Editor's choice

Editor's choice: Evidence to inform
Fiona Godlee
BMJ 2007;334, doi:10.1136/bmj.39252.523519.47

US editor's choice: Changing what we do
Douglas Kamerow
BMJ 2007;334, doi:10.1136/bmj.39253.656134.3A

Editorials

Decision aids for women with a previous caesarean section
Jeremy A Lauer, Ana P Betrán

Community based health insurance in developing countries
Manuela De Allegri, Rainer Sauerborn
BMJ 2007;334:1282-1283, doi:10.1136/bmj.39240.632963.80

β-blockers and statins in non-cardiac surgery
Stephen Bolsin, Mark Colson, Myles Conroy
BMJ 2007;334:1283-1284, doi:10.1136/bmj.39217.382836.BE

Diabetic ketoacidosis
Ketan K Dhatariya
BMJ 2007;334:1284-1285, doi:10.1136/bmj.39237.661111.80

Centralised application services for specialist training
Tony Delamothe
BMJ 2007;334:1285-1286, doi:10.1136/bmj.39252.411192.80

Letters

This week's letters

Glomerular filtration rate: Reporting eGFR has benefits
Charlotte E Bebb, Richard P Burden
BMJ 2007;334:1287, doi:10.1136/bmj.39247.723206.3A

Glomerular filtration rate: eGFR in changing drug regimens
Jeffrey K Aronson
BMJ 2007;334:1287, doi:10.1136/bmj.39247.716806.3A
**HIV and pregnancy: Are we doing enough?**
A Jayasuriya, P S Allan  
*BMJ* 2007;334:1287-1288, doi:10.1136/bmj.39241.438519.3A

**Genetics and insurance: Effect on premiums is small**  
R Guy Thomas  
*BMJ* 2007;334:1288, doi:10.1136/bmj.39247.696238.3A

**Rickets: Prevention message is not getting through**  
Scott Williamson, Stephen Greene  
*BMJ* 2007;334:1288, doi:10.1136/bmj.39247.699780.3A

**MTAS: Response from the BMA**  
Sam Everington, Jonathan Fielden, Michael Rees, Jo Hilborne, Hamish Meldrum, Chris Spencer-Jones  
*BMJ* 2007;334:1288, doi:10.1136/bmj.39252.476875.BE

**News**

**Greater vigilance needed to tackle domestic abuse, says BMA**  
Zosia Kmietowicz  
*BMJ* 2007;334:1289, doi:10.1136/bmj.39252.343958.4E

**Academics join forces in training fight as junior doctors face uncertainty over their future**  
Lynn Eaton  
*BMJ* 2007;334:1289, doi:10.1136/bmj.39252.540417.FA

**Citizens' alliance condemns EC report as "undocumented" and "biased"**  
Ray Moynihan  
*BMJ* 2007;334:1290, doi:10.1136/bmj.39251.457315.4E

**US cancer groups highlight symptoms of early ovarian cancer**  
Janice Hopkins Tanne  
*BMJ* 2007;334:1290-1291, doi:10.1136/bmj.39251.412870.DB

**Richard Granger resigns as chief executive of Connecting for Health**  
Adrian O'Dowd and Michael Cross  
*BMJ* 2007;334:1290-1291, doi:10.1136/bmj.39251.605475.DB

**Denmark halves Down's births by non-invasive screening in early pregnancy**  
Susan Mayor  
*BMJ* 2007;334:1291, doi:10.1136/bmj.39251.369815.DB

**In Brief: News**

**Teenage measles outbreak shows shortcomings in Japan's immunisation programme**  
Peter Moszynski  
*BMJ* 2007;334:1292, doi:10.1136/bmj.39251.641736.4E

**Netherlands bans smoking in enclosed public places but allows closed smoking rooms**  
Tony Sheldon  
*BMJ* 2007;334:1292-1293, doi:10.1136/bmj.39248.516366.DB
Is Wisconsin or Hawaii the healthiest US state?
Janice Hopkins Tanne
BMJ 2007;334:1293, doi:10.1136/bmj.39251.380428.DB

Community treatment orders stay in mental health bill
Clare Dyer
BMJ 2007;334:1293, doi:10.1136/bmj.39252.466817.DB

Scientists plead for right to create interspecies embryos
Andrew Cole
BMJ 2007;334:1294, doi:10.1136/bmj.39251.667164.DB

King's Fund accepts funding for seminars from US insurance company
Owen Dyer
BMJ 2007;334:1294, doi:10.1136/bmj.39251.500220.4E

Red Cross concerned over deterioration in medical services in Afghanistan
John Zarocostas
BMJ 2007;334:1295, doi:10.1136/bmj.39251.642859.DB

GPs condemn Labour for failing the NHS
Zosia Kmietowicz
BMJ 2007;334:1295, doi:10.1136/bmj.39248.595741.DB

Doctors say no to more independent treatment centres
Zosia Kmietowicz
BMJ 2007;334:1295, doi:10.1136/bmj.39251.445694.4E

Drink and drugs fuel sexual health problems in youth, group warns
Anne Gulland
BMJ 2007;334:1295, doi:10.1136/bmj.39251.438299.4E

Vitamin D from sun exposure may protect against solid cancers, researchers find
Roger Dobson
BMJ 2007;334:1295, doi:10.1136/bmj.39251.425995.4E

EC recognises threat to use of MRI
Rory Watson
BMJ 2007;334:1295, doi:10.1136/bmj.39248.627384.DB

Shortcuts from other journals: Limiting residents' working hours saves lives
BMJ 2007;334:1296, doi:10.1136/bmj.334.7607.1296

Shortcuts from other journals: Africa trains non-doctors to fill the workforce gap
BMJ 2007;334:1296, doi:10.1136/bmj.39247.635463.80

Shortcuts from other journals: Abnormal haematocrit linked to higher surgical mortality in men over 65
BMJ 2007;334:1296, doi:10.1136/bmj.334.7607.1296-b
Shortcuts from other journals: **Patients with complex needs get high quality care**


Shortcuts from other journals: **FDA considers curbing use of erythropoietins for patients with cancer**

BMJ 2007;334:1297, doi:10.1136/bmj.334.7607.1297

Shortcuts from other journals: **Prophylactic fluconazole prevents fungal infections in preterm babies**

BMJ 2007;334:1297, doi:10.1136/bmj.334.7607.1297-a

Shortcuts from other journals: **Cardiac resynchronisation works for eligible patients with heart failure**

BMJ 2007;334:1297, doi:10.1136/bmj.334.7607.1297-b

**Feature**

**Obesity: In search of fat profits**
Geoff Watts
BMJ 2007;334:1298-1299, doi:10.1136/bmj.39241.483681.AD

**Specialist training: MTAS: which way now?**

BMJ 2007;334:1300, doi:10.1136/bmj.39252.407350.68

**Observations**

**Life and death: Let’s get tough on the causes of health inequality**
Iona Heath
BMJ 2007;334:1301, doi:10.1136/bmj.39247.502813.59

**Analysis**

**Selection for specialist training: what can we learn from other countries?**
Tony Jefferis
BMJ 2007;334:1302-1304, doi:10.1136/bmj.39238.447338.AD

**Research**

**Two decision aids for mode of delivery among women with previous caesarean section: randomised controlled trial**
Alan A Montgomery, Clare L Emmett, Tom Fahey, Claire Jones, Ian Ricketts, Roshni R Patel, Tim J Peters, Deirdre J Murphy, DiAMOND Study Group

**Equitable utilisation of Indian community based health insurance scheme among its rural membership: cluster randomised controlled trial**
M Kent Ranson, Tara Sinha, Mirai Chatterjee, Fenil Gandhi, Rupal Jayswal, Falguni Patel, Saul S Morris, Anne J Mills
Clinical review

Diagnosis and treatment of sciatica
B W Koes, M W van Tulder, W C Peul

Practice

Pregnancy plus: Inherited thrombophilia and pregnancy associated venous thromboembolism
Wendy Lim, John W Eikelboom, Jeffrey S Ginsberg

Views & reviews

Personal views: Should doctors go to patients' funerals?
Bruce Arroll, Karen Falloon
BMJ 2007;334:1322, doi:10.1136/bmj.39251.616678.47

Review of the week: Seeds of discontent
Abi Berger
BMJ 2007;334:1323, doi:10.1136/bmj.39246.670428.59

From the frontline: Stubbed out
Des Spence
BMJ 2007;334:1324, doi:10.1136/bmj.39251.717257.59

In and out of hospital: Back from Basra
James Owen Drife
BMJ 2007;334:1324, doi:10.1136/bmj.39247.654410.59

Between the lines: Sheer delight in doing evil
Theodore Dalrymple
BMJ 2007;334:1325, doi:10.1136/bmj.39251.456817.59

Medical classics: The Bell Jar
Iain McClure
BMJ 2007;334:1325, doi:10.1136/bmj.39240.652813.DB

Obituaries

This week's obituaries

Prudence Tunnadine
Caroline Richmond
BMJ 2007;334:1326, doi:10.1136/bmj.39246.488044.BE

Charles Alan Blake Clemetson
Michael Innis, F Edward Yazbak
BMJ 2007;334:1327, doi:10.1136/bmj.39245.750637.BE

Ian Thomas Twistington Higgins
Millicent Higgins
BMJ 2007;334:1327, doi:10.1136/bmj.39245.682106.BE

Frank Ian Lee
Pamela Lee
BMJ 2007;334:1327, doi:10.1136/bmj.39245.789398.BE

Margaret Lauretta Mabel Manford
Dai Davies
BMJ 2007;334:1327, doi:10.1136/bmj.39245.702245.BE
Barry Windsor Roper
Irene Roper
BMJ 2007;334:1327, doi:10.1136/bmj.39239.686100.BE

Graham Waterson Somerville
Neil Somerville
BMJ 2007;334:1327, doi:10.1136/bmj.39239.670694.BE

Minerva

Minerva

BMJ 2007;334:1328, doi:10.1136/bmj.39248.411424.AD1

Minerva
J E Tomlinson, R I S Winterton, H Peach, J Dunbar
BMJ 2007;334:1328, doi:10.1136/bmj.39248.411424.AD

Fillers

A memorable patient: Lost in the process
Lynette Wilkinson
BMJ 2007;334:1312, doi:10.1136/bmj.39213.432315.DE

A memorable patient: Appendicitis in the Himalayas
Ram Hari Ghimire
BMJ 2007;334:1321, doi:10.1136/bmj.39217.714884.BE

Corrections

Effect of insulating existing houses on health inequality: cluster randomised study in the community

BMJ 2007;334, doi:10.1136/bmj.39246.620486.AE

Managing suspected research misconduct

BMJ 2007;334, doi:10.1136/bmj.39246.631875.AE

Career focus

Read this week’s articles on
Decision aids for women with a previous caesarean section
Focusing on women’s preferences improves decision making

Rates of caesarean section are a cause of concern worldwide, although the problems vary according to the setting. In many poor countries, mostly in Africa, where average rates are 2%, caesarean section is underused because of lack of facilities and trained personnel. In other developing countries, such as ones in Latin America and eastern Asia, incidence is 30% of all births or higher, even though large sections of the population lack access to basic obstetric care, while in developed countries it has steadily risen to about 20–25%. Despite such big differences between countries, the modifiable causes of rising caesarean section rates and what to do about them are unclear.

In this week’s BMJ, a randomised controlled trial by Montgomery and colleagues looks at the effect of two computer based decision aids compared with usual care in pregnant women who have had a previous caesarean section. One aid provided structured information about possible outcomes and their probabilities associated with different modes of delivery and left women’s preferences implicit; the other was a decision analysis model that required women to define their preferences, while information about probabilities was concealed.

Importantly, one of the outcomes measured in the trial was the actual birth method, which usefully separates how choices are experienced from the option chosen. The trial found that both aids significantly improved the subjective experience of women about their choices compared with usual care. However, rates of caesarean delivery were similar in the information group, and lower in the decision analysis group compared with usual care.

Unlinking the experience of decision making from its outcome brings a refreshing perspective to the problem of overuse of caesarean section. In light of these authors’ findings, it is tempting to conclude that the rise in caesarean rates is due to delivery being seen as purely a medical problem, and the solution is guidelines and recommendations. In 1985, representatives of a study group convened by the World Health Organization wrote, “there is no justification for any region to have caesarean section rates higher than 10–15%.” At the time, such levels were considered high but acceptable in developed countries. However, now that caesarean rates in many countries exceed 20%, the recommendation has been dramatically overtaken by events. Notably, rates continue to rise despite evidence showing that caesarean delivery may increase the risk of maternal death.

Surprisingly little research exists on determinants of caesarean section, at either the aggregate or the individual level. The few randomised trials that have been published found no effect of decision aids on caesarean section rates. This is despite evidence in other areas of medical care showing that decision aids such as pamphlets and videos can improve people’s knowledge of the options, create realistic expectations of their benefits and harms, improve decision making, and increase participation in the process. Against this background, Montgomery and colleagues may have opened up a promising new avenue for research.

As the study was underpowered to measure an effect on birth method reliably, this finding requires confirmation. That information alone had no impact on rates of caesarean birth is consistent with the results of previous trials. That decision analysis did have an effect may have two important corollaries.

Firstly, in this study women seem to have been part of the decision making process regarding mode of delivery. Previous trials of decision aids may not have shown a correlation between women’s preferences for birth method and the actual birth method because women lacked this decision making power.

Secondly, the result seems to confirm the psychological principle that people do not reliably make decisions involving choice under uncertainty, in the sense that, depending on how the uncertain options are presented, their choices systematically contradict their aims. Reasons for this include widespread avoidance of negative outcomes (loss aversion) and difficulties in reasoning about probabilities.

Although this principle is less well recognised in medical decision making, it poses profound challenges for conventional notions of informed choice in medical care. Although a definitive answer must await further research, the present study suggests that women with a previous caesarean section make better choices about mode of delivery when the purely cognitive demands of reasoning about the probabilities of uncertain birth outcomes are separated from their preferences about the outcomes. Interestingly, the study also suggests that this improvement in decision making is possible even when women’s subjective experience of the decision making process is less positive. If this hypothesis can be confirmed, it could help bridge the gap between mere knowledge about the outcomes of decisions and effective decision making.
Community based health insurance in developing countries

Removing financial barriers is only the first step towards better access to care

In this week’s BMJ, a cluster randomised controlled trial by Ranson and colleagues describes a community based health insurance scheme run by the Self Employed Women’s Association (SEWA) in Gujarat, India. Community based health insurance is a valuable way to finance the delivery of health services in developing countries. By combining the risk of falling sick with resources, such insurance facilitates access to care and offers financial protection against the cost of illness. In doing so, community based health insurance aims to overcome inequities in access and socioeconomic status by reducing existing gaps between the poor and the less poor.

Research from Asia and sub-Saharan Africa shows that community based health insurance has been less effective in securing equity than expected. Poor people are less likely to enrol in such schemes, and limited evidence shows that once enrolled their use of the services is not great enough to compensate for pre-existing inequities in access. Therefore, the major challenge for community based health insurance is how to secure greater equity across socioeconomic groups, in terms of both enrolment and access to services.

The scheme described by Ranson and colleagues aimed to make access to health services and protection from the cost of illness more equitable among its members. SEWA focused on interventions after enrolment because many poor people have already enrolled, but it is unclear whether they use the services as much as those who are less poor. The trial compared four interventions in 16 rural sub-districts: after sales service with supportive supervision, prospecitive reimbursement, both packages, and neither. The trial found that none of the interventions secured greater equity, measured by the ability of poorer members to enjoy a greater share of the scheme benefits.

We believe that the disappointing results of the current trial should not discourage policymakers from implementing similar schemes or be used as a reason to abandon efforts to test the impact of similar interventions aimed at increasing equity in developing countries. Our experience in sub-Saharan Africa mirrors that reported by Ranson and colleagues, and it suggests that removing financial barriers to access through enrolment in such schemes is only the first step towards better access to care and greater financial protection against the cost of illness for poor people.

Distance to services as well as social and educational deprivations have a central role in determining poor people’s access to services, including health insurance, Future research could test whether greater equity can be achieved by targeting interventions exclusively to people most in need—the very poor. Given the limited resources usually available to community based health insurance schemes, targeted interventions may prove to be more cost effective than interventions aimed at all members, as attempted by SEWA.

The structure of the scheme itself could be another reason why the interventions implemented by SEWA did not increase equity. The SEWA scheme uses an ex-post reimbursement policy—people have to pay for care in advance and claim reimbursement afterwards. Even the increased support provided by the interventions described in the study may have been insufficient for poor people to learn “how to work the system.”

We realise that the structure of some schemes may require them to use ex-post reimbursement, but our experience in sub-Saharan Africa suggests that systems that do not require members to advance cash in times of illness may increase equity in access (data currently under analysis).

The success of community based health insurance in developing countries depends on discovering which interventions increase equity between very poor people and those who are less poor. In doing so, we must remember that although schemes can learn from one another’s experience, each scheme is set within its own context and has its own set of challenges. Thus, while SEWA may be trying to improve equity in use of health services, many schemes still struggle to secure...
equity in enrolment in the first place. In any case, we should be encouraged to follow the example set by SEWA, which rather than adopting standardised “pre-packaged” solutions, first identified barriers to access and then developed and tested interventions aimed at overcoming these specific barriers.

7 Dör DM, Karen R, Steinberg DM. The impact of Filipino micro health-insurance units on income-related equality of access to healthcare. Health Policy 2006;77:304-17.

**β** blockers and statins in non-cardiac surgery

Routine use to prevent perioperative cardiac complications is not evidence based...
reduce the risk of myocardial events by 25%—which is a relatively low target, as the current literature suggests perioperative rates of death or acute coronary syndromes are 30–42% lower in statin users than in patients who are not taking statins at the time of surgery—a trial of at least 6000 people would be needed. For the same reduction in overall survival more than 12 000 patients would be needed. The DECREASE IV trial plans to recruit over four years to assess the effects of a β blocker (bisoprolol) and a statin (fluvastatin), but it may face similar difficulties to those seen for the POISE trial.

The risks of myocardial events associated with sudden withdrawal of treatment are similar for β blockers and statins. However, while the safety profile of β blockers is well documented this is not so for statins, which are associated with serious liver and muscle toxicity, although these are rare in perioperative use. The benefits of statins in reducing myocardial ischaemic events in the general population and high risk patients are well known, but robust evidence to confirm that these drugs are valuable in routine perioperative use has not been published. So, on the basis of the evidence currently available what should practising clinicians do? We suggest that patients already receiving β blockers or statins before surgery should continue with treatment. Only patients who need heart rate or blood pressure control, or both, in the perioperative period should start treatment with β blockers. No patient should start taking statins in the perioperative period specifically to reduce the likelihood of perioperative cardiac events.

Diabetic ketoacidosis
Saline should be used for fluid replacement rather than Hartmann’s solution

Diabetic ketoacidosis is a life threatening condition caused by insulin deprivation or inadequate use of insulin in people with type 1 (or occasionally type 2) diabetes mellitus. Precipitants include deliberate insulin omission, intercurrent illness, surgery, trauma, alcohol, late presentation of previously undetected type 1 diabetes, and the use of drugs that alter carbohydrate metabolism. People with diabetic ketoacidosis need swift intervention by specialists because of the substantial morbidity and mortality arising from the acid-base imbalance, profound fluid loss, and electrolyte disturbances.

Current guidelines written by diabetes specialists from the United States and the United Kingdom recommend initial replacement of fluids and electrolytes and intravenous insulin. The fluid advocated in these guidelines is 0.9% saline. However, people may be treated by emergency and intensive care doctors as well as diabetes specialists, and the type of fluid used can vary.

During the first few hours of hospital admission many people with diabetic ketoacidosis are treated by emergency or intensive care doctors who commonly prefer to use Hartmann’s solution (sodium lactate intravenous infusion). Subsequent care is usually delivered by the diabetes team, who prefer to use 0.9% saline. The conflict arises because guidelines for fluid replacement in the acute setting are written by diabetes specialists, whereas no widely accepted guidelines have been written by emergency or intensive care doctors for fluid replacement in diabetic ketoacidosis.

For decades, 0.9% saline has been the fluid of choice for diabetic ketoacidosis, and its use continues to be advocated in modern textbooks on diabetes. Early studies on diabetic ketoacidosis in the 1970s used 0.9% saline, and this approach was reinforced a decade later. However, giving patients large amounts of chloride can cause a hyperchloroemic metabolic acidosis, so administration of 0.9% saline for diabetic ketoacidosis could potentially worsen the metabolic acidosis. Thus, 0.9% saline may be the fluid of choice simply because evidence for the efficacy of other fluids is lacking. The question of which fluid replacement is optimal in patients with acute diabetic ketoacidosis is, therefore, still unanswered.
Saline 0.9% contains 150 mmol/l of sodium and chloride. Hartmann’s solution contains 131 mmol/l of sodium, 111 mmol/l of chloride, 29 mmol/l of bicarbonate (as lactate), 5 mmol/l of potassium, and 2 mmol/l of calcium. The pH of 0.9% saline and Hartmann’s varies according to temperature. At 25°C the pH of 0.9% saline is about 4.5 and that of Hartmann’s solution is about 6.0. Although Hartmann’s solution has a lower chloride concentration and higher pH, its routine use in diabetic ketoacidosis could be argued against for several reasons.

Firstly, people with diabetic ketoacidosis already have a high lactate to pyruvate ratio, and the 29 mmol/l of lactate in Hartmann’s solution could potentially exacerbate this and lead to more adverse outcomes.2 Secondly, Hartmann’s solution raises plasma lactate and generates more glucose from the lactate.7 Thirdly, giving a solution containing even 5 mmol/l potassium to a patient who may be hyperkalaemic could lead to potentially fatal cardiac arrhythmias, such as bradycardia and asystole. Fourthly, bicarbonate is not recommended for patients with pH greater than 7.0 because it could worsen the acidosis.10 Finally, because low serum sodium at presentation is a risk factor for developing cerebral oedema, initial treatment with a relatively hypotonic fluid could be harmful.11 Thus, Hartmann’s solution does not seem to be optimal for use in diabetic ketoacidosis, and Hartmann himself strongly argued against its use after some of his insulin deprived patients died.12

Diabetes specialists accept that acidosis caused by large volumes of 0.9% saline is mild and transient, and it is not associated with adverse outcomes or prolonged length of stay.1 The low base deficit in the face of a normal pH may be a cause of concern and may lead to the perception of persistent hyperperfusion. However, this is a trap for the unwary, because if a high chloride concentration is found, then the base deficit can be safely ignored.

The primary treatment in diabetic ketoacidosis is replacement with large volumes of fluid. This in itself substantially reduces blood glucose and begins to correct the acidosis. Ideally, a randomised study comparing 0.9% saline and Hartmann’s would provide information about the optimum type of fluid replacement. This is unlikely to happen, though, partly because of the potential dangers of Hartmann’s solution discussed above. In the absence of such a trial and in view of the large body of supporting evidence that has led to the development of the guidelines,1 2 the fluid of choice in the initial resuscitation of people with diabetic ketoacidosis should remain 0.9% saline.

The next substantial criticism of the new system was that it was a poor discriminator of applicants. (The “evidence” for this is the large numbers of “high flyers” without job offers, a claim that will have to await the end of round two for proper substantiation.) The new application form was blamed for giving precedence to free text answers about competency over evidence of clinical experience. Its masking of medical school and country of training—an attempt to reduce discrimination—was seized on as a weakness rather than a strength.

