Regulation and revalidation of doctors

Response from the General Medical Council

EDITOR—The report from the chief medical officer for England has implications for all UK doctors and needs to be considered very carefully.¹ Its aim is a system of medical regulation that puts patients' safety first through the early detection, and where possible, remediation, of poor performance. If the report contributes to that aim, and commands public and professional support, it should be welcomed by everyone involved in health care.

The Merrison report was the collective effort of Sir William Merrison and the other 14 members of his committee of inquiry, who took both oral and written evidence.² A different process has been followed in this case. The government, sensibly, has therefore decided on a period of consultation during which the recommendations can be properly debated, tested, and costed. We have already said that we believe that the recommendations to divorce oversight of medical education from the other regulatory functions of standards, registration, and fitness to practise are not in patients' best interests. We will now be consulting widely with our partners before we submit our considered response.

It may be another 30 years before there is another opportunity such as this. We must seize it so that future generations of patients can say that we did not fail them.

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Competing interests: GC is president of the GMC.

1 Pringle M. Regulation and revalidation of doctors. *BMJ* 2006;333:161-2. (22 July.)
2 Merrison report. *Report of the Committee of Inquiry into the Regulation of the Medical Profession*. London: HMSO, 1975. (Cmnd.6018.)

Dangers and opportunities

EDITOR—Pringle's editorial reinforces the General Medical Council's corporate view that its prime function is, and always will be, the protection of the public by promoting the highest standard of medical care in the United Kingdom, something that is best delivered in partnership with others.¹

Pringle welcomes the bipartite approach to revalidation, especially the element applying to career grade doctors. This, however, is to adopt only one view of the intention of revalidation, to be as near an absolute guarantee of competence as can be devised. The alternative view is that such a process would be better managed in an incremental fashion with the first step to define the meaning of registration or the holding of a licence with the guarantee of competence developing as a by-product. No matter which system prevails, 50% of all doctors will remain below average.

Pringle describes the 2003 proposals for revalidation as being entirely those of the GMC, perhaps forgetting Sir Liam Donaldson's own letter to Dame Janet Smith of 10 November 2004,² which led her to believe that they were in the joint ownership of the GMC and the Department of Health. Pringle does not track Sir Liam's shift of opinion.

Pringle challenges Donaldson's lack of cogent reasoning to move the overview of undergraduate medical education to a Postgraduate Medical Education and Training Board that is often perceived as struggling to deliver its existing core responsibility and points to the contentious issue of the standard of proof in fitness to practise cases.

The GMC will use this report as a catalyst to produce a better future despite Pringle's premature belief that it would be a political disaster for the medical profession to reject Donaldson's proposals. He seems, however, to forget that the views of one, senior doctor are merely the basis for four months of consultation that will involve the public as much, if not more, than the government and the medical profession. To say the direction is set is perhaps a perilous conclusion one week into those four months.

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DEPARTMENT OF HEALTH

1 Pringle M. Regulation and revalidation of doctors. *BMJ* 2006;333:161-2. (22 July.)

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Summary of other responses

Pringle's editorial on revalidation, which was largely supportive of the chief medical officer's report, came in for unbridled criticism.¹ Eleven respondents, mostly general practitioners from the United Kingdom, warned against introducing fundamental new measures in such haste, expressing serious concerns about abolishing self regulation and about the safety of patients.

Adam Pringle sets the tone in criticising the hurry: "Anybody pretending to intellectual validity and scientific rigour would test and validate their tools first, and design their system later." He also takes issue with the proposed enforced membership of general practitioners in the Royal College of General Practitioners, as does Adrian Midgley, who—along with the majority—suspects a "power grab." David Lewis also reflects on the power and politics of the report when he asks for the motives behind and soundness of the proposals.

