Letters

Adjuvant trastuzumab for breast cancer

Assessing HER2/neu status incurs more costs for treatment

Editor—The results of recent trials are likely to continue to fuel the demand for trastuzumab in the adjuvant setting of early breast cancer,[1] as well as a possible neoadjuvant treatment in the near future. However, Dent and Clemons did not discuss the difficulty in obtaining accurate and reproducible assessment of HER2/neu gene overexpression. Immunohistochemical testing measures HER2/neu protein expression whereas in situ hybridisation measures gene amplification.

Patients with equivocal immunohistochemical results require in situ hybridisation to determine definitive status because interobserver variability using immunohistochemical testing is appreciable.

At least 20% of patients with positive immunohistochemical results will be truly negative for HER2/neu gene amplification; these patients would not benefit from trastuzumab.[2]

These difficulties in assessing HER2/neu status have been encountered in studies testing trastuzumab, and in situ hybridisation testing has been used as the gold standard.[3] As the clinical utility of trastuzumab widens guidelines on HER2/neu testing must be clear to ensure appropriate use of trastuzumab. Clearly this testing will incur additional costs to trastuzumab treatment.

Malcolm R Kell *consultant surgeon*
malcolm.kell@breastcheck.ie

Colm P Power
Mater Misericordiae University Hospital, University College Dublin, Republic of Ireland

Competing interests: None declared.

1 Dent R, Clemons M. Adjuvant trastuzumab for breast cancer. *BMJ* 2005;331:1035-6. (5 November.)
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Advent of pharmacogenetics raises many issues

Editor—Kell and Power [previous letter] at last clarify for everyone that at least 20% of patients with positive immunochemical results will not benefit from trastuzumab.[1] These are expensive false positives at £20 000 yearly per patient, both for the health system and for patients' quality of life—or, indeed, life at all, bearing in mind the death rate from the treatment.

The advent of pharmacogenetics raises important issues. Full and equitable access to treatment will be increasingly difficult to achieve as increasing numbers of expensive patient adapted treatments for pathological subclasses become identified and available. Only some people will be suitable for these targeted treatments, and only a proportion of those targeted will benefit. Greater openness and debate, not just among health professionals but also with the wider public, would help to explore the legitimacy of these approaches.

The ethics and economics of blanket prescribing are intertwined and difficult to define or assess. Is it right to knowingly prescribe an inexpensive drug that will be of little or no benefit to the majority, knowing that, for some patients, alternative targeted treatments are available? This choice is further complicated by the fact that they are expensive and targeting is not infallible.

More of these types of drug are in the scientific and pharmaceutical pipelines. The price of progress will be high. Research partnerships in the developed world must work to ensure that benefits are available worldwide to all who have cancer. Participants in underdeveloped countries should equally be assured of the best available standard treatment in the control arm of trials, and be accorded equal care and respect in gaining consent as patients in well developed countries. The more fortunate members of society must shoulder responsibility for this.

Hazel Thornton *honorary visiting fellow, Department of Health Sciences, University of Leicester*
"Saionara," Colchester CO5 7EA
hazelcagct@keme.co.uk

Competing interests: None declared.

1 Dent R, Clemons M. Adjuvant trastuzumab for breast cancer. *BMJ* 2005;331:1035-6. (5 November.)

An increasingly common ethical and economic conundrum

Editor—The advent of increasingly expensive and effective treatments over the next few years is likely to make this kind of ethical discussion even more common.[1]

However, the £20 000 headline figure for a course of trastuzumab obscures the real cost of using this agent. In the original paper 261 adverse outcomes occurred in 1679 patients receiving placebo and 133 in 1672 patients receiving trastuzumab[2]; the published relative risk reduction of 0.48 obscures the number needed to treat (NNT) of 13 (95% confidence interval 10 to 18). From a cost effectiveness point of view, £260 000 in trastuzumab buys only one additional patient a disease free survival. This may be a worthwhile investment, but in a hard pressed NHS for the same sum you can't help thinking that it could pay for an additional consultant oncologist, or a bevy of extra specialist nurses.