The countries that Jefferis analysed do things the way Britain used to. All have application forms covering undergraduate and graduate training, honours and prizes, research and publications, and extracurricular and community activity. To help in selection, all four countries use reports and references—from medical school deans, referees, supervisors, and the like (some solicited by telephone). Programme directors rank candidates in order of preference using the application form, references, and interview. Candidates’ preferences and those of the programmes are then matched centrally, “without controversy.” Jefferis doesn’t explore how these systems protect candidates from selectors’ biases towards “people like us,” which was a laudable aim of the UK’s proposals.

The remaining serious criticism of MTAS was that it would leave 12 000 junior doctors jobless from August, which no amount of tweaking with computer programs or application forms would have altered. A large proportion of the “excess” applicants are thought to be doctors trained overseas—including some working in non-training grade trust posts, some doing unpaid observerships or locums as they try to get substantive appointments, and others currently overseas. Jefferis found that the countries he looked at avoided these problems—while international graduates made up an integral part of their medical workforce their applications were considered only after those of domestic graduates.

John Tookes’s inquiry into the UK’s specialty training scheme, Modernising Medical Careers, is looking much more widely than merely “the mechanics of the process,” although it is hard to imagine this won’t consume a lot of its attention, given the shortfalls of the discredited system. In its current consultation phase the inquiry wants to explore “alternative solutions, grounded in evidence.” Jefferis’s article shows that a scheme that combines central computerised application with local selection is not necessarily an impossible dream.

**Why the numbers didn’t add up**

Last year’s Postgraduate Medical Education and Training Board survey indicated that there were 17 500 SHOs in educationally approved posts in the UK. Posts available for MTAS recruitment were estimated at 18 500, not including posts filled by general practitioner trainees. In total, the UK had around 23 000 posts at SHO level—so plenty to go round. But there was also an unknown number of trust grade doctors and doctors outside the UK with, or eligible for, General Medical Council registration. In total, 34 000 doctors applied, hugely in excess of the SHO population for whom the posts were intended.

Until last year, international medical graduates appointed to training posts were given permit-free training visas. Without warning, the government announced last year that this scheme was withdrawn. Doctors without right of residence could work only if no suitable UK or European Union candidates had applied for the job and the employing trust could apply for a work permit using the “resident labour market test.” Meanwhile, such doctors could apply for permission to work through the highly skilled migrant programme. These doctors would be able to apply on an equal footing to UK citizens, but they would ideally be granted a visa for only two years and would then need an extension. They would therefore not have a visa to cover the whole of the training programme, and the Department of Health recommended that they should not be eligible for training programmes longer than two years.

For the time being, however, these doctors have been granted equal eligibility to UK citizens and others with a right to work pending an appeal against a High Court judgment that restrictions on permit free training were lawful. Thus, these doctors were included in the first round of application to MTAS and added to the excess of applicants.

“to make informed choices and to compile their application.”

Britain’s year one was always going to be tough, but many things made it tougher, in ways that those responsible for its implementation should have predicted. Computer crashes and security breaches are par for the course for the United Kingdom’s public sector information technology projects, few of which deliver on time, on budget, and to specification. By opting for a “big bang” approach—including all training jobs, at all levels, in all geographical areas—the system was maximally stressed. An added complication was that while the senior house officer (SHO) grade is disappearing overnight, the many doctors filling such posts aren’t, and nor are the service needs they have been fulfilling.

The breakneck speed with which the changes were introduced just about overwhelmed the human resources needed to process the applications. The need to build in flexibility was sacrificed to getting the scheme off the ground. Many juniors, and those who should have been advising them, did not appreciate the scale of cultural change and how qualitatively different the new selection process was going to be. Understanding—let alone “buy in”—was lacking.

1 Eaton L. Remedy UK loses its high court case. http://blogs.bmj. com/category/comment/mtas/

2 Jefferis T. Selection for specialist training: what can we learn from other countries? BMJ 2007 doi: 10.1136/bmj.39238.447338.AB


4 Coombes R. MTAS: which way now? BMJ 2007 doi: 10.1136/bmj.39252.407350.68

GOMERULAR FILTRATION RATE

Reporting eGFR has benefits

Giles and Fitzmaurice overlooked one of the main aims of the recent guidelines on chronic kidney disease and did not take into account the accepted definition of stages 1 and 2, or the recommendations on screening.\(^1\)\(^2\) Reducing late referral of people who are heading towards dialysis (and avoiding the associated poor outcome) was one of the intentions of the guidelines.\(^2\)

The main reason for late referral is that glomerular filtration rate (GFR) can be very low when the serum creatinine is only modestly increased and the severity of the kidney disorder is underestimated. In spite of its shortcomings, eGFR reporting is the best method available to aid interpretation of serum creatinine. Since this was introduced in our unit (together with a programme of education in primary care), the proportion of new patients receiving dialysis who were referred late (defined as within 90 days) has fallen from 38% to 25% (P<0.01).

The diagnosis of stages 1 and 2 does not depend on GFR alone. Stages 1 and 2 refer to people known to have another kidney problem—either functional (proteinuria) or structural (polycystic disease)—and in whom the GFR is at least 60 ml/min (normal or nearly so).

The guidelines did not advocate a screening programme but recommended testing for kidney disease in those at risk, including patients with diabetes and hypertension in whom such testing has been normal practice for several years. The suggested improvements in sample collection and analysis deserve attention in their own right, irrespective of policies on eGFR reporting.

Charlotte E Bebb consultant nephrologist
Richard P Burden consultant nephrologist
Renal Unit, Nottingham University Hospitals (City Hospital Campus), Nottingham NG5 1PB
charlotte.bebb@nuh.nhs.uk

Competing interests: RPB was a member of the Chronic Kidney Disease Guideline Development Committee.


---

eGFR in changing drug regimens

Giles and Fitzmaurice did not discuss using estimated renal function to guide changes in the dosage regimens of drugs that are eliminated unchanged by the kidneys, that have active metabolites that are eliminated by the kidneys, or whose pharmacodynamic effects are affected by renal insufficiency.\(^1\) This is particularly important for drugs that have a low therapeutic index.

Recommendations about drug dosage regimens are based on creatinine clearance. This is customarily derived from the Cockcroft-Gault equation for adults\(^2\) or the Schwartz-Haycock equation for children.\(^3\)

The eGFR estimated by the modified four variable modification of diet in renal disease (MDRD) equation underestimates true GFR more than the Cockcroft-Gault equation does in younger patients and less in older patients; overall, MDRD underestimates true GFR more than Cockcroft-Gault does.\(^4\) There are further differences in critically ill patients with burns.\(^5\) There is currently no information on how to use the eGFR to calculate changes in drug dosage regimens.

Clinical biochemistry laboratories would help doctors if they reported not only the MDRD-derived eGFR in ml/min/1.73 m\(^2\) but also the Cockcroft-Gault estimated creatinine clearance in ml/min/70 kg, for which only the age and sex of the patient are needed (and not also ethnic group, as for eGFR). General practitioners could programme the appropriate equations into their computerised records.

Jeffrey K Aronson reader in clinical pharmacology
Department of Clinical Pharmacology, Radcliffe Infirmary, Oxford OX2 6HA jeffrey.aronson@clinpharm.ox.ac.uk

Competing interests: JK is a member of the Joint Formulary Committee of the British National Formulary and the Paediatric Formulary Committee of the British National Formulary for Children. However, the opinions expressed here do not necessarily reflect those of other members of those committees.


HIV AND PREGNANCY

Are we doing enough?

Gray and McIntyre report that the rates of mother to child transmission of HIV are dramatically reduced by antiretroviral use, caesarean section, and avoidance of breastfeeding.\(^1\) However, none of these effective interventions can take place without awareness of the mother’s HIV status.

In the United Kingdom, all antenatal clinics routinely offer HIV testing.\(^2\) Most mothers accept screening. Two recent cases, however, highlight the deficiencies in the existing system. In 2006 the two infants were diagnosed with HIV within a few weeks of one another. Both mothers had had antenatal screening, and both tested HIV negative.

Current antenatal testing policies fail to take into account ongoing risk exposure. In addition, women who seroconvert during pregnancy are at a greater risk of transmitting HIV to their babies as the maternal viral load is at its highest at seroconversion. An alternative explanation is that both patients were tested during the serological window period. The information leaflet on HIV testing distributed in our antenatal clinic does not include an explanation about the HIV window period,\(^3\) and retesting is not routinely
offered to those at higher risk.

Subsequent to these two cases, local antenatal services have altered their HIV testing policies to offer repeat testing of high risk individuals at 32 weeks of pregnancy. Midwives are being advised to consider ongoing risks in all women. Contact tracing as is currently offered to HIV positive women should be offered to high risk HIV negative women as well. High risk women who initially refuse testing in pregnancy should be offered counselling by trained health advisers, with mechanisms in place to offer testing again later in their pregnancy. We see this as a safety net for those left down by the current antenatal system.

A Jayasuriya specialist registrar
P S Allan consultant
Department of Genitourinary Medicine, Coventry and Warwickshire Hospital, Coventry CV1 4FH
ashini@doctors.net.uk
Competing interests: None declared.
1 Gray GE, McIntyre A. HIV and pregnancy. BMJ 2007;334:950-3. (5 May.)

GENETICS AND INSURANCE

Effect on premiums is small

Neither Holm nor Ashcroft addresses the quantitative question: how much difference would genetic information make to insurance prices? Would banning insurers from access to genetic tests raise prices by 0.01% or 1% or 100%? The answer is that it probably makes very little difference indeed. Certainly all estimates of the difference to date, under a variety of approaches and assumptions, have been negligible by comparison with the variations in insurance prices which exist for many other reasons.

To the very minor extent that prices do rise as a result of restricting insurers’ access to genetic tests, this may not be a bad thing. In a competitive market, the logical corollary of an increase in insurance prices is an equivalent increase in claim payouts.

The effect of a ban—if there is any measurable effect, which is highly doubtful—is a small redistribution towards people who are affected by actuarially relevant genetic predispositions.

R Guy Thomas honorary lecturer
Institute of Mathematics, Statistics and Actuarial Science, University of Kent, Canterbury CT2 7NF
r.g.thomas@kent.ac.uk
Competing interests: None declared.
1 Ashcroft R. Should genetic information be disclosed to insurers? No. BMJ 2007;334:1197. (9 June.)
2 Holm S. Should genetic information be disclosed to insurers? Yes. BMJ 2007;334:1196. (9 June.)
3 Guy Thomas. www.guythomas.org.uk
4 Genetics and Insurance Research Centre. Publications. www.ma.hw.ac.uk/ams/girc/publications.php

RICKETS

Prevention message is not getting through

Ten years ago vitamin D deficient rickets was diagnosed in six children in Manchester, which highlighted the need to implement the government’s policy on vitamin D supplementation. In Tayside in the past four months we have diagnosed vitamin D deficient rickets in five infants in an almost identical scenario. None of these children or mothers had received vitamin D supplementation. Their families were unaware of the need for this, despite the UK government recommendations for the universal use of vitamin supplements to all breastfeeding infants to prevent rickets, which have existed for over 10 years. This recommendation is particularly important for those of Asian, African, Afro-Caribbean, or Middle Eastern origin with reduced exposure to sunlight.

The NHS Direct website is not specific and is ambiguous about the need for vitamin supplements (www.nhsdirect.nhs.uk/articles/article.aspx?articleId=1122). The recommendations are laid out more clearly as a component of the “Healthy Start” initiative (www.healthystart.nhs.uk), which has replaced the welfare food scheme, but the uptake of vitamins was particularly low when this scheme was last audited. None of the affected families we saw was eligible for this scheme as it is not directed specifically at immigrant groups.

The Scientific Advisory Committee on Nutrition has just published a position statement on vitamin D, with particular reference to preventing rickets, which highlights the need for a public health campaign and to supplement infants in high risk groups. The signs and symptoms of rickets were recognised by the general practitioner in only one of our cases. We must disseminate the message to all health visitors and general practitioners across the UK.

Scott Williamson specialist registrar
Stephen Greene consultant paediatrician
Nine Wells Hospital, Dundee DD1 9SY
s.williamson@dundee.ac.uk

Competing interests: None declared.
2 HMSO. Department of Health COMA report on weaning and the weaning diet. 1994. Report No.45
5 Scientific Advisory Committee on Nutrition. Update on MTAS

Response from the BMA

The MTAS debacle is the worst insult visited on the profession by any government in many years. The priority now is to get as fair and transparent a solution as possible, which minimises further damage while also protecting patients.

The BMA will support the estimated 18000 applicants now left hunting for jobs in round 2. We have achieved a small number of extra posts to increase the chances in some of the most competitive areas, but we will lobby the government to find some more. These must be posts with real training and opportunities to progress to consultant (or general practitioner) status.

As round 2 kicks off it must be fair and transparent and contain both ST and FTSTA posts across the specialties and regions. A robust appeals mechanism must be opened forthwith to ensure that those unfairly treated by the system can be identified and given a secure return to training.

We have an assurance from the secretary of state that no one will be left unemployed in England between rounds 1 and 2. We will vigorously support any member made unemployed in this way (telephone 0870 60 60 828). And we are contributing to the independent review of the process under Sir John Tooke.

It is also crucial that the secretary of state heeds our calls, made last month, for a new body to design the future of postgraduate training. This work must start now if this painful episode is not to fester on, further sapping the morale of the profession and having a negative impact on patient care.

Sam Everington acting chairman, BMA Council, Jonathan Fielden chairman, CCSJ, Michael Rees chairman, MASC, Jo Hillborne chairman, JIC, Hamish Meldrum chairman, GPC, Chris Spencer-Jones chairman, CHMCH
BMA, London WC1H 9JP
Competing interests: None declared.
More vigilance needed to tackle domestic abuse

Zosia Kmietowicz LONDON

Doctors and other health professionals need to be more vigilant for signs of domestic abuse and should know what questions to ask so that they can take quick action, says a report from the BMA. Produced by the BMA’s Board of Science, it recommends that all health professionals should have training in how to deal with domestic abuse.

The report documents the four main types of domestic abuse—physical, sexual, psychological, and financial—which all have long term effects on the victim. Health problems that result can include fractures, burns, depression, post-traumatic stress disorder, chronic pain syndrome, arthritis, problems with hearing and sight, seizures, and headaches. Stomach ulcers, heart disease, and raised blood pressure are indirect consequences.

Gene Feder, professor of primary care research and development, at Barts and the London NHS Trust, said that research among women who had been domestically abused identified doctors as the people they would most like to talk to about their situation. With appropriate training doctors can provide effective support to victims of abuse, such as referral to expert voluntary agencies, he said. But he said that inappropriate questions to try to identify abuse could do more harm than good.

Domestic abuse is common and affects all parts of society, including many vulnerable groups, such as disabled people. An estimated half a million elderly people are being abused at any one time in the United Kingdom, most of them by family members.

As many as three in 10 women and two in 10 men have experienced domestic abuse of some form in their life, with one in 20 women having serious injury or long term health problems, said Professor Feder.

Although domestic abuse affects men and women, 80% of victims are women, and 30% of the abuse starts in pregnancy, says the report.

Vivienne Nathanson, head of BMA science and ethics, said, “The figures we provide in this report are shocking, but perhaps more alarming is that they are likely to be grossly underestimated. Domestic abuse is an unspoken scar on our society, and many individuals never report that they are victims. Sometimes this is because of social stigma or simply because they do not know who to turn to. Other times it can be because the victims are so vulnerable that they are not in a position to seek help.”

“Doctors and other health professionals are well placed to help victims and their families, and our message to them today is: if you suspect abuse is taking place, it is important that you help your patient to discuss this.” It is also very important for doctors to realise that men can be victims too. Men are less likely to be believed, and, therefore, they tend not to seek help.”

The report is available at www.bma.org.uk

Academics join forces in training fight as junior doctors face uncertainty over their future

Lynn Eaton LONDON

As many as 45% of applicants for training posts starting this August have not yet been offered a job, according to a survey by a group of medical academics who joined forces this week to reiterate their growing concern at the problems surrounding junior doctors’ appointments.

The Fidelio group, led by Morris Brown and Steve O’Rahilly, both of Cambridge University, announced the findings of their survey a few days before round one of the application process in England came to an end on Friday. As the BMJ went to press it was still unclear how many applicants had not been offered a job. Because it was decided that individual deaneries handle applications rather than the centralised computer system, only individual deaneries hold this information (BMJ 2007;334:653).

“It’s not at all clear where the data is going to come from,” said Professor Brown, who had collated replies to his own survey from 1300 applicants up to Monday 18 June. At that stage 45% of applicants had not yet received an offer, 32% had been offered one post, 15% had been offered two posts, 6% had been offered three posts, and 2% had been offered four posts. But he acknowledged that this was a small sample of the more than 30 000 applicants, who could still be offered posts before the end of round one.

The Fidelio group is hoping that the change of prime minister may signal an opportunity for a change of heart, possibly with the suspension of run-through training, after the foundation programme, when doctors train to specialise. “Gordon Brown is a great advocate of getting rid of red tape,” said Professor Brown. “We are asking him to take a red line to this.”

Richard Marks, of Remedy UK, the group set up in protest at changes in doctors’ training and the medical training applications service (MTAS), said it was understood that as many as a quarter of posts could be held back for round two. “The big question is how many will be specialist training and how many not,” he said.

Concern is also growing at the effect on academic medicine. Professor Brown’s survey found unsuccessful applicants with first class honours and distinctions.

“We’ve got one arm of government wanting better clinical research,” said Professor O’Rahilly, indicating that the Department of Health was failing to reflect the Treasury’s push to make the United Kingdom a centre of medical research excellence, as outlined in the Cooksey report (BMJ 2006;333:1239).

“But we are taking our brightest people, and making it more difficult for them to get training,” he said.

Professor Morris Brown: the best applicants have been culled
EC report on drug advertising found to be “biased”

Ray Moynihan BYRON BAY, AUSTRALIA
An international alliance of consumer groups, insurers, and professional associations has stepped up its attacks on the European Commission’s current round of public consultation over drug advertising.

The EC released a report for public consultation earlier this year on current sources of patient information, and it is seeking public comment by the end of June. The report gives strong support to the idea of allowing drug companies to give more information directly to patients, a proposal that critics argue will undermine Europe’s strict ban on direct to consumer drug advertising.

In an open letter sent to two commissioners last week, the alliance, which includes Health Action International, the Medicines in Europe Forum, and the International Society of Drug Bulletins, attacked the “shaky and undocumented nature of the commission’s analysis and the resultant bias in its conclusions.”

Specifically the alliance argues that the commission’s report gives an incomplete list of currently available sources of information for patients and alleges that the report omits many providers of information that are independent of drug companies.

Clearly supporting the industry’s desire to speak more directly to consumers, the EC report concludes that the “pharmaceutical industry possesses the key information on their medicines but this information can currently not be made available to patients and healthcare professionals.”

In response, the letter to the commissioners argues that “key” information about the sometimes serious side effects of drugs is often overlooked by companies, or even covered up, as seen in recent high profile scandals involving some drugs for arthritis, psychosis, and diabetes. “Increasingly frequent health scandals are on-going reminders of the medical and legal dangers of excessive promotion of new medicines.”

The EC has defended its consultation process and rejected the allegation that it is planning proposals to lift the ban on advertising drugs to consumers. Similarly the drug industry’s public position is that it does not want full advertising in Europe, rather just the ability to give patients more information.

The draft report on current provision of information to patients taking medicinal products is available at http://ec.europa.eu

US groups highlight symptoms of early ovarian cancer

Janice Hopkins Tanne NEW YORK
Women in the United States should watch out for the early signs of ovarian cancer, which have been described in a consensus statement from the American Cancer Society, the Gynecologic Cancer Foundation, and the Society of Gynecologic Oncologists.

Ovarian cancer is often called the “silent killer” because it is thought to have no early warning signs and is usually detected when it has already spread beyond the ovary. Although when the disease is detected early about 93% of women survive for five years, only 19% of cases are found that early, the American Cancer Society said.

The consensus statement lists four symptoms that may be early signs of ovarian cancer—bloating, pelvic or abdominal pain, trouble eating or feeling full quickly, and urgent or frequent urination.

Barbara Goff, director of gynaecological oncology at the University of Washington, in Seattle, stressed in a television interview that although these were common symptoms, they were important when they were new to a woman, persisted every day or every other day for more than several weeks, or became progressively more severe.

Dr Goff published an article in JAMA, the journal of the American Medical Association, which said that women with ovarian cancer reported these symptoms before they were diagnosed (2004;291:2705-12). Dr Goff and her coauthors said that women with symptoms that were new or more severe or frequent than expected needed further investigation. Debbie Saslow, director of breast and oncological cancer for the American Cancer Society, said, “It has been a longstanding challenge to balance educating women about ovarian cancer symptoms while emphasising that these symptoms are very common, sometimes vague, and usually not related to ovarian cancer. “There is no standardised guideline for the follow-up of women with symptoms. Many experts would agree that women should be given a thorough bimanual [pelvic and rectal] pelvic examination, transvaginal ultrasound, and a blood test for the tumor marker CA125. Each of these tests alone has a very low level of accuracy for early stage cancer. It is hoped that the combination . . . increases the accuracy.”

The statement is at www.sgo.org

Richard Granger resigns as chief of NHS IT programme

Richard Granger’s departure might destabilise the £12bn project

Adrian O’Dowd LONDON
The NHS’s electronic care records system is on track to be rolled out next year despite the sudden resignation of Richard Granger, who was in charge of implementing the system, the Department of Health claims.

Mr Granger is chief executive of the Department of Health agency Connecting for Health, which is responsible for new information technology (IT) systems in the NHS. He announced his departure two days after giving reassurances to MPs as part of the health select committee’s inquiry into electronic patient records.

Although Mr Granger will stay in the post until October, there are fears that his departure could destabilise the £12.4bn (€18.3bn; $24.4bn) National Programme for IT in the NHS.

The programme includes electronic prescription and appointment booking services, a patients’
Denmark halves Down’s births by non-invasive screening in early pregnancy

Susan Mayor LONDON

The number of children born with Down’s syndrome in Denmark halved over the past three years after non-invasive screening in early pregnancy was extended to women of all ages, new research reported at the conference of the European Society of Human Genetics shows.

The study assessed the effect of guidelines introduced by the National Board of Health in Denmark in 2004, which offer screening for Down’s syndrome to all pregnant women rather than restricting it mainly to women aged over 35 years.

Women were offered screening in the first trimester, measuring nuchal translucency in the fetus combined with a maternal blood test for chromosomal abnormalities.

Testing allowed a combined risk for Down’s syndrome and other trisomies to be calculated. Women for whom the risk was more than one in 300 were offered an invasive procedure, analysing chromosomes from fetal cells obtained either by chorionic villus sampling or amniocentesis.

Data from the Central Cytogenetic Registry for three counties of Denmark with a total population of 1.1 million, equivalent to about one fifth of the national population, from 2004 to 2006 showed a doubling in the number of fetuses prenatally diagnosed as having trisomy 21 after introduction of the guidelines. This resulted in almost 50% fewer children born with Down’s syndrome. The number of invasive procedures also decreased, from about 11% of all pregnancies to 5%.

Reporting the findings, Karen Brøndum-Nielsen, from the Kennedy Institute, Glostrup, Denmark, said, “Although we have not yet studied the whole of the population, these numbers are significant enough to show that the new guidelines have been accepted by a great majority of Danish parents.” It is important to investigate the psychosocial aspects of testing, however, she said.

Looking further into the history of children born with Down’s syndrome showed that their mothers had often declined the offer of screening or had taken it too late in pregnancy.