Several respondents mention the Shipman case as the impetus behind the proposals, yet they all consider that no system will be able to prevent a second Shipman. The report "instead uses the smokescreen of Shipman to drive through a series of politically motivated hammer blows to the dying freedom and independence of the medical profession," writes Ben Dean, a senior house officer in Oxford. "It is merely another measure that increases the power of an increasingly authoritarian regime." Michael Peckitt, a philosophy tutor in Hull, argues that even with mentoring and other supervision schemes, "this net will simply not catch most of the desired suspects."

Peter Gooderham, a law tutor from Cardiff, makes the case for self regulation of the medical profession: "The civil standard of proof is a major threat to the medical profession. That applies notwithstanding the necessary adjustment in sanctions which certainly should apply if this is brought about. A finding against a professional person at a regulatory body is a major blight on his or her scope to practise. So also, to a lesser extent, is the very fact of a case being brought." Equally passionate about self regulation is Lord Walton of Detchant, a former president of the GMC, illustrating the issue by offering to serve in any committee "made up of doctors, distinguished laymen and a minority of lawyers, to

examine in depth the regulation of the legal profession."

According to Martin Toal, a pharmaceutical physician, the chief medical officer has missed at least one opportunity to improve standards. Provision of study leave is under increasing financial pressure, to the point where trusts have encouraged doctors to accept funding from the pharmaceutical industry to attend meetings and conferences—self evidently "unacceptable and potentially harmful to patient safety."

Overall, the chief medical officer's report seems not to have resolved the uncertainty, perhaps just created more.

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Competing interests: None declared.

1 Electronic responses. Regulation and revalidation of doctors. *bmj.com* 2006. <http://bmj.bmjournals.com/cgi/letters/333/7560/161> (accessed 27 Jul 2006.)

Is public health action worth while if many cases are being missed?

EDITOR—Harnden et al seem to propose that the incidence of pertussis is grossly underestimated.¹ They comment on the low notification rates for pertussis (barely 500 notifications in the past two years, according to the Health Protection Agency²). Forty per cent of children with persistent cough having pertussis infection sounds like a lot but depends on the prevalence of persistent cough, which cannot be deduced from their article.

Eighteen practices in Oxfordshire participated in the study, which ran for three and a half years; 289 children were "eligible for recruitment," or only four or five per practice per year. If 40% of them had pertussis, that would make roughly 110 cases of pertussis, 30 each year, and roughly two cases of pertussis per practice per year, implying that the number of notifications might not be such a gross underestimate.

Given that the study also showed that children with serological evidence of pertussis infection were also more likely to have had whooping, vomiting, and sputum production, and to have been less likely to wheeze, perhaps most cases of pertussis are notified.

The methods section, however, does not give sufficient detail for readers to be clear whether all children with cough lasting 14 or more days were eligible for the study—perhaps chronic cough is far more common than the 289 eligible children would imply?

Guidelines from the Health Protection Agency recommend that cases are treated and (if appropriate) immunised, and that all incompletely vaccinated members of households containing vulnerable contacts should be treated and immunised.³

The accompanying editorial by Butler et al raises several pertinent questions.⁴ If only a small minority of cases is identified, we should add another question: is public

health action for these few cases worth while?

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- 1 Harnden A, Grant C, Harrison T, Perera R, Brueggemann AB, Mayon-White R, et al. Whooping cough in school age children with persistent cough: prospective cohort study in primary care. *BMJ* 2006;333:174-7. (22 July.)
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- 4 Butler C, Francis N, Dinant G-J. Whooping cough in general practice. *BMJ* 2006;333:159-60. (22 July.)

Why do poor outcomes persist in diabetic pregnancy?

EDITOR—Macintosh et al report the continued poor outcome of diabetic pregnancy in the United Kingdom, noting high rates of perinatal mortality and congenital malformation in the babies of women with type 1 and type 2 diabetes.¹ We reported some years ago that in our population, perinatal mortality in babies of women with type 2 diabetes was higher than in babies of women with type 1 diabetes.² Macintosh et al found no such difference and dismiss our findings as "not generalisable."

