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## Cholesterol lowering margarine may not be useful in healthy fat modified diet

EDITOR—A new margarine spread that reduces intestinal absorption of cholesterol was launched in the United Kingdom in April.<sup>1</sup> Benecol contains stanol esters derived from wood pulp. National press advertisements indicate that it reduces serum concentrations of low density lipoprotein cholesterol by an average of 14% when taken as three servings daily as part of a healthy diet. This is based on the findings of a study of mildly hypercholesterolaemic subjects in North Karelia, Finland.<sup>2</sup> During this study, intake of dietary fat was about 35% of total energy intake and cholesterol intake above 300 mg per day. A mean reduction in total cholesterol concentration of 7.4% was achieved after 6 months and of 10.2% after 12 months. Such a 10% reduction translates into a 13% reduction in the risk of coronary disease over 10 years, using the computer program for risk estimation provided with the new British guidelines.<sup>3</sup>

A review of clinical trials with phytosterols found that the serum lipid response varies widely (reductions in the concentrations of low density lipoprotein cholesterol

of 2-33%) depending on study design, amount of phytosterol intake, and initial cholesterol concentration.<sup>4</sup> When sitostanol was used with a low intake of fat (less than 30% of total energy intake) and cholesterol (less than 200 mg/day) it did not lower cholesterol concentration significantly.<sup>5</sup> The evidence therefore suggests that this margarine spread may reduce cholesterol concentration in people consuming an average British diet, but in those following a healthy fat modified diet this costly product is unlikely further to reduce lipid concentrations.

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- 1 Mayr S. Cholesterol lowering margarine launched in United Kingdom. *BMJ* 1999;318:960. (10 April).
- 2 Miettinen TA, Puska P, Gylling H, Vanhanen H, Vartiainen E. Reduction of serum cholesterol with sitostanol-ester margarine in a mildly hypercholesterolemic population. *N Engl J Med* 1995;333:1308-12.
- 3 Joint British recommendations on prevention of coronary heart disease in clinical practice. British Cardiac Society, British Hyperlipidaemia Association, British Hypertension Society, endorsed by the British Diabetic Association. *Heart* 1998;80(suppl 2):S1-S29.
- 4 Jones PJ, MacDougall DE, Ntanos F, Vansone CA. Dietary phytosterols as cholesterol-lowering agents in humans. *Can J Physiol Pharmacol* 1997;75:217-27.
- 5 Denke MA. Lack of efficacy of low-dose sitostanol therapy as an adjunct to cholesterol-lowering diet in men with moderate hypercholesterolaemia. *Am J Clin Nutr* 1995;61:392-6.

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beside at least three other studies—five prospective studies cited in the World Cancer Research Fund's report did not find a significant association with red meat.

It is not yet proved that heterocyclic amines or *N*-nitroso compounds definitely increase rates of colon cancer.<sup>3</sup> Bingham herself has shown that the endogenous production of *N*-nitroso compounds varies widely between individuals and also depends on other components of the diet (for example, resistant starch).<sup>4</sup> Recent research has shown that chicken, which is often recommended as a healthy substitute for red meat, can contribute heavily to the uptake of heterocyclic amines.<sup>5</sup>

Cummings and Bingham's statement that "non-starch polysaccharides (fibre) and vegetables are established factors that reduce risk" is also misleading. As is shown in the World Cancer Research Fund's report, none of four prospective cohort studies on non-starch polysaccharides showed a significant reducing effect on colon or rectal cancer.

The protective effect of vegetables is also far from proved. Of four prospective cohort studies cited in the World Cancer Research Fund's report, one found no effect with green salad; one found a significant reduction in risk with rising vegetable consumption only in women; one found an increasing risk with increasing amounts of dark green vegetables in men; and one found no significant effect with any of 15 kinds of vegetables and fruits.

These few examples show that there is no evidence in the prospective literature for an upper limit of 140 g of red meat a day, nor for a general protective effect of fibre or vegetables. Public interest in cancer prevention is high, and scientists should be careful with statements or recommendations.

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## Diet and the prevention of cancer

### Author's recommendations are not justified

EDITOR—The epidemiological literature justifies only two of the conclusions that Cummings and Bingham draw in their review about diet and the prevention of cancer: the recommendations to avoid (high doses of) vitamin supplements and mouldy foods.<sup>1</sup> Even the cited report of the World Cancer Research Fund shows that the overall evidence for dietary recommendations is weak if one takes into account the more reliable data from prospective cohort and intervention studies.<sup>2</sup>

Cummings and Bingham give an excellent example of publication bias in their section on colorectal cancer and red meat: they cite two prospective studies that support a role for red meat in colorectal carcinogenesis. What they do not mention is that—

- 1 Cummings JH, Bingham SA. Diet and the prevention of cancer. *BMJ* 1998;317:1636-40. (12 December).
- 2 World Cancer Research Fund. *Food, nutrition and the prevention of cancer: a global perspective*. Washington, DC: WCRF and American Institute for Cancer Research, 1997.
- 3 Steineck G, Gerhardsson de Verdier M, Overvik E. The epidemiological evidence concerning intake of mutagenic activity from the fried surface and the risk of cancer cannot justify preventive measures. *Eur J Cancer Prev* 1993;2:293-300.
- 4 Bingham SA. The potential role of endogenously formed *N*-nitroso compounds in colorectal cancer. *ECP News* 1997;31:12-5.
- 5 Sinha R, Rothman N, Brown ED, Salmon CP, Knize MG, Swanson CA, et al. High concentrations of the carcinogen 2-amino-1-methyl-6-phenylimidazo-[4,5-b]pyridine (PhIP) occur in chicken but are dependent on the cooking method. *Cancer Res* 1995;55:4516-9.

