Letters

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Elective caesarean section on request

Patients do not have right to impose their wishes at all cost

EDITOR—Paterson-Brown seems to assume that an autonomous patient has an unconditional right to have her wishes fulfilled.[1] The (negative) right to decline treatment needs to be distinguished from the supposed (positive) right to demand it. In English law, the principle of autonomy allows, for example, competent people the right to refuse life saving treatment, and doctors have a correlative duty to respect this right.[2] A dying patient, however, does not have the right to impose a duty on a healthcare professional to end his or her life.

With respect to medical and surgical interventions, the law is also clear. A patient, however competent, cannot invariably impose his or her demands and force a practitioner to act in a way which he or she believes to be contrary to the patient's best interests. This prerogative would be viewed by the courts as "an abuse of power as directly or indirectly requiring the practitioner to act contrary to the fundamental duty which he owes to his patient" (per Lord Donaldson).[3]

Healthcare professionals could not preserve their professional integrity, self respect, or credibility if they were to act as mere instruments to the "foolish" or "irrational" demands of patients, particularly if this ran contrary to good medical practice or violated their deeply held values.[4] Decision making should be a collaborative enterprise based on mutual respect with the shared goal of the good of the patient.

Distributive justice also deserves consideration here. If patients demand expensive treatments such as caesarean sections, in circumstances for which there is little or no evidence of benefit—and, indeed, there may be evidence of harm—the costs should be considered.

The profession and the public, in the interest of patient welfare, should consider setting limits to personal autonomy and to professional self effacement.

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All types of anaesthesia carry risks

EDITOR—We agree with Paterson-Brown that obstetricians should perform an elective caesarean section if a fully informed woman requests it.[1] Obstetric anaesthetists are faced with a similar dilemma. A woman who is to have a caesarean section may have the procedure performed under regional or general anaesthesia. Once she has been fully informed of the relative risks of anaesthesia, her right to choose the type of anaesthesia is accepted by anaesthetists. In practice, it is uncommon for women not to choose the anaesthetic technique recommended. While some obstetricians argue that vaginal and abdominal delivery may be equally safe, in contrast, regional anaesthesia is regarded as considerably safer than general anaesthesia with respect to maternal mortality.[2]

The position of Amu et al, that maternal choice alone should not determine the method of delivery, seems less tenable.[1] Various risks of caesarean section are quoted, including hysterectomy because of haemorrhage, increased risk of maternal death, and Mendelson's syndrome. Mendelson's syndrome, however, which is most commonly associated with general anaesthesia, is extremely rare nowadays. Only one instance is cited in a 1991-3 report on confidential inquiries into maternal deaths in the United Kingdom,[2] while the increased risks of hysterectomy, haemorrhage, and maternal death associated with caesarean section are almost certainly due to the fact that it is often the method of delivery chosen for patients at high risk. All types of anaesthesia carry risks, however, particularly increased morbidity, a point not mentioned by Amu et al.

Amu et al conclude by stating that active participation by patients should be encouraged to arrive at a safe and logical informed decision about the method of delivery. The implication is that to choose caesarean section for an uncomplicated pregnancy is illogical. We do not believe that the 31% of female obstetricians in London who would choose caesarean section for themselves in those circumstances are making an illogical choice.[3] This population of women really is without doubt fully informed of all risks and hazards. Pregnant women must be made aware that they all are potential candidates for anaesthesia, and potential risk factors should be sought and assessed during pregnancy.[4] In obstetric practice in the 1990s, most women who give birth, irrespective of the mode of delivery, receive regional analgesia or anaesthesia.

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Obstetricians are more than technicians

EDITOR—Paterson-Brown thinks that doctors should perform elective caesarean sections on request as long as the woman is fully informed.[1] We consider such advice to be irresponsible. How can a mother be properly informed when there is an almost total lack of reliable information on mortality related to the procedure and on the short and long term morbidity of caesarean section compared with vaginal delivery in normal women at term? Existing evidence suggests that vaginal delivery is generally safer for the mother. Nor should we forget

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the baby. The need for resuscitation at birth and the incidence of both transient tachypnoea and respiratory distress are considerably higher after caesarean delivery. In addition, caesarean section leaves a scar on the uterus, which not only has implications for future pregnancies but will complicate any subsequent pelvic surgery. It is true that the pelvic floor may be damaged during vaginal delivery. Rather than stimulate ever more ready recourse to caesarean section, however, our first concern should surely be to review aspects of the modern management of labour that may contribute to it—for example, maternal posture and mobility, the use of epidural anaesthesia, the length of the second stage of labour, and the liberal use of episiotomy.

Informed maternal choice is fundamental to the practice of midwifery and obstetrics today. Maternal autonomy is, however, only one element in ethical clinical practice: another is not doing harm. To carry out a caesarean section on a woman when, in the opinion of the obstetrician, it is not in the best interests of her and her baby is, therefore, unethical. Here, the autonomy of the doctor not to act unethically must be exercised. Unfortunately, maternal autonomy is often assumed as doing what the woman requests at a particular moment. It is far more complex than that. Doctors should help the mother in the process of exercising her autonomy in the best interests of herself and her child. Despite her assertion to the contrary Paterson-Brown consigns the obstetrician to being little more than a technician in the matter. Our patients expect and professional standards require more of us than that.

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Safest option is still to aim for vaginal delivery

Editor—The debate about elective caesarean on request will continue.[1] Maternal and fetal mortality have been reduced to a point that allows us to shift the focus to reduction of morbidity, but we caution against dismissing the mortality associated with caesarean section.

Elective caesarean section is now regarded as safe, but we believe that the relevant comparison of mortality is between elective caesarean and trial of labour resulting in a number of emergency caesarean sections and vaginal deliveries. The mortality ratio in healthy women between caesarean and vaginal delivery has been estimated at 5:1.[2] If the attributable mortality ratio of elective versus emergency caesarean is 1:1.5 as has been suggested,[2] then a success rate of vaginal delivery of approximately 40% would lead to a maternal death rate equal to that for elective caesarean. Thus for healthy women without complications a trial of labour with an emergency caesarean rate of less than 60% provides a safer alternative to elective caesarean.

