Letters

The General Medical Council and the future of revalidation

GMC member responds

Editor—Esmail and Kmietowicz give an inaccurate account of the General Medical Council's policy development on revalidation, ignoring an iterative process with interested parties since 1998 in an attempt to introduce the most fundamental change to medical regulation since its foundation in 1858.[1 2] The GMC clearly has had regard to the legitimate interests of three principal groups—government and the NHS, patients and the public, and the various tribes that make up the UK medical profession.

Despite suggestions to the contrary, an initial exploratory meeting on revalidation convened by Sir Donald Irvine in June 1998 was held in the context of a high profile professional conduct case, but well before the Bristol inquiry report and absolutely nothing to do with Rodney Ledward or, indeed, Harold Shipman. It was recognised then that some doctors were not keeping fully up to date nor were they indulging in reflective practice. Irvine correctly proposed that there was a need to make registration with the GMC more meaningful to the public than a mere recognition that doctors had reached a certain standard of professional knowledge in their early 20s.

Both articles promote the idea that the doctors' regulator should be filling the vacuum within the NHS created by its failing to fulfil its public responsibility to monitor doctors' clinical standards. Clinical governance is now, slowly, being developed and eventually will extend from systems and teams to individuals—but is it reasonable, as both authors postulate, that such monitoring should become the financial and moral responsibility of the GMC sitting in London and Manchester rather than local managers at the coalface?

Although revalidation is a continuing process, it becomes summative only every five years. The NHS and its local systems must not be allowed to abrogate their responsibility for the safety of patients on a day to day basis. Nor should they demand that the GMC and its prime function of assuring fitness to practise and the meaning of the medical register be inappropriately promoted as the first line of defence for the maintenance of clinical quality and safety.

MARK THOMAS

Brian D Keighley *general practitioner*
The Clinic, Balfron, Stirlingshire G63 0TS
Bkeighley@aol.com

Competing interests: BDK is a GMC elected medical member for Scotland and a non-executive director of the BMJ Publishing Group.

1 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7. (14 May.)
2 Kmietowicz Z. Revalidation in the UK. *BMJ* 2005;330:1145. (14 May.)

Revalidation, discretionary points, clinical excellence awards—steps on the same ladder

Editor—With reference to the article by Esmail,[1] the purpose of revalidation is to ensure that doctors provide safe, effective health care for patients. The quality of health care that the patient receives could therefore be the basis of revalidation, rather than a measure of the skills and knowledge of the doctor.

Clinical governance could be adapted for purposes of revalidation as the means by which a doctor is held responsible and assessed to ensure the provision of a high quality of health care and the maintenance of the means to achieve it. Revalidation could be granted for fulfilling the requirements of clinical governance.

The advisory committee on clinical excellence awards administers a tried and tested scheme for granting clinical excellence awards, and the trusts have committees responsible for the granting of discretionary points in an integrated scheme. Revalidation could be incorporated in this scheme avoiding a plethora of committees. Involvement of the advisory committee would inspire public confidence.

Revalidation and granting of awards could be a combined exercise. Criteria should be established for revalidation as for the awards. Revalidation may not be required in the first few years after appointment. This strategy could dramatically reduce the cost of the scheme.

Submission of evidence is best simplified as for the awards. Preparation of a folder of evidence would be more appropriate for appraisals.

Similar schemes could be envisaged for general practitioners, involving the primary care trusts.

Professor David Hatch in giving evidence to the Shipman inquiry made an illuminating contribution about revalidation, saying that nobody had given him the opportunity to demonstrate his fitness to practise.[2] Every effort should be made to present revalidation as a process that benefits the doctor as well providing protection for the patient.

Anton E A Joseph *consultant radiologist*
Mayday Healthcare NHS Trust, Croydon, Surrey CR7 7YE
aeajoseph@hotmail.com

Competing interests: None declared.

1 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7. (14 May.)
2 The Shipman Inquiry. Reports. Fifth report—Safeguarding patients: lessons from the past—proposals for the future. www.the-shipman-inquiry.org.uk/fifthreport.asp (accessed 7 Jun 2005). (Section 26.12, p 1030.)