A seven week old fetus with nuchal oedema, which may indicate Down’s syndrome.
Measles outbreak shows shortcomings in Japan’s immunisation programme

Peter Moszynski LONDON

An outbreak of measles in Japan has led to the closure of more than a hundred schools and universities in the past month and to calls for a new push to eradicate the virus completely. Japan is one of the few industrialised countries yet to eliminate the disease.

In 1978 Japan introduced a mandatory measles vaccinations programme for preschool children. But mandatory vaccination stopped when the law was revised in 1994. Although vaccination rates remained at about 90%, according to the National Institute of Infectious Diseases, this was short of the 95% coverage needed to eradicate the disease from the general population.

Nobuhiko Okabe, director of the institute’s infectious disease surveillance centre, warned last week that the gaps in immunisation coverage had led to the virus affecting older age groups than usual, causing greater risk of this extremely infectious disease spreading in the general population.

“The outbreak is not as widespread as in 2001, when between 200 000 and 300 000 patients, most of whom children, were estimated [to have been infected. But] an epidemic among teenagers and young adults, who can wander across a much wider range than infants, could extend infections to large numbers of people of all ages,” he warned.

Although there is no comprehensive count of patients with measles, a nationwide survey by the institute of about 450 medical institutions found 286 people aged 15 years and older had contracted the disease by 20 May, and there had been about 907 cases in children.

Every year about 20 million people worldwide, mainly children, contract measles. In 2005 there were 345 000 measles related deaths, but in developed countries that have taken eradication measures the disease is now rare. In 2004 the World Health Organization received reports of only 37 cases of measles in the United States.

Peter Strebel, of WHO’s expanded programme on immunisation, told the BMJ, “In general, outbreaks of measles that affect teenagers and young adults are usually the result of the accumulation of susceptible persons who either have never been vaccinated—for example, as a result of earlier years in which routine vaccination coverage was less than 95%—or who were vaccinated but did not respond—so called vaccine failures because the vaccine is approximately 85-95% effective depending on the age at which it is given.

“In Japan, I believe the main challenge has been getting on-time vaccination coverage with the first dose above 95%, and, until recently, the lack of a second dose of measles vaccine in their routine childhood immunisation schedule.”

Netherlands bans smoking in enclosed public places but allows closed smoking rooms

Tony Sheldon UTRECHT

Smoking is to be banned in all Dutch cafes, restaurants, hotels, and sports facilities from July 2008, when the Netherlands’ government axes the previous unsuccessful policy of industry self-regulation.

Ministers rejected the hospitality industry’s proposal to phase out smoking gradually by 2011, provoking a furious response from the industry’s umbrella body, Royal Dutch Horeca, which accused the government of being unreliable. Doctors welcomed the ban
Is Wisconsin or Hawaii the healthiest?

Janice Hopkins Tanne  NEW YORK

Two different analyses of US health care have found two different answers. The federal Agency for Healthcare Research and Quality used 129 quality measurements and concluded that Wisconsin was the healthiest US state. The non-profit making Commonwealth Fund rated states on 32 health measures, and Hawaii came out best.

The federal agency focused on the quality of the health system’s performance. The Commonwealth Fund study also considered access to care and health outcomes, said Dina Belloff, senior policy analyst with the Rutgers Center for State Health Policy and an author of the Commonwealth Fund study.

The reports are part of efforts by the federal government, healthcare foundations, and other organisations to assess healthcare quality, push for improvements by hospitals and doctors, and inform the public.

The federal agency’s third annual report was the first to release a score for each of the 50 states and the District of Columbia. Wisconsin came highest with 65.76; Louisiana came lowest with 29.16.

The agency compiled information on performance measures, such as antibiotics before surgery; colonoscopy or sigmoidoscopy to detect colon cancer for men over 50; foot examinations for patients with diabetes; ease of making medical appointments for Medicare patients (mostly patients aged 65 years and older); use of recommended care for heart attack; avoiding hospital admission for children with asthma; and the number of low birthweight babies.

The Commonwealth Fund’s “state scorecard” study also used government data to rank the 50 states and the District of Columbia on five measures—access to care, quality of care, potentially avoidable use of hospitals and costs of care, equity, and healthy lives, defined as mortality before 75 years from conditions that could have been avoided by timely and appropriate care.

Wisconsin, Iowa, New Hampshire, Vermont, and Maine were the top performers in the Commonwealth Fund’s ratings. Better access to care and higher rates of people with health insurance are closely associated with better quality of care, the report says.

The reports are part of efforts by the federal government, healthcare foundations, and other organisations to assess healthcare quality, push for improvements by hospitals and doctors, and inform the public.

One analysis made Hawaii (left) top, while the other named Wisconsin (right)

Community treatment orders stay in mental health bill

Clare Dyer  BMJ LEGAL CORRESPONDENT

The UK government made a final push to get controversial reforms to mental health laws through parliament this week after making a range of concessions to opponents after a series of defeats for the bill in the House of Lords.

As the BMJ went to press on Tuesday, the mental health bill was entering the final day of its report stage in the House of Commons, and the government had survived a key vote the night before on safeguards attached to proposed new orders for compulsory treatment in the community.

The health minister Rosie Winterton outlined the concessions that the government was prepared to make to allay criticism from opposition parties, backbench Labour MPs, mental health campaigners, and healthcare professionals. Detained patients, community patients, and patients subject to guardianship will be given access to advocacy services to speak up for them and champion their rights.

For any patients under 18 years of age, mental health institutions for adults will be required to provide an age suitable environment and facilities for their “personal, social, and educational” needs. The Department of Health and local managers will have to be notified if a child younger than 16 years old is held in an adult institution, and children would not be expected to stay there longer than 48 hours, she said.

A further amendment will spell out that any conditions attached to supervised community treatment must be for the purpose of ensuring that patients receive treatment to protect other people or to prevent the risk of harm to their own health or safety. This follows concerns that conditions could be used inappropriately to restrict a patient’s behaviour and lifestyle.

But Ms Winterton strongly defended community treatment orders, one of the most controversial elements in the bill, claiming that most mental health professionals supported them and arguing that they were “absolutely vital” in preventing relapse.

She said the opposition amendments, imposing extra safeguards, would restrict the ability of doctors to treat their patients.
Scientists plead for right to create interspecies embryos

Andrew Cole  LONDON

A leading body of medical scientists has concluded that the creation of interspecies embryos, which are part human and part animal, is vital in the fight against a wide range of diseases.

The Academy of Medical Sciences says there are no “substantive ethical or moral” reasons why research on human embryos containing animal material should not be carried out under exactly the same regulatory framework that exists for other work with embryos. It stipulates that no modified embryos should be reimplanted into a woman and that none should be grown in vitro beyond 14 days. The academy set up a working group of leading doctors and geneticists in March to examine the situation after the government’s white paper, which proposed a blanket ban on all interspecies embryo research (BMJ 2007;334:12), and a public consultation on hybrid research by the Human Fertilisation and Embryology Authority (BMJ 2007;334:925).

The government later modified its position, in its draft Human Tissue and Embryos Bill, to allow some limited forms of interspecies laboratory work while still opposing the creation of true hybrid embryos, in which human sperm is mixed with animal eggs or vice versa (BMJ 2007;334:1074).

But the working group sees no reason why this type of research should be banned. Its chairman, Martin Bobrow, said it had found no scientific reason why researchers would need to generate true hybrid embryos.

“However, given the speed of this field of research, the working group could not rule out the emergence of scientifically valid reasons in the future.”

Interspecies research is an increasingly attractive option for many scientists because it overcomes the shortage of human eggs available for research by substituting an animal egg, with its nucleus removed, which acts as host for human cells.

The resulting human-animal embryos are a rich source of stem cells, which can be used to study diseases from developmental abnormalities in young children to cancer and Parkinson’s disease as well as to help to develop new drugs.

Two teams of scientists, at Newcastle University and King’s College, London, have applied for a licence from the Human Fertilisation and Embryology Authority to fuse animal eggs with human cells to make embryos that would be 99.9% human and 0.1% cow or rabbit.

The report accepts that many members of the public experience a “yuck factor” about interspecies embryos because they think it breaks a fundamental taboo. But this argument is difficult to sustain, it says, noting that many medical advances such as in vitro fertilisation, vaccination, and antibiotics involve manipulation of nature.

King’s Fund accepts funding for seminars from US insurance company

Owen Dyer  LONDON

The King’s Fund, one of Britain’s leading charitable institutions working on healthcare policy, has formed a partnership with Humana Europe, the regional subsidiary of a large US health insurer that bids for NHS commissioning contracts.

Humana Europe is widely believed to be on a Department of Health shortlist of approved companies eligible to bid for commissioning work from primary care trusts. Under the terms of the agreement with the King’s Fund, the company will provide £30 000 (£45 000; $60 000) towards the cost of seminars that NHS officials will attend.

A health policy expert, Tom Granitir, from Humana’s Kentucky based parent organisation will also be seconded to the fund as an adviser in a joint public health project, focusing on encouraging healthy lifestyles.

Daniel Reynolds, a spokesman for the King’s Fund, said the charity was “dipping our toe into the water” of partnership with private enterprise on an experimental basis.

“Private companies are playing an increasing role in the NHS, and we have to accommodate that reality,” he added.

The £30 000 payment would not compromise the fund’s independence, he said. “Some people have asked us if this means we’re running out of money. We aren’t, and even if we were, £30 000 would hardly go very far.”

Rebecca Rosen, medical director of Humana Europe, who previously worked at the King’s Fund and remains a senior associate of the charity, said that Humana hopes to capitalise on its reputation for changing patients’ behaviour in the United States through incentive based schemes.

One Humana programme in the US provides insured patients with pedometers that can be plugged into a computer, allowing patients to claim air miles on a website in exchange for exercising. It also recently launched health coaching and online support for people signed up to its insurance policy, including support in tobacco cessation, weight management, physical activity, stress management, nutrition, and back care.

Humana is seeking contracts with primary care trusts to improve health among schoolchildren and could launch a similar scheme here, offering rewards in the form of sports equipment from a participating sponsor, she said.

The joint project will also examine ways to help employers encourage healthy lifestyles among their staff, she said.

Dr Rosen acknowledged that there is suspicion about US healthcare companies seeking NHS contracts. “But no one is proposing bringing US-style health care to Britain,” she said.
Two wounded Afgan nationals are taken to a hospital for treatment in the Pakistani border town of Chaman

Red Cross concerned over deterioration in medical services in Afghanistan

John Zarocostas GENEVA

The International Committee of the Red Cross has warned that the deterioration in medical services in remote areas of Afghanistan is making it increasingly difficult for civilians wounded in hostilities to be reached by health workers.

Pierre Krähenbühl, the agency’s director of operations, said that the deterioration has been steady and that “important needs are still unmet. The civilians most in need are also the most difficult to reach.”

Getting wounded civilians out quickly is often a challenge, he said, adding that Afghanistan’s harsh terrain did not help.

He emphasised that the situation in Afghanistan is worse now in humanitarian terms than a year ago, with hostilities now spread in many parts of the country and an increasing number of war wounded people admitted to hospitals.

“Many are unable to access medical care,” he told reporters.

The unwillingness of many doctors to be posted in facilities outside cities, mostly because of heightened insecurity, added to the problem, agency officials say.

Mr Krähenbühl said that the agency had increased its support to hospitals to help deal with the large influx of war wounded people and was also providing emergency help to people newly displaced by the escalation in hostilities.

The agency’s operation in Afghanistan, its fourth biggest operation worldwide, was reassigned emergency status last year and is far from over in terms of medical and relief needs, he said.

He cited a series of bombing raids and fighting on the ground in Herat last month that resulted in many civilians deaths, more than 2000 displaced people, and 170 houses wholly or partially destroyed.

The agency also supports Afghan Red Crescent Society clinics and volunteers, who go out to “delicate” areas of the country to set up community based first aid teams, he said.

The committee says its goal in Afghanistan “is to provide essential and quality surgical services to victims affected by the conflict or other emergencies.”

The agency supports three hospitals—JPHH1 in Jalalabad, Mirwais in Kandahar, and Sheberghan in Jawzjan—with supplies, training, and capacity building support to cope with the influx of wounded people.

An increasing number of people wounded or killed are civilians, the committee says. It has called on all the different parties in the conflict—the international forces, the Afghan army and police, and armed opposition groups—to respect international humanitarian law and not target civilians.

In 2006, 1744 war wounded people were treated in facilities supported by the agency, Mr Krähenbühl said.

According to official Afghan sources 4000 people were killed in hostilities in 2006, which included 670 civilians.

GPs condemn Labour for failing the NHS

Zosia Kmietowicz LONDON

GPs at their annual meeting in London last week sent a resounding message of no confidence in the UK government’s handling of the NHS, with the secretary of state singled out for what one representative described as “squandering millions of taxpayers’ money... and the goodwill of a dedicated profession.”

The motion of no confidence in both the government and Patricia Hewitt, proposed “with regret” by Eric Rose, a GP in Milton Keynes, was carried overwhelmingly by the conference of representatives of local medical committees. Referring to the catchphrase of entrepreneur Sir Alan Sugar in the television show The Apprentice, Dr Rose said, “I hope we will hear some very Sugary words [when Gordon Brown reshuffles the cabinet]—you’re fired!” to great applause.

“Ten years ago when Labour came to power, I, along with many others, had great hopes. After all, this was the party that created with NHS and whose pre-election slogan had been ‘Ten days to save the NHS,’” Dr Rose told conference. “Ten years later the reality is that a golden opportunity has been wasted, and the dangers to the fabric of the NHS appear even greater.”

He recited a list of policies introduced by Labour that had failed to deliver benefits to patients. Among them were NHS Direct, rolled out to the whole country despite two independent studies that showed few benefits. “In the last few days I have learnt that two thirds of all callers are passed on to other services—aren’t we surprised?” said Dr Rose.

Walk-in centres had predominantly improved access to health services for people with few health needs, Labour’s choice agenda had no proved benefits, and the abandoned NHS University had cost £72m (€107m; $142m; BMJ 2007;334:1036).

Dr Rose also catalogued the abolition of systems that had been previously working well, including community health councils; the joint committee on postgraduate training for general practice; the application system for doctors’ training posts, the destruction of which has “caused untold damage to the careers of a generation of young doctors”; and the home oxygen supply system. See News doi:10.1136/bmj.39251.445694.4E
Limiting residents’ working hours saves lives

New regulations limiting the working hours of residents in American teaching hospitals came into force on 1 July 2003. Over the next 18 months, absolute mortality rates in high risk medical inpatients in these hospitals fell by a small but significant 0.25%, relative to similar patients in non-teaching hospitals unaffected by the new rules. Researchers used nationally representative data on more than 1200000 adult patients to examine the impact of limiting working hours to 80 or fewer a week and capping continuous shifts at no more than 24 hours.

Medical inpatients older than 80 benefited the most. Their absolute risk of death fell 0.71% between July 2003 and December 2004 (relative change 6.97%, P=0.005). It is not yet clear why. The new rules had no effect on death rates in surgical patients, possibly because surgical residents (or their bosses) failed to follow them. Improvements associated with less tired surgical residents may also have been wiped out by problems with continuity of care and handovers.

Only patients with conditions associated with a high mortality such as heart failure, sepsis, and major joint replacement surgery were analysed. Even so, the researchers were mildly surprised by their positive findings. Previous smaller studies have consistently failed to detect any change in patient outcomes after July 2003. Ann Intern Med 2007;147:73-80

Abnormal haematocrit linked to higher surgical mortality in men over 65

Most healthy adults have enough cardiovascular reserve to tolerate mild anaemia or polycythaemia. But in older people who need major surgery, even slight deviations in haematocrit values are associated with a higher risk of death, say researchers from the US.

They mined a national quality improvement database for more than 300000 patients over 65 (mostly men) who had their haematocrit value measured shortly before major surgery. They found a clear link between 30 day mortality and haematocrit values that were higher or lower than normal. Each percentage point deviation either way was associated with an increase of 1.6% (95% CI 1.1% to 2.2%) in the risk of death compared with a normal haematocrit of 39.0-53.9%. A combined outcome of death, cardiac arrest, or heart attack was also more common in patients with an abnormal haematocrit result.

The researchers did their best to adjust for multiple confounding factors, but their observations still don’t prove that abnormal haematocrit measurements cause postoperative deaths directly. A linked editorial (pp 2525-6) warns doctors not to correct abnormalities before surgery, because treatments such as transfusions and synthetic erythropoietins may do more harm than good. JAMA 2007;297:2481-8, 2525-6

Patients with complex needs get high quality care

Patients with multiple illnesses can be hard to manage, but that doesn’t adversely affect their overall quality of care, according to a study
from the US. Quite the opposite in fact.

In three separate US cohorts, patients had consistently better care as their number of comorbid conditions increased. The researchers defined quality by the proportion of recommended care processes received by each patient. The score went up significantly (by 1.7-2.2%) for each extra condition they had, up to a maximum of five. Beyond that, the data were too sparse to be conclusive.

Patients with complex illnesses had more consultations and more hospital admissions than those with a single diagnosis, which partly explained the better quality of care. Being cared for by a specialist may be another contributing factor. The positive association between complexity and quality of care was strongest for patients who had seen at least one specialist. But it remained positive even for patients who didn’t.

These unexpected findings should reassure observers who worry that using quality indicators in incentive programmes, such as performance related pay, might penalise providers who care for patients with multiple comorbidities.


**FDA considers curbing use of erythropoietins for patients with cancer**

**SPENDING BY MEDICARE FOR PART B DRUGS**

The controversy surrounding overuse of synthetic erythropoietins in the US has shifted lately to patients with cancer, who are given these agents for the anaemia associated with chemotherapy. While treatment helps patients avoid blood transfusions, the potential risks include thromboembolism (already seen in patients with chronic renal failure) and the stimulation of tumour growth, which could lead to shorter survival.

The evidence of harm is patchy but worrying according to three recent comment articles, and the US Food and Drugs Administration (FDA) is gearing up to place further restrictions on synthetic erythropoietins for patients with breast cancer, small cell lung cancer, and some head and neck cancers.

Data from clinical trials suggest treatment with synthetic erythropoietins can reduce survival in patients with these cancers, although the principal manufacturers disagree, and few good data are available to resolve the argument. Product labels already have a “black box” warning that urges prescribers to hold off treatment in all patients with serum haemoglobin concentrations above 120 g/litre.

Agents such as epoetin alfa are lucrative for their manufacturers and costly for the American authorities, says one article (pp 2448-51). Drug advertisements continue to overstep the evidence, citing benefits such as better quality of life that go beyond avoiding transfusions. The adverts seem to work. Medicare payments covering erythropoietins for patients with cancer increased more than fourfold between 1999 and 2004.


Prophylactic fluconazole prevents fungal infections in preterm babies

Preterm infants weighing less than 1500 g at birth are vulnerable to fungal infections that can be lethal. Some neonatal intensive care units already give fluconazole prophylaxis to their babies, a strategy that worked well in the latest European trial.

In eight Italian units, four to six weeks of fluconazole reduced the risk of invasive fungal infections, which occurred in 2.7% (3/112) of babies given 6 mg/kg, 3.8% (4/104) of babies given 3 mg/kg, and 13.2% (14/106) of babies given a placebo (P=0.005 for both active groups compared with placebo). *Candida albicans* and *Candida parapsilosis* were the most common infecting species. Prophylaxis with fluconazole also helped prevent colonisation with *Candida*, but it had no effect on progression from colonisation to infection. Mortality rates were comparable in all three groups (8.0% (9/112) v 8.7% (9/104) v 9.4% (10/106)).

Emerging resistance was not a problem in this short term trial, but the authors say it’s too early to discount the possibility of later problems in neonatal intensive care units that routinely use fluconazole prophylaxis.

Because colonisation and infection rates are variable, units will need to adapt their prevention strategies locally. Other important measures include rigorous hand washing and prevention of vertical transmission by treating vaginal candidiasis in the mothers, say the authors.


**Cardiac resynchronisation works for eligible patients with heart failure**

Cardiac resynchronisation is a mechanical treatment for severe heart failure that uses biventricular pacing to improve the function of the left ventricle. About one fifth of patients attending heart failure clinics are eligible for the treatment, which improves symptoms, prolongs survival, and helps prevent hospital admission, according to a thorough and systematic review of the evidence.

Compared with best medical treatment alone, additional cardiac resynchronisation reduced all cause mortality by 22% (13.2% v 15.5%, relative risk 0.78, 95% CI 0.67 to 0.91) and hospital admission by 37% (19% v 27%, 0.63, 0.43 to 0.93). In 14 randomised trials, cardiac resynchronisation also improved patients’ quality of life.

The survival benefits looked similar in a further 95 observational studies. A review of safety data showed that 4.3% of patients had periprocedural complications (0.3% died). Between 6% and 7% of devices broke down in the first year.

Cardiac resynchronisation looked consistently good value for money across all recent economic evaluations, costing no more than $20000 (£10 150, €15000) for each quality adjusted life year saved.

The authors conclude that this technology works for patients who still have severe symptoms, low ejection fraction, and ventricular dys-synchrony—identified by long duration of the QRS complex—despite the best available medical treatment.

*JAMA* 2007;297:2502-14
IN SEARCH OF FAT PROFITS

A pill to prevent obesity is proving as elusive to the drug industry as weight loss is to a growing proportion of the population. Geoff Watts assesses the latest candidates.

With at least 400 million people worldwide judged to be obese,¹ the hard pressed personal trainer needs an assistant. But not necessarily someone else in shorts and running shoes, badgering overweight people to do five minutes more on the exercise bike. The new help—out of sight, and in a laboratory somewhere—could be a “chemical metabolic engineer.”

Pharmacological attempts to tackle obesity are nothing new. Thyroid hormones have long been known to cause weight loss; unfortunately, that is not all they do. But the molecular biology of metabolic control has moved rapidly during the past decade or so. This is perhaps why Ronald Evans, speaking to the 2007 experimental biology meeting in Washington, DC, at the end of April, felt sufficiently confident about the future to invoke that bold concept of chemical metabolic engineering.

Professor Evans runs the gene expression laboratory at the Salk Institute in La Jolla, California. The genes he studies include a family that code for peroxisome proliferator activated receptors (PPARs). Different members of the PPAR family have different functions. One called PPARδ, his current preoccupation, seems to act as a master regulator of the body’s metabolism. Its activity determines whether the body’s cells store fat or burn it.

Professor Evans has shown the role of PPARδ through genetic manipulation.² He has created mice in which the gene, instead of being switched on when required to regulate the body’s fat stores, remains in the “on” position all the time. These modified mice weigh 20-35% less than their normal counterparts eating the same diet. They are also resistant to high fat diets that would otherwise make them grossly obese.

As Professor Evans commented in his Washington presentation,³ although this genetic metabolic engineering shows the effects of PPARδ in mice, it’s hardly suitable as a remedy for humans. What we need is a chemical method of flipping the switch: a pill that can put the body into fat burning mode whenever circumstances require. Indeed, he seems to have such an agent: “a synthetic chemical designed to mimic fat,” as he described it at the Washington meeting. Whether this compound would be suitable for human use remains to be seen. Either way, if Professor Evans really has identified the metabolic master switch, it should be just a matter of time before this compound, or some other like it, can be devised to manipulate the system.

Complex regulation

That at least is the hope; turning it into reality may not be so easy. Most living things have always had to cope with variable access to food. To keep energy intake in balance with energy output, natural selection has endowed mammals and other higher organisms with a means of storing energy in times of feast and mobilising it in times of famine. But, during the millions of years over which this system evolved, the prevailing condition has usually been shortage rather than surplus.

