Letters

Nicotine replacement therapy should be prescribable on NHS

EDITOR—I welcome the publication of the open letter to the prime minister about tobacco—the most important preventable cause of death in Europe.[1] As Jo E Asvall points out in the letter, tobacco control demands the support of, and action by, the total government, not just the Department of Health. Among the actions Asvall calls for is that "support for smoking cessation is made widely available, particularly through primary health care professionals, including doctors, nurses, pharmacists, and dentists."

Nicotine replacement therapy (nicotine gum, patches, nasal spray, and oral inhaler) is now fully established as an effective adjunct to such professional advice and support. Systematic review of many trials has shown a doubling of sustained smoking cessation when nicotine replacement therapy is compared with placebo.[2] The offer of nicotine patches to motivated subjects for a week in the first instance could be a useful policy.[3] But the recommendation of such therapy by health professionals and the use of such therapy by smokers are severely limited by NHS "blacklisting."

I can prescribe on the NHS for alcohol problems and even obesity. I can also prescribe for tobacco addiction—but only products of unproved efficacy for this problem, such as tranquillisers and antidepressants, not one of proved effectiveness. Why not nicotine replacement therapy? So much for evidence based medicine.

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Advice to authors

We receive more letters than we can publish: we can currently accept only about one third. We prefer short letters that relate to articles published within the past four weeks. We also publish some "out of the blue" letters, which usually relate to matters of public policy.

When deciding which letters to publish we favour originality, assertions supported by data or by citation, and a clear prose style. Letters should have fewer than 400 words (please give a word count) and no more than five references (including one to the BMJ article to which they relate); references should be in the Vancouver style. We welcome pictures.

Letters should be typed and signed by each author, and each author's current appointment and address should be stated. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

We may post some letters submitted to us on the world wide web before we decide on publication in the paper version. We will assume that correspondents consent to this unless they specifically say no.

Letters will be edited and may be shortened.

Dietary treatment of active Crohn's disease

Dietary treatment is best for children

EDITOR—Nick Wight and Brian B Scott conclude that dietary treatment of active Crohn's disease is poorly tolerated and no more effective than steroids.[1] Their editorial is chiefly based on adults. In children with Crohn's disease the importance of growth must influence the effect of any treatment. Enteral feeding is particularly useful for children with growth failure.

For children the side effects of corticosteroid treatment, particularly moon face, striae, and slowing of growth (with long term use), are of great concern to the child and to parents. Enteral feeding is as effective as corticosteroids in inducing a clinical remission in childhood.[2] Furthermore, mean height velocity was significantly greater in the enterally fed group. A group of children with Crohn's disease was randomly allocated to treatment with steroids (n = 6), cyclosporin (n = 6), and enteral nutrition (n = 6).[3] Mucosal histological findings and the percentage of lymphokine secretory cells (interleukin 2 and γ interferon) in mucosal tissue, before and after treatment, was observed. Enteral nutrition produced a significant improvement in all three variables; with steroids only interleukin 2 secretory cells were reduced in number.

A cohort study of seven children with Crohn's disease has shown that all children had a clinical remission when given enteral nutrition with a polymeric diet as primary treatment.[4] All seven had histological improvement on enteral nutrition, two with a return to normal histological findings.

In my view enteral nutrition with a polymeric diet is at present the correct first option for treating children with Crohn's disease[5]: it has advantages in terms of effectiveness, compliance, and the avoidance of side effects.

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1 Wight N, Scott BB. Dietary treatment of active Crohn's disease. *BMJ* 1997;314:454-5. (15 February.)
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Diet is the best treatment

EDITOR—Nick Wight and Brian B Scott's editorial comparing elemental diet and corticosteroids in active Crohn's disease did not provide a complete picture.[1] It is naive to assume that all patients with Crohn's disease can be managed alike and that one treatment can therefore be claimed to be better than another. Each patient requires an individual approach. Faced with a choice between two similarly effective treatments, wise doctors will first choose the one that does not have unfortunate side effects, even though they know that some patients will not have the tenacity to stick with it. The references quoted by the authors are selected to show elemental diet at its worst. In a recent survey at this hospital only 15.2% of a series of patients who had 112 treatment episodes failed to complete a course of elemental diet and only 5.4% needed to take it by nasogastric tube.

Wight and Scott surprisingly make no reference to the long term effectiveness of treatment. Elemental diet followed by the detection of food intolerances provides a strategy for maintaining longterm remission.[2] In the East Anglian multicentre trial, diet resulted in a significantly superior remission rate at two years when compared with corticosteroids.[3]

Treatment of Crohn's disease with prednisolone often leads to "corticosteroid poisoning." Treatment with elemental diet does not and seems likely to offer a way of

unravelling the cause of the condition. Contrary to the statement of Wight and Scott, there is no theoretical advantage for feeds based on amino acids. Clinical evidence suggests that the presentation of nitrogen is irrelevant to the effectiveness of elemental diet and that the crucial factor is the content of long chain triglycerides.[4] Trials are in progress to confirm this observation, and the identification of fat as a major factor in Crohn's disease may be an important step towards understanding of the disease.

Diet is the suitable treatment for mild to moderate Crohn's disease because food intolerances are few and diets straightforward. Diet is suitable treatment for severe Crohn's disease because without it it is indeed difficult to avert the need for surgery.[5] And diet is particularly appropriate for adolescents with growth failure. Wight and Scott's editorial does a group of long suffering and poorly supported patients a disservice.