Although deaths from elective caesarean in the United Kingdom have decreased, they still accounted for 16.5% of all deaths from caesarean section in the most recent confidential inquiry.[3] In the most recent confidential inquiry into stillbirths and deaths in infancy there were 42 deaths after ruptured uterus.[4] Three quarters concerned women with pre-existing uterine scars, highlighting one of the long term implications of a caesarean section.

One of the main reasons driving this "fashion" for elective caesarean seems to be a desire to avoid damage to the pelvic floor during childbirth. The evidence for this is incomplete, and it has been suggested that many of the studies in this field of research are subject to criticisms such as small numbers, case selection, lack of long term follow up, and failure to consider the impact of other possible risk factors for pelvic floor dysfunction, such as family history, connective tissue disorders, and lifestyle.[5]

So while we concede that obstetric care should seek to minimise the risk of injury to the pelvic floor, we believe that for now the safest option should still be to aim for a vaginal delivery in an uncomplicated pregnancy but the woman should participate fully in the decision making process.

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Unnecessary caesarean sections should be avoided

Editor—The fact that 31% of 85 London based female obstetricians with an uncomplicated singleton pregnancy at term would choose an elective caesarean section for themselves[1] is presented as a changing view and interpreted to mean that the concept of a prophylactic caesarean section is not outrageous because almost a third of female obstetricians would choose it for themselves.

This does not mean, however, that almost a third of female obstetricians worldwide would make this choice—these obstetricians are far less than 1% of all female obstetricians worldwide. In our anonymous postal survey of all obstetricians in the Netherlands (response rate 67%) only 8 out of 567 obstetricians (1.4%) opted for caesarean section in an uncomplicated singleton pregnancy.

Prophylactic caesarean section must still be considered clinically unjustifiable because of its excess maternal mortality and morbidity (including infertility) and its excess neonatal and respiratory morbidity in comparison with vaginal birth.[2] Financial costs are much higher. Women are denied the experience of giving birth themselves, instead becoming victims of medicalisation.

The paper states that vaginal delivery of a fetus in breech presentation is becoming a rare obstetric art. In our survey 60-79% of obstetricians would opt for vaginal delivery of a breech fetus in primigravidas and 86-94% for such a delivery in multigravidas compared with 43% and 60% of our London colleagues.

Although caesarean section is comparatively safe in some parts of the world, short and long term maternal mortality and morbidity are serious problems elsewhere.[3] If Paterson-Brown's suggestion is taken up lightly by obstetricians in other places it will definitely lead to more maternal deaths and misery for women who already have a disproportionate share of ill health in this world. As part of a confidential inquiry into maternal deaths in the Netherlands, we stated: "If the caesarean birth rate in the United States of America was similar to the rate in the Netherlands (9%), approximately half a million more births would occur annually by the vaginal route. At present, these births occur by caesarean section and would be associated with approximately 130 extra maternal deaths, if the reported Dutch death rates after caesarean section were applied in the United States."[2]

Demanding unnecessary intervention in some cases implies denying that service in other cases. "Developed" countries have unnecessarily high rates of caesarean section, while "developing" countries have a high unmet need for caesarean section.[4] The suggestion that a valid reason is not needed to perform caesarean section will worsen this unacceptable gap.

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Maternal age is important

Editor—Paterson-Brown et al argue against open access for caesarean section in the absence of a medical indication.[1] I take issue with their assertion, however, that maternal age does not influence vaginal delivery rates. A wealth of data show increased incidence

of instrumental and caesarean deliveries in older women.[2 3] I recently examined this issue at Queen Charlotte's and Chelsea Hospital in London and found that this effect is incremental—the older the woman the lower her chances of having a spontaneous vaginal delivery.[4]

In the Queen Charlotte's series of over 6000 nulliparous women, those aged 35 had only a 49% chance of a spontaneous vaginal delivery compared with a 71% chance in women aged 20. By the time a woman was 40 or older, her risk of an instrumental delivery in labour was 42%. It could be argued that older women or their obstetricians may be more anxious, which may prompt higher rates of intervention, but the incremental increase in operative delivery rates, and the fact that there was also an incremental increase in failure to progress as a cause of instrumental delivery, point to a genuine biological effect. Older women have a right to know that their chances of a spontaneous vaginal delivery decreases with each year they delay childbirth. If they then request an elective caesarean section to avoid the high risk of emergency operative delivery (and its proved long term sequelae), then shouldn't obstetricians grant them that wish?

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Pregnant women should have choices

EDITOR—Paterson-Brown et al are incorrect when they say that there is no relation between maternal age and increased risk of caesarean section.[1] Studies have shown that there is,[2] and this point is increasingly important as women leave childbirth to a later age.

Two further issues have not been evaluated in this debate. Firstly, estimates suggest that a caesarean section costs £760 more than a vaginal delivery, and therefore every 1% increase in the rate of caesarean sections nationally costs £5m.[3] Secondly, with the onset of clinical governance it is important that we give women correct advice when recommending a delivery route when the evidence for benefit is still uncertain. Women are routinely counselled, however, and given choices regarding regarding other surgical interventions (for example, different surgical treatments for menorrhagia) and such choices should therefore be available to pregnant women when the delivery route is discussed. Some women do not wish to experience natural childbirth, and professionals should support these women as well as those who wish to achieve a normal vaginal delivery.

Senior midwives have participated in this debate, and I have heard the argument that maternal choice should be discouraged as with "proper explanation and support" women would not choose an elective caesarean delivery without a clear obstetric indication. I hope that this debate in the pages of the *BMJ* will generate a response from midwives.

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Protease inhibitors in HIV infection

Lipodystrophy may be a consequence of prolonged survival

EDITOR—Berger's article on HIV protease inhibitors and the putative increased risk of heart disease contains inaccuracies and could be unnecessarily alarming.[1] Several recent reports describe one or more syndromes in HIV infected people known variously as buffalo hump, protease paunch, or lipodystrophy.[2 3] The symptoms include fat accumulation associated with increased abdominal girth or abnormal dorsal cervical fat coupled with wasting in extremities. Some reports have also highlighted hypertriglyceridaemia, hypercholesterolaemia, and insulin resistance.[2]

Case reports on small numbers of patients have suggested that these symptoms are associated with protease inhibitors. However, similar symptoms occur in some HIV positive patients not receiving protease inhibitors.[3 4] They may therefore be a characteristic of HIV infection, possibly unmasked by prolonged survival associated with treatment with protease inhibitors.

