Letters

Economic benefit analysis of primary prevention with pravastatin

Modelling economic benefits after such long term treatment is inappropriate

EDITOR—The West of Scotland Coronary Prevention Study Group used an epidemiological model to estimate the cost effectiveness ratio for cholesterol lowering with pravastatin.[1] Although the title suggests otherwise, this is not a direct health economic analysis of original trial data, and why such an analysis has not been published is unclear. Original trial data would provide direct estimates of the number of life years of survival in treated and untreated groups, over the five years of the study. Similarly, a direct estimate of the drug costs would have been available; these would have been offset by an estimate of savings from the reduction in non-fatal adverse events.

A close approximation to this can be carried out by using published data. The all cause death rate in the treated group over five years in the trial was 3.2%, compared with 4.1% in the untreated group.[2] With a starting population of 10 000, this corresponds to a total number of life years remaining of 49 200 compared with 48 975—a saving of 225 life years. The net cost of treating this population for five years is estimated at £22 811 769,[1] or £101 386 per life year saved during treatment. This is similar to our estimate of the average cost effectiveness in a lower risk population of £136 000.[3]

The cost effectiveness ratio can be dramatically reduced by modelling survival after treatment has stopped. The treated group continues to benefit in terms of life years gained, but there are no additional costs of treatment. Given the large cost of treatment relative to the financial savings, the effect on the cost effectiveness ratio is considerable.

This approach has two major flaws. Firstly, treatment is unlikely to be stopped after five years in most patients. Secondly, survival after treatment is stopped is not known. The mechanism of action of statins is not completely understood, and a rebound increase in mortality after treatment is stopped is possible. It is also possible that those receiving treatment will adopt less healthy lifestyles and that, once treatment has stopped, survival will be poorer than among those never treated. Thus I believe it is inappropriate to model economic benefits after stopping long term treatment, and policy decisions should not be based on such models.

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1 Caro J, Klittich W, McGuire A, Ford I, Norrie J, Pettitt D, et al for the West of Scotland Coronary Prevention Study Group. The West of Scotland coronary prevention study: economic benefit analysis of primary prevention with pravastatin. *BMJ* 1997;315:1577-82. (13 December.)
2 Shepherd J, Cobbe SM, Ford I, Isles C, Lorimer AR, Macfarlane PW, et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. *N Engl J Med* 1995;333:1301-7.
3 Pharoah PDP, Hollingworth W. Cost-effectiveness of statins in lowering cholesterol in patients with and without pre-existing coronary heart disease: life table method applied to health authority population. *BMJ* 1996;312:1443-7.

Assumptions are methodologically flawed

EDITOR—Caro et al state that the West of Scotland coronary prevention study established that treating hypercholesterolaemia with pravastatin is an effective strategy for preventing coronary heart disease,[1] which is the leading cause of death in the United Kingdom.[2] Although the relative reductions in risk of death or of developing heart disease sound impressive, the absolute numbers are small.[3] Is treatment of these patients cost effective, as the economic model suggests?

The authors estimate from the trial data the monthly risks of developing heart disease and mortality over five years. They model survival beyond the trial as it is important to consider the "adverse implications of cardiovascular disease that do not result in death during the trial." Thus life expectancies for patients with and without heart disease are estimated from observational data. At the end of the trial, drug treatment is assumed to stop and population life expectancies, adjusted for coronary disease, are applied to survivors.

In 10 000 patients a 0.9% reduction in mortality observed in the trial would avoid 90 deaths during the five years of treatment (95% confidence interval −20 to 180). The cost of treating one patient with pravastatin for five years is about £2000 with a correction for savings from prevented coronary events. If it is assumed that deaths were equally distributed over the five years, which seems reasonable from the published mortality curve, this results in an average 2.5 life years gained per death prevented, or about 225 life years (95% confidence interval −50 to 450) at a cost per life year saved of £89 000 (95% confidence interval 45 500 to ∞) within the trial period. The economic model estimates a total benefit of 2460 life years gained.[2] Thus most of the benefit of intervention is based on extrapolation assumptions, not on the trial data.

The analysis presumes that pravastatin has a permanent preventive effect rather than merely delaying costs, but it assumes that treatment costs stop at five years. The assumption that patients with moderate hypercholesterolaemia who have avoided the development of heart disease through treatment with pravastatin have the life expectancy of the general population when treatment stops is clearly insupportable. Caro et al's estimate of just over £20 000 per life year saved is thus methodologically flawed and unduly optimistic.[2] Finally, they fail to address the issue of inappropriate medicalisation. The West of Scotland study indicates that, of 10 000 patients treated with pravastatin for five years, 9755 would receive no benefit.

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Advice to authors

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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, whether typed or sent by email, should give each author's current appointment and full address. Letters sent by email should give a telephone and fax number when possible. We encourage you to declare any conflict of interest. Please send 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.

Group. The West of Scotland coronary prevention study: economic benefit analysis of primary prevention with pravastatin. *BMJ* 1997;315:1577-82. (13 December.)
2 Shepherd J, Cobbe SM, Ford I, Isles CG, Lorimer AR, Macfarlane PW, et al. Prevention of coronary heart disease with pravastatin in men with hypercholesterolemia. *N Engl J Med* 1995;333:1301-7.
3 Freemantle N, Barbour R, Johnson R, Marchment M, Kennedy A. The use of statins: a case of misleading priorities? *BMJ* 1997;315:826-8.

