

Performance indicators for primary care groups

Current indicators have been chosen for ease of collection rather than scientific validity

EDITOR—McColl et al provide a welcome alternative¹ to performance indicators proposed by the NHS Executive and the Department of Health.² They have suggested a range of evidence based interventions which are likely to produce behaviour change at practice level. The proposed indicators are very different from the performance indicators in current use, which seem to have a political role at health authority level, often being used simply to search for poorly performing doctors.

I have looked at the performance indicators that have been described in the literature, and in particular the scientific evidence underpinning them. Little evidence exists for the validity of using the common indicators in current use.³ A consistent finding is that indicators are often chosen for their ease of collection rather than their scientific validity. The most commonly used indicators include uptake of cervical cytology, immunisation rates, and various prescribing indicators. I have found little published research showing the importance of a high or low indicator. This applies particularly when the indicators have been accepted as proxy measures of individual general practitioners' clinical competence. Others have also reviewed performance indicators and have identified additional areas that raise doubts about their validity.^{4,5}

The new indicators will need to be differentiated from the non-clinical indicators that are currently popular markers of clinical competence. In practice these often reflect historic support that has been provided for the practice rather than the competence of the individual general practitioner. Thus the proposed introduction of evidence based clinical indicators for primary care groups provides a more acceptable way forward.

Although McColl et al's paper refers to cost effectiveness of proposed interventions, the likely timescale over which they will operate requires consideration, as it has an important implication for the primary care groups at which they are targeted. Although secondary and tertiary prevention may reduce morbidity and mortality over decades, the short term effects of the implementation of interventions will create upward pressure on costs, particularly prescribing

costs. This issue should not present obstacles to the promotion of evidence based interventions at the level of primary care groups but must be taken into account when these groups and health authorities are funding health improvement plans.

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Will they discriminate against small general practices?

EDITOR—We believe that the debate over performance monitoring in primary care groups and general practices¹ has overlooked a combination of factors that may already be giving rise to a discriminatory effect against small general practices. An improvement to a system in which quarterly figures are used in isolation would be a rolling average of the current quarter plus the three preceding quarters.

Indicators such as infant immunisation rates are measured by proportional coverage of a target group. For any practice, aggregating quarterly infant vaccination figures over several years would measure the long term coverage of that practice. Quarterly coverage would vary about this figure; the higher variability in smaller practices is explained by binomial variation, where the standard deviation of a proportion p is given by $(p(1-p)/n)$ —the variability of p increases as n decreases.

Practices slightly above target in the long term would probably fall below in some quarters, while those slightly below target in the long term would occasionally rise above. Preschool immunisation figures are above 90% in England and Wales,² so it would follow that most practices are above target in the long term. Hence the number of practices losing out because of quarterly variations will be greater than the number gaining.

We therefore predict that the most affected group is the group of small practices. The effect is to their disadvantage and results in reduced payment and an appearance of poorer performance. We have calculated the expected effect in an imaginary group of 100 small practices and 100 large practices, each achieving 95% long term coverage with a target of 90%. Quarterly coverage varies about 95%, with greater variability in the small practices. In a single quarter one large practice and nine small practices would be expected to fall below 90% and lose payment, despite identical long term coverage rates (table). If the results of four quarters were aggregated only one small practice and no larger practices would be expected to fail.

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Competing interest: This work was funded by a small bursary from the West London Research Network.

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Local consensus opinion must be reflected

EDITOR—McColl et al state the criteria that primary care groups should use for selecting performance indicators.¹ Performance indicators, they say, should be attributable to health care, sensitive to change, based on

Probability of failing to reach infant immunisation targets, by size of practice

Practice	Single quarter			Four quarters aggregated		
	No of patients in target group	Minimum for 90% coverage	P	No of patients in target group	Minimum for 90% coverage	P
Small	22	20	0.09	88	79	0.01
Large	110	99	0.01	440	396	<0.001

reliable and valid information, and precisely defined and should reflect important clinical areas and include a variety of dimensions of care.

We would add a further criterion: they should reflect local consensus opinion. The process of developing indicators of performance is as important as the evidence base behind them. There is a widespread perception in general practice that "indicators of good practice" are often developed by academics and managers who are remote and whose knowledge of clinical practice no longer includes personal experience. The same view is held about many guidelines, with the result that their impact on practice has often been negligible.

If performance indicators are to be embraced by clinicians then ownership is essential. To that end we have adopted an inclusive approach to developing quality indicators in East Sussex, Brighton and Hove. A consensus group of doctors, nurses, and managers working in primary care is currently considering a range of indicators in the first stage of a Delphi approach. We hope by this process to establish a group of primary care quality indicators that not only fulfil McColl et al's criteria but also enjoy broad local support. Only then, we believe, will practitioners be willing to consider and adjust their own practice when they are seen to be performing differently from others.

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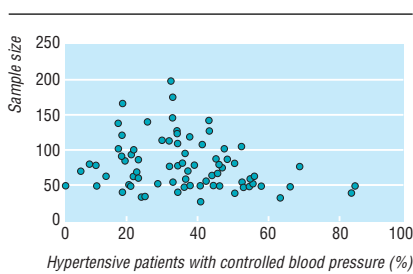
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Performance of these indicators is critical

EDITOR—We agree with McColl et al that performance indicators for use by primary care groups should be more evidence based,¹ but the interpretation of the available evidence and the implementation of performance indicators is not as straightforward as they suggest. Of the eight primary care interventions discussed, the control of hypertension arguably has the strongest combination of evidence, potential impact, and cost effectiveness. Unfortunately, assessing control of hypertension among a group of general practitioners is difficult. The apparent performance of a practice might have more to do with digit preference, the number of available blood pressure readings per patient, or mere chance than with any underlying variation in medical practice.

The authors give the mean level of control among hypertensive patients as 40%. In a multipractice audit we found that the figure changed from 37% to 54% according to whether control was defined as <160/90 or ≤160/90 mm Hg.² These results were based on the mean of up to three measurements per patient. The mean control changed from 26% to 62% with the different definitions when only one reading was available. Chance has a major role too: we found



Funnel plot showing proportion of hypertensive patients with controlled blood pressure and sample size used in each practice. The spread of the proportions is largest when the sample size is low. Detailed analysis of the variance indicates that a sample size of 200 is needed to discriminate reliably between practices

that the main determinant of whether a practice performed particularly well or particularly badly was the sample size in that practice (even though we used sample sizes of 10% of elderly patients, as others have done).³

In the 76 practices in our audit, control of treated hypertensive patients varied between zero and 86%. The figure shows a funnel plot illustrating the influence of sample size. A sample size of 200-250 per practice is necessary to obtain even minimally reliable results (a signal to noise ratio over unity). This clearly has resource implications and may increase the funding required to deliver clinical governance.