As Jeffrey Flier of Beth Israel Deaconess Medical Center in Boston has pointed out,⁴ “Since survival is more acutely threatened by starvation than by obesity, it should come as no surprise that the system is more robustly organised to galvanise in response to deficient energy intake… than to excess energy.” To lay down fat rather than dispose of it, in other words. Most people in most developed countries now have effortless access to unlimited amounts of an unparalleled variety of foods; so the emergence of obesity is hardly to be wondered at. In seeking artificially to throw the metabolic master switch from energy saving to energy burning, scientists are trying to buck the trend of our entire evolutionary history.

Underpinning this hurdle—and in part accounting for the difficulty of crossing it—is the emerging complexity of the systems controlling food intake and energy balance. Each discovery raises new hopes of a remedy: hopes that have thus far turned out to be difficult if not impossible to fulfil. Leptin is a case in point (box). Since then several other signalling molecules have been found, many of them concerned principally with the modulation of appetite. One such hormone is peptide YY, or PYY. Made by cells in the lower part of the gut, it’s released in response to food. Experiments by Stephen Bloom of Imperial College have shown PYY to lessen appetite in humans’ and reduce their food intake over 24 hours by a third. This finding triggered another small flood of speculative enthusiasm.

Could PYY be therapeutically useful? “In animals it works for at least two or three weeks without any great problems,” says Professor Bloom. “There’s no reason to think it won’t work in humans, but it just hasn’t been administered for any length of time.” There has been interest in giving it through a nasal spray, although Professor Bloom is not convinced that PYY in short bursts would be effective.

He has also been pursuing another gut hormone from the same family: pancreatic polypeptide. In a small preliminary experiment,³ he and his colleagues showed that an intravenous infusion blunted the appetite of 10 volunteers, who also ate less of a buffet lunch served two hours later. As with PYY,
sustained exposure to pancreatic peptide seems to be necessary. It might, Professor Bloom cautiously suggests, be incorporated into chewing gum. “These peptides are absorbed across the buccal membrane, and chewing is something that people suffering from excessive hunger quite like doing.”

One pitfall he doesn’t expect is unacceptable side effects. His confidence stems from observations of a type of benign pancreatic tumour that secretes the hormone in abnormal amounts. “These people may have had high levels of pancreatic polypeptide for 10 or 15 years. It doesn’t appear to raise blood pressure or heart rate, or have any other side effects.”

### Picking the right path

PPARδ, PYY, and pancreatic polypeptide are only three of the hormones and receptors currently under scrutiny. Other types of chemical intervention have also been tried. One of the few anti-obesity drugs currently on the market, orlistat, inhibits pancreatic lipase and so prevents dietary fat absorption. Fenfluramine, on the other hand, by triggering yet another frenzy of speculation. In fact this idea is not so far removed from attempts to prevent adult obesity by nutritional intervention in early life: a concept already being explored through the European Union funded Early Nutrition Programming Project.

He drew attention to rodent experiments showing that adult energy balance can be preprogrammed by administering leptin in utero and in early life. “Might one be able to supplement human milk with leptin?” he wondered aloud in a recent press interview—triggering yet another frenzy of speculation.

### LEPTIN: FALSE HOPES

The excitement over leptin began in the mid-1990s with the location of the mouse obesity gene dubbed “ob” and, subsequently, the leptin protein for which it coded. Strains of leptin deficient mice grew fat; but once leptin had been administered, their obesity vanished. Here, it seemed, was the anti-obesity magic bullet that might work in humans. It was not to be. Except in a small number of people whose obesity is due to inherited leptin deficiency, attempts at using it therapeutically have not been effective. Indeed, most fat people turn out not to have less leptin but proportionately more of it: a parallel with insulin resistance in diabetes.

It’s now thought that fat cells produce leptin not so much to prevent the emergence of obesity in times of plenty as to protect against too much weight loss when times are hard. Extra doses of leptin have little effect on metabolism or behaviour. To predict the future of obesity management is far from easy. But this didn’t deter Professor Cawthorne from having a go when the Department of Trade and Industry’s foresight programme requested his thoughts on the matter.

He drew attention to rodent experiments showing that adult energy balance can be preprogrammed by administering leptin in utero and in early life. “Might one be able to supplement human milk with leptin?” he wondered aloud in a recent press interview—triggering yet another frenzy of speculation. In fact this idea is not so far removed from attempts to prevent adult obesity by nutritional intervention in early life: a concept already being explored through the European Union funded Early Nutrition Programming Project.

Geoff Watts is the BMJ’s science editor

geoff@scilg.freeserve.co.uk

### Competing interests

None declared.


11. Early Nutrition Programming Project. [http://earnnet.web.med.uni-muenchen.de/index2.htm](http://earnnet.web.med.uni-muenchen.de/index2.htm)
MTAS: which way now?

Rebecca Coombes asks key players involved in the medical training application service (MTAS) what they would have done differently.

Patrick Maxwell, professor of nephrology, Imperial College London

What is your connection to MTAS?
I chaired a working group on MTAS and Modernising Medical Careers (MMC) at the Academy of Medical Sciences.

What would you go back and change about the system before it was launched?
I would not have had a “big bang” approach. Problems would have been flushed out if there had been more beta testing. From an academic perspective, I have major reservations about the assessment system, which seemed to emphasise political correctness rather than assessing excellence.

What aspects of MTAS should stay and what needs to be overhauled?
What might be useful is a central applications handling system like that used for university entries.

Martin Marshall, deputy chief medical officer for England

What is your connection to MTAS?
I have lead responsibility within the Department of Health for the MMC programme.

What would you go back and change about the system before it was launched?
I would like to have more evidence before I answer this question. Too many of the criticisms of MTAS have been based on anecdote. We now need to ensure that we take a more balanced view of what has gone well (and some aspects have gone well), what has gone badly, and what needs to be changed. That is why we await the Tooke review (the review of MMC headed by John Tooke (BMJ 2007;334:818)) and why the MMC team is talking to stakeholders before drawing firm conclusions.

One thing I am clear about is that the development of MTAS requires committed professional leadership and engagement, and for a number of reasons this wasn’t achieved as effectively as anyone would have liked.

What is your prescription for reforming MTAS into a workable system?
In the long term we need a computerised matching system. But it should not be used until it is adequately piloted and its performance evaluated, any bugs fixed, and the system shown to be totally secure. The shortlisting process also needs to be fixed. The scoring system did not ensure accurate discernment between candidates, and the process was excessively time consuming for consultants. Options include the use of a clinical problem solving or applied knowledge test as a long listing or short listing test—broadly similar to the process used in other countries. This ensures that all candidates reaching interview are of a high standard.

Carol Black, chairwoman of the Academy of Medical Royal Colleges

What is your connection to MTAS?
The royal colleges, presidents of which are members of the Academy of Medical Royal Colleges, provided the person specifications against which the candidates for specialty training should be judged.

What would you go back and change about the system before it was launched?
We would require a demonstration that the application system was capable of enabling full recognition and sound balanced assessment of the achievements of trainees as they work through the curriculum. Beyond these principles, I don’t think we should set “no go” areas, because active debate and compromise are the only ways to re-establish professional ownership for MMC.

Michael Rees, chairman of the BMA’s medical academic staff committee

What is your connection to MTAS?
I am personally involved in many individual cases of MTAS applicants who believe they were let down by the system.

What would you go back and change about the system before it was launched?
I would not have run this ill conceived system at all. It has been a complete disaster. Why did anyone think that this method of appointing junior doctors would be workable? Carrying out an untried system like this without some evidence that it would work is inexcusable. Many doctors have commented on the similarity to the US matching system; however, this scheme carries out interviews locally, and matching takes place afterwards so that institutions and applicants each rank their choices.

What is your prescription for reforming MTAS into a workable system?
There is no reason to believe that this system could be resurrected. Everyone has lost faith in it, and it should be abandoned. We should go back to local advertisements and appointments. MTAS has potentially undermined research in the NHS and the principle of achievement at medical school. We have tried to do two separate things at the same time—introduce an untested new career structure and do this through an untested computer system, where both are in need of overhaul.

A longer version of this article including a response from Tom Dolphin, deputy chairman of the BMA’s Junior Doctors Committee, is available on bmj.com
Let’s get tough on the causes of health inequality

Doctors have a duty to draw public attention to social injustice as a cause of ill health

The UK government has a clearly stated commitment to tackling health inequalities, while perversely allowing disparities in wealth to widen. The problem is that health inequality is directly related to socioeconomic inequality and cannot be separated from its underlying cause or solved independently. It is convenient for governments to believe that this can be done but the medical profession should not collude with them. There has been some attempt to tackle health inequalities by initiatives across government, but the rhetoric has outweighed the substantive achievement considerably and the health service still seems to be expected to make the major contribution.

Two entirely different but potentially complementary approaches to tackling health inequalities date back to the 1840s. During that decade both Edwin Chadwick and Friedrich Engels described the appalling conditions endured by poor people in 19th century Britain. Chadwick published his Report into the Sanitary Conditions of the Labouring Population of Great Britain in 1842 and, two years later, Engels followed with The Condition of the Working Class in England.

Chadwick laid out a statistical analysis and proposed technical solutions. Engels used a much more polemical argument and advocated political action. Chadwick demonstrated that the poor lived in squalid and overcrowded conditions and that these caused illness and disease, which then made many people too sick to work and trapped them in a downward cycle of worsening poverty and destitution. He also showed that violence, and alcohol and opium abuse, were consequences rather than causes of the conditions of poverty. His principal recommendation was a proper system of drainage and sewage disposal combined with clean water supplies and regular refuse collection. Engels argued for fundamental social change, and in 1848 he collaborated with Karl Marx to write The Communist Manifesto.

There is no doubt that Chadwick’s interventions were enormously beneficial, saved many lives, and redressed health inequalities to some extent. However, they did nothing about poverty as such or about the unresolved injustice it expresses. In contrast, Engels was primarily concerned with social justice and his work and influence led eventually to profound social upheaval and change in many countries, with enduring benefits for the poorest people. Neither the technical nor the political response is sufficient on its own; both are required.

As a general practitioner working in the same deprived urban area for many years, I find it impossible not to be keenly aware of the lottery of social conditions and the resulting differences between people: differences in their power, their hopes, their opportunities. Many people are obliged by circumstance to live lives leached of dignity and respect and clouded by a sense of having been wronged. Such lives are exacerbated by the arrogance and complacency of those who have the good fortune to find themselves on the winning side of our unequal society. This profound social injustice is untouched by effective sewers or even today’s technical expedients, which ostensibly include the financial incentives of the quality and outcomes framework and the ever more extensive prescribing of preventive pharmaceuticals.

Invaluable epidemiological research over the past two decades has documented the extent of health inequalities and has succeeded in turning this form of inequality into a political issue. Democratically elected politicians will always be discomfited by documented evidence of inequality and injustice, although it remains a mystery why governments can be shamed so much more readily by inequalities in health than by those in wealth. The problem is that while epidemiology can identify the problem, it cannot provide the answer. Further, we now seem to have developed a health inequalities “industry,” which is rapidly becoming another employment opportunity for the affluent (piggybacking on the distress of the poor becomes a substitute for difficult political effort—opium for the intellectual masses).

Perhaps the British have always favoured technical remedies but here is the impasse—some health problems require a political response. The productive complementarity between Chadwick and Engels has shifted damagingly towards the technical. Does reducing health care to standardised tick-box interventions really address the challenges of health inequalities? Yes, to some meagre extent it does, and the health opportunities of some patients with diabetes and other conditions have been improved as a result, but the fundamental causes of the inequality are left entirely intact. The challenges of ensuring dignity and self efficacy and a sense of justice are ignored.

The UK remains a markedly unequal society, ranked 21st out of the 27 countries of the European Union in terms of the proportion of the population living in relative poverty. In these adverse circumstances, health opportunities will be substantially altered only by genuine political and social change. Disease and disability are caused by biology but also by the ways in which society is organised and in whose interests it operates. Doctors have a clear responsibility to pursue political answers alongside technical ones and to seek out and draw public attention to injustice as a cause of ill health. Once acknowledged, injustice demands redress, and so doctors also have a responsibility for advocacy—to speak to the powerful on behalf of the powerless. Only in these ways can medicine contribute fully to the narrowing of health inequalities.

Iona Heath is a general practitioner, London iona.heath@dsl.pipex.com
Selection for specialist training: what can we learn from other countries?

The chaos surrounding the UK’s centralised application service led to the system being abandoned. Tony Jefferis examines how similar systems work elsewhere.

The UK Medical Training Application Service (MTAS) for specialist training had a bad start. Doctors were angry at its inefficiencies and unfairness.¹ ² Many reasons were cited for its problems including using an untried system,³ using the same system for new entrants as for those already committed to a specialty, underestimating the numbers of international medical graduates applying, using a flawed computer system, and, finally, buckling to public outcry by revising the timetable and conditions of application. The secretary of state for health apologised in the House of Commons, the website closed for a security review, and the system was eventually abandoned.

Despite all this, a central application portal with local selection has considerable merit. It has been used successfully in the United States, Canada, and, in a modified form, in Australia and New Zealand for at least 30 years (box). It provides an orderly and transparent way for candidates to decide where to train and for programme directors to decide whom to enroll into postgraduate medical training. So how do these countries make it work?

Selection process
All four countries have a clearly publicised timetable, outlining each step of the process. The US, Australia, and New Zealand have one round of applications each year. Canada has two, the second being primarily for international graduates and candidates not matched in the first round. Candidates are given two to three months to organise an application before submission.

Candidates can make an unlimited number of applications, to as many programmes as they wish. What restricts the number of applications is the cost, the time involved, and the likelihood of success. All schemes charge their applicants for the process. In the US the charge is $60 (£30; €44) for 10 applications, more pro rata, and Canada charges $205 (£97; €143; $194) for four applications, more pro rata. In Australia and New Zealand the charge for registration as a surgical trainee is AU$3900 or NZ$4350 (£1640; €2420; $3280) for registration, allowing an unlimited number of applications. Other specialties cost less.⁵

Application form
All have application forms with similar content, covering undergraduate and graduate education, medical education, previous training, honours and prizes, research and publications, and extracurricular and community activity.

The process of being admitted to specialty training begins before qualification in the US and Canada. Medical school is a highly competitive graduate programme in both countries. The specialty application form requires details of the candidate’s achievements and aptitudes as a medical student. Students take the licensing examination before matching in the US, but after in Canada. Weight is given to applicants who have research experience and peer reviewed publications. Extracurricular activity is also graded, with credit being given to those who have important and consistent leadership roles. In Canada, a major determinant of eligibility for a programme is appropriate electives.

Applicants for specialty training in Australia and New Zealand are qualified doctors who are in basic medical training, similar to the foundation training in the UK. Until this year they were then selected for core training in a specialty, and after two to four years...
applied for higher specialty training programmes. In 2007 specialty training in surgery is changing to a single programme called Surgical Education and Training. Like the programme in the UK this combines core and specialist training. Doctors wishing to enter specialist training register with the college while in basic medical training, before submitting their application.4

International applicants are given a special track in all four countries. They have to show eligibility for each of the programmes and they are considered after local graduates.

**Reports and references**

All four countries’ application procedures use reports and references to help with selection. In the US, candidates are asked for letters of recommendation from the dean of their medical school and other referees. The references cover a series of professional attributes and are sometimes supplemented by telephoning the referees. In the past some candidates had been given misleading references, and programme directors took steps to improve this through direct contact with the referee using questions based on the Accreditation Council of Graduate Medical Education competencies.

Canada has a similar system, requiring a letter from the dean and letters of reference and recommendation, especially from elective supervisors. These letters state the type and duration of the referee’s contact with the individual and comment on cognitive skills, knowledge, problem solving, patient management, behaviour, attitudinal skills, communication skills, working relationships, ability to work in a team, motivation, punctuality, sense of responsibility, and aptitude relevant to their chosen discipline. Applicants also need to supply a transcript of their medical school achievements and a personal statement.

As entry to specialist training in Australia and New Zealand follows basic medical training, references come from the candidate’s supervisors. Details of what is required vary, but there are some consistent principles. The candidates must supply between five and eight referees. These are their supervisors or managers they have worked for over the past two years. Some or all of these referees are approached to give a structured reference, either over the telephone or by completing a standard form. The domains include clinical skills, surgical competence, potential, and the ability to interact with patients and others.

**Interview**

In the US and Canada each institution grades the application form, letters of recommendation, personal statement, dean’s letter, research experience, extracurricular activity and community involvement and then makes an overall evaluation. Candidates ranked most highly are called for interview. The ratio of candidates to places varies but can be as high as 10:1 since there is no certainty about how the candidates will rank the institution.

At most interviews there are several interviewing stations, usually with two faculty members in each. The candidates are all asked the same questions. Rating is done on the candidate’s appearance, communication skills, maturity, self confidence, ability to work effectively, compatibility with the programme, and overall rating. In some programmes current residents rate the candidate’s suitability.

In Australia and New Zealand the colleges arrange the interviews. They are held either centrally in the individual colleges for smaller specialties or in the state capitals for larger specialties. The interview

---

**Computerised job application doesn’t have to be an unhappy process**

---

**National application portals for specialty medical training**

**United States**

Electronic Residency Application Service (ERAS) is run by the Association of American Medical Colleges [www.aamc.org/students/eras](http://www.aamc.org/students/eras). It was computerised in 1996.

**Canada**

Canadian Resident Matching Service is run by the Association of Medical Colleges [www.carms.ca](http://www.carms.ca). It was computerised in 2002.

**Australia and New Zealand**

The process is run by individual specialty colleges. The Royal Australasian College of Surgeons, for example, computerised in 2007.
is conducted with several stations rather than a panel. The questions are semi-structured, with each candidate being interviewed on similar subjects. The interviewers rate the candidate’s communication skills, personal presentation and character, decision making ability, clinical knowledge, and professionalism. The competition ratio varies but, for example, this year in surgery it is about four candidates to one place.

**Ranking**

In all four countries the programme directors rank all the candidates in order of preference using the application form, the references, and the interview. The weight given to each section varies, but the range is 20-35% for the application form and academic profile, 35%-40% for references, and 35-40% for the interview. Individual programmes use different criteria for tie breakers when candidates have identical scores—for example, the medical licensing examination result or the overall consensus of the faculty.

**Matching**

The candidates’ preferences and those of the programmes are matched centrally. There is no controversy about this; programme directors and trainees are happy with the process. The number of candidates selected who fail to complete their programme is small. However, change does bring difficulties, and trainees in New Zealand were concerned that some potential specialists were denied entry to their chosen field in the transition to the surgical education and training system this year. The number of candidates getting their first choice specialty varies: 95% in Canada, not necessarily at their institution of choice, and only 50% in Australia in popular surgical specialties.

**UK directions**

The UK needs to design a medical specialty application process for postgraduate training. All use a central portal and local selection with a clearly defined timetable. Ranking is based on an application form, multiple references, and semi-structured interviews. The UK system would benefit from changes to the application process and better references.

**SUMMARY POINTS**

- The US, Canada, Australia, and New Zealand have computerised selection for postgraduate training.
- All use a central portal and local selection with a clearly defined timetable.
- Ranking is based on an application form, multiple references, and semi-structured interviews.
- The UK system would benefit from changes to the application process and better references.

The major concerns about the recent UK experience were that the forms were available for only two weeks, and candidates had to describe their professional achievements in ways which relied heavily on linguistic dexterity. Perhaps the UK should adopt a more conventional scheme for application forms.

Some aspects of medical training are not mentioned in the UK application forms, in an attempt to be fair. For example, the name of the medical school and country where a doctor trained is purposely kept from the selection panel. This is good equal opportunity practice. However, the pooling of international medical graduates with those from the UK and the rest of Europe has been one of the reasons that the system was oversubscribed. Although international graduates are an integral part of the medical workforce in the US, Canada, Australia, and New Zealand, their applications are considered only after domestic graduates. This is not possible in the UK because of employment law.

Should we change?

The references and supporting letters of recommendation are important in ranking the candidates. The matching systems all use references based on a series of professional attributes and some supplement the information by personal contact. References in the UK tend to be bland, rarely giving an accurate picture of the candidate. Even the current 360° summaries on each foundation trainee tend to group at the upper end of the scale. The UK needs to develop a more discerning system of references to differentiate between candidates. This could then form part of the ranking process. The current system with references based on the attributes of Good Medical Practice could be adapted by using up to six referees and developing a consistent scoring system.

In many ways the UK interview, with semi-structured questions and standardised evaluation, is as fair as elsewhere. Nevertheless, candidates need to know that they will be evaluated on their professionalism, communication skills, decision making, character, and clinical ability at interview.

There is much to put right in the current medical application process. Some specialties have already done so, notably general practice and histopathology. It would be unfortunate if all progress was abandoned and the system reverts to a past that was not as golden as it is sometimes painted.

Two decision aids for mode of delivery among women with previous caesarean section: randomised controlled trial

Alan A Montgomery, senior lecturer in primary care research,1 Clare L Emmett, trial coordinator,1 Tom Fahey, professor of general practice,2 Claire Jones, research assistant,3 Ian Ricketts, professor of assistive systems and healthcare computing,3 Roshni R Patel, specialist registrar in obstetrics and gynaecology,4 Tim J Peters, professor of primary care health services research,1 Deirdre J Murphy, professor of obstetrics,5 on behalf of the DIAMOND Study Group

ABSTRACT

Objectives To determine the effects of two computer based decision aids on decisional conflict and mode of delivery among pregnant women with a previous caesarean section.

Design Randomised trial, conducted from May 2004 to August 2006.

Setting Four maternity units in south west England, and Scotland.

Participants 742 pregnant women with one previous lower segment caesarean section and delivery expected at ≥37 weeks. Non-English speakers were excluded.

Interventions Usual care: standard care given by obstetric and midwifery staff. Information programme: women navigated through descriptions and probabilities of clinical outcomes for mother and baby associated with planned vaginal birth, elective caesarean section, and emergency caesarean section. Decision analysis: mode of delivery was recommended based on utility assessments performed by the woman combined with probabilities of clinical outcomes within a concealed decision tree. Both interventions were delivered via a laptop computer after brief instructions from a researcher.

Main outcome measures Total score on decisional conflict scale, and mode of delivery.

Results Women in the information programme (adjusted difference −6.2, 95% confidence interval −8.7 to −3.7) and the decision analysis (−4.0, −6.5 to −1.5) groups had reduced decisional conflict compared with women in the usual care group. The rate of vaginal birth was higher for women in the decision analysis group compared with the usual care group (37% vs 30%, adjusted odds ratio 1.42, 0.94 to 2.14), but the rates were similar in the information programme and usual care groups.

Conclusions Decision aids can help women who have had a previous caesarean section to decide on mode of delivery in a subsequent pregnancy. The decision analysis approach might substantially affect national rates of caesarean section.

Trial Registration Current Controlled Trials ISRCTN84367722.