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1 Wight NJ, Scott BB. Dietary treatment of active Crohn's disease. *BMJ* 1997;314:454-5. (15 February.)
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Authors' reply

EDITOR—In response to J A Walker-Smith's comments we need to state that we deliberately did not include trials with paediatric patients because of the acknowledged importance of enteral feeding in patients with growth failure.

The purpose of our literature review was to examine the results of all the controlled trials reported in peer review journals that compared the ability of steroids and dietary treatment to induce remission in active Crohn's disease. Contrary to the comments of T S King and colleagues, we were not selective but included all the reported trials that fulfil these criteria, and we deliberately did not study trials investigating the ability of diets to maintain remission in Crohn's disease. We are impressed with the tolerance of dietary treatment of Crohn's disease at King and colleagues' institution, but most gastroenterology units in Britain do not have the authors' level of experience and skill and their results will necessarily be considerably worse. We agree that "corticosteroid poisoning" is a considerable clinical concern, but patients need to be confident that the treatment that their doctor recommends is the one most likely to have a favourable clinical outcome. The trials in our review suggest that, on the basis of intention to treat, the outcome in patients with active Crohn's disease is more likely to be favourable with steroids.

There are many theoretical reasons why dietary treatments may be effective if they are tolerated. The trials in our review tend to support the views of King and colleagues that the presentation of nitrogen in enteral feeds may not be important. There nevertheless remains a valid theory that whole protein in the diet of patients with Crohn's disease may induce an immune response in the gut, perpetuating the disease process.

It would be a disservice to patients with active Crohn's disease not to base treatment on the results of properly conducted clinical trials.

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Hypothesis that people with coronary heart disease are living longer is supported

EDITOR—Luc Bonneux and colleagues argue that the fall in mortality from coronary heart disease in the Netherlands is at least partly due to increasing numbers of survivors of coronary heart disease dying of other disorders.[1] Several commentators have estimated that 30-40% of the recent fall in coronary heart disease can be attributed to improved treatment rather than a reduction in the incidence of the disease.[2 3]

A similar effect to that reported by Bonneux and colleagues can be seen within the overall category of coronary heart disease in England. In work that was carried out in the former Yorkshire Regional Health Authority we analysed deaths in England within the category coronary heart disease between the years 1975 and 1992. Death rates were standardised, with the European standard population being taken as the reference population. Coronary heart disease is covered in the ninth revision of the *International Classification of Diseases* by categories 410 (acute myocardial infarction), 411 (other acute and sub-acute forms of coronary heart disease), 412 (old myocardial infarction), 413 (angina pectoris), and 414 (other forms of chronic coronary heart disease). In our analysis we distinguished deaths due to acute disease (410, 411) from deaths due to chronic disease (412, 413, 414).

Total mortality from coronary heart disease fell by an average of 2.05% a year between 1975 and 1992 (equivalent to a fall of 30% over the whole period). The fall was, however, confined to acute disease. Mortality from chronic disease rose by an average of 1.5% a year over the same period (or 29% overall from 1975 to 1992). In 1975, 21% of all deaths from coronary heart disease were attributed to chronic disease, whereas in 1992 the proportion was 39%.

These results support the hypothesis that people with coronary heart disease are living longer. This will have important implications for national health policy; the need for treatment services may paradoxically rise despite falls in overall mortality. This is because people will require treatment over a longer time before death eventually occurs; the very success of modern treatments for coronary heart disease will thus fuel the demand for their greater use.

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1 Bonneux L, Looman CVN, Barendregt JJ, Van der Maas PJ. Regression analysis of recent changes in cardiovascular morbidity and mortality in the Netherlands. *BMJ* 1997;314:789-92. (15 March.)
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Cyclosporin can be used in early rheumatoid arthritis

EDITOR—We were surprised that Frank A Wollheim did not comment on the recent paper by Pasero *et al* in his review of disease modifying drugs in rheumatoid arthritis.[1 2] In this multicentre, prospective, randomised trial 361 patients with early (<4 years since diagnosis) active rheumatoid arthritis were enrolled. Cyclosporin at 3 mg/kg/day was significantly superior to control treatment (42 patients took antimalarials, 34 auranofin, five penicillamine, 25 sulphasalazine, and 66 myocrisin) in delaying progression in the number of eroded joints and the joint damage score after 12 months of treatment. When the patients without erosion at baseline were considered (37 in the group treated with cyclosporin and 54 in the control group) erosions developed in only four (11%) of the patients treated with cyclosporin but in 28 (52%) of the controls. This is a particularly encouraging paper that promotes early aggressive treatment in rheumatoid arthritis; the additional benefit is that the effect is produced with monotherapy.

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1 Pasero G, Priolo F, Marubini E, Fantini F, Ferraccioli G, Magaro M, *et al.* Slow progression of joint damage in early rheumatoid arthritis treated with cyclosporin A. *Arthritis Rheum* 1996;39:1006-15.
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Senior house officer training

Training must be more structured

EDITOR—The study by Elisabeth Paice and colleagues confirms that there is still considerable concern about trainees in the senior house officer grade.[1] The Yorkshire Deanery shares these concerns and in an effort to

improve matters has inspected all its senior house officer posts according to the requirements of the royal colleges for educational approval—for example, the Royal College of Surgeons.[2]

During our survey of 1023 posts we interviewed around 600 senior house officers in every specialty and all districts. We collected information in a structured way about work, training, and education. We found that five essential criteria need to be addressed in assessing any training post: consultants' support; clinical experience; training and education; appraisal; and contractual compliance.