We strongly disagree with the authors that treating elderly hypertensive patients is less cost effective than treating younger patients. Treating elderly patients delivers a greater benefit in the short term because the baseline risk is so much higher. The morbidity and mortality from coronary heart disease and cerebrovascular disease are substantially reduced in elderly patients: only 18 older people need to be treated for five years to prevent such events. More than twice as many younger patients need to be treated to prevent one death, and two to four times as many to prevent one cardiovascular event.⁴

Performance indicators certainly need to reflect important clinical areas and be sensitive to change, but even those with the best evidence base may fail to deliver in routine practice. The performance of performance indicators is a critical issue.

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Authors' reply

EDITOR—We share Myers's concerns about the lack of scientific evidence underpinning proposed performance indicators. We presented a method to identify primary care interventions of proved efficacy and suggested performance indicators that could monitor their use.

We are evaluating our indicators in all 18 practices of a future primary care group, several of which are small practices. By presenting confidence intervals when comparing practice values with a local or an estimated national mean we have made the problems addressed by Shah and Cook more transparent. The training of those using and interpreting performance indicators should include how to understand the role of chance in the variation of indicator values.

Scanlon and Tarrant suggest the local development of indicators reflecting local consensus opinion with a Delphi approach. Primary care groups should use local consensus to prioritise their action. If they use only their local indicators, however, they will be unable to compare themselves with others outside their small locality. Nationally agreed clearly defined indicators would enable wider comparisons and help to identify variations in practice. Consensus indicators derived from Delphi approaches are not necessarily evidence based.²

The implementation of performance indicators is not straightforward. We stated that indicators require evaluation both before and after introduction into routine use. Our current evaluation project highlights the difficulties, many of which can be overcome. Interpretation of evidence is not straightforward (see our table 2¹). We used our sources of evidence in an "illustrative way to demonstrate the potential for developing evidence based process indicators."

Cranney and Barton's data show that control of hypertension is a problem that needs to be addressed whatever definition is used. Our method emphasised the importance of having indicators that reflect the detection and control of hypertension. These are not yet part of currently proposed indicators.³ We agree that primary care groups will need to balance the accuracy of indicator values against the cost of data collection. If our indicators were widely accepted then providers of primary care software would be more likely to provide straightforward mechanisms for data collection. Evidence for the efficacy of antihypertensive treatment in elderly patients is strong.⁴ Our reference to its relative cost effectiveness was from a Department of Health document.⁵

Our evidence based indicators could help to turn evidence into everyday practice and to have an impact on the population's health. They will be useful not only for

primary care groups engaging in clinical governance but also to justify investment in primary care interventions which should deliver clear health gains.

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Antenatal screening

Obtaining selective consent to scanning, rather than screening, is possible

EDITOR—McFayden et al stated that first trimester ultrasound screening “should include the accurate presentation of all available information before screening to ensure that consent is truly informed.”¹ In 1997 we evaluated the content and readability of the leaflets used in 14 centres offering first trimester nuchal translucency screening using a number of predefined variables.²

Only one of the leaflets met all of the criteria deemed necessary for an informed choice to be made. Thirteen of the leaflets indicated that ultrasound scanning was used to screen for Down's syndrome and chromosomal abnormalities, although only two leaflets gave any description of the syndrome, and this was limited to “mental handicap.” Few of the leaflets gave information on the sensitivity or specificity of the test, or on interpreting results. Eight mentioned diagnostic testing, and two referred to the option of termination. Nine leaflets explained that nuchal translucency screening was separate from other elements of the early pregnancy scan, and four leaflets indicated that written consent was required.

The content and readability of the leaflets used to inform women of the aims and limitations of screening for nuchal translucency varied widely but the majority could be considered as failing to meet the criteria for informed choice. Even under conditions of informed choice, however, uptake of ultrasound screening is markedly

above that which would be expected for other prenatal screening tests. This high uptake has been attributed to expectant couples' overwhelming desire to “see the baby.”³

Since the first centre was accredited by the Fetal Medicine Foundation (a charity established to provide training and audit of first trimester ultrasound screening) in 1993, uptake of nuchal translucency screening has fallen from 96.9% to 86.6% of all women having ultrasound screening (R Snijders, personal communication). This decline shows that offering the option of “selective consent” has the potential to overcome the previously reported high uptake of ultrasound screening.

Selective consent can be easily accommodated by the early pregnancy scan because its pregnancy monitoring functions (assessing gestation and viability, and identifying multiple pregnancies) are distinct from its screening functions. Therefore, couples who wish to decline screening for chromosomal abnormalities do not have to forgo “seeing the baby” or accurately dating the pregnancy. The data suggest that an increasing, albeit small, percentage of women who have ultrasound scans are making an informed choice to selectively decline screening for chromosomal abnormalities. It may be that the way forward in facilitating informed choice for ultrasound screening is to separate “scanning” (to monitor the pregnancy) from “screening” (for fetal abnormality).

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Better understanding of factors influencing uptake is needed

EDITOR—There is agreement that women should receive information about ultrasound screening before it is used to detect fetal abnormalities.^{1,2} Regrettably, this does not always happen.

When women are offered biochemical screening for Down's syndrome they are provided with information, both verbal and written, before the test and are given an opportunity to decide whether they want to be screened. A similarly explicit consent procedure is needed for ultrasound screening.

There are two difficult areas in screening regardless of whether it is ultrasonic or biochemical (or a combination of the two). Firstly, practices are inconsistent, which causes confusion. Different screening tests may be offered at the same stage of pregnancy. Even when the same test is offered, different cut off points may be used. Some screening tests express the “risk at

term” and others express it at the time of screening. Some women are offered a screening test if they are younger than 37, while others are offered diagnostic amniocentesis if they are older. It is hardly surprising that there is confusion.

Because there are variations in screening policies, screening is not provided on an equitable basis. We need a national screening framework to give guidance on which screening policies are appropriate, to monitor performance, and to provide accurate and comprehensible information for women and health professionals.

Secondly, it is not clear why there are striking differences in the uptake of serum screening. Although about two thirds of women in the North Thames region decided to have this screening, uptake varied from 27% to 93% at different hospitals.³ These variations in uptake may be influenced by the information given before the test and by the way it is given, or by the knowledge and attitudes of the person who offers it. If a test has a “good press” then a woman is more likely to decide to have it. There is no “correct” uptake figure but it is difficult to accept that such differences reflect women's choices alone. We need to understand more about the factors influencing the uptake of both types of screening.

