Economies in the NHS

SIR,—If Mr Fowler is keen on economies in the NHS he should look no further than the Welsh Office where before DHSS circulars are forwarded to family practitioner committees, district health authorities, local medical committees, community health councils, etc, they are retyped on Welsh Office stationery. The Welsh Office also changes the reference numbers and dutifully corrects references within the circular so that it conforms to previous Welsh Office modifications to old DHSS circulars. The result of all this bureaucratic nonsense is unnecessary expense, delay, and chaos. We frequently learn of changes to regulations in the medical press but are then informed by the Welsh Office that these changes do not apply to Wales until the appropriate circular has been released. During reorganisation some of these circulars were delayed for up to six months. About six years ago, as an LMC secretary, I received, with a covering letter from the FPC, a photostat of a letter from the DHSS to the Welsh Office, a photostat of a letter from the Welsh Office to the FPC, and a modified Welsh Office circular, informing us that the drug tariff book would be delayed through lack of paper.

The recent circular concerning the new regulations controlling barbiturate drugs, which came into effect on 1 January 1985, was not received by our FPC for redistribution until 15 January 1985. As usual, chaos reigned as pharmacists were refusing to dispense prescriptions issued before we were notified of the regulation change.

As all DHSS circulars refer equally to England and Wales, there would be a resultant increase in efficiency and reduction in expenditure if all these circulars were sent out directly by the DHSS. No doubt similar economies could be made in Scotland and Northern Ireland.

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Coronary bypass surgery for the reduction of mortality: an analysis of the trials

SIR,—Professor J R Hampton's review of the mortality results of the three major coronary surgery trials (3 November, p 1166) contains a considerable number of factual errors in the data referred to and misinterpretations of some basic aspects of the design and conduct of the trials, which appear to influence the validity of some of his conclusions. In his analysis of the Veterans Administration trial Professor Hampton finds it remarkable that almost all patients continued to receive the treatment they had been allocated: "Only in 42 of those assigned to medical treatment was surgery later considered necessary." In fact the correct number of crossovers to surgery at five years was at least 95, as can be derived from figure 11 of the Veterans Administration report not referred in the review.¹ Furthermore, Professor Hampton insists that the long term survival data in the Veterans Administration study "referred to a subgroup formed at the end of the trial," in spite of the explicit declaration of the investigators that "the protocol was revised and the study was restarted in January 1972" because of two specified reasons.¹

In his analysis of the European study Professor Hampton presents the following data which are incorrect (the correct data are given in parentheses): mean age 56 (50); mean ejection fraction 62% (65%); previous β blocker treatment 55% (75%); five year mortality in the medical patients with two vessel disease 15% (12%) and those with three vessel disease 22% (18%); and five year mortality in the surgical patients with two vessel disease 8% (9%) and those with three vessel disease 13% (6%). The reduction in mortality of 53% is correct, but the 95% confidence interval of 25% to 81% is inaccurately calculated; it ought to be 30% to 71%. The referred numbers of crossovers are truthfully reproduced but the calculated percentages of them are incorrect: 3.7% (7%) for the surgical patients who were not operated on and 29% (24%) for the medical patients who were actually operated on.

There are also some peculiar errors in the data quoted from the Coronary Artery Surgery Study (CASS). The figure of 88% for smokers is incorrect; it should be 40%. The five year mortality is calculated as the percentage of the deaths in the respective groups and subgroups in spite of the fact that 31% of the patients were not followed up for longer than four years; five year figures are given by CASS life tables.

