

## Cochrane reviews *v* industry supported meta-analyses

### We should read all reviews with caution

EDITOR—That industry sponsored meta-analyses differ in conclusions from Cochrane reviews does not mean that industry sponsorship is the only source of bias or that Cochrane reviews should be uncritically accepted.<sup>1</sup>

Allegiances of authors of meta-analyses are not only associated with selective attention to relevant studies and more positive conclusions in the case of industry ties.<sup>2</sup> We should be sceptical about a comparative review from the director of a Cochrane Centre that puts the centre in such a favourable light.

Cochrane reviews are sometimes conducted on literature that is not ready for meta-analysis, with adverse implications for clinical practice and public policy. A recent Cochrane meta-analysis concluded that couples therapy was not better than individual therapy for depression.<sup>3</sup> The offering of couples therapy should be a matter of “patient preference and availability of specific resources.” Yet, the studies reviewed were all seriously flawed. None had close to the minimal cell size necessary for inclusion in a meta-analysis, much less for a non-equivalence trial. Such a premature conclusion serves to discourage the commitment of scarce resources to having marital therapists available or to research providing an adequate comparison between the two forms of therapy.

Whether the Cochrane Collaboration is free of bias should not be left to the collaboration to decide. Bjordal et al showed that only investigators associated with negative findings had been recruited to the review group for a Cochrane report on low level laser therapy in osteoarthritis.<sup>4</sup> The review

had numerous deficiencies in ways consistently supporting its negative conclusion.

The Cochrane Collaboration describes itself as “the gold standard in evidence-based healthcare” ([www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME](http://www3.interscience.wiley.com/cgi-bin/mrwhome/106568753/HOME)).

The paragraph in This week in the *BMJ* for the paper by Jørgensen et al admonished us to “Read industry supported drug reviews with caution.” This should be expanded to all reviews, including those of the Cochrane Collaboration.

**James C Coyne** professor of psychology in psychiatry  
University of Pennsylvania School of Medicine,  
Philadelphia, PA 19104, USA  
[jcoyne@mail.med.upenn.edu](mailto:jcoyne@mail.med.upenn.edu)

Competing interests: None declared.

- 1 Jørgensen AW, Hilden J, Gøtzsche PC. Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review. *BMJ* 2006;333:782-5. (14 October.)
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### Has Cochrane really achieved its goals?

EDITOR—I am amazed that the *BMJ* chose to publish this review, given its small sample size yet broad conclusions.<sup>1</sup> I believe that if the results had been in the other direction it would be less likely to have been published.

It is true that Cochrane reviews report specific items more thoroughly than journal based reviews. However, much of this is due to the insistence of addressing methodological issues which are specious at times and the fact that Cochrane reviews are not limited by page length. For example, the issue of reporting allocation concealment, although it makes sense, does not mean that if not reported it was not done,<sup>2</sup> nor does it even consistently demonstrate that it is an important methodological issue to report.<sup>3</sup>

It is disappointing that the *Cochrane Library* has become an ivory tower, given that many of the reviews are out of date and methodologically weak. The *Cochrane Library* was established to be a clinically useful resource, but is that really true? There are many Cochrane reviews that would not be

published in a paper journal, as they contain zero or just a few trials. There are far too many Cochrane reviews stating that, although upwards of 10 trials were found, the reporting is poor and therefore more research is required before a clinical recommendation can be made. Do you really think it is useful to say that several trials do not permit an inference on effectiveness?

The pharmaceutical industry is an obvious target for attack, and this amounts to little more than bullying. Pharma has an obvious conflict in wanting to publish favourable results. Why does the Cochrane group not go after the agencies claiming to promote health for the goodness of all, but mismanaging money and misusing evidence, such as the World Bank or World Health Organization<sup>4,5</sup>—not targets that are so uniformly accepting of criticism.

**Marko Tostad** epidemiologist  
Mount Sinai Hospital, New York, NY 10029, USA  
[mtostad@mail.com](mailto:mtostad@mail.com)

Competing interests: None declared.