We were disappointed to find that one third of the posts were unsatisfactory when judged against these criteria.[3] We found consultants' support to be generally excellent (88% (899/1023) of senior house officers found it satisfactory), showing that consultants take their clinical responsibilities towards patients seriously. The most disturbing finding was that at least one third of senior house officers did not obtain sufficient clinical experience to prepare them for the next stage of their careers as specialist registrars, despite the fact that there was always sufficient clinical material available (62% (629/1023) considered the experience satisfactory). The duties of senior house officers have usually been designed to satisfy service needs and little thought has been given to devising a properly organised programme of activities. Particularly in specialties that do not have preregistration house officers, senior house officers spend much of their time on inappropriate duties while valuable learning opportunities are lost or even disregarded. We found that almost half of our senior house officers never attended outpatient clinics because they were too busy doing repetitive tasks on the wards (47% attended regularly (440/936; 87 posts in anaesthetics were excluded).

Lack of structure to the working day (only 4% (42/1023) had a job plan) was also responsible for one third of the senior house officers being dissatisfied with their training and education (63% (644/1023) were satisfied). Protected time for teaching and study, as required by the royal colleges for educational approval, was rarely available. Appraisal as an educational tool was in its infancy, with only 8% (79/1023) of trainees having had the benefit of such an exercise.

Only 59% (604/1023) of posts truly complied with the requirements of the new deal on junior doctors' hours. Working in some specialties—notably, general medicine—was extremely stressful.

Structured training for senior house officers and specialist registrars is urgently needed.

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1 Paice E, West G, Cooper R, Orton V, Scotland A. Senior house officer training: is it getting better? A questionnaire survey. *BMJ* 1997;314:719-20. (8 March.)
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Improved training may have more to do with money than with new shifts

EDITOR—Elisabeth Paice and colleagues seem to link the progress made in senior house officer training in certain specialties to the introduction of partial shift working.[1] However, in the same issue Pamela J Baldwin and colleagues report the unpopularity of shifts among senior house officers and their detrimental effects on continuity of patient care and training.[2] Clearly there is a lack of consensus: are shifts under the new deal good or bad for your training?

My colleague and I studied psychological morbidity in 60 medical house officers in two teaching hospitals in the same city over a year[3] using a 30 item version of the general health questionnaire[4] and a well validated job satisfaction scale.[5] The house officers were also invited to complete Likert scales rating their satisfaction with their work rota, the impact of their rota on free time, and implications of their rota for continuity of care. These items were grouped together as a rota satisfaction scale. In addition, the house officers were asked to estimate the number of hours they worked in an average week and to complete a Likert scale rating the quality of their training.

Complete responses were obtained from 59 house officers, with telephone reminders being necessary in some cases. When the data were analysed by working pattern, shift systems had clearly resulted in reduced hours of work when compared with a one in six on call rota. The mean (SD) hours of work were: 68.7 (6.9) on call, 65.0 (5.7) on partial shifts, and 59.8 (6.0) on full shifts. However, shift systems seemed to have adverse effects on psychological wellbeing, job satisfaction, and quality of training as well as being unpopular (table).

It may not be possible to generalise these results across specialties, grades, or hospitals. Factors other than working patterns are also important—for example, the extent of non-medical duties[1] and support from senior staff.[2]

Nevertheless, it is surprising that such an important development in the working practices of junior medical staff has been subject to so little formal evaluation. The improvement in training reported by Paice and colleagues probably has more to do with the injection of £870 000 than it does with shifts under the new deal.

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1 Paice E, West G, Cooper R, Orton V, Scotland A. Senior house officer training: is it getting better? A questionnaire survey. *BMJ* 1997;314:719-20.(8 March.)
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Impact of existing peer review visits needs to be increased

EDITOR—Elisabeth Paice and colleagues show improved satisfaction for senior house officer posts between 1992-3 and 1994-5, but they do not comment on their reported increase in the number of doctors discussing their progress with consultants (appraisal).[1] The senior house officer educational audit project[2] was started in 1993 and collects information every six months in standardised anonymous questionnaires; by 1996 it provided results from 62 posts (94% response rate) in nine different specialties. When results from the six months up to 30 April 1994 were compared with those from the six months up to 30 April 1996 the proportion of senior house officers reporting that they had appraisals increased from 25% (5/20) to 63% (10/16) ($\chi^2 = 5.14$, $P = 0.02$, $df = 1$, difference in proportions = 38% (95% confidence interval 7% to 68%)). The proportion reporting use of personalised educational targets increased from 25% (5/20) to 69% (11/16) ($\chi^2 = 6.89$, $df = 1$, $P < 0.01$, difference in proportions = 44% (14% to 73%)).

Susan Williams and colleagues also comment on the psychological distress experienced by senior house officers,[3] and results from the senior house officer educational audit project have not yet shown a significant improvement in access to support for stress (4/20 in 1993, 6/16 in 1994, $\chi^2 = 0.62$, $df = 1$, $P = 0.43$, difference in proportions = 18% (12% to 47%)).

In their editorial Evan Harris and Paula Ferreira ask for annual inspections of senior house officer posts, with the withdrawal of funding from unsuitable posts.[4] We believe that the impact of existing peer review visits needs to be increased by publicising, well in advance, the date of the visit, the standards

Median (range) scores among house officers for different working patterns*

Measure	On call (n=24)	Partial shift (n=18)	Full shift (n=17)	P value†
General health questionnaire (30 items)	1 (0-9)	3.5 (0-17)	4 (0-20)	<0.05
Job satisfaction scale	72.5 (48-91)	59.5 (41-81)	59 (36-83)	<0.01
Rota satisfaction scale	12 (9-15)	6.5 (3-11)	4 (3-10)	<0.001
Quality of training	4.5 (2-6)	2 (1-5)	2 (1-5)	<0.001

*Higher scores indicate a more favourable outcome except in general health questionnaire, when higher scores indicate greater psychological distress.
†Kruskal-Wallis analysis of variance. Subsequent analysis of individual differences using the Mann-Whitney U test showed no significant differences between full shifts and partial shifts, but significant differences were found between both types of shift system and on call rotas.

expected, the arrangements for involving local educationalists (clinical tutors, course organisers), and the distribution list for any recommendations made. An independent educationalist should be in attendance during the visits and should make an individual report set against existing educational standards. Assessment of posts needs to be objective and should be seen as such. Subsequent grading of each post as accepted or recommended could be used as an additional incentive for hospitals to improve training, alongside the more draconian measure of withdrawal of funding.