If testing for HER2/neu gene amplification identifies 20% of patients with a positive immunohistochemical test result who won't benefit from trastuzumab [Kell and Power, letter in this cluster], then from a health economist's point of view the test saves £4000 per patient tested. I doubt the cost of setting up a comprehensive in situ hybridisation service would exceed that sum, on a patient by patient basis.

In terms of the human cost mentioned by Thornton [previous letter], we have had similar problems in rheumatology—when counselling patients who wish to try treatment with anti-tumour necrosis factor α (a mere £9000-£12 000 per patient yearly, with an NNT of 10 for benefit over cheap, aggressive methotrexate) but don't satisfy criteria from the National Institute for Health and Clinical Excellence (NICE) for eligibility.

Matthew L Grove *consultant rheumatologist*
Tyneside General Hospital, North Shields NE29 8NH
Matthew.Grove@northumbria-healthcare.nhs.uk

Competing interests: None declared.

1 Dent R, Clemons M. Adjuvant trastuzumab for breast cancer. *BMJ* 2005;331:1035-6. (5 November.)
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The other side of the coin

Editor—The editorial by Dent and Clemons in the middle of media frenzy about the use of trastuzumab was appropriate.[1] As suggested, equity of access to such novel and expensive treatments should be through well designed funding processes. In calculating the cost of treatment, the overall cost of the drug, its administration cost, the cost of related investigations, and the opportunity cost should be taken into account. Assuming that 25% of patients will be suitable for trastuzumab treatment, the overall cost of treatment in the UK will be over £200m (based on the cancer incidence figures for 2003[2]). This could otherwise have been invested in breast cancer research or prevention or early detection programmes, which will prevent recurring cost of treatment in future.

In analysing the number needed to treat (NNT) in the HERA trial,[3] we found that 19 patients need to be treated to prevent one recurrence. The trial shows that 7.9% had at least one grade 3 or 4 adverse cardiac event in the treatment arm resulting in patient morbidity and reduced quality of life. This would increase the total cost of treatment as well. Hence, more emphasis should be on risk benefit analysis.

The recent announcement by the secretary of state for health that trastuzumab will be made available to all patients in the United Kingdom has increased an interest in cancer organisations and the expectations of patient groups. However, policy decisions should be unbiased and based on sound evidence and following the principles of health economics.

Somasundari Gopalakrishnan *honorary fellow*
somla@tiscali.co.uk
John Linnane *deputy director of public health*
Walsall Teaching Primary Care Trust, Walsall WS1 1TE

Competing interests: None declared.

1 Dent R, Clemons M. Adjuvant trastuzumab for breast cancer. *BMJ* 2005;331:1035-6. (5 November.)
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Editorial does not mention health economics of drug

Editor—Why does the *BMJ*, which promotes itself as a journal dedicated to evidence based medicine, publish an editorial that talks only of the hazard ratio of a treatment without any reference to the absolute reduction in recurrence observed?[1]

From the original paper I calculate the absolute reduction in recurrence rate at one year with trastuzumab to be 5.5%,[2] giving a number needed to treat of 18 (rather than the 13 mentioned by Grove [letter in this cluster]).

There was no reduction in total mortality (no "lives saved"), but this might be due to the limited follow-up.

Although the exact figures may change with further experience this means, at present, that of 100 suitable patients given the drug for a year, 94 will have been exposed to the (not insignificant) side effects without any effect on their outcome at one year and the taxpayer (in the United Kingdom) will be faced with a bill of more than £400 000 per recurrence prevented.

Whether this is a cost efficient or even ethical use of limited healthcare resources is an important question that was not raised, let alone addressed, in the editorial.

E Hamish McLaren *retired consultant physician*
Badmany House, Beith, Ayrshire KA15 2JL
handsmclaren@btinternet.com

Competing interests: None declared.

1 Dent R, Clemons M. Adjuvant trastuzumab for breast cancer. *BMJ* 2005;331:1035-6. (5 November.)
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Stockpiling oseltamivir

What is the number needed to treat with oseltamivir to prevent one flu death?

Editor—I, like Collier,[1] would like to know the basis of secretary of state for health Patricia Hewitt's claim that the acquisition of 14 million doses of the antiviral drug oseltamivir (Tamiflu) would reduce the number of (flu) deaths in Britain.[2] Who has given her this advice? Would they also tell us the number needed to treat?