The review contains two rather amazing suggestions about the design and conduct of the European study. Firstly, Professor Hampton covertly suggests that the number of patients was not calculated in advance as being adequate. This is false; the calculated number was 700 as reported in the article ignored by Professor Hampton.² Secondly, he bluntly states that (in the European study) "the results have been inspected and reported continuously up to a point where a significant difference between treatment groups was apparent," and concludes that "the CASS was a much better study in this respect, with a single report after a defined period." This statement grossly misrepresents the design of the European study. The reviewer chooses to ignore the fact that in spite of a "statistically significant" difference already apparent in the first interim report the study continued; this rejects his suggestion: "All patients were to be followed up to their death or to the closing date of the study—the date of 5-year follow-up for the last included patient—March 24, 1981."³ This protocol statement was asserted in the first article² (neglected by the reviewer) and repeated in each of the interim reports.⁴⁻⁶ Incidentally, the reviewer also ignores the declaration of the CASS investigators that their article on survival was "first end point report."⁷

Finally, Professor Hampton gets himself entangled in the subset analysis in which the subsets of the two studies are differently defined and the referred figures of mortality are wrong. This confusing analysis results in Professor Hampton departing from his initial explanation of the survival differences: "Since the inclusion criteria for the European study and the CASS were different, the results of the studies might be expected to be different." The applicability of this explanation is strongly supported by the marked differences in the incidence of prognostic predictors between the two studies largely overlooked in the review.

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- 1 Takaro T, Hultgren HN, Detre KM, Peduzzi P. The Veterans Administration cooperative study of stable angina: current status. *Circulation* 1982;65 (suppl 11):60-7.
- 2 Varnauskas E, Olsson B. The European multicenter CAB trial. In: Yu PN, Goodwin JF, eds. *Progress in cardiology*. Philadelphia: W B Saunders, 1977: 83-9.
- 3 European Coronary Surgery Study Group. Long-term results of prospective randomised study of coronary artery bypass surgery in stable angina pectoris. *Lancet* 1982;ii:1173-80.
- 4 European Coronary Surgery Study Group. Coronary artery bypass surgery in stable angina pectoris: survival at two years. *Lancet* 1979;i:889-93.
- 5 European Coronary Surgery Study Group. Second interim report. Prospective randomised study of coronary artery bypass surgery in stable angina pectoris. *Lancet* 1980;ii:491-5.
- 6 European Coronary Surgery Study Group. Prospective randomised study of coronary artery bypass surgery in stable angina pectoris: a progress report on survival. *Circulation* 1982;65(suppl 11): 67-71.
- 7 CASS Principal Investigators and their Associates. Coronary artery surgery study (CASS): a randomized trial of coronary artery bypass surgery. Survival data. *Circulation* 1983;68:939-50.

** Professor Hampton replies below.—Ed, BMJ.

SIR,—I am very grateful for the corrections supplied by Professor Varnauskas. The figures in my paper came from the various publications of the European study, and I am afraid that it is inevitable when multiple publications emanate from one trial that inconsistencies and inaccuracies will appear. Trialists (and editors of medical journals) should bear in mind that few studies merit more than a single publication.

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Death or dialysis

SIR,—The provision of renal dialysis facilities is an emotive subject. While we do not deny a lack of dialysis facilities in the United Kingdom, we are concerned about the remedy prescribed by Mrs Elizabeth Ward in her leading article (22-29 December, p 1712)—namely, the provision of private dialysis facilities.

The three cases which she illustrates are typical of patients who would not be likely to receive comprehensive medical management from the "private sector." Diabetics, paraplegics, children, and patients with psychiatric illness need not only dialysis but also extensive multidisciplinary skills, social support, and, above all, continuity of care. The private sector would be able to provide a "washeteria" type of dialysis service but probably only to ambulant patients from large units. Private facilities would therefore have to be placed in or near major cities to provide a minimum of 288 dialyses per month. The sick, the old, the difficult, and the very young would be left to the NHS. Besides the cost of dialysis, the cost of transporting patients with chronic renal failure to and from the central dialysis facility has to be borne. Therefore it is advisable that continued emphasis should be placed on home haemodialysis and continuous ambulatory peritoneal dialysis. In addition, there is a need for satellite units, especially for patients awaiting early transplantation and for those unsuitable for home treatment.