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When midwives perform obstetric tasks at night, trainees can spend more supervised time in clinics

EDITOR—Both the survey by Susan Williams and colleagues and the survey by Pamela J Baldwin and colleagues highlighted the need for close support and feedback by senior doctors in order to build the confidence and improve the training of senior house officers.[1 2] To achieve these goals and ensure appropriate training it is important to recognise the different requirements of career and vocational trainees within a specialty.

Most hospitals have accommodated decreased hours by giving junior doctors a day off after a night on call. However, this means that they are likely to miss outpatient clinics or other daytime commitments which represent good training opportunities. Whereas this tradeoff may be acceptable for middle grade staff who need the exposure to on call work, it is probably inappropriate for trainees in general practice.

We reduced the hours worked by trainees in general practice by sending them home after 10 00 pm, rather than by giving them the following day off (during prime training time). This not only improves training but also ensures that staff of at least middle grade review obstetric and gynaecological patients at all times. This is in line with the current expectations of patients and risk management teams.

To facilitate this change we have diverted much work that is traditionally out of hours (early pregnancy assessment, registrar review, and antenatal assessment) to daily clinics, which also provide supervised training opportunities. In addition, we audited bleep calls received by senior house officers at night and found that most were for an assistant at a caesarean section. Therefore, we trained midwives in how to assist. Midwifery training in suturing, cardiotocographic interpretation, venesection, and intravenous cannulation was already in place in our unit.

We have now been running the system for more than a year and are pleased to report it is a success. Midwives now undertake all the tasks of obstetric senior house officers at night, with only urgent gynaecological admissions producing extra work for the registrar. This type of admission is rare with our system of daily clinics. An anonymous questionnaire has confirmed that the senior house officers think that their training is better, and the middle grade doctors do not have a significantly higher workload.

We would recommend this system to other similar units, with the one caveat that the number of midwives may need to be increased when the extra pair of hands provided by a senior house officer is removed from the labour ward at night.

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1 Williams S, Dale J, Glucksman E, Wellesley A. Senior house officers' work related stressors, psychological distress, and confidence in performing clinical tasks in accident and emergency: a questionnaire study. *BMJ* 1997;314:713-8. (8 March.)
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Blood donation, body iron stores, and risk of myocardial infarction

Confidence intervals and possible selection bias call study results into question

EDITOR—The importance of stating the 95% confidence interval when reporting results has been shown in a recent paper by Tomi-Pekka Tuomainen and colleagues.[1] In their paper blood donation reduced the risk of myocardial infarction anywhere between 3% and 98%. An estimate with such imprecision seems to be of little use. Moreover, although the association was only marginally significant to begin with ($P = 0.047$), the authors commented that further adjustments attenuated the association marginally. The confidence interval cannot become considerably wider with further adjustments; even a marginal change at the lower limit of the confidence interval can cause a change in the sign, rendering the association non-significant.

The authors urged that new studies be carried out to confirm their findings. However, although the results of several previous studies were unable to corroborate the hypothesis that raised iron concentrations increase the risk of coronary heart disease,[2-5] none of these diverging results was cited in the paper.

Blood donors are not compensated in Finland; they donate blood for altruistic reasons, and evidently such people may also have a great interest in their own health. Thus there was probably substantial selection bias which cannot be adjusted for, especially when only one death was observed among the blood donors. In Finland the study was cited in various news media as firm evidence that blood donation reduces the risk of myocardial infarction. The prestige of the *BMJ* was used as confirmation of the validity of the study; this seemed ethically questionable to us.

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1 Tuomainen T-P, Salonen R, Nyyssönen K, Salonen JT. Cohort study of relation between donating blood and risk of myocardial infarction in 2682 men in eastern Finland. *BMJ* 1997;314:793-4. (15 March.)
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Authors' reply

EDITOR—We welcome the comments of Harri Hemilä and Mikko Paunio. We have been among the first advocates of the use of confidence intervals when estimates of relative risk are presented in epidemiological studies.[1] Confidence intervals are especially necessary when they are wide—that is, when the sampling variation is large. In our study this was due to the small number of subjects who had donated blood (153 out of 2682).[2]

We do not consider P values as important as the strength of the association. In our study, blood donors had as much as an 86% reduction in the risk of acute myocardial infarction after adjustment for risk factors when compared with non-donors. This point estimate did not change much, whichever risk factors we adjusted for. The range of risk factors measured in the Kuopio ischaemic heart disease study is extensive, as shown by our previous publications on the same cohort.[3 4]

Several studies have concluded that there is no association between iron status and the risk of coronary disease events.[5] All of these negative studies, however, have unreliable measurements of iron status (such as serum iron concentration, transferrin iron saturation) or other design problems, as detailed elsewhere.[5] Comparing the number of positive and negative studies, or the number of subjects in these, seems quite a primitive method from which to derive an overall conclusion. Another reason for not referring to studies using iron status measurements was the lack of space in our short report. A review has been presented earlier.[5]

As we suggested,[2] a randomised blood donation trial in healthy people may be the only possible study design that could ultimately verify or refute a theory about the role of iron balance in coronary disease. There exists a widespread conviction that the more iron in the diet the better. This is what is still written in medical textbooks. This conviction is, however, the enemy of the truth.