A Rouse *consultant in public health*
Heart of Birmingham Primary Care Trust, Birmingham B16 9PA
samplesize@tiscali.co.uk

Competing interests: None declared.

1 Cole A. Experts question wisdom of stockpiling oseltamivir. *BMJ* 2005;331:1041. (5 November.)
2 East Asia is most at risk of human flu epidemic, experts say. Michael Day. *BMJ* 2005;331:921. (22 October.)

Roche clarifies data for improved mortality with oseltamivir

Editor—Experts question the wisdom of stockpiling oseltamivir (Tamiflu).[1] A question was asked about data supporting an improvement in mortality with the drug.

Two datasets were presented at the second European Influenza Conference in Malta (www.eswi.org) in September. A large retrospective cohort study of patients with influenza-like illness (n = 176 001) taken from a US health database showed that oseltamivir (75 mg twice daily, n = 39 202) significantly reduced the risks of pneumonia by 32% ($P < 0.001$) and of death by 91% ($P < 0.05$) (Nordstrom et al). In Canadian patients with laboratory-confirmed influenza (A or B) requiring hospital admission (< 15- > 64 years; n = 359), oseltamivir reduced the risk of death by 68% (McGeer et al). Treatment with oseltamivir therefore statistically and meaningfully reduces the risk of death in patients of all ages and from all walks of life, infected with influenza A or B.

The news item also reported that oseltamivir does not prevent infection with the flu virus, and that at best it would reduce the severity of illness. On the basis of data from clinical trials, oseltamivir was approved by the European Medicines Agency (EMEA) for preventing flu in adults and adolescents aged ≥ 13. Additionally, a recent large scale study examined the effectiveness of oseltamivir (75 mg once daily) in protecting family members who had come into contact with a person infected with flu: oseltamivir protected around 80% of contacts from flu infection.[2]

Furthermore, although oseltamivir has certainly been proved to reduce the duration of illness by ≤ three days, it also reduces the risk of admission, bronchitis, pneumonia, and related antibiotic use associated with flu.[3]

James R Smith *international medical leader*
F Hoffman-La Roche, CH-4070 Basel, Switzerland
james.smith.js1@roche.com
Regina Dutkowski *clinical science leader*
Hoffmann-La Roche, Nutley, NJ 07110, USA

Competing interests: JRS and RD are employees of Roche, which manufactures Tamiflu (oseltamivir).

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Health in Africa

International experience may provoke animosity towards those returning home

Editor—Lucas's editorial once again raises the important issue of migration of healthcare professionals from Africa to the West.[1] However, this is a general issue faced by all developing nations and includes internal migration in Africa from poorer to wealthier African countries.[2–5]

The way in which healthcare professionals returning to their home country from a period of working or training abroad are received may be an important consideration. They are often welcomed back, and the experience gained abroad will be shared with colleagues. However, there may occasionally be animosity from those who have not gained international experience to those who have.

The returning healthcare professional may find it difficult to adjust to working in a developing nation with restriction on facilities, investigations, and drugs. The impact of this on their personal job satisfaction is not determined. Furthermore, the international experience gained will include experience of personnel departments and conditions of service that value the healthcare professional. In my experience the value placed on public sector healthcare professionals in the developing world is minimal, and this can be very frustrating.

Andrew C Don-Wauchope *lecturer in clinical medicine*
Trinity College, Dublin 8, Republic of Ireland
donwauca@tcd.ie

Competing interests: None declared.

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There is more to the crisis

Editor—The human resources crisis addressed by Lucas raises concern.[1] For some time the notion has prevailed that instituting local incentives—local postgraduate training, subsidised housing, subsidised means of transportation, etc—might help stem the trend of mass migration of personnel. Ghana was mentioned by Lucas as an example of a country that has been relatively successful in that light. As a Ghanaian,

having worked in Ghana and international health, as well as mingling with various migrant African professionals overseas, I find the suggestions and solutions too simplistic.

