Ethical market in organs

Market of organs is unethical under any circumstances

EDITOR—Although we admire Harris and Erin's commitment to solve the dilemmas posed by a shortage of organs, we strongly disagree not only with their conclusions but also with their assumption—namely, that the selling and buying of human organs can be made ethical.¹

Harris and Erin harness their theory to the laudable commitment to raise donation rates but arrive at the definition of an ethical market by promoting a system that seems to depend only on a restricted group of citizens—those who find the monetary incentives proposed appealing.

Firstly, the integrity of the human body should never be subject to trade. Can we truly define this system as ethical because the selling and buying of organs is administered by the state?

Secondly, how can a system be called ethical when it implicitly penalises the weakest people and exacerbates discrimination based on census? Will a healthy well-off citizen ever decide to give away part of his or her body for monetary gain? Donation rates might be boosted, but, although both the rich and the poor will continue benefiting from transplantation indiscriminately, organ procurement will be increased only by contributions from poor people.

Any commitment towards raising donation rates can be better channelled by using targeted investments, as shown by our experience at the Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione (ISMETT), a transplant programme recently established in an area with a large shortage in cadaveric organs. Living donation was vigorously pursued from the start of the programme in July 1999. Of 120 transplants

performed to date (livers and kidneys), 33% have been from living donors, all family related. At the same time, however, considerable energy has been invested in promoting cadaveric donation. Those efforts have been rewarded by a 314% increase in the donation rate (from 2.8 donors per million in 1999 to 8.9 in 2001).

Any financial incentive to organ procurement, even if government regulated, must be avoided as it dangerously undermines human dignity by obscuring the difference between being human and marketing. We recently expressed our concern about the American Medical Association's suggestion of exploring monetary incentives for organ donation,² and we are frightened by the enthusiastic support for it by such notable experts as Harris and Erin.

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1 Harris J, Erin C. An ethically defensible market in organs. *BMJ* 2002;325:114-5. (20 July.)

2 Marino IR, Cattoi A, Cirillo C. Health at any price. *Italianeuropet* 2002;3:170-80.

Proposal is problematic

EDITOR—The American Medical Association may be eight years behind a proposal from Harris and Erin for an ethically defensible market in organs,¹ but they in turn were three years behind my proposal that the NHS become the sole purchaser of live donated kidneys.²

One serious potential problem with such a proposal, referred to by me but not by them, is the impact it may have on the cadaveric donation of organs other than kidneys (which cannot be the subject of live donation). If the market in live kidneys leads to a collapse in organ donation, heart and liver transplantation could be seriously damaged. I know of no way of assessing how serious this danger is other than empirically.

The assertion in some rapid responses that a net flow of organs from the poor to the rich would result is not a good argument against a market.³⁻⁵ Even though it is probably true, the consequence would be a net flow of cash from the richer (via taxation and the NHS budget) to the poorer, which is surely a

good thing. How can reducing the options open to poor people be to their benefit? It is notable that those who argue that poor people should not be allowed to sell organs are in general not poor themselves.

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Defending the indefensible?

EDITOR—We welcome the continuation of the debate on the ethics of buying and selling organs from living donors.¹ Unfortunately the statement by Harris and Erin, with its strong advocacy of paid donation, misses some important issues.

They propose that the market would be made ethically defensible by being monopolistic and having the NHS as sole purchaser, which avoids potential donor exploitation. The NHS is an unusual health-care delivery system, being "free at the point of delivery." This argument must not be allowed to slide into justification of such a market in a mixed healthcare system where people who can afford it take up private health care, as this continues the risk of exploitation of vulnerable donors.