We pointed out the potential selection bias in our work—the possibly increased health consciousness of blood donors[2]—and we have repeated this in all interviews given to the media. However, the media tend to simplify issues to make them understandable.

A fundamental problem in all epidemiological studies is that whichever covariates you measure and adjust for statistically, there always remains a possibility that some unmeasured, or too imprecisely measured, confounding factors might explain some of the observed association. We appreciate this, and for this reason our conclusions were cautious and suggested[2] that further clinical trials were needed to resolve the issue conclusively.

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1 Salonen JT, Alfthan G, Huttunen JK, Pikkarainen J, Puska P. Association between cardiovascular death and myocardial infarction and serum selenium in a matched-pair longitudinal study. *Lancet* 1982;ii:175-9.
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Most British research and development in primary care arises outside rural areas

EDITOR—What a breath of fresh air to read Mike Pringle's suggestions on improving primary care, which were not exclusively based on the worries of some inner London practices but gave equal consideration to enhancing rural practice.[1] He is prudent to note that innovations need to be evaluated in primary care. I believe, however, that rural developments are at a specific disadvantage compared with urban ones. Almost all the British research and development arises outside rural areas, and so attempts at improvement through evidence based practice have to graft research from urban settings on to countryside problems.

Let me illustrate this with some crude secondary research I did, using papers from last year's Medline (January 1996 to January 1997). This identified 269 items from *Family Practice* and the *British Journal of General Practice*, of which 167 seemed to be research papers or short reports. Three of these arose from places in Britain that were not clearly specified (for example, multicentre surveys) and 58 came from outside Britain, but for 106 articles a specific British address was given as the origin. Of this core British research and development base of 106 papers, 22 papers came from London, 71 from other "cathedral cities" such as Sheffield and Newcastle upon Tyne, and 10 from other urban areas such as Luton and Birkenhead. This left at most three papers that might be described as having arisen from "country towns" (including Cambridge)—less than 3% of the studies.

Research into rural primary care needs to be cultivated. For over two years the Anglian network "Promoting research and development in primary health care" has been doing just that, on a modest scale.[2] Readers interested in the history of NHS innovations may not be surprised to know that the launch of our network in the fens owed a great deal to the foresight and help of an academic in faraway Nottingham ...Pringle.

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1 Pringle M, Heath I. Distributing primary care fairly. *BMJ* 1997;314:595-7. (22 February.)
2 Caan W. Research and development in primary care. *Br J Gen Pract* 1995;45:442.

Chaplains on transplant teams facilitate permission being given for organ donation

EDITOR—Naomi Craft's news item entitled "Communication increases donor transplant rate" is an interesting example of reinventing the wheel.[1]

Nearly 30 years ago, when I was transplant resident at the Peter Bent Brigham Hospital in Boston, Massachusetts, we routinely saw grieving relatives of brain damaged potential donors, and we were always accompanied by the hospital chaplain.

Whenever we did this we were never refused donation of an organ.

When I came back to Charing Cross Hospital I continued the practice, and the chaplaincy became an integral part of the programme. Once again, I do not remember ever having been refused donation of organs when the chaplain participated in the discussion.

I suppose that the grieving relatives felt that the chaplain was on their side rather than mine and was able to clarify this distressing problem.

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1 Craft N. Communication increases donor transplant rate. *BMJ* 1997;314:697. (8 March.)

Amiodarone pulmonary toxicity

Authors did not emphasise typical radiological and histological features sufficiently

EDITOR—In their editorial on amiodarone pulmonary toxicity Gillian A J Jessurun and Harry J G M Crijns made several misleading statements about the diagnosis of this dangerous condition.[1] Although they are correct in stating that pulmonary toxicity has rarely been reported after low doses of amiodarone or after short periods of treatment, they make statements relating to the clinical and pathological features that are not supported by the literature or our own experience. They suggest that hyperinflation is a common radiological manifestation of amiodarone toxicity, that the spirometric pattern usually suggests obstruction, and that the presence of lamellar inclusion bodies on electron microscopy is specific for amiodarone toxicity. These statements are incorrect and misleading.

The radiological findings in amiodarone lung vary, but the commonest pattern is of asymmetric bilateral alveolar opacification, which may mimic tuberculosis if seen in the upper zones and pulmonary oedema if seen in the midzones and lower zones; other patterns include solitary or multiple masses and lobar or segmental consolidation. Pleural effusions may be seen together with other findings but rarely alone. The radiological differential diagnosis therefore includes infection, heart failure, and malignancy. Computed tomography is more sensitive than plain radiography and may be helpful in distinguishing the appearances from those seen in other conditions; the infiltrate is typically rather dense owing to the presence of iodine. Lung function tests characteristically show a restrictive pattern with reduced diffusing capacity; an obstructive pattern is unusual.[2]

The accumulation of intra-alveolar macrophages seen on cytological examination of bronchoalveolar lavage fluid or on histopathological examination of lung biopsy specimens is not specific for amiodarone; it is also seen in reactions to methotrexate, mitomycin, cyclophosphamide, nitrofurantoin, and bleomycin. Electron microscopy may show lamellated intralysosomal "myelin bodies" because of a direct effect of amiodarone on cellular phospholipases leading to phospholipid accretion.[3] These ultrastructural features may be seen in a variety of diseases, including the phospholipidoses, and reflect exposure to amiodarone rather than toxicity.[4]

The authors give undue prominence to amiodarone pulmonary toxicity presenting as bronchiolitis obliterans organising pneumonia. The number of published case reports of this condition remains in single figures even though eight years have passed since its first description.[5] Bronchiolitis obliterans organising pneumonia is a rare presentation of amiodarone pulmonary toxicity, and we would remind readers of the

more typical radiological and histological features detailed above.

