



A good death

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A good death

Sharing control in death: the role of an "amicus mortis"

EDITOR—May I offer one further ingredient to a good death as discussed by Smith in his editorial¹—having an "amicus mortis," a friend at death. Most items on his list of principles use the word control or imply it, yet the very process of death entails losing control. Control of strong drugs is especially difficult for the one who is dying. An amicus mortis makes it easy. I wrote the following within days of my wife's death from cancer four years ago, and it was read at her funeral.

"Towards the end I was given the privilege of care. I don't want to belittle the role of the care team. None the less, I was the lucky one in charge, especially at night, and my task was an easy one, aided by small doses of morphine towards the end.

"She had no pain, no distress, no loss of dignity, no catheters, none of the things my patients in hospital have to put up with. In the last week our nightly family parties had to be in her room. Her last hours were tranquil."

The role of amicus mortis is life enhancing, and there should thus be no shortage of supply. I had a further small dose of being an

amicus mortis at the end of last year when my father died. My older brother, enviably in full retirement, played the main part. He closed down his home in the Carolinas for a couple of months for the purpose. He endorses this view.

The chosen person must have time and love and prescribing power. Perhaps it is an unfair advantage to have a doctor-husband or doctor-sons available, but prescribing power can easily be delegated, and the other attributes are just as important.

I fully agree with Smith that there is nothing macabre or morbid about thinking of death and planning your funeral throughout life, but I suggest that it is equally important to choose and cultivate your amicus mortis—and see to it that he (or she) doesn't die first.

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¹ Smith R. A good death. *BMJ* 2000;320:129-30. (15 January.)

Research on dying is scanty

EDITOR—It is true that no one can fully answer Smith's question about the state of dying in Britain.¹ The current fashion for evaluative studies of health service outcomes and the low priority given by grant bodies to descriptive research (generally discarded as needs assessment) have led to an emphasis instead on the costs and outcomes of treatments for the living. Admittedly, surveys of terminal care and bereavement have been conducted.^{2,3} But these, by the very nature of survey design, can only tap the surface. Neither has the more detailed body of research carried out on selected groups of patients (including those in hospices) led to the wider profession or the public being fully informed about death.

Smith's principles of a good death are timely and greatly welcomed.¹ While information about dying should be more widely available, and regarded as less taboo, an informed profession is also required to act in the best interests of patients: to provide them with preparatory information to demand and initiate timely and appropriate help. When people are fortunate enough to have access to a hospice or a good palliative care team they may be given adequate support, information, and preparation. But such services are patchily provided through-

out Britain, which is perhaps inevitable when the NHS largely relies on charity to provide them.

This is not a value free commentary. I speak as one who recently cared, alone, for my 79 year old father, who died at home from stomach cancer in a rural part of England. The individual health professionals involved (general practitioner and district nurse) were caring, kind people, doing their best within an extremely limited system. The only specialised professional was a Macmillan nurse based at the hospital whose role was to advise the very busy district nurses on aspects of their workload relating to terminal care; no help or support was given by Marie Curie nurses because they were "scarce." The outcome was lack of preparation for the distressing final stages, and great difficulty contacting doctors and nurses out of hours at times of need. This, in turn, resulted in totally inadequate pain relief and lack of help with incontinence and distress in the final 24 hours.

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Death's embrace: *Death and a Woman* by Hans Baldung Grien from the exhibition "Grunewald and his contemporaries: paintings from the Kunstmuseum, Basel" in the National Gallery, London, until 21 May 2000

This is just one example of what can happen in the face of a patchy infrastructure for terminal care in this country—but it is one example too many.

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Quality of death can be measured outside hospices

EDITOR—Henry Fielding said: "It hath often be said that it is not death, but dying which is terrible," though striving for a good quality of death for patients¹ should not prevent us saving life and treating disease.

Most scientific work on death applies to death from cancer in hospices, which is greatly different from the experience of death in geriatric wards—for example, in the number of unexpected deaths. We audited the quality of expected deaths in acute inpatient geriatric practice by measuring whether five standards were attained:

- Patients should be free from symptoms (pain, anxiety, dyspnoea, pressure sores)
- Death should occur in familiar surroundings—that is, the patient should not be moved within three days of death
- Relatives should be aware that the patient is dying and be present if desired
- Necropsy should be requested if cause of death is unclear
- The patient's general practitioner should be informed of the death (by telephone within 24 hours) and diagnosis (by discharge summary within seven days).

The table shows the results. We identified issues around the time of death related to symptom control and communication with general practitioners that needed attention within our department.

Results of audit of quality of death in acute inpatient geriatric practice. Values are numbers (percentages) of patients unless stated otherwise

Standard	1995 (n=28)	1998 (n=16)
Patient was symptom free	19 (67)	11 (69)
Patient died in familiar surroundings	18/24 (75)*	15 (94)
Relatives were aware	21/26 (81)†	14 (88)
Necropsy performed if cause of death unclear	1/2‡	1/2‡
GP informed within 24 hours	6 (21)	2 (13)
GP informed within 7 days	6 (21)	6 (38)

GP=general practitioner.