Author's reply

EDITOR—These letters reflect two major mistakes. To reach their estimate of 225 life years gained, both sets of authors must make two extraordinary assumptions. The first is that the additional survivors die immediately at the end of the trial. Not knowing the survival after treatment is stopped is no excuse for this untenable assumption. A more realistic alternative is to assign each individual his age specific life expectancy. This is still conservative because the life table includes subjects with heart disease and other life threatening conditions, while trial patients were generally healthy men with hyperlipidaemia.

The second major mistake is to assume that preventing (or delaying) the onset of cardiovascular disease has no implications for life expectancy. Thus these authors would have us believe that the 286 additional men who remained healthy because they took pravastatin derived no benefit. Not only is this clinically unsupportable, but our extensive Scottish data confirm that this is not so: cardiovascular events that are not immediately fatal still reduce life expectancy.

The authors' insistence on relying solely on the trial data would be proper if one simply lists the costs and consequences observed during the trial (as we suggest should be done). If one insists on quantifying benefits only in terms of life years gained then one must, to remain unbiased, estimate the impact of events on life expectancy, not trial expectancy. This estimate does not involve projecting a continued treatment benefit or an assumption of "permanent preventive effect"; it is simply an attempt to understand the consequences of a transition from health to cardiovascular disease (regardless of treatment), a necessary step in valuing the results of the trial. Contrary to Pharoah's assertion, a trial lasting five years cannot provide complete data on the impact on survival of preventing a chronic disease that runs its course over a decade or more.

We agree that treatment is unlikely to stop after five years. We are now estimating the effect of continuing treatment. This does involve projections of treatment benefit, and so we thought that it should be reserved for a secondary analysis.

As with any preventive intervention (for example, cancer screening), only some people will benefit. Nevertheless, until we can more precisely identify these individuals this trade off is unavoidable. Whether this is "inappropriate medicalisation" or not is best left to individual patients and their doctors.

The authors' estimates of what are essentially "trial years gained" are not useful. If proper healthcare decisions are to be made they must be based on balanced appraisal of the available evidence rather than concerted efforts to accommodate data to one's preconceived point of view.

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Day case surgery has benefited patients with cataract in North Gwent

EDITOR—According to Boulton, day case cataract surgery is not being done as often as it could be in Scotland.[1] In North Gwent such operations have been available for two years. Our local general hospital has no ophthalmic beds; it has only outpatient and day case facilities and an innovative consultant who does no private practice. We used to have the usual long waits for cataract surgery. Day case surgery was the obvious answer, so funds for the necessary equipment were raised by local people and local fundholders. Fundholders bought the service first, and now commissioning groups and total purchasing projects are buying it.

Patients love the service. Contraindications are few: the frailest patients benefit the most because they do not have the disruption of a hospital stay. Social services and our community nurses have been helpful. Assessment is done by optometrists and consultants and the patients' own general practitioner. General practitioners hold the waiting lists.

I am sure that the reasons why this went ahead were that the consultant concerned is motivated to do the best for his NHS patients and that the trust, having no ophthalmic beds, could expand its services and make money. Consultants with a financial interest in private patients often do not push for a better service, and trusts with an investment in inpatient capacity would say that they would lose income, even though in the real world these beds and staffing costs could be transferred to other specialties. One trust with ophthalmology beds has even written a memo to staff asking them to discourage day cases and to promote inpatient care.

In this matter, patients' and taxpayers' interests are best served by the devolution of day cases to smaller local units under the influence of strong general practitioner commissioning groups. This is better than trusts trying to capture patients from each other and still tending to serve certain vested interests under a flawed internal market system.

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1 Boulton A. Scottish trusts miss cataract surgery targets. *BMJ* 1997;315:1330. (22 November.)

Article about mental health law gave practical guidance

EDITOR—Leigh's comments[1] on Barker's article[2] would be less offensive if they were helpful. While his narrow reading of the Mental Health Act (1983) is correct, he does not seem to be aware that practitioners are required to pay attention to the more stringent conditions set out in the code of practice to the act.[3 4]

Paragraph 2.25 of the code of practice states explicitly: "Other than in exceptional circumstances, the second medical recommendation should be provided by a doctor with previous acquaintance of the patient."[3] With regard to who should make an application for admission, paragraph 2.30 states: "The approved social worker is usually the right applicant .... The doctor should therefore advise the nearest relative that it is preferable for an approved social worker ... to make the application." Since this is exactly the guidance that Barker gives it is hard to see how Leigh can justify calling the article "muddled," "wrong," and "a travesty of the act."

Although Leigh is correct in that the treatability criterion does not apply to section 2 of the act, his point could have been made simply and without vituperation.

Finally, Leigh does not understand that this ABC article aimed to provide succinct, practical guidance to practitioners, and not "to emphasise some of the idiosyncrasies involved [in the Mental Health Act]." That would be the material for a very different—and very long—article.

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1 Leigh TH. Article about Mental Health Act was misleading. *BMJ* 1998;316:781. (7 March.)
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Risk language and dialects

Expressing risk in relative rather than absolute terms is important

EDITOR—Calman and Royston remind health professionals of their obligation to communicate risk in a language and dialect with which individuals or groups are comfortable.[1] It is not only in clinical medicine that appropriate communication of risk is essential. The environmental health literature is littered with examples of failed dialogue.