- 1 Jørgensen AW, Hilden J, Gøtzsche PC. Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic review. *BMJ* 2006;333:782-5. (14 October.)
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### Ten questions to assess bias in medical research

EDITOR—Jørgensen et al show that much published research may be biased.<sup>1</sup> The following 10 questions, the result of my experience as a hospital physician, may be a practical way to assess bias.

1 Is the research conducted by or together with the sponsor?

2 Is there open access to the complete study design?

3 Is there a declaration of competing interests?

4 Are members of the publishing committee receiving money or other benefits from the sponsor (grants, consulting fees, lecture fees, other) and/or reporting stock holding?



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5 Are members of the publishing committee employees and/or stock holders of the sponsor?

6 Are employees of the sponsor involved in any way in the data management? (If question 5 is judged yes or unknown tick the same here.)

7 Are employees of the sponsor involved in any way on judgment committees, i.e. clinical endpoint committee? (If question 5 is judged yes or unknown tick the same here.)

8 Was the study monitoring partly or totally done by the sponsor?

9 Was the data management partly or totally done by the sponsor or a for-profit organisation?

10 Does the abstract address critically the limitations of the study?

Answer each question "yes," "unknown," or "no." Count two "unknown" as one "yes." The possibility of bias arises with the number of questions you judged yes or unknown. Be careful if you have ticked yes 50% or more of the time and discuss the paper with your colleagues.

**Manfred Gogol** *head, department of geriatrics*  
Krankenhaus Lindenbrunn, Lindenbrunn 1,  
Coppnenbruegge 31863, Germany  
gogol@krankenhaus-lindenbrunn.de

Competing interests: None declared.

1 Jørgensen AW, Hilden J, Gøtzsche PC. Cochrane reviews compared with industry supported meta-analyses and other meta-analyses of the same drugs: systematic reviews. *BMJ* 2006;332:782-6. (14 October.)

## How to formulate research recommendations

### Format is not enough

**EDITOR**—The spectrum of appropriate recommendations for future research cover more than described in the recent very useful article.<sup>1</sup> The recommendation "no further research is needed" is necessary to protect patients from harmful or useless research and to save limited resources for clinical research. This extreme of research recommendations is especially important for systematic reviews of any kind—information assessment, health technology assessment, summing clinical evidence, or Cochrane reviews.

I searched Cochrane reviews for their recommendations, and found that only 17% of reviews do not recommend further research. Reviewers recommend further research even when they have serious reservations about the intervention.<sup>2</sup> Authors of reviews may abstain from definitive recommendations when they find strange, probably fabricated or manipulated data.

The most serious reason for not recommending "no further research" does not seem to be the absence of the appropriate format of recommendations, but rather the desire to avoid harm to the authors of the original research and damage to the field of their own research. The discussion about the famous example of the excessive research of aprotinin shows that a decision to recommend not to do further trials may be difficult.<sup>3</sup>

More research is needed and more detailed guidelines need to be created on criteria for recommending "no further research is needed."

**Vasily Vlassov** *director*  
Russian branch of the Nordic Cochrane Centre,  
Cochrane Collaboration, PO Box 13, Moscow  
109451, Russia  
vlassov@cochrane.ru

Competing interests: None declared.

- 1 Brown P, Brunnhuber K, Chalkidou K, Chalmers I, Clarke M, Fenton M, et al. How to formulate research recommendations. *BMJ* 2006;333:804-6. (14 October.)
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### The pie or the slice?

**EDITOR**—Brown et al set out a useful framework for guiding future research in clinical trials, but the title of their paper ("How to formulate research recommendations") contains the inherent assumption that all research can be reduced to the EPICOT acronym.<sup>1</sup> In many areas of health services research (diabetes, obesity, mental health, or sexual health, for example), and particularly for complex interventions aimed at behaviour change or incorporating new service models, the most pressing unanswered research questions are qualitative. There is another paper to be written about how to formulate these qualitative questions, which are likely to include

- What are the priorities of patients, clinicians, and policy makers for further research in this field?
- What is the mechanism by which particular complex interventions work, and how might existing interventions be modified to optimise impact?
- What factors explain the gap between the effect size typically shown in research trials and that demonstrated in real practice?