### Whether meat is a risk factor for cancer remains uncertain

EDITOR—Meat looks decreasingly likely to be a direct cause of cancer. Concerned by the discrepancy between evidence on meat and cancer and authoritative statements such as those of Cummings and Bingham,<sup>1</sup> last December I chaired a workshop of cancer epidemiologists, nutrition experts, and researchers on the colon from Australia, New Zealand, and Britain.

We found that since the report by the Committee on Medical Aspects of Food and Nutrition Policy<sup>2</sup> two more prospective studies have failed to show an association of meat intake with colorectal cancer.<sup>3</sup> There are now 12 prospective studies reporting meat intake and subsequent large bowel cancer, but in only two was a significant association found.<sup>4</sup> Even in these the association was weak (relative risk < 2.0) and seen only in people with the highest fifth of meat intake. These two studies come from groups in the United States.

As well as this accumulation of mostly negative prospective studies, a multinational combined report of five follow up studies of vegetarians and socially matched omnivore controls (total 76 000 subjects) found the relative risk of colorectal cancer in the vegetarians to be 0.99 (indistinguishable from 1.00).<sup>5</sup> This is as near as we are likely to get to randomised controlled trials of meat eating.

Our review concentrated on meat and large bowel cancer because, as the report of the Committee on Medical Aspects of Food concluded, the evidence is weak that lower intakes of meat would lower the incidences of breast, lung, prostate, or pancreatic cancer.<sup>2</sup>

If meat made no positive contribution to the diet it would be straightforward to warn that in a minority of subjects in a minority of epidemiological studies there seemed to be a small risk of colorectal cancer. But nutritional advice to the general public can't be as simple as this when it concerns one of the central foods groups of most people. Meat is the major source of available iron, vitamin B-12, zinc, and protein in Britain and most other affluent countries. There is of course no need to char or heavily brown meat, poultry, or fish when frying or grilling, and our workshop recommended not to.

The paper's conclusions from our workshop are published in the *European Journal of Cancer Prevention*.<sup>6</sup> Our conclusion—that it remains uncertain whether meat is a risk factor for cancer—coincides with British opinions reported last December in the *Sunday Times Magazine*.<sup>7</sup>

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Competing interests: Professor Truswell received a fee from Meat and Livestock Australia for his time acting as chairman of the workshop mentioned.

- 1 Cummings JH, Bingham SA. Diet and the prevention of cancer. *BMJ* 1998;317:1636-40. (12 December.)
- 2 Chief Medical Officer's Committee on Medical Aspects of Food. *Nutritional aspects of the development of cancer*. London: Stationery Office, 1998. (Department of Health report on health and social subjects 48.)

- 3 Gaard M, Tretli S, Løken FB. Dietary factors and risk of colon cancer: a prospective study of 50 535 Norwegian men and women. *Eur J Cancer Prev* 1996;5:445-54.
- 4 Willett WC, Stampfer MJ, Colditz GA, Rosner BA, Spitzer FE. Relation of meat, fat and fiber intake to the risk of colon cancer in a prospective study among women. *N Engl J Med* 1990;323:1664-72.
- 5 Key TJ, Fraser GE, Thorogood M, Appleby PN, Beral V, Reeves G, et al. Mortality in vegetarians and non-vegetarians: a collaborative analysis of 8300 deaths among 76 000 men and women in five prospective studies. *Public Health Nutr* 1998;1:33-41.
- 6 Truswell AS. Report of an expert workshop on meat intake and colorectal cancer risk convened in December 1998 in Adelaide, South Australia. *Eur J Cancer Prevention* 1999; 8:175-8.
- 7 Girling R. Eat me, it's OK. *Sunday Times Magazine* 1998 20 Dec.

### Consumption of oily fish should be encouraged

EDITOR—In their review of dietary factors in the development of cancer Cummings and Bingham emphasised the importance of lifestyle factors in most cancers of the large bowel, breast, and prostate.<sup>1</sup> They failed to mention the value of fish in the diet; as a source of n-3 polyunsaturated fatty acids, fish have been suggested to have a protective effect in breast and colorectal cancer in particular.

Ecological studies have suggested a reduced incidence of breast and colorectal cancer in those populations consuming higher proportions of fish.<sup>2,3</sup> n-3 Fatty acids have also been shown to increase the resistance of cultured cells to transformation by irradiation and transfection in contrast to the effects of n-6 fatty acids.<sup>4</sup> A large rise in mortality from colorectal and breast cancer has accompanied the increase in the ratio of n-6 to n-3 fatty acids in the Japanese diet in the past 50 years.<sup>5</sup>

As with most of the dietary advice given in the review, there is no evidence to confirm that increasing the proportion of n-3 fatty acids in the diet will reduce the risk of cancer. Advice to encourage the consumption of oily fish may, however, be of benefit.