Even if the monopolistic broker is an NHS-like beast, no guarantee exists that it would not still prey on vulnerable people, but at a state rather than an individual level since poor people are the most likely volunteers to sell their organs. Furthermore, a system similar to that described may be controlled locally, but could lead to major problems if applied on a wider scale.² Financial compensation for donors would probably differ between countries encouraging "transplant tourism." At worst the poor of the developing world could become a vast organ reservoir for elderly people with degenerative disease in the developed world.³

The potential for harm to the donor must be acknowledged, and this highlights the moral difference between the sale of organs and voluntary donation. Multidisciplinary teams looking after a donor may be uncomfortable with participating in paid donation; bodily integrity is highly valued,

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and its violation is not well compensated for except by spiritual or philosophical gains.⁴ Recently published guidelines on living donor transplantation emphasise the paucity of information on long term consequences of living kidney donation and urge lifelong follow up for donors.⁵ Presumably the monopsony would also provide this aspect of care?

Fair distribution among recipients is an important principle of organ allocation. While nodding to this, Harris and Erin immediately break the principle of equity of access by suggesting a preference for living donors who subsequently require transplantation. This argument slips easily into preferential access for other groups—for example, age bias.

Transplantation in general and paid donation in particular are frequent subjects of philosophical and ethical debate. If society chooses the road to paid organ donation, the accompanying debate must be transparent and complete.

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Diagnosing brain death

Honesty is best policy

EDITOR—Altruistic organ donors (and potential donors) have never had explained to them the implications of the process of donation, as is required for fully informed consent. The editorial by Baumgarten and Gerstenbrand does little to clarify the situation.¹ They still retain the term "brain death," which has long been replaced by "brain stem death," and, more recently, "death for transplant purposes" has been used by the Department of Health. At the very least it should be made clear precisely what the (potential) donor understands by death. Without that understanding, consent will surely be invalid.

If it is only neurologists who should apply the tests for the "fatal syndrome" of death, have we been negligent for 25 years in allowing any practitioners of five years' seniority to apply the tests? Can those who are prepared to make the critical diagnosis of death on the brain stem test criteria not be considered as part of the transplant team? Is it understood that the apnoea test itself can cause further brain damage or even death, as has been shown clearly by Coimbra?²

Anaesthetists are uneasy with the diagnosis of death. There is a division of practice among anaesthetists.³ Some give full anaesthesia to organ donors (because they respond to surgery much like any other patient), whereas others withhold anaesthesia (which might look like an admission that the donors are still alive) but suppress the responses to surgery by other means.

A recent Australian opinion is that, rather than redefining those who are brain dead as dead, it may be more honest to acknowledge that such individuals are not dead and that removing their organs is in fact killing them and, and that the long term viability of the transplantation programmes is likely to be better served by telling the truth than by trading in fiction.⁴ This must be a better approach than writing that we should not disturb the current pragmatic consensus that lets the brain dead be dead.¹ Honesty is still the best policy.

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Guidelines for United Kingdom were not described

EDITOR—The article by Baumgarten and Gerstenbrand discussed the diagnosis of brain stem death from an international perspective but did not describe the well established principles used in clinical practice in the United Kingdom.¹ We would like to place on record the following points.

In the United Kingdom, the criteria for the diagnosis of brain stem death and the clinical method of confirming it have been accepted for many years.

There is no need for the obligatory involvement of a neurologist; properly trained doctors of appropriate seniority of any specialty can perform the tests and make the diagnosis.

It is established practice that the medical staff making the diagnosis must be separate from staff involved in the recovery and transplantation of donor organs.

The guidelines concerning management of an organ donor, including the mechanism for establishing brain stem death, were published by the Intensive Care Society in June 1999. These guidelines are available from the society (www.ics.ac.uk).

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Adrenal insufficiency after treatment with fluticasone

Second line controller treatment might have been tried

EDITOR—The lesson of the week from Drake et al highlighted iatrogenic adrenal suppression due to high doses of fluticasone in children.¹ The real lesson here is not to use drugs off label without having any other alternative or being aware of the potential adverse effects.

It is unclear from the report whether the prescribers told the parents of these children of the potential for developing adverse effects at five to seven times the maximum recommended dose in children (>200 µg/day of fluticasone). Presumably the prescribers were aware of the decline in the therapeutic ratio above 200 µg/day but had weighed the potential benefits against the risks in each specific case, even though no data indicate any efficacy gain above this dose in children. It is not stated in the report whether any attempt had been made to step down to a lower dose, or whether second line non-steroidal controller treatment had been tried before increasing to such high doses.