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Women are being given incomplete information

EDITOR—There is a normal fetal loss rate during screening for maternal α fetoprotein of about 1/3000 due to inaccuracy and lack of specificity; 1/200 fetuses aborted as a result of an ultrasonically diagnosed abnormality were found not to be significantly abnormal at post mortem examination. This information was used in Oliver et al's study of informed consent.¹

The consent presumed to have been given during attendance at an antenatal consultation is not the same during attendance for a scan (even a booking scan). Methods, protocols, and gestational age specific risks should be communicated to parents, which is where the appropriate duty of responsibility resides. Despite Carroll's view, termination of pregnancy is the only practical and “useful” outcome or treatment that comes from screening for Down's syndrome²; however, the termination rate varies inversely with gestational age at diagnosis.

The use of “reassurance scans” is increasingly prevalent in situations in which consent to serum antenatal testing has been refused, possibly since guidance from the Royal College of Obstetricians and Gynaecologists was published.³

No clear or consistent approach to the timing and specification of consent has emerged from the correspondence or from the editorial by McFadyen et al.² It is necessary to obtain specific consent because “soft markers” and borderline appearances are increasingly identified during first trimester scans as the technology becomes more sophisticated.

It is not feasible to be selective about results after scanning. Even patients who have said that they don't wish to be given information about an abnormality cannot not be told.

The following points should be considered:

- If it is desirable to obtain the views of those “in the know” to shed light on the issues discovered by patients having screening, then surely the best group to ask what their wishes were, or would be, in subsequent pregnancies is those who have had “non-reassuring events.”
- If counselling is so important, why is a written record of details of the event so uniformly lacking from patients' records, and should patient held records include a specific consent?
- Should sonographers be appraised of patients' wishes and modify their scanning accordingly?
- Why is the rate of invasive testing so high in some Scandinavian areas?
- What is the measure and amount of patient knowledge, and is there an optimum amount?³
- Why does there appear to be a clutter of conflicting evidence and figures available to the profession, and yet information available to patients is so basic and, frankly, misleadingly so?

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Icelandic gene database will uphold patients' rights

EDITOR—Berger's news story on the Icelandic gene database¹ gives an inaccurate and biased account of a complex issue.

The proposed database will not exclude biotechnology companies or pharmaceutical companies from access to data on Icelandic patients, nor are exclusive rights given to one company to develop new drugs or to test candidate drugs. These studies will continue to be allowed as long as they

adhere to our regulations, which are similar to those of other western countries.

The central database will be privately owned and run, but Icelandic health authorities will have access to the information provided that they comply with specific regulations. Other scientists will also have access unless commercial interests are affected.

The data will remain where it originates from, that is, at hospitals and health care stations, and will continue to be used for patient care and research. Scientists are of course free to cooperate with anyone they choose.

The government of Iceland and the unusually well educated public, which is predominantly in favour of this experiment, would not consider implementation of the database unless they were convinced that the numerous stipulations in the system set up to preserve patients' rights were sufficient. The legislation on a medical database is supplemented by a recent law on patients' rights as well as a comprehensive legislation on data protection, reflecting European resolutions and directives.

Extraordinary steps were taken to ensure that the many relevant bodies concerned had an opportunity to comment on the bill at various stages, and we did indeed get numerous valuable suggestions that improved the bill.

The various international obligations that Iceland has undertaken have been analysed and adhered to, and many experts on these issues have maintained that our precautions are outstanding and will lead the way for other similar databases. Such databases are certainly on the way.

More information on the issues can be obtained from the website (www.stjr.is/htr).

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1 Berger A. Private company wins rights to Icelandic gene database. *BMJ* 1999;318:11. (2 January.)

Modernising mental health services

Personality disorders are arbitrary medicalisation of human variation

EDITOR—Over the past few months the issue of personality disorder has come up several times, most recently in Marshall's editorial on *Modernising Mental Health Services*.¹ It seems that the reporting of the Michael Stone case fuelled the madness or badness argument to the point that the home secretary chose, in the usual populist rhetoric, “to take a pop” at psychiatrists.

The difficulty with personality disorders is that, by their nature, they are an arbitrary and subjective medicalisation of human variation. It is hardly surprising that they are often not amenable to treatment. A supervising consultant psychiatrist once asked me to name any psychiatrist I knew who did not have a personality disorder. When I considered this poisoned chalice and declined to

reply, he said a person without a personality disorder is a person without a personality.

If personality disorder is sufficient legal grounds to detain someone, some questions need answering: when should he or she be released, and does the duration of detention fit the crimes committed or is it a value call for the psychiatrist? We find ourselves in difficult ideological times if society cannot cope with the less savoury aspects of human variation. The profession should be bigger than to fall for the myth, driven by tabloid headlines, of a safe society.

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Strategy does not seem to be based on systematic evidence

EDITOR—We were surprised to see that the government's plans for modernising the NHS mental health services are not based on any of the findings from its own research and development programme.¹ Although we appreciate that these are “emerging findings” and that many of the recommendations are based on examples of good practice, not a single systematic review and few randomised controlled trials were quoted. The Cochrane Library, for example, provides readily available evidence for mental health policy on case management,² assertive outreach,³ use of hospital beds,⁴ and effective community mental health teams.⁵

Surely at a time when the government is encouraging all clinicians to use evidence based medicine (through the National Institute for Clinical Excellence and the Commission for Health Improvement), there should be a clear link between committing £700m on new policies and evidence of effectiveness.

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Strategy is driven by public opinion

EDITOR—I support Marshall's views on the government's strategy document, *Modernising Mental Health Services*.¹ He highlights many important criticisms of this publication, including the worrying nature of the

proposed changes to the law. These changes would allow indefinite detention of patients who have committed no crime but whose untreatable personality disorder is considered to make them a danger to themselves or others.

This is a policy plagued with contradictions. The document states the government's commitment to a modern, decent, and inclusive society but then outlines legislation that will forcibly remove unwanted people from such a society.² The document contains a lengthy explanation of the stigma that surrounds mental illness, which, it says, is derived from ignorance and inaccurate sensationalist media coverage. However, rather than heeding its own information, it proposes knee jerk policies which threaten to return psychiatry to the custodial times of the Victorian asylum. Furthermore, the government seems unaware of the apparent dichotomy between this restrictive proposal and several of its well publicised priorities. The recent social services white paper stated that promoting independence was one of the government's top priorities.³ Marshall highlights the tension between this proposal and the government's policies on social exclusion and user participation.¹

This proposed change in legislation raises some important ethical considerations that do not seem to have been properly addressed. For example, to what extent is public safety deemed more important than individual liberty? Extrapolated further, the argument that public safety is more important than individual liberty would result in measures such as the banning of road vehicles to prevent road traffic accidents. There is also an important therapeutic consideration; increasing the custodial role of doctors could increase the strain on the clinical relationship.