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Competing interest: Dr Barber has received financial support for research and conference attendance from Scotia Pharmaceuticals and Ross Products Division, Abbott Laboratories; he has undertaken research on the effects of n-3 fatty acids in cancer.

- 1 Cummings JH, Bingham SA. Diet and the prevention of cancer. *BMJ* 1998;317:1636-40. (12 December.)
- 2 Kaizer L, Boyd NE, Kriukov V, Titchler D. Fish consumption and breast cancer risk: an ecological study. *Nutr Cancer* 1989;12:61-8.
- 3 Caygill CPJ, Charlett A, Hill MJ. Fat, fish, fish oil and cancer. *Br J Cancer* 1996;74:159-64.
- 4 Takahashi M, Przetakiewicz M, Ong A, Borek C, Lowenstein JM. Effect of w3 and w6 fatty acids on transformation of cultured cells by irradiation and transfection. *Cancer Res* 1992;52:154-62.
- 5 Okuyama H, Kobayashi T, Watanabe S. Dietary fatty acids—the n-6/n-3 balance and chronic elderly diseases. *Prog Lipid Res* 1997;35:409-57.

### No evidence has linked ovarian cancer with high intakes of fat and meat

EDITOR—Cummings and Bingham state that their review on diet and the prevention of cancer<sup>1</sup> was prompted by reports from the Committee on Medical Aspects of Food<sup>2</sup> and the World Cancer Research Fund.<sup>3</sup> In

their otherwise careful review the authors state that “high intakes of fat, milk products, and meat increase risk” of ovarian cancer.

The Committee on Medical Aspects of Food concluded that “there are too few studies which have examined the relationship between meat, fat and dairy products and ovarian cancer to draw conclusions.”<sup>2</sup> Likewise, the World Cancer Research Fund concluded that “the evidence relating milk consumption and the risk of ovarian cancer is limited and inconsistent: no judgement is possible.”<sup>3</sup> Both reports cited Engle et al's paper as indicating no significant association of this cancer with dairy products.<sup>4</sup>

Thus there is no scientific support for Cummings and Bingham's statement, which was in any case unreferenced. If their review becomes widely quoted the erroneous notion that milk products (which many regard as highly nutritious and acceptable foods) cause ovarian cancer may become accepted. Surely this is not something that responsible nutritionists would want.

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- 1 Cummings JH, Bingham SA. Diet and the prevention of cancer. *BMJ* 1998;317:1636-40. (12 December.)
- 2 Chief Medical Officer's Committee on Medical Aspects of Food. *Nutritional aspects of the development of cancer*. London: Stationery Office, 1998. (Department of Health report on health and social subjects 48.)
- 3 World Cancer Research Fund. *Food, nutrition and the prevention of cancer: a global perspective*. Washington, DC: WCRF and American Institute for Cancer Research, 1997.
- 4 Engle A, Muscat JE, Harris RE. Nutritional risk factors and ovarian cancer. *Am J Epidemiol* 1989;130:497-502.

### Authors' reply

EDITOR—Defining the precise relation between diet and the risk of cancer is difficult. There are many cancers, multiple foods and nutrients, and other confounding factors such as exercise, smoking, and alcohol. It is therefore essential to have consistency in the evidence from population studies, animal and human studies, and the molecular and cellular pathology of cancer.

The two recent major reviews of diet and cancer independently showed a large measure of agreement about food items such as fruit, vegetables, and meat and the risk of cancer.<sup>1,2</sup> Some of the results used in these reviews, however, were from epidemiological studies, particularly cohort studies, set up several years ago. Accurate methods for dietary assessment have only recently been developed, and earlier crude assessments of dietary intake, based on short lists of food and food frequency questionnaires, were used in most of these studies. These crude assessments give a substantial degree of measurement error that is not amenable to correction.<sup>3</sup> Thus, for several reasons, these epidemiological studies cannot alone form the basis of recommendations on diet and cancer.

The Committee on Medical Aspects of Food concluded that “there is moderately consistent evidence that diets with less red

meat are associated with reduced risk of colorectal cancer" (page 4),<sup>1</sup> and the World Cancer Research Fund concluded that "red meat probably increases risk" (page 246).<sup>2</sup> In the recent meta-analysis of five cohorts referred to by Truswell, meat eaters were not at greater risk of colon cancer than those who were not meat eaters.<sup>4</sup> The amount of meat consumed by meat eaters was not, however, established; it may well have been low since the cohorts were recruited from people who shopped at health food shops or read vegetarian magazines, friends and relatives of vegetarians, and Seventh Day Adventists.

Cancer rates in vegetarians are 41% of those in the general British population.<sup>5</sup> Nevertheless, neither the Committee on Medical Aspects of Food nor the World Cancer Research Fund recommended that no meat should be eaten. The Committee on Medical Aspects of Food recommended that intakes should not rise and that consumers eating more than 140 g a day should consider a reduction. The World Cancer Research Fund recommended that individuals consume less than 80 g daily.

Barber asks for special mention to be given to fish and n-3 fatty acids. However, both the Committee on Medical Aspects of Food and the World Cancer Research Fund were unconvinced that either fish or polyunsaturated acids were protective. Moreover, selecting individual nutrients, as opposed to foods, to protect against cancer can be dangerous, as trials of  $\beta$ -carotene and vitamin E have shown.