*Four patients died within three days.

†Two patients did not have any relatives.

‡Reflects low rate of necropsy.

Standards of quality of death are universally applicable, though the different emphasis between, say, medical and hospice practice needs to be recognised. We believe that development of these standards will

allow us to measure quality of death in medical and geriatric practice.

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The results of this audit were first presented to the British Geriatric Society in Cork in April last year.

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Principles of palliative care are yet to be applied in acute hospitals

EDITOR—Smith states in his editorial, "There is a suspicion that for the majority who die in acute hospitals or nursing homes the experience is bad."¹ Similar stories abound in Australia even with its well developed palliative care services. However, palliative care is accessible to only some terminally ill patients and usually those dying of cancer. The "good dying" in hospitals still eludes most in Western countries, as indicated by a recent bequest in Toronto, Canada.²

Research commissioned by the South Australian parliament in 1991 found that the majority of respondents considered public hospitals to be unsatisfactory in providing care for terminally ill patients.³ They felt excluded from medical decision-making and had problems in communicating with hospital specialists. This and other anecdotal evidence prompted a group of researchers in South Australia to investigate the care of terminally ill patients in acute hospitals.

Two studies have now been completed observing the care of terminally ill patients during their last six days of life in medical wards in two acute hospitals.^{4,5} The findings indicate that there are barriers to the care when patients are dying, including the strict adherence to hospital routine. Inexperienced health professionals without an understanding of the philosophy of palliative care or the skills required often undertook the care. The data showed that it could be a very isolating experience for patients left alone in a side room, most of whom were unresponsive. The presence or absence of family members influenced the amount of care received.^{4,5} The results of these two studies suggest that the principles of palliative care are yet to be included in the culture of acute hospitals. It is as though the hospital environment reflects the busyness of everyday life in society, which still denies the naturalness and inevitability of death.

Where to from here? The questions go beyond the boundaries of medicine and belong to the human race. While the sanctity of life is overridden so often by the culture of war, and death is portrayed as a successful outcome, we will live with this paradox. There are bigger questions still to be asked about death and dying in society before deaths in hospital are attended with humanity and compassion. I, for one, hope my last days are not alone in a side room in an acute hospital. But I welcome the debate both in medical journals and in all facets of society.

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Care pathway in Wales aims to improve care of dying patients

EDITOR—People always have died and always will die.¹ Palliative care has now come out of hospices and is accepted as a mainstream specialty, influencing care across the NHS. In Wales a care pathway, developed from the work of Ellershaw et al,² is being introduced across the whole region in various care settings, including acute hospitals and nursing homes.

The aim is to improve care of dying patients by implementing agreed evidence based clinical guidelines facilitated through the care pathway. The Clinical Effectiveness Support Unit and the National Assembly of Wales are supporting the process and evaluation.

Results of the pilot study in Bangor have shown important changes in practice, with improved analgesic prescribing. The availability of analgesics to control pain rose from 72% to 98% when the care pathway was implemented. The care pathway thus anticipates potential problems and empowers carers and nurses to give timely and effective interventions.

The pathway ensures that the diagnosis of dying is not attached inappropriately, either too early or late. The relatives are informed of anticipated events and retain choices and control.

We agree with many of the principles of a good death³: indeed, they underpin the pathway. We do not prescribe a lingering death, but all must be aware that the precise moment of death is unpredictable and not in our or anyone's control.

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Older Americans hold on to life dearly

EDITOR—The study of Salkeld et al in Australia of the choices of older patients in hypothetical illness scenarios is particularly pertinent to those of us dealing with patients in nursing homes.¹ We are struck by the

contrasting attitudes and expectations of the elderly patients with whom we are in daily contact. In our experience, most older Americans hold on to life very dearly and usually opt for even noxious treatments, such as chemotherapy, to gain a few months or years of life that is reduced in quality. These attitudes are consistent with observations in patients of 80 years or more who were in hospital, many of them in poor health.² When they were asked to choose between their current state of health or a shorter life in excellent health, over two thirds were unwilling to exchange even 10% of life expectancy for the benefit of excellent health.²

Basic expectations also seem to differ between elderly Australians and Americans. While many would attest to having had a fair or good long life, we rarely hear any suggestion that one has lived overlong or "on borrowed time at the expense of younger people." Patient choices are amenable to influence and alteration.³ The choices of the subjects in the study of Salkeld et al conformed to attitudes and opinions of the investigators, who note in several places that all subjects had already "exceeded average life expectancy." Certainly people are unwilling to lose independence of function or decision, but we cannot readily accept (even for Australians) that 80% would rather be dead than suffer a hip fracture and subsequent admission to a nursing home. (Is there any incidence of suicide or request for death when such events are actually faced?)