An additional irony is that, despite Mr Dobson's statement that care in the community has failed in its duty to protect the public,² a recent study showed that the proportion of homicides committed by mentally ill people has fallen significantly since the introduction of care in the community.⁴

This policy seems to be driven by the weight of public opinion and the need for tabloid approval rather than by responsible decision making on behalf of everyone, including society's most vulnerable members. The government has ordered its proposed alterations to current mental health law to be scrutinised by a review panel, which is to report back in April. The medical profession must be ready to speak out against these unjust and ill thought out policies.

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Psychiatrists should oppose community treatment orders

EDITOR—At a meeting in Bradford on 8 January a group of senior psychiatrists set out their objections to the measures proposed by the government for increased control of psychiatric patients. We welcome the reservations expressed in Marshall's editorial¹ but would like to outline why we feel there are good grounds to oppose proposals for community treatment orders as well as the more obviously controversial idea of preventive detention for people with personality disorders.

The introduction of community treatment orders will mean that people who have been psychiatric patients will not have the same human rights as the rest of the population, even when they are functioning well and have committed no crime. They will not have the basic right to determine what happens to their bodies, in particular whether to continue taking powerful drugs that are known to have severe and unpleasant side effects.

Community treatment orders, like preventive detention of people with personality disorders, are fundamentally measures of social control. Rather than improving the quality of care, they are likely to further estrange challenging patients from mental health services. By reducing the rights of people with mental disorder they will add to the stigma such people experience.

We believe there are many other psychiatrists who are uneasy about these issues. We invite these psychiatrists to join us in the campaign we are mounting, alongside the campaigns of some mental health user groups, to oppose the introduction of these coercive measures.

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1 Marshall M. Modernising mental health services. *BMJ* 1999;318:3-4. (2 January.)

Government has failed, not community care

EDITOR—Marshall's commentary on the new mental health strategy *Modernising Mental Health Services* fails to challenge the most fundamental flaw of the document—the assertion that community care has failed.¹ Indeed, community care has provided most patients with the freedom denied to their predecessors. The reason that it has not been able to deal effectively with the most severe cases is more likely to be that “it has not been properly tried,” as declared by Graham Thornicroft, chairman of the national committee set up to advise on mental health policy.² It is ironic that the substitute for community care will probably be community care in a more punitive guise.

The strategy document insists that the legal framework is outdated. There are not many people who would disagree—but not for the reasons the government suggests. The attempt to “ensure compliance with appropriate treatment” is a framework for social control. It will do little for recruitment levels and may actually decrease compliance in the long term. Likewise, “detention for those with a severe personality disorder” is not for any therapeutic reason. Therefore, why should psychiatrists provide their scarce time and beds to act as prison officers? Prison seems the more appropriate setting.

In conclusion, the government's strategy for modernisation has been to increase bureaucracy, blur the boundaries of psychiatric care, and exert greater social control over psychiatric patients. Far from modernising the service, such an approach is likely to reverse the progress that has already been made. No matter what spin the government puts on this document, it indicates that the government has failed and not community care.

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2 Dean M. Mental care versus public safety in the UK. *Lancet* 1998;352:1995.

Maggots are useful in treating infected or necrotic wounds

EDITOR—In their editorial Wise et al highlight the problems of the development of antibiotic resistant bacteria and outline several strategies to combat this problem.¹ We propose another option: the use of fly larvae (maggots) to treat infected or necrotic wounds.

This technique was described in detail in the medical press in the early part of this century and has been reintroduced in the United Kingdom and elsewhere with considerable success over the past three years. To date, over 3500 containers of sterile larvae of *Lucilia sericata*, the common green-bottle, have been supplied to nearly 400 centres.

Clinical indications for larval treatment, or “biosurgery,” include infected or necrotic wounds of all types, including those infected or colonised with antibiotic resistant strains of bacteria such as methicillin resistant *Staphylococcus aureus*.² Particularly spectacular results have been reported in the treatment of feet in diabetes.³

The mechanisms by which larvae kill bacteria in wounds are not fully understood but may include the production of natural antibiotic-like agents,⁴ the modification of wound pH, and the ingestion and destruction of bacteria as part of normal feeding processes. Growth promoting agents have also been detected in larval secretions,⁵ a finding that is consistent with the clinical observation that the introduction of larvae

often causes a previously indolent wound to heal rapidly.

Currently, many patients receive larval treatment as the last resort, when conventional treatments, including repeated courses of antibiotics, have failed. We suggest that the earlier application of maggots should be considered to clean up problem or infected wounds at an earlier stage, which in many cases would obviate the need for topical or systemic antimicrobial treatment.

More information on larval treatment may be found at www.smtl.co.uk.

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Prescribing of nutritional supplements is increasing in general practice

EDITOR—Potter et al state that making nutritional supplementation a routine part of hospital prescribing has cost implications.¹ Although we agree with this statement, we believe that the issue is far wider than that of hospital prescribing. Prescribing of enteral feed products in primary care is one of the most rapidly increasing areas of drug expenditure.

As part of a study for the NHS Executive,² we analysed prescribing analysis and cost (PACT) data for the West Midlands region for enteral feed products from January-March 1994 to March-June 1997. All health authorities showed an increase in the cost and volume of products prescribed, with cost

increases varying from 39% to 142% and volume increases from 26% to 135% (table). Price increases and changes in product mix accounted for only a small part of the rise in expenditure, suggesting that the main cause was an increase in prescribing volume.

The assertion of Potter et al that the benefits of routine nutritional supplementation were not restricted to particular subgroups or trials is unsafe because of the clinical heterogeneity of the group as a whole. The odds ratios in their figure 3 indicate significant reductions in death rate for several groups, including patients who were well nourished, aged over 70, or had non-neoplastic disease.

Our qualitative findings suggest that a significant proportion of current prescribing is not for clinical circumstances that nutritional supplementation has been recommended for. Indeed, there is inadequate evidence to support some current use, particularly in terms of cost benefit, since the outcomes used in trials may not have been those of greatest importance. For example, improved quality of life or reductions in morbidity may be more clinically important than improved muscle tone or immune function.³⁻⁵ Furthermore, use in some patients with terminal illness or severe neurological damage poses ethical dilemmas not yet adequately addressed.

The conclusion of the paper could have been more definitive. Enteral feeding should be prescribed only for those patients for whom, on current evidence, there is benefit, albeit of limited definition. We strongly endorse the conclusion that large pragmatic trials are required and have recommended to the NHS Executive that enteral feeding be evaluated within the health technology assessment programme. In the interim, clear national guidance is required on both initiation and exit criteria.