They seem not to have grasped one of the main points of our study, that in women with type 1 diabetes, perinatal mortality was no different to the background (non-diabetic) rate because pregnancy loss owing to late intrauterine death had become rare in type 1 diabetes. The higher rate of perinatal mortality in the babies of women with type 2 diabetes was largely due to the continued occurrence of late intrauterine deaths.² A factor of likely importance in late intrauterine death is maternal obesity, which is strongly linked with type 2 diabetes and independently associated with late fetal loss.^{3,4}

The question remains why perinatal mortality from late intrauterine death remains so high in women with type 1 diabetes in the UK. Macintosh et al blame poor glycaemic control, but it may not be the whole story. In our unit 42% of women with type 1 diabetes have HbA_{1c} values $\leq 7.0\%$ at presentation to the diabetes pregnancy service, a figure not much better than the 35% reported by Macintosh et al, yet late intrauterine death has largely been eliminated. Successful outcomes in diabetic pregnancy depend on the combined skill and commitment of all members of the diabetic and obstetric teams, and good communication and cooperation between them. Organisational issues are likely to be critical. It would be interesting to know from the UK data if some units consistently perform better than others, and, if so, to explore whether

organisational deficits underlie poorer outcome in some clinics.

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- 1 Macintosh MCM, Fleming KM, Bailey JA, Doyle P, Modder J, Acolet D, et al. Perinatal mortality and congenital anomalies in babies of women with type 1 or type 2 diabetes in England, Wales, and Northern Ireland: population based study. *BMJ* 2006;333:171-80. (22 July.)
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Stirrups or no stirrups for routine speculum examinations?

Patient comfort is secondary to cervical smear quality ...

EDITOR—Seehusen et al suggest performing gynaecological examinations without stirrups to reduce stress for women.¹ They also conclude that examination without stirrups does not affect the quality of cervical smears. Their study tackles the problem of discomfort during gynaecological examinations, which may hamper adherence to cervical cancer screening, but several aspects should be considered in interpreting the results.

The primary goal when obtaining cervical smears should always be to achieve the highest possible quality so that screening achieves its goal of detecting early stages of cervical cancer. Although reduction in pain and discomfort during the examination is important and highly welcomed, it needs to remain secondary to the quality of smears. If the quality is insufficient, false positive or negative findings can put women at risk of undetected cancer or unnecessary psychological stress or procedures.

If a study compares two methods of obtaining cervical smears it has first to be shown that the alternative method does not yield clinically inferior results. Non-significant differences between cervical smear quality ($P=0.84$ in the study by Seehusen et al), however, are not proof of non-inferiority. The standard method to deal with non-inferiority is the confidence interval approach.² If, for example, it is accepted that the proportion of cervical smears of good quality may be 5% lower than with the standard method, the lower end of the 95% confidence interval for the between-group difference should be above this a priori defined threshold for non-inferiority.

We did not find any randomised non-inferiority trials in Medline and the Cochrane database. It seems too early to conclude that gynaecological examinations can safely be performed without stirrups.

Non-inferiority in terms of the quality of cervical smears should be shown before this alternative method can be adopted in clinical practice.

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- 1 Seehusen DA, Johnson DR, Earwood JS, Sethuraman SN, Cornali J, Gillespie K, et al. Improving women's experience during speculum examinations at routine gynaecological visits: randomised clinical trial. *BMJ* 2006;333:171-4. (22 July.)
- 2 Jones B, Jarvis P, Lewis JA, Ebbutt AF. Trials to assess equivalence: the importance of rigorous methods. *BMJ* 1996;313:36-9.

... but we do not need to do a trial of smear quality

EDITOR—Predictably, in this age of evidence based medicine, Spaar and Puhan (previous letter) have called for a randomised trial to determine whether using different positions for taking cervical smears makes a difference to smear quality.¹ A very large trial would be necessary to be confident that no difference had been missed. This would comprise a wasteful and unnecessary use of resources.