Despite all the effort, successive governments have tried to retain professionals, especially health professionals. A recent World Bank publication and a follow-up Ghanaian news commentary on the publication indicated that on average 45% plus of qualified Ghanaian tertiary level graduates have left the country, and continue to do so.[2 3] Many were educated with state funds.

Many educated indigenous Africans contribute to the crisis. The politicians might contribute their share through bad governance and policies at the expense of providing good and adequate healthcare to the African population.[4] Many politicians are tertiary level educated and see entry into politics as a path to quick enrichment. Just as with their counterpart health professionals who chose to leave, any patriotism, integrity, and accountability get thrown overboard as they enter the fray of free for all corrupt practices and national abandonment. As Deming showed, achieving a robust self driven national economy entails management reform, incorporating quality assurance in every step of production and management.[5] Africa, and African health systems have a lot to learn from this.

Albert M E Coleman *associate specialist psychiatrist*
Greenacres Community Mental Health Trust, Worthing and Southlands Hospitals NHS Trust, Worthing, West Sussex BN11 2DH
albert.coleman@gmail.com

Competing interests: AMEC is from Ghana and has contributed on a related issue in the *BMJ*.

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Croatia's brain drain

Editor—The migration of medical professionals from developing countries has become a global problem.[1] Although the temporary migration of doctors for training purposes benefits the country doctors emigrate from through upgrading skills, permanent migration represents a net transfer of human capital from the emigrating country.[2] New member states of the European Union have almost systematically experienced the alarming predictions of a brain drain after joining the union.[3] Croatia may face a similar future when it joins the EU.

We surveyed 204 final year medical students from the Medical School, University of Zagreb, Croatia (response rate 85%), and analysed the results with logistic regression. Eighty four students were considering emigrating, mostly to the EU (57 respondents), especially Slovenia (22). Comparison of the results of the same survey performed a year before indicated an increase in the percentage of students considering emigration, from 31% to 41%, and confirmed Slovenia as the most common target country.[4] The logistic regression results indicate that better ranked (odds ratio 0.85, 95% confidence interval 0.77 to 0.94), younger medical students (odds ratio 2.16, 1.10 to 4.24), and those interested in scientific work (odds ratio 2.16, 1.10 to 4.24) considered emigrating from Croatia.

A serious shortage of doctors in Croatia is reported.[5] According to the new legislative scheme, a shortfall of 398 consultants in internal medicine and 340 consultants in surgery is predicted by 2007. Croatia thus faces substantial problems in healthcare provision.

Ozren Polasek *research assistant in medical informatics*
opolasek@snz.hr

Kolcic Ivana *research assistant in epidemiology*
Andrija Stampar School of Public Health, Medical School, University of Zagreb, Zagreb, Croatia

Competing interests: None declared.

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Postpartum eclampsia of late onset: a complicated case

Editor—The message of the lesson of the week on postpartum eclampsia of late onset, that such eclampsia can occur in women with uncomplicated pregnancies, is undoubtedly important.[1] However, this case does not illustrate an uncomplicated pregnancy because "clinically significant proteinuria" was present from 30 weeks onwards in a woman who was already at an increased risk of pre-eclampsia because of her obstetric history.[2] Proteinuria can precede hypertension in the development of pre-eclampsia, and had her proteinuria been quantified, it may have alerted her obstetricians to the possibility of postpartum pre-eclampsia.

Hypertension often does not become evident until the fourth or fifth postpartum day, and women with antenatal pre-eclampsia or at increased risk should continue to have their blood pressure measured past the usual rather short postpartum stays increasingly seen in hospitals in the United Kingdom and Canada.

Kirsten Duckitt *obstetrician and gynaecologist*
Prince George Regional Hospital, Prince George, BC, Canada V2M 1S2
kduckitt@doctors.org.uk

Competing interests: KD is the author of a systematic review on risk factors for pre-eclampsia.

1 Munjuluri N, Lipman M, Valentine A, Hardiman P, Maclean AB. Postpartum eclampsia of late onset. *BMJ* 2005;331:1070-1. (5 November.)
2 Duckitt K, Harrington D. Risk factors for pre-eclampsia at antenatal booking: systematic review of controlled studies. *BMJ* 2005;330:565.