In the cases that are associated with protease inhibitors differences are emerging between the various types of drug. One cross sectional analysis of 116 patients receiving one or more protease inhibitor in combination with nucleoside reverse transcriptase inhibitors found that symptoms of lipodystrophy developed more rapidly in patients receiving ritonavir–saquinavir than in those receiving indinavir,[2] while in two other studies high relative risks occurred with ritonavir or indinavir. Carr and colleagues recently suggested that the differences between protease inhibitors may at least partly relate to variable degrees of inhibition of the cytochrome *P*-450 3A enzyme.[5] This is consistent with a high risk being associated with ritonavir, the most potent inhibitor of this enzyme currently available.

Roche is performing exploratory analyses of over 500 patients participating in three ongoing clinical trials of combination therapy with saquinavir either alone or in combination with nelfinavir or ritonavir. Preliminary data suggest that mild increases in triglyceride and cholesterol concentrations occur in some patients with long term treatment, and these rises seem greatest in patients receiving ritonavir plus saquinavir. When saquinavir is the only protease inhibitor, very little lipid disturbance is seen; in one study of saquinavir with two nucleotide reverse transcriptase inhibitors large increases in triglyceride concentrations occurred in only 2% of 90 patients at 48 weeks.

Protease inhibitors have been clearly shown to prolong life and reduce opportunistic infections in HIV, not only in clinical trials but in practice. More research is needed to assess the potential long term effects of these drugs on lipid metabolism. In the meantime, however, their clinical benefits should not be overlooked.

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Article contained some inaccuracies

EDITOR—Berger's report on lipodystrophy in HIV infection contains some minor inaccuracies.[1] Firstly, the term lipodystrophy refers primarily to the peripheral loss of fat tissue which occurs in the limbs and face, not to truncal obesity. Increased abdominal fat is not seen in all cases.[2] Also, she states that the condition occurs most commonly in association with the drugs ritonavir and saquinavir. However, although the condition has been strongly associated with the use of these two protease inhibitors in combination,[3] it has rarely been seen with saquinavir alone.

She then discusses whether lipodystrophy and metabolic changes, such as hyperlipidaemia, are due to an effect of the protease inhibitors or advancing HIV disease itself. However, many patients with hyperlipidaemia do not have clinical lipodystrophy and it is premature to assume that these conditions have a common cause.

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Palliative care needs to be provided on basis of need rather than diagnosis

EDITOR—Williams et al and Russon and Alison raise important debates about extending palliative care beyond the initial remit of cancer.[1 2] The example of anorexia nervosa in their debate is a rare example of a potential role for palliative care. But good evidence suggests that people with progressive circulatory and neurological disorders have problems that require a palliative approach.[3]

Palliative care is an active approach to managing the whole patient and family and their problems which applies to many conditions. The potential numbers of people with these conditions far exceed those of people with cancer. Although pain is slightly less prevalent in the last year of life in these conditions than in cancer, breathlessness, constipation, and many other symptoms and family needs are equally or more common.[4]

Although the Calman Hine recommendations include the development of palliative care in cancer centres, palliative care in other settings is as important. What is required to take this forward? Firstly, a better understanding is needed of the problems that patients and their families experience towards the end of life and of the likely effective treatments. For some patients a dual approach to care needs to be adopted, with the possibility of death being acknowledged and discussed while efforts are continued to preserve or lengthen life. A better understanding of prognostic indicators would aid this process. Secondly, specialist palliative care services need to widen their brief so that they can include patients with conditions other than cancer. Such a step may require resources and the development of working relationships and collaboration with those who work in other specialties.

The National Council for Hospice and Specialist Palliative Care Services has recently prepared evidence to encourage such a step.[5] A challenge for medical professionals is to develop mechanisms of providing specialist palliative care on the basis of need rather than diagnosis.

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Only half of GPs in study knew that advance directives could carry legal force in UK

EDITOR—Zaman and Battcock are right: doctors need to know more about advance directives.[1] We hope that our paper will help them.[2] Like Zaman and Battcock, we conducted a postal survey, surveying all 270 general practitioners who refer patients to our hospitals in Hampshire and London; 214 (79%) replied. Of these, only 104 (49%) were aware that there were circumstances under which advance directives currently carried legal force in the United Kingdom.

A further six questions answered by these 104 doctors showed that most did not know important aspects of the law in relation to advance directives. For example, 13 thought that doctors were legally obliged to give all treatment that was requested in a valid directive, and only 44 knew that they were obliged to withhold treatment that was refused; only 15 were aware that the nomination of relatives or friends as proxy decision makers does not carry any legal force. Only one respondent answered all six supplementary questions correctly.

Zaman and Battcock are not strictly correct when they state that advance directives are invalid in the case of patients receiving treatment under the Mental Health Act. These directives may still be valid provided that the treatment to which they refer is not covered by the terms of the patient's detention under the act.[3] This precedent was set in the Sidaway case, when the right of a schizophrenic patient to refuse leg amputation was upheld even though he had been detained under the act.[4]

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Acute obstructive hydrocephalus complicating bacterial meningitis

In meningitis, one antibiotic is better than than two

EDITOR—A recent lesson of the week highlighted the possibility of meningitis in childhood presenting as obstructive hydrocephalus, with cerebrospinal fluid from ventriculostomy proving sterile but subsequent lumbar fluid yielding *Streptococcus pneumoniae*.[1] In the two paediatric cases described, treatment consisted of both a third generation cephalosporin and benzylpenicillin. In children between 3 months and 18 years of age, however, it is recommended practice for empirical treatment to consist of a third generation cephalosporin alone.[2 3] The article may be misleading in giving the impression that use of two antibiotics in this type of case is routine.