This prompts further consideration that advance preferences or directives may not conform with those when crisis is at hand. In abstract discussion (or in living wills) tube feeding, having to breathe on a respirator, and even intravenous treatments are often abjured, but such prohibitions are rarely carried forward when the acute illness is faced. The attitudes of those already in nursing homes with hip fractures might be compared with those of the subjects in the study by Salkeld et al. Our rehabilitation department deals with over 80 patients recovering from hip fracture annually; many remain for long term care. While some of those receiving long term care are depressed, most soon accommodate, adjust, and have a reasonable quality of life.

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New models of journals must be sought

EDITOR—Alderson and Roberts argue that the nature of journals (the fact that in a commercial environment editors choose the more interesting articles on offer) is distorting science.¹ Quite so. But the answer is not to attempt to change the nature of journals (goodness knows, we need better communication) but to seek new models that will separate the validation of science from the reporting of it.

Electronic publishing (where selection on economic grounds is no longer an issue) will enable us to do this, provided we don't get caught up in trying to make commercially based journals what they can never be—bias free.

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- 1 Alderson P, Roberts I. Should journals publish systematic reviews that find no evidence to guide practice? Examples from injury research. *BMJ* 2000;320:376-7. (5 February.)

Population, consumption, and entrapment

Raise living standards to reduce population growth

EDITOR—The *BMJ* marked the passing of the 6 billion mark of the globe's population with a series of articles over which Maurice King cast his shadow.¹ In his article King raised the spectre of an international conspiracy led by the United States which is aimed at preventing free discussion of the possibility that certain countries in the developing world may have become entrapped.² To King, entrapment occurs when a population exceeds the carrying capacity of its ecosystem and is unable to buy in extra food or to migrate elsewhere. Personally, we do not believe in this conspiracy theory and find it significant that, in moving along this path, King has been abandoned even by Charles Elliott, his coauthor for previous articles.³

King's argument has for years been predicated on the idea that entrapment exists in Africa and Asia on a large scale and that therefore a policy of one child for each family must be widely adopted.⁴ Assuming that his diagnosis is correct, King fails to explain how he plans to achieve such drastic measures in countries where couples want to have, on average, six or more children.

China adopted such a policy for years and, although it has had remarkable success, it has been successful using measures that have often been considered coercive. India established a similar, although less draconian, policy of two children per family and has not succeeded in enforcing it easily.

Indeed, it has been pointed out that:

In much of the Third World, contraceptives are readily accessible yet fertility rates remain high. According to the UN family planning agency's

1999 report, 99 percent of Costa Rica's population has access to contraception, along with 96 percent of Haiti's, 93 percent of Zimbabwe's and 89 percent of Peru's. Yet all of these countries have fertility rates well above the level needed to replace those who die ... If fertility levels in developing countries depend first and foremost on the number of children desired by parents, then the population control movement faces a wrenching dilemma. Purely voluntary programs will do little to reduce fertility. Only those population programs that override parental preferences through bribes, bullying, threats or outright coercion will lower birthrates significantly.⁵

We believe that a change in attitude is possible if we raise the global standard of living for couples. This, however, will take both time and effort, and by definition it will not succeed if true entrapment exists. The dilemma that King faces is, therefore, to let us know whether his stated objective—a one child family—justifies the stern, unpopular, totally coercive, and, in our view, unethical measures that will be required.

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*Charles Elliott and Maurice King will be arguing the evidence for the policing of the lockstep at greater length later in the year.

Improve access to contraception to curb population growth

EDITOR—Loefer is right in stating in his letter that in terms of population the adverse "influence of the Pontiff reaches far beyond Catholics."¹ The Pope says that contraceptives are "anti-life" yet they are cost effective in reducing the mortality of both mothers and infants.^{2,3} He is one of the people who influences our culture by portraying "any quantitative concern for population as intrinsically coercive."⁴ As a contributor to the 9 October issue of the *BMJ* in which population was discussed, I think that our omission of a frontal attack on the Pope derived from a fear that this might be counterproductive. This highlights his baleful influence.

Could the lack of any mention of population by Haines et al in their editorial on the International Poverty and Health Network be another manifestation of this influence?⁵ As the authors acknowledged, poverty has many dimensions and not all could be mentioned but population growth is the unrecognised multiplier of most major problems in the world.

It is a vicious cycle: for those living in poverty in rural areas it seems advantageous

to have more not fewer children, given high infant mortality and the "social security" factor ("every new mouth has two hands"). Yet with more children the limited resources of any poor family are further partitioned, bringing smaller shares for all and exacerbating poverty.

There is an added environmental dimension, highlighted by the equation $I = PAT$, in which I stands for the impact on the environment; P is the population; A is per capita affluence (with intrinsic effluence); and T is the per capita impact of technology. (The T factor is lower when the technology is greener.) Science can and will deliver reductions in the T factor but there are absolute constraints. Greener technologies are expensive and are often beyond the means of pre-industrialised countries.