Communities often create risk dichotomies, demanding absolute safety and being unable to perceive any grey areas between safe and dangerous. On occasion this may be correct—for example, should we evacuate or not? Environmental standards tend to dichotomise. If the standard is 15 ppb,

people may deduce that 14 ppb is safe and 16 ppb dangerous. Expressing risk in relative rather than absolute terms, as shown by Calman and Royston, avoids making an environmental standard into a watershed figure with all results above the standard perceived as dangerous and everything below the standard as safe. Risk numbers should be expressed in ranges, such as 1-9 ppb as low risk, 10-19 as moderate risk, etc.

Several elements of risk can be used to describe risk to communities. Among these are concentrations (for example, g/l); exposures (how much is likely to be inhaled?); probabilities (how likely is it to happen?); quantities (how much effluent was released?); and risk levels (expected deaths per year). All of these outline different aspects of risk, but practitioners often confuse elements when attempting to put risks into context. Saying that a risk is like a drop in a swimming pool may be misleading: a small concentration of a hazardous chemical could be associated with a substantial risk. It also may not answer the question the public is asking. Questions about risk require answers about risk. Calman and Royston's model is a useful contribution to the task.

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1 Calman KC, Royston GHD. Risk language and dialects. *BMJ* 1997;315:939-42. (11 October.)

Lottery can be used to show risk

EDITOR—We were interested to read the paper by Calman and Royston about the language of risk.[1] Expression of the wide range of risks encountered in clinical practice requires a logarithmic scale similar to the pH scale.[2] In our experience, however, such scales are correctly understood by only a small proportion of the population and are therefore of limited value in communicating degree of risk to patients.

There is, however, a near-logarithmic scale of risk that is used by most of the population every week to calculate their chance of radically enhancing their monetary status.[3] We refer to the chance of winning a prize in the twice weekly National Lottery. The "risk" of winning a prize varies according to the number of balls matched and increases in accordance with a factorial scale. The table shows the probability of matching a number of balls for a £5 stake.[4] The degree of risk could therefore be referred to by the number of balls that it corresponds to: a 6-ball risk would be negligible (<1 in 10^6) whereas a 3-ball risk would be more common (1 in 10 to 1 in 100). This would correspond to the personal experience of patients, who are likely to have won the occasional £10 (the 3-ball prize) and know people who have won 4-ball prizes but who only dream of winning the jackpot.

This concept would be useful in discussing the occurrence of very rare events whose probability is less than one in a million but, like winning the lottery jackpot, still occur to someone. It also allows discussion of the concept of risk doubling: this can be compared with doubling the stake to £10/week, which would increase the chance of winning a £10 prize for 3 balls to around once a month but would increase the chance of winning the jackpot to only once every 26 891 years.

Patients are increasingly demanding that doctors explain the risks to which they are being exposed. This scale of beneficial events would facilitate communication of the probability of an adverse event occurring.

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1 Calman K, Royston G. Risk language and dialects. *BMJ* 1997;315:939-42. (11 October.)
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Risk scales should be tested by non-medical agencies, such as the media

EDITOR—The relevant risk of using contraception is an important factor when one is advising a couple on the choices available to prevent an unwanted pregnancy. For those professionals who deal with family planning this was particularly relevant after the Committee on Safety of Medicines released a statement about the risk of thromboembolism associated with combined oral contraception in 1995.[1] In a family planning consultation the woman is usually fit and wishes to use a method of contraception with minimal side effects. The reaction to the "pill alert" showed that not only did women obtain their first information from the media but the medical profession did as well.[2]

After reading Calman and Royston's article about risk it seemed to me, as a professional, that presenting the risk on a visual scale was ideal.[3] This is fine in a one to one consultation. But how do the media report events? A single event, although rare, will be reported in the headlines of a newspaper with no presentation of relevant risk. Most people reading such a headline will associate it with risks on the community risk scale. The risk of an event in someone using oral contraception would be equivalent to that of an event occurring once in a large town. Unfortunately, everyone in that town will know about it because of local and maybe national headline news. More common events, such as numbers of heart attacks from smoking, are not newsworthy.

Research at the Marie Stopes Centre shows that women are confused about the risk of oral contraception. When choosing a method they balance risks with the risk of pregnancy. The morbidity of pregnancy is no longer seen as a risk in Britain, in contrast to countries where maternal morbidity is high.[4] Users of contraception will be influenced by information from their partner, mother, friends, and women's magazines. Research shows that information about contraception comes mainly from sources other than the medical profession.[5]

The authors comment that most people would judge an event with a risk magnitude of 4 on a risk scale of 1-10 to be minimal or even negligible. No matter how good the explanation of risk in a consultation, the many other influences outside the surgery or clinic will always have a role in the woman's understanding of the risk. The authors propose that the risk scales need to be tested. Maybe this should be done initially with agencies that provide information outside the medical profession so that when important information has to be transmitted it is consistent and accurate.

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Probability of matching number of balls for £5 stake, compared with verbal and logarithmic scales of probability

No of balls	Probability	Verbal scale	Logarithmic risk scale
3	1:11	High	9
4	1:206	Moderate	8
4 + bonus	1:8878	Low	7
5	1:11 098	Very low	6
5 + bonus	1:466 127	Minimal	4-5
6	1:2 796 763	Negligible	< 4

Fate of special hospitals in England has not yet been decided

EDITOR—The News in brief in the issue of 28 March contained a paragraph entitled "Closure plans for secure hospitals."[1] This was part of a selectively quoted strategic plan produced by the High Security Psychiatric Services Commissioning Board. The plan was leaked, as it is officially with the minister of health at present.