It would also be relevant to know about the children's lung function before admission as the lung bioavailability of fluticasone is directly correlated to predicted forced expiratory volume in one second, such that systemic absorption would be reduced in more severe asthma.

This report should not detract from using appropriate low doses of inhaled corticosteroids, including fluticasone, in asthmatic children as they have a high therapeutic ratio at conventional labelled doses.²⁻⁴ Their use above such doses may result in patients falling off the precipice of the systemic dose-response curve.

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Competing interests: BJJL has received financial support for clinical trials, attending postgraduate meetings, staff training and equipment from companies who make inhaled steroids, including GlaxoSmithKline, AstraZeneca, 3M Healthcare, Aventis, Schering Plough. The mother and spouse of the author have shares in GlaxoSmithKline, which makes fluticasone.

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Data on fluticasone are reassuring but what about doctors' prescribing?

EDITOR—Drake et al reported on four asthmatic children with symptomatic hypoglycaemia caused by high dose and long term treatment with inhaled fluticasone propionate and concomitant infectious disease.¹ Children received 500-1500 µg fluticasone daily for 16 months to five years. Despite this high dosage, linear growth was linear even if below that predicted from parental height. Inhaled corticosteroids are well known to cause only temporary slowing of growth in children. Properly used in the recommended doses according to the severity of the disease, inhaled corticosteroids do not prevent the attainment of normal adult height.² According to this report, the four children in the cases described by Drake et al will also probably reach their expected adult height—if they survive their doctors' prescribing.

The case reports do not provide any information on the severity of asthma in these subjects. Overtreatment with fluticasone was likely since after the hypoglycaemic episodes all children tolerated a dose reduction and, in case 1, fluticasone withdrawal without any reported deterioration in the asthma. Overdosing on inhaled corticosteroids in children (up to a dose of 4800 µg/day beclomethasone equivalent) has been documented in the *BMJ*, even if it was previously reported that most of the therapeutic benefit of inhaled fluticasone is achieved with a total daily dose of 100-250 µg.^{3,4}

Overtreatment is likely to be associated with normal airway capacity and with consequent greater systemic absorption of the drug throughout the lung. The consequence of this is a greater likelihood of side effects.⁵

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Dose-response curve should have been highlighted

EDITOR—The article by Drake and accompanying commentary miss the point.¹ The main problem is the enormous doses of fluticasone for chronic asthma over long periods in these children. The authors concentrated on the hypoglycaemia, but growth stunting was noted too.

Drake et al would have served their readers better if they had highlighted the dose-response curve of inhaled fluticasone. In adults and adolescents 80% of the therapeutic benefit of 1000 µg/day dose is achieved at a dose of 70-170 µg/day, well within the maximum licensed dose for children (200 µg/day).² Moreover, the maximum therapeutic benefit in these groups was achieved at 500 µg/day after plateauing at 100-200 µg/day. The dose-response in relation to systemic effects remains linear.³

Whether prescribed by a respiratory specialist or a general practitioner, these massive doses of inhaled corticosteroids for chronic asthma, in children and adults, should be relegated to the past.⁴

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Lowest possible dose of inhaled glucocorticoids should be given

EDITOR—Drake et al did not mention whether their patients had weight loss and fatigue, but it is notable that they did not have cushingoid features despite having significant suppression of the hypothalamopituitary-adrenal axis from exogenous inhaled glucocorticoid.¹ We have also observed that features of adrenal insufficiency—including impaired growth, poor weight gain, fatigue, and hypoglycaemia—predominated over the peripheral effects of excess exogenous glucocorticoids in eight children with asthma.² Three of these had received inhaled glucocorticoids other than fluticasone, and only one had had doses higher than 600 µg/day.