INTRODUCTION

Caesarean section has become an increasingly common method of delivery. From 1980 to 2001 the rate in the United Kingdom increased from 9% to 21% of all births1 and was most recently reported as 23%.2 Similar increases have been reported in the United States and Australia.3 An evaluation of caesarean sections by the American College of Obstetricians and Gynecologists reported that first time mothers with term singleton cephalic pregnancies and women with a previous caesarean section account for the greatest increase in rates of caesarean section and much of the variation between institutions.5 Higher rates of caesarean delivery are associated with increased maternal and neonatal morbidity.6

Rising rates of caesarean deliveries are assumed to have been driven by obstetricians, reflecting medico-legal concerns about vaginal birth after previous caesarean section (VBAC), vaginal breech delivery, and fetal distress in labour. In contrast, over a similar time period there has been increased emphasis on involvement of patients in making medical decisions.78 The traditional paternalistic model of care is based on the premise that the obstetrician knows best and by taking the lead on decisions could reduce anxiety and risk for the mother and her baby.10 The shared model of medical decision making, in which clinician and patient exchange information, reveal preferences for treatment, and jointly come to a decision, is now promoted in preference to other models.1011 Decision aids are designed to help people select between various treatment strategies by providing information on the options and outcomes relevant to a person’s health. A Cochrane review has reported that decision aids can improve knowledge and realistic expectations, reduce decisional conflict, and increase active participation in decision making.12 A recent consensus process identified key aspects of quality of patients’ decision aids relating to content, development, and effectiveness.13

Determining the optimal mode of delivery for a woman who has experienced a previous caesarean section requires consideration of the risks and benefits of
repeat section and of vaginal birth after previous caesarean section alongside her views and preferences for a particular type of birth experience. While women may want and be given a larger role in decision making, this may be without access to comprehensive and balanced information about possible risks and benefits. There is also the potential for selective use of risk based information that may increase anxiety and unduly influence the decision making process.

**Objectives**

We investigated the effects of two computer based decision aids (an information programme and individualised decision analysis) on decisional conflict and actual mode of delivery among a group of pregnant women with one previous caesarean section. We also explored effects on knowledge, anxiety, and satisfaction with the decision.

**METHODS**

**Participants**

The sample comprised pregnant women with one previous lower segment caesarean section, no current obstetric problems, and delivery expected at ≥37 weeks. Women of all parities were included, but their most recent delivery must have been a caesarean section. We excluded women with limited ability to speak or understand English.

**Recruitment setting and procedures**

Three maternity units in south west England and one unit in Scotland recruited women from May 2004 to January 2006. The rates of caesarean section for these units ranged from 22% to 25%, which is representative of the UK national rate. A research midwife recruited women during their initial booking visit at the antenatal clinic, usually at around 10–20 weeks’ gestation. Women received an information sheet, a consent form, and a baseline questionnaire.

**Randomisation**

After administering the baseline questionnaire and receiving written informed consent, the trial coordinator randomised women to one of three groups. Allocation was stratified by maternity unit and preferred mode of delivery at baseline and blocked by using randomly permuted and selected blocks of sizes 6, 9, 12, and 15. One member of the study team (AAM) generated the randomisation sequence by computer, and another member of staff with no other involvement in the trial performed the allocation.

**Interventions**

Both interventions were computer based. Women allocated to receive an intervention had an appointment with a researcher to allow the decision aid to be delivered with a laptop computer, usually in the woman’s own home. The appointment started with a brief training session to ensure the woman was comfortable using a computer and able to navigate through the decision aid. After the training session the woman was left to navigate through the programme at her leisure, spending as much time as she needed on each section and with the opportunity to repeat sections if she wished. The protocol and interventions are described in detail elsewhere.

**Table 1 | Characteristics of women in trial at baseline. Figures are numbers (percentages) unless stated otherwise**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Usual care (n=247)</th>
<th>Information (n=250)</th>
<th>Decision analysis (n=245)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Mean (SD) age (years)</strong></td>
<td>32.4 (4.6)</td>
<td>32.8 (4.7)</td>
<td>32.5 (4.8)</td>
</tr>
<tr>
<td><strong>Mean (SD) gestational age (weeks)</strong></td>
<td>18.7 (4.4)</td>
<td>19.2 (4.5)</td>
<td>19.0 (4.4)</td>
</tr>
<tr>
<td><strong>Mean (SD) deprivation:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Townsend score (England)</td>
<td>-0.53 (2.7)</td>
<td>-0.56 (2.6)</td>
<td>-0.35 (2.9)</td>
</tr>
<tr>
<td>Carstairs index (Scotland)</td>
<td>-0.96 (3.5)</td>
<td>0.01 (4.2)</td>
<td>-0.40 (4.4)</td>
</tr>
<tr>
<td><strong>Hospital:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ninewells</td>
<td>61 (25)</td>
<td>63 (25)</td>
<td>62 (25)</td>
</tr>
<tr>
<td>Southmead</td>
<td>119 (48)</td>
<td>118 (47)</td>
<td>118 (48)</td>
</tr>
<tr>
<td>St Michaels</td>
<td>63 (26)</td>
<td>63 (25)</td>
<td>61 (25)</td>
</tr>
<tr>
<td>Weston</td>
<td>4 (2)</td>
<td>6 (2)</td>
<td>4 (2)</td>
</tr>
<tr>
<td><strong>Household income (£1000):</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>£20</td>
<td>42 (18)</td>
<td>44 (19)</td>
<td>48 (20)</td>
</tr>
<tr>
<td>£20-30</td>
<td>53 (23)</td>
<td>57 (24)</td>
<td>49 (21)</td>
</tr>
<tr>
<td>£30-40</td>
<td>51 (22)</td>
<td>46 (19)</td>
<td>44 (19)</td>
</tr>
<tr>
<td>£40-50</td>
<td>43 (18)</td>
<td>37 (16)</td>
<td>46 (19)</td>
</tr>
<tr>
<td>&gt;£50</td>
<td>46 (20)</td>
<td>52 (22)</td>
<td>50 (21)</td>
</tr>
<tr>
<td><strong>Highest educational qualification:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>12 (5)</td>
<td>10 (4)</td>
<td>7 (3)</td>
</tr>
<tr>
<td>GCSE/NVQ1-3</td>
<td>99 (40)</td>
<td>92 (37)</td>
<td>97 (40)</td>
</tr>
<tr>
<td>A level/HND</td>
<td>42 (17)</td>
<td>47 (19)</td>
<td>36 (15)</td>
</tr>
<tr>
<td>Degree</td>
<td>92 (38)</td>
<td>97 (39)</td>
<td>103 (42)</td>
</tr>
<tr>
<td><strong>Parity:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>225 (91)</td>
<td>227 (92)</td>
<td>217 (89)</td>
</tr>
<tr>
<td>2</td>
<td>16 (6)</td>
<td>11 (4)</td>
<td>19 (8)</td>
</tr>
<tr>
<td>3</td>
<td>6 (2)</td>
<td>10 (4)</td>
<td>7 (3)</td>
</tr>
<tr>
<td><strong>Previous caesarean section:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Elective</td>
<td>62 (25)</td>
<td>55 (22)</td>
<td>49 (20)</td>
</tr>
<tr>
<td>Emergency</td>
<td>184 (75)</td>
<td>192 (78)</td>
<td>193 (80)</td>
</tr>
<tr>
<td><strong>Living with partner:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>11 (5)</td>
<td>12 (5)</td>
<td>11 (5)</td>
</tr>
<tr>
<td>Yes</td>
<td>232 (95)</td>
<td>234 (95)</td>
<td>232 (95)</td>
</tr>
<tr>
<td><strong>Mean (SD) decisional conflict scale (total)</strong></td>
<td>38.0 (17.1)</td>
<td>40.2 (16.6)</td>
<td>37.8 (17.2)</td>
</tr>
<tr>
<td><strong>Mean (SD) decisional conflict subscales:</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uncertainty</td>
<td>33.7 (17.9)</td>
<td>35.6 (18.0)</td>
<td>33.3 (17.2)</td>
</tr>
<tr>
<td>Informed</td>
<td>47.5 (25.5)</td>
<td>47.5 (27.2)</td>
<td>47.2 (27.1)</td>
</tr>
<tr>
<td>Clear values</td>
<td>37.3 (22.0)</td>
<td>39.6 (20.9)</td>
<td>36.9 (20.8)</td>
</tr>
<tr>
<td>Supported</td>
<td>38.9 (22.5)</td>
<td>43.1 (21.4)</td>
<td>40.7 (22.4)</td>
</tr>
<tr>
<td>Stick with decision</td>
<td>35.1 (18.8)</td>
<td>37.4 (17.5)</td>
<td>34.0 (18.7)</td>
</tr>
<tr>
<td>Anxiety</td>
<td>35.7 (12.2)</td>
<td>35.8 (11.8)</td>
<td>35.6 (11.1)</td>
</tr>
<tr>
<td>Knowledge</td>
<td>47.2 (19.7)</td>
<td>45.9 (19.6)</td>
<td>46.1 (19.3)</td>
</tr>
<tr>
<td><strong>Total score on decisional conflict scale:</strong></td>
<td>53.7 (5)</td>
<td>52.3 (5)</td>
<td>50.0 (5)</td>
</tr>
<tr>
<td>Preferred mode of delivery:**</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal</td>
<td>111 (45)</td>
<td>112 (45)</td>
<td>111 (45)</td>
</tr>
<tr>
<td>Elective caesarean</td>
<td>53 (21)</td>
<td>52 (21)</td>
<td>50 (20)</td>
</tr>
<tr>
<td>Unsure</td>
<td>83 (34)</td>
<td>86 (34)</td>
<td>84 (34)</td>
</tr>
</tbody>
</table>
Usual care—This comprised the usual level of care given by the obstetric and midwifery team. Women in the two intervention groups also received usual care.

Information programme—This provided information about the outcomes associated with planned vaginal delivery, elective caesarean section, and emergency caesarean section, including descriptions of possible health outcomes for both mother and baby. Two of the research team (DJM, RRP) obtained the probabilities of these outcomes from a literature review to reflect the best available evidence at the time. The programme gave the probabilities of having and not having the event, in both numerical and pictorial format. At the end of the appointment, women received a password that allowed them to access the information programme again through the internet, providing an opportunity to review the information with their partner. We did not provide hard copies of information to avoid the potential for wider dissemination and cross contamination across the different groups.

Decision analysis—The steps involved in decision analysis are described in detail elsewhere. Women were given information about the outcomes associated with planned vaginal delivery, elective caesarean section, and emergency caesarean section. This comprised descriptions, but not explicit probabilities, of outcomes for both mother and baby. Secondly, women were required to consider the value they attached to possible outcomes by rating each on a visual analogue scale from 0 to 100. Though these ratings are not strictly equivalent to utility values, we considered this to be a pragmatic method of assessment and the information produced to be sufficient for this study. We combined the values with the probabilities of each outcome in a decision tree to produce a recommended “preferred option” based on maximised expected utility. Women received a computer printout of the outcome of the decision analysis and were encouraged to discuss this with their midwife or obstetrician at subsequent antenatal visits.

Both intervention groups—Women in both intervention groups were contacted again by letter at 35 weeks’ gestation to encourage discussion of the intervention with their obstetrician or midwife, or both, when they attended the clinic at 36-37 weeks to finalise their birth plan. Stickers in the woman’s records alerted health professionals to her participation in the study.

Outcome measures
There were two primary outcomes and eight secondary outcomes:
Decisonal conflict scale—This is a 16 item questionnaire that measures degree of uncertainty about which course of action to take and the main modifiable factors contributing to uncertainty. Previous research indicates that an effect size of 0.3-0.4 SD is meaningful, and that total scores <25 or ≥37.5 are associated with decision implementation or delay, respectively.22

Actual mode of delivery (vaginal birth v caesarean section)—The interventions were not designed to promote one mode of delivery over another. Any change in the proportions of vaginal birth or caesarean delivery, however, might have a substantial impact on healthcare providers. The study was therefore powered to detect any such effects.

Secondary outcomes—We investigated anxiety,23 knowledge, subscales of the decisional conflict scale,22 and satisfaction with the decision.24

Collection of follow-up data
The primary follow-up for questionnaire based outcomes was at 37 weeks’ gestation. This was timed for three to seven days after a scheduled clinic visit at around 36 weeks when women met their obstetric team to discuss and finalise their plans for delivery. We obtained data on mode of delivery from hospital maternity records and assessed satisfaction with the decision in a further follow-up questionnaire about six weeks after delivery.

Sample size
Differences of 0.3-0.4 SD are important for the total score of the decisional conflict scale, and differences of this magnitude are feasible for interventions of this kind.25 With regard to mode of delivery, UK data indicate that about 33% of women with a previous caesarean section are delivered vaginally,21 and a previous trial of counselling observed that 51% of women achieved vaginal delivery for the trial groups overall.26 A change from 30-33% to 51% corresponds to an odds ratio of about 2.1-2.4, and this would certainly be considered as clinically important.

With two sided 1% α, a total sample size of 600 provides 82.99% power to detect a standardised difference of 0.35-0.5 in total score on the decisional conflict scale between the groups, and 84-95% power to detect odds ratios of 2.1-2.4 in women achieving vaginal delivery. A pairwise α of 1%, corrected for multiple comparisons between groups using Tukey’s procedure, yields an overall study α of 3.4%. To allow for preterm deliveries, malpresentations, and losses to follow-up, we originally aimed to recruit 660 women to the trial. However, this underestimated the number of participants for whom we could not obtain follow-up data so we increased the number to 740 and extended the recruitment period once realistic estimates of attrition emerged.

Statistical analysis
We used descriptive statistics to characterise the group of individuals recruited to the trial in relation to those eligible and to investigate comparability of the groups at baseline. The primary analyses comprised three pairwise intention to treat comparisons between usual care and the information and decision analysis groups for each of the two primary outcomes. We used appropriate (that is, standard or logistic) multivariable regression models, adjusted for maternity unit, initial preference regarding mode of delivery, and value of the outcome variable at baseline. We used Tukey’s procedure to adjust P values. Secondary outcomes were analysed in the same way and without any additional adjustment for multiple comparisons between groups.

We used preplanned subgroup analyses with appropriate interaction terms in the regression models to ascertain any differential effects of the interventions on the two primary outcomes according to previous caesarean section occurring before or after labour; previous successful vaginal delivery; and preferred mode of delivery at baseline.

RESULTS
Participants
Of 1148 women invited to participate in the trial, 742 were randomised, and primary outcome data were obtained for 600 (81%) for the decisional conflict scale and 713 (96%) for mode of delivery (figure). Women who consented to participate were slightly older (32.5 v 31.9 years, P=0.05) and less deprived (P=0.02) than those who did not take part. Table 1 shows characteristics of the study sample and outcome data at baseline. Overall mean (SD) age at randomisation was 32.6 (4.7) years, and mean gestational age was 19.0 (4.4) weeks. Most women (91%) had had only one previous live delivery.

Table 2 | Descriptive statistics for primary outcomes at follow-up

<table>
<thead>
<tr>
<th></th>
<th>Usual care</th>
<th>Information</th>
<th>Decision analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean (SD) total score on DCS</td>
<td>27.8 (14.6) (n=201)</td>
<td>22.5 (13.2) (n=201)</td>
<td>23.6 (15.1) (n=198)</td>
</tr>
</tbody>
</table>

Information v usual care

<table>
<thead>
<tr>
<th>Difference between groups in total score on DCS</th>
<th>n</th>
<th>Crude figure</th>
<th>Adjusted figure* (95% CI)</th>
<th>P value†</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information v usual care</td>
<td>n=201</td>
<td>-5.3</td>
<td>-6.2 (-8.7 to -3.7)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Decision analysis v usual care</td>
<td>n=201</td>
<td>-4.2</td>
<td>-4.0 (-6.5 to -1.5)</td>
<td>0.005</td>
</tr>
<tr>
<td>Decision analysis v information</td>
<td>n=198</td>
<td>1.1</td>
<td>2.2 (0.3 to 4.7)</td>
<td>0.19</td>
</tr>
</tbody>
</table>

Odds ratio for vaginal v elective/emergency caesarean section

| Information v usual care | n=201 | 0.95 | 0.93 (0.61 to 1.41) | >0.9 |
| Decision analysis v usual care | n=201 | 1.38 | 1.42 (0.94 to 2.14) | 0.22 |
| Decision analysis v information | n=198 | 1.45 | 1.53 (1.01 to 2.30) | 0.11 |

DCS=decisional conflict scale.

*Adjusted for preferred mode of delivery at baseline, hospital, and value of outcome variable at baseline (for DCS only).
†Adjusted for multiple comparisons with Tukey’s procedure.

Participants
Of 1148 women invited to participate in the trial, 742 were randomised, and primary outcome data were obtained for 600 (81%) for the decisional conflict scale and 713 (96%) for mode of delivery (figure). Women who consented to participate were slightly older (32.5 v 31.9 years, P=0.05) and less deprived (P=0.02) than those who did not take part. Table 1 shows characteristics of the study sample and outcome data at baseline. Overall mean (SD) age at randomisation was 32.6 (4.7) years, and mean gestational age was 19.0 (4.4) weeks. Most women (91%) had had only one previous live delivery.

RESULTS
Participants
Of 1148 women invited to participate in the trial, 742 were randomised, and primary outcome data were obtained for 600 (81%) for the decisional conflict scale and 713 (96%) for mode of delivery (figure). Women who consented to participate were slightly older (32.5 v 31.9 years, P=0.05) and less deprived (P=0.02) than those who did not take part. Table 1 shows characteristics of the study sample and outcome data at baseline. Overall mean (SD) age at randomisation was 32.6 (4.7) years, and mean gestational age was 19.0 (4.4) weeks. Most women (91%) had had only one previous live delivery.
Overall mean (SD) score on the decisional conflict scale at baseline was 38.6 (17.0) on a scale of 0-100, with higher scores indicating greater decisional conflict. Scores exceeding 37.5 are associated with delay in decision making or feeling unsure about implementation. Around twice as many women had a preference for a vaginal delivery compared with elective caesarean section, but over a third were uncertain about their preferred mode of delivery (table 1). Of 250 women allocated to the information group, 59 (24%) accessed the intervention again through the website at least once.

**Primary analyses**

**Decisional conflict**—Total decisional conflict was reduced in all three groups at follow-up compared with baseline (table 2). Both interventions reduced decisional conflict more than usual care, with effect sizes of 0.31 SD (95% confidence interval 0.22 to 0.51) and 0.24 SD (0.09 to 0.39), respectively, for information programme and decision analysis (tables 1 and 3). There was no evidence of any difference between the intervention groups (table 3).

**Mode of delivery**—A higher proportion of women in the decision analysis group (37%) delivered vaginally compared with in the usual care (30%) and information programme groups (29%) (table 2). The lower 95% confidence limits for the odds ratios, however, are consistent with no difference between decision analysis and the other groups (table 3), and the observed increased rate of vaginal birth in this group could be a chance finding.

**Secondary analyses**

**Decisional conflict, anxiety, knowledge, and satisfaction**—Scores of <25 on the decisional conflict scale are associated with implementing decisions. Women in the information programme and decision analysis groups were more likely than women in usual care to report decisional conflict scores below this level (tables 4 and 5). Anxiety and knowledge scores were higher in all three groups at 37 weeks’ gestation compared with baseline (table 4), though women in the two intervention groups had lower anxiety scores and higher knowledge scores that those in the usual care group (table 5). In all women the overall satisfaction with the decision measured six weeks after delivery was 4.3 out of a possible 5. Compared with usual care, satisfaction was higher in the decision analysis group but not in the information programme group (table 5). There were no differences between the interventions for anxiety, knowledge, or satisfaction (table 5).

**Subgroup analyses**—The effects of the interventions on total scores on the decisional conflict scale at 37 weeks’ gestation did not differ according to whether the previous caesarean section was elective or emergency (P=0.70) or the preferred mode of delivery at baseline (P=0.66). The effect may differ, however, depending on whether women had had a previous vaginal delivery: the information programme seemed to have a greater effect among women who had successfully delivered vaginally previously (P=0.07) (table 6).

For actual mode of delivery, there was no evidence of any interaction between study group and type of previous caesarean section (P=0.97), previous successful vaginal delivery (P=0.27), or preferred mode of delivery at baseline (P=0.35).

**DISCUSSION**

**Summary of main findings**

Computer based decision aids can reduce decisional conflict among pregnant women with one previous caesarean section. Both decision aids in our study were associated with greater knowledge and less anxiety compared with usual care. The intervention based on decision analysis was associated with a higher proportion of women achieving a vaginal birth.

**Strengths and limitations of the study**

We achieved a high rate of recruitment and a low loss to follow-up, reflecting the importance placed by women and health professionals on this aspect of obstetric care. The study was comparatively large and the
results are of direct clinical relevance to care of patients. In addition to the usual questionnaire based outcomes, we defined mode of delivery as a primary outcome and powered the trial accordingly. Our target odds ratio of at least 2.1, in the context of continually rising rates of caesarean section and falling rates of vaginal birth after previous caesarean section, however, was probably overly optimistic, and a larger sample size may have improved the precision around a smaller but still clinically important effect size. The choice of a clinically important effect size is often a matter of judgment, but from the effect observed in our study, use of the decision analysis intervention by women with a previous caesarean section could result in about 4000 fewer caesarean sections a year in England and Wales.12

A further potential limitation was the way in which women accessed the interventions with a laptop computer provided by a study researcher. An alternative would have been to provide the decision aids exclusively through the internet. However, we considered it necessary to ensure that all women allocated to receive an intervention had the opportunity to use it at least once. We will be exploring implementation issues further with a sample of health professionals. Ideally, women who do not speak English should be able to access these interventions.

Comparison with existing literature
For decisional conflict and knowledge, our findings are consistent with those of a Cochrane review of decision aids for patients developed and evaluated in various settings and conditions.11 The 95% confidence intervals for decisional conflict as a continuous outcome include effect sizes considered important, and 8-10% more women in the intervention groups reported total decisional conflict below a threshold score of 25, which is associated with implementing decisions. Notably, women in the intervention groups in our study reported reduced anxiety compared with those in usual care. This is an important finding, as detailed descriptions and probability information about obstetric complications might be considered as potentially alarming. Our results show that use of a decision aid early in pregnancy may be able to address many questions and concerns that women have and that this effect persists through to delivery.

For mode of delivery, the results are intriguing. A recent randomised trial of a paper based decision aid for women with a previous caesarean section found a reduction in decisional conflict but no evidence of an effect on mode of delivery.27 An earlier comparison of verbal versus leaflet interventions aimed at promoting vaginal birth among women with a previous caesarean section found no difference between groups in terms of mode of delivery but did report an overall higher proportion of women delivering vaginally compared with the national average.26 Given the lower confidence limits of the odds ratios in our trial it is certainly possible that this is a chance finding.

Table 5| Comparisons of secondary outcomes between groups

<table>
<thead>
<tr>
<th>Difference</th>
<th>Crude figure (95% CI)</th>
<th>Adjusted* figure (95% CI)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Anxiety:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information v usual care</td>
<td>−3.6 (−5.2 to −0.7)</td>
<td>−3.0 (−5.2 to −0.7)</td>
<td>0.010</td>
</tr>
<tr>
<td>Decision analysis v usual care</td>
<td>−3.4 (−5.0 to −0.5)</td>
<td>−2.8 (−5.0 to −0.5)</td>
<td>0.016</td>
</tr>
<tr>
<td>Decision analysis v information</td>
<td>0.2 (−2.1 to 2.4)</td>
<td>0.2 (−2.1 to 2.4)</td>
<td>0.076</td>
</tr>
<tr>
<td>Knowledge:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information v usual care</td>
<td>12.3 (9.7 to 15.9)</td>
<td>12.8 (9.7 to 15.9)</td>
<td>0.001</td>
</tr>
<tr>
<td>Decision analysis v usual care</td>
<td>10.6 (8.1 to 14.2)</td>
<td>11.2 (8.1 to 14.2)</td>
<td>0.001</td>
</tr>
<tr>
<td>Decision analysis v information</td>
<td>−1.7 (−4.7 to 1.4)</td>
<td>−1.6 (−4.7 to 1.4)</td>
<td>0.30</td>
</tr>
<tr>
<td>Satisfaction with decision:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information v usual care</td>
<td>0.06 (−0.06 to 0.19)</td>
<td>0.06 (−0.06 to 0.19)</td>
<td>0.31</td>
</tr>
<tr>
<td>Decision analysis v usual care</td>
<td>0.14 (0.02 to 0.27)</td>
<td>0.14 (0.02 to 0.27)</td>
<td>0.022</td>
</tr>
<tr>
<td>Decision analysis v information</td>
<td>0.08 (0.04 to 0.20)</td>
<td>0.08 (0.04 to 0.20)</td>
<td>0.20</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Odds ratio</th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Total score on DCS as binary (&lt;25 v ≥25):</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Information v usual care</td>
<td>1.54 (1.29 to 2.34)</td>
<td>2.04 (1.29 to 3.24)</td>
<td>0.002</td>
</tr>
<tr>
<td>Decision analysis v usual care</td>
<td>1.40 (0.98 to 2.42)</td>
<td>1.54 (0.98 to 2.42)</td>
<td>0.063</td>
</tr>
<tr>
<td>Decision analysis v information</td>
<td>0.91 (0.48 to 1.81)</td>
<td>0.75 (0.48 to 1.18)</td>
<td>0.22</td>
</tr>
</tbody>
</table>

DCS=decisional conflict scale.