As I understand it, the document contains several options; the closure of the three hospitals and building of six to eight replacement units is only one. This option has many complications, not the least being the cost and the availability of land and accommodation.

In recent years Broadmoor Hospital has developed rapidly, with standards of psychiatric practice equivalent to those anywhere in the NHS and a professorial department of international repute linked to the Institute of Psychiatry in London. This academic presence makes recruitment and retention of high quality medical staff easier than it otherwise might be, given the shortages of such staff in forensic psychiatry nationally. Staff shortages are, however, always a danger in this particular area of forensic psychiatry, and such selective leakage of information can be a self fulfilling prophecy. In the circumstances, I must make it clear that all the indications are that Broadmoor Hospital will not be closing, nor will Ashworth or Rampton Hospital. The feeling is that the service will become more regionally based and those patients who no longer need high-secure care will move out to medium-secure and low-secure facilities.

In a press release Mr Frank Dobson, the secretary of state for health, said: "A review of Broadmoor, Ashworth and Rampton Hospitals has been received. The government has no intention of simply accepting its findings. Public safety and security will come first. The review was commissioned by the previous government. Ministers consider that they are in no way bound by it. They are taking a long hard look at the whole of mental health."

This emphasises the need to have a much broader view with much greater depth and analysis than the throwaway comment in the *BMJ*. That paragraph does not represent government policy or support the work being undertaken at the high-secure hospitals.

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1 News in brief: Closure plans for secure hospitals. *BMJ* 1998;316:956. (28 March.)

Sexual abuse is not the only childhood adversity that may lead to later depression

Editor—Cheasty et al have provided further support for the association between childhood sexual abuse and adult depression.[1] This adds to the growing body of research that describes the effects of childhood maltreatment on the development of adult psychopathology and further highlights the need for interventional psychiatry.[2]

Sexual abuse is often considered to be the most severe and traumatic form of maltreatment. While the authors indicate the importance of the severity of the experience (for example, penetration), other important factors in the development of early and late psychopathology include the age at which abuse is experienced and its duration.[3] The use of broad labels such as "sexually abused" to categorise subjects may simplify research by defining control comparisons but obscures the heterogeneity and co-occurrence of other forms of adversity.[4] Important adversities that often accompany maltreatment include physical and emotional abuse, neglect, divorce, poverty, and placement in care.[4] It is not only difficult to disentangle the impact of these co-occurring risk factors from those associated with sexual abuse, but it is uncertain to what extent their effects are additive.

Future research on the effects of childhood adversity such as sexual abuse on mental illness requires standardised definitions and examination of the risk factors in isolation and in conjunction with other stressors to determine the effects of co-occurring risk factors.[2] This may help in the identification of the pathways that lead from childhood sexual abuse not only to depression but also to the numerous other disorders associated with it, such as somatisation disorders, substance abuse, personality disorder, eating disorders, and post-traumatic stress disorder.[5]

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1 Cheasty M, Claire AW, Collins C. Relation between sexual abuse in childhood and adult depression: case-control study. *BMJ* 1998;316:198-201. (17 January.)
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Training in plastic surgery is being set up in The Gambia

Editor—With the demise of the overseas training scheme in plastic surgery[1] and the implications of Calmanisation for training in general for visiting surgeons,[2] alternative strategies for meeting the training requirements of surgeons from the developing world need to be considered. Training in the developing world may be the way forward.[3] Although considerable difficulties in terms of logistics, personnel, and working conditions can be expected, such schemes are feasible and can be tailored to local requirements.

A pilot scheme involving The Gambia and plastic surgeons from the United Kingdom is being developed and may form the basis for a more structured training programme for west Africa (I F Starley et al, summer meeting of British Association of Plastic Surgeons, 4 July 1997). There are several advantages to developing a training programme for surgeons in The Gambia. The country is easily accessible and has good telecommunications links. Politically it is stable and is keen to develop such a scheme. The medical infrastructure is based at the Royal Victoria Hospital, Banjul, and, though limited, has the potential for development. Key medical and nursing staff have been identified with a view to developing such a training scheme.

The potential advantage of such a scheme is not limited to The Gambia. In view of the country's geographic location in west Africa, it can provide a basis for a more comprehensive training programme for all surgeons and nurses in the region.

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1 Wise J. Surgical training for overseas doctors to end. *BMJ* 1997;315:971. (18 October.)
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Management of *Helicobacter pylori* infection

Eradication treatment should be limited to patients with proved peptic ulceration

Editor—Benefits from treating *Helicobacter pylori* infection may depend less on the choice of eradication regimen than on the selection of patients to be treated. Rauws and van der Hulst make sound recommendations for the former at the expense of misleading on the latter.[1] Their advice to general practitioners to test and prescribe eradication treatment in dyspeptic patients aged under 45 reflects that of the European Helicobacter Study Group[2]; neither set of recommendations is evidence based.