Several explanations have been put forward for this phenomenon of symptomatic adrenal insufficiency.^{2,3} One explanation is abrupt withdrawal or reduction in the dose of exogenous glucocorticoid associated with non-compliance, especially during

Differences between Cushing's syndrome and paradoxical adrenal insufficiency with inhaled glucocorticoids

intercurrent stress, in patients with inadequate adrenocortical reserve.^{2,3} We believe that most patients receiving treatment with chronic inhaled glucocorticoids who default occasionally on their drug treatment are less likely to have profound suppression of the hypothalamopituitary-adrenal axis, akin to patients receiving prednisolone on alternate days. Our patients were reportedly compliant with their inhaled treatment, and this may have resulted in persistent adverse effects on the axis.

In his commentary Hindmarsh suggests a lack of endogenous or exogenous glucocorticoid at certain times of the day.¹ This might occur with beclomethasone dipropionate,³ but it is unlikely to occur with fluticasone, owing to its longer elimination half life and greater steady state accumulation with repeated dosing. We also believe that the insidious weight and growth failure documented in our patients implies that cortisol deficiency was present for more than a few hours per day. Presentation with hypoglycaemia (in two of our patients) was an acute episode on the background of a chronic problem.

We think that this phenomenon of symptomatic adrenal insufficiency during treatment with inhaled glucocorticoids is likely to be influenced by individual sensitivity to glucocorticoids and differential tissue and possibly drug sensitivity, with greater effects on the hypothalamopituitary-adrenal axis than other tissues (figure).

However unusual and rare this complication might be in the context of the many children treated with inhaled glucocorticoids who do not experience any adverse systemic effects, adrenal insufficiency is potentially life threatening, and general practitioners and paediatricians

need to be aware of it.²⁻⁴ Presentation may be acute with hypoglycaemia or insidious with poor weight gain, poor growth in height, and fatigue. We emphasise the importance of using the lowest effective dose of inhaled glucocorticoid, stepping down when asthma is controlled, and regularly monitoring growth and assessing function of the hypothalamopituitary-adrenal axis in children with growth failure.²

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Summary of rapid responses

EDITOR—The lesson of the week by Drake et al prompted 10 electronic responses, eight of which came from respondents with links to pharmaceutical companies—six to GlaxoSmithKline, manufacturers of fluticasone, one to AstraZeneca, manufacturers of budesonide, and one to both.¹ Consequently, much of the correspondence is devoted to explaining the respective advantages or disadvantages of one drug over the other.

Mike Devoy and Yvonne Greenstreet, as well as Peter Daley-Yates—all employees of GlaxoSmithKline—argue that fluticasone has less of an effect on the hypothalamopituitary-adrenal axis than budesonide at clinically equivalent doses. This is because differences in systemic exposure are related to bioavailability and not lipophilicity, tissue distribution, or half life of a drug. Devoy and Greenstreet further point out that it affects children's growth less than budesonide. Cathy Jackson, a shareholder in GlaxoSmithKline, remarks that the inhaler device should have been specified as this determines the suppression of the hypothalamopituitary-adrenal axis.

Lars-Göran Carlsson, Bengt Lindberg, and Jarl Ingelf, who work for AstraZeneca in Sweden, counter that water soluble steroids such as budesonide are more rapidly eliminated. Thus fluticasone's suppression of the hypothalamopituitary-adrenal axis was three times that of budesonide in a dose-response study in children.

Nearly all respondents thought that the high dosage may have caused the adrenal crisis. Ranjan Suri and Sheila Mackenzie from the Royal London Hospital even

ask for the evidence that children had asthma that merited treatment with inhaled corticosteroids because patients with mild asthma do not need such treatment and are more likely to be sensitive to side effects.

Most respondents argued that the lowest possible dose should be used. Lipworth (letter above), Devoy and Greenstreet, and Minna Kaila, a paediatric allergist from the University of Tampere, Sweden, point out that, instead of high doses of steroids, long acting β agonists or leukotriene receptor agonists should have been given as second line treatment.

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Education on preventing HIV is paramount

How many antiretroviral drugs for HIV infection?

EDITOR—The cover photograph of 30 March showing a patient's lunchtime drug treatment for HIV disease, held in his hand, speaks volumes over any written word. My colleagues and I, currently working at a rural mission hospital in Central Malawi, now all agree that antiretroviral drugs such as these are simply not a practical option for our patients with HIV/AIDS.

