therapeutic disasters brings also some fear of harm. Thus although he may hope the new treatment has a better benefit:risk ratio than current treatment he is as yet too uncertain to commit himself and his patients unreservedly to the choice. Ethical problems may arise as the trial proceeds and the results become available. If they indicate that the new treatment is indeed superior the doctor's level of uncertainty about it will fall and eventually reach a threshold of conviction. At this point it is clearly unethical for him to withhold the new treatment from the control group and the trial ends. If he had been so convinced in the first place the trial should never have started. But how does the reduction in his uncertainty about the treatment relate to his ethical duty to the patients?

Whenever a doctor decides that he should use a new treatment because he thinks it will be better than the old he runs a risk (α) of being wrong, the old treatment being better. If, on the other hand, he decides that the new treatment offers no advantage there is a risk (β) that he is missing a useful effect and thus denying his patients the chance of benefit. Values must be assigned to these risks before a trial can be designed with sufficient power to detect a specified treatment effect. Traditionally α is set at 0.05 and β around 0.1³ but these values are often chosen arbitrarily by statisticians who have not been briefed about the clinical realities of the situation. Since α and β represent the likelihoods of erroneous conclusions from the trial, their size should reflect the consequences of that error.⁴ For example, the consequences of wrongly deciding that an expensive and toxic treatment was more effective than a harmless one would be more serious than if their toxicity was equal. To guard more securely against the more undesirable error the clinician must set his level of α appropriately low, perhaps lower than the traditional 0.05. In a different situation $\alpha=0.1$ might be appropriate.

Values of α and β , then, reflect thresholds for action, levels at which the doctor's risk of error and his degree of uncertainty are low enough to allow him to make a firm choice about treatment. Until these thresholds are reached he has not attained a level of conviction at which contrary action becomes unethical.

The greater the uncertainty and the more serious the consequences of error the greater is the clinician's responsibility to become more sure. An efficient and well-designed clinical trial can give him the necessary information. His attitude and responsibilities to his patients are not changed by embarking on the trial; all that may alter is the confidence with which he gives or withholds the new treatment.

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- ¹ Carter, S K, and Mathé, G, *Biomedicine*, 1978, 28, 6.
- ² Peto, R, *Biomedicine*, 1978, 28, 24.
- ³ Freiman, J A, et al, *New England Journal of Medicine*, 1978, 299, 690.
- ⁴ Chaput de Saintonge, D M, Vere, D W, and Sharman, V L, *British Journal of Clinical Pharmacology*, 1977, 4, 492.

Prescription for a better British diet

SIR,—I welcome the publication of this modest and well-balanced paper (24 February, p 527) by our most experienced nutritionists, who have contributed greatly to this subject during the past 25-30 years. At a time when not only the medical profession but the whole population is persistently bombarded by often ill-conceived dietetic advice coming from people who have little knowledge and experience about nutrition, this unpretentious and well-documented plan could indeed be the basis for a better British diet.

There are many points which were probably

deliberately left out of discussion in this plan for a national diet. Individually these can be easily modified according to need. But it appears to be absolutely essential to have a properly documented basis for discussion in view of the fact that, for example, the already very high national fat consumption increased by over 25% during the past 25 years and alcohol consumption even more.

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SIR,—I have long been saddened by the apparent lack of influence which we have as a profession on the diet consumed by most of our patients, so I welcome the article on nutrition (24 February, p 527).

It is apparent from this article and its bibliography that a great deal has been done to improve nutrition in Britain and I am therefore all the more surprised that the cost of whole-wheat products, unpolished rice, and brown sugar remains higher than that for the refined carbohydrate foods which fill the shelves of stores and bakeries and the bellies of our children.

If the committee on nutrition now recommends a diet containing 15% less meat and 15% more cereal should there not be a reference to the quality of that cereal? What power can be used to implement these recommendations? If power for such implementation does exist should it not also be used to keep down the cost of carbohydrate foods of better nutritional value as an encouragement and incentive to their more general use?