Both sets of recommendations advocate the safety net of specialist referral when eradication has failed in primary care. This ignores the reality that fewer than one quarter of dyspeptic patients with *H pylori* infection have peptic ulcer disease and that only this group of patients can be confidently expected to benefit from eradication treatment.[3] Treating all dyspeptic patients infected with *H pylori* would therefore result in most of those with non-ulcer dyspepsia or gastro-oesophageal reflux disease receiving an unproved treatment. Even if a sizeable placebo effect is assumed, symptoms may recur or persist in many of these patients. They may also recur or persist in a minority of those with peptic ulcer disease who have not initially responded to eradication treatment either because of antibiotic resistance or because of poor concordance with treatment. The combination of a high prevalence of dyspeptic patients who also happen to be positive for *H pylori*, a high frequency of failure of treatment, and a blanket recommendation that all patients in

whom treatment has failed should be referred for specialist opinion could result in gastroenterology services being overwhelmed.

Furthermore, knowledge of the potential causal association between *H pylori* infection and gastric cancer may have an impact on both doctors' and patients' behaviour.[4] Widespread testing for *H pylori* and subsequent labelling of patients with positive results could result in a high proportion of the population requiring or demanding medical follow up. Until evidence is forthcoming from trials, general practitioners may wish to avoid such dilemmas by limiting eradication treatment to patients with proved peptic ulceration.

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1 Rauws EAJ, van der Hulst RWM. The management of H pylori infection. *BMJ* 1998;316:162-3. (17 January.)
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Authors' reply

EDITOR—We agree that there is no evidence based reason to treat all dyspeptic patients who are positive for *H pylori* with antimicrobial drugs.[1] Most of these patients have no peptic ulceration or organic disease other than gastritis. Therefore, endoscopy is usually not indicated in young dyspeptic patients, who are managed empirically by the primary care doctor with one or repeated (healing) courses of acid suppressants, followed by either daily maintenance treatment or treatment on demand when symptoms recur. The drawbacks of this approach, which is not evidence based, are the high cost of empirical treatment and the inappropriate management of peptic ulcer disease.

Since peptic ulcer disease is related to *H pylori* infection in about 98% of cases, testing for the organism will identify patients with an ulcer and those at risk. Certainly, a considerable number of patients who are positive for the organism will never develop an ulcer but may still benefit from successful eradication treatment.[1]

The Maastricht consensus meeting of the European Helicobacter Study Group was organised to aid daily clinical practice. Although evidence based data are lacking, both gastroenterologists and primary care doctors formulated guidelines for the diagnostic and therapeutic approach for dyspeptic patients aged under 45 who did not have serious symptoms. In these younger patients who are positive for *H pylori* on testing, it was considered "advisable" that the organism should be eradicated without further investigation. We do not recommend widespread testing for *H pylori* in relation to the organism's potential causative role in gastric cancer.

As an estimated two fifths of patients presenting with dyspepsia each year are aged under 45,[2] the Maastricht guidelines may lead to economic savings,[3] a reduction in the endoscopic workload,[4] and cure and may also prevent diseases related to *H pylori*.[5]

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1 Talley NJ, Hunt RH. What role does Helicobacter pylori play in dyspepsia and non-ulcer dyspepsia? Arguments for and against H pylori being associated with dyspeptic symptoms. *Gastroenterology* 1997;113:S67-77.
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Patients with implants should be given implant cards

Intraocular lens implant cards contain inadequate clinical data

EDITOR—Purkayastha emphasises the potential of implant cards for patients who have had implants.[1] Such schemes will be clinically useful only if the cards contain adequate information about the implant.

A future clinician may need to know about a patient's implant in order to site a matching one on the contralateral side or to manage the complications of poor fit or biocompatibility. In the case of intraocular lens implants, information is needed about the design and size of the lens, materials and coatings used, dioptric power and "A" constant, and manufacturer's address or telephone number. Intraocular lens packs already include an implant card for the patient. We looked at lens implants made by four manufacturers and found that none of the implant cards contained all of the necessary data (table). Information stickers, intended for insertion in the case notes, were similarly lacking in clinically important detail. While all cards and stickers included the manufacturer's name and model number, most did not state the design, implant materials, or "A" constant. This lack of basic information frequently leads to unnecessary problems when attempts are made to match an unfamiliar implant for cataract surgery to the second eye.

We can foresee only one disadvantage of having full information on implant cards for patients. If late problems are identified with a particular type of implant, publicity could result in unnecessary anxiety among patients who are having no problems and more claims for compensation from those who are having problems. The potential of the system is not being realised, and we urge manufacturers to include all relevant information on both information stickers and implant cards.

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1 Purkayastha S. Patients with implants should be given implant cards for reference. *BMJ* 1997;315:1377. (22 November.)

Information given on patient implant cards and stickers for case notes

	Implant (manufacturer)			
Information	**Cilco MZ20BD (Alcon)**	**AMO Phacoflex II SI30NB (Allergan)**	**C11UB (Chiron)**	**7BUV 20–24/401G4 (Surgidev)**
Implant cards:				
Size	+	+	–	+
Shape	+	–	–	–
Materials	–	–	–	–
Coatings	+	–	–	–
Dioptric power	+	+	+	+
"A" constant	–	–	–	–
Postal address	+	+	+	+
Telephone No	–	+	–	+*
Stickers for case notes:				
Size	+	+	+†	+
Shape	+	–	+	–
Materials	–	–	–	–
Coatings	+	–	–	–
Dioptric power	+	+	+	+
"A" constant	–	–	+†	–
Postal address	–	–	–	–
Telephone No	–	–	–	+*

*Toll free telephone number, available only to callers in North America.
†Two types of stickers provided, one giving size but not "A" constant and other giving "A" constant but not size.