As family doctors in several countries routinely use stirrups—notably, the United States and Canada—while those in others, such as the United Kingdom and Australia, routinely use feet on the couch positions, a simple ecological study to determine whether smear quality differs substantially between those countries would be sufficient. Perhaps the more important outcome (although more difficult to assess) would be effectiveness of the national cervical screening programme, since extra discomfort may reduce the willingness of many women to attend for smear testing. In that case, even if the stirrups position produces slightly better smears, the gain would need to be greater than the loss due to women staying away from an uncomfortable procedure.

Trials are wonderful but highly complex procedures. Doing them well is difficult, and their validity can easily be compromised by errors in their execution. The effort needed to perform them should be reserved for problems that really need such methods. Otherwise we use a sledgehammer to crack a nut.

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- 1 Seehusen DA, Johnson DR, Earwood JS, Sethuraman SN, Cornali J, Gillespie K, et al. Improving women's experience during speculum examinations at routine gynaecological visits: randomised clinical trial. *BMJ* 2006;333:171-4. (22 July.)

Patient's perspective

EDITOR—I have had examinations with and without stirrups in the United States and United Kingdom.¹ Before my move to the US, smears had always been done without stirrups, and it was just another examination—no more uncomfortable than having teeth drilled.

When I needed a routine cervical smear by my (lovely female) general practitioner in the US, I was in for a shock. I was supine, and stirrups were used (objective). I was flat on my back with my bottom on the edge of a cliff and my legs held up over the edge (subjective). As for choice, she would not take the smear unless I had stirrups.

Back in the UK, skip forward to a referral to a consultant gynaecologist. I had stirrups, and it was great—as far as having a strange man looking at your intimate parts can be positive. I was still supine, but the stirrups were placed lower, and my bottom was not on the edge of the bed. It felt as if they supported my legs to give me a bit of a rest.

In my experience, use of stirrups is not the issue. My female general practitioner used them: I hated it, feeling out of control and extremely vulnerable. I almost didn't go back. The male consultant, whom I didn't like, used them: no problem.

If the experience is not neutral or positive, women will not be examined, and you cannot quality control a nonexistent sample. As with other things in life, it's what you do with it that counts.

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Doctors and patients need to hunt together

EDITOR—In the outcome of the interactive case report of his case, Neville vividly describes his frustration with the failure to explain his symptoms: the awareness of the ebbing away of doctors' sympathy, the wish that investigations would find something—anything—wrong, and so end the uncertainty.¹

Failure to find a cause for a problem is frustrating for doctors and patients, but it helps no one if doctors protect themselves from their failure by distancing themselves from the patient. We all know the frustration of failure to find a cause for a problem, if only when the engineer comes to look at the washing machine. When telling a patient the result of an investiga-

tion it is surely more helpful to say what the investigation rules out than just to say that it is normal. "This test shows that your problem is not due to kidney disease, cancer, or a fracture, but it has not given us any leads towards what is causing your symptoms" is both more true and less undermining.

As Peile points out in his commentary, no patient is every fully investigated. Patients often believe there is a test for everything, and doctors are better being honest about the limitations of medical knowledge and admitting the shared frustration. Thinking widely requires a relaxed and open mind and cannot be achieved if the relationship has become implicitly, even if not explicitly, adversarial. In this hunt doctors and patients are on the same side.

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- 1 Fox M, Young A, Anggiansah R, Anggiansah A, Sanderson J. A 22 year old man with persistent regurgitation and vomiting: case outcome [with commentaries by K Neville; E Peile; SA Azer; S Dosani; D Macauley; and R Logan]. *BMJ* 2006;333:133-7. (15 July.)

Minerva might help you get something published

EDITOR—Like Williams,¹ we have been interested in getting something published and have investigated where we might do so. As we had the impression that Minerva frequently published pictures from our specialty, ophthalmology, we reviewed which specialties had the most pictures published in Minerva in 2005.

The specialty with most photographs published was dermatology with 16. Ophthalmology was second, but a long way behind with six. So our advice to Williams is to team up with a dermatologist if he wants a photograph published in Minerva.

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- 1 Williams GS. "Call for papers." *BMJ* 2006;333:207. (22 July.)

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