Everyone wants (and poorer people deserve and should be actively helped to obtain) more A factor (affluence). Therefore the P factor (population) should not be left out of the equation by those who wish to alleviate pollution (which hits the poorest people hardest) and ill health related to poverty. Population should not be seen as a constant to which we should forever try to adjust. Human numbers can be stabilised, non-coercively. We are failing to provide the contraceptive services most women now want.^{2,3}

At the end of their article Haines et al had seven excellent recommendations. Knowing the authors, I am confident that they will be pleased to agree one more: making certain that every woman in the world wishing to control her fertility by the use of contraception can actually obtain it for herself or her partner.

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Eradicating war is essential to eliminate poverty and improve health

EDITOR—We welcome the editorial on the International Poverty and Health Network and will encourage Medact to participate in the work of the network.¹

Medact is an organisation of health professionals who are concerned about major threats to health, such as violent conflict, poverty, and environmental degradation. To the editorial's otherwise comprehensive list of objectives we would like to add one which we regard as vital: the elimination of war.

War and the preparation for it are both the causes and the results of poverty.² This is most obvious in countries such as Afghanistan and in many countries in Africa, notably Angola, which have been in the midst of war for decades; at the same time these are among some of the world's poorest countries. Many poor countries spend more on their military than on health and education combined.³ We welcome last year's cancellation of the debts of the 25 poorest countries announced by Gordon Brown, the chancellor of the exchequer, who also specified that the money saved should not be spent on arms. Even more recently, the retiring president of the International Monetary Fund, Michel Camdessus, called on the developed world to stop exporting arms to poorer countries.

The adverse effects that spending on arms has on health care are evident also in developed countries: the NHS underwent its annual winter turmoil and there has recently been a study of the regional inequalities that exist in health care in the United Kingdom.⁴

Of the members of the North Atlantic Treaty Organisation and the European Union, the United Kingdom is among those countries that spend the most on their military, and it is likely to remain so if plans to spend £34bn on the Eurofighter and £15bn on new aircraft carriers go ahead.³ The United Kingdom is also among the countries that spend the least on health care. Yet Lord Robertson at NATO, Javier Solana at the European Union, and sources leaking information from the Ministry of Defence are all pressing for increases in the defence budget. We hope that they do not find themselves in an overstretched NHS accident and emergency department late on a winter's night—or do we?

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Will eradication of *Helicobacter pylori* improve symptoms of non-ulcer dyspepsia?

Studies included in meta-analysis had heterogeneous, not homogenous, results

EDITOR—Jaakkimainen et al's meta-analysis concludes that an improvement in dyspeptic symptoms occurred among patients with non-ulcer dyspepsia in whom *Helicobacter pylori* was eradicated.¹ Unfortunately, there is a small but crucial problem at the heart of the analysis. The authors report that the summary estimates are statistically homogenous, but this is incorrect. In the observational studies the P value of <0.001

indicates massive heterogeneity between the results of the studies included. In the therapeutic trials the P value of 0.046 also indicates heterogeneity.

Meta-analysts faced with such heterogeneity have three choices: they may ignore the heterogeneity and pool the results with a fixed effects model; they may use a random effects model, which takes the heterogeneity into account; or they may decide not to pool the results. In this instance the authors chose to use a fixed effects model despite the heterogeneity. In consequence the confidence intervals of the pooled estimates are narrow and significance is imputed. A random model might well lead to a summary estimate that does not reach significance. The data extracted from the individual trials have not been published in bmj.com so it is not possible to check this.

The authors have carried out a sensitivity analysis of the therapeutic trials and noted that the single regimen trials measured only short term outcomes and were of lower methodological quality. In contrast, the two trials of triple treatment measured outcomes at 12 months and were of higher quality; these trials showed a much smaller summary estimate of eradication, which barely reaches significance (odds ratio 1.4, 95% confidence interval 1.0 to 2.3). There is clinical as well as statistical heterogeneity between these two groups of studies, so a summary estimate that combines both is of doubtful meaning. Thus in my opinion the best option is not to pool the triple treatment and single treatment trials.

For this reason the conclusion that "eradication of *H pylori* was associated with an almost twofold increase in dyspeptic symptoms among patients referred to specialist clinics" is misleading because it is based on a summary estimate that makes no clinical sense and is statistically questionable. Until a systematic review is carried out with a wider search strategy and more robust statistical analysis I do not think this meta-analysis should influence guidelines or clinical practice.

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Competing interests: None declared.

- 1 Jaakkimainen RL, Boyle E, Tudiver F. Is *Helicobacter pylori* associated with non-ulcer dyspepsia and will eradication improve symptoms? A meta-analysis. *BMJ* 1999;319:1040-4. (16 October.)

This meta-analysis is potentially misleading

EDITOR—Jaakkimainen et al carried out a meta-analysis to determine whether eradication of *Helicobacter pylori* will improve symptoms associated with non-ulcer dyspepsia.¹ Their conclusions differ from those that we have reached in a systematic review addressing the same question; we carried out our review for the United Kingdom health technology assessment programme. We are concerned that the authors' paper may provide

a misleading impression of the effect of *H pylori* eradication treatment on symptoms of non-ulcer dyspepsia. Our review was conducted using a protocol peer reviewed by the Cochrane Collaboration and will be submitted to the *Cochrane Library*.