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BMJ introduces a fast track system for papers



Publication cycle

EDITOR—Congratulations on instituting a fast track system for publishing papers¹—it's no small undertaking.

I am intrigued though by the design of your chosen fast track logo. With its oval wheels and crossbar, should I infer that only men with particularly robust spines need apply?

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- 1 Goldbeck-Wood S, Robinson R. *BMJ* introduces a fast track system for papers. *BMJ* 1999;318:620. (6 March.)

Editor's reply

We chose a bike as our symbol of fast tracking for four reasons. Firstly, the bike is the most efficient machine in the universe, more efficient even than a salmon, an albatross, or an asteroid. Secondly, some of us (me included) love bikes. Thirdly, we will still be riding bikes long after cars have been banished for destroying our climate, our countryside, and our most beautiful cities. Fourthly, the symbol of the bike is ironic, representing our continuing doubts about fast tracking.

The oval wheels add to the irony. The *Lancet's* staff, who have instant access to the Lancetmobile, would perhaps not recognise the symbol, but those who cycle through London will recognise it as the symbol of bike paths. Fast tracking is the way through the crowded traffic. London's annual race between a car, a tube train, a bus, a motorbike, and a bike is always won by the bike. I must concede, however, that the *Lancet's* bird might be faster, especially if it's a crow.

Richard Smith Editor

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Competing interest: Rather holier than thou about cycling to work every day.

Increase in the costs and volume of enteral feeds prescribed in primary care between March 1994 and June 1997

Health authority	Net ingredient cost (£)			Volume (ml/mg)		
	Jan-Mar 94	Mar-Jun 97	% change	Jan-Mar 94	Mar-Jun 97	% change
1	37 934	52 652	39	6 050 524	7 621 742	26
2	73 028	112 021	53	11 032 784	15 803 464	43
3	201 985	347 399	72	31 179 406	47 493 366	52
4	54 028	93 506	73	8 959 298	13 618 480	52
5	41 800	74 823	79	6 530 928	10 338 700	58
6	64 565	116 970	81	10 019 342	15 896 147	59
7	62 408	113 231	81	9 791 167	15 512 360	58
8	56 892	110 519	94	8 547 513	15 039 007	76
9	25 860	51 432	99	4 027 733	7 245 085	80
10	115 242	245 444	113	17 247 166	34 416 280	100
11	23 760	57 533	142	3 483 516	8 171 425	135

Trends in deaths from malignant neoplasia of liver are poor indicator of hepatitis C infection

EDITOR—Taylor Robinson et al have suggested that increasing mortality from liver cancer in the United Kingdom may be the result of cirrhosis induced by hepatitis C virus.¹ However, the increase they report is in deaths from malignant neoplasia of the liver (hepatocellular carcinomas, cancers of the intrahepatic bile ducts, and liver cancers

Trends in mortality from liver cancer. Values are numbers of deaths

Year	1990	1991	1992	1993	1994	1995	1996
Total malignant neoplasia of the liver	1388	1524	1603	1705	1764	1760	1818
Hepatocellular carcinoma	665	743	751	490	506	508	580
Cancer of intrahepatic bile ducts	483	570	657	684	740	749	737
Liver cancer, not primary or secondary	240	211	195	531	518	503	501

Source: Office for National Statistics, mortality statistics for 1990-6.

that are not specified as either primary or secondary³). The number of deaths due to hepatocellular carcinoma (which is aetiological linked to hepatitis C) has been fairly stable between 1990 and 1995 (table).

To assess the burden of disease related to hepatitis C virus more accurately we examined the text of death certificates in 1996 that recorded liver cancers. Twenty six (4.5%) of the 580 deaths coded as hepatocellular carcinoma (ICD-9 (international classification of diseases, ninth revision) code 155.0) mentioned hepatitis C compared with one (0.1%) of the 737 deaths coded as cancer of the intrahepatic bile ducts (ICD-9 code 155.1) and five (1.0%) of the 501 liver cancers that were not specified as either primary or secondary (ICD-9 code 155.2). Hepatitis C virus is not known to be aetiological associated with cancer of the intrahepatic bile ducts (ICD-9 code 155.1), and the data suggest that coding errors to this cause are rare.

Trends in the total number of deaths from malignant neoplasia of the liver are therefore insensitive to changes in the incidence of disease related to hepatitis C virus. Deaths from both hepatocellular carcinoma (ICD-9 code 155.0) and unspecified liver cancers (ICD-9 code 155.2) may include deaths related to hepatitis C virus, but those currently attributed to the virus represent a small proportion of such cases. Few deaths coded as hepatocellular carcinoma in 1996, however, had alternative aetiological factors mentioned: 29 (5.0%) hepatitis B, 13 (2.2%) unspecified hepatitis, 14 (2.4%) alcohol, and 38 (6.6%) another underlying condition. In an additional 44 (7.6%) cases unspecified cirrhosis or micronodular cirrhosis was mentioned, suggesting that these may be alcohol related. Overall, 416 (71.7%) of all deaths from hepatocellular carcinoma had no mention of possible aetiological factors. Dramatic increases in deaths related to hepatitis C could therefore occur before any impact on routine data is detected.

Progression to hepatocellular carcinoma after hepatitis C may take several decades,³ and an epidemic of this cancer has been predicted among people infected by injecting drug use since the 1960s.⁴ To detect the emergence of such a problem requires surveillance systems that monitor end stage liver disease attributed to hepatitis C. The Public Health Laboratory Service is currently establishing such a scheme in collaboration with hepatologists from the British Association for the Study of the Liver.

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- 1 Taylor Robinson SD, Foster GR, Arora S, Hargreaves S, Thomas HC. Increase in primary liver cancer in the UK, 1979-94. *Lancet* 1997;350:1142-3.
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More studies are needed before giving magnesium sulphate for pre-eclampsia

EDITOR—Clark et al argue that magnesium sulphate reduces the risk of eclampsia and should therefore be given to all women with severe pre-eclampsia.¹ The study they refer to in support of this view has reported outcome for 685 women out of 822 randomised. A more reliable guide to clinical practice is a systematic review of all relevant trials. Four trials have now compared magnesium sulphate with placebo or no anticonvulsant,² and the relative risk for the overall effect on eclampsia is 0.33 (95% confidence interval 0.11 to 1.02). Although this suggests that magnesium sulphate may reduce the risk of eclampsia, it is little help in estimating the size of such an effect. For example, the confidence interval includes everything from a 90% reduction in risk to a 2% increase. The number of events is also small (3 v 11), and there are many examples where high hopes based on this level of evidence have been dashed by the results of larger trials. For example, in the first trial of fetal movement counting, the numbers of stillbirths were 3 v 12. In the subsequent large trial the numbers were 99 v 100.³

Even if magnesium sulphate does prevent eclampsia, before it can be safely recommended we need to know whether, overall, it does more good than harm. As discussed by Idama et al,⁴ data from case-control studies have suggested that in utero exposure to magnesium sulphate may protect very low birthweight babies from cerebral palsy. This hypothesis awaits confirmation in randomised trials, however. What they fail to mention is a trial of magnesium sulphate tocolysis that was stopped because of an excess of deaths among babies exposed to magnesium sulphate.⁵ Although this trial was small, it is a timely warning that

magnesium sulphate is not innocuous. We need to know far more about its short term effects on the woman and her child, and we need information about possible effects on long term development of the exposed children. Clinicians have plenty of reason to be uncertain about the role of magnesium sulphate for women with severe pre-eclampsia. Those who wish to contribute to the further evaluation of magnesium sulphate are welcome to join the collaboration on the magpie trial (magpie@ndm.ox.ac.uk).