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1 Jessurun GAJ, Crijns HJGM. Amiodarone pulmonary toxicity. *BMJ* 1997;314:619-20. (1 March.)
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Amiodarone should be used with caution in patients in intensive care

EDITOR—Gillian A J Jessurun and Harry J G M Crijns omitted one risk factor for amiodarone pulmonary toxicity from their editorial—namely, the possible relation between the condition and high inspired oxygen concentrations, notably in the perioperative period.[1] There are several reports of acute amiodarone pulmonary toxicity occurring postoperatively after general and cardiac surgery in patients receiving long term amiodarone treatment,[2 3] and the complication may occur more commonly in patients who receive a fractional inspired concentration of oxygen of $>50\%$.[4] Furthermore, a study of prophylaxis for supraventricular tachyarrhythmias after pneumonectomy showed a high incidence of postoperative adult respiratory distress syndrome: three of 11 patients given amiodarone developed adult respiratory distress syndrome, compared with no patients in the groups given verapamil and placebo.[5]

In the intensive care unit amiodarone is widely used as an agent of first choice in the treatment of supraventricular tachyarrhythmias associated with sepsis and adult respiratory distress syndrome. Its efficacy and relative lack of negative inotropism seemed to outweigh the potential toxicity. A recent case, however, calls this practice into question. An 82 year old man who apparently died of adult respiratory distress syndrome and multiple organ failure after vomiting and pulmonary aspiration was found at postmortem examination to have characteristic changes of amiodarone pulmonary toxicity (endogenous lipid pneumonia with foamy macrophages). Review of his management showed that he had received 0.9 g amiodarone/day for six days. This prompted a review of postmortem findings of 10 consecutive patients who died of adult respiratory distress syndrome, which showed that a further two patients had had a histological diagnosis of amiodarone pulmonary toxicity rather than hyaline membrane disease. Both had received amiodarone treatment for over 48 hours.

These findings emphasise that, despite its efficacy, amiodarone should be used with great caution in this critically ill population. The high inspired oxygen concentration may predispose to acute amiodarone pulmonary toxicity, while the presence of pre-existing disease (adult respiratory distress syndrome) may well mask the condition's development.

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Author's reply

EDITOR—Andrew Leonard and colleagues have misinterpreted several important messages in our editorial. We clearly stated that the clinical diagnosis of amiodarone pulmonary toxicity may be supported (not confirmed) by radiological signs such as hyperinflation or a ground glass or reticular pattern, which may of course present bilaterally. In addition, variable results of lung function tests are possible.[1 2]

We agree with the authors that the presence of lamellar inclusion bodies is associated with the cytotoxicity of amiodarone and not specific for amiodarone pulmonary toxicity. Indeed, bronchiolitis obliterans organising pneumonia is a rare manifestation of amiodarone pulmonary toxicity. The main goal of the editorial, however, was to alert doctors to the possible occurrence of the condition, since it is reversible and has a good prognosis.

The adverse effects of high inspired oxygen concentrations, mentioned by L Donaldson and colleagues, are caused by interaction with amiodarone. This drug influences the production of toxic oxygen radicals and may induce the accumulation of phospholipids in the pulmonary tissue by a direct cytotoxic effect on the alveolar-capillary membrane. We disagree with the use of amiodarone in intensive care units as an agent of first choice for the symptomatic treatment of supraventricular arrhythmias. It is better clinical practice to diagnose and treat the underlying cause of the recurrent or incessant arrhythmia, such as electrolyte or acid-base disturbances, hypovolaemia caused by sepsis, and congestive heart failure.

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Systematic reviews provide information not contained in traditional narrative reviews

EDITOR—David W Kaufman and Samuel Shapiro make several criticisms of our report on the risks of major gastrointestinal complications during treatment with non-steroidal anti-inflammatory drugs.[1 2] Some of these criticisms go to the heart of any attempt to combine data from observational studies.

Kaufman and Shapiro point to the varying quality of the studies included in the meta-analysis and the different definitions of outcome and exposure. No relations were apparent between these factors and the estimates of relative risk reported in the studies. The comparative analyses of the individual drugs required within study comparisons and should have been unaffected by factors that might confound between study comparisons. The consistency of findings across studies with varying methodologies is reassuring and can, we think, be regarded as a strength rather than a weakness of these data.

Kaufman and Shapiro point to the limitations of the analysis of published dosage data. The purpose of this exercise was to see if the claimed advantage of ibuprofen persisted when the drug was consumed in higher doses.[3 4] The analysis suggests that it does not. This message is important for clinicians.

Kaufman and Shapiro criticise the selection of studies for inclusion in the review. We included epidemiological studies that found a relation between the use of non-steroidal anti-inflammatory drugs and major gastrointestinal complications and contained comparative data on the risk with individual compounds. Had the purpose of our study been to provide an estimate of the average risk across all of the drugs, the exclusion of some early negative studies would have biased the estimate upward. The purpose of the study, however, was to compare risks with individual drugs; it is unlikely that this was biased by the inclusion criteria that were used.