Gurr is correct. It was not our intention to identify dairy products as significant risk factors for ovarian cancer. In fact, the opening sentence of this part of our review stated that "the major known risk factors for other sites are non-dietary."

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1 Chief Medical Officer's Committee on Medical Aspects of Food. *Nutritional aspects of the development of cancer*. London: Stationery Office, 1998. (Department of Health report on health and social subjects 48.)

2 World Cancer Research Fund. *Diet and cancers: a review of the literature on genetic, cellular and physiological mechanisms*. London: WCRF, 1994.

3 Bingham SA, Day NE. Use of biomarkers to validate dietary assessments and the effect of energy adjustment. *Am J Clin Nutr* 1997;65:1130-75.

4 Key TJ, Fraser GE, Thorogood M, Appleby PN, Beral V, Reeves G, et al. Mortality in vegetarians and non-vegetarians: a collaborative analysis of 8300 deaths among 76 000 men and women in five prospective studies. *Public Health Nutr* 1998;1:33-41.

5 Thorogood M, Mann J, Appleby P, McPherson K. Risk of death from cancer and ischaemic heart disease. *BMJ* 1994;308:1667-70.

## Anomalies occur in registrations of fetal deaths in multiple pregnancies

EDITOR—In a monozygotic monochorionic multiple pregnancy the fetal death of one conceptus may have profound consequences, such as neonatal death, cerebral palsy, and

severe mental disability for the livebirth co-conceptus. Because of these consequences the importance of registering a twin fetus papyraceus has been discussed previously.<sup>1-4</sup>

A fetal death must be registered if delivery takes place after 24 weeks' gestation, irrespective of the gestational age at the time of death. When a fetus papyraceus is delivered it is frequently not registered and the legal requirement is not met. Furthermore, if it is registered, anomalies in the registration process have important repercussions for the statistical analysis of data on multiple pregnancies and for the counselling of parents.

Firstly, when the sex of the fetus papyraceus is indeterminate it may be recorded as such on the fetal death certificate. Although the sex may be registered as indeterminate it is always arbitrarily coded as male in the national statistics. Analysis of all fetal and infant death certificates of twins in England and Wales during 1993-5 showed 15 stillbirths registered as sex indeterminate but coded as sex male.

Secondly, if the sex of a fetus is indeterminate some registrars allow the parents to choose which sex is recorded on the certificate. This is understandable as the fetus then assumes a personality and may even be given a name. The number of registrars who allow this parental choice of sex, and how frequently they do so, is not known.

If the twins are monozygotic and monochorionic they must be of like sex, and the correct recording and coding of the sex influences the interpretation of the national statistics. It is also important for the follow up of the surviving liveborn infant(s) and the counselling of parents. If the fetal death/livebirth pair is of unlike sex it greatly reduces the odds that the surviving liveborn infant will have serious disability.

These deficiencies in the data are easily remediable if, at the time of registration of a fetal death, the registrar notes whether parental choice has been exercised in registering the sex of the fetus. Also, if the sex is registered as indeterminate it should be coded as such and not arbitrarily designated as male.

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1 Heys RF. Selective abortion. *BMJ* 1996;313:1004.

2 Pharoah POD, Cooke RWI. Registering a fetus papyraceus. *BMJ* 1997;314:441-2.

3 Griffiths G. Registering a fetus papyraceus. *BMJ* 1997;314:442.

4 Heys RF. Regulations on registration of a fetus papyraceus need to be revised. *BMJ* 1997;314:1352-3.

## Should immunisation against hepatitis B take priority over provision of clean drinking water?

EDITOR—The World Health Organisation has suggested universal immunisation with hepatitis B vaccine.<sup>1</sup> The Indian Academy of Paediatrics has recommended vaccination to

paediatricians in the country and to the government; paediatricians have in turn been recommending it. The cheapest Indian vaccine costs 360 rupees (£5.21) for three doses.

The *India Development Report 1997* suggests that a third of the population earn less than 57 rupees (83p) per capita per month.<sup>2</sup> The main causes of death in India are diarrhoea, respiratory infections, and malnutrition.

Does the World Health Organisation really want universal immunisation with hepatitis B vaccine to take priority over the provision of clean drinking water? At what stage of development of a country's infrastructure does the prevention of hepatitis B by vaccination take priority? Is there any study about this? We would like to be rid of this vermin, but the Pied Piper must be paid.

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2 Parikh KS, ed. *India development report 1997*. Delhi: Oxford Press, 1997.

## Chlamydia screening can have high take-up rates if right methodology is used

EDITOR—A report by the expert advisory group to the chief medical officer suggested that a screening programme in the United Kingdom for *Chlamydia trachomatis* should be based around the opportunistic testing of women attending primary care and the tracing of their contacts.<sup>1</sup> Duncan and Hart discuss some of the possible negative consequences of this decision.<sup>2</sup> There are some further reasons why the Department of Health's stated strategy is a bad idea.