Since 1978 in the Mersey region we have established three large peripheral satellite units, currently catering for eight to 15 patients each,

and another five subsatellite units, capable of treating two to four patients each. These units have minimal nursing staff cover and the subsatellite units are run with the aid of a corps of voluntary helpers, our "dialysis friends." The patients remain under the medical supervision of the regional dialysis unit. This expansion in our dialysis facilities, coupled with an active transplant programme, has enabled us to treat an increasing number of patients over the age of 60, and in the past three years we have been aware of very few patients who have not been accepted.

Reuse of dialysers and of blood lines and other disposables is practised, with an appreciable reduction in costs. For 1984 the cost of satellite dialysis averaged £38.50 per treatment, £21.50 less than the price quoted by Mrs Ward, and calculated on the same basis as judged from the commercial option she sent to our regional health authority. We feel that expansion of dialysis facilities can best be achieved by making full use of existing parent and satellite units as well as appointing more consultants with an interest in renal disease in non-teaching hospitals to expand the number of kidney units. By opening such units we will be able to provide a comprehensive renal service under the aegis of the NHS to all who need it.

While the problems of selection for dialysis will always remain, their nature will change fundamentally, with clinical considerations predominating. Many nephrologists now seriously question the wisdom of accepting all older patients for treatment, especially when other major systems are affected—for example, by degenerative disorders that have already produced serious morbidity and which carry the risk of early mortality on dialysis or after transplantation. Perhaps the unlimited availability of dialysis that exists in other countries may result in a prolongation of suffering for some of these patients, and this can hardly be desirable.

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SIR,—A comparatively simple method of funding renal dialysis and related treatment by credit transfer from donor districts to renal units could solve the problems of Professor J S Cameron and Dr Mary McGeown and her colleagues (19 January, p 236) and also those of many long suffering patients in the United Kingdom.

Even allowing for the cost of treating the older patients with more complicated problems, to whom Professor Cameron refers, the deduction of, say, £20 000 annually from a donor district's budget for each such case would be a relatively painless financial exercise. In any event, no responsible clinician could possibly begrudge the selective detachment of funds from his own health district's budget to support the continued survival of such gravely threatened patients. Moreover, under this system, it would be much easier to set up new dialysis centres without imposing additional strain on the budgets of those hospitals selected for much needed extension of the present painfully inadequate service.

The concept of credit transfer support for end stage renal failure (easily adaptable to other forms of high technology care in specialist centres) would be a logical extension of the sensible system of management budgeting recently outlined by Mr Philip Davies and Mr Malcolm Prowle (1 December, p 1552). Doubtless those authors would also have

advocated such a method as I envisage had this been included in their terms of reference rather than persistently opposed by the DHSS and successive ministers.

Everyone working in the NHS has a responsibility for more cost effective and efficient use of existing resources. As to increasing the total health budget, whatever Dr K R Llewellyn's feelings may be about "part time soldiers" and the future electoral prospects of the Labour party (19 January, p 237), it would surely be an excellent idea if politicians of all British parties had the courage (like President Mitterand's present administration in France) to impose reasonable lodging and other charges for the generality of shorter term hospital patients.

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Plasma theophylline concentrations, six minute walking distances, and breathlessness in patients with chronic airflow obstruction

SIR,—The disconcerting revelation by Dr A J Miller and colleagues (12 January, p 159) that independent analysis of the data from Dr D W Evans's study (15 December, p 1649) showed a significant increase in expiratory flow indices with theophylline which Dr Evans failed to find and their further revelations about the same data should not be allowed to obscure the two points of major importance in that paper which they both miss. Dr Evans's results clearly show that walking distance did not improve after Uniphyllin (theophylline) but did after the vehicle without the theophylline. Thus a single dose of their preparation in whatever strength actually reduced measured walking distance 12 hours later under the circumstances of Dr Evans's trial. This may be true considering the widespread effects of theophylline but it is the first published demonstration and needs further consideration by the author and perhaps further study. I suppose this clear result that the treatment was worse than the placebo is as intuitively unacceptable to Dr Miller and colleagues as it is to Dr Evans since both ignore it. What I find more obviously unacceptable is the disregard of one of the fundamental principles of a scientific paper so ably set out in your columns over recent years that conclusions must not incorporate speculation unsupported by the findings of the study. Dr Evans's final sentence clearly conveys the idea that routine use of theophylline is probably useless and that those of us who use it had better justify our practice. Neither the design of his trial nor his review of published reports justifies such a conclusion and I am surprised that your referees allowed it.