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Breast screening

No need to reconsider breast screening programme on basis of results from defective study

EDITOR—In a recent news article Mayor discusses a study whose results question the mammography screening recommendations of the National Board of Health and Welfare in Sweden.¹

The Swedish study to which the article refers has many methodological limitations and fallacies and should not be considered seriously.² Varying trends in the incidence of breast cancer among the county councils influence mortality trends, which was not taken into account by Sjönell and Ståhle. Furthermore, they could not distinguish between the effects of the screening programme and those of "opportunistic screening." They did not take account of the fact that the programmes started at different times in the county councils and were of different intensities or that a long follow up is needed to detect the effects of the programme. In addition, half of the study population was diagnosed with breast cancer before the screening programmes started. These patients obviously could not have benefited from the screening programme.

The main problem of the study is, however, the attention it has received from the mass media, which may create uncertainty among women about whether they should participate in the screening programme. Was it ethical to publish this study? This is a question primarily for the *Swedish Medical Journal*, which published the paper,

but it is also an issue for the *BMJ* and others following the story. We believe that the article by Sjönell and Ståhle would not have passed the scientific review process for an original article in the *BMJ* or other major peer reviewed journal.

We, as well as Sjönell and Ståhle, are concerned about the ethical questions surrounding screening programmes and the need for evidence based recommendations for health policy programmes. This was one reason why the national board supported randomised controlled studies on mammography screening in Sweden. The national recommendations for mammography are based on these considerations and we see no reason to change them on the basis of such a defective study.

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1 Mayor S. Swedish study questions mammography screening programmes. *BMJ* 1999; 318: 621. (6 March.)

2 Sjönell G, Ståhle L. Hälsokontroller med mammografi minskar inte dödlighet i bröstcancer. (In Swedish.) *Läkartidningen* 1999; 96: 904-13.

Informed consent for mammographic screening

EDITOR—The General Medical Council's recently published guidelines on seeking patients' consent has a specific section on consent to screening from which I quote: "You should be careful to explain clearly the likelihood of positive/negative findings and possibility of false positive/negative results."¹ In the invitations to the NHS breast screening programme this has yet to be the case. One would assume that in the name of probity, these invitations should also explain that after 10 years of mammographic screening in Sweden mortality from breast cancer has not reduced significantly and that during this time there have been nearly 100 000 false positive diagnoses.²

In his attempt to explain away these disappointing results Michael Dixon claimed: "When screening is opened up to national programmes a much larger population of radiologists is involved. Inevitably, it takes some time for them to climb up the learning curve in accurately detecting abnormalities."² If that is indeed the case, why weren't the millions of women who have participated in the NHS breast screening programme to date warned that they were unwittingly subjects of some radiologist's "learning curve"?

I have always believed that there were double standards of informed consent between offers of treatment, in and out of clinical trials, and invitations to screening; this example reinforces my prejudice.

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1 General Medical Council. *Seeking patient's consent: the ethical considerations*. London: GMC, 1999.

2 Mayor S. Swedish study questions mammography screening programmes. *BMJ* 1999; 318: 621. (6 March.)

Postmarketing surveillance study of a non-chlorofluorocarbon inhaler

Such studies initiated by manufacturer are designed to promote product

EDITOR—The study by Ayres et al may have been selectively designed to promote a product as safe; they endorse it as conforming to unpublished guidelines for postmarketing surveillance studies under safety assessment of marketed medicines.¹ Withdrawals from the study are mainly for reasons "not related to safety," and the withdrawal rate of the product under evaluation is almost three times that of the salbutamol inhaler with conventional propellant.

I have several reservations about the study. Postmarketing surveillance studies initiated by the manufacturer are primarily designed to promote a product to the medical profession and the general public. One incentive for patients to enter such a study is the availability of a prescribed drug without charge. Participating general practitioners receive a generous fee—particularly attractive and effective in medical recruitment to this study since "neither the patient nor doctor had to undertake any procedures related to the study." Criteria of drug safety in this study relate mainly to hospital admissions and perceived adverse effects.

One basic safety criterion—whether the hydrofluoralkane inhaler is reliable—has been omitted from this study. The manufacturer (3M), which sponsored the study, is certainly aware of the problem of failure of the inhaler caused by the nozzle becoming blocked. My practice prescribed and dispensed 356 hydrofluoralkane inhalers to 66 patients, but four fifths of the patients reported or returned the inhalers as faulty, a problem that was not batch related. I reported this problem elsewhere² and to the Medicines Control Agency in the United Kingdom and the Federal Drugs Agency in the United States, to both of which I sent representative defective samples.

Although blockage of hydrofluoralkane inhalers can be minimised by washing them regularly, this suggests a low margin of safety for this device. Might conflict of interest and suppression of data have resulted in the *BMJ*'s pages being used for promotional purposes by 3M?

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1 Ayres J, Frost CD, Holmes WF, Williams DRR, Ward SM. Postmarketing surveillance study of a non-chlorofluorocarbon inhaler according to the safety assessment of marketed medicines guidelines. *BMJ* 1998; 317:926-30. (3 October.)

2 Bamber MG. Difficulties with CFC-free inhaler. *Lancet* 1996; 348:1737.

Postmarketing surveillance studies remain unethical

EDITOR—When is a research study not a research study? When it's a postmarketing surveillance study conducted under the

safety assessment of marketed medicines guidelines. Otherwise it would require ethics committee approval, wouldn't it? As Ayres et al point out, they did not obtain such approval in this case.¹

Presumably that is why the authors ask us to believe that in their non-interventional observational design general practitioners decided, purely on clinical grounds, to prescribe one patient the standard salbutamol inhaler and the next five patients the inhaler just released on to the market. The authors also ask us to believe that this decision had nothing to do with the fact that the general practitioners were being paid for each patient entered into the study. The patients gave their written informed consent for information to be extracted from their notes, but how much they were told is unclear.