*Adjusted for preferred mode of delivery at baseline, hospital, and value of outcome variable at baseline (for DCS, anxiety, and knowledge only).

Table 6| Mean score on decisional conflict scale at 37 weeks’ gestation by group and previous successful vaginal delivery

<table>
<thead>
<tr>
<th>Previous vaginal delivery</th>
<th>Usual care</th>
<th>Information</th>
<th>Decision analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>27.6 (16.7) (n=188)</td>
<td>23.0 (12.9) (n=186)</td>
<td>23.5 (15.0) (n=180)</td>
</tr>
<tr>
<td>Yes</td>
<td>31.5 (13.7) (n=13)</td>
<td>17.1 (15.6) (n=15)</td>
<td>25.3 (16.3) (n=18)</td>
</tr>
</tbody>
</table>
The observed difference in rates of vaginal birth, however, is clinically important and warrants consideration. Why should a decision aid influence the mode of delivery? Why should a more complex intervention based on decision analysis be more effective than the simpler information programme? The key elements of decision analysis are the ascertainment of utilities by the woman herself (values placed on possible outcomes) and the provision of a recommended method of delivery by computer printout. Ongoing parallel qualitative work indicates that explicit consideration of personal values attached to potential outcomes challenges women’s perceptions of the optimal decision and this may influence their resolve to achieve a vaginal birth. The technique combines utility and probability information and recommends the option that gives the best chance of achieving an outcome(s) that is valued. It is more commonly used to inform policy decisions and is not universally supported as an individual decision aid for patients.28 Our results add to other empirical evidence that individualised decision analysis is feasible and acceptable and has value as an aid to patients’ decision making.25 29 30

Implications for practice

We have shown that women making decisions about mode of delivery after a previous caesarean section benefit from access to computer based decision aids in reducing decisional conflict and anxiety and increasing knowledge. The decision aids could be made readily available through the internet and therefore distributed widely to potential users. Although the content was carefully designed to not favour one mode of delivery over another, even a small absolute change in decisions could have a substantial impact on national rates of caesarean section.

We thank the women who took part in the study. Other members of the Decision Aids for Mode Of Next Delivery (DIAMOND) Study Group are as follows: Julia Frost, Alison Shaw (qualitative study); Peter Gregor (applied computing); Sandra Hollinghurst (economic evaluation); Beverley Lovering, Anne Schiegemlitch, Kate Warren (recruitment); Maureen Macleod, Irene Munro (recruitment, delivery of interventions, data collection); Helen Watson (data collection); and Kav Vedhara (health psychology).

Contributors: AAM (guarantor), TF, and DJM had the original idea for the study and, with TJP, carried out the design; AAM, TF, RRP, TJ, and DJM obtained funding; AAM, CLE, TF, CJ, RRRP, IR, TJP, DJM developed the interventions; and CLE was also responsible for data collection. AAM, CLE, and TJP carried out the analysis: AAM and CLE drafted the manuscript, which was revised by TF, CJ, IR, RRP, TJ, and DJM.

Funding: BJPA Foundation. AAM was part supported by a postdoctoral fellowship from the UK Department of Health National Coordinating Centre for Research Capacity Development.

Competing interests: None declared.

Ethical approval: South west multicentre research ethics committee.

16 Emmett CL, Shaw ARG, Montgomery AA, Murphy DJ. Women’s experience of decision-making about mode of delivery after a previous caesarean section: the role of health professionals and information about health risks. BMJ 2006;331:1438-45.
26 Fraser W, Maunsell E, Hodnett E, Moutquin J-M. Randomized controlled trial of a prenatal vaginal birth after caesarean section


Accepted: 18 April 2007
ABSTRACT
Objective To evaluate alternative strategies for improving the uptake of benefits of a community based health insurance scheme by its poorest members.
Design Prospective cluster randomised controlled trial.
Setting Self Employed Women’s Association (SEWA) community based health insurance scheme in rural India.
Participants 713 claimants at baseline (2003) and 1440 claimants two years later among scheme members in 16 rural sub-districts.
Interventions After sales service with supportive supervision, prospective reimbursement, both packages, and neither package, randomised by sub-district.
Main outcome measures The primary outcome was socioeconomic status of claimants relative to members living in the same sub-district. Secondary outcomes were enrolment rates in SEWA Insurance, mean socioeconomic status of the insured population relative to the general rural population, and rate of claim submission.
Results Between 2003 and 2005, the mean socioeconomic status of SEWA Insurance members (relative to the rural population of Gujarat) increased significantly. Rates of claims also increased significantly, on average by 21.6 per 1000 members (P<0.001). However, differences between the intervention groups and the standard scheme were not significant. No systematic effect of time or interventions on the socioeconomic status of claimants relative to members in the same sub-district was found.
Conclusions Neither intervention was sufficient to ensure that the poorer members in each sub-district were able to enjoy the greater share of the scheme benefits. Claim submission increased as a result of interventions that seem to have strengthened awareness of and trust in a community based health insurance scheme.
Trial registration Clinical trials NCT00421629.

INTRODUCTION
Poor people in developing countries are less likely to seek care when sick than those who are better off. The costs of care can drive the poor deeper into poverty. Community based health insurance can potentially protect people from healthcare costs and ensure equitable pooling of risk between richer and poorer, and sick and healthy, members. The World Health Organization has called for investigation of mechanisms to bring the poor into such schemes.

Empirical evidence suggests, however, that the scope for equitable redistribution of resources through community based health insurance schemes is limited. Membership is generally small; schemes cover on average around 10% of target populations. Community based health insurance has tended to exclude the poorest people from membership, generally charging a flat premium that is unaffordable. Within schemes, utilisation of health care may be inequitable (or equity neutral), although evidence is limited. Utilisation of health care by insured members has been found to be higher among households located close to health facilities, probably the better off ones. Studies in Rwanda and the Philippines found that utilisation by socioeconomic status was equity neutral among insured people and inequitable among uninsured people.

According to WHO, more than 75% of total expenditure on health in India is private, and most of this flows directly from households in the form of out of pocket payments to the private, for profit healthcare sector. Because poor people lack the resources to pay for health care, they are far more likely than less poor people to avoid going for care or to become indebted or impoverished trying to pay for it. The richest fifth of the population are six times more likely than the poorest fifth to have been admitted to hospital, whether in the public or private sector. Peters and colleagues estimated that at least 24% of all Indians admitted to hospital fall below the poverty line because of their admission and that out of pocket spending on hospital care might have raised by two percentage points the proportion of the population in poverty. Less than 10% of the population (roughly 75 million people) are covered by some form of health insurance, and the vast majority of these are either civil servants or formal sector workers.
Debate continues as to whether insurance is a viable model for tackling the problems of limited access and medical indebtedness in poor communities in India. The World Health Report 2000 noted that prepayment schemes (including community based health insurance) represent the most effective way to protect people from the costs of health care and called for investigation into mechanisms to bring poor people into such schemes.\textsuperscript{6} India’s National Health Policy (2002) encouraged the setting up of private insurance companies and the introduction of government funded district based insurance schemes on a pilot basis.\textsuperscript{19} Although the private insurance sector has grown tremendously in recent years and implementation of pilot district based schemes has increased, empirical data about the impact of insurance among poor communities are lacking. Evidence on community based health insurance schemes in India suggests that they tend to have limited coverage of the population and that the poorest people often find the premiums prohibitively expensive but that they do provide important financial protection among people who are able to enrol.\textsuperscript{20-22}

We assessed interventions aimed at improving the distributional impact of a community based health insurance scheme in rural India, by means of a cluster randomised trial. We believe it to be the first study to examine whether community based health insurance schemes can be made more equitable in terms of improving the uptake of benefits by poorer members. Cluster randomised design is not uncontroversial for the evaluation of complex interventions,\textsuperscript{22} and we were interested in exploring the feasibility and value of such a design,\textsuperscript{24} as well as seeking to collect relevant data on context and processes.\textsuperscript{25-27}

**METHODS**

Since 1992, the Self Employed Women’s Association (SEWA)—a trade union of more than half a million poor women working in the informal sector and based in the Indian state of Gujarat—has been

### Table 1 | Objectives of interventions, with corresponding functions and processes

<table>
<thead>
<tr>
<th>Objectives of interventions</th>
<th>Functions and processes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Standard scheme</strong></td>
<td></td>
</tr>
<tr>
<td>To recruit members, and provide them with support between the annual enrolment campaigns</td>
<td>House to house visits to members’ homes are rarely made by SEWA Insurance aagewan. Refresher visits to villages during the nine month period between campaigns occur very infrequently. Insured members are not guided in terms of types of facilities that they should use if they need inpatient care</td>
</tr>
<tr>
<td>To provide aagewans with training and supervision.</td>
<td>SEWA Insurance aagewans receive most of their supervision from district specific team leaders, in the setting of a weekly (or fortnightly) meeting, and they receive capacity building once every few months in the setting of cluster meetings, which bring together the aagewans of several districts. Rarely do they receive direct guidance in planning their village visits, direct supervision during their visits, or feedback on the number, location, and quality of their visits</td>
</tr>
<tr>
<td>To process members’ hospital admission insurance claims</td>
<td>Responsibility for compiling an insurance claim lies primarily with the insured members. Members are supposed to present the required documents to an aagewan or SEWA office in order to submit a claim. Not uncommonly, the aagewans help members to get the required documents if the member faces difficulty. Reimbursement of successful claims generally occurs between two weeks and two months after the claim is submitted to SEWA Insurance</td>
</tr>
</tbody>
</table>

**After sales service and supportive supervision**

| To improve members’ understanding of the insurance (particularly the hospital admission component) and the requirements for making a claim | Aagewans will make house to house visits among all insured households, so that each member household is visited at least twice after enrolment. Aagewans will provide information tailored to local language and culture |
| To ensure that members have ready access to the information needed to submit a claim | Members will periodically be provided with a wall piece reminding them of the insurance and providing a local contact telephone number. They will also be provided with a preaddressed, prestamped postcard that is to be mailed to SEWA Insurance if they need assistance or have a claim to submit |
| To ensure that after sales service is particularly strong among the poorest members | Equity sensitisation among aagewans, to include a participatory poverty mapping exercise in the sub-district to which the aagewan is assigned and ongoing reminders of the barriers that prevent the poorest members from availing themselves of the hospital admission benefits. Ensuring that house to house visits include (or focus on) the poorest members |
| To provide aagewans with an increased level of support and supervision | Provide aagewans with a list of all members in their sub-district and their addresses. Jointly develop visit plans for house to house visits (“microplanning”). Monitor progress with the house to house visits by using bar codes (to be collected by aagewans at member household). Accompany aagewans on their house to house visits, intensively in the initial weeks and gradually reduced. Hold regular meetings with aagewans to review their work and build capacity. Periodic visits to randomly selected villages to seek community input on the performance of aagewans. This monitoring and accompanying will initially be done by the research team and will gradually be passed over to the operations team where staff are available |

To involve aagewans in developing the intervention in order to increase acceptability and sustainability

| Self assessment exercises with aagewans to identify their training and information needs |

**Prospective reimbursement**

| To direct members to inpatient facilities with acceptable levels of quality | A standardised procedure is developed for screening hospitals for inclusion in this scheme. Even after inclusion, hospital performance is periodically re-evaluated |
| To facilitate access to hospital admission by removing financial barriers | Members are encouraged to use (relatively) low cost public and trust hospitals in (or near) their sub-district. For two such hospitals in each sub-district, mechanisms are developed so that 80% of the total, predicted cost of hospital admission is paid directly to the claimant within 48-72 hours of admission. The balance of the cost (up to 2000 rupees) will be paid to the claimant at the time of discharge from hospital, on the condition that relevant certificates and receipts are produced |
| To make it easier to claim and receive benefits under the scheme | Members will be reminded about the benefits of the hospital admission insurance and educated about prospective reimbursement in a campaign delivered by aagewans and staff of the research team. Responsibilities for compilation and submission of claims are (largely) shifted away from SEWA Insurance members (and their families) and on to SEWA staff |

SEWA=Self Employed Women’s Association.
providing insurance to its members and their families. The insurance is voluntary, combining insurance for assets, life, and hospital admission in a single policy. Women are the principal members and can also buy insurance for their husbands and children.

Most members—more than 97% of those who joined in 2003—pay an annual premium of 85 rupees (£1; €1.5; $2) for the least expensive policy. This covers the costs of inpatient care to a maximum of 2000 rupees a year. Members can also make a one time fixed deposit of 1000 rupees in SEWA Bank, and interest from this deposit is used to pay the annual premium. Members with fixed deposits account for roughly 30% of current members. In 2003, SEWA Insurance had 101 809 members in Gujarat state, two thirds of them (67 584) in rural areas and one third (33 080) in Ahmedabad City. The scheme is run by a team of fulltime staff and local women leaders (aagewans), who form the critical link between members and scheme administrators.

Surveys in 2003 found that the poorest households in the general population were able to enrol in the scheme.28 In rural areas, for example, 32% of members were drawn from households below the 30th centile of socioeconomic status, and 8% of members were from the poorest tenth. The submission of claims for hospital admission was equitable in Ahmedabad City; however, in rural areas, financially better off members were significantly more likely to submit claims than were the poorest members. Qualitative research revealed that poor people faced barriers to accessing hospitals with inpatient facilities, such as lack of money to pay for the hospital admission or travel to hospital,29 and barriers to filing an insurance claim, such as lack of skills and capabilities, the costs of completing a claim, and lack of cooperation from doctors.

On the basis of these insights, we developed and tested in a randomised trial the impact of two interventions that aimed to improve the equity of claims in rural areas. These interventions were after sales service and supportive supervision, and prospective reimbursement, implemented singly and together (table 1). After sales service and supportive supervision involved making house to house educational visits to SEWA Insurance members after enrolment and providing supportive supervision to the workers. In addition to education, households were provided with a reminder wall piece and a prestamped and preaddressed postcard for communicating with SEWA Insurance. Prospective reimbursement involved making arrangements with two hospitals in each subdistrict so that members could be reimbursed before discharge from hospital. In communities that received both interventions (the “both” intervention area), these were implemented simultaneously and in an integrated manner. To enhance the generalisability of our findings, we defined the interventions in terms of processes rather than simple elements.30 Thus, under the prospective reimbursement intervention, we improved financial access to hospital admission by developing mechanisms so that 80% of the predicted cost of hospital admission (up to a maximum of 1600 rupees) could be reimbursed within 48 hours of admission, but the specifics of the intervention—for example, the type of person responsible for paying the cash benefit—varied between sub-districts.

Assessing the effectiveness of such interventions is important to public health and health care in India.

Table 2 Household level data collection to assess primary outcome (socioeconomic status)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Survey of general, rural population</th>
<th>Baseline member survey</th>
<th>Baseline claimant census</th>
<th>Follow-up member survey</th>
<th>Follow-up claimant census</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sampling universe</td>
<td>Households in 11 rural districts (2001 population, 19 298 638) from which SEWA Insurance draws its members</td>
<td>36 837 adult female members in 2003 who reside in 16 rural sub-districts</td>
<td>713 hospital admission claims, January to September 2003</td>
<td>25 497 adult female members in 2005 who reside in 16 rural sub-districts</td>
<td>1440 hospital admission claims, April to December, 2005</td>
</tr>
<tr>
<td>Intended sample size</td>
<td>800</td>
<td>1200</td>
<td>713</td>
<td>1200</td>
<td>1440</td>
</tr>
<tr>
<td>Sampling method</td>
<td>Two stage random sampling</td>
<td>Two stage random sampling, stratified by sub-district</td>
<td>NA (all claimants interviewed)</td>
<td>Two stage random sampling, stratified by sub-district</td>
<td>NA (all claimants interviewed)</td>
</tr>
<tr>
<td>Sampling at first stage</td>
<td>Towns/villages sampled with PPS</td>
<td>Villages (or clusters of villages) sampled with PPS</td>
<td>NA</td>
<td>Villages (or clusters of villages) sampled with PPS</td>
<td>NA</td>
</tr>
<tr>
<td>Sampling at second stage</td>
<td>Randomly selected start point, then every second household</td>
<td>Systematic random sampling from list</td>
<td>NA</td>
<td>Systematic random sampling from list</td>
<td>NA</td>
</tr>
<tr>
<td>Interviewers</td>
<td>10 SEWA Insurance interviewers</td>
<td>10 SEWA Insurance interviewers</td>
<td>20 district based, SEWA rural development interviewers</td>
<td>10 SEWA Insurance interviewers</td>
<td>10 SEWA Insurance interviewers</td>
</tr>
<tr>
<td>Criteria for counting household as absent</td>
<td>No Hh member present on day of first (and only) visit</td>
<td>No Hh member contacted after two visits separated by minimum of 24 hours</td>
<td>No Hh member contacted after two visits separated by minimum of 24 hours</td>
<td>No Hh member contacted after two visits separated by minimum of 24 hours</td>
<td>No Hh member contacted after two visits separated by minimum of 24 hours</td>
</tr>
<tr>
<td>Achieved sample size</td>
<td>784 (98%)</td>
<td>967 (81%)</td>
<td>674 (95%)</td>
<td>1072 (89%)</td>
<td>1326 (92%)</td>
</tr>
<tr>
<td>Reasons for “non-response”</td>
<td>Refused interview, n=1 (6%); all Hh members absent, n=15 (94%)</td>
<td>Hh moved/not found, n=202 (67%); all Hh members absent, n=31 (13%)</td>
<td>Refused interview, n=2 (5%); Hh moved/not found, n=27 (69%); all Hh members absent, n=10 (26%)</td>
<td>Hh moved/not found, n=72 (56%); all Hh members absent, n=56 (44%)</td>
<td>Hh moved/not found, n=55 (48%); all Hh members absent, n=59 (52%)</td>
</tr>
</tbody>
</table>

Hh=household; NA=not applicable; PPS=probability proportional to size; SEWA=Self Employed Women’s Association.
and elsewhere, given the widespread inequities in use of health services. The Indian health system has characteristics that make it less accessible to poor people, including user fees; stigmatisation by medical staff; and a paucity of health workers, clinics, and hospitals where poor people live, in rural areas and urban slums. Removing such supply-side barriers is difficult for non-governmental organisations, given their limited financial resources and the complete absence of regulatory checks and balances to guide and support them in rehabilitating the healthcare system. Community based organisations can, however, tackle select social, economic, and cultural factors that prevent people from seeking health care. Great interest exists in evaluating the impact of such interventions on disease prevention and access to health care in India and elsewhere.

To reduce contamination, we randomised the trial at the level of sub-districts, an existing administrative unit. We considered sub-districts for inclusion if they had 500 or more female SEWA Insurance members aged 18 or above in 2003. Out of the 27 sub-districts that met this criterion, we excluded those in which all members were mandatorily enrolled in the scheme by a donor agency (three sub-districts) or which had no general hospital of 25 beds or more (one sub-district). Of the remaining 23 sub-districts, we selected the 16 with the highest number of female SEWA Insurance members. These sub-districts spanned a large agricultural area in the north of Gujarat state.

Within the selected sub-districts, the interventions were to be delivered to all female and male members of SEWA Insurance for 2004 and 2005. The only members excluded from the interventions were those for whom address data were so incomplete that district, sub-district, or village could not be determined (approximately 3.5% of members in the 2004 database and those for whom address data seemed to be complete but who could not be found at the village level (<1% to 8%, by sub-district, in 2004).

We randomly allocated four study sub-districts to each of after sales service and supportive supervision, prospective reimbursement, both, and standard scheme (control). Interventions were launched on 1 August 2004. The first trial related visits to SEWA Insurance member households in the three intervention areas were made between August and December 2004. Interventions continued to the end of 2005.

The primary outcome measure was the socioeconomic status of claimants relative to the membership base in their sub-districts of residence; detailed description of this measure can be found elsewhere. Just before the beginning of the trial, a representative survey of the general rural population from which SEWA Insurance draws its members gathered data on a wide range of potentially relevant markers of socioeconomic status (table 2). We then developed a summary index of socioeconomic status for this population by using survey data, principal components analysis, and methods described by Henry and colleagues. Subsequently, at baseline and again postintervention, we determined the distribution of socioeconomic status among SEWA Insurance members by representative surveys of members’ households in the 16 trial sub-districts. We ranked the membership base in each sub-district according to socioeconomic status, so that the poorest household ranked zero, the wealthiest 100, and the median household 50 (fig 1, top panel).

Interviews with members of claimants’ households before and after the intervention enabled a sub-district specific rank score for each claimant’s household to be calculated (table 2), on the basis of the same socioeconomic variables and index described in the previous paragraph. For these households, we converted socioeconomic index values into sub-district specific rank scores (on a scale of 0-100) by linear interpolation based on the rank of the members’ households with the closest (that is, the next lowest and the next highest)
We stratified sub-districts by mean socioeconomic status of claimants relative to scheme members at baseline, and the intracluster correlation, the mean socioeconomic index values (fig 1, middle and bottom panels). We assigned rank scores of 0 and 100 to claimants whose socioeconomic index values were lower or higher than those of any sampled member in the same sub-district.

Secondary outcomes were rates of enrolment in SEWA Insurance, mean socioeconomic status of the insured population relative to the general rural population, and rate of submission of claims.

### Statistical analysis

We calculated the required sample size for the trial on the basis of the primary study outcome and took into account the intracluster (sub-district) correlation, the mean socioeconomic status rank score of claimants relative to scheme members at baseline, and the intracluster variance of this parameter.36 We determined that the minimal effect to be detected as statistically significant would be a reduction of 20 points in the mean socioeconomic index values (fig 1, middle and bottom panels). We assigned rank scores of 0 and 100 to claimants whose socioeconomic index values were lower or higher than those of any sampled member in the same sub-district.

We stratified sub-districts by mean socioeconomic status of claimants relative to members in order to minimise imbalance across the intervention groups. Within each of four strata, we randomly assigned subdistricts to an intervention or standard scheme by drawing one of four differently coloured balls from a bag. Each colour represented one of the three intervention groups or the standard scheme. The balls were drawn without replacement. SEWA Insurance staff did the random assignment, so that they would understand the process and perceive the allocation as fair. Staff were aware of the sub-district that was being allocated but were blind to the interventions being drawn because they could not see into the bag or feel any difference between balls.

The trial was “open” in so far as neither the participants nor the personnel could be blinded to intervention assignment after randomisation. We sought to minimise bias by training interviewers to administer the surveys in a uniform manner across intervention groups and by close supervision.

