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# Letters

## Developing primary palliative care

### Completion of community palliative care management form should be mandatory

EDITOR—Murray et al propose that people with terminal conditions should be able to die at home with dignity.[1] They fall short of initiating a practical, pragmatic, less idealistic, cost neutral solution.

Once a patient has been identified as requiring palliative care by their criterion "Would I be surprised if my patient were to die in the next 12 months?" a simple procedure should compulsorily take place. A form detailing palliative care management should be completed by the patient's general practitioner. This form should include details of the diagnosis, prognosis, and management plans and be emailed or faxed to the out of hours provider—the "unscheduled care services" to which the editorial refers. Additionally, any scheduled drugs that may be required to keep the patient at home should be prescribed and delivered to the patient's home. If these two simple procedures became part of a national plan, many (not all) of the problems that arise in the community would be overcome.

The gold standards framework and development of education and research programmes are commendable. These require adequate time and resources, as well as the willingness of healthcare professionals to participate. In a health system with limited resources, improving efficiency and using existing resources is where this programme should begin.

In hospital medicine completion of a "do not resuscitate" form is mandatory. Completion of an equivalent form for palliative care management in the community should be compulsory too. Only with a compulsory procedure where accountability and responsibility can be identified will terminally ill patients be able to access appropriate palliative care.

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Competing interests: None declared.

1 Murray SA, Boyd K, Sheikh A, Thomas K, Higginson IJ. Developing primary palliative care. *BMJ* 2004;329:1056-7. (6 November.)

### Changed role of general practitioners has been taken into account

EDITOR—To say that general practitioners should be in the front line to provide palliative care, as Murray et al say in their editorial,[1] is to misunderstand totally the changed role of general practice in primary care. From today most general practitioners in the United Kingdom will have given up their commitment out of hours, and the health boards must have made alternative on call arrangements.

General practice is responsible for 25% of the week's on-call; the other 75% is being covered by the new out of hours organisations. Between 6 00 pm on a Friday and 8 00 am on a Monday there are 62 hours of out of hours cover. A lot can happen in 62 hours.

A patient's general practitioner can be involved in setting up a care plan and can pass that information on to the out of hours service, but it is no longer possible for most general practitioners to be involved personally, or as a practice, in the out of hours provision of that care.

I have seen how complex some palliative care can become. At times, front rooms resemble intensive treatment units, with the amount of equipment and pharmacology that patients need to be kept comfortable in their own home. One really has to question the sense of bringing the hospice into the house.

If more patients are to be given the right to die with dignity at home then resources will have to be increased. Specialist palliative care nurses should be given more autonomy, with an increase in their prescribing powers so as to avoid the current nonsense where out of hours doctors must drive to a patient's house just to sign forms such as the authorisation for an increase in syringe driver rates.

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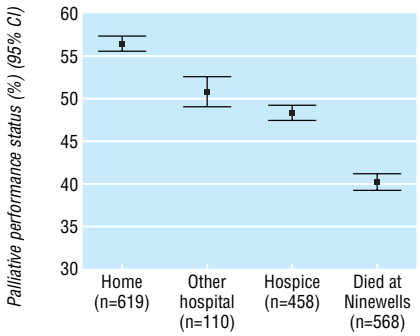
Competing interests: None declared.

1 Murray SA, Boyd K, Sheikh A, Thomas K, Higginson IJ. Developing primary palliative care. *BMJ* 2004;329:1056-7. (6 November.)

### Community palliative care services are not sufficiently funded

EDITOR—Murray et al say that community palliative care should be available to more patients, including those with non-malignant disease.[1] We report the reality of achieving community care for patients discharged from a cancer centre.

Data from 2000 consecutive patients referred to a hospital palliative care team were collected prospectively. Outcome was categorised as discharge home (patient's or carer's); transfer to another hospital or nursing home, transfer to specialist palliative care unit, died in Ninewells, or referral back to original medical or surgical team. Performance status, using the palliative performance scale (see bmj.com for details), was determined at referral.[2]




Outcome after referral to specialist palliative care in relation to palliative performance status

Altogether 96% had cancer and 4% non-malignant disease. On average, patients were in their late 60s (median 69 years) and able to do little for themselves (median palliative performance score 50%). Thirty five per cent (703) were bedbound all or most of the time, and 38% (755) lived alone.