The hospital serves a population of 237 000, who are mainly subsistence farmers growing cassava and maize to make *nsima*, the staple carbohydrate food. The district covers some 3000 km², and the capital, Lilongwe, is 210 km away. The prevalence of HIV here is conservatively estimated at one third of the population.

Yet it is not this large number of potential clients needing antiretroviral drugs that makes us pessimistic about their use. Neither is it the logistical challenge, with so few healthcare workers, of distribution and collection in this rural setting, especially in the rainy season when roads are impassable. The cost of the drugs is certainly an issue, although this has fallen significantly. The monthly income for farmers and their families is seasonal and highly variable, averaging just 1500 Malawi Kwacha a month—less than £14.

Simply finding a glass of clean drinking water to take the antiretroviral drugs is not guaranteed. Neither is compliance with the

regimen of four times daily since most farmers do not have watches or clocks. The required monitoring of liver and marrow function while taking antiretroviral drugs could be done at the teaching hospital, were transport available. Drug interactions, especially with treatment of tuberculosis, would pose yet more problems since many people have both diseases. Simple side effects lessen compliance with and adherence to antiretroviral treatment. Completing just a five day course of antibiotics or antimalarial drugs is a rare achievement here. Drug resistance seems to be inevitable.

Thanks to your photograph, our conclusion on using antiretroviral drugs was drawn simply on the suggested triple therapy, multidosing regimen: "If I have to take all these just for lunch, where is the room for my *nsima*?" This is not just for some days or weeks, but for life. Education on preventing HIV has to be our main way forward, especially when all of our resources are so scarce.

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September 11 might be shock treatment for addressing global health inequalities

EDITOR—Smith's editorial rightly points to the heightened interest in global health issues by world leaders but overemphasises the impact of the recent report on macroeconomics on health for bringing this about.^{1,2}

World development reports and indicators and human development reports have been published for decades by the World Bank and United Nations Development Programme, respectively. These annual reports detail global health inequalities and can be accessed on the internet. For example, the *Human Development Report 1997*, commenting on globalisation and health, said that globalisation has its winners and losers and that poor countries lose out because the rules of the game (such as international rules on drug patents) are biased against them.³ Unfortunately, no reaction to advancing global health could be traced directly to these seminal reports.

I think that the terrorist attack of 11 September 2001 is the primary reason for the heightened interest in global health issues. This deplorable act sensitised world leaders to the threats that poor, lawless states may be transformed by terrorists and showed them how propaganda videos by Al-Qaeda and the Iraqi government use the imagery of worsening health profiles in poor countries to win over sympathisers. It therefore seems that the current focus on

health issues by world leaders is, primarily, a way to counter such terrorist propaganda.

Current world leaders are the custodians of capitalist globalisation, a phenomenon that generally affects global health negatively through polarisation of social classes and ecological unsustainability.⁴ Thus, their actions on global health before September 11—exemplified by the vilification of poor countries' governments that posit that HIV drugs are unaffordable, and elaborate measures to prevent HIV positive people from entering developed countries⁵—have parallels in other class polarisation measures of capitalist societies.

Now, there is consensus, but less action, that efforts to improve the public's health globally must address the problem of poverty and health inequalities across the globe. So far, global health concerns seem to be the residue of world leaders' security policies. The most recent G8 summit, where Africa was given 10% of its request for development and health assistance while Russia was given over thrice Africa's aid package specifically to destroy or improve the safety of its nuclear arsenals, underscores the priorities of world leaders.

We are surely far from the stage where world leaders show sincerity of purpose on global health inequalities, but September 11 represents a sad but important milestone in changing their attitudes towards the complex ramifications of global health inequalities.

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Results of study on walk-in centres are only to be expected

EDITOR—I was surprised by the obvious bias in the study by Grant et al comparing the quality of care in walk-in centres with that in general practice and from NHS Direct.¹ The authors are astute enough to limit their conclusions to the range of conditions under study. I don't think there was much of a range. All the conditions assessed are classic walk-in conditions. Note also they are "conditions," not patients. I doubt the walk-in clinics would have done so well with real standardised patients.