There is no sound microbiological basis for using a cephalosporin and a penicillin together, with the exception of patients who may be infected with *Listeria monocytogenes*. Listeriosis is extremely uncommon in England and Wales, with only 64 reported cases in the first seven months of 1997, including a total of 14 neonatal cases.[4] A third generation cephalosporin is adequate cover for *Neisseria meningitidis*, *Streptococcus pneumoniae*, *Haemophilus pneumoniae*, or *Escherichia coli*, and benzylpenicillin provides no extra benefit. Two β lactam antibiotics should not be given together unless this is unavoidable: there is potential for antagonistic interaction between agents, as both act by inhibiting cell wall synthesis. It is not likely that the penicillin was used to cover the possibility of listeriosis, as the drug of choice in such cases is ampicillin (with or without an aminoglycoside).[5]

We recommend that empirical treatment for patients aged between 3 months and 18 years who are suspected of having bacterial meningitis (not thought to be due to listeria or tuberculosis) should be monotherapy with high doses of a third generation cephalosporin, such as cefotaxime or ceftriaxone. Patients in the United Kingdom with a rash typical of meningococcal sepsis may be treated with a high dose of benzylpenicillin alone.

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Use of dexamethasone remains contentious

EDITOR—Mactier et al illustrate an important complication of bacterial meningitis—namely, acute obstructive hydrocephalus.[1] The authors say that they could not find any record of the incidence of this complication in children. A series of 79 cases over 11 years in Australia has been published; it shows an incidence of 2.8%.[2]

Interestingly, the first child Mactier et al described did not receive intravenous dexamethasone, whereas the child in the second case did, but when the drug was started, or its role in treating acute obstructive hydrocephalus, was not mentioned. Despite the drug's early promise, its use remains contentious. A recent meta-analysis showed that if it is

started with or before parenteral antibiotics, dexamethasone can benefit children with pneumococcal meningitis.[3] However, there were limitations on the analysis undertaken.

The use of dexamethasone in meningitis clearly requires further research, but questioning whether it should be used should not delay the administration of intravenous antibiotics.

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Hydrocephalus was probably non-obstructive

Editor—Mactier et al make important points about the management of patients who are seriously ill with acute bacterial menininginitis, particularly about draining cerebrospinal fluid via ventriculostomy.[1] Raised intracranial pressure leading to cerebral herniation is well recognised in patients with bacterial meningitis.[2] It is probably multifactorial in origin, with inflammatory cytotoxic oedema, interstitial oedema due to increased permeability of the blood-brain barrier, venous thrombosis, infarction, and hydrocephalus contributing.[3] Mactier et al, however, refer to "obstructive" hydrocephalus. In fact the hydrocephalus in both cases is likely to be non-obstructive or communicating in origin, as there does not seem to be any evidence for obstruction of the internal cerebrospinal fluid pathway. In particular, figure 3 (computed tomography scan of case 2) shows a dilated fourth ventricle, indicating obstruction ouside the ventricular system. Communicating hydrocephalus in bacterial meningitis reflects failure of cerebrospinal fluid circulation in the basal cisterns and failure of resorption through arachnoid granulations.

The failure to diagnose meningitis on examination of ventricular cerebrospinal fluid is well recognised. Samples of lumbar and ventricular cerebrospinal fluid may show considerable disparity even when the meningeal inflammatory process is severe, and the diagnosis of acute bacterial meningitis should not be discounted when ventricular cerebrospinal fluid is normal or mildly inflammatory. The authors are correct in advising that lumbar puncture should not be performed in patients who have impairment of consciousness before brain imaging.

Finally, the comment that "diagnosing critically high intracranial pressure is difficult" is wrong. Intracranial pressure is easily, reliably, and safely monitored in the appropriate setting—which is a neurosciences intensive care unit. Although there is no hard proof that such monitoring, the use of ventricular drainage, or other methods of controlling intracranial pressure will improve outcome, it seems logical that the experience and knowledge of those involved in neurological intensive care, particularly with regard to the management of raised intracranial pressure, altered cerebral perfusion, and autoregulation, should be available for patients with bacterial meningitis. Unfortunately the lack of available beds in such units in the United Kingdom may prevent these patients benefiting from modern, targeted treatment.

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Neuroimaging has limitations

Editor—Mactier et al's lesson of the week concludes with a recommendation that all patients with suspected meningitis and decreased level of consciousness should urgently have brain imaging to exclude obstructive hydrocephalus before lumbar puncture.[1] It is most important to understand the limitations of neuroimaging in children with acute meningitis, and to avoid the commonly held misconception that lumbar puncture is safe if neuroimaging is normal.

Lumbar puncture should be avoided in children with clinically diagnosed meningitis if consciousness is impaired or there are clinical signs of raised intracranial pressure, as it may precipitate herniation of the brain or coning. Coning may occur after lumbar puncture in children with meningitis even when neuroimaging has been normal.[2]

Brain imaging is of no value in the immediate diagnosis of meningitis and is an insensitive method for the detection of raised intracranial pressure.[3] The role of brain imaging is to identify complications of meningitis or to exclude focal brain pathology simulating meningitis. Positive indications for computed tomography or magnetic resonance imaging are progressive focal neurological signs, prolonged decreased level of consciousness, prolonged or focal seizures, increasing head circumference, evidence of continuing infection, or recurrence of symptoms. Brain imaging should not be done until antibiotic treatment has been started, raised intracranial pressure has been controlled, and intubation and ventilation started, if necessary.

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1 Mactier H, Galea P, McWilliam R. Acute obstructive hydrocephalus complicating bacterial meningitis in childhood. *BMJ* 1998;316:1887-9. (20 June.)
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50 years of the NHS

Junior doctors should have contributed to discussion on NHS

Editor—The article on the love-hate relationship that people have with the NHS presented several views of the system in which most of us work.[1] I noticed that responses were "invited" by the *BMJ* and that the article contained replies from three chairpeople, two chief executives, five professors, three consultants (two in psychiatry), the general secretary of the Royal College of Nursing, a member of the University of York, and even a broadcaster. It strikes me that general practitioners were somewhat underrepresented—as the largest single group of doctors to have completed their training—with only one reply.