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SIR,—Any bitterness from the "Prescription for a better British diet" (24 February, p 527) over the suggested reduction of 15% in consumption of meat can be sweetened by the consequent decrease by 55m head a year in the rearing and slaughter, usually in cruel conditions, of food animals for British tables (the furore over biomedical experiments concerns the exploitation of 5½m animals a year).

In 1976 the Vegetarian Society published a "Green Plan" for Britain's farming, food, health, and environment with aims like those of the "prescription" and with practical suggestions for attaining the objectives; for instance, we launched a campaign for real bread to restore interest in and consumption of hi-fi cereal foods. It is encouraging to note the increase in sales of brown bread as those of white bread continue their decline; sales of flour for home-baking are also rising.

With Britain's ruinous dependence on imports of food and feed, as well as of fuel, timber, and woodpulp, we did not in the Green Plan restrain ourselves from urging feasible changes in agricultural and trading policies. The EEC's disarray over its excessive milk production, measured in enormous subsidies and mountains of butter and skimmed milk and lakes of whey, and its dependence on imported proteins prompt a salutary decrease in the production and consumption of dairy produce. British cows yield milk prolifically off grass for few months in the year: the farmer has to feed 3½ lb of concentrates to obtain 1 gallon of milk. Dairy products present some questionable nutritional properties; it is better to encourage breast-feeding and to benefit from the trend, already established, for more extensive sowings of temperate oilseeds as sources of dietary oils and fats. As about 75% of British beef originates in the dairy herd, reduced consumption of meat is

fittingly accompanied by corresponding changes in the use of milk.

Instead of accepting no change in consumption of pulses and nuts (which the prescription commends as "these pleasant and nutritious foods"), we advocate increases ("a bean-feast"), exploiting the opportunities offered in oriental cuisines that are now increasing the British culinary repertoire with these staples. Pulses, being nitrogen-fixing plants, contribute usefully to agricultural rotations. The ecological consequences of desirable nutritional changes will ease their adoption.

Sugar is also overproduced in the EEC; so the prescription would entail some agricultural disruption, albeit welcome, but too small. Home production off present acreages could supply half of the present consumption. We should aim to reduce our consumption to our output. Potatoes might well be grown instead of sugar-beet—which, however, makes a useful entry into a cereal rotation. Sugar is a crop with potential as an alternative to petroleum in manufacturing. Such industrial corollaries bear on the feasibility of national policies for farming and food. Straw is another major crop ripe for industrial application—for example, to make paper.

Meat eaters heeding the prescription and the US dietary goals might be persuaded to reduce their consumption of beef, rather than of poultry or pig meat (sheep meat is being eaten less and less in the UK). However, if the agricultural aims of the prescription are to be served, production of broilers and pigs, being the most intensive forms of rearing and causing the severest drift of labour from the land, should be curbed as a priority.

The future for Britain, lampooned as "a nation of constipated, toothless fatties," looks good if it recognises its role now as a leader in a spell of industrial devolution, casting out the food cults in meretricious high standards of living and restoring the values of simple, nutritious food produced from a green and pleasant land. Doctors and nutritionists can certainly accelerate salutary dietary changes. Since the American Heart Association's recommendations in 1964, per capita consumption of incriminated foods has declined as follows: liquid milk and cream, 20%; butter, 36%; eggs, 13%; and animal fats and oils, 51%. Consumption of vegetable fat and oil has risen by 64% in the same period. Discussions among producers, consumers, and doctors are overdue. They should elevate "cheap" (and now even "fast") food from its loss-leader predicament to its proper status.

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Fats and atheroma

SIR,—Sir John McMichael (20 January, p 173) states that "substantial rises in cholesterol concentration after thyroidectomy . . . did not produce an excess of coronary atheroma in man" and repeats the reference¹ that he gave in 1974 when writing on the same subject.² At that time, Thompson³ pointed out that Blumgart *et al*¹ stated that their results did not disprove the role of cholesterol in the production of atheroma.

