about 25 years) for the last two presentations. We recognise — and acknowledged in the paper — that the language we chose is likely to have had an effect on the patient response and initial statements such as 'what if you were unlikely to have a stroke' may already have prejudiced the response. Nevertheless we could see no way round this problem without sanitising the presentations such that they had little relationship to dialogue in routine consultations. By describing the exact statements used, GPs can at least see which is closest to their own presentations. And despite the criticism we still think that our main conclusions stand: that different presentations of the same underlying risk information elicit different responses from patients, that many patients with hypertension would choose not to take treatment if their risk was explained, and that 'informed consent' to treatment is an elusive goal if different ways of being informed can produce such different responses.

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Postal survey responses and questions about income and seeking consent for linkage to medical records

We congratulate Shah *et al* for their investigation of how questions about income and the seeking of consent for linkage to medical records affected response to a postal survey.[1] These are important methodological issues for primary care researchers. We would be more cautious, however, in the conclusions that should be drawn from their work.

The comparison between income and control group appears largely confounded, by the inclusion of items in the questionnaire of the latter group, regarding benefits and pensions. Self-report between different forms of income (e.g. benefits, salaries, and pensions) has been shown to vary.[2] Nevertheless, within this study population, the distinction between banded income estimate and benefits or pensions received may well be quite fine.

Of more note are the conclusions drawn regarding consent. The authors conclude that fears that increasing safeguards on the use of individual data could limit research may be unfounded. In their survey, they point to the fact that only 13% of responders who were asked for consent actually refused. In practice, however, such non-responders may well represent a significant and important sub-group, with implications for representativeness and generalisability.

Furthermore, the actual level of non-response in this survey is much greater, with only 113 out of 208 surveyed (54%) actually returning the questionnaire and providing consent. This, despite a rigorous process of two postal and one telephone follow-up. Losing half of your intended sample would seriously affect the usefulness of much primary care-based epidemiological work.

Factors other than income are known to affect response to postal questionnaires. The nature and purpose of the survey would very probably effect response rate, and may well interact with such a request to link responses to medical records. It would be important to determine the nature of such an interaction, both within the current study and generally.

Finally, uncertainty about the implementation of the new *Data Protection Act* continues to cause concern for clinicians and researchers.[3] We strongly support the ethical and legal imperative to obtain patient consent, even if that requires the prospective collection of consent, where it has not previously been considered necessary. The findings of Shah *et al* are not grounds for complacency, but rather indicates the requirement of a properly funded infrastructure underpinning primary care research.

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The impact of frequent users of OOH services

Vedsted *et al* recently published data regarding frequent attenders to out-of-hours (OOH) services. We have been studying patients' use of Bridgwater out-of-hours and night emergency service (BONES). This primary care cooperative serves 10 practices and 73 401 patients. Computerised records have been kept for four-and-a-half years, during which time there have been 68 995 contacts. Of these, 54% were dealt

Table 1. Proportion of contacts accounted for by the most frequent attenders.

	Normal hours	Out of hours
Top 0.1%	-	5%
Top 1.0%	6%	17%
Top 3.0%	15%	32%

with entirely by telephone, 32% attended the centre, and 14% required visiting. A total of 62% of contacts required advice only, 31% received active treatment, and 6% required admission. General practitioners' workload is high; however, most patients used the service infrequently over the study period. Only 4.5% of patients average more than one OOH contact a year.

The average patient contacts the service approximately once every 4.8 years, requires face-to-face contact with a GP out of hours once every 8.8 years, and only needs active treatment once every 12.5 years. Table 1 indicates the proportion of contacts accounted for by the most frequent attenders.

Thus, the top 0.1% of users account for 5% of contacts. We looked further at this group of very frequent users (VFUs). There was no significant difference between the sexes. The under-five-year-olds were significantly over-represented, as were, to a lesser extent, the 25 to 34 and 35 to 44 year age bands. The older age bands were not over-represented. These results are interesting in that, unlike Vedsted *et al*, they suggest that frequent users of OOH services are different to those of the daytime service, where female patients and the more elderly are over-represented. The proportion of the workload they generate OOH is even greater than that during the day and our data shows that GPs are far more likely to rate contacts of VFUs as inappropriate. They are a small and targetable group of patients whose behaviour, if modifiable, could dramatically reduce OOH workload.

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Evolutionary ethics — a continuing frustration?

The introduction of multi-centre research ethics committees (MRECs) in autumn 1997 was intended to streamline the obtaining of ethical approval from large numbers of local research ethics committeess (LRECs). However, the difficulty in implementing the new system prompted the NHS Executive to issue further guidance in September 1998, explicitly stating the remit of LRECs in handling MREC approved applications.[1] Our experiences in obtaining LREC approval suggest that not all LRECs adhere to these guidelines.

MREC approval was obtained for two follow-up studies of historical cohorts. LREC approval was sought from 225 and 137 committees respectively. Each LREC application averaged 47 pages – consuming 109 000 sheets of paper! It was apparent that many LRECs did not have sub-committees and requested an average of seven copies of the application. If each LREC had a sub-committee with the recommended three members, 59 000 sheets would have been saved.

Although approval was eventually forthcoming from all LRECs approached, approximately 10% made comments and requests for changes beyond the remit of LREC review. These included changes to approved documentation and requests for protocol amendments, in direct conflict with MREC conditions of approval. In two cases, the same committee was inconsistent in their interpretation of data protection issues.

Despite frustrations of other researchers in obtaining local approval,[2-5] LRECs continue to apply their discretion in following established guidelines. Having endured five frustrating months in an expensive and tedious process, we welcomed the new operational guidelines developed by the Central Office for Research Ethics Committees (COREC). In this recent initiative from the Department of Health (http://www.doh.gov.uk/research), it has been decided that for non-therapeutic studies involving no local researcher, MREC approval is sufficient, the need for local review being redundant. For studies with subject contact by a health professional unrelated to the research team (e.g. general practitioners), LRECs are to be informed, but only where the competence of the person is questioned may the LRECs become involved.

These changes represent a clear improvement to the ethical review process. However, they do not address the difficulties encountered with some LRECs not adhering to the guidelines. It is imperative that each LREC only requests a reasonable number of copies of all documents for a sub-committee, and that they review the study for local issues only within the suggested three weeks. Furthermore, latest guidelines on the use of personal information in medical research (http://www.mrc.ac.uk/) need to be widely disseminated to LRECs.

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