Although the evidence based medicine movement has many strengths, and the systematic review of randomised trials with a clear definition of population, intervention, comparison, and outcome is rightly seen as the gold standard in the evaluation of simple interventions, there is a danger that the research agenda will be impoverished rather than enriched if we sign up to a "framework for future research" that focuses exclusively on this slice of the pie.

**Trisha Greenhalgh** *professor of primary health care*  
University College London, London N19 5LW  
p.greenhalgh@pcps.ucl.ac.uk

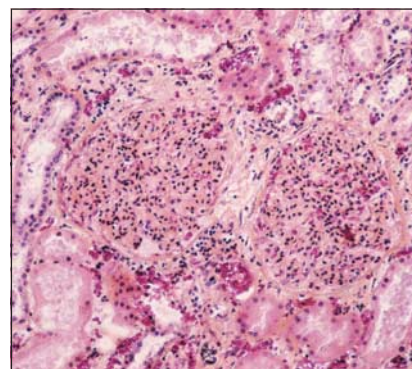
Competing interests: None declared.

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## Acute renal failure

### Estimated glomerular filtration rate should be entered on drug charts

**EDITOR**—Hilton's review of the management of acute renal failure highlights the key issue



of preventing this common and costly complication in hospital, particularly since supportive care rather than definitive treatment is the most commonly available therapeutic strategy.<sup>1</sup>

The estimated glomerular filtration rate should be clearly highlighted on all hospital drug charts in the same way that drug allergies are documented. With routine reporting of the estimated glomerular filtration rate, an opportunity now exists to highlight those at risk of acute renal failure from an early stage in their admission. High risk groups include elderly patients, in whom a normal serum creatinine may represent significantly impaired renal function, and patients with established chronic renal failure.

Clear documentation of the estimated glomerular filtration rate would give medical, nursing, and pharmacy staff every opportunity to avoid prescribing potentially nephrotoxic drugs to patients with impaired renal function and would also allow correct and prompt dose adjustment of commonly prescribed drugs such as antibiotics.

This would be a cheap and simple method to help reduce the clinical and cost burden of acute renal failure, a condition in which prevention is far easier than cure.

**Gavin Dreyer** *specialist registrar*  
Department of Nephrology, North Middlesex  
University Hospital, London N18 1QX  
Gavin.Dreyer@nmh.nhs.uk

Competing interests: None declared.

1 Hilton R. Acute renal failure. *BMJ* 2006 333:786-90 (14 October.)

### Beware development of abdominal compartment syndrome

**EDITOR**—In her review of acute renal failure Hilton acknowledges that the immediate care of most such patients in the United Kingdom is provided in intensive care units by intensivists but does not sufficiently emphasise the effective clinical approach to resuscitation in intensive care.<sup>1</sup> In particular, adequate renal perfusion pressure must be maintained in patients who have a raised intra-abdominal pressure, and this can often prevent the need for renal replacement therapy.

Abdominal compartment syndrome occurs if the intra-abdominal pressure is greater than 20 mm Hg and associated with organ dysfunction such as oliguria.<sup>2</sup> If unrecognised or untreated a persistently raised intra-abdominal pressure can result

in acute renal failure. This condition is well recognised by intensivists: three quarters of intensive care units measure intra-abdominal pressure through the intravesical route.<sup>3</sup> If abdominal compartment syndrome develops, acute renal failure can be prevented by continued fluid resuscitation, use of vasopressors, and decompression of the abdomen. Improved recognition of this condition by surgeons and physicians would benefit patient care.

**Jeremy S Bewley** *consultant in intensive care*  
Bristol Royal Infirmary, Bristol BS2 8HW  
jeremy.bewley@ubht.nhs.uk

Competing interests: None declared.