Sir John McMichael's statement is based on the study of eight patients in whom thyroidectomy had been done as a therapeutic measure for congestive heart failure. These eight patients included a man, aged 22, with a pre-operative cholesterol concentration of 3.6 mmol/l (138 mg/100 ml) and an average cholesterol concentration of 6 mmol/l (233 mg/100 ml) during the postoperative year that he survived. At necropsy "severe atherosclerosis"

of the aorta was found but no atheroma of the coronary arteries. Another of the eight patients, a woman aged 44, had a serum cholesterol concentration of 7 mmol/l (273 mg/100 ml) before thyroidectomy and a concentration of 6 mmol/l (230 mg/100 ml) before she died four years later.

These eight patients are as relevant to the debate on fat and atheroma as the flowers that bloom in the spring. It is time that this outworn reference was given a well-deserved rest.

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¹ Blumgart, H L, Freedberg, A S, and Kurland, G S, *American Journal of Medicine*, 1953, 14, 665.

² McMichael, J, *Lancet*, 1974, 1, 1340.

³ Thompson, G, *Lancet*, 1974, 2, 102.

SIR,—With reference to the last comments in Drs K G Taylor and D J Betteridge's letter on "Fats and atheroma: an inquest" (17 February, p 485), I wish to point out that dietary limitation of cholesterol-containing foods is unnecessary and ineffective in reducing serum cholesterol. Over four-fifths of the body's cholesterol is endogenous and dietary cholesterol intake is compensated for anyway.¹ Restricting eggs to two per week is bad dietary practice—they are extremely nutritious, cheap, readily available, and easy to store and cook; at most I might consider a limitation of four per week. Reduction of milk would be unwise: research has shown that it has hypocholesterolaemic properties.² Limiting total fat and refined carbohydrates in the diet are the all-important factors.

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¹ Davidson, S, et al, *Human Nutrition and Dietetics*. Edinburgh, Churchill Livingstone, 1975.

² Howard, A N, and Marks, J, *Lancet*, 1977, 2, 255.

SIR,—I would like to deal with some of the supposed evidence in favour of an aetiological significance of cholesterol in atheroma, such as that quoted by your correspondents Drs K G Taylor and D J Betteridge (17 February, p 485).

Evidence from animal experiments is always a little suspect, but it is very much more so when vegetarian animals are made to take foods they never normally eat. Suppose we reversed the experiments and fed human beings the strict vegan diet of rabbits and rhesus monkeys. Such persons would develop muscular weakness and probably B₁₂ deficiency. This could be cured by giving essential amino-acids (first-class proteins) and vitamin B₁₂. Would Drs Taylor and Betteridge regard this as evidence that all rabbits and rhesus monkeys should have supplements of essential amino-acids and B₁₂?

Drs Taylor and Betteridge remind us that the probability that an individual will develop a coronary infarct increases in proportion to his serum cholesterol concentration. In myxoedema this relationship is not just a probability. The serum cholesterol is a direct measure of the severity of the disease. Do they suggest that this means that cholesterol causes myxoedema or it can be cured by lowering the cholesterol with polyunsaturated fats?

Most experiments purporting to show an improvement with polyunsaturated fats have been criticised because they do not exclude

other factors such as smoking, obesity, and hypertension (Professor J Yudkin would add sucrose), which by themselves or together may have been responsible for the result. While I cannot claim to have studied them all, it is reasonable to expect that after years of what can only be called determined research there would be little room left for argument if the significance of cholesterol in atheroma were anything like that of cigarette smoking in cancer of the lung.

Finally, the cholesterol of premenopausal women is higher than that of men, yet their incidence of coronary heart disease is lower. Would Drs Taylor and Betteridge recommend that men under 45 should eat more butter, cream, and eggs in the hope of lowering their incidence of coronary heart disease to that of premenopausal women.

We are all agreed on the desirability of a "sensible diet" but that this diet should deprive us of most of our eggs, butter, and cream with substitution by polyunsaturated fats is far from having been demonstrated. Even the plea that it may do good and cannot do harm is no longer tenable. Sir John McMichael has done well to ask for an inquest. I hope you will call on him to reply to any further criticisms from the peculiar entrenched form of logic which seems to have overtaken so much of the profession.