Chlamydia screening has two aims—reduction of morbidity in individuals, and interruption of transmission in populations. Men are at least as important as women in the dynamics of transmission. Restricting male participation in screening to that of traceable contacts makes successful eradication of chlamydia unlikely. Continued transmission in populations means continued morbidity in individuals—mostly women. Some evidence suggests short term benefits in women screened, irrespective of population coverage, although interpretation of this is problematic.<sup>3</sup>

Opportunistic testing of women attending primary care has recently been piloted in the United Kingdom.<sup>4</sup> This study (quoted in the report to the chief medical officer) achieved coverage of under 30% among its target population. The alternative—systematic, register-based population screening of both men and women—was assumed to be unfeasible by the advisory group. Our experience challenges this assumption. Taking a random sample of 18-45 year olds from the list of an urban group practice, we achieved an 83% acceptance rate to a postal request for a urine



specimen to be tested for chlamydia.<sup>5</sup> Rates were not significantly different between men and women or across five year age bands.

Our greater response rate may be due to differences in target population, but methodological factors are probably also important. A practitioner and patient already have enough to cover in a typical consultation without attempts being made to introduce a new screening agenda. Raising these issues at home has advantages of time and privacy, gives opportunities to provide supporting information, and does not require attendance at a health facility.

If the low response in the north London study is repeated in national pilot studies using similar methodology then few individuals are likely to achieve long term health benefits and community transmission is unlikely to be greatly reduced. In other words, chlamydia screening based on the advisory group's model is not only unhealthy but unlikely to work.

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- 1 CMO's Expert Advisory Group. *Chlamydia trachomatis*. London: Department of Health 1998.
- 2 Duncan B, Hart G. Sexuality and health: the hidden costs of screening for *Chlamydia trachomatis*. *BMJ* 1999;318:931-33. (3 April.)
- 3 Abter EIM, Mahmud MA. Screening for chlamydia to prevent pelvic inflammatory disease. *N Engl J Med* 1996;335:1531.
- 4 Grun L, Tassano-Smith J, Carder C, Johnson AM, Robinson A, Murray E, et al. Comparison of two methods of screening for genital chlamydial infection in women attending in general practice: cross sectional survey. *BMJ* 1997;315:226-30.
- 5 Macleod J, Rowsell R, Horner P, Crowley T, Caul EO, Low N, et al. Postal urine specimens: are they a feasible method for genital chlamydial infection screening? *Br J Gen Pract* (in press).

## Effect of discussion and deliberation on public's views of priority setting

### More data are needed for readers to make judgment about study

EDITOR—Dolan et al conclude that people's views on setting priorities differ systematically when they have been given the opportunity to discuss and deliberate, yet they present data that show the stability of the public's opinions.<sup>1</sup> After discussion more than half of the respondents (52%) did not change their minds about who should be involved in priority setting. A further 40% shifted only one point on a five-point scale, which was aggregated to three points, suggesting that the scale discriminated poorly between different preferences. When the participants considered which groups should be prioritised 63% did not change their minds and, overall, only two groups were prioritised differently the second time.

The assumption that respondents to questionnaire surveys fail to consider their replies carefully underlies this study, though we are not aware of any evidence to support this. The authors also present no data to

support the implication that the second, more considered, responses have greater validity. Academic training may affirm the belief that decisions should be pondered over, but an instinctive view on what is right and wrong may reflect the values of society and be appropriate for priority setting.

The theoretical framework used for the authors' sample selection is not presented in the paper, although they do give a description of the respondents in table 1, including their political allegiance. They do not explain, however, why these characteristics were important to the study. Others are not included but seem to us to be relevant—for example, occupation and family or personal history of handicap or chronic disease.

Data from the focus groups should have been presented, as otherwise we cannot know if the content of the discussion influenced the small number of people who changed their minds and the results lose both validity and generalisability. The possibility of bias being introduced by the facilitator has also not been addressed, and the participants' understanding of some of the terms used was not explored. For example, in the second survey, more participants wanted to discriminate against people who were "responsible for their own illnesses" but fewer people would penalise people who drank alcohol or smoked.

The results of this study do not justify the conclusions, and the omission of the core of the results brings into question the external and internal validity of the paper. We applaud the *BMJ's* willingness to publish qualitative research such as the outcome of focus groups, but should we await the data from this study in another journal?

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- 1 Dolan P, Cookson R, Ferguson B. Effect of discussion and deliberation on the public's views of priority setting in health care: focus group study. *BMJ* 1999;318:916-9.

### Authors' reply

EDITOR—There is insufficient space for us to deal with all of Hanratty and Lawlor's points, some of which will be discussed further in forthcoming publications that present the qualitative results of our study. Instead, we will focus here on the methodological issue that lies at the heart of their response—namely, the relative validity of "instinctive views" as compared to "considered responses" about priority setting.

The authors are right that we do not provide evidence that the latter are more valid than the former, but then that was not the intended purpose of the paper. Rather, our more modest goal was to directly test whether instinctive and considered views were different from one another. If preferences do change after discussion and deliberation then the philosophical question about which type of preferences are most appropriate for

informing priority setting decisions becomes an important practical one.

Many of the points that Hanratty and Lawlor make about our results are almost literally about whether a glass is half-empty or half-full. For example, the fact that one-half of respondents did not change their minds about the degree of involvement that different groups should have in priority setting also means, of course, that one-half of respondents did change their minds. It is ultimately a matter of judgment as to whether this is a meaningful difference or not, but the fact that only four of the 60 respondents gave the same response to all five groups in this question on both occasions does cast some doubt on the stability of preferences.