- Hilton R. Acute renal failure. *BMJ* 2006;333:786-90. (14 October.)
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## How to measure renal function in clinical practice

### Age affects estimated glomerular filtration rate

**EDITOR**—I read the overview by Traynor et al regarding how to measure renal function.<sup>1</sup> Especially for primary care doctors, an abnormal estimated glomerular filtration rate in patients older than 70 may be normal and estimates below an MDRD (modification of diet in renal disease) estimated glomerular filtration rate of <60 ml/min/1.73 m<sup>2</sup> (despite a normal serum creatinine) are not validated by the MDRD equation.<sup>2</sup>

Patients older than 40 generally lose between 0.8-1 ml/min of glomerular filtration rate per year due to nephron loss as a normal ageing process.<sup>3</sup> Hence one cannot assume that an estimated glomerular filtration rate of less than 60 ml/min/1.73 m<sup>2</sup> is indicative of chronic kidney disease in elderly patients. Higher rates of loss (>4 ml/min/1.73 m<sup>2</sup>) would be suggestive of progressive chronic kidney disease or precipitating factors such as hypertension. Hence an 80 year old may be normally expected to have an estimated glomerular filtration rate of 45-50 ml/min/1.73 m<sup>2</sup>.

With this in mind, for general practitioners the registry of chronic kidney disease would have to include all their elderly patients who need regular monitoring. This may overwhelm their service and detract from the management of other patients.

**Sunil Bhandari** *consultant nephrologist*  
Hull and East Yorkshire Hospital NHS Trust  
sunil.bhandari@hey.nhs.uk

Competing interests: None declared.

- Traynor J, Mactier R, Geddes CC, and Fox JG. How to measure renal function in clinical practice. *BMJ* 2006;333:733-7. (7 October.)
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### Estimated glomerular filtration rate in general practice

**EDITOR**—The introduction of routine reporting of estimated glomerular filtration rate with every serum creatinine requested seems to have led to three outcomes in general practice: worried patients, increased workload, and confused clinicians.<sup>1</sup>

Although the national service framework for renal services does not say that estimated glomerular filtration rate should be used as a screening tool for renal disease among unselected patients, but rather should be used to give further information about patients already known to be at risk of renal disease, this is effectively what has happened. In common with other doctors, general practitioners request baseline biochemistry in situations ranging from investigation of symptoms, to “work-up” of known disease, to monitoring of long term illness, and so on. Of the 30 estimated glomerular filtration rates in my practice lablinks inbox recently that originated from unselected patients of varying health, social class, and ethnic origin, 18 were less than 90 (and in only two of these cases was the creatinine outside the normal range) and required further follow-up. The high risk patients will mostly have had their urine tested already—perhaps we should routinely dip test urine of everyone having blood taken for serum creatinine to avoid the worry of recall.

Estimated glomerular filtration rate is not a population screening test; no screening test would ever have been introduced without extensive data relating to the performance of the test in the population concerned, and without much clearer information to clinicians.

**Jo Richardson** *general practitioner*  
London E14 3BQ  
jo.richardson@GP-F84710.nhs.uk

Competing interests: None declared.

- Traynor J, Mactier R, Geddes CC, Fox JG. How to measure renal function in clinical practice. *BMJ* 2006;333:733-7. (7 October.)

## GMC to convene meeting for prescribing debate

**EDITOR**—I am pleased that Aronson et al recognise the need for evidence to inform the debate over prescribing, and I note that they have broadened their interest to include postgraduate education.<sup>1</sup> The General Medical Council's education committee already has information relating to the undergraduate phase and is collecting more through its ongoing research into how well its requirements, described in *Tomorrow's Doctors*,<sup>2</sup> prepare new graduates for the foundation programme and beyond.

However, there is a paucity of evidence relating to factors that could improve the quality of prescribing in later stages of a doctor's training and career. There is a growing risk that this debate will escalate in the wider media, where the underlying issues are not widely understood, with

resulting alarm to patients and the public about their safety. It is essential that this perception does not become entrenched. The GMC therefore strongly supports the value of acquiring such evidence and will convene a meeting of interested parties to take this important matter forward.