We have identified several problems with Jaakkimainen et al's meta-analysis. Firstly, the search strategy is substantially incomplete, with only one electronic database being searched, no text words used, no "grey literature" included (this literature is important for obtaining papers in press in a fast moving field), and non-English language papers excluded.

Secondly, we believe that there is a potential problem with the selection of trials. Single treatment trials will not have eradicated *H pylori* adequately, and confounding may have arisen where the treatment has benefits on dyspepsia other than *H pylori* eradication (for example, bismuth and erythromycin).²

Thirdly, we are concerned by the exclusion of the trial by McColl et al³ and wonder whether this was because the trial did not exclude all patients with reflux-like symptoms. A list of excluded studies, and reasons for exclusions, should be available in bmj.com.

Fourthly, as discussed by Cates in his response in bmj.com [published above], the misinterpretation of odds ratios as effect sizes, the handling of tests for heterogeneity, and the application of a fixed effects model are all potential flaws in the analysis. Even on the basis of the studies presented here it is simply not true to say that "eradication of *H pylori* is associated with an almost twofold improvement in dyspeptic symptoms."

Fifthly, the quantitative estimate that is required by clinicians and researchers planning trials is a measure of the likely absolute benefit (or number needed to treat) of *H pylori* eradication in non-ulcer dyspepsia. Nowhere in this paper are any figures quoted that could be used to determine what this might be.

The benefit from *H pylori* eradication may be modest, and any application in clinical practice would require careful consideration and a supportive cost effectiveness analysis in comparison with alternative treatments. We would like to extend Fischer's comments in bmj.com⁴ and emphasise how contact with the relevant Cochrane review group is helpful in ensuring quality in all phases of systematic reviews.

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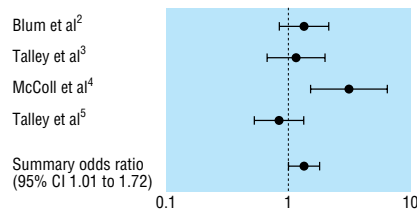
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Meta-analysis included unreliable studies

EDITOR—In their two meta-analyses Jaakkimainen et al concluded, firstly, that "people infected with *Helicobacter pylori* are about one and a half to twice as likely to have non-ulcer dyspepsia compared to controls" and, secondly, that "eradicating *H pylori* results in an almost twofold improvement in dyspeptic symptoms."¹ These conclusions are based on flawed analyses.

In addition to the critique given in several responses about the paper in bmj.com we would like to raise the following points. In the first meta-analysis, of 23 epidemiological studies, Jaakkimainen et al examined the association between *H pylori* infection and non-ulcer dyspepsia. Unfortunately, they failed to eliminate unreliable studies (for example, those in which organic causes of dyspepsia were not excluded by endoscopy (eight studies), those in which the symptom profile of non-ulcer dyspepsia was not defined (five), and those in which the patient and control populations were not matched for age (12). Lack of age matching is particularly important because of the direct relation between advancing age and prevalence of *H pylori* infection.

In the second meta-analysis, of five controlled clinical trials, the authors examined the effect of treatment of *H pylori* infection on dyspeptic symptoms. Here, several criteria should have been applied for the selection of the studies: an appropriate definition of non-ulcer dyspepsia; careful blinding; validated outcome measures of cure of the infection and relief of symptoms; adequate follow up of at least six months; and calculation of a study sample size that is adequate to detect the predefined therapeutic gain. Only two of the five studies fulfil these criteria.^{2,3} A high quality study, published in 1998, was not included for



Odds ratios and summary odds ratio for proportion of patients with complete or almost complete relief of dyspeptic symptoms 6-12 months after treatment in eradication trials

unknown reasons.⁴ An additional negative study has recently been published.⁵

We have conducted a meta-analysis using the four studies that should be included in an up to date review (figure). We did not find significant symptomatic improvement in the group assigned to receive eradication treatment compared with the control group.³⁻⁵ We are convinced, therefore, that both meta-analyses presented by Jaakkimainen et al are flawed and should be disregarded when doctors are deciding whether to treat *H pylori* infection in patients with non-ulcer dyspepsia.

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More studies should have been included in meta-analysis

EDITOR—Studies such as Jaakkimainen et al's meta-analysis on *Helicobacter pylori* infection and non ulcer dyspepsia¹ will help to clarify currently controversial issues. Unfortunately, the authors' conclusions regarding the efficacy of *H pylori* eradication for non-ulcer dyspepsia may be questionable as only five treatment studies were included—a source of bias recognised by the authors in their discussion.

Several key studies were omitted despite apparently meeting the inclusion criteria—namely, being randomised control trials with accepted definitions of dyspepsia and non-ulcer dyspepsia, using accepted and effective eradication regimens, and having symptoms of dyspepsia as a defined outcome measure.