Thirty one per cent (619) were discharged home, 28% (568) died in Ninewells; and 28% were transferred to another place of care (458 to a hospice, 110 to a district or community hospital or nursing home). Twelve per cent (245) were discharged back to the referring team.

Patients discharged home had a better performance status than those who did not (figure). The probability of getting home with a performance status of 60 or more was better than 1 in two patients (55%; 343/619), but as performance status fell to 40 or less, probability was $<1$ in 10 patients (9.5%; 67/703).

Current community palliative care services are not sufficiently funded to offer a serious alternative to acute hospital care for most patients.

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Competing interests: None declared.

1 Murray SA, Boyd K, Sheikh A, Thomas K, Higginson IJ. Developing primary palliative care. *BMJ* 2004;329:1056-7. (6 November.)
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P+ *Details of the palliative performance scale are on bmj.com*

## Screening may not reduce suicide in later life

EDITOR—O'Connell et al are wise to warn against a reductionist approach to the complex topic of suicide in older people since an epidemiological perspective makes older people who commit suicide into objects of disease processes rather than subjects struggling to control their lives.[1] They also prescribe vigorous screening and aggressive treatment despite the difficulties in reaching the highest risk group, reluctance to accept stigmatising labels, and the limited efficacy of available interventions.

Much seems to depend on the meaning of problems for individual people. Proud but rather rigid people who would rather not live if unable to do so with their normal vigour may opt for suicide, especially if depressed mood alters their judgment about their illness or disability. Older men living alone whose lives are changed for the worse by loss may be the highest risk group, but they may also be those least likely to engage with services.

We do not advocate therapeutic nihilism, but the limitations must be understood. Coping strategies built over a lifetime can collapse under the impact of successive adverse events, and professionals' ability to influence either coping strategies or adverse events is limited. A perceived failure to prevent suicide can have adverse effects on social and healthcare workers, so policies for identifying those at risk need to be realistic. Better management of disabilities, improved pain control, and greater financial security for vulnerable older people, with antidepressant and psychological treatments on offer to those with depression symptoms, may be more positive approaches than vigorous screening.

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Competing interests: None declared.

1 O'Connell H, Chin A, Cunningham C, Lawlor B. Recent developments: suicide in older people. *BMJ* 2004;329:895-9. (16 October.)

## Side effects deserve greater emphasis at end of life

EDITOR—We agree with many of the points made by Stevenson et al on managing comorbidities at the end of life, particularly the emphasis on assessing the overall benefits of treatment kept in perspective through numbers needed to treat or absolute risk reduction, often much smaller than the relative risk reductions more commonly cited.[1 2]

We believe that side effects deserve greater emphasis. Pharmacokinetics and sensitivities to drugs are often more marked and less predictable in disease, as Stevenson et al say. With this comes an increased risk of doing harm. For example, the risk of oesophageal perforation associated with bisphosphonate treatment is increased because of reduced oesophageal motility and difficulty remaining erect for the requisite half hour.

The authors say that current and emerging evidence can help generate a framework to improve clinical decision making in patients at the end of their life. The patient population discussed is invariably excluded from the trials investigating many of the conditions mentioned. For these patients, the same effects of treatment cannot be assumed, and decisions must be made empirically. This is a situation that we cannot envisage changing.

One recently described approach that may help guide clinicians involves dividing patients into four categories according to the style of care provided—aggressive management, usual, palliative (emphasis on symptom control but no secondary prevention), and terminal care. [3]

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Competing interests: None declared.

1 Stevenson J, Abernethy AP, Miller C, Currow DC. Managing comorbidities in patients at the end of life. *BMJ* 2004;329:909-12. (16 October.)
2 Bogaty P, Brophy J. Increasing burden of treatment in the acute coronary syndromes: is it justified? *Lancet* 2003;361:1813-6.
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## Paediatric cardiac surgical mortality after Bristol

### Details of risk adjustment tools were not given

EDITOR—The paper by Aylin et al on paediatric cardiac mortality in England after Bristol provides some interesting and potentially perturbing results.[1] The reduction in paediatric cardiac surgical mortality is encouraging, but the identification of hospitals with excess mortality is worrying.

Since 2003 all paediatric intensive care units in England and Wales have contributed data on all admissions to the paediatric intensive care audit network (PICANet), funded by the Department of Health.[2] Families of patients treated in paediatric intensive care units in the United Kingdom may be reassured that in the data thus far reported no unit has an unexpectedly high mortality.