Surely the most telling omission in the journal is that there are no replies from junior doctors. I assume that either no junior doctors were canvassed or their replies were not deemed worthy of publication. Junior doctors are leaving the NHS at worrying rates: is this due to being overworked or underpaid, or is it perhaps that our views of the NHS are simply not regarded as important?

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1 Our love-hate relationship with the NHS. *BMJ* 1998; 317:8-9. (4 July.)

Demand must be reduced or funding must be increased

Editor—I am grateful to Portillo for his clear arguments about NHS funding.[1] As doctors we are in a strange position for any industry—that is, of being able to generate a huge demand for our product. This arises because we are dealing with a general population that is scared and anxious about its health. People are being encouraged to report more symptoms to a doctor as quickly as possible and to fear the worst. How many children with self limiting viral illnesses are brought to our surgeries because of fears of meningitis?

We are also dealing with a scared and anxious medical profession whose members are all consciously or unconsciously practising defensive medicine. We are all scared to miss things. We are usually going to give way to the request for an extra *x* ray even if it is not necessary on clinical grounds. After all, we rationalise, it might show something unexpected. Our real reason is to appease our patient and our fear is of complaints and lawyers.

So long as the meeting place between doctor and patient is dominated by unrecognised fears that affect both patient and doctor the NHS will be unable to reduce the anxiety driven demands of the public and the anxiety driven responses of the doctors.

In a private industry in which payment is made for each service this demand would generate extra profits for a company. In a

cash limited service extra demand will generate strain on the resources and result in anguish and disappointment for doctors and patients alike. This friction between demand and resources is reaching a head. Without a reduction in demand or without extra funding I see only disappointment and stress for patients, doctors, managers, and politicians.

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1 Portillo M. The Bevan legacy. *BMJ* 1998;317:37-40. (4 July.)

Picture painted of health service in Singapore was too rosy

EDITOR—Having just arrived from Singapore I was surprised to read about the success of the Singaporean health service.[1] In reality the cost of medical care there is expensive and quite beyond the reach of the average family. Any form of surgical intervention further increases the cost, and many people travel to India and Malaysia for treatment because costs in these countries are lower.

Effective primary care as practised in United Kingdom is non-existent; any aid to the poor is considered "welfarism" and is strongly condemned by the ruling government. Many doctors and health professionals disagree with Lim's rosy picture of the system but are afraid of identifying themselves for fear of repercussions. I feel sad and sorry for those who are poor, those who are unemployed, and those who are elderly; for them there is very little health care. Perhaps, as the NHS celebrated its golden jubilee, it would have been more appropriate to highlight the health services of India and Malaysia which provide a reasonably good service under trying conditions.

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1 Lim JME. The importance of social context. *BMJ* 1998; 317:51-2. (4 July.)

UK blood service is responding to current needs

EDITOR—Booth's comments on blood donation have to be considered in the context of delivering a national service to donors, hospitals, and patients. The National Blood Service needs to collect 10 000 voluntary blood donations every day to meet the needs of all the hospitals in England and north Wales. We are keen to consider partnerships with hospitals where our combined efforts could provide a better as well as a cost effective service to patients and donors. Indeed, we already hold many sessions on hospital sites throughout the country. However, voluntary blood donor sessions need to be located in the centre of communities to make it easy for donors to attend.

To improve flexibility and convenience for donors we have been increasing the number of static units and locality based blood collection teams. This has enabled us to increase opening hours by reducing staff travelling times and to introduce donor appointment systems to help avoid long queues.

The copper sulphate screening test used at donor sessions may seem archaic, but it is still the simplest, quickest, and most robust method for detecting a pass or fail against the haemoglobin standard acceptable for blood donation. All those who fail this test have their haemoglobin checked by a reference technique at the session to ensure nobody is turned away unnecessarily. The same applies to all the mandatory microbiology screening tests required to minimise the risk of transfusion transmitted infections. Sensitive and specific automated rapid screening tests with "go"/ "no go" standards and positive sample identification systems are backed up by confirmatory testing algorithms for any reactive samples.

All donor screening has to be undertaken in an environment of good manufacturing practice under the control of blood centres licensed by the Medicines Control Agency to ensure the safety and security of the blood supply. What seems like a simple somewhat old fashioned "shop window" at our donor sessions is backed up by a complex national laboratory network.

Although autologous predeposit blood donation seems attractive, it is suitable for only a small proportion of patients and requires the enthusiastic support of local surgical teams. It can work well. Similarly, the provision of donor and therapeutic apheresis services has shown our willingness to undertake joint ventures with hospitals in response to clinical need. The National Blood Service is an integral part of the NHS and therefore, by definition, welcomes opportunities to extend and develop such hospital partnerships.

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1 Booth F. UK blood donation needs reorganisation. *BMJ* 1998;317:281. (28 July.)

Risk of breast cancer among female airline cabin attendants

Findings may have been due to exposure to cosmic radiation or recall bias

EDITOR—We agree with Wartenberg and Stapleton that dicophane (DDT) is one of the possible aetiological factors for breast cancer in female airline cabin attendants.[1] Two other factors (exposure to cosmic radiation and recall bias) also merit attention.

We are not told how the cases and controls were selected or matched in their survey. The exposure data should be only data up to the date of diagnosis for flight attendants in whom breast cancer was diagnosed (cases) and data up to the date of pseudo-diagnosis for controls (the date on which the breast cancer was diagnosed in the cases). The cabin attendants with breast cancer would have stopped flying because of illness, and controls would have continued to fly; this would distort the measurement of exposure to cosmic radiation. Moreover, the cabin attendants with breast cancer would probably have had fewer flights in the year before the diagnosis owing to the undiagnosed breast cancer. Ideally, exposure should be measured until the year before diagnosis to avoid this bias. The breast is the organ most sensitive to radiation carcinogenesis in postpubertal women,[2] and hence cosmic radiation cannot be ruled out as a potential factor in the aetiology of breast cancer. A cohort study of Canadian air pilots showed an increased risk of acute myeloid leukaemia, the type of leukaemia induced by exposure to radiation (standardised incidence ratio 4.72 (90% confidence interval 2.05 to 9.31)).[3]

Recall bias needs to be considered in any study in which exposure is measured after a disease has been diagnosed or an event has occurred.[4] In the case of exposure to DDT, recall bias could have led to the non-significant increase in risk that Wartenberg and Stapleton found. Because of the strong link between pesticides and cancers, flight attendants with breast cancer would have been more likely than controls to recall pesticide spray. It is always important to verify the records, if they are available, to measure their agreement with reported exposure in a proportion of cases and controls.