The debate about how much deliberation should be required of preferences that might be used to help set priorities in different contexts will continue. Instinctive views have their place, but so do views based on mature debate. In the context of unfamiliar and complex decisions about priority setting in health care, we contend that allowing respondents the time and opportunity to discuss their responses will enhance the legitimacy of those responses.

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## Probiotics used in trials should be independently checked microbiologically

EDITOR—MacFarlane and Cummings report on the use of probiotics and prebiotics.<sup>1</sup> Strategies to modulate the flora in a beneficial way may help to decrease the use of antibiotics,<sup>2</sup> which has obvious important advantages. It is essential that properly conducted clinical trials are carried out, but most of the studies so far reported have been deficient in many respects.

When setting up a clinical trial with a conventional (that is, chemical) pharmaceutical agent it is taken for granted that the test substance is pure and totally defined and that the doses used are exactly what they purport to be. This is clearly not, however, the case when probiotics are on trial.

Bioyoghurts vary widely in the content and nature of the probiotic bacteria that they contain,<sup>3</sup> and there is no quantitative information on their packaging. Probiotic supplements do not always contain the stated species and quantitatively are often woefully defective (or even sterile).<sup>4,5</sup> It should therefore be mandatory when trials of probiotics are reported that the test substance (bioyoghurt or supplement) contained a well defined probiotic strain and was independently checked microbiologically for quality and quantity at the outset. Furthermore, if different batches are used (as is likely for trials

with bioyoghurts) such checks should be made throughout the study. Only in this way can evidence based results be obtained that can be used as guidance for application to more general situations.

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- 1 MacFarlane GT, Cummings JH. Probiotics and prebiotics: can regulating the activities of intestinal bacteria benefit health? *BMJ* 1999;318:999-1003. (10 April.)
- 2 Hamilton-Miller JMT. Living in the "post-antibiotic era": could the use of probiotics be an effective strategy? *Clin Microbiol Infect* 1997;3:2-4.
- 3 Yoghurt: how healthy is it? *Which* 1993;Apr:38-41.
- 4 Hamilton-Miller JMT, Shah S, Smith CT. "Probiotic" remedies are not what they seem. *BMJ* 1996;312:55-6.
- 5 Probiotics—the friendly bacteria. *Health Which* 1997;Aug:134-5.

## Patient education is way to influence maternal requests for caesarean section

**EDITOR**—The issue of whether women who decide to have elective caesarean section should pay for it raises several important points. That women request elective caesarean section for maternal rather than obstetric reasons has a considerable cost implication: at Watford General Hospital it accounted for at least 38% of all elective deliveries by caesarean section over one year.<sup>1</sup> The reasons for such requests may in part be due to heightened public awareness and publications such as the General Medical Council's *Duties of a Doctor*. Points pertinent to the management of obstetric patients are "Involve the patient in their management" and "Respect the patients' wishes."

This problem can be addressed in several ways. One is to decline requests, but this would run contrary to the recent recommendations of patient choice. Alternatively, women could be charged for the procedure,<sup>2</sup> but how much should be charged? A small amount is unlikely to dissuade patients and would not help health service funding. If patients were charged the full amount (and the actual cost of an elective caesarean section is disputed) this might reduce demand but would lead to ill feeling. Women might resent being treated in an NHS hospital by NHS staff but paying for their treatment, which is against NHS philosophy.

The third way to address the problem is through patient education—providing information on which patients can make informed choices. The commonest reason for patients to request an elective caesarean section is that they decline "trial of scar," which accounts for over three fifths of requests.<sup>1</sup> Do they decline trial of scar because they fear that the chances of vaginal delivery are low or consider it to be dangerous to their baby or their own health? Much evidence suggests that a trial of scar after one previous caesarean section is safe to both the fetus and the mother, with a high chance of spontaneous vaginal delivery (85% in Learman et al's study).<sup>3</sup> The proportion of intrapartum deaths in 1994-5 that were due to rupture of a caesarean scar was 3.4%,<sup>4</sup> and

only one maternal death was due to rupture of a caesarean scar in 1994-6.<sup>5</sup>

With education and information the patient will still have a choice, but the number of women requesting elective caesarean section should fall. Surely this is a better way of reducing demand than by imposing financial pressure.

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These views are personal and do not necessarily reflect those of the staff who work in the author's department.

- 1 Jackson NV, Irvine LM. The influence of maternal request on the elective caesarean section rate. *J Obstet Gynaecol* 1998;118:115-9.
- 2 Mackenzie IZ. Should women who elect to have caesarean sections pay for them? *BMJ* 1999;318:1070. (17 April.)
- 3 Learman LA, Everson LR, Shibalki S. Predictors of repeat caesarean delivery after trial of labour. Do they exist? *J Am Coll Surg* 1996;182:257-62.
- 4 *Confidential enquiries into stillbirths and deaths in infancy, 5th Report*. London: Stationery Office, 1998.
- 5 *Why mothers die. Report on confidential enquiries into maternal deaths in the United Kingdom 1994-1996*. London: Stationery Office, 1998.