The method of analysis used by PICANet may be superficially similar to that used by Aylin et al, but on closer inspection it may not. PICANet produces mortality ratios that are carefully adjusted for the illness severity of children on admission to the unit using published risk adjustment tools.[3] This results in clearly different distributions of mortality ratios by unit when plotting crude (unadjusted) and adjusted mortality. Thus, ranking units according to their mortality will result in a different order when using crude and adjusted mortality. This phenomenon has been found elsewhere when good quality risk adjustment is applied.[4 5] It is curious therefore that the distribution of crude mortality seen in Aylin et al's supplemental figures is almost equivalent to that of the adjusted odds ratios seen in the main paper.

Although, with perfect risk adjustment this can happen, a more likely and troubling cause could be the lack of valid and appropriate risk adjustment. Aylin et al do not describe the method of risk adjustment. The NHS must identify areas of the service that are falling behind in performance, but valid, reliable, and robust scientific techniques must be used to do this. To provide reassurance and therefore support to their work, Aylin et al must provide clear details of the adequacy of the risk adjustment tools they used in this study.

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1 Aylin P, Bottle A, Jarman B, Elliot P. Paediatric cardiac surgical mortality in England after Bristol: descriptive analysis of hospital episode statistics 1991-2002. *BMJ* 2004;329:825-7. (9 October.)
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### Paediatric cardiac hospital episode statistics are unreliable

EDITOR—The lack of accuracy of the hospital episode statistics used by Aylin et al to analyse the paediatric cardiac surgical mortality in England after Bristol is worrying.[1] Indeed, Aylin's group reported that hospital episode statistics "manifestly contain errors" and that their available data sources "have such clear limitations that one could ask whether any reliable conclusions can be drawn."[2] We have also shown hospital episode statistics data to be inaccurate for this complex specialty.[3]

This latest study raises more concerns about hospital episode statistics data, showing that errors are not consistent across the country.[1] A centre with a high proportion of outcome returns from hospital episode statistics (Oxford, for example) would almost inevitably identify more deaths than one with low returns, potentially giving a false impression of relative surgical performance.


MAURO FERMARIELLO/SPL

The central cardiac audit database collects, validates, and analyses data from all UK paediatric cardiac units, centrally tracking mortality using direct links to the Office for National Statistics (where all deaths in England are registered). It started collecting data in 2000, so it does not have comprehensive data for comparison with all the epochs described by Aylin et al, but it has data on 2913 infants who had open heart operations in England during 2000-2.

Aylin et al report only 2607 infant operations in epoch 6 (1999-2002), which implies serious errors in their case ascertainment. They report an overall English perioperative mortality for infant open heart operations in epoch 6 of 4%, with 105 deaths identified over the three years. The central cardiac audit database has identified 185 deaths (7.8% mortality) in the cohort of 2385 open heart infant operations during 2000-2, its validated, centre specific mortality for all open heart infant operations in England for 2000-2 ranging between 3.3% and 10.7%. Two centres had higher mortality than Oxford, in contrast to Aylin et al's report. The 95% confidence intervals for difference in mortality between Oxford and all of England were −4.1% to 8.7%, a large overlap, which means any difference is statistically insignificant.

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Competing interests: None declared.

1 Aylin P, Bottle A, Jarman B, Elliot P. Paediatric cardiac surgical mortality in England after Bristol: descriptive analysis of hospital episode statistics 1991-2002. *BMJ* 2004;329: 825-7. (9 October.)
2 Aylin P, Alves B, Best N, Cook A, Elliott P, Evans SJ, et al. Comparison of UK paediatric cardiac surgical performance by analysis of routinely collected data 1984-1996: was Bristol an outlier? *Lancet* 2001;358:181-7.
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**Authors' reply**

EDITOR—Parry et al call for clarity of our methods for risk adjustment. We adjusted by type of operation, by incorporating the 11 open procedure groups as factors into our regression model. The use of procedure groups for risk adjustment is in line with another published method.[1] In contrast, recently published centre comparisons based on the central cardiac audit database were not risk adjusted.[2]

Gibbs et al and Morris and Archer on bmj.com remain concerned by the lack of accuracy of hospital episode statistics.[3] Work commissioned by the Bristol inquiry showed reasonable agreement between these and the UK cardiac surgical register. Hospital episode statistics also recorded 99% of 30 day postoperative deaths in hospital for the procedures of interest.[4] Morris and Archer confirm that the Oxford centre was approached by the Department of Health in 2001 on the basis of both hospital episode statistics data and cardiac surgical register returns since 1995, in which it was thought that it was an outlier with respect to transposition of the great arteries in infants.[3] Oxford was also aware of a possible downturn in its results and consequently ceased such surgery in 2000 (J Morris, personal communication).