Although the point estimate for exposure to DDT that Wartenberg and Stapleton report is high (odds ratio 2.2), the wide confidence interval (0.4 to 10.9) suggests that recall bias could account for the observed odds ratio. We agree with the authors' suggestion that large studies will be the way forward to determine the role of DDT in breast cancer among airline attendants. These studies should also explore the joint effect of DDT and cosmic radiation.

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1 Wartenberg D, Stapleton PC. Risk of breast cancer is also increased among retired US female airline cabin attendants. *BMJ* 1998;316:1902. (20 June.)
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Large European studies are now being carried out

EDITOR—Wartenberg and Stapleton suggest[1] that pesticides used in aircraft could contribute to the increased risk of breast cancer among flight attendants previously reported from Finland[2] and Denmark.[3] The frequency and magnitude of exposures to pesticide are unknown but probably limited. To our knowledge, pesticide spraying was practised only on international flights to a few destinations. Exposure of Finnish flight attendants has certainly been rare and is unlikely to have contributed to our findings. Furthermore, there is little evidence for organochlorine pesticides as a risk factor for

breast cancer.[4 5] Therefore there is little evidence to support the suggestion that pesticides could contribute substantially to the risk of breast cancer.

In our view, the strongest factors that have been shown empirically to affect risk of breast cancer among cabin crew are parity and age at first birth.[1] More research is clearly needed to elucidate the reasons for increased risk of breast cancer among cabin crew. Two European studies (coordinated by EP and MB) are now being carried out. One is being done in 10 countries and among 30 000 pilots and 45 000 members of cabin crews, with mortality from cancer as the end point; the other, a Nordic study, is of cohorts from five countries, with smaller numbers of cases and incidence of cancer as the end point. These studies are expected to provide more information on the issue.

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Authors' reply

EDITOR—We did not address several issues in our letter because of space limitations. The study design that we used was a retrospective cohort postal survey of members of an organisation of retired flight attendants from one American airline. As Badrinath and Ramaiah suggest, selection bias, follow up bias, and recall bias could all have occurred. With regard to selection bias, we were more likely to have omitted flight attendants who developed breast cancer (or died) than healthy flight attendants owing to their lack of continued involvement in organisations for flight attendants. In terms of follow up bias, the suggestion that we should have adjusted flying times seems logical, but all of the women who developed breast cancer either received the diagnosis several years after stopping work or reported that they continued to work after diagnosis.

Therefore we do not believe that our method underestimated exposure to radiation differentially, although we also believe that radiation may have been a contributing factor to the breast cancers. Recall bias, as in all survey studies, is likely but difficult to evaluate since we know of no available records of pesticide use. Auvinen et al suggest that, although they do not know the magnitude and frequency of pesticide use in the past, it was probably limited. We based our suggestion on the World Health Organisation's recommendation in 1961 for pesticide treatments on international flights.[1] More data, from additional studies, are needed to resolve this.

We disagree that there is little evidence that organochlorine pesticides are a risk factor for breast cancer. Results in the literature are mixed, but several studies currently under way were designed to test the hypothesis of a link between DDT and breast cancer more specifically than those already conducted. We recognise that reproductive factors are likely to contribute to the risk in our population (parity, age at first birth, age at menarche, age at menopause), but our sample was too small to assess this effect directly.

Overall, our preliminary study was too small to rule out or confirm any risk factor for breast cancer among flight attendants. We simply proposed adding use of DDT pesticides to the list of risks to be considered in exploring the aetiology of breast cancer among flight attendants. We look forward to the results of the studies being carried out to provide further insight.

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1 Aircraft disinfection. Eleventh report of the expert committee on insecticides. *WHO Tech Rep Ser* 1961;206.

Patients with prostate cancer should be enrolled in a national, controlled trial

EDITOR—I endorse the views of Mulley and Barry on treating prostate cancer.[1] British urologists are deluged with data from the United States which encourages radical prostatectomy, yet there is no good evidence from randomised controlled trials to validate their policy.

If the editorial had been written by an American urologist the conclusion would have been entirely different. Mulley and Barry failed to emphasise the powerful financial motives behind much of what is published about prostate cancer in the United States. There is an undoubted bias in favour of papers that promote screening and radical surgery, including papers that estimate the resulting financial reward per urologist.[2] We should note that the American urologist invited by one journal to review "watchful waiting" in early prostate cancer is one of the leading exponents of screening and radical prostatectomy in the United States.[3] There is therefore no shortage of biased, uncontrolled, non-randomised data in support of radical surgery.

The crux of this problem is that radical prostatectomy was "let out of the bag" before being properly evaluated in a randomised controlled trial. What we need is a large study comparing watchful waiting, radiotherapy, and radical prostatectomy.

We need a system to license new forms of treatment as "approved for clinical trial only." Any costly new treatment should only be available through a nationally approved and controlled trial. Patients would only have access to the new treatment by agreeing to abide by the protocol, which would include randomisation. Doctors would only be licensed to use the treatment within the trial and only after appropriate training. Trials could recruit much larger numbers of patients and do this more quickly than is currently the case. Those centres involved in the trial could then train others wishing to use the new technique if it is subsequently approved for use across the NHS.

I do not think that it is too late to consider such a trial for early prostate cancer in the United Kingdom but only if an approach is adopted along the lines suggested—that is, only approved clinical trials for all patients being considered for radiotherapy or radical prostatectomy. How else can we collect the evidence on which to base advice for future generations of men with this enigmatic cancer? How else can we respond to the reasonable plea from Mulley and Barry: "Banish dogma, get more data."