McColl et al randomised 160 patients to omeprazole, amoxicillin, and metronidazole and 158 to placebo. The authors used a validated Glasgow dyspepsia severity score and at one year found a significant benefit in resolution of symptoms for those who had become *H pylori* negative (21% v 7% for

those who remained infected).² Similarly, an earlier study by Gilvarry et al reported a significant reduction in symptoms in patients successfully treated with bismuth, tetracycline, and metronidazole compared with bismuth and placebo (symptom score 14.2 and 9.2 at inclusion and at one year follow up respectively).³

A contradictory, and equally valid, study by Talley et al was also not included for analysis. In that study, 278 subjects were randomised to triple treatment that included a proton pump inhibitor or to placebo; symptom scores at one year did not differ between the groups, but an improvement in symptoms with resolution of chronic gastritis was reported.⁴

Although these studies are not perfect with regard to assessment of compliance, description of the randomisation process, and even presentation (as referred to in the meta-analysis), their design is adequate and their findings significant. Their lack of inclusion in the meta-analysis could affect its findings and conclusions. The jury in the trial of *H pylori* infection is still out; the evidence put forward should include all relevant information.

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Authors' reply

EDITOR—As two letters point out here, heterogeneity exists with the summary estimate of the association studies in our meta-analysis. For this reason we undertook sensitivity analyses to explain the robustness of the estimate and the reasons for statistical heterogeneity. Heterogeneity improved in the subgroup analyses (study design, control of confounders, and study quality), and the summary estimate remained stable. Pantoflickova et al think that studies should be eliminated if dyspepsia is not defined or organic causes not excluded by endoscopy. When we pooled 11 studies meeting these criteria the summary odds ratio was 2.0 (95% confidence interval 1.6 to 2.4).

The summary estimate for the five eradication trials is not generalisable. We base this argument mainly on the lack of robustness of the estimate when we performed the sensitivity analysis. Even though a random effect model may produce a more conservative

estimate,¹ the appropriateness of its use has been debated.²

Inclusion of more studies will indeed produce a more stable estimate. What is not obvious in our paper is that we reviewed more studies than are referenced, including McColl et al's trial.³ We calculated a similar estimate (not published) to that of Pantoflickova et al when we compared improvement in symptoms in groups receiving eradication treatment with that in a control group. Our pooled estimate compared groups in which *Helicobacter pylori* had and had not been eradicated. For this reason, the inclusion criteria for our paper were limited to studies that provided data allowing calculation of an odds ratio in relation to eradication, not just treatment.

The literature search was conducted through March 1999 and did not include studies published after this. The search began with quite broad criteria for including studies, including observational studies and non-randomised trials. We did not include the qualitative review of all studies in our paper, or all the summary estimates. We mentioned in our discussion the point that Delaney et al make about our search strategy. Studies obtained from the "grey literature" rely on the cooperation of editors. This may introduce another selection bias.

Changing clinical practice for a common condition with multiple therapeutic strategies requires a broad look at the literature and a full understanding of the consequences of treatment. For non-ulcer dyspepsia, this includes fully examining acid suppression treatment, motility agents, and lifestyle changes along with eradication of *H pylori*. We do not know why Delaney et al would prefer presenting number needed to treat as the pooled measure. We hesitate to provide this number, given concerns about pooling studies with variations in the background level of risk related to different entry criteria and clinical settings.⁴

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Use of unlabelled and off licence drugs in children

Use of unlicensed drugs may be recommended in guidelines

EDITOR—Conroy et al report the widespread use of drugs that are either not licensed for use in children or are prescribed outside the terms of their product licence (off label prescribing) in children admitted to hospital.¹ Although it is not illegal to use medicines in this way, the responsibility for any adverse events becomes the clinician's or the pharmacist's rather than the manufacturer's. However, much unlicensed use may be recommended in local or national guidelines.

As part of our trust's response to the use of unlicensed drugs in children, I reviewed all drugs recommended in our local paediatric medical guidelines. These contained 69 guidelines for acute management and elective investigation of children. The guidelines recommended 86 drugs, but only 47 (55%) were licensed for use in children. A further 14 drugs were licensed only for children above a certain age or weight, 24 were unlicensed or off label, and the status of one drug (methylcellulose) was unknown. Five drugs used for investigations were not licensed or the licence was restricted. National guidelines also recommend drugs that are unlicensed for use in children.

The British Thoracic Society guidelines for treating tuberculosis recommend that pyrazinamide is given routinely, although this drug is not licensed for use in children.² Primaquine is recommended by national guidelines for use in vivax malaria, although it is unlicensed.³

Paediatric guidelines (both local and national) need to acknowledge the licensed status of the drugs they recommend. Linking guidelines to the Royal College of Paediatrics and Child Health's formulary (*Medicines for Children*)⁴ might facilitate this.

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A European paediatric rule is needed to protect children

EDITOR—Drugs for the paediatric rheumatic diseases are now used in new dosages, through new routes of administration, or in new combinations, but data on safety and efficacy tend to be from small, uncontrolled series. Moreover, most if not all of the drugs for the paediatric rheumatic diseases are

prescribed outside the terms of their product licence (used off label) in most European countries, as described by Conroy et al.¹

Childhood chronic illnesses with high morbidity should be the target of intense research aimed at ameliorating or curing the disease. Yet securing funding for trials in children is difficult: the pharmaceutical industry has little interest in funding these trials, the potential market is small, the enrolment period is long, and most childhood chronic conditions are rare illnesses.