A series of studies of the admittedly complex pharmacokinetics and pharmacodynamics of theophylline from this department over the past several years, some of which are cited by your correspondents, has convinced us of the bronchodilator effect of theophylline¹ and therapeutic value of steady state theophylline concentrations in the conventional therapeutic range from twice daily dosage of slow release oral preparations in patients with chronic partially reversible airways obstruction. The consequent improved management in our chest clinic practice has benefited quite a large proportion of such patients judged by

their ability to return to work, go shopping, walk the dog, or perform ordinary household chores.

I have to agree with Dr Miller and colleagues that this paper can only obfuscate the issues.

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1 Whiting B, Kelman AW, Barclay J, Addis GJ. Modelling theophylline response in individual patients with chronic bronchitis. *Br J Clin Pharmacol* 1981;12:481-7.

SIR,—The paper by Dr W V Evans on the effects of theophylline in patients with chronic bronchitis (15 December, p 1649) illustrates some of the methodological problems which have clouded this important area of therapeutic practice.

Firstly, any patient who showed partial reversibility of airways obstruction with β_2 adrenoceptor agonists was excluded even though fulfilling the standard Medical Research Council criteria for chronic bronchitis. It might be concluded that such a group of patients is unlikely to respond to any form of bronchodilator therapy and it would have greatly enhanced interpretation of the results if an inhaled β_2 agonist treatment period had been included for comparison. Secondly, it is implicit in the conclusions that the effects of chronic treatment with a drug can be predicted from single dose responses in these patients: it would be clinically useful if this were so, but evidence points to the contrary.¹ Thirdly, it could be expected that measurements which require either patient effort or subjective assessment, such as walking time, respiratory function tests, and visual analogue scales, might be affected by adverse drug effects, and this illustrates the importance of studying patients who have previously been shown to tolerate the drug at therapeutic plasma concentrations. Although 19 of the 20 patients are described as having had long term oral theophylline prescribed, the theophylline concentrations achieved previously are not reported, and experience suggests that many patients are given subtherapeutic doses.²

The efficacy of bronchodilator therapy was recently assessed in the long term management of 25 patients with chronic bronchitis³ who showed at least 10% improvement in forced expiratory volume following inhalation of 2.5 mg salbutamol by nebuliser: patients with episodic attacks of wheeze not associated with chest infection or with a history of atopy and those with cardiac or hepatic dysfunction were excluded. Before entry into the study the dose of a sustained release theophylline preparation (Nuelin SA, Riker Laboratories) required to give a "trough" plasma theophylline concentration in the range 10-15 $\mu\text{g/ml}$ at steady state was determined in each patient. Seven patients continued to use inhaled beclomethasone throughout the study but no other additional therapy was permitted.

Each patient received four three week periods of treatment, during which they took two puffs from a metered dose inhaler four times daily and individualised tablets twice daily. The active treatments were salbutamol 200 μg (Ventolin, Allen and Hanbury) four times daily and sustained release theophylline (Nuelin) twice daily; the placebo inhalers and tablets were identical. In a randomised double blind crossover design each patient received theophylline tablets, salbutamol inhaler, theophylline tablets plus salbutamol inhaler, and placebo. Pulmonary function tests were carried out before and at the end of each treatment period, daily measurements of peak flow rate were obtained throughout the study, and daily symptoms of cough, wheeze, dyspnoea, and sputum production were recorded in a diary. If patients felt their treatment was not effective they had immediate access to a physician through a radiopaging service but were not permitted to use additional bronchodilator therapy. On clinical assessment if additional therapy was considered necessary because of non-infective