The analytic strategy was that recommended by Murray for a cluster randomised trial with a repeated cross section (pre-test, post-test) design with a control group.37 With all the data pooled, the expected value of the outcome indicator \( Y \) can be expressed, in a regression framework, as:

\[
Y = \alpha + \beta_1 \text{TREATMENT\_GROUP} + \beta_2 \text{TIME} + \beta_3 \text{TREATMENT\_GROUP} \times \text{TIME}
\]

where \( \text{TREATMENT\_GROUP} \) is a dummy variable coded 0 = baseline, 1 = postintervention. This equation is a simplified representation, as three indicator variables rather than just one represented the different intervention groups. **Table 1** shows the numbers of clusters and participants randomly assigned, receiving intended intervention, and analysed for primary outcome...

<table>
<thead>
<tr>
<th>Strata</th>
<th>Sub-districts</th>
<th>Total members (n)</th>
<th>Mean claims/sub-district</th>
<th>Lost to follow-up</th>
<th>Moved/not found</th>
<th>All household members absent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lowest numbers of insured women (7 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=7865)</td>
<td>Mean claims/sub-district 17.5 (range 4-37)</td>
<td>Lost to follow-up (n=2) (2.9%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=2) All household members absent (n=0)</td>
</tr>
<tr>
<td>Did not meet eligibility criteria (4 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=11 005)</td>
<td>Mean claims/sub-district 43.5 (range 8-62)</td>
<td>Lost to follow-up (n=9) (5.2%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=8) All household members absent (n=1)</td>
</tr>
<tr>
<td>Excluded:</td>
<td>Sub-districts</td>
<td>Total members (n=10 026)</td>
<td>Mean claims/sub-district 41.0 (range 12-56)</td>
<td>Lost to follow-up (n=7) (4.3%)</td>
<td>Refused interview (n=1)</td>
<td>Moved/not found (n=3) All household members absent (n=3)</td>
</tr>
<tr>
<td>Lowest numbers of insured women (7 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=15 409)</td>
<td>Mean claims/sub-district 76.3 (range 14-203)</td>
<td>Lost to follow-up (n=21) (6.9%)</td>
<td>Refused interview (n=1)</td>
<td>Moved/not found (n=14) All household members absent (n=6)</td>
</tr>
<tr>
<td>Did not meet eligibility criteria (4 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=8566)</td>
<td>Mean claims/sub-district 71.0 (range 29-137)</td>
<td>Lost to follow-up (n=32) (11.3%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=10) All household members absent (n=22)</td>
</tr>
<tr>
<td>Excluded:</td>
<td>Sub-districts</td>
<td>Total members (n=10 717)</td>
<td>Mean claims/sub-district 120.3 (range 22-196)</td>
<td>Lost to follow-up (n=33) (6.9%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=18) All household members absent (n=15)</td>
</tr>
<tr>
<td>Lowest numbers of insured women (7 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=6815)</td>
<td>Mean claims/sub-district 79.8 (range 23-119)</td>
<td>Lost to follow-up (n=17) (5.3%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=5) All household members absent (n=12)</td>
</tr>
<tr>
<td>Did not meet eligibility criteria (4 sub-districts)</td>
<td>Sub-districts</td>
<td>Total members (n=11 344)</td>
<td>Mean claims/sub-district 89.0 (range 39-206)</td>
<td>Lost to follow-up (n=32) (9.0%)</td>
<td>Refused interview (n=0)</td>
<td>Moved/not found (n=22) All household members absent (n=10)</td>
</tr>
</tbody>
</table>
each case contrasted with the standard scheme group), and three interactions with time captured the net change in each treatment group or “impact” of the programme. We used a mixed effects regression model in SAS to estimate all coefficients, by using the approach of Kenward and Roger to estimate the relevant degrees of freedom for the statistical tests.  

**RESULTS**

All 16 clusters randomised at baseline were retained at follow-up (fig 2). A small percentage of interviews were unsuccessful both in the pre-intervention survey (2.9-6.9% per group) and in the postintervention survey (5.3-11.3%), primarily because the family was absent from home at successive visits or the interviewer was unable to locate the household.

At baseline, the four treatment groups were very similar with respect to the primary outcome measure, the mean socioeconomic status of claimants relative to members in the same sub-district (table 3). Secondary outcome indicators, on the other hand, were quite variable between groups: enrolment rates were 26.7-52.6/1000 general population, socioeconomic status of members relative to the general population was 41.6-51.2 per group, and submission rates for hospital admission claims were 8.9-19.2/1000 members per group. The standard scheme group had more “best” values with respect to the four outcome indicators than any other group, and the after sales service group had “worst” values for three out of four outcome indicators. The four groups also differed somewhat in terms of their total population and population density but were fairly similar with respect to the percentage of the population that was female and literate. Members’ characteristics varied: the percentage of women who had also enrolled their spouse was 15.6-35.5% per intervention group and the percentage of women who paid by fixed deposit was 6.6-19.3% per group.

Rates of coverage of the interventions were high (table 4). In after sales service and “both” areas, for example, 96.3% and 97.8% of respondents reported receiving the reminder wall piece. In prospective reimbursement and “both” areas, 82.1% and 85.6% of respondents reported receiving the silver identity card needed for receipt of reimbursement in hospital. The silver card seemed to be less memorable than the reminder wall piece: they were distributed together in the “both” sub-districts, yet a higher percentage of members recalled the latter. Leakage of the interventions was minimal.

After the intervention, respondents in the intervention areas were no more knowledgeable about SEWA Insurance than those in the standard scheme area (table 4). That is, the interventions did not seem to have any significant impact on knowledge, as assessed by this survey.

The survey of claimants showed that members in different intervention areas differed significantly in terms of how they first notified SEWA Insurance of their claim (table 4). In prospective reimbursement and “both” areas, claimants were 25.4-27.0 percentage points more likely than those in the standard scheme areas to have first notified SEWA Insurance of their claim by calling from the hospital before discharge. Claimants rarely used the postcards to notify SEWA Insurance of their claim.

Between 2003 and 2005, the mean socioeconomic status of SEWA Insurance members (relative to the

---

**Table 3** | Baseline information for each group (interventions and standard scheme) for individual and cluster level. Values are mean* (SD) unless stated otherwise

<table>
<thead>
<tr>
<th></th>
<th>Standard scheme</th>
<th>After sales service</th>
<th>Prospective reimbursement</th>
<th>Both</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary and secondary outcome indicators at baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SES of claimants relative to members in same sub-districts</td>
<td>58.8 (12.8)</td>
<td>58.9 (11.3)</td>
<td>56.4 (8.5)</td>
<td>57.1 (10.9)</td>
</tr>
<tr>
<td>Enrolment rate (per 1000 population aged 18-55 years)</td>
<td>43.8 (55.7)</td>
<td>52.6 (85.9)</td>
<td>26.7 (15.9)</td>
<td>35.1 (27.7)</td>
</tr>
<tr>
<td>SES of scheme members relative to rural population</td>
<td>41.6 (4.8)</td>
<td>51.2 (6.2)</td>
<td>49.1 (6.6)</td>
<td>42.0 (3.3)</td>
</tr>
<tr>
<td>Rate of hospital admission claim submission (per 1000 members per nine months)</td>
<td>19.2 (11.9)</td>
<td>8.9 (6.0)</td>
<td>18.4 (11.2)</td>
<td>17.4 (9.0)</td>
</tr>
<tr>
<td>Member factors at baseline†</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percentage households in which spouse is also covered</td>
<td>19.4 (6.49)</td>
<td>24.5 (14.1)</td>
<td>35.5 (25.7)</td>
<td>15.6 (10.1)</td>
</tr>
<tr>
<td>Percentage women, fixed deposit</td>
<td>10.2 (3.92)</td>
<td>19.3 (10.3)</td>
<td>6.6 (6.15)</td>
<td>11.4 (5.60)</td>
</tr>
<tr>
<td>Sub-district factors at baseline‡</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number</td>
<td>4</td>
<td></td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Total population:</td>
<td>1 105 405</td>
<td>996 265</td>
<td>1 037 084</td>
<td>664 835</td>
</tr>
<tr>
<td>Percentage female</td>
<td>47.7 (0.437)</td>
<td>47.8 (0.751)</td>
<td>47.9 (0.278)</td>
<td>48.6 (1.43)</td>
</tr>
<tr>
<td>Percentage literate, (aged ≥6 years):</td>
<td>65.3 (19.2)</td>
<td>62.4 (18.4)</td>
<td>67.8 (8.42)</td>
<td>64.1 (11.8)</td>
</tr>
<tr>
<td>Female literacy</td>
<td>51.6 (21.0)</td>
<td>49.6 (17.5)</td>
<td>52.8 (10.8)</td>
<td>50.8 (12.5)</td>
</tr>
<tr>
<td>Male literacy</td>
<td>77.9 (17.5)</td>
<td>74.2 (19.3)</td>
<td>81.4 (6.38)</td>
<td>76.8 (11.2)</td>
</tr>
<tr>
<td>Population density, people/km²</td>
<td>635 (432)</td>
<td>255 (219)</td>
<td>440 (500)</td>
<td>439 (383)</td>
</tr>
</tbody>
</table>

SES=socioeconomic status.

*Means for each intervention group are unweighted average of four relevant sub-district level means.
†2003 scheme membership figures.
‡Data from 2001 population census.
rural population of Gujarat) rose significantly, on average by 6.9 on the 100 point scale (P<0.001) (table 5). No association existed, however, between the interventions and either changes in the enrolment rate or the change in socioeconomic status of members. Rates of claims increased significantly, on average by 21.6 per 1000 members (P<0.001). However, differences between the intervention groups and the standard scheme were not significant. Neither time nor interventions had any systematic effect on the socioeconomic status of claimants relative to members in the same sub-district.

**DISCUSSION**

This trial shows that, in a community based insurance scheme in rural Gujarat, neither switching from reimbursement to upfront payment nor strengthening contacts between members and administrators was sufficient to ensure that the poorer members in each sub-district were able to enjoy the greater share of the scheme benefits. Instead, the rate of claims increased across the study area. This was in spite of the fact that we achieved high rates of coverage with our interventions, with virtually no leakage from intervention to standard scheme areas. The interventions themselves were designed on the basis of extensive qualitative research about the barriers that might prevent poor members making a successful claim.29

**Strengths and limitations**

Our trial was based on a small number of randomisation units (sub-districts) in each intervention group. However, on the basis of the standard errors of the estimated impacts of the interventions, we could have detected as statistically significant an average change in the socioeconomic status score of claimants relative to members in the same sub-district of just 16 points—an even smaller change than the 20 point change we initially set out to detect. The trial was therefore not underpowered on the primary outcome.

On the other hand, the trial does seem to have had disappointingly low power with respect to the secondary outcomes. Large increases in rates of claims occurred in 11/12 intervention sub-districts, compared with only 1/4 standard scheme sub-districts (fig 3), but these contrasts were not statistically significant if analysed intervention group by intervention group as the study protocol demanded (table 5). We note, however, that both interventions involved making individual contact with members in their homes, and we are inclined to believe that this feature of the interventions had a greater impact than elements unique to either specific intervention, such as the postcard, enhanced supervision, or reimbursement before discharge from hospital. Qualitative interviews, not documented here, revealed that members greatly appreciated the home visits, even though our postintervention survey suggested that the visits did not increase members’ knowledge about the scheme’s benefits or processes. The house to house visits may have increased submission of claims by increasing members’ trust in the scheme or by increasing some aspect of their knowledge that was not captured by the postintervention survey, such as the identity of the local aagewan.

An additional limitation of the trial may have been the short period allowed for implementation and then stabilisation of the interventions. When we started to monitor the primary outcome, the interventions had been running for a maximum of eight months (1 August 2004 to 1 April 2005). Although most of the key intervention functions were implemented within that period, improvements could have been made had there been more time. We do not think a longer implementation period would have increased the interventions’ impact.

### Table 4 | Implementation and use of interventions

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Control group</th>
<th>Any intervention effect?</th>
<th>Point estimate in intervention groups, relative to control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Received reminder wall piece</td>
<td>0%</td>
<td>Yes; P&lt;0.0001</td>
<td>96.3%*** (94.0% to 98.7%)</td>
</tr>
<tr>
<td>Received postcard</td>
<td>0%</td>
<td>Yes; P&lt;0.0001</td>
<td>85.3%*** (79.8% to 90.8%)</td>
</tr>
<tr>
<td>Received silver prospective reimbursement card</td>
<td>0%</td>
<td>Yes; P&lt;0.0001</td>
<td>0.4% (~6.2% to 7.0%)</td>
</tr>
<tr>
<td>Knowledge about SEWA insurance†</td>
<td>93.5%</td>
<td>No; P=0.4357</td>
<td>NA</td>
</tr>
<tr>
<td>Know that they are currently insured</td>
<td>81.8%</td>
<td>No; P=0.1893</td>
<td>NA</td>
</tr>
<tr>
<td>Know hospital admission is covered</td>
<td>25.1%</td>
<td>No; P=0.4448</td>
<td>NA</td>
</tr>
<tr>
<td>Know ceiling is 2000 rupees</td>
<td>35.6%</td>
<td>No; P=0.0916</td>
<td>NA</td>
</tr>
<tr>
<td>Know delivery is not covered</td>
<td>1.30</td>
<td>No; P=0.8295</td>
<td>NA</td>
</tr>
<tr>
<td>Correct out of three vignettes</td>
<td>2.9%</td>
<td>Yes; P=0.0133</td>
<td>0.8% (~19.1% to 20.7%)</td>
</tr>
<tr>
<td>Called from hospital</td>
<td>0%</td>
<td>Yes; P&lt;0.0008</td>
<td>2.0%*** (0.9% to 3.1%)</td>
</tr>
</tbody>
</table>

**Note:**

NA=not applicable; SEWA=Self Employed Women’s Association.

*P<0.05.

***P<0.001.

†Results on members’ knowledge of non-health benefits not reported.

‡Means of first notifying SEWA Insurance about claim.
on the primary outcome measure, but it may have resulted in a greater (and possibly statistically significant) increase in the impact on claim rate.

We believe that our trial is methodologically highly innovative. As far as we are aware, it is one of the first cluster randomised trials to use an equity outcome and to evaluate a health financing intervention in a developing country. The summary index of socioeconomic status used to characterise both claimants and members is simple and transparent, has a strong theoretical basis and a systematic approach to indicator selection, and is locally appropriate—incorporating variables that are important indicators of socioeconomic status in a particular study setting—and the corresponding survey instrument can be easily and quickly administered. Also, the primary outcome measure used (the socioeconomic status rank score) is simple to interpret because it varies on a scale from 0 to 100, with 50 indicating an equity neutral outcome, and is efficient because it draws on data from claimants and members at all levels of socioeconomic status.

The cluster randomised design brings both advantages and disadvantages. The study has strong internal validity, and we used qualitative methods both at baseline and during implementation of the interventions to understand the processes at work. Relevance to other settings, or external validity, depends on understanding the context of the insurance programme and the factors that influence its operation, including aspects such as physical access to health services that we were not able to cover in the trial. Basing the study within the research cell of SEWA and involving SEWA staff in the research, plus the expertise of the external researchers in community based health insurance in India and elsewhere, meant that the team had in-depth knowledge of both SEWA and community based health insurance schemes elsewhere, so the relevance of study findings to other settings could be assessed, in so far as the state of knowledge on community based health insurance permits.

**Policy implications**

The lack of equity impact in our trial may have resulted from a variety of factors. Firstly, the interventions did not tackle barriers such as distance to hospital, transportation costs, and the opportunity costs of hospital admission, especially for female members with many household responsibilities. Secondly, the interventions were more effective than anticipated among less poor members, suggesting that barriers faced by the poorest people in seeking hospital admission and submitting a claim were just as relevant to the less poor members. Thirdly, although the interventions were designed to meet the specific needs of the poorest members, we had no way of delivering them selectively to these people as it was logistically and ethically impossible to separate the poorest members from the less poor ones during delivery of the interventions.

SEWA Insurance is continuing and extending the interventions because of their perceived and projected benefits, including the increased rate of claims. The rural claims rate is now close to that of Ahmedabad City (51 per 1000 members over nine months in 2005), reducing urban-rural inequities. Scheme administrators believe that over a longer period the interventions will lead to higher rates of retention and enrolment, by enhancing members’ trust in and satisfaction with the scheme. Future studies should design and test other interventions to make the scheme more equitable.

More broadly, this study feeds into a small but developing literature on whether and how community based health insurance can benefit the poorest people. SEWA insurance has some unusual features, including its base in an organisation of which the prime goals are to organise female workers to achieve work security, income security, food security, and social security and

---

**Table 5 | Time effect and intervention effect**

<table>
<thead>
<tr>
<th>Indicators</th>
<th>Change in all groups (2003-5)</th>
<th>Any intervention effect?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Members per 1000 population</td>
<td>~13.8 (~31.8 to 4.2)</td>
<td>No; P=0.899</td>
</tr>
<tr>
<td>SES of members (relative to population)</td>
<td>6.9*** (3.0 to 10.8)</td>
<td>No; P=0.915</td>
</tr>
<tr>
<td>Claims submission per 1000 members (nine months)</td>
<td>21.6*** (15.4 to 27.8)</td>
<td>No; P=0.236</td>
</tr>
<tr>
<td>SES of claimants (relative to members)</td>
<td>~4.1 (~10.1 to 1.9)</td>
<td>No; P=0.810</td>
</tr>
</tbody>
</table>

SES=socioeconomic status.

***P<0.001.

†Impacts expressed as absolute changes; point estimates, 95% confidence intervals, and P values derived from mixed effects regression models relating each outcome to intervention group, time, and the interaction of the two, accounting appropriately for clustering within intervention areas and within sub-districts.
to make women individually and collectively self reliant, economically independent, and capable of making their own decisions. This contrasts with an alternative approach to community based health insurance, in which a single purpose organisation is formed to provide insurance. The relative merits of different organisational and management approaches to community based health insurance need to be explored further.

Contributors: MKR and TS participated in the study’s conception and design, acquisition of data, analysis and interpretation of data, and drafting the article. MC and AIM participated in the study’s conception and design and critically revising the article for important intellectual content. FG, RJ, and FP participated in the acquisition of data and critically revising the article for important intellectual content. SSW participated in the study’s conception and design, analysis and interpretation of the data, and critically revising the article for important intellectual content. MKR is the guarantor.

Funding: Wellcome Trust (UK).

Competing interests: None declared.

Ethical approval: Executive Committee of the Self-Employed Women’s Association (Ahmedabad, Gujarat) and Ethics Committee of the London School of Hygiene and Tropical Medicine.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Community based health insurance is often cited as a means of improving access to health care and financial protection in developing countries. The scope for equitable redistribution of resources by such schemes may be limited by small membership, exclusion of the poorest people, and inequitable utilisation of benefits.

No previous study has evaluated strategies for improving the uptake of benefits of a community based health insurance scheme by its poorest members.

WHAT THIS STUDY ADDS

Neither switching from reimbursement to upfront payment nor strengthening contacts between members and administrators was sufficient to ensure that poorer members were able to enjoy the greater share of the scheme’s benefits.

13 Dör DM, Koren R, Steinberg DM. The impact of Filipino micro-health insurance units on income-related equity of access to healthcare. Health Policy 2006;77:304-17.
17 Matthews S, Cahill KR. Lessons from across the world: how India can break barriers to develop health insurance. IRDA Journal 2004;II (11):7-12.
18 Gupta I, Trivedi M. Social health insurance redefined: health for all through coverage for all. Econ Polit Wkly 2005;Sep 17:4132-40.
27 Rothwell PM. External validity of randomised controlled trials: “to whom do the results of this trial apply?” Lancet 2005;365:82-93.

Accepted: 20 March 2007
Diagnosis and treatment of sciatica

B W Koes, M W van Tulder, W C Peul

Sciatica affects many people. The most important symptoms are radiating leg pain and related disabilities. Patients are commonly treated in primary care but a small proportion is referred to secondary care and may eventually have surgery. Many synonyms for sciatica appear in the literature, such as lumbosacral radicular syndrome, ischias, nerve root pain, and nerve root entrapment.

In about 90% of cases sciatica is caused by a herniated disc with nerve root compression, but lumbar stenoses and (less often) tumours are possible causes. The diagnosis of sciatica and its management varies considerably within and between countries—for example, the surgery rates for lumbar discectomy vary widely between countries. A recent publication confirmed this large variation in disc surgery, even within countries. This may in part be caused by a paucity of evidence on the value of diagnostic and therapeutic interventions and a lack of clear clinical guidelines or reflect differences in healthcare and insurance systems. This review presents the current state of science for the diagnosis and treatment of sciatica.

Who gets sciatica?

Exact data on the incidence and prevalence of sciatica are lacking. In general an estimated 5%-10% of patients with low back pain have sciatica, whereas the reported lifetime prevalence of low back pain ranges from 49% to 70%. The annual prevalence of disc related sciatica in the general population is estimated at 2.2%. A few personal and occupational risk factors for sciatica have been reported (box 1), including age, height, mental stress, cigarette smoking, and exposure to vibration from vehicles. Evidence for an association between sciatica and sex or physical fitness is conflicting.

How is sciatica diagnosed?

Sciatica is mainly diagnosed by history taking and physical examination. By definition patients mention radiating pain in the leg. They may be asked to report the distribution of the pain and whether it radiates below the knee and drawings may be used to evaluate the distribution. Sciatica is characterised by radiating pain that follows a dermatomal pattern. Patients may also report sensory symptoms.

Physical examination largely depends on neurological testing. The most applied investigation is the straight leg raising test or Lasègue’s sign. Patients with sciatica may also have low back pain but this is usually less severe than the leg pain. The diagnostic value of history and physical examination has not been well studied. No history items or physical examination tests have both high sensitivity and high specificity. The pooled sensitivity of the straight leg raising test is estimated to be 91%, with a corresponding pooled specificity of 26%. The only test with a high specificity is the crossed straight leg raising test, with a pooled specificity of 88% but sensitivity of only 29%. Overall, if a patient reports the typical radiating pain in one leg combined with a positive result on one or more neurological tests indicating nerve root tension or neurological deficit the diagnosis of sciatica seems justified. Box 2 shows the signs and symptoms that help to distinguish between sciatica and non-specific low back pain.

What is the value of imaging?

Diagnostic imaging is only useful if the results influence further management. In acute sciatica the diagnosis is based on history taking and physical examination and treatment is conservative (non-surgical). Imaging may be indicated at this stage only if there are indications or “red flags” that the sciatica may be caused by underlying disease (infections, malignancies) rather than disc herniation.

Diagnostic imaging may also be indicated in patients with severe symptoms who fail to respond to conservative care for 6-8 weeks. In these cases surgery might be considered and imaging used to identify if a herniated disc with nerve root compression is present and its
Box 1 | Risk factors for acute sciatica1-8

**Personal factors**
- Age (peak 45-64 years)
- Increasing risk with height
- Smoking
- Mental stress

**Occupational factors**
- Strenuous physical activity—for example, frequent lifting, especially while bending and twisting
- Driving, including vibration of whole body

location and extent. It is important as part of the decision to operate that the clinical findings and symptoms correspond well with the scan findings. This is especially relevant because disc herniations identified by computed tomography or magnetic resonance imaging are highly prevalent (20%-30%) in people without symptoms who do not have sciatica.6-8 In many people with clinical symptoms of sciatica no lumbar disc herniations are present on scans.7,8 At present no one type of imaging method shows a clear advantage over others. Although some authors favour magnetic resonance imaging above other imaging techniques because computed tomography has a higher radiation dose or because soft tissues are better visualised,9-11 evidence shows that both are equally accurate at diagnosing lumbar disc herniation.11 Radiography for the diagnosis of lumbar disc herniation is not recommended because discs cannot be visualised by x-rays.11

What is the prognosis?
In general the clinical course of acute sciatica is favourable and most pain and related disability resolves within two weeks. For example, in a randomised trial that compared non-steroidal anti-inflammatory drugs with placebo for acute sciatica in primary care 60% of the patients recovered within three months and 70% within 12 months.12 About 50% of patients with acute sciatica included in placebo groups in randomised trials of non-surgical interventions reported improvement within 10 days and about 75% reported improvement after four weeks.13 In most patients therefore the prognosis is good, but at the same time a substantial proportion (up to 30%) continues to have pain for one year or longer.12,13

What is the efficacy of conservative treatments for sciatica?
Conservative treatment for sciatica is primarily aimed at pain reduction, either by analgesics or by reducing pressure on the nerve root. A recent systematic review found that conservative treatments do not clearly improve the natural course of sciatica in most patients or reduce symptoms.14 Adequately informing patients about the causes and expected prognosis may be an important part of the management strategy. However, educating patients about sciatica has not been specifically investigated in randomised controlled trials.