In December 1997 I was invited to take part in a postmarketing surveillance study under the safety assessment of marketed medicines guidelines to assess the safety of the newly released irbesartan. I and other general practitioners were asked to assess the safety of the drug compared with that of amlodipine when given for one year to patients with mild to moderate hypertension. This was "an open, observational cohort study" and it was planned that 1500 general practitioners would each recruit and follow up an average of eight patients, for which each would be paid £420. It was emphasised that patients should be identified only after the prescribing decision had been made and that it was not necessary to tell the patients that they were part of a study.

The prescribing decision that I would have taken, on clinical grounds, was to prescribe irbesartan to three patients and then amlodipine to one before again prescribing irbesartan to three patients. Irbesartan is not included in any published guidelines on hypertension treatment, and at that time 28 days' treatment cost £17.22, compared with 14p for bendrofluazide and £1.49 for atenolol.

Both of these studies lead me to conclude that a postmarketing surveillance study is research—research in which treatment decisions are made for research purposes without fully informed consent and in which doctors, by pretending that their prescribing decisions are normal clinical practice, betray their patients' trust. If general practitioners must get involved in such studies at least we should insist that ethics committee approval is required.

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1 Ayres JG, Frost CD, Holmes WF, Williams DRR, Ward SM. Postmarketing surveillance study of a non-chlorofluorocarbon inhaler according to the safety assessment of marketed medicines guidelines. *BMJ* 1998; 317:926-30. (3 October.)

Authors' reply

EDITOR—Both Bamber and Paterson are mistaken in the context of the safety assess-

ment of marketed medicines guidelines. The guidelines were published in 1994.¹ Contrary to Bamber's assertion, they specifically forbid studies being conducted for promotional reasons and also forbid inducements being offered to investigators to participate. The fees that we paid complied with BMA guidelines. Furthermore, the Medicines Control Agency had to approve the protocol, data collection forms, invitations to general practitioners to participate, and schedule of fees before the study could start.

In non-interventional studies, patients continue to pay prescription charges. Such studies can collect information only from data recorded in the patient's notes, as we explained. The guidelines required us to submit a detailed report on the conduct of the study and outcomes to the Medicines Control Agency; it was satisfied with the safety of the hydrofluoralkane inhaler.

The study protocol clearly stated that patients were to be enrolled on the basis of clinical need to be prescribed salbutamol. The decision on which product to prescribe was a matter for the general practitioner's clinical judgment. To doubt that this was the case, as Paterson does, is to question the integrity of general practitioners in almost 650 practices in the United Kingdom. The pattern of prescribing salbutamol with a chlorofluorocarbon inhaler to one patient and with a hydrofluoralkane inhaler to the next five did not affect prescribing decisions since this was the sequence of patients entering the study, not necessarily the sequence in which prescriptions were written.

Paterson correctly states that the guidelines do not require patients to consent to receiving the study drug since it is being prescribed in the normal way. We obtained patients' consent for information from their notes to be used in the study, in recognition that this is a sensitive issue.

Bamber raises issues concerning the study results. Most withdrawals from the hydrofluoralkane inhaler were related not to safety but to patients' preference for previous treatment (a well known phenomenon, also seen when patients switch from branded to generic salbutamol inhalers). This is discussed in the paper.

Bamber repeats his assertion that blockage was a problem with the hydrofluoralkane inhaler. The Medicines Control Agency forwarded his "faulty" inhalers to an independent laboratory for testing. Its report concluded that the sample was not delivering the correct dose but that, after instructions in the patient information leaflet for cleaning the adaptor were followed, the sample performed as expected.

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¹ Medicines Control Agency, Committee on Safety of Medicines, Royal College of General Practitioners, BMA, and Association of the British Pharmaceutical Industry. Guidelines for company-sponsored safety assessment of marketed medicines (SAMM guidelines). *Br J Clin Pharmacol* 1994;38:95-7.

Maintenance programmes are denied to addicted prisoners in Victoria

EDITOR—In my role as a peer programme advisor (infection control, harm minimisation) and as a drugs and alcohol counsellor at a Melbourne centre with over 700 patients on methadone and 300 on naltrexone I wonder at the prison system in Victoria.

We have no maintenance program for methadone, no needle exchange, and do not allow inmates to continue on naltrexone programmes when they enter prison. But we do provide harm minimisation sessions, mandatory HIV and hepatitis sessions, and bleach for injecting equipment.

If we are to go some way towards providing similar medical treatment to that provided in the community we should at least allow prisoners to continue on methadone and the more recent naltrexone programmes. Some of our patients who were taking naltrexone when they entered prison were denied further treatment. What happens if one of these patients lapses and we have a death from overdose? Is there not a duty of care?

Prisoners' families were funding naltrexone treatment, which constitutes an abstinence program. Surely this practice should be emulated in prison as well as the methadone maintenance programmes described by Byrne and Dolan.¹

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¹ Byrne A, Dolan K. Methadone treatment is widely accepted in prisons in New South Wales. *BMJ* 1998; 316:1744.(6 June.)

Crisis in cremation

Poor form filling makes medical referees essential

EDITOR—I was one of the medical referees who received and completed Horner's questionnaire on cremation forms as part of the BMA survey in June 1997.¹ I was interested to learn that only 21% of cremation certificates presented to Horner were complete, and this prompted me to survey the forms presented to me in Chesterfield.

From September 1997 I looked at 1000 consecutive sets of papers presented to me for authorisation of cremation. At the same

Proportion of cremation forms requiring interventions

Source of form	Total No	No (%) requiring intervention
Coroner's office	260	29 (11%)
General practitioners	324	104 (32%)
Hospital doctors	416	127 (31%)
All forms	1000	260 (26%)

time as starting the survey I produced a handout giving guidance on how to complete certificates B (completed by the attending doctor) and C (confirmatory certificate from independent doctor of 5 years' standing), which was distributed to all junior doctors at Chesterfield and North Derbyshire Royal Hospital. The table shows the papers received and numbers requiring intervention. Ninety seven forms had incomplete or incorrect details of name, address, or age; 64 had incomplete or incorrect details of pacemakers or radioactive implants; 39 required investigation of medical details; in 29 the patient had not been seen within 14 days of death; 24 had discrepancies in date, time, or place of death; 22 did not state whether the coroner was informed of the death; and 14 did not give the date the patient was last seen alive.

Interestingly, on three occasions the body had not been seen after death; six forms were unsigned; three doctors signing part C were discovered to be ineligible; five doctors completing form B had never attended the patient; and on two occasions forms B and C recorded different causes of death. Two hundred and seventeen forms had one error; 36 forms had two errors, and seven forms had three or more.