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1 Mulley AG Jr, Barry MJ. Controversy in managing patients with prostate cancer. *BMJ* 1998;316:1919-20. (27 June.)
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Bournewood: an indefensible gap in mental health law

Law Commission's proposals for incapacity jurisdiction strike reasonable balance

EDITOR—We agree with Eastman and Peay that capacity will become a major issue for mental health services,[1] particularly in the light of the consultation paper *Who Decides?*.[2] The Law Commission's proposals on which the paper was based[3] afford a mechanism that could resolve much of the practical difficulty arising from the Appeal Court's decision while also affording the rights that the House of Lords' decision denies.[4]

The Law Commission proposed an incapacity jurisdiction, to provide an integrated framework for decisions concerning personal welfare, health, or financial matters of incapacitated people. As with similar provisions,[5] the court was intended to be a jurisdiction of last resort. Its jurisdiction would be invoked only if the making of an order would be of greater benefit to the incapacitated person than would no order.

The recommendation for the incapacity jurisdiction covered giving or refusing approval for particular forms of health care, appointing managers to give or refuse such consent, and requiring people to allow a

proxy to take over responsibility for their health care. In relation to mental disorders the Law Commission recommended that the court's incapacity jurisdiction should extend to the power to order admission to hospital for assessment or treatment of mental disorder if there are grounds for admission under section 2 or 3 of the Mental Health Act and it is in the person's best interest to be admitted.

Although the existence of another court might seem a further burden on busy clinicians, we believe that it would help considerably. The right to apply to the mental health review tribunal and the right of the nearest relative to obtain the patient's discharge would not apply during the first period of detention in these circumstances, since a judicial determination would already have been made. This provision would mean that most cases would not need to be reviewed, since the median period for admission of patients with dementia is 5-10 weeks.

Who Decides? asked whether a new provision for compulsory admission to hospital is needed. The House of Lords' judgment has underlined the urgency of a new procedure, and the Law Commission's proposals for an incapacity jurisdiction strike a reasonable balance between the rights of incapacitated people and the duties of clinicians. The risk of confusion between the two procedures would be minimised if an NHS directive advised psychiatrists to use the incapacity jurisdiction procedures wherever they would have used informal admission.

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1 Eastman N, Peay J. Bournewood: an indefensible gap in mental health law. *BMJ* 1998;317:94-5. (11 July.)
2 Lord Chancellor's Department. *Who decides? Making decisions on behalf of mentally incapacitated adults.* London: HMSO, 1997. (Cm 3803.)
3 Law Commission. *Mental incapacity.* London: HMSO. 1995. (Com 231.)
4 Shah A, Dickenson D. The Bournewood case and its implications for health and social services. *J R Soc Med* 1998; 91:349-51.
5 *Children Act 1989.* London: HMSO, 1991.

Law is inappropriate for patients admitted informally but who lack capacity

EDITOR—Why do Eastman and Peay think of patients with a mental disorder as constituting a special class of patients whose treatment must be regulated by specific mental health legislation?[1] In the wake of the House of Lords overturning of the Court of Appeal's decision in the Bournewood case, concern is being expressed about what Lord Steyn called "an indefensible gap in our mental health law" for non-objecting patients without capacity who are admitted to hospital informally. What should the safeguards be for these so called detained patients?

Many see these safeguards as requiring changes in mental health law or the involvement of the Mental Health Act Commission.[2] This is inappropriate. One of the options mentioned by Eastman and Peay needs to be put more strongly and extended. We fail to see any difference between patients with mental incapacity, whether they have a mental or a physical disorder. Both groups require the same protections, whether they are on a psychiatric, medical, or surgical ward. We see the Law Commission's proposals[3] and the subsequent consultative paper *Who Decides?*[4] as offering an excellent framework for all patients who lack capacity, including those who are mentally ill. The range of useful options presented will, we believe, improve the care of all patients. A mental health act or the Mental Health Act Commission has no role.

One could go further. The Bournewood case illustrates the disjunction in mental health legislation between the legal criteria for detention in hospital and the question of capacity. The question of capacity has no direct role, yet for all patients (other than those who are mentally ill) non-consensual treatment cannot be given in their best interests unless they lack the capacity to make treatment decisions. We see no justification for this discrepancy. If a patient with a mental disorder has the capacity to make treatment decisions why should this not be respected as it is for all other patients?

Who Decides? discusses provisions for all patients with incapacity, including those who object and thus might require treatment against their will. These provisions include advance directives, continuing powers of attorney covering healthcare decisions, managers appointed by the court, and judicial decisions. Thus a mental health act for interventions with a paternalistic justification is not needed. Indeed, a strong case can be made that mental health legislation discriminates against patients with a mental disorder, supporting prejudicial stereotypes of difference, incompetence, and dangerousness.[5]

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Descriptions of adverse drug events should be standardised

EDITOR—A news item on pharmacogenomics mistakenly asserted that about two million Americans are hospitalised annually as a result of drug interactions instead of asserting that they were hospitalised as a result of adverse drug reactions.[1 2] The category of adverse drug reactions may include drug interactions as one of many causes of the reaction but the reverse is not true. Readers should be cautious because many seemingly similar terms exist. Examples of terms used to describe drug interactions include adverse drug interaction, drug-drug interaction, drug-laboratory interaction, and drug-food interaction.

A drug interaction has been defined as "an action of a drug on the effectiveness or toxicity of another drug," and "an adverse reaction to a drug has been defined as any noxious or unintended reaction to a drug that is administered in standard doses by the proper route for the purpose of prophylaxis, diagnosis, or treatment."[3] However, the WHO's original definition of adverse drug reaction excluded therapeutic failures, intentional and accidental poisoning, and drug abuse, as well as adverse events due to medication errors such as errors in administration or non-compliance.[2]

The more inclusive term "adverse drug event" has recently come into use.[4] According to Bates et al this term, which is defined as an injury resulting from medical intervention related to a drug, is preferred since it is more comprehensive and clinically important than the term adverse drug reaction.[4]

Because there is no uniformity in the use of these terms, it is sometimes difficult to compare studies and derive incidence rates for adverse drug reactions and drug interactions. Let us hope that standardisation of these terms occurs as rapidly as our understanding of these phenomena evolve.