Such cards would facilitate recall

EDITOR—I agree with Purkayastha that patients should have implant cards,[1] but for a slightly different reason—early failure of an implant. At present there are few hip implants that have proved long term results in various age groups,[2 3] and some newer implants seem to fail early.[4] In addition, many studies have poor follow up, and it is becoming accepted that loss to follow up matters.[5]

The idea of having implant cards is attractive but, given that a patient may have several implants or implants in various combinations (for example, hybrid), then to carry a card for each component may be cumbersome. Alternatives would be to have a data card (incorporating silicon chip technology) that can be updated by "swiping" each time a component is implanted or to have an identification chip implant in a subcutaneous site, which could be scanned and information recalled from an implant register. Such a database could then be used to facilitate adequate follow up and allow early notification of people with implants that might fail, either because of design faults or because of batch failures.

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General practice must decide on its own education system

EDITOR—The new NHS (Vocational Training for General Medical Practice) Regulations 1997 came into force on 30 January. Their main purpose is to render summative assessment mandatory and to strengthen the role of the Joint Committee on Postgraduate Training for General Practitioners in setting standards and in monitoring vocational training. Although this will remove the ambiguity that surrounded summative assessment, it has taken over three years to bring about the necessary regulatory change—a delay that has caused much confusion and uncertainty in the profession, particularly among many general practice registrars and trainees.[1]

It is now clear that no serious change in the structure of general practice training can be contemplated without the full agreement of the profession and the necessary change in regulations. Also, there will have to be more sensitivity to the views of the general practice registrars and trainees and of those responsible for implementing the joint committee's policies in the future.[2] Perhaps the most significant lesson is, however, that the regulations have become an obstacle to progress. This is particularly important in the context of a changing primary care led NHS, in which training for general practice will continue to require regular review and change.[3]

Regulations for vocational training have served us well in the past, but it is now time to move on by revoking all of these and allowing general practice, like any other medical discipline, to decide for itself, through its college, what system of education it should have.

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Regulation of body weight is social skill

EDITOR—Wilding's clinical review on obesity treatment repeats an important error: "Body weight is very tightly regulated … for example a daily excess of 100 kcal (418 MJ) … would result in a 4 kg weight gain in a year."[1] It would not, as those of us who have tried experimental overfeeding can testify.[2 3]

An extra 418 MJ intake causes an immediate increase in metabolic rate, and in the steady state a weight gain of 4 kg would cause an increase in maintenance energy requirements of about 209 MJ/day in women and 212 MJ/day in men,[4] so only a fraction of the excess intake would be stored as excess fat. The error is important, because Wilding suggests that controlling obesity involves finding a specific group of people with poor regulation of intake and correcting their metabolic error. In fact, most of us have poor physiological regulation of energy intake, which is why body weight in adults typically fluctuates between maxima and minima that are 10 kg apart.[5] In our society, regulation of body weight within a desirable range is a social skill, so I believe that the best hope for preventing and treating obesity depends on fostering these skills rather than discovering new hypothalamic neurotransmitter drugs.

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Mouth care and skin care in palliative medicine

Chlorhexidine mouth washes are important in mouth care

EDITOR—Regnard et al did not mention the use of 2% chlorhexidine mouth rinses in the section on mouth care and the risk factors for oral problems in their article in the ABC of Palliative Care.[1] We have regular contact with groups of children with chronic disorders— for example, epidermolysis bullosa—and others who are treated with high dose chemotherapy and irradiation. One of the problems from which they suffer is severely blistered oral mucosa (children with epidermolysis bullosa) and mucositis related to chemotherapy or radiation.

The most widely investigated and used mouth care regimen is 2% chlorhexidine mouth rinse daily. Many workers have reported decreases in dental bacterial plaque and gingivitis.[2 3] This leads to decreased oral bacterial loading, which is important, particularly in patients who are undergoing a period of immunosuppression as part of their treatment.[4] Chlorhexidine does not greatly affect the progress of mucositis, and although the 7% ethanol base does cause a burning sensation, the antibacterial and local cleaning action are of great benefit to these patients. Although tooth brushing is the ideal oral hygiene method, most patients who are debilitated are unable to do this effectively and the mouth is not cleaned effectively. Mouth rinsing may also be difficult, and this difficulty can be easily overcome by soaking pink dressing sponges in chlorhexidine. When the teeth are closed on the sponges, the chlorhexidine is carried to the oral mucosa, gingivae, and teeth.

We believe that this logical approach to mouth care is more effective than the anecdotal remedies suggested by Regnard et al. Was the recommendation to use gin a misprint?