Although my figures are better than Horner's, over a quarter of cremation papers were unsatisfactorily completed. The problems vary from simple administrative matters, which could be handled by a clerk, to more complex medical queries requiring lengthy investigation. Families have to pay £76 for the two certificates, so a considerable amount of money is being paid for a service that is often performed poorly. While this situation remains, every effort should be made to protect the position of the medical referee.

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¹ Horner S. Crisis in cremation. *BMJ* 1997;317:485-6. (22 August.)

Cremation form should be abolished

EDITOR—Horner's leader emphasises a problem which has arisen because of the overwhelming popularity of cremation as a means of disposing of bodies.¹

The regulations which govern the three part cremation form, completed by three different doctors, originated when this alternative to burial was uncommon. Then there was a real fear that cremation might be used to dispose of the evidence of crime. However, the system is clumsy, ineffective, and completely obsolete.

Both the medical certificate of cause of death and the cremation form are legal documents, not medical evidence. If we really wanted more information about diagnoses and cause of death then almost everyone should have a necropsy, which is the opposite of standard practice.

If there is serious concern about a death the medical certificate of cause of death allows this to be recorded, and coroners and their officers are available to resolve issues.

Why not abolish the cremation form altogether and amend the medical certificate of cause of death to include two further questions: "Have you any reason to suppose there is suspicion about the cause of death, or that it may have been caused by wrongdoing, or that a cremation should not be performed?" and "Is the patient currently fitted with a cardiac pacemaker?" This would reduce the paperwork and remove a non-clinical chore from doctors. It would do no credit to the profession to try to maintain the old way purely because of the fees involved.

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1 Horner S. Crisis in cremation. *BMJ* 1997;317:485-6. (22 August.)

May have been created to increase fees

EDITOR—The crisis situation described by Horner's editorial on cremation is not one that I recognise nor would any of my colleagues in other national cremation organisations.¹ A picture of medical referees as "trapped in a system from which there was no escape—required to attend virtually every day, for a fee which does not even pay their travelling costs" makes emotive reading. However, Horner seems to have

Advice to authors

We prefer to receive all responses electronically, sent either directly to our website or to the editorial office as email or on a disk. Processing your letter will be delayed unless it arrives in an electronic form.

We are now posting all direct submissions to our website within 72 hours of receipt and our intention is to post all other electronic submissions there as well. All responses will be eligible for publication in the paper journal.

Responses should be under 400 words and relate to articles published in the preceding month. They should include ≤ 5 references, in the Vancouver style, including one to the BMJ article to which they relate. We welcome illustrations.

Please supply each author's current appointment and full address, and a phone or fax number or email address for the corresponding author. We ask authors to declare any competing interest. Please send a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

Letters will be edited and may be shortened.

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overlooked the fact that there are recommended travelling fees for medical referees which are quite generous.

Interestingly, the author instigated the sending of a questionnaire to medical referees in June 1997. The letter accompanying the questionnaire made reference to the "derisory level of fees paid to medical referees," and the survey was explicitly intended to assist negotiations in a review of the fees paid to them. It is hardly surprising if the answer to questions as to whether fees should be doubled or trebled received a positive response. This was hardly a piece of objective research.

If there are to be any changes to the death certification procedure they should include the implementation of the recommendations made in the Brodrick committee's report² and the prompt elimination of the medical confirmation certificate form C. This form must be signed by a second doctor who certifies the fact and cause of death.

Medical fees incurred by families who require cremation services are already a burden and are the object of a great deal of criticism from within the funeral industry. Those of us involved in the national cremation movement are best placed to see the signs of any impending crisis. In this respect, the author seems to be somewhat of a lone voice as the cremation movement, the Home Office, and the funeral directing profession do not have any experience of the crisis to which he refers.

The illusion of a crisis may be being created to justify increases in fees. This may not be the case but I am sure that that is how many people will perceive the content of the editorial; this perception does not augur well for the reputation of the medical profession.

The claims of a crisis and delays in cremation services are misleading, alarmist, and give a false impression of the present situation. Such claims will do little to comfort the bereaved at a difficult time.

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1 Horner S. Crisis in cremation. *BMJ* 1998;317:485-6. (22 August.)

2 Home Office. *Report of the committee on death certification and coroners*. London: HMSO, 1971. (Cmnd 4810.)

Publication time for letters

Letters are not published fast enough in the *BMJ*

EDITOR—The delay between publication of articles and their commenting letters in the paper *BMJ* is now seriously interfering with the educative importance of the letters, which often radically alters the significance of the article to non-expert readers. Although I wrote this letter electronically, I read the paper journal, as I imagine do most of your readers.

The *BMJ* manages to have special issues such as the Christmas edition and the children's issue. I suggest it is time for a special letters issue. This would contain the

entire backlog of letters for which publication is intended. After publication of this catch up issue an agreed minimum time lag could be introduced. The current lag is not acceptable.

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Editors' reply

We, too, fret about the delay between the appearance of articles and the letters in response to them, and we have several strategies for countering the problem.

Firstly, we have introduced rapid responses on our website. We regard these as a big success, although ironically they have put more pressure on our paper pages by increasing the number of contributions we have to consider. All rapid responses are considered for publication in the paper edition of the journal.

Secondly, we are—when we can—increasing the number of pages we allocate to letters. We will look at increasing the pages still more, but we cannot go too far because pressure on other sections of the journal is also high and our research shows that most readers do not want more letters pages. Taylor's idea of a whole issue devoted to letters would not be popular with readers.

Thirdly, we are increasing our rejection rate. This is inevitable, and the delay has arisen in part because we did not increase our rejection rate fast enough. Fifteen years ago we were able to publish about 60% of letters. Now we are down to 30%, but we probably need to drop to 20%, or even 15%. We have to reject many good letters making cogent points. Authors, needless to say, often protest vigorously. The rejection rate and subsequent protests would be heartbreaking if we didn't have the option of rapid responses. The problem of too many letters is of course in most ways a good one to have: many specialist journals receive few letters.

Fourthly, we are culling letters we've already accepted. This causes much grief among authors, but we need to shorten the delay.

Fifthly, we are increasingly shortening letters and publishing a summary of comments when we receive a great many on a particular subject.

Our aim is to publish letters within six weeks of the articles to which they are responding, but this target will probably take a while to reach. One crumb of comfort is that we are now taking about as long to publish letters as the *New England Journal of Medicine* has taken for years. Has Taylor written to its editor to complain?

Richard Smith *Editor*
Marcus Müllner *Editorial registrar*
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Rapid responses



Rapid responses submitted directly to our website are available on www.bmj.com