In the meantime may I (not for the first time) suggest that "a little of what you fancy does you good"—at least until it is proved to do otherwise.

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Malnutrition in infants receiving cult diets

SIR,—We have read with interest and not a little concern the paper "Malnutrition in infants receiving cult diets" by Dr I F Roberts and others (3 February, p 296), which has excited considerable publicity and comment in the news media. We are concerned about the inaccurate references to diets in this paper and the unwarranted adverse comments about acceptable diets that have ensued.

The authors of this article have clearly confused different diets based on the sole consumption of plant foods. The result is that, while attention is quite rightly drawn to the serious consequences of feeding certain extremely limiting diets, the confusion about the nomenclature of diets is likely to cause unnecessary concern to parents who for a variety of reasons wish to feed their children a diet based on plant foods.

We saw the 13-month-old boy described in this paper at Kingston Hospital with the late Dr Frey Ellis before he went to the Hospital for Sick Children. This child was receiving a "fruitarian" and not a vegan diet. Indeed, the father of this child persistently refused to accept expert advice on a balanced vegan diet including the use of a soya-based milk and supplements of vitamin B₁₂. The other three infants described in the paper are not known to us, but it is evident that they were receiving macrobiotic diets. These are known to be dangerous,¹ and should be clearly distinguished from vegetarian and vegan diets.² The failure to distinguish between fruitarian and vegan diets has resulted in the statement that "Vegan and the more extreme macrobiotic diets are obviously inadequate for growing children. . . ." We agree entirely about the fruitarian and

macrobiotic diets, but cannot agree about a balanced vegan diet for we know that children have been, and are being, reared very successfully on such a regimen. Mothers who wish to feed their children on a vegan diet can obtain free advice and information from the Vegan Society, 47 Highlands Road, Leatherhead, Surrey.

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¹ American Medical Association Council on Foods and Nutrition, *Journal of American Medical Association*, 1971, 218, 397.

² Dickerson, J W T, and Fehily, A M, *Practitioner*, 1979, in press.

SIR,—Nutrient deficiency is more likely to occur if the variety of food in the diet is restricted, especially so when the diet is devoid of foods of animal origin. Even so, a properly constructed vegan diet, composed of a mixture of cereals, pulses, nuts, fruit, and vegetables, can meet all the requirements for nutrients provided that it is supplemented with vitamins B₁₂ and D.^{1 2}

Most vegan mothers breast-feed their babies well into the second year of life. Breast milk can meet all the nutrient requirements for the first six months of life provided that the supply is adequate. In the 20 vegan mothers we have studied the milk composition and yield, when estimated by test weighing of the infants, were normal; the milk was richer in linoleic acid than that from omnivores.^{2 3} Breast milk will continue to meet the nutrient requirements of the infant after six months provided that it is supplemented with a suitable weaning food such as Farex, which consists of a mixture of cereal and soy-bean flour. The infant can then gradually be introduced to a properly balanced vegan diet with suitable vitamin supplements. Over the past 15 years my colleagues²⁻⁴ and I have studied about 60 children born of vegan mothers and reared on vegan diets. Their development, as judged by their rate of growth and general health, seems to be quite normal.

We were involved with the first case described in the paper "Malnutrition in infants receiving cult diets: a form of child abuse" by Dr I F Roberts and others (3 February, p 296). The parents of this child were following a "fruitarian" diet, which excludes cereals and pulses as well as food of animal origin, and were attempting to wean the child on a similar diet. The authors, who omitted to mention that the child was eventually rehabilitated on a properly balanced vegan diet, incorrectly concluded that "Vegan . . . diets are obviously inadequate for growing children, with deficiencies of total energy, suitable protein, fat-soluble vitamins, and some minerals."

One of the most disturbing aspects of this paper was the unscientific manner in which it was presented. Assessment of nutrient intake was scanty; why one child developed kwashiorkor and another marasmus was not discussed. A more accurate assessment of nutritional state might have revealed that the children were being virtually starved. If this were the case then qualitative differences in diet become of secondary importance. The