**Peter Rubin** *chairman, education committee*  
General Medical Council, London NW1 3JN  
smcnamara@gmc-uk.org

Competing interests: None declared.

- Aronson JK, Barnett DB, Ferner RE, Ferro A, Henderson G, Maxwell SR, et al. Poor prescribing is continual. *BMJ* 2006;333:756. (7 October.)
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## Prevention of diabetes

### Ethical consideration

**EDITOR**—Drugs to prevent the onset of diabetes in patients at risk work. However, they seem to be less effective than intensive lifestyle interventions. The authors point to intensive programmes involving up to 16 one to one sessions to promote healthier behaviour and correctly ask if those standards are economical to offer to larger populations.<sup>1</sup> A further concern is whether healthy behaviour is maintained after active intervention has ceased. Comparing both approaches misses one point. Many patients would opt for the soft way of taking a pill when given the choice. Financial resources in medicine all over the world are increasingly restricted, and rationing will ask questions about effectiveness, appropriateness, and justice. Health behaviour modification fits all three categories, and if patients were to have no choice but to take part in a well balanced lifestyle intervention its effectiveness would be even greater.

**Philipp Andreas Conradi** *general practitioner*  
Otto-Dix-Ring 98, 01219 Dresden, Germany  
pconradi@hotmail.com

Competing interests: None declared.

- Heneghan C, Thompson M, Perera R. Prevention of diabetes. *BMJ* 2006;333:764-5. (14 October.)

### Lifestyle and metformin are the way forward

**EDITOR**—The concern expressed by Heneghan et al<sup>1</sup> that drug treatment to prevent diabetes may not be as attractive as it first seems, may be justified for rosiglitazone but is not for metformin, which is effective, safe, and cheap.

While the 31% reduction in new cases of diabetes with metformin in the Diabetes Prevention Program (DPP)<sup>2</sup> seems unimpressive compared with the lifestyle groups' 58%, in certain subgroups metformin was more impressive. Reduction of incidence of diabetes in the young (under 45) was 44% and in the obese (BMI >35) 53% (lifestyle 48% and 51%, respectively). It would be interesting to see an analysis of the “young and obese.”

Moreover, subjects in the programme were highly selected to be appropriate for a

trial of intensive lifestyle modification. For example, smoking prevalence was only 7%. We are unlikely to see the same gains from lifestyle intervention in the real world.

As Heneghan et al point out,<sup>1</sup> rosiglitazone was associated with a non-significant 37% increase in cardiovascular endpoints in the DREAM study<sup>2</sup>; metformin seems safe. The UKPDS<sup>3</sup> showed a 36% reduction for all-cause mortality, and 42% for diabetes related death with metformin in the obese (BMI above 25.6).

Regarding cost, lifestyle intervention in the Diabetes Prevention Program cost \$2780 (£1486; €2213) / person over three years. Cost of drug treatment with 8 mg rosiglitazone/day, (as per DREAM) for three years would be nearly £2000 using the drug tariff, but metformin 850 mg twice daily (as per the programme) would cost less than £40. Furthermore, the cost effectiveness analysis of the UKPDS showed overall cost savings from reduced hospital costs with metformin.

Although the UKPDS is considered a diabetes study, the entry criterion was a fasting glycaemia above 6.0 mmol/l, or what we now consider as impaired fasting glycaemia. We should be prepared to follow the clear evidence base and prescribe metformin to any overweight patient with abnormal fasting glucose, after three months of lifestyle advice.

**John S Ashcroft** *general practitioner*  
Old Station Surgery, Ilkeston, Derbyshire DE7 8ES  
john.ashcroft@nhs.net

Competing interests: None declared.