GMC prepares to deliver notable improvements

Editor—Esmail is looking at things from the wrong end of the telescope when claiming that the General Medical Council has failed to grasp the issue of scrutinising doctors' performance.[1] Surely the main lesson that has emerged from the various recent inquiries is that employers of doctors (including primary care trusts) need to ensure that they have in place local systems that can deal quickly, effectively, and fairly with poor or dangerous practice.

That approach has—rightly—underpinned the government's quality agenda since 1997, and it was reaffirmed by Lord Warner at the conference of the Council for Healthcare Regulatory Excellence in March this year, when he said that the responsibilities of employers must be properly exploited before we load more on to regulators. We need proper clarity on the respective roles of each. What is needed is a proper understanding of the role of clinical governance in improving the quality of care and protecting patients from harm, and of the relation between clinical governance and GMC procedures, including revalidation. How curious, then, that Esmail does not even mention clinical governance once. By contrast, Dame Janet Smith devoted an entire chapter of the fifth report to it.[2]

The GMC is determined to look forwards, rather than backwards. As our contribution to Sir Liam Donaldson's review, established after the fifth report, we

have set out a vision for the development of medical regulation over the next few years, which includes creating a robust system for revalidating doctors' licences to practise. As the regulator we want local systems to be subject to robust quality assurance so that evidence such as patient surveys, complaints records, professional development, clinical audits, and prescribing records provide the basis for confirming that doctors are up to date and fit to continue practising. We are certainly not "burying our head in the sand" but preparing to deliver the most significant improvements in professional regulation for 150 years.

Amanda Watson *director of licensing and revalidation*
General Medical Council, London NW1 3JN
jwren@gmc-uk.org

Competing interests: None declared.

1 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7. (14 May.)
2 The Shipman Inquiry. Reports. Fifth report—Safeguarding patients: lessons from the past—proposals for the future. www.the-shipman-inquiry.org.uk/fifthreport.asp (accessed 7 Jun 2005).

Regulation, regulation, regulation

EDITOR—Although impressed by the intellectual rigour Dame Janet Smith brought to her inquiry,[1] I am left with some questions after reading the article by Esmail.[2] Did she consider recommending the system her own profession uses to revalidate solicitors, barristers, and judges. And, if she did, why did she reject it?

I hope she would agree that both professions merit a similar standard of regulation. My own experience implies that incompetent doctors are responsible for no greater levels of morbidity, or even of premature mortality, than incompetent lawyers.

Dame Janet is also reported to have urged the General Medical Council to assume the power to expel "unsuitable" medical students, proposing "a test of ethics as a useful and sensible means of weeding out and failing students who had not managed to absorb essential ethical principles that they would be expected to practise throughout their career."[3]

If the government does decide to enshrine that wholesome advice in legislation I hope it will impose the same regulation on law schools. More importantly I hope it will devise a new "suitability" test for MPs before they enter parliament and a system for their regular revalidation once they get there. You don't need to monitor world affairs too closely to see that an unethical politician can be several hundred thousand times more lethal than a Dr Shipman.

Were the government to embark on such public spirited legislation, it would, of course, need to set up another regulating body to revalidate and "weed out" the revalidators and "weeders out," and a body to revalidate and weed out the revalidators and weeders out, of the revalidators and weeders out, and so on.

By which time, with luck, my days will have drawn to a peaceful unrevalidatable close.

Michael O'Donnell *former general practitioner turned journeyman writer*
Loxhill GU8 4BD
michael@odonnell99.freeserve.co.uk

Competing interests: MO'D has a deep mistrust of equivocating adjectives such as "suitable" and "appropriate."

1 The Shipman Inquiry. Reports. www.the-shipman-inquiry.org.uk/reports.asp (accessed 7 Jun 2005).
2 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7. (14 May.)
3 Pritchard L. "Weed out" unethical medical students, Dame Janet urges." *BMA News* 2005 May 14.

Profession needs to debate regulator's role

EDITOR—Esmail insinuates that the public has lost confidence in the medical profession.[1] This is not true. The public puts doctors at the top of the professional tree in poll after poll. The elites of medicine have lost their nerve, and that is the problem. Esmail proposes that doctors are afraid of revalidation. We are not. What we, and our patients, do not want is to invest time and money in a harebrained scheme. We are loath to support yet another cottage industry in medical governance.