## Use of mini-mental state examination by GPs to diagnose dementia may be unnecessary

**EDITOR**—We have a critical comment on the North of England dementia guideline's emphasis on the use of cognitive screening tests such as the mini-mental state examination by general practitioners.<sup>1</sup> We do not oppose the use of screening tests but emphasise that in a primary care setting general practitioners have different and equally effective means of diagnosing dementia. To illustrate this we report on an evaluation study of the diagnostic accuracy of general practitioners who applied the Dutch national dementia guideline for general practitioners.<sup>2</sup>

In this study a cross sectional comparison was conducted between the diagnoses of a sample of 64 general practitioners and an outpatient memory clinic in the district of Nijmegen in the Netherlands. The general practitioners were recruited by mailing and were representative of the Dutch population of general practitioners regarding age, sex, and practice size.<sup>3</sup> A case finding approach was used, with elderly patients suspected of having dementia being diagnosed according to the national guideline and subsequently referred to the memory clinic. The dementia guideline held diagnostic criteria of the *Diagnostic Statistical Manual of Mental Disorders*<sup>4</sup> and comprised 29 diagnostic key recommendations for a cognitive, physical, and behavioural examination. A cognitive screening test such as the mini-mental state examination was optional. The memory clinic's diagnosis acted as a gold standard. We related the general practitioners' diagnostic accuracy to whether or not they used the mini-mental state examination.

For the analysis of accuracy, data on 93 patients were available. In 18 cases the mini-mental state examination was applied. The

average rate of application of the recommendations was 86% (SD 8.6%) and did not differ between general practitioners who used the mini-mental state examination and those who did not (Mann-Whitney U = 683, P = 0.3). The overall accuracy as expressed by Cohen's  $\kappa$  was 0.5, which is moderate. Use of the mini-mental state examination was not associated with better diagnostic accuracy (Pearson  $r = 0.04$ , P = 0.4).

Thus use of the mini-mental state examination may be unnecessary to diagnose dementia in general practice when diagnostic recommendations are applied.

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- 1 Eccles M, Clarke J, Livingstone M, Freemantle N, Mason J. North of England evidence based guideline development project: guideline for primary care management of dementia. *BMJ* 1998;317:802-8. (19 September.)
- 2 De Bruyne GM, Meyboom-de Jong B, Muskens JB, Weytens JTNM, Wind AW. De NHG-standaard dementiesyndroom [Guideline on dementia of the Dutch College of General Practitioners]. *Huisarts Wetenschap* 1991;34:598-607.
- 3 Harmsen J, Hingstman L. *Cijfers uit de registratie van huisartsen, peiling 1996 [Numbers of the registration of general practitioners in the Netherlands]*. Utrecht: Netherlands Institute of Primary Health Care, 1996.
- 4 *Diagnostic and Statistical Manual of Mental Disorders*. 3rd ed, revised. Washington, DC: American Psychiatric Association, 1987.

## Conservative management of genuine stress incontinence in women

### Study's flaws may be misleading

**EDITOR**—Bø et al's study comparing the various methods used in the conservative management of genuine stress incontinence has several flaws, which may mislead readers.<sup>1</sup> The study has been described as pragmatic, reflecting current practice. This view is undermined by the instructions to the women in the vaginal cone and electrical stimulation groups not to perform pelvic floor exercises while using their treatments; this does not reflect current clinical practice. In a prospective randomised study comparing the efficacy of pelvic floor exercises in combination with vaginal cones and pelvic floor exercises alone the combination of the two treatments was significantly more efficacious than either alone.<sup>2</sup>

In a prospective randomised study comparing the efficacy of pelvic floor exercises in combination with vaginal cones, vaginal cones alone, and vaginal electrical stimulation alone, again the combination of two techniques produced greater improvement in urinary incontinence.<sup>3</sup>

We are also concerned about the differing numbers of visits to a therapist for each group. The pelvic floor exercise group had weekly visits whereas the other groups were seen monthly. This would introduce

bias; Wyman et al proposed that the specific conservative treatments are not as important as having frequent contact with the patients, with education and counselling.<sup>4</sup> Thus the pelvic floor exercise group should have a better response to treatment owing to the increased time they had with a therapist.

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- 1 Bø K, Talseth T, Holme I. Single blind, randomised controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999;318:487-93. (20 February.)
- 2 Haken J, Benness C, Cardozo L, Cutner A. A randomised trial of vaginal cones and pelvic floor exercises in the management of genuine stress incontinence. *Neurourol Urodyn* 1991;10:393-4.
- 3 Wise BG, Haken J, Cardozo L, Wise BG, Plevnik S. A comparative study of vaginal cone therapy, cones and Kegel exercises and maximal electrical stimulation in the treatment of female genuine stress incontinence. *Neurourol Urodyn* 1993;12:436-7.
- 4 Wyman JF, Fantl JA, McClish DK, Bump RC. Comparative efficacy of behavioral interventions in the management of female urinary incontinence. *Am J Obstet Gynecol* 1998;179:999-1006.