- 1 Heneghan C, Thompson M, Perera R. Prevention of diabetes. *BMJ* 2006;333:764-5. (14 October.)
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## Living organ donation needs debate on harm to donors

EDITOR—Conspicuously absent from the article by Friedman et al,<sup>1</sup> and from the rapid responses to it that have been published to date, is a detailed account of the inevitable morbidity and risk of serious harm that is inflicted on the donor by doctors in the course of their ordinary paid employment. The short term risks include life threatening haemorrhage, pulmonary embolism, pneumothorax, infection, transfusion transmitted hepatitis, and AIDS.<sup>2,3</sup> In the longer term, there is increased risk of hypertension and renal failure.<sup>3,4</sup> The long term psychological effects on the donor are not known.

In another article elsewhere,<sup>5</sup> Friedman et al reported 105 episodes of serious haemorrhage; blood transfusion was needed in at least 19 cases and reoperation required in 29. Two patients died, and two patients

developed renal failure. These figures were obtained by questionnaires sent to 893 transplant surgeons, only 24% of which were returned. Although such a low response provides no basis for an estimate of the rate of occurrence of these complications, it is clear that they are not rare.

Whether or not these risks are adequately explained to those asked to donate or sell one of their kidneys may, in due course, become a matter of concern to the lawyers. Of most concern to those in the medical profession who subscribe to the “first, do no harm” principle—in the belief that the laity’s trust in us depends on it—should be the ever more open flouting of that principle without published protest. I submit that we continue to condone that abuse at our peril. Let us have a fully informed discussion and debate about this presently stealthy move towards a purely utilitarian basis of practice, before its potentially disastrous consequences become inevitable. It may well be that some, or even many, of those who have become involved in these practices without sufficient awareness of these considerations will welcome a frank examination of their ethical basis at this stage.

**David W Evans** *retired physician*  
Queens’ College, Cambridge CB3 9ET  
dwevansmd@tinyworld.co.uk

Competing interests: None declared.

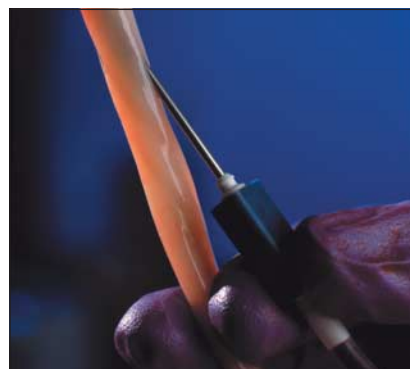
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## Commercial cord blood banking

### Immediate cord clamping is not safe

EDITOR—Edozien has provided a balanced analysis of the issue of commercial cord banking.<sup>1</sup>

A need exists for further emphasis on the importance of delayed cord clamping. In addition to the Cochrane meta-analysis,<sup>2</sup> further trials have shown substantial benefits in very low birthweight infants<sup>3</sup> and also



term infants. Cord blood collection must not be allowed to restrict this practice. The value of delayed cord clamping has been shown whereas the value of commercial cord blood banking is still largely hypothetical at present.

Commercial cord blood banking is an insurance, not with a monetary return in the event of a claim but with the prospect of a successful medical treatment. Like all commercial insurance there is a premium to pay and risk of collapse unless the venture is underwritten by the government or the insurance industry as a whole.

**David J R Hutchon** *consultant obstetrician and gynaecologist*  
Memorial Hospital, Darlington DL3 8QZ  
DJRHutchon@Postmaster.co.uk

Competing interests: None declared.

- 1 Edozien LC. NHS maternity units should not encourage commercial banking of umbilical cord blood. *BMJ* 2006;333:801-4. (14 October.)
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### Public cord blood banking should be more widely adopted

EDITOR—Given the availability of NHS public donor access for cord blood banking, the UK should not follow the American lead in allowing the establishment of private cord blood banking.<sup>1</sup> Economics and the low rate of ultimate use for any single family clearly argue for public banking to allow for access to compatible stem cells by the person best matching the cells and the one needing it the most.

In the United States, the absence of widespread public banks or the small number of banks willing to process from a specific hospital make public banking less likely. Recently in Houston, the University of Texas M D Anderson Hospital has started a local public banking programme that now involves two hospitals and is soon to be expanded to two others. Some units have already been matched and distributed to non-local transplantation facilities.