Esmail asserts that revalidation is better than appraisal. He provides no evidence, only opinion. Appraisal, by definition, is a means of determining a doctor's effectiveness. This requires that activity data be gathered and then analysed. These data are currently available, albeit incompletely, but are not analysed. They can be refined by using logbooks. That is all that is required to identify poor performance.

Esmail claims that 3% of doctors are seriously deficient. Who says? The Bolam case?[2] Standards set by professors who hardly see patients and who preside over college examinations that these same doctors pass? Professional elites may be obsessed with assessment; patients are not. It is time to put a halt to the self flagellation over Bristol and Shipman and concentrate on improving quality. The public has moved on, and so should we.

The profession needs to debate the role of the regulator. A referendum is essential. Do we persist with self regulation, which allows a small, self appointed group to tell us what to do? Or, do we want a Driver and Vehicle Licensing Agency (DVLA)-style regulator, which would leave us alone to get on with caring for the sick? I know what I would vote for. Determining doctors' fitness to practise is an inappropriate job for a regulator. That is the job of those who employ doctors.

Olusola O A Oni *consultant orthopaedic surgeon*
Anstey LE7 7TH
ooni141400@aol.com

Competing interests: None declared.

1 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7. (14 May.)
2 Bolam *v* Friern Hospital Management Committee [1957] 1 WLR 583.

Revalidation process would not pass appraisal

EDITOR—Catto's paper in the series on the GMC and the future of revalidation, although very thoughtful, does not tackle many of the problems with revalidation as it has been discussed hitherto.[1] Catto also fails to understand that Dame Janet Smith's inquiry report is largely irrelevant to revalidation, particularly for doctors who are not general practitioners.

The current appraisal process, on which revalidation seems likely to be based, is clunky, time consuming, bureaucratic, and largely irrelevant to an assessment of whether a doctor is fit to practise.

Firstly, the current process does not contain any mention of 360° appraisal, surely one of the most effective ways of shining a light into the darker corners of a doctor's practice.

Secondly, although audit is no doubt essential, to perform meaningful audit is extraordinarily difficult if the person being audited is not a surgeon. If I see a patient with pneumonia on a post-take ward round and then hand that patient over to my respiratory physician colleague, is the patient's ultimate outcome my responsibility or that of my colleague, or both? Even something as simple as prescribing audit requires a degree of commitment and funding that most NHS trusts would struggle to match at present. Providing evidence that a doctor has attended training courses is all well and good, but it does not prove that the doctor has changed his or her practice on the basis of the training received.

The General Medical Council needs to get a lot smarter in its approach to revalidation if it is to overcome the huge cynicism that exists in the profession and, more importantly, if it is actually going to achieve its aim of satisfying itself, parliament, and the public that doctors on the register are, and remain, fit to practise.

Roger A Fisken *consultant physician*
Friarage Hospital, Northallerton, North Yorkshire DL6 1JG
roger.fisken@stees.nhs.uk

Competing interests: None declared.

1 Catto G. Building on the GMC's achievements. *BMJ* 2005;330:1205-7 (21 May.)

Underwater birth and neonatal respiratory distress

Case report does not constitute reliable evidence

EDITOR—We were concerned and dismayed to see the case report by Kassim et al of respiratory distress for a baby born in water being cited as evidence of the risk of underwater birth.[1 2] Respiratory conditions can occur after any birth, and in the absence of discernible antenatal fetal compromise they are not particular to water birth. This account by two neonatologists and a radiologist from a prominent London

centre is likely to provoke fear among practitioners and parents.

Having recently reviewed the evidence about immersion in water during labour and birth we concluded that a clear need existed for further evidence about the safety and effectiveness of water birth.[3] This systematic review provided no basis to deny this care option for women with uncomplicated pregnancy.

Unfortunately this case report contributes to unreliable evidence and information women are offered when making decisions and choices for labour and birth. Safety and effectiveness of immersion in water for birth should be evaluated in a well designed randomised controlled trial. Neither opponents nor proponents serve women and babies well by continuing to accumulate anecdotal reports to support their own biases.

Elizabeth Cluett *senior lecturer*
University of Southampton, School of Midwifery, Southampton SO17 1BJ
e.cluett@soton.ac.uk

Rona McCandlish *research fellow*
National Perinatal Epidemiology Unit, University of Oxford, Oxford OX3 7LF

Ethel Burns *research midwife lecturer*
Oxford Brookes University, Oxford OX3 7PD

Cheryl Nikodem *head, post graduate students and research*
University of the Western Cape, Bag X 17, Belville 7535, South Africa

Competing interests: None declared.