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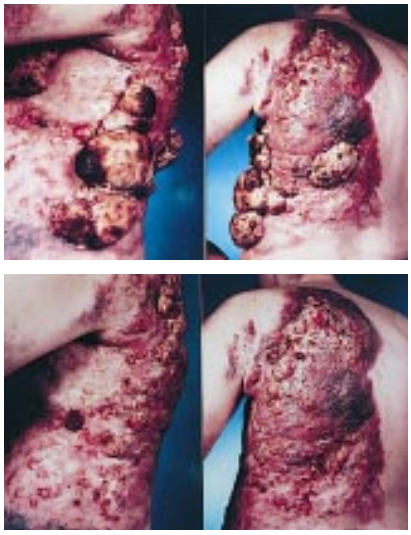
Surgical debridement of dead tissue may be important in skin care

EDITOR—We were surprised that Regnard et al did not mention the role of surgical debridement of dead tissue in the treatment of pressure sores and fungating chest wall



Patient with multiple recurrent breast cancer masses on chest wall anterior and posterior before (top) and after (bottom) surgical excision. After surgery, residual disease was easier to dress and was less troublesome, and patient was able to sleep more comfortably

tumours in their article in the ABC of Palliative Medicine.[1] The reason that patients get malodour from pressure sores and ulcerating or fungating tumours is the presence of dead tissue which subsequently becomes infected. Removal of dead material surgically can not only dramatically improve the smell but will reduce the amount of discharge, which means that dressings are less likely to leak and therefore need to be changed less frequently. Surgery also has a role in patients with large and often multiple tumour masses growing out through the chest wall as these can be difficult to dress and can be extremely uncomfortable for the patient. Excision of these masses makes it easier for both the patient and the carers to manage what can be a difficult problem (figure).

As was pointed out in the ABC of Breast Diseases, the management of patients with M stage cancer should be multidisciplinary, and the role of the surgeon, although small, should not be forgotten.[1 2]

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1 Regnard C, Allport S, Stephenson L. ABC of palliative care: Mouth care, skin care, and lymphoedema. *BMJ* 1997,315:1002-5. (18 October.)
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Simple antiseptic mouthwashes are best for infection

Editor—Regnard et al's article on mouth care in palliative care patients requires some comment.[1]

Aphthous ulcers are not thought to be of infective origin, although they may become secondarily infected with oral commensal bacteria.[2] Discussion of their management under the subheading of infection creates confusion in the table on local measures for oral problems. Although the corticosteroid and tetracycline mouthwashes advocated for treating infected mouth are appropriate for aphthous ulceration, their inappropriate use in infected mouths is far more likely to exacerbate rather than improve the situation. Both mouthwashes are predisposing factors to oral candidal infection,[3] a problem recognised elsewhere in the article as a concern in palliative care patients. A simple antiseptic mouthwash such as chlorhexidine would be more appropriate in most cases of superficial mucosal infection.

In their discussion on the management of dry mouth the authors identify several saliva substitutes, some of an acidic nature such as fruit juice. Although these may be an option for some patients, caution is required as they will rapidly precipitate dental caries if used in a dry mouth for any length of time. Another aspect of management which was not mentioned is the stimulation of residual salivary function. Patients often prefer salivary stimulation to substitution.[4] Several chemical and mechanical salivary stimulants are available, of which sugar free chewing gum is effective and widely available.[4] As a final point, we suggest that candidiasis is far more often a complication of a dry mouth than its cause.[5]

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Clinically proved treatments for xerostomia were ignored

Editor—Regnard et al's suggestions for improving xerostomia are based almost entirely on anecdotal evidence.[1] Furthermore, these suggestions ignore the evidence from numerous clinical trials.

The symptoms of xerostomia are managed with both saliva substitutes and saliva stimulants. In studies that have compared saliva substitutes and stimulants patients have generally preferred the saliva stimulants.[2] The choice of saliva stimulant depends on several factors including the aetiology of xerostomia, the patient's general condition and prognosis, the presence of teeth, and, most importantly, the patient's preference. Examples of saliva stimulants that have been found effective in clinical trials include mints, chewing gum, malic acid, and pilocarpine.[3]

Saliva has several functions, and hyposalivation may result in poor oral hygiene, oral discomfort, and oral infections. Pineapple is a natural saliva stimulant. Its effect on oral hygiene is probably related more to a non-specific increase in salivary flow than to a specific effect of the enzyme ananase. Indeed, other saliva stimulants have a similar effect on "dirty mouths" and "coated tongues." It should be noted that oral candidiasis is a complication of hyposalivation and not, as stated in the article, a cause of hyposalivation.[4]

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Possible association between low birth weight and later heart disease needs to be investigated further

Editor—Barker and Osmond say that the association between birth weight and adult disease relates to growth retardation in early life.[1] Alternatively, babies with a low birth weight might consume a diet that is associated with greater risk of disease.[2 3] Firstly, low birth weight might affect appetite and preference for certain foods. Secondly, parents might feed their babies foods with a higher energy or fat content in order to compensate for their low birth weight. Patterns of nutrient intake may be established from 3 years of age,[4] so if birth weight were associated with childhood diet the cumulative effect through a lifetime might be considerable.

We used data from the national diet and nutrition survey,[5] a representative sample of children aged 1½ to 4½ years in Great Britain, and tested the hypothesis that energy and fat intake varied by birth weight. A total of 1664 subjects (89.5% survey respondents) had complete data on diet (measured using a four day weighed intake record including both weekend days), birth weight (obtained by maternal recall), social class, and current weight. Males had higher birth weight (mean (SE) 3405 (18.9) g *v* 3279 (18.0) g), energy intake (4895 (38) kJ *v* 4631 (38) kJ), and fat intake (1757 (19) kJ *v* 1678 (19) kJ). There were no differences in percentage energy from fat (35.7 (0.2)% *v* 36.1 (0.2)%).