Kaufman and Shapiro counsel against meta-analysis of observational studies, preferring narrative reviews. The problem lies with the desire to reduce the data to a single pooled estimate. The other steps in a systematic review, such as a comprehensive literature search, evaluation of the quality of studies, consistent extraction and presentation of the relevant data, and analysis of the reasons for variability in results, provide information that is not contained in the traditional narrative review. It is paternalistic to suggest that systematic reviews of observational data should not be performed because they are open to misinterpretation. Epidemiologists have a responsibility to

educate decision makers in how to interpret and use these studies. Our students all receive copies of Shapiro's writings.[5]

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Does setting good practice standards for research ethics committees increase their legal liability?

EDITOR—As a result of our paper[1] Neville W Goodman and Alaisdair MacGowan "feel most beleaguered" and fear that research ethics committees must brace themselves to be sued when they fail to meet the standards of good practice that we have set them.[2] We stated that research ethics committees should be held accountable if they failed to meet these standards, but our article was concerned with moral, not legal, accountability.

Could research ethics committees be held legally accountable if a participant in a trial was harmed by research that they had sanctioned? Research ethics committees probably lack the necessary personality to be a defendant in a civil action.[3] Participants who have been harmed by research could sue either the health authority or individual members of the committee. To ensure that they received adequate compensation, suing the health authority would be the better bet. However, there would still be formidable barriers to success in proving causation, defining the nature of the duty of care that research ethics committees owe, and determining a reasonable standard of practice. These problems would be even greater when individual members of different backgrounds were sued. There is considerable doubt over whether any claim against members of research ethics committees would be successful.[3] It remains unclear what, if any, legal liability members of research ethics committees might have in England, and even in North America findings of liability are rare.[4] Nevertheless, it is a sorry reflection of the post-modern values of some researchers, clinicians, and even members of ethics committees that they accuse those seeking to improve practice of increasing their own legal liability. The law, after all, is one medium through which society ultimately holds all its citizens to account.

We believe that members of research ethics committees should not be held legally liable until there are clear standards of practice, members have received adequate training for this task, and their skill has been adequately evaluated and certified. If we want our research ethics committees to vet the safety of complex clinical research effectively they must be properly constituted, trained, and supported. In the meantime their members should remain good citizens trying to do their best.

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Mechanism of accountability needs to be developed for changing role of healthcare professionals

EDITOR—We were interested to read Terence English's personal paper about extending nurses' professional roles.[1] We set up the first course to train nurses in endoscopy and to insert percutaneous endoscopic gastrostomy feeding tubes that was approved by the English National Board,[2] and we therefore have first hand experience of many of the issues he addressed. It may be important to make a distinction for the debate between an extension of the nurses' traditional role and nurses' more recent involvement in several task oriented roles traditionally undertaken by medically qualified staff. In the former category it is clear that the role is defined by nursing skills. Things may be much less clear when the nurses' role becomes more procedure oriented, as in the task of harvesting saphenous vein grafts cited by English or in our unit, where nurses undertake independent endoscopic procedures. Clearly, nurses and doctors bring skills other than technical dexterity to these tasks, and this must be recognised. Here we also concur with English that "the professional organisations that represent nurses and doctors ... have the responsibility of entering discussions at an early stage of developments so that they can inform and educate their members of the benefits of closer cooperation and changing roles." The extension of vicarious liability by hospital trusts to indemnify nurses and possibly others to perform tasks traditionally done by doctors has yet to be tested. The overriding principle must surely be that the operator has the necessary clinical skills and has received adequate and recognised training. To underpin this principle there is an urgent need for a mechanism of accountability, both to the patient and to the professions, which should be developed jointly by both professional organisations. If we do not find such a mechanism, leaving the individual operators and perhaps the public to reach a new understanding of what is a nurse and what is a doctor, we may find that the changing role of healthcare professionals will be defined by lawyers.

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Alcohol misuse among doctors

Treatment should be offered

EDITOR—Bryan Christie's news article on the possibility of mandatory testing for alcohol misuse among doctors raises some serious issues.[1] As director of the largest treatment programme for addicted doctors in the Commonwealth, I am alarmed by the suggestion that intrusive and unhelpful monitoring techniques would be suggested by no less an authority than James Griffith Edwards.[1] To suggest that all doctors have liver function tests every two years as a screening test for alcohol misuse or alcohol dependency is intrusive and, in fact, has been shown to be ineffectual.[2] At the stage when a doctor arrives at work smelling of alcohol, the disease is highly advanced.[3] As pointed out by the sheriff in Gerald Davies's case, there was a conspiracy of silence surrounding him; this has been the case in all of the recent reports on addicted doctors.[4]

In November 1995 I described Homewood Health Centre's support programmes for addicted doctors in Canada to the annual meeting of the British Doctors and Dentists Group in England. Representatives of both the General Medical Council and the BMA were present. Little seems to have been learnt from the meeting.

Tragedies such as those described in Christie's article will continue until a confidential programme to support doctors, run by the BMA and funded by the members themselves, is available to help addicted doctors and their families in what is the most lonely and isolating condition that a doctor can experience. The use of intrusive mandatory testing will do nothing to help earlier intervention for and identification of addicted doctors.

Recently, the BMA developed a stress related support programme for doctors, but experiences in other parts of the Commonwealth have shown that it is too broad and repeatedly misses the addicted doctor.[5]

I hope that Gerald Davies has been offered the treatment he so desperately needs because, with appropriate treatment, the prognosis for addicted doctors is excellent and their return to work as respected members of the profession is entirely possible.