1 Kassim Z, Sellars M, Greenough A. Underwater birth and neonatal respiratory distress. *BMJ* 2005;330:1071-2. (7 May.)
2 This week in the *BMJ*. Underwater birth poses risks for the baby. *BMJ* 2005;330. (7 May.)
3 Cluett ER, Nikodem VC, McCandlish RE, Burns EE. Immersion in water in pregnancy, labour and birth. *Cochrane Database Syst Rev* 2004;(2):CD000111.

Authors' reply

Editor—Cluett et al point out that respiratory conditions can occur after any birth and in the absence of discernible antenatal fetal compromise. However, we had emphasised data that excluded other causes of neonatal respiratory distress in our case—namely, the mother was apyrexial, the membranes had been ruptured less than 18 hours at delivery, the infection screen on the infant gave negative results, there was no fetal distress, and the baby was born vaginally and required no resuscitation. Most importantly, our paediatric radiologist (MS) reported the chest radiograph to show widespread changes consistent with aspiration of birthing pool water. It is implicit in her report and is also obvious from the figure we included of the chest radiograph that the chest radiograph did not show pneumonia, transient tachypnoea of the newborn, airleak, or any other cause of respiratory distress other than aspiration of birthing pool water—hence we made the diagnosis.

We disagree with Cluett et al: it is important for practitioners and parents to be aware of the potential risks of water birth. We want mothers to be able to make a fully informed decision regarding place of delivery.

Zainab Kassim *clinical research fellow in neonatology*
Anne Greenough *professor of neonatology and clinical respiratory physiology*
anne.greenough@kcl.ac.uk
Department of Child Health, Guy's, King's and St Thomas' School of Medicine, King's College Hospital, London SE5 9RS

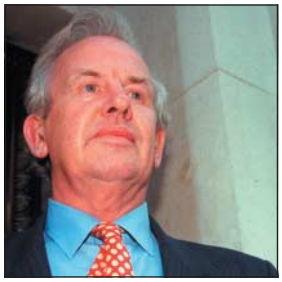
Maria Sellars *consultant in radiology*
Department of Radiology, King's College Hospital, London

Competing interests: None declared.

Was Rodney Ledward a statistical outlier?

Initial investigations of outliers must be chosen carefully

Editor—In their paper investigating whether Rodney Ledward was a statistical outlier Harley et al do not define what they mean by statistical outlier.[1] If it is a person whose outlying position in the distribution is almost certainly not due to chance, then they have failed. The numbers outside the 95% confidence intervals are as anticipated from the size of the population, and therefore they are simple outliers. They probably have refined the analysis so that those at the extremes are more likely to be aberrant performers, but they have not shown statistically that this is so. To do so, it would be necessary to show that a disproportionate number were outside the expected confidence intervals. This might be done by demonstrating two populations or possibly by recalculating the confidence intervals, using only those between, say, the 20th and 80th centiles and looking for wide outliers (using 0.1% intervals), clusters, and asymmetry outside the new intervals.


STEPHAN ROUSSEAU/EMPICS

This criticism makes the cautions expressed in the article the more valid. Attempting to uncover true bad performance by global audit is necessarily a very nonspecific process. Although most bad performers will be outliers, the converse is not true. This means that the initial investigations of outliers must be chosen carefully and those investigated treated with delicacy in an absolutely confidential process.

C Kevin Connolly *retired physician*
Aldbrough St John, Richmond, North Yorkshire DL117TP
ck-r.connolly@medix-uk.com

Competing interests: None declared.

1 Harley M, Mohammed MA, Hussain S, Yates J, Almasri A. Was Rodney Ledward a statistical outlier? Retrospective analysis using routine hospital data to identify gynaecologists' performance. *BMJ* 2005;330:929. (23 April.)

Statistical method may be difficult to apply in clinical practice

Editor—Harley et al make an interesting proposal for retrospectively detecting outliers.[1] However, we think that, as presented, the method may be quite difficult for clinical audit teams to understand and apply in routine practice.