Among males only, fat intake adjusted for energy intake increased with decreasing birth weight, after adjustment for age, social class, and current weight (table). Mean fat intake in the lowest fifth of birth weight was 5%, or 2.3 g, higher than that in the highest fifth. We could not confirm a further hypothesis that fat intake would be higher

Mean (95% confidence interval) daily energy and fat intake by fifth of birth weight adjusted for age, social class, and current weight

	Males (n=805)			Females (n=778)		
Fifth of birth weight	Range of birth weight (g)	Mean difference in daily energy intake from baseline (kJ)	Mean difference in daily fat intake from baseline (kJ)	Range of birth weight (g)	Mean difference in daily energy intake from baseline (kJ)	Mean difference in daily fat intake from baseline (kJ)
5	>3860	0.0	0.0	>3700	0.0	0.0
4	3550-3860	245 (28 to 462)*	41.4 (–15.0 to 97.8)	3450-3700	27 (–201 to 255)	30.1 (–26.3 to 86.5)
3	3300-3549	151 (–66 to 368)	45.1 (–11.3 to 101.6)	3200-3449	105 (–121 to 331)	–3.8 (–56.4 to 52.7)
2	2980-3299	162 (–59 to 383)	75.2 (18.8 to 131.7)†	2900-3199	20 (–215 to 256)	–11.3 (–71.5 to 45.1)
1	<2980	128 (–98 to 354)	86.5 (30.1 to 146.7)‡	<2900	–103 (–337 to 132)	0.0 (–56.4 to 56.4)

*P=0.03, †P=0.009, ‡P=0.004.

for subjects of low birth weight who remained small and had a continuing incentive for parents to feed them more or a sustained alteration of appetite than it would be for those who experienced catch up growth.

Evidence that the relation between birth weight and cardiovascular disease later in life could be mediated, at least in part, by the influence of birth weight on subsequent diet was confined to males. Whether this small difference, were it to be sustained, could have a significant cumulative effect on risk of cardiovascular disease is not clear. Our study, however, was limited to the preschool years. The association at 1½–4½ years may be the tail end of a stronger relation in infancy, or, alternatively, differences in fat intake by birth weight may remain, or even be amplified, in later life. It may be of interest to investigate this relation at other ages.

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The national diet and nutrition survey of children aged 1½–4½ years was funded jointly by the Department of Health and the Ministry of Agriculture, Fisheries and Food, and was conducted by the Office for National Statistics and the Medical Research Council, Dunn Nutrition Unit.

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BMA must voice its opposition to Cuban embargo

EDITOR—In 1992 we participated in a study tour of Cuba's health system. We witnessed a service that was the pride of the developing world and that, in the way it was organised, offered many examples for our own service. During our stay the then American president, George Bush, signed the Cuban Democracy Act. At a stroke Cuba was denied access to foodstuffs and medicines produced by any subsidiary of any American multinational company anywhere in the world (direct sales of anything from the United States to Cuba having been barred since 1961).

The impact on the health and nutrition of the Cuban people has now been well documented.[1-3] The report of the American Association for World Health states: "A humanitarian catastrophe has been averted only because the Cuban government has maintained a high level of budgetary support for a health care system designed to deliver primary and preventative health care to all its citizens."[3]

We welcome the fact that a *BMJ* editorial[4] has joined the *Lancet*,[5] the Pope, and 143 countries in the United Nations General Assembly in criticising or condemning what has become the most severe and sustained economic blockade ever imposed on a country in peacetime. One of us belongs to the union UNISON, which has a record of voicing its opposition to that blockade in both national and international forums. The other, as a BMA member, looks forward to the day when the BMA is prepared to do the same.

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Punishment of doctors must fit their crime

EDITOR—All readers, parents of children with congenital heart disease, and paediatric cardiologists will sympathise with the parents of Deborah Jenkins, who had severe complex congenital heart disease and died at the age of 6 after an exploratory operation by Dr James Taylor, a paediatric cardiologist at the Hospital for Sick Children, Great Ormond Street, London. Deborah's parents had consented to cardiac catheterisation but had expressly said that a balloon catheter should not be used.[1 2] Thus if Dr Taylor used a balloon catheter against their consent he broke the law. No one, especially medical practitioners, is above the law, and therefore he had to be punished and was suspended from the medical register for six months.

The waters of comprehension and compassion have been muddied by the genuine and understandable anger of the public at the "rotten apples" in the profession of medicine: those who assault and sexually interfere with their patients. The public is also understandably disillusioned when it believes that such "rotten apples" have been let off with a mere caution because doctors have closed ranks to protect their own.

The medical profession has been given the opportunity to regulate itself. As Sir Donald Irvine, the president of the General Medical Council, has pointed out, however, self regulation is a privilege, not a right.[3] But the case of Deborah Jenkins and Dr Taylor has nothing to do with rotten apples. Most medical practitioners do their best to help their patients, to advise them, to treat their symptoms, and to guide them to better health. Although disaster may strike, it is always in the framework of the doctor attempting to do the best for the patient. The intention is essentially benign, not malign; if a child loses his or her life it is by accident, not design.

If Dr Taylor did break the law he must be punished in some way, but that way should be reasonable and appropriate. By contrast, his punishment has been inappropriate, excessive, and vicious. Dr Taylor is a fine, caring, highly skilled, and greatly experienced paediatric cardiologist who has always carefully considered all the interventional options open to him in every patient. We admire him, and he is respected by generations of paediatricians. The severe castigation that he has received has irrevocably impaired his fine reputation.

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