Differences between analyses of the central cardiac audit database and our own are not necessarily inconsistent.

Firstly, we look only at mortality in hospital, and results published from the database include all perioperative deaths.

Secondly, hospital episode statistics lack an indicator to specify whether an operation is open, and so this must be inferred from the operation code. We exclude any operations that could be either open or closed, which could account for the alleged shortfall. However, we also examined mortality in a group of 11 well defined open procedures, which gave similar results between centres.

Lastly, Gibbs et al provide central cardiac audit database results for a different time. Oxford has confirmed to us that it stopped transposition of the great arteries because of several deaths in late 1999 (hence included in our analysis but not included in figures from the central cardiac audit database) and early 2000 (J Morris, personal communication).

Hospital episode statistics is the only available database spanning our period of analysis from 1991 to 2002. It is coded independently of clinicians and is available for public scrutiny. Further collaborative work to identify and correct inconsistencies between hospital episode statistics and clinical datasets might be a useful consequence of our work and could enhance the credibility of both sources of data.

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Competing interests: The work was funded by Dr Foster Limited. BJ served on the panel for the Bristol Royal Infirmary inquiry. PA was an expert witness for the inquiry.

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4 Aylin P, Alves B, Best N, Cook A, Elliott P, Evans SJW, et al. Comparison of UK paediatric cardiac surgical performance by analysis of routinely collected data 1984-96: was Bristol an outlier? *Lancet* 2001;358:181-7.

## Patients' interests: paramount in randomised trials

EDITOR—Patients and the public recognise the need for large randomised trials. Trialists must also recognise the responsibilities they owe to their study participants. There has been some debate on whether these responsibilities are always fully discharged.

The early stopping of the MA17 trial, with data released to the media before the trial participants or health professionals had been given time to assess the implications, led to speculation in the medical press about how far patients' interests were being considered.[1] Similarly, recent articles have alleged that several pharmaceutical companies may have withheld product safety data, ranging from harmful effects of paroxetine in adolescents, to cardiovascular events associated with rofecoxib, with consequent speculation about the possibility of similar adverse effects from other COX-2 inhibitors.[2 3]

Sir Tom McKillop, the chief executive officer of AstraZeneca, said: "If we put consumer protection as the only thing the regulator needs to worry about, that will be a huge block to progress and innovation."[4] This may dissuade potential trial participants from entering studies because of a perceived (or real) lack of concern for their welfare and rights.

Research must be based on collaborative partnerships between patients and professionals in industry and academia—a key objective of the National Cancer Research Institute. This approach will help ensure the proper conduct of clinical studies, reduce treatment uncertainties, help patients to understand potential risks and benefits, and

improve the public perception of clinical research.

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Competing interests: None declared.

1 Baum M. Current status of aromatase inhibitors in the management of breast cancer and critique of the NCIC MA-17 trial. *Cancer Control* 2004;11:217-21.
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## Placebos in medicine

### Placebo use is well known, placebo effect is not

EDITOR—In their paper on the use of placebos in clinical practice, Nitzan and Lichtenberg say that they were unable to find more than one other study on the use of placebos in a clinical context.[1 2] Eight similar studies are indexed in PubMed (see bmj.com).

In the accompanying editorial, Spiegel points out that the Cochrane review on the placebo effect probably underestimated the placebo effects of treatments.[3 4] Spiegel gave some methodological explanations for this underestimation but did not mention a much more important reason.

A problem with the Cochrane review, as mentioned in three letters by Lilford and Braunholtz, Kuppers, and Shrier,[5] is that the included studies were done in a setting completely different from the situation in clinical practice. The included studies are three armed studies, in which patients are randomly allocated to a supposedly active treatment, to a placebo, or to no treatment. The placebo effect is then defined as the difference in effect in the patients receiving placebo compared with those receiving no treatment.