It might be helpful to think in terms of test statistics. For each consultant in each year, the authors used the Mahalanobis distance to help calculate a kind of test statistic, and they compared this with a reference distribution. From table 2 of their paper (see bmj.com), some 16% of the consultants were flagged as outliers each year. If the most unusual 16% of consultants are flagged each year, then we would expect 3% of consultants to be flagged in three or more of five years simply by chance (simple binomial model). In practice, the authors found that 11 of about 100 consultants were flagged as outliers in three or more years, including Ledward.

We also detected a basic error in the method in the second paragraph of the methods subsection ("Stage 2"). Harley et al used as a cut-off point the mean of the square root of χ^2, which is given by the $\sqrt{7}$ degrees of freedom, which in their study is stated as $\sqrt{7}=2.66$. However, the expectation (mean) of $\sqrt{x}$ is not generally the same as the square root of the mean of x. A distribution with 7 degrees of freedom actually has mean 2.55 (52nd percentile), not 2.66 (58th percentile) as quoted in the paper. This could have made a practical difference to the results.

Benjamin J Cowling *senior research assistant*
Anthony J Hedley *chair professor*
Department of Community Medicine, University of Hong Kong, Hong Kong SAR, China
commed@hkucc.hku.hk

Competing interests: None declared.

1 Harley M, Mohammed MA, Hussain S, Yates J, Almasri A. Was Rodney Ledward a statistical outlier? Retrospective analysis using routine hospital data to identify gynaecologists' performance. *BMJ* 2005;330:929. (23 April.)

Authors' reply

Editor—Connolly and Cowling and Hedley raise several technical issues relating to our article. Connolly says that we have not shown that the number of outliers we identified is above that expected by chance alone. When considering the annual analyses, by chance alone one would expect 5% of consultants to be outliers. As table 2 in our paper shows, in any year, we found three times as many outliers as predicted by chance alone.

Cowling and Hedley indicate that our method may be difficult for clinical audit teams to apply routinely. As indicated in our paper, we believe that it is premature to consider routine implementation of our approach without further rigorous prospective testing. Nevertheless, the issue of implementation is important; as we indicate in our discussion, national bodies need to be engaged in this type of work.

Cowling and Hedley also point out there is a 3% chance of an outlier consultant

appearing as an outlier in three or more years. Although this statement serves as a useful reminder about the role of chance in determining outliers, the underlying assumptions of the binomial model they used—constant probability and independent events—make the usefulness of this calculation unclear. In general, such assumptions apply only really in simple artificial demonstrations and as such are questionable in complex situations such as the one we describe. Furthermore, in our data set not all consultants appear in all five years, thus providing a further basis for questioning the underlying assumptions.

We thank Cowling and Hedley for pointing out that the inclusion of a 1/2 in our computation of the mean of the $\sqrt{\chi^2}$, would provide a better approximation of the mean. So by using $(\kappa - 1/2)$ (where κ is the degrees of freedom) and not κ, the mean reduces slightly and the revised number of statistical outliers for table 2 is now 17, 18, 21, 16, and 11 for 1991-2 through to 1995-6, respectively. Ledward is now an outlier in four of the five years analysed.

Mike Harley *director*
S.F.Elias@bham.ac.uk

John Yates *professor*
Inter-Authority Comparisons and Consultancy, Health Services Management Centre, University of Birmingham, Birmingham B15 2RT

Mohammed A Mohammed *senior research fellow*
Department of Public Health and Epidemiology, University of Birmingham, Birmingham B15 2TT

Shakir Hussain *statistician*
Abdullah Almasri *visiting statistician*
Department of Primary Care and General Practice, University of Birmingham

Competing interests: None declared.

Ledward's managers knew for 10 years that he was a risk

Editor—Looking at statistics will not add anything if managers are aware of problems that place patients at risk but fail to act, as happened in the Ledward case.[1 2] Jean Ritchie QC chaired the inquiry into Rodney Ledward and found that as early as 1986, 10 years before his suspension, senior management was aware of Ledward's "high complication rate and his cavalier manner."[3] She also identified that "a culture of not telling tales was a big part of the problem." What is better, telling tales or managers turning a blind eye to safety issues?

Whistleblowing is nowadays encouraged in the NHS, and there is an expectation of "a climate of openness and dialogue in the NHS, which encourages all staff to feel able to raise concerns about healthcare matters in a reasonable and responsible way without fear of victimisation." That quote comes from Andrew Foster, director of human resources for the NHS, in a letter dated 25 July 2003 that accompanied a policy pack produced in partnership with Public Concern at Work about whistleblowing.[4] The pack was circulated to all chief executives in NHS trusts, primary care trusts, and strategic and special health authorities.