Data are still needed for HPV immunisation programme

Editor—Finn questions the non-availability of human papillomavirus (HPV) type specific data for the United Kingdom.[1] We maintain that the data that are available for the UK on HPV type specific prevalence in the general population, in cervical cancer cases, and for precursor cases (cervical intraepithelial neoplasia, CIN), are limited at present. No true population-based data are available, and wide variations in overall and type-specific HPV prevalences have been reported among samples of women undergoing routine cytological screening.[2–4] Furthermore, UK rates of HPV infection may have increased since the study,[4] cited by Finn, was conducted.[5] Published UK data on HPV type specific prevalence in men, and on type specific HPV seroprevalence in men and women, are also not currently available.

Such data are needed for the modelling and cost effectiveness studies necessary to plan an HPV vaccination programme for the UK. Once the programme begins, pre-vaccination baseline data will be essential to monitor its impact, and to answer some of the questions discussed by Finn and ourselves.

O Noel Gill *head*
Noel.Gill@hpa.org.uk
Catherine M Lowndes *consultant scientist (epidemiology)*
HIV and STI Department, Health Protection Agency, Centre for Infections, London NW9 5EQ

Competing interests: None declared.

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India plans to audit clinical trials

Editor—Regulation of clinical trials by India's government is an essential step towards protecting the interests of the poor, uneducated, and gullible public of India from being made unsuspecting human guinea pigs for the rich and powerful global healthcare industry.[1] This measure needs to be emulated by the governments of other developing countries and the World Health Organization.

The healthcare and life science industry sends "offshore" more than $200bn worth of business, and most of this is in research and in clinical trials. This is estimated to grow at a rate of 8-10%. India gets around $280m of this lucrative business. Industry sources estimate that India could increase its share to

around $12bn by 2015.[2] India is an attractive destination for the healthcare related industry to conduct clinical trials because of its heterogeneous mix of people, large number of patients, and well trained doctors and other ancillary staff. Another reason is that the cost of conducting clinical trials in India is one fifth to one seventh of its cost in the United States or Europe. Conducting clinical trials in developing countries is a form of outsourcing against which the anti-outsourcing brigades of the developed nations would hardly raise any voice.

Any industry with the potential to earn this much money can have its own pitfalls unless regulated. The absence of adequate regulations and proper laws in developing countries eager to cash in on the opportunities of globalisation can lead to the conducting of risky and questionable clinical trials. Unethical and even illegal trials are conducted without fear because there is no law to safeguard the interests of individuals who volunteer for these trials.[3]

Biju Basil *resident in psychiatry*
bijubasil@yahoo.com
Maju Mathews *assistant professor in psychiatry*
Jamal Mahmud *chief resident in psychiatry*
Drexel University College of Medicine, Philadelphia, PA 19124 USA

Babatunde Adetunji *attending psychiatrist*
MHM Correctional Services, Philadelphia, PA 19102

Kumar Budur *attending psychiatrist*
Cleveland Clinic Foundation, Cleveland, OH 44195, USA

Competing interests: None declared.

1 Mudur G. India plans to audit clinical trials. *BMJ* 2005;331: 1044. (5 November.)
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CAM before the storm: authors' reply

Editor—Predictably, our editorial on the integration of complementary therapies (CAM) into the NHS failed to satisfy the enthusiasts or sceptics.[1]

We do not think that the debate about appropriate evaluative methodologies has been resolved. For example, the distinction between contextual and specific effects is problematic, as is the choice of controls for complex interventions. The quality of the debate is not enhanced by rhetorical flourishes such as "scientific evidence ignored" in Canter and Ernst's letter, or the notion that we "appear nervous" at the National Institute for Health and Clinical Excellence (NICE) taking on the task of incorporating CAM into guidelines.[2] We would be delighted. We do not think that politics and scientific medicine are as distinct as they imply in their last sentence, as revealed in even a cursory look at the history of medicine or the social epistemology of science.[3 4]

We think that pragmatic randomised controlled trials do have greater external validity than explanatory trials[5] and find the notion that they are "methodologically weaker" bizarre.

CAM's popularity continues to grow along with the call for its integration into the NHS. We repeat our view that CAM interventions should be subjected to rigorous evaluation using appropriate methodologies. We are convinced this needs to be a collaborative effort between trialists, health service researchers, complementary therapists and, not least, patients. .