The other major issue to be faced by all parties is the paucity of “minority” donors, who often have a mix of ethnic origins that complicate the matching process. In such circumstances, personal banking might make more economic sense if it were not for the low utilisation rate.

Public banking should be encouraged. In the US it should be substantially funded by the federal government.

**Robert James Carpenter Jr** *doctor, maternal-fetal medicine*  
Houston, TX 77030-2339, USA  
zygote@icsi.net

Competing interests: None declared.

- 1 Edozien LC. NHS maternity units should not encourage commercial banking of umbilical cord blood. *BMJ* 2006;333:801-4. (14 October.)

## Good financial management does not lead to better services

EDITOR—According to its website, the Healthcare Commission believes that “management of finances and the quality of services go hand in hand” ([www.healthcarecommission.org.uk](http://www.healthcarecommission.org.uk)).<sup>1</sup> However, the Healthcare Commission’s own data, released on 12 October 2006, imply that this optimism is misplaced. I analysed the scores for “use of resources” and “quality of services” for all primary care trusts in the United Kingdom. The Pearson’s correlation between these two scores is  $-0.01$ . Acute trusts ( $R=0.25$ ) and mental health trusts ( $R=0.34$ ) show a similar lack of correlation between resource management and quality of care.

**James H MacCabe** *MRC fellow in health of the public research*  
Department of Psychiatry, Institute of Psychiatry,  
London SE5 8AF  
[j.maccabe@iop.kcl.ac.uk](mailto:j.maccabe@iop.kcl.ac.uk)

Competing interests: None declared.

<sup>1</sup> O’Dowd A. Watchdog brands two thirds of NHS trusts as “fair” or “weak.” *BMJ* 2006; 333: 769. (14 October.)

## Belittlement and harassment of medical students

### Seems to achieve focus

EDITOR—Until recently I would have disagreed with Aref-Adib,<sup>1</sup> but now I am inclined to agree. Last summer I was involved in the production of a BBC programme *Thoroughly Modern Medic*, in which six third year medical students were subjected to a week of 1950s’ style ward based teaching. In essence, we subjected them to a traditional regime of education by humiliation in which, although to some extent artificially staged for the TV cameras, the action was unscripted and was treated seriously by all concerned.

At the outset, the students had a good grasp of the basic skills required to take a history and examine a patient, but most of them struggled to place the information gathered into any sort of diagnostic framework. After a week of being put on the spot and being forced to face up to the shortcomings of their thought processes, their approach to the task was dramatically transformed, being able to present the information clearly and systematically and arrive at a rational and justifiable differential diagnosis.

Having kept in contact with several of the students since filming was completed, they confirmed that the experience had been carried over into their normal practice and had proved beneficial to them in their fourth year of learning. In at least one case, the result was a significant improvement in performance, demonstrated by a rise from consistently being in the bottom fourth of examination results to becoming one of the higher performers.

When I was at medical school, I dreaded the ward round as I knew that I would be

made to appear a fool, but maybe it was my desire to avoid that fate that ultimately made me a better doctor.

**Jonathan D Belsey** *researcher in evidence based medicine*  
J B Medical, Little Cornard, Sudbury CO10 0PB  
[jbelsey@jbmedical.com](mailto:jbelsey@jbmedical.com)

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<sup>1</sup> Aref-Adib G. Belittlement and harassment of medical students: Is a source of medical education *BMJ* 2006;333:809. (14 October.)

## The roots of education are bitter but the fruits are sweet

EDITOR—As a student, and even more often as a junior doctor, I have been told repeatedly that the first step to learning is to accept ignorance—and what better time to accept ignorance than when asked something you do not know.<sup>1</sup> One professor I trained with always said, “I can tolerate a hundred I don’t know but not one guess.” If a student feels belittled and bullied would it not be imperative to speak to his or her mentor and try to address their concerns? Students have as much a duty to learn as a senior has a duty to teach. It is when these two rhyme that makes teaching effective.