From that date, no organisation had any excuse not to protect a whistleblower or to take notice of concerns raised in a reasonable and responsible manner. A chief executive is responsible for avoiding clinical governance failures and ensuring that there is no breach of statutory duty in relation to section 18 of the Health Act 1999.

A whistleblowing policy that is properly and effectively implemented should make redundant any need to trawl statistics to find those doctors who need help or need to be removed to protect the public.

Nigel Dudley *consultant in elderly medicine*
St James's University Hospital, Leeds LS9 7TF
nigel.dudley@leedsth.nhs.uk

Competing interests: ND has an interest in patients' safety and managers' regulation.

1 Harley M, Mohammed MA, Hussain S, Yates J, Almasri A. Was Rodney Ledward a statistical outlier? Retrospective analysis using routine hospital data to identify gynaecologists' performance. *BMJ* 2005;330:929. (23 April.)
2 This week in the *BMJ*. Catch me as soon as you can. *BMJ* 2005;330:0. (23 April.)
3 O'Neale Roach J. Management blamed over consultant's malpractice. *BMJ* 2000;320:1562.
4 Department of Health, Foster A. Whistleblowing in the NHS: policy pack. London: DoH, 2003. www.dh.gov.uk/assetRoot/04/07/47/32/04074732.PDF (accessed 5 June 2005).

Treatment of postmenopausal osteoporosis

Exercise was not mentioned

Editor—I was surprised that Reginster's editorial on the treatment of postmenopausal osteoporosis did not mention exercise,[1] which is both the most important factor in its causation and the chief cause of its morbidity.

Thirty five years ago, Chalmers and Ho presented demographic evidence that osteoporotic fractures of the femoral neck were inversely related to the level of physical activity.[2] Osteoporosis is therefore a disorder of civilisation.

Although osteoporosis predisposes to age related fractures, the essential cause of these fractures is loss of balance and falling. This was shown by Aitken in 1984, who found that those who suffered fractures of the femoral neck had the same bone density as controls.[3]

Maintaining physical activity into old age, not only conserves bone strength; more importantly it improves muscle coordination and balance, which are crucially important in preventing falls. So we must not let our current enthusiasm for drug treatment of osteoporosis divert us from promoting exercise programmes, which are much more important because they are effective in preventing falls.[4]

Alan W Fowler *retired orthopaedic surgeon*
Bridgend CF31 1QJ
alan@awfowler.fsnet.co.uk

Competing interests: None declared.

1 Reginster J-Y. Treatment of postmenopausal osteoporosis. *BMJ* 2005;330:859-60. (16 April.)
2 Chalmers J, Ho KC. Geographical variations in senile osteoporosis. *J Bone Joint Surg* 1970;52B:667-75.
3 Aitken JM. Relevance of osteoporosis in women with fractures of the femoral neck. *BMJ* 1984;288:597-601.
4 Kai MC, Anderson M, Lau EM. Exercise interventions; defusing the world's osteoporosis time bomb. *CMAJ* 2002;167:S1-35.

Author's reply

Editor—I apologise for not mentioning the role of physical exercise and physical activity in the prophylaxis and management of osteoporosis. Because of space constraints, I focused my review on the pharmacological management of the disease.

A concurrent body of evidence shows that exercise intervention augments bone mineral accrual in children and adolescents,[1] reduces the risk of osteoporosis and delays the physiological decrease of bone mineral density in adults,[2] and prevents the risk of falls in elderly subjects.[3] Maintaining physical activity (not only into old age) improves bone quality and also positively impacts on muscle coordination and balance, which are the main determinants of the propensity to fall in elderly people.[4]

Jean-Yves Reginster *director*
Bone and Cartilage Metabolism Research Unit, CHU Centre-Ville, 4020 Liège, Belgium
jyreginster@ulg.ac.be

Competing interests: None declared.