#### Authors' reply

EDITOR—We tried to give the best possible treatment for all groups within a pragmatic setting. Thus the electrical stimulation and vaginal cones groups had 30 and 20 minutes' training daily, respectively, whereas the exercise group had less than 8-10 minutes' training. This should favour the electrical stimulation and vaginal cones groups, and it is strange that Khullar et al do not mention this as a flaw. Another flaw that works against the exercise group is that both the vaginal cones and electrical stimulation groups had individual treatment with direct proprioception to the pelvic floor, while the exercise group was taught without proprioception.

If the women are contracting simultaneously with the current, how can we then conclude that it is the electrical stimulation and not the voluntary contraction that gives the effect? The point of this study was to evaluate the effect of electrical stimulation and cones. An interesting hypothesis is whether contraction simultaneously with electrical stimulation gives better results than contraction without. This should be investigated in a future study. Other studies have shown no significant additional effect of adding electrical stimulation to exercise.<sup>1</sup>

Strong motivation and instruction are important factors in increasing muscle strength and part of strength training regimens. One of the benefits advocated by manufacturers of vaginal cones and electrical stimulators is that these methods can be used at home without the therapist, thus being cheaper. These methods have been used in this way in the Scandinavian

countries for years. In our study all groups had the same monthly visits, for motivation, individual follow up, and contact with the therapist. The exercise group had weekly contacts in groups in addition. This may have enhanced their improvement. This is the way we teach pelvic floor muscle exercise, and it is difficult to understand how this group contact could give such huge differences in a provocation test at the office of a blinded investigator.

Khullar et al give references to their own work presented as two abstracts. As far as we can see their results are similar to our findings. In the first study exercise and vaginal cones did not give significantly different results. However, the drop out rate in the vaginal cone group was 25%, and no intention to treat analysis was performed. In the second study, adding pelvic floor muscle exercise to treatment with vaginal cones was more effective than treatment with vaginal cones alone.

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- 1 Knight S, Laycock J, Naylor D. Evaluation of neuromuscular electrical stimulation in the treatment of genuine stress incontinence. *Physiotherapy* 1998;84:61-71.

#### Private medical care surely benefits NHS indirectly

EDITOR—In a news article Warden reports an address given by the shadow health minister outlining the Conservative party's new policy on health.<sup>1</sup> The article also gives views on these plans expressed by Professor Chris Ham, which should be challenged.

If people choose to pay for private medical care then they are relieving the NHS of that burden (real or potential). As taxpayers they are also supporting the NHS. It is surely inequitable that they should be obliged to pay for a service that they do not use; moreover if tax relief were allowed on health insurance premiums the loss to the Treasury would be only the amount of tax payable on the insurance premium. For a maximum rate taxpayer, relief would amount to 40% of the premium; 60% of the premium would still come out of their taxed income.

It is, I suggest, fundamentally untrue to suggest that such people are not doing anything for the less well off, as they are relieving the state, almost totally, of the cost of any medical care they may need. What Professor Ham is talking about is not equity but pure left wing, sting the rich, socialism. The NHS will remain underfunded just so long as it is centrally funded as at present, and thus remains a political football.

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- 1 Warden J. NHS "cannot cope," says Tory. *BMJ* 1999;318:1028. (17 April.)

#### Economics of PFI in the NHS

EDITOR—In his editorial Smith rehearsed all the old arguments about the private finance initiative (PFI) in the NHS.<sup>1</sup> As he says, these criticisms are becoming familiar but this does not mean that they are correct.

I accept that the private sector cannot borrow as cheaply as the public sector. However, deals under the private finance initiative achieve greater value for money because their increased operational savings more than outweigh the additional costs of borrowing. When measured over the lifetime of the contract, every major scheme to date has cost the same or less than the publicly funded alternative. Furthermore, in deals under the private finance initiative the private sector carries the risk of cost overruns and time delays. In the past these risks were carried by the taxpayer and could be sizeable. By contrast, the Norfolk and Norwich Hospital is months ahead of schedule and Greenwich Hospital is set to be built in only 120 weeks.

Smith also asserts that the Scottish programme "will cost ... £2bn more" than the publicly funded alternative, but he does not seem to have compared like with like. Schemes in the private finance initiative include the maintenance and support costs for facilities throughout the period of the contract, unlike publicly funded schemes. Therefore it is not surprising that publicly funded schemes seem to be less expensive than their private counterparts.

Does the initiative lead to reduced bed numbers? The services at any new hospital are determined by NHS clinicians and managers long before a decision is taken on whether it should be built using public or private capital. At Hereford,<sup>1</sup> the trust and health authority agreed that changing patterns of service delivery meant that fewer acute beds were needed. This was reflected in the specification for the new hospital. Whether it had been procured through public or private capital, the same number of beds would have been provided. Figures published in Hansard show that in almost all of the first 15 major private finance initiative schemes the same number of beds would have been provided if they had been built with public funding.<sup>2</sup> Despite Smith's suggestion to the contrary, the number of private beds in these schemes has changed significantly only in one scheme, at Calderdale. The national beds inquiry set up by the current government will provide a useful framework for determining local services and bed numbers in the future.

There are many other issues regarding the private finance initiative that I will raise in a future article such as the openness and accountability of the process and the system of capital charges in the NHS.

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- 1 Smith R. PFI: perfidious financial idiocy. *BMJ* 1999;319:2-3. (3 July.)

- 2 *House of Commons Official Report (Hansard)* 1999 Feb 2:cols 202-6.

#### Rapid responses



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