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1 Tanne JH. The new word in designer drugs. *BMJ* 1998;316:1930. (27 June.)
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Other method for adjustment of multiple testing exists

EDITOR—Perneger's paper on Bonferroni adjustments consists almost entirely of errors.[1] He states that the Bonferroni adjustments are concerned with the wrong hypothesis and that the two groups are identical on all 20 variables (the universal null hypothesis). This misses the main point of multiple test adjustments.

Similarly he says, "If one or more of the 20 P values is less than 0.00256 … we can say that the two groups are not equal for all 20 variables, but we cannot say which, or even how many, variables differ." Researchers who adjust P values almost always present them for their individual hypotheses. With n hypotheses each tested at level α, Perneger claims that "the formula for the error rate across the study is $1-(1-\alpha)^n$." This formula assumes independence of the

test statistics; the actual bound on the error probability is nα.

Perneger sees multiple adjustment as a violation of common sense, as a given comparison will be interpreted differently according to how many other tests were performed. In other words, it's all right to dredge your data and not tell anyone.

Perneger queries whether adjustment should take place for each investigator—"taking the number of tests he or she has done in their lifetime into consideration." None but opponents of multiple adjusting have ever suggested this absurd idea.

"The integration of prior beliefs with evidence is best achieved by Bayesian methods, not by Bonferroni adjustments." Bayesians compute probabilities for simultaneous statements about multiple variables—which is just their way of adjusting. There is nothing new, and no solution here.

Perneger takes it for granted that the Bonferroni method should be used for multiple testing adjustments, whereas it has been known for almost 20 years that there is another procedure, the Holm method, that is uniformly superior to the Bonferroni method and applies in every case that the Bonferroni method does.[2] This has led the *American Journal of Public Health* to declare this alternative as the method of choice.

If we used hypothesis testing sensibly, computing benefits and costs of right and wrong decisions, and using the resulting optimal decision making procedure, then arguments about multiple adjustment would be unnecessary and we could concentrate on the real question—whether a given study should be statistically analysed at all.

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1 Perneger TV. What's wrong with Bonferroni adjustments. *BMJ* 1998;316:1236-8. (18 April.)
2 Aickin M, Gensler H. Adjusting for multiple testing when reporting research results: the Bonferroni vs Holm methods. [With comment, pp 628-9]. *Am J Public Health* 1996;86:726-8.

Counselling is not appropriate for all patients with cancer

Editor—Young makes important points in stating that psychological interventions differ in theory and practice[1]; each intervention must be defined so that the correct terminology is used by health professionals to facilitate appropriate interventions. She claims that our evaluation of the use of adjuvant psychological therapy in patients with cancer erroneously interchanged the terms "psychotherapy," "counselling," and "adjuvant psychological therapy," and that we dismissed "the benefits of counselling for patients with cancer on the basis of a study that used adjuvant psychological therapy."[2] She infers that the low response rate in our study may indicate that adjuvant psychological therapy might not have been "appropriate" although other approaches to counselling might have been effective.

We believe that since all categories of counselling are part of the "therapeutic enterprise"[3 4] the terminology is interchangeable. Information giving and reassurance are a form of counselling since they help to "contain" the person to whom they are given, "containment" being the necessary condition of patient support.

We do not, however, dispute that different approaches have their own theoretical underpinning nor that they are made explicit. Our report provided a reference to the theory underlying adjuvant psychological therapy.

When we elicited consent from patients to enter the trial, the method of counselling was described. The low response rate suggests, among other things, that these patients had an ability to cope, or a wish to be seen to be coping, or simply an aversion to the ethos of counselling. Patients' refusals to participate are as interesting as their acceptances, and it is imperative that we listen to their voices.

We do not dismiss the benefits of counselling for patients with cancer. We have evaluated a specific approach in a specific group of patients with cancer and concluded that adjuvant psychological therapy need not be routinely offered to men with testicular tumours. We make a plea for caution with regard to the blind faith that counselling will be gratefully received and will be effective despite a dearth of sound evidence.

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Any variability in outcome comparisons adjusted for case mix must be accounted for

Editor—Parry et al draw attention to the difficulties faced by those wishing to use comparative outcome data to indicate performance.[1] They clearly show the importance of adjusting for differences in case mix and allowing for random variation by establishing 95% confidence intervals for estimates of adjusted outcome. In addition to the uncertainty in the observed mortality, however, there is uncertainty in the predicted mortality. The overall lack of clarity in the rankings of the neonatal intensive care units might therefore be even greater if this additional uncertainty were acknowledged, which would reinforce the reservations expressed about decision making with these kinds of data.

Predictive models are only approximations to reality. They must be estimated from previous data and thus are themselves prone to noise and random fluctuation. Both the size of the original dataset and the predictive ability of the variables used determine the precision of the predicted outcome. In practice this uncertainty is reflected in the covariance matrix of the estimated model variables, and Hosmer and Lemeshow show how this can be used to calculate the uncertainty associated with the expected mortality.[2]

The potential influence of this variability can be illustrated with an example from stroke medicine. We calculated the expected 30 day fatality in a cohort of 436 patients with stroke admitted to a Scottish hospital, using an externally validated logistic regression model derived from 530 patients from the Oxfordshire community stroke project. We used the ratio of observed to predicted mortality to standardise the outcome for case mix (a method independent of unit size), which gave a value of 0.95. We calculated two different 95% confidence intervals for this ratio. For the first we used only simple binomial variation (95% confidence interval 0.79 to 1.11); the second, for which we used binomial variation plus model uncertainty (0.75 to 1.16), was 28% larger. This considerable increase in uncertainty might be found in other circumstances, such as the study described by Parry et al. Indeed, the clinical risk index for babies model used for adjustment for case mix was derived from a similar number of cases (812), but without explicit knowledge of the model covariance it is impossible to confirm this hypothesis.[3]

In the current climate of continual comparison of outcomes and performance review, it is vitally important that all sources of variability in outcome comparisons adjusted for case mix are accounted for; the consequences of a false positive declaration of significantly substandard performance are becoming ever more serios.

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