Mistakes made as a student should be a stepping stone to learning, as mentioned by Samuel Smiles: “It is a mistake to suppose that men succeed through success; they much oftener succeed through failures. Precept, study, advice, and example could never have taught them so well as failure has done.”<sup>2</sup>

**Deepak Parasuraman** *senior house officer paediatrics*  
Tameside General Hospital, Ashton-under-Lyne,  
Lancashire OL6 9RW  
[drdeepak01@gmail.com](mailto:drdeepak01@gmail.com)

Competing interests: None declared.

<sup>1</sup> Aref-Adib G. Belittlement and harassment of medical students: Is a source of medical education *BMJ* 2006;333:809. (14 October.)

<sup>2</sup> Smiles S. 1812-1904. Scottish author. [www.brainyquote.com/quotes/authors/s/samuel\\_smiles.html](http://www.brainyquote.com/quotes/authors/s/samuel_smiles.html) (accessed 20 Oct 2006).

## Medical education must be more patient centred

### Si jeunesse savait, si villesse pouvait

EDITOR—Wellbery seems distressed by her students not appreciating the relevance of what they are studying, especially when it comes to the psychosocial side of medicine.<sup>1</sup>

I think there are two dynamics in play here. Firstly, the students are rapidly acquiring new skills and knowledge and are proud of their scientific prowess. To face up to its limitations before they have fully mastered its possibilities may be disheartening for them.

Secondly, the teacher’s appreciation of the depth of the material is (I hope) informed both by technical excellence and wide experience of meeting people and their diseases. To the teacher, and other more experienced doctors, the technical

knowledge may be so well assimilated that our focus moves rapidly to the personal and social interactions involved in properly caring for patients. Expecting young students to fully appreciate what is happening here may be asking too much of them.

We all learn as we progress through medicine, and what was relevant to me as a student often seems much less relevant now. This may be because I have fully assimilated the material, or it may be I do not need it in my current role. I have now (17 years after graduation) appreciated the relevance of much material that seemed irrelevant to me as a student.

I think our perceptions of relevance and irrelevance alter significantly throughout our careers. It follows that to expect students to immediately appreciate the relevance of all that they are taught is somewhat optimistic.

**Peter G Davies** *general practitioner principal*  
Keighley Road Surgery, Illingworth, Halifax  
HX2 9LL  
[npgdavies@blueyonder.co.uk](mailto:npgdavies@blueyonder.co.uk)

Competing interests: None declared.

<sup>1</sup> Wellbery, C. Medical education must be more patient centred to be relevant. *BMJ* 2006;333:813. (14 October.)

## Good in theory but not in practice

EDITOR—As a final year medical student I have encountered patient centred medical education.<sup>1</sup> In principle, the theory is commendable. But it is in the practice of patient centred teaching where the problem lies. Too often such teaching is designated to non-clinical staff. They, armed with PowerPoint slides, with management speak buzzwords, bore us with endless generalisation and jargon.

In satisfying GMC led tickboxes for “communication skills” and “patient centredness” we develop lifelong prejudices against “psychosocial” aspects of medicine. So much time and effort has been devoted to this kind of teaching that it has edged out physiology, anatomy, and first principle led clinical medicine.

Where is the patient who has complex psychological needs, who has hidden agendas and fears, who is angry, who needs explanation, appeasement, understanding? In the general practitioner’s office, in the accident and emergency department, or on the wards—not in a lecture theatre.

To say that we may not be the best judges of what we will need to know<sup>1</sup> may be true, perhaps. However, I recognise good quality medical education. I am the best judge of that, uniquely placed as the recipient. Communication should be taught by committed clinicians who encounter the issues of which they speak, should entail pragmatic examples as Wellbery suggests, and can only be taught effectively by example.

**Alex Stockdale** *fifth year medical student*  
Edinburgh University, Edinburgh EH8 9YL  
[s0236903@sms.ed.ac.uk](mailto:s0236903@sms.ed.ac.uk)

Competing interests: None declared.

<sup>1</sup> Wellbery C. Medical education must be more patient centred to be relevant. *BMJ* 2006;333:813. (14 October.)