To address these problems, in 1996 a European network called the Paediatric Rheumatology International Trials Organisation was founded to facilitate and coordinate the development, conduct, and reporting of clinical trials with or without the support of pharmaceutical companies. Thirty two countries now belong to the organisation.

In 1997 the organisation obtained a three year grant from the European Union for a randomised controlled clinical trial of medium and high dose parenteral methotrexate in children with juvenile chronic arthritis that does not respond to standard doses. This trial is built on the current standard of care where the costs of insurance coverage, medications, clinic visits, and laboratory tests are paid by the usual method of medical reimbursement—that is, through a national health system or medical insurance system. Interestingly, approval by an ethics committee has been denied in four countries because of lack of insurance coverage, because of lack of support by a pharmaceutical company, and because drugs were not given free of charge.

The problems faced by the organisation, and surely by other paediatric groups, in dealing with pharmaceutical companies and ethics committees underline the difficulties of designing and conducting clinical trials for children, especially if the issue is to seek approval from regulatory agencies.

As stated by Conroy et al,¹ the European Medicines Evaluation Agency² issued guidance on the clinical investigation of medicinal products in children that simply encourages companies to investigate drugs in children when clinically appropriate.³ The same difficulties led the Food and Drug Administration to issue the “paediatric rule,”^{4,5} by which manufacturers of products likely to be used in children have to test those products in the relevant paediatric population.

Like Conroy et al, we urge the European Union and the European Medicines Evaluation Agency to issue a similar paediatric rule for the European Community to assure children and their families the same rights as adults to receive drugs that have been fully tested.

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Prescriptions on bioterrorism have it backwards

EDITOR—Rosen makes several factual misstatements in his editorial on bioterrorism.¹ For example, the vaccine for anthrax has been shown to be effective only for the cutaneous form of anthrax and not for the inhalation form used in weapons.² He states that anthrax vaccine is not being produced, but the Pentagon has embarked on a massive effort to produce this vaccine and to inoculate all US troops on active duty. This programme is now under sharp attack in Congress for possible adverse effects and lack of scientific justification.³ The statement regarding bioterrorism that “... it is hard to raise money to defend against a problem that has such a low incidence”⁴ seems reasonable, but is just not true. Last year, the United States allocated \$10bn (£6.25bn) for anti-terrorism, with a substantial portion for bioterrorism.⁴ In contrast, food borne diseases, which have high morbidity and mortality, have received far less attention and fewer resources.

Rosen does, however, make some important observations. Bioterrorist attacks have indeed been rare. The incident in 1984 in Oregon with no fatalities and the two chemical attacks in Japan in 1994-5 mentioned in the editorial are the only ones documented.

We agree with Rosen that: “It has also become apparent that the management of any biological attack must depend on systems already in place for managing new diseases or new epidemics of old diseases. Unfortunately, US public health surveillance systems are not modern, and there has been little thought about how an epidemic might be recognised quickly. Most state public health departments are underfunded and do not have the staff to investigate anything more than a recognised epidemic.”¹

Sadly, Rosen's prescription to encourage antibioteerrorism programmes is likely to make this deplorable situation worse. Some programmes, such as secret research sponsored by the military that could trigger a new arms race in chemical and biological warfare agents, are inherently dangerous.⁵ Diverting resources and attention to the “unusual and infrequent event”¹ of bioterrorism increases vulnerability to the mun-

dane but deadly everyday problems such as chronic and infectious diseases and environmental insults.

In short, the proponents of antibioteerrorism programmes have it backwards. Instead of pumping more resources into ill advised and risky antibioteerrorism programmes, we should build national and international public health systems that can adequately reduce, detect, and respond to natural disease outbreaks and industrial chemical spills. Then, in the unlikely event of a bioterrorist attack, these systems will be available to manage the challenge.

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Pathogen causing infection related to body piercing should be determined

EDITOR—We accept Ferguson's contention that wearing body jewellery is essentially a personal experience,¹ but such jewellery does have clinical implications.² Maybe Ferguson would not be astonished at having been asked to remove his ornaments if he appreciated that x rays cannot penetrate steel and that the ornaments may have been creating diagnostic difficulties. This would be especially true if computed tomography was being performed. Requests to remove body jewellery may be clinically necessary and should be seen as part of the process of saving a life.