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1 Christie B. Inquiry calls for doctors to be tested regularly for alcohol. *BMJ* 1997;314:769. (15 March.)
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Eliminating stress is the way forward

EDITOR—Bryan Christie's news article on calls for alcohol testing in doctors warns that we are about to witness yet another knee jerk response to an important issue in the medical profession.[1] Although attractive to the media, intrusive programmes such as those suggested by James Griffith Edwards will waste valuable resources and may still fail to identify the minority of those who are alcohol dependent.[1] Physical and biochemical markers of alcohol misuse are not specific, or may be normalised by a period of abstention,[2] and people either have to be very ill or very brave to admit that a problem exists. What is surely more important is to identify the reasons behind increasing alcohol use and misuse.

There is a continuing failure of employing authorities to acknowledge and deal with the almost suicidal levels of stress in the medical profession; this stress is caused by inadequate resources, low esteem, lack of appreciation, and increasing demands—both professional and managerial. None of us need look far to see examples of this stress in our medical (and increasingly, teaching) colleagues. Those individuals with insight, and who are able to, are leaving through early retirement, usually on health grounds. We are gradually losing the most skilled members of the NHS, only for them to be replaced (or in some cases not replaced) by those with inadequate experience, which in turn compounds the pressure on those remaining. While the reasons for retirement may be wrapped up in acceptable medical diagnoses, the true reason in most cases is stress related.

Until this is recognised and addressed, more patients will continue to be at a higher risk of medical misjudgment as a result of the effects of stress on doctors than will be at risk from contact with doctors who have serious alcohol related problems.

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1 Christie B. Inquiry calls for doctors to be tested regularly for alcohol. *BMJ* 1997;314:769. (15 March.)
2 Anderson PD. Alcohol and drug related problems. In: Weatherall DJ, Ledingham JGG, Warrel DA, eds. *Oxford textbook of medicine.* 3rd ed. Oxford: Oxford Medical Publications, 1996:4272.

Breast cancer screening for younger women is not an efficient use of resources

EDITOR—Suzanne Fletcher concludes an otherwise excellent editorial on breast cancer screening in women younger than 50 by stating: "As time goes on and questions remain about the usefulness of screening women in their 40s for breast cancer, the wisdom of the organisers of the British trial becomes increasingly apparent."[1] I would like to make a mathematical estimate of this wisdom.

The United Kingdom Coordinating Committee for Cancer Research breast screening trial has the statistical power to show a reduction in relative risk of 20% in cause specific mortality from breast cancer for a cohort of women aged 40 at the time of entry. The incidence of breast cancer occurring between the ages of 40 and 50 is 1 per 1000 women a year—a 1% risk over that decade. Given that these cancers will occur throughout the decade, in the worst case scenario for mortality from breast cancer 0.3% of these women will die of the disease. The reduction in relative risk of 20% applies to this 0.3%—that is, 6 out of 10 000 women screened over a decade might benefit. If this is weighed up against the undoubted harms detailed in Fletcher's editorial my doubts about the wisdom of the organisers of this trial begin to become more understandable.

There are also issues of health economics and opportunity cost. A person's life can never have a price put on it. However, given the ethical issue of justice in the allocation of scarce resources it could easily be urged that the millions of pounds squandered on the screening trial for women under the age of 50 could save more lives if it were used to develop the Calman-Hine proposals for specialist cancer services[2] or to fund the infrastructure for clinical trials of treatment.

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1 Fletcher S. Breast cancer screening in women aged under 50. *BMJ* 1997;314:764-5. (15 March.)
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Vegetarians and vegans may be most at risk from low selenium intakes

EDITOR—Margaret P Rayman suggests that fortification of staple foods with selenium should be considered to prevent deficiency of this trace element.[1] The following observations may indicate otherwise.

In a recent survey in Norfolk 24 hour dietary intakes were measured prospectively in 901 subjects. Average daily intakes of selenium (estimated from standard food composition tables supplemented with new analytical values from our laboratories and others[2]) were 50 μg in women (n = 506) and 59 μg in men (n = 395). Missing values for food composition and known variations in selenium content due to soil conditions led us to select a subset of 36 men and 31 women who ate appreciable amounts of locally grown foods. They weighed all food and drink and collected duplicate food samples for seven days as well as providing blood and toenail samples. Selenium in food, blood, and toenails was measured by modifications of the Olsen method.[3] Serum concentrations averaged 1.10 μmol/l in women and 1.17 μmol/l in men; calculated daily selenium intakes over the seven day period averaged 38 and 50 μg respectively. Analysis of duplicate food samples, however, yielded figures of 83 and 107 μg respectively, suggesting that food tables underestimate selenium intake, particularly in areas (such as Norfolk) where soil concentrations are reported to be high.

Previous estimations of daily selenium intake in Britain showed little change from 60 μg in 1978[4] to 62 μg in 1992.[5] Changes in the flour used in breadmaking, however, have resulted in marked changes in the contribution of different food groups to intake since 1978, the contribution from cereals falling from 50% to 18% of total intake but that from meat increasing from 28% to 39% in 1992. This suggested that people eating vegetarian and vegan diets might be most at risk from low selenium intakes. We therefore compared the toenail selenium concentrations of the Norfolk sample with those of 23 vegetarian and 34 vegan subjects matched for age and sex. The 57 vegetarians (including vegans) had significantly lower average toenail selenium concentrations than the omnivores (541 *v* 685 ng/g, $P < 0.001$, paired *t* test). Average concentrations in the vegans were even lower than those in the vegetarians (506 *v* 591 ng/g, $P < 0.01$). Eight subjects who described themselves as vegetarians ate tuna occasionally and had average concentrations of 644 ng/g, which possibly reflected the high selenium content of this fish: 100 g of canned tuna contains about the same amount of selenium as four or five brazil nuts.

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