For example, for Mrs Smith who presents with coronary heart failure, deteriorating renal function, failing sight, diabetes, deafness, and no social support, general practice would have come into its

own. Walk-in clinics can perform quick tasks well, or they would be out of business. Grant et al might as well have compared the management of these "cases" by obstetricians if they want walk-in clinics to look good. What is interesting is that the general practitioners did do a complete job on the cases with the lowest referrals. They created less work for others and avoided unnecessary costs for the system.

The choice of cases set general practice up to do comparatively badly by limiting them to the easy procedures that walk-in clinics can handle. The conclusion might be that walk-in clinics do a limited range of easy things adequately but refer more than is needed.

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1 Grant C, Nicholas R, Moore L, Salisbury C. An observational study comparing quality of care in walk-in centres with general practice and NHS Direct using standardised patients. *BMJ* 2002;324:1556. (29 June.)

More on doctors and pilots

Monitoring by Big Brother may not be a Bad Thing

EDITOR—I endorse the concerns of Macdonald about the work of his doctor son compared with that of his pilot son.¹ But aside from the reasons given for their very different conditions, I believe that history plays a part.

Air flight is a modern trade, born into a modern age with sophisticated citizens and a strong legislative framework, even at the start and more so today. Doctors share this environment now, but medicine developed as a profession with unsophisticated citizens, a much weaker framework of government and legislation, and much greater emphasis on self employment.

I believe that this has contributed to a culture in medicine that resists the kinds of monitoring that airline pilots take for granted. Airline pilots cannot fly privately for other airlines at weekends (I assume) within their contracts, and they are expected to arrive for work suitably rested. Without denying doctors their rights to earn their income where they can, I see no enthusiasm from doctors for close monitoring of how they spend their time, even in the NHS. Yet without this monitoring, those who fund or analyse the NHS can continue to believe that low productivity, not necessarily low staffing, is a root cause of the problems.

To a considerable degree, airline pilots may have Big Brother watching them, but partly to protect them and the public. If a pilot were working outside his or her hours, the plane would not take off. Perhaps we should be prepared to face this in the NHS too, with operations stopping when a surgeon is working outside of hours. But for this to happen, the profession would need to

accept that monitoring by Big Brother has something to offer rather than tending to see it as a threat.

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1 Macdonald E. One pilot son, one medical son. *BMJ* 2002;324:1105. (4 May.)

Doctors have only themselves to blame

EDITOR—Much of the sentiment in Macdonald's opinion piece comparing doctors and pilots is entirely accurate.¹ Doctors, however, should carry the blame for the way things are.

For too long we as doctors have whinged about overworking; yet when working times were reduced, we whinged about the reduced training options, the lack of experience, the advent of shiftwork (very much an issue here in the Republic of Ireland). We cannot have it all ways.

Pilots are subjected to exemplary training requirements and supervision. As an orthopaedic senior registrar I was often supervised and often not. Teaching was of the "stand at the front of the class" type. Training sessions were scheduled at 7.30 am on a Saturday so that "other work" in other hospitals could be done.

Who decided this? The profession and its members.

Now that I have moved into medical management, I am continually surprised at the major obstruction to reforms of working hours from inside the profession. I also recognise that much of this results from doctors, with the highest altruistic dedication, taking on huge workloads, trying to be all things to all people, and getting a kick out of being busy, helping people, curing patients, and saving lives. We have but ourselves to blame.

Rather than bemoaning our plight, we could look at the work that was done in the airline industry to enhance teamwork, improve safety, and open up communication between staff of all levels of experience. Then we might have fewer problems with medical negligence, near miss incidents, and clinical notes that are illegible, deficient, inaccurate, or obtuse (startling evidence of current practice).

We must either grow up and face reality or be enslaved by others who will impose it on us.

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1 Macdonald E. One pilot son, one medical son. *BMJ* 2002;325:1105. (4 May.)

Rapid responses

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