In this era of evidence based medicine, with doctors being urged to reduce use of antibiotics, we were surprised to read the author's recommendation of the blind treatment of infections related to body piercing. Ferguson recommends the use of flucloxacillin on the grounds that these infections are likely to be caused by *Staphylococcus aureus*, without any supporting evidence. The microbiology of infections related to body piercing has not been determined, although the bacteria associated with surgical sutures and staples have been. These are a mixed flora, with *S epidermidis* the commonest organism; the bacteria are enveloped in a complex biofilm, which is thought to protect the organism from host defence factors and to account

for their persistence on suture surfaces until they are removed with the sutures.³

Genital piercing is more likely to be infected with bacteria from the periurethral microflora. *Escherichia coli* is the commonest bacterium to cause urinary tract infections,⁴ but it cannot be assumed to remain the infecting pathogen in the presence of a foreign body. Intraoral piercings are likely to be infected with oral commensals.

We believe that body jewellery associated with infection should be removed and an antibiotic decided on after signs of local and systemic dissemination have been examined.

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Patient information systems are not more expensive than leaflets

EDITOR—Graham et al, who compared a touch screen system with leaflets for providing women with information on prenatal tests,¹ and Wyatt in his commentary² may be too conservative in their conclusions. Graham et al mention the cost of developing the system and Wyatt says because there is limited evidence of benefit for these expensive tools over well designed leaflets they should be used only in the context of rigorous research studies. However, the study did not include an economic comparison of the use of the computer and leaflets. A full economic analysis would compare the estimated development costs of £25 000 and the subsequent maintenance costs with the costs of the alternative. It would then compare the costs with the marginal benefits during the period that the system is in use.

If the system is readily transferable to another site, development costs at that other site would not be anywhere near £25 000. Given the high volume of use that could be achieved in antenatal care, the cost per patient could be small. For example, use of a computer with touch screen and a printer costing £2000 capital with 5% maintenance in years 2-4 might have a four year cost (without discounting) of £2600. Aberdeen Maternity Hospital had 4734 deliveries in 1997, a mean of 13 a day.¹ If, over four years, 10 000 women (53%) used the system, the attributable cost per woman is 26 pence. This may compare favourably

with the cost of leaflets. In our own study of patients with cancer,³ maintaining a computer system (and replacing it after four years) was cheaper than giving full access to the expensive cancer booklets (typically £3.00 each).

Although Graham et al found no difference in knowledge, they did note a reduction in anxiety in the intervention group. Is the possible reduction in anxiety worth 26 pence per woman? The marginal benefits are attenuated by the fact that, as Graham et al and Wyatt point out, this group in the Aberdeen population had a good baseline knowledge of prenatal tests, so only minor improvements in knowledge may be achievable in that context. More than half of their sample (55%) came from affluent areas. Evaluation of the system in an area of high deprivation, where non-print media may have benefits over the written word among a population with lower literacy and knowledge levels, may show different outcomes.

Further evaluation, including economic analysis, of the use of the system in an area with higher levels of deprivation is worthwhile and would also show the feasibility of "technology transfer" for such systems. However, the simple costing exercise in this letter may show that Wyatt is wrong and that the system should continue in routine use in Aberdeen.

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Joint committee on postgraduate training for GPs needs more money for its work

EDITOR—Since 1976 the Joint Committee on Postgraduate Training for General Practice has presided over the standards of vocational training in general practice in the United Kingdom. Despite the committee having a relatively low profile compared with the two other competent authorities in the United Kingdom (the General Medical Council and Specialist Training Authority) its influence extends well beyond general practice. It is responsible for approving training posts for intending general practitioners in hospitals and primary care and has tried to improve training for senior house officers in all disciplines.

Unfortunately, its low profile has been reflected in the value and support afforded it

by the government. Its crucial role in ensuring quality training is now threatened.

In 1997 the committee's outgoing chairman, Denis Pereira Gray, opened discussions with the Departments of Health over remuneration for the three officers. A proper rate was set for these posts, and the minister of health gave support in principle. Meanwhile, ad hoc arrangements ensure that some financial recompense is available to the officers from other, inappropriate sources. The activities of the Specialist Training Authority and General Medical Council are supported by charges on doctors. The joint committee has no power or inclination to charge for its certificates.

For many years the government has supported standard setting by medical royal colleges in the form of a grant in aid. In 1975 the Royal College of General Practitioners decided to transfer all general practice grant in aid to the joint committee and to supplement it with a matching sum. The grant in aid for general practice compares unfavourably with that for other disciplines. In 1995 (latest available figures) standard setting costs for the United Kingdom's 33 000 general practitioners were supported by a grant in aid of £58 725—in stark contrast to the £48 649 and £38 532 for 2900 career grade pathologists and 750 ophthalmologists respectively.

A 1998 government review of grant in aid praised the committee's efficiency and frugality.¹ Its financial problems now threaten its core regulatory functions.

Despite the voluntary return in 1998 of unused funds because of an unfilled post, the Department of Health requires a reduction of 7.5% in budgets for the year 2000-1 (or over 10% if pension contributions are taken into account). Consequently, with cramped premises, barely sufficient staffing, and increasing statutory responsibilities, the committee is faced with reducing its services. This government demands quality in the NHS and looks to its competent authorities to mediate and promote it. Ironically, this very quality is now endangered by the government's shortsighted parsimony.

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Rapid responses

Correspondence submitted electronically is available on our website