Trevor D Thompson *clinical lecturer*
Academic Department of Primary Care, University of Bristol, Bristol BS6 6JL
trevor.thompson@bristol.ac.uk

Gene Feder *professor of primary care research and development*
Centre for Health Sciences, Barts and the London, Queen Mary's School of Medicine and Dentistry, London E1 4AT

Competing interests: None declared.

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Consultants' hours of work: a new perspective

Editor—An estimated 6000 consultant years would be lost to the NHS if consultants exercised their (agreed) option of retiring at 60.[1] I calculated the hours I worked as a trainee between 1982 and 1991, working on-call rotas of between 1:2 and 1:5. I then calculated the hours I have worked as a consultant from 1991 to date, taking into account the extra hours I was required to spend on-call in the hospital for the two years it took to "normalise" out of hours service commitments after the introduction of the Calman reforms to doctors' training. I have assumed five weeks' holiday a year over the whole period.

A 40 hour week (allowing five weeks' holiday) equates to 1880 hours per year (one "standard" year). As a trainee I worked just over 34 000 hours. Many of these hours worked (around 50%) were paid at the old pre-Calman rate of one third of standard. As a consultant of 14 years I have yet to exceed that total, having contributed 32 600 hours.

The time I spent as a trainee works out to be the equivalent of 18.1 standard years, and my time as a consultant to 17.4 standard years. I need only work another 3.8 years at my current workload (which job plan and appraisal both agree that I contribute about 47 hours per week) to have reached the same number of hours that a person working 40 standard years (one "standard career") would have worked. When I pass this milestone I will be 50 years old.

This means that if I survive long enough to retire at 60, the NHS will have received 10 free "consultant years" (equivalent to 12.4 "standard years") from me. Multiply this by the number of consultants working in the NHS (some of whom contribute more hours than I do) and the value for money gained by the NHS from its medical workers can be viewed in a new perspective.

Austin A Leach *consultant anaesthetist*
Royal Liverpool University Hospital, Liverpool L7 8XP
austin.leach@rlbuht.nhs.uk

Competing interests: None declared.

1 Brettingham M. Trusts should cut workload of senior physicians to retain them. *BMJ* 2005;331:798. (8 October.)

Lady doctors: where are the gentleman doctors?

Editor—McCann's personal view on Guy Fawkes's influence on medicine after 400 years intrigued me.[1] I recently made an appointment to see a doctor. We agreed a time, and I asked which doctor I would be seeing. "Dr——," the receptionist replied. "She's one of our lady doctors." As I walked away I wondered whether, if it had been a doctor of the other sex I would be seeing, the receptionist would have responded: "He's one of our gentleman doctors." The answer is obvious. Of course not. Why does this unequal distinction continue, and is it found more generally than in doctors' (and dentists') surgeries?

It seems that it is. Consider tea lady (not gentleman), cleaning lady (not gentleman), ladies' toilet (not gentleman's—although gents' is still used). On the other hand, we hear: "I'll take the next question from the lady (gentleman) in front."

Why the marking?

Firstly, there is the gratuitous reference to someone's sex: "The doctor you'll be seeing is female." Secondly, given that we need (?) to apologise for the fact that the doctor is female, we will accord her the courtesy of labelling her not just as female or woman but with the courtesy term of lady. A similar argument can, with some boldness, be made to explain cleaning lady or tea lady. When there is no need for embarrassment or guilt, when the label is not specific to a category (doctor, dentist, cleaner), then we are happy to use both "lady" and "gentleman."

Some language changes are rapid, vocabulary for example, hence the swift turnover of slang. But language that embraces cultural attitudes is slower to change. Does that explain why, in these days when there are more female medical students than male ones and where many general practitioners are women, a doctor who is not a man has to be marked as female and protected by the designation "lady"?

Alan Davies *emeritus professor*
University of Edinburgh EH8
a1adavie@staffmail.ed.ac.uk

Competing interests: None declared.

1 McCann P. Guy Fawkes's influence on medicine after 400 years. *BMJ* 2005;331:1091. (5 November.)