1 MacKelvie KJ, McKay HA, Khan KM, Crocker PRE. A school-based exercise intervention augments bone mineral accrual in early pubertal girls. *J Pediatr* 2001;139:501-8.
2 Ernst E. Exercise for female osteoporosis. A systematic review of randomised clinical trials. *Sports Med* 1998;25:359-68.
3 Campbell AJ, Robertson MC, Gardner MM, Norton RN, Tilyard MW, Buchner DM. Randomised controlled trial of a general practice programme of home based exercise to prevent falls in elderly women. *BMJ* 1997;315:1065-9.
4 Reginster JY, Gosset C, Reginster-Haneuse G. Falls among the elderly: a community problem. *Arch Public Health* 1996;54:363-72.

Some patients stop treatment when variables improve

Editor—Lawton et al describe perceptions of oral hypoglycaemic agents among people of Pakistani and Indian origin.[1] We have observed another phenomenon quite often among patients. When treatment is started in asymptomatic patients with high blood pressure or high plasma glucose picked up on screening the general population, some patients believe that the treatment is necessary only to bring the blood pressure or the plasma glucose within the normal range. At review they say that they have stopped taking the treatment because they were told that blood pressure or plasma glucose concentration had been normal the previous time. We find ourselves repeating the message that the blood pressure, blood glucose, or the HbA_1C is within the normal range because of the treatment; hence if they stop taking the drugs the variables will go up again. We have observed this phenomenon more in South Asians than white people.

Although we concur that there are cultural differences, we agree with Greenhalgh that we should place more emphasis on educating the patient in preference to focusing on cultural differences.[1] As health professionals we are learning throughout our lives, and we should give patients a fair chance to learn about their chronic illness. Help should be provided by all the

healthcare professionals involved, preferably in the patient's mother tongue. Most patients are very keen to learn about themselves and their illnesses, irrespective of their literacy.

K Kain *senior lecturer in community diabetes*
k.kain@leeds.ac.uk

A J Catto *senior lecturer*
Academic Unit of Molecular Vascular Medicine
Level 7, The LIGHT Laboratories, Clarendon Way, University of Leeds, Leeds LS2 9JT

Competing interests: None declared.

1 Lawton J, Ahmad N, Hallowell N, Hanna L, Douglas M. Perceptions and experiences of taking oral hypoglycaemic agents among people of Pakistani and Indian origin: qualitative study [with commentary by T Greenhalgh]. *BMJ* 2005;330:1247-50. (28 May.)

Incomprehensible consent forms

Plain English is important

Editor—Pothier's letter showing how many patients may not understand consent forms deserves a wide circulation.[1] It has long been clear that much of the current system of ethical review and research governance has less to do with the protection of patients than legal cover for healthcare providers. Many of us have been recurrently frustrated when our efforts to design reader friendly consent documents, reflecting what is known about the principles of good communication to a population whose reading age averages somewhere around 13-14, are torn up by gatekeeping committees in favour of versions drafted by lawyers for the benefit of other lawyers.

Frankly, unless we are going to retain a bunch of lawyers to translate the documents back into comprehensible English for the benefit of patients, I often wonder what their signatures are really worth and whether their consent can be said to be informed in any meaningful sense.

Robert Dingwall *professor*
Institute for the Study of Genetics, Biorisks and Society (IGBiS), University of Nottingham, Nottingham NG7 2RD
robert.dingwall@nottingham.ac.uk

Competing interests: None declared.

1 Pothier DD. Many patients may not understand consent forms. *BMJ* 2005;330:1151. (14 May.)

Child friendly consent forms lead the way

Editor—The letter from Pothier on the importance of understandable consent forms is to be welcomed.[1] In our health services research with young children we developed a consent form that conveys in simple, child friendly language issues that a child might want to consider when making a decision to become involved (or not) in a qualitative research study.[2 3] The form is designed as an A5 booklet that children can read themselves, or go through alongside a carer or the researcher. The consent process is broken down into a series of questions. The preferences expressed in children's responses then inform their decision and the way the research is conducted—for example, tape recording, or note taking as a method of data recording.

This is very different from standard consent forms issued by the Department of Health[4] but may well provide a model more appropriate for practice in the new child centred NHS.[5]

Katherine Curtis *research fellow*
k.curtis@city.ac.uk

Helen Roberts *professor of child health*
City University, London EC1Y 4TY

Competing interests: None declared.