Obviously, neither the patient nor the doctor in such a trial will have any substantial belief in the (placebo) treatment or consider it particularly meaningful. This situation is completely different from clinical practice, where the patient and the doctor believe in the therapeutic powers of a treatment that they probably consider meaningful. The difference between randomised trials and clinical practice is always a problem, but much more so in the study of placebos and related phenomena. This is one of the main reasons why the Cochrane review does not exclude the existence of strong placebo effects in some situations of clinical practice.

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Competing interests: None declared.

1 Nitzan U, Lichtenberg P. Questionnaire survey on use of placebo. *BMJ* 2004;329:944-6. (23 October.)
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P+ *Details of eight studies of placebos are on bmj.com*

### Medical paradoxes need disentangling

EDITOR—As Spiegel's editorial highlights,[1] paradoxes around the placebo effect can be overcome by distinguishing between a dummy pill and the effects of thoughts, feelings, and human relationships.[2]

Placebos may seem like a less toxic solution than pharmacological treatments for functional or chronic conditions but this carries side effects—disrupt trust, and outcome is disturbed. Doctors in Israel give placebo treatments without informing their patients, at trial closure investigators often don't tell people if they got placebo,[3] and patients often turn to complementary medicine without informing their doctors.

The issue should not be about prescribing placebos but rather about the need to increase our general knowledge around healing mechanisms,[4] to harness directly what placebo harnesses indirectly, in an ethical and practical manner, encouraging a sense of trust and partnership between the public and healthcare specialists.

Placebo effect research presents evidence of the extent to which individuals possess natural self healing capabilities that can be nurtured in a healthcare interaction.[5] A medical system that does not place central value on doctors taking time to establishing safe, trusting and collaborative relationships, is not "evidence based" and ignores the obvious impact on outcome from the quality of human caring, becoming less cost effective in the long run.

It is time we stop considering perceptions, feelings, and human interactions in health care as variables that need to be controlled in the pursuit of medical science but include and study these as critically meaningful mediators and moderators of therapeutic outcomes in clinical trials, and daily care.

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1 Spiegel D. Placebos in medicine. *BMJ* 2004;329:927-8. (23 October.)
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### Is placebo analgesia always in the mind?

EDITOR—Spiegel discussed placebos in medicine.[1] A study published in the 1979 edition of *Advances in Pain Research and Therapy* offered a tantalising glimpse of a possible mechanism for placebo analgesia.[2]

A hundred or so patients who had their wisdom teeth extracted were assigned (random double blind) to a fixed dose of an opiate or the same volume of saline for postoperative analgesia. The difference in the proportion of patients in the opiate versus the saline group who expressed satisfactory pain relief did not reach significance. Placebo analgesia worked in a case of organic pain, postoperative pain.

The researchers then broke the code after collecting analgesia data and then randomised (again double blind) the saline responders to saline or a dose of naloxone. All the saline responders who received naloxone complained of their pain again. This indicates that endogenous analgesic systems of encephalins or endorphins might be important.

So is placebo analgesia all in the mind? Or does the mind work through known neuropharmacological pathways?

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Competing interests: None declared.

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2 Levine JD, Gordon NC, Fields HL. The role of endorphins in placebo analgesia. In: Bonica JJ, ed. *Advances in pain research and therapy*. Vol.3. New York: Raven Press, 1979: 547-51.

### Pain that is relieved by placebo is not therefore unreal

EDITOR—In his editorial on placebos in medicine Spiegel rightly says that it is not because pain is relieved by placebo that it is not real.[1]

I would go one step further. As Professor Raymond Villey, one of my teachers in Caen, told me almost 30 years ago: "Beware of the pain that cedes to placebo: it's most certainly organic."

I have seen that proved again and again. I have no explanation other than the one given for the soldiers at Anzio: the patient with "real" pain wants it to go away so much that any straw will be clutched at to relieve the pain, including placebo. On the other hand, the patient with "psychological" pain gains from the pain in some manner. There will be much less incentive to see the pain relieved, and placebo may be as ineffective as the other pain treatment.

As for the dose-response to placebo, in clinical trials the adverse reactions to placebos of high dose non-steroidal anti-inflammatory drugs are much more common than those to placebos of low dose non-steroidal anti-inflammatory drugs.[2] Explanations to the fore, please.

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Competing interests: None declared.

1 Spiegel D. Placebos in medicine. *BMJ* 2004;329:927-8. (23 October.)
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