1 Pothier D. Many patients may not understand consent forms. *BMJ* 2005;330:1151. (14 May.)
2 Curtis K, Liabo K, Roberts H, Barker M. Consulted but not heard: a qualitative study of young people's views of their local health service. *Health Expect* 2004;7:149-56.
3 City University Child Health Research and Policy Unit. *Healthy futures. Appendix 7: consent form for younger children.* www.city.ac.uk/chrpu/projects/healthyfutures.html (accessed 18 May 2005).
4 Department of Health. *Consent key documents.* www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/Consent/ConsentGeneralInformation/fs/en (accessed 18 May 2005).
5 National service framework for children, young people and maternity services. www.dh.gov.uk/PolicyAndGuidance/HealthAndSocialCareTopics/ChildrenServices/ChildrenServicesInformation/ChildrenServicesInformationArticle/fs/en?CONTENT_ID=4089111&chk=U8Ecln (accessed 18 May 2005).

SARS changed medical dress code

Editor—I used to subscribe to the view of Rushton's lecturer in that doctors should appear like the upright members of society they are supposed to be.[1] The "scrub uniform" worn by American doctors as seen on television in American medical drama series such as *ER* did not seem appropriate. A jacket and tie were the order of the day, even when I was a student, so much so that I was asked if I worked for the accountants Price Waterhouse, while waiting for a bus at London Bridge, going home from Guy's (their office was also at London Bridge).

All this changed when the severe acute respiratory syndrome (SARS) spread its terror among healthcare workers and the public in Hong Kong during the second quarter of 2003. Doctors, afraid of taking the disease away with them on leaving the hospital, would immediately seek out theatre uniform on arrival and change in the most convenient locality. Before leaving, they would change back and many would have a top to toe shower, too. When SARS finally retreated, and the healthcare workers could breathe a collective, if sad, sigh of relief that only eight of their colleagues had died, the medical dress code in Hong Kong had irrevocably tipped towards the American model.

Since then, with the threat of SARS and the even more dreaded H_5N_1 avian flu hanging over the profession like the sword of Damocles, public hospitals have been providing doctors and nurses with theatre scrub-like work clothes. The wards don't look the same any more.

Peter K K Au-Yeung *specialist anaesthetist*
Yan Chai Hospital, Tsuen Wan, New Territories, Hong Kong
lovpetay@netvigator.com

Competing interests: None declared.

1 Rushton DN. Medical dress code. *BMJ* 2005;330:1182. (21 May.)

The tide of prescribing for depression is turning

Editor—Hollinghurst et al report that opportunity costs indicate that the development of psychological therapies is a feasible alternative to antidepressants for depression.[1] A change in practice is long overdue.

I did as I was taught. I used a depression rating score and diagnosed depression. This often meant using my position of authority and knowledge to convince patients that they had an illness called clinical depression. I used fluoxetine (Prozac). To begin with, treatment was suggested for three months; later this was extended to six months; and eventually editorials suggested continuing treatment long term. I followed the evidence and expert advice and used selective serotonin reuptake inhibitors (SSRIs) to treat premenstrual tension, eating disorders, anxiety, postnatal depression, panic disorder, obsessive-compulsive disorder, and even social phobia.

Life, children, marriage, and time change your perspective. More importantly, eight years' of full time work in the same general practice gave me a longitudinal perspective of mood issues that short, skewed, and processed research could and will never elicit. We are at sea with uncontrollable emotional swells slowly lifting us up and down. We delude ourselves if we think we fight these forces of nature with modern medicine. The medical nirvana of emotional flatlining is neither attainable nor desirable.

Drug treatment helps in a very small and select group of patients with depression. The antidepressant and "everybody's depressed" message was spun by a greedy pharmaceutical industry and a myopic medical profession. Stop the widespread use of antidepressants as they are eroding our wellbeing and dismiss life as a simple spark of synaptic electricity. More talk therapies, please. Time for society to invest and recognise the role of friends, family, faith, music, art, exercise, and the maligned idea of community in managing mood. Making us happy is not in the gift of health care or drug treatment, of that I am certain.

Des Spence *general practitioner*
Glasgow G20 9DR
destwo@yahoo.co.uk

Competing interests: None declared.

1 Hollinghurst S, Kessler D, Peters TJ, Gunnell D. Opportunity cost of antidepressant prescribing in England: analysis of routine data. *BMJ* 2005;330:999-1000. (30 April.)