Box 3 summarises the evidence of effectiveness for commonly available conservative treatments for sciatica, including injection therapy. Strong evidence of effectiveness is lacking for most of the available interventions. Little difference in effect on pain and functional status has been shown between bed rest and advice on staying active.14 As a result of this finding, bed rest—for a long time the mainstay of treatment for sciatica—is no longer widely recommended.14 Analgesics, non-steroidal anti-inflammatory drugs, and muscle relaxants do not seem to be more effective than placebo in reducing symptoms. Evidence for opioids and various compound drugs is lacking. A systematic review reported that no evidence exists for traction, non-steroidal anti-inflammatory drugs, intra-muscular steroids, or tizanidine being superior to placebo.13 This review suggested that epidural injections of steroid might be effective in patients with acute sciatica.13 However, a more recent systematic review of a larger number of randomised trials reported that there was no evidence of positive short term effects of corticosteroid injections and that the long term effects were unknown.14 The same systematic review reported that active physical therapy (exercises) seemed not to be better than inactive (bed rest) treatment and other conservative treatments, such as traction, manipulation, hot packs, or corsets.14

What is the role of surgery in sciatica?
Surgical intervention for sciatica focuses on removal of disc herniation and eventually part of the disc or on foraminal stenosis, with the purpose of eliminating the suspected cause of the sciatica. Treatment is aimed at easing the leg pain and corresponding symptoms and not at reducing the back pain. Consensus is that a cauda equina syndrome is an absolute indication for immediate surgery. Elective surgery is the choice for unilateral sciatica. Until recently only one relatively old randomised trial was available that compared surgical intervention with conservative treatment for
patients with sciatica.16 This study showed that surgical intervention had better results after one year, whereas after four and 10 years of follow-up no significant differences were found.16

A Cochrane review summarised the available randomised clinical trials evaluating disc surgery and chemonucleolysis.17 In chemonucleolysis the enzyme chymopapain is injected in the discus with the purpose of shrinking the nucleus pulposus. The review reported better results with disc surgery than with chemonucleolysis in patients with severe sciatica of relatively long duration varying from more than four weeks to more than four months. Chemonucleolysis was more effective than placebo. Indirectly therefore the review suggested that disc surgery is more effective than placebo. On the basis of data from three trials the authors concluded that evidence is considerable that surgical discectomy provides effective clinical relief for carefully selected patients with sciatica as a result of lumbar disc prolapse that fails to resolve with conservative care. A recent review came to the same conclusion.18 The Cochrane review further concluded that the long term effects of surgical intervention are unclear and that evidence on the optimal timing of surgery is also lacking.17

Randomised controlled trials not yet included in systematic reviews

Two additional randomised controlled trials have been published comparing disc surgery with conservative treatment. One trial (n=56) compared microdiscectomy with conservative treatment in patients who had had sciatica for six to 12 weeks.19 Overall, no significant differences were found for leg pain, back pain, and subjective disability over two years of follow-up. Leg pain, however, seemed to initially improve more rapidly in patients in the discectomy group. The large spine patient outcomes research trial (a randomised trial) and related observational cohort study was carried out in the United States.20 21 Patients with sciatica for at least six weeks and confirmed disc herniation were invited to participate in either a randomised trial or an observational cohort study. Patients in the trial were randomised to disc surgery or to conservative care. Patients in the cohort study received disc surgery or conservative care based on their preference. In the randomised trial (n=501) both treatment groups improved substantially over two years for all primary and secondary outcome measures. Small differences were found in favour of the surgery group, but these were not statistically significant for the primary outcome measures. Only 50% of the patients randomised to surgery received surgery within three months of inclusion compared with 30% randomised to conservative care. After two years of follow-up 45% of patients in the conservative care group underwent surgery compared with 60% in the surgery group.20

The observational cohort included 743 patients. Both groups improved substantially over time, but the surgery group showed significantly better results for pain and function compared with the conservative group. The authors did mention caution in interpreting the findings because of potential confounding by indication and because outcome measures were self reported.21

Box 4 | Clinical guideline for diagnosis and treatment of sciatica from Dutch College of General Practice

**Diagnosis**
- Check for red flag conditions, such as malignancies, osteoporotic fractures, radiculitis, and cauda equina syndrome
- Take a history to determine localisation; severity; loss of strength; sensibility disorders; duration; course; influence of coughing, rest, or movement; and consequences for daily activities
- Carry out a physical examination, including neurological testing—for example, straight leg raising test (Lasègue’s sign)
- Carry out the following tests in cases with a dermatomal pattern, or positive result on straight leg raising test, or loss of strength or sensibility disorders: reflexes (Achilles or knee tendon), sensibility of lateral and medial sides of feet and toes, strength of big toe during extension, walking on toes and heel (left-right differences), crossed Lasègue’s sign
- Imaging or laboratory diagnostic tests are only indicated in red flag conditions but are not useful in cases of suspected disc herniation

**Treatment**
- Explain cause of the symptoms and reassure patients that symptoms usually diminish over time without specific measures
- Advise to stay active and continue daily activities; a few hours of bed rest may provide some symptomatic relief but does not result in faster recovery
- Prescribe drugs, if necessary, according to four steps: (1) paracetamol; (2) non-steroidal anti-inflammatory drugs; (3) tramadol, paracetamol, or non-steroidal anti-inflammatory drug in combination with codeine; and (4) morphine
- Refer to neurosurgeon immediately in cases of cauda equina syndrome or acute severe paresis or progressive paresis (within a few days)
- Refer to neurologist, neurosurgeon, or orthopaedic surgeon for consideration of surgery in cases of intractable radicular pain (not responding to morphine) or if pain does not diminish after 6-8 weeks of conservative care
A patient’s perspective (A)

After an episode of lumbago during a vacation I continuously had low back pain and tingling feet for about nine months. Then suddenly my right foot started to hurt badly and after a while the pain became so severe that I was unable to leave my house. The specialist ordered an MRI (magnetic resonance imaging) scan and it revealed a large lumbar disc herniation. Since it only got worse after that I decided to have surgery. After the operation I recovered quickly and the back pain and leg pain were completely gone. I soon was able to go back to work and rebuild my social life. Unfortunately after a couple of months the low back pain and the other symptoms returned, although not as severe as before surgery. A new MRI scan now revealed two small disc herniations and two bad intervertebral discs. The specialist told me that it was too early for a second operation.

Now it is unclear to me what the doctor can do about it and I don’t even know which measures I can take myself. The constant back and leg pain are greatly interfering with my work and my social life. I sometimes feel like an elderly person because of my physical limitations. I try to stay positive, but it is hard to cope with the uncertainty.

C Penning, aged 32, Rotterdam

The results indicate that both conservative care and disc surgery are relevant treatment options for patients with sciatica of at least six weeks’ duration. Surgical intervention may provide quicker relief of symptoms compared with conservative care, but no large differences have been found in success rate after one or two years of follow-up. Patients and doctors may thus weigh the benefits and harms of both options to make individual choices. This is especially relevant because patients’ preference for treatment may have a direct positive influence on the magnitude of the treatment effect.

What are the recommendations in clinical guidelines?

Although in many countries clinical guidelines are available for the management of non-specific low back pain this is not the case for sciatica.22 Box 4 shows the recommendations for sciatica (lumbosacral radicular syndrome) in clinical guidelines recently issued by the Dutch College of General Practice.12

After excluding specific diseases on the basis of red flags, sciatica is diagnosed on the basis of history taking and physical examination. Initial treatment is conser-

A patient’s perspective (B)

My complaints started about four months ago with pain in the lower back. Soon after the pain radiated into my legs, for which I went to my general practitioner. His analysis was no herniated disc. A muscle relaxant in combination with referral to a physiotherapist would reduce the symptoms. Three weeks of physiotherapy followed by several treatments by a chiropractor did not provide any symptom relief. In fact the symptoms became worse—especially during walking and standing. Lying down and cycling were much better tolerated. Additional complaints were reduced strength in the left leg, not being able to stand on the heel or toes, a cold feeling in the lower leg at the end of the day, while in the morning it felt like standing in a bunch of needles.

About one month ago a neurologist diagnosed a herniated disc on the right side based on an MRI scan that was taken. However, this could not explain the symptoms in the left leg. The symptoms in the left leg could be due to spinal stenosis. The complaints were not severe enough to recommend surgery and the neurologist told me that a substantial improvement was to be expected within a period of 3-4 months. His advice was to continue normal daily activities as much as possible. At present (one month later) I feel some improvement of my symptoms.

J Vreuls, aged 49, The Hague

vative, with a strong focus on patient education, advice to stay active, continuing daily activities, and adequate treatment for pain. In this phase imaging has no role. Referral to a medical specialist—for example, neurologist, rheumatologist, spine surgeon—is indicated in patients whose symptoms do not improve after conservative treatment for at least 6-8 weeks. In these referred cases surgery may be considered. Immediate referral is indicated in cases with a cauda equina syndrome. Acute severe paresis or progressive paresis are also reasons for referral [within a few days].

Promising developments

More evidence based information has become available on the efficacy of surgical care compared with conservative care for patients with sciatica. Although evidence is limited, initial findings suggest no important differences in long term (one or two years) effect between these two approaches. This finding may be partly explained by patients who initially received conservative care later undergoing disc surgery. In all available studies it seems that a substantial proportion of patients improve over time. This holds true for patients undergoing surgery or receiving conservative care. Patients undergoing disc surgery are more likely to get quicker relief of leg symptoms than patients receiving conservative care. If symptoms do not improve after 6-8 weeks patients may opt for disc surgery. Those who are hesitant about surgery and can cope with their symptoms may opt for continued conservative care. Patient preference is therefore an important feature in the decision process.

Since the mid-1990s a switch has occurred in the management of sciatica from passive treatments, such as bed rest, to a more active approach, with patients being advised to continue their daily activities as much as possible.

Future research

More information is needed on the importance of clinical signs and symptoms for the prognosis of sciatica and the response to treatment. This includes the value of size and location of the disc herniation, visible nerve root compression, sequestration, and the results of history taking and physical and neurological examinations. Subgroup analysis in a Finnish trial showed that discectomy was superior to conservative treatment in patients with disc herniation at L4-5.24 No strong evidence exists for or against the efficacy of many of the available conservative treatments. Much progress can be achieved here. Questions remain about the efficacy of analgesics for sciatica and the value of physical therapy and of patient education and counselling. No trial has yet evaluated the effectiveness of behavioural treatment and multidisciplinary treatment programmes.

Tumour necrosis factor α has been identified in animal and human studies as one factor in the development of sciatica.23 24 The first randomised trial evaluating a tumour necrosis factor α antagonist in patients with sciatica did not find a positive result.25
SUMMARY POINTS

Most patients with acute sciatica have a favourable prognosis but about 20%-30% have persisting problems after one or two years. The diagnosis is based on history taking and physical examination. Imaging is indicated only in patients with "red flag" conditions or in whom disc surgery is considered. Passive (bed rest) treatments have been replaced with more active treatments. Passive treatment is conservative for about 6-8 weeks. Disc surgery may provide quicker relief of leg pain than conservative care but no clear differences have been found after one or two years.

Contributors: BWK wrote the first draft. MWvT and WCP critically appraised and improved the manuscript. BWK is guarantor.

Competing interests: None declared.

Provenance and peer review: Commissioned; peer reviewed.

14. Luijsterburg PA, Verhagen AP, Ostelo RWJ, Os TAG van, Peul WC, Koes BW. Effectiveness of conservative treatments for the lumbosacral radicular syndrome: a systematic review. Eur Spine J 2007 Apr 6;[Epub ahead of print].

CORRECTIONS AND CLARIFICATIONS

Improved effectiveness of partner notification for patients with sexually transmitted infections: systematic review

In this research article by Sven Trelle and colleagues (BMJ 2007;334:354-7; doi: 10.1136/bmj.39150.648762.BE) the penultimate paragraph of the comments should have read: " noch 3% of the number needed to treat 37 [not 27]."

Cover picture
In the 26 May issue of the BMJ we put a picture of a roundworm on the cover of the printed journal, beside the words “Anaemia in developing countries.” As we should have known, it is not roundworms, but hookworms, that occur with iron deficiency anaemia (as the editorial in that issue pointed out).

Drug eluting stents: What fuels public policy?
During the preparation of this letter by Mark H Wilson (BMJ 2007;334:599-600, 24 Mar, doi: 10.1136/bmj.39150.648762.BE), we wrongly marked up the position and email address of the author. His correct affiliation is director of medical ethics (healthresearch@sympatico.ca).

Short Cuts Extra: INR easily monitored at home
In this item by Harvey Marcovitch about the use of portable coagulometers (BMJ 2007;334:928, 5 May, doi: 10.1136/bmj.39191.635637.AD) the penultimate sentence should have read: "Paired results were highly correlated (r=0.91), and only three (5%) of the home tests differed from laboratory results by >15% [not >20%]."
PREGNANCY PLUS

Inherited thrombophilia and pregnancy associated venous thromboembolism

Wendy Lim, John W Eikelboom, Jeffrey S Ginsberg

Pulmonary embolism is the leading cause of maternal mortality in developed countries and accounts for 20% of pregnancy related deaths in the United States. The risk of pulmonary embolism and deep vein thrombosis, collectively known as venous thromboembolism, is increased during pregnancy and is further increased by the presence of inherited or acquired thrombophilias. We summarise the epidemiology and diagnosis of venous thromboembolism in pregnancy and discuss the anticoagulant management of women with inherited thrombophilia who are at risk of, or who develop, venous thromboembolism during pregnancy and the postpartum period.

Non-inherited conditions that increase the risk of venous thromboembolism in pregnancy

- General conditions
- Previous venous thromboembolism
- Obesity
- Prolonged immobilisation
- Major trauma
- Surgery
- Cardiac disease
- Antiphospholipid antibodies
- Malignancy

Pregnancy related conditions

- Older maternal age
- Multiple pregnancy
- Gestation <36 weeks
- Caesarean section

The role of thrombophilia testing in pregnancy is controversial, and recommendations for testing are based on expert opinion; the lowest quality of evidence. In general, testing pregnant women without a strong family history of venous thromboembolism who show an increased risk of the condition include those with known thrombophilia and those with a strong family history of venous thromboembolism.

How are women at increased risk of thromboembolism managed during pregnancy?

Women with no history of venous thromboembolism who show an increased risk of the condition include those with known thrombophilia and those with a strong family history of venous thromboembolism.

The role of thrombophilia testing in pregnancy is controversial, and recommendations for testing are based on expert opinion; the lowest quality of evidence. In general, testing pregnant women without a strong family history of venous thromboembolism who show an increased risk of the condition include those with known thrombophilia and those with a strong family history of venous thromboembolism.

METHODS

We searched Medline and the Cochrane database of systematic reviews for studies evaluating the epidemiology, diagnosis, prevention, and treatment of venous thromboembolism during pregnancy and the postpartum period in women with inherited thrombophilia, using the key words “venous thrombosis”, “deep vein thrombosis”, “pulmonary embolism”, “pregnancy (complications)”, “thrombophilia”, and “anticoagulants.”

Table 1 | Prevalence and risk of venous thromboembolism during pregnancy in relation to inherited thrombophilias

<table>
<thead>
<tr>
<th>Thrombophilia</th>
<th>Prevalence among women with venous thromboembolism in pregnancy (%)</th>
<th>Relative risk of venous thromboembolism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Factor V Leiden (heterozygous) w8-w10-w12</td>
<td>8-44</td>
<td>5-7</td>
</tr>
<tr>
<td>Factor V Leiden (homozygous) w8-w10-w12</td>
<td>9-17</td>
<td>10-41</td>
</tr>
<tr>
<td>Prothrombin gene mutation (heterozygous) w11-w12</td>
<td>3-17</td>
<td>3-10</td>
</tr>
<tr>
<td>Prothrombin gene mutation (homozygous)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Compound heterozygote (Factor V Leiden and prothrombin gene mutation) w9-w15</td>
<td>4-9</td>
<td>9-107</td>
</tr>
<tr>
<td>Antithrombin deficiency w10-w11 (c80% activity)</td>
<td>7-12</td>
<td>10 to unknown</td>
</tr>
<tr>
<td>Protein C deficiency w11-w12 (75% activity)</td>
<td>10</td>
<td>2 to unknown</td>
</tr>
<tr>
<td>Protein S deficiency w11-w12 (65% activity)</td>
<td>8</td>
<td>—</td>
</tr>
</tbody>
</table>

Prevalence varies according to ethnic group.

Risk of venous thromboembolism

Two major factors influence the risk of venous thromboembolism during pregnancy in women with thrombophilia: the type of thrombophilia and the circumstances of any previous venous thromboembolism—that is, provoked or unprovoked. Thrombophilias that are associated with a high risk of venous thromboembolism during pregnancy include antithrombin deficiency, protein C or S deficiency, compound heterozygosity for factor V Leiden and prothrombin gene mutation (G20210A) or other combinations of thrombophilia, and homozygosity for these conditions. Lower risk thrombophilias include heterozygosity for factor V Leiden or the prothrombin gene mutation (table 1). Women with the prothrombin gene mutation (G20210A) have a low risk of recurrence during pregnancy.

Women without inherited thrombophilia and those whose previous episode of venous thromboembolism was associated with a temporary risk factor (that is, provoked) have a low risk of recurrence during pregnancy. Women with lower risk thrombophilias who have no history of venous thromboembolism have a low risk of venous thromboembolism in pregnancy (relative risk 0%, 95% confidence interval 0% to 2.7%) and antepartum prophylaxis is not routinely recommended. Among women with lower risk thrombophilias and previous venous thromboembolism, the role of antepartum prophylaxis remains controversial. A retrospective study of pregnant women with previous venous thromboembolism found that the rate of recurrence during pregnancy was 7.5%, irrespective of whether the first episode was unprovoked, pregnancy related, or occurred during use of oral contraceptives. By contrast no recurrences occurred among women with a previous provoked venous thromboembolism. Consensus guidelines recommend that women

Table 2 | Anticoagulant options and doses for use during pregnancy and post partum

<table>
<thead>
<tr>
<th>Anticoagulant</th>
<th>Prophylactic dose</th>
<th>Therapeutic dose</th>
<th>Safety in pregnancy*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dalteparin</td>
<td>5000 IU once daily</td>
<td>200 IU/kg once daily, 100 mg/kg twice daily</td>
<td>Safe; category B</td>
</tr>
<tr>
<td>Enoxaparin</td>
<td>40 mg once daily, 30 mg twice daily</td>
<td>1.5 mg/kg once daily, 1 mg/kg twice daily</td>
<td>Safe; category C</td>
</tr>
<tr>
<td>Nadroparin</td>
<td>2850 IU once daily</td>
<td>171 IU/kg once daily</td>
<td>Safe; category C</td>
</tr>
<tr>
<td>Tinzaparin</td>
<td>4500 IU once daily</td>
<td>175 IU/kg once daily</td>
<td>Safe; category C</td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td>Fixed doses: starting dose 5000 U every 12 hours, increasing through pregnancy† Adjusted doses: every 12 hours to achieve 6 hour anti-Xa level 0.1-0.2 U/ml by protamine titration</td>
<td>Intravenous route: bolus and infusion to maintain 6 hour activated partial thromboplastin time 2.0-2.5 times baseline; subcutaneous route: dosed every 12 hours to achieve 6 hour activated partial thromboplastin time 1.5-2.5 times baseline</td>
<td>Safe; category C</td>
</tr>
<tr>
<td>Warfarin</td>
<td>Not used</td>
<td>Adjusted dose to achieve international normalised ratio 2.0-3.6</td>
<td>Not recommended in first or second trimester, may be safe in late pregnancy; category X</td>
</tr>
</tbody>
</table>

*Based on FDA categories. A=controlled studies show no risk; B=no evidence of risk in humans; C=risk cannot be ruled out; D=positive evidence of risk; X=contraindicated in pregnancy.
†Multidose vials of dalteparin and enoxaparin contain benzyl alcohol; manufacturer of dalteparin (Pharmacia, Surrey) recommends against use of multidose vials in pregnant women.
‡Consider anti-Xa level monitoring, target anti-Xa 0.5-1.2 U/ml measured four hours after administration.
§Consensus recommendations: every 12 hours: 5000-7000 U in the first trimester, 7500-10 000 U in the second trimester, and 10 000 units in the third trimester.
with unprovoked or oestrogen related venous thromboembolism receive antepartum prophylaxis, whereas prophylaxis may not be necessary in women with provoked venous thromboembolism. In a small prospective study of 23 women with thrombophilia who became pregnant after an episode of venous thromboembolism, the rate of recurrence was 8.3% (1 of 12 pregnancies) in women treated with prophylactic heparin compared with 25% (7 of 28 pregnancies) in women who did not receive prophylaxis. The recurrences occurred mainly in women with antithrombin deficiency or who were homozygous for factor V Leiden.

Risk of bleeding
Bleeding complications are minimally increased or not increased when using prophylactic dose low molecular weight heparin or unfractionated heparin. Unfractionated heparin may be associated with heparin induced thrombocytopenia and osteoporosis; both of which are less common with low molecular weight heparin.

Risk to the fetus
Low molecular weight heparin and unfractionated heparin do not cross the placenta and are considered safe for use during pregnancy.

How is a thrombotic event managed during pregnancy?
Women who are at risk for venous thromboembolism during pregnancy should be educated about the signs and symptoms of the condition and should seek prompt medical attention if these develop. Women who are of childbearing age and are identified with an inherited thrombophilia or have a history of venous thromboembolism should be educated about the potential need for antithrombotic prophylaxis during pregnancy. Consultation with a doctor with expertise in maternal-fetal medicine is recommended if a pregnancy is planned.

Women who develop venous thromboembolism during pregnancy are treated with therapeutic doses of low molecular weight heparin or unfractionated heparin for at least the same duration as if the event had occurred outside pregnancy. Although level I evidence is lacking, it is logical to presume that whatever aspect of pregnancy that potentially contributed to the occurrence of thrombosis will persist throughout pregnancy. For this reason, anticoagulation should be maintained for the duration of pregnancy and for at least six weeks post partum. Less commonly, warfarin may be used after the first trimester. Treatment should be started as soon as possible and in consultation with a specialist (table 2). Therapeutic doses of low molecular weight heparin are based on body weight, and should be adjusted accordingly as pregnancy progresses. Anti-Xa level monitoring of low molecular weight heparin may be carried out to ensure that therapeutic levels of anticoagulation are achieved. Therapeutic dose unfractionated heparin is given as a twice daily subcutaneous injection and requires laboratory monitoring to achieve a mid-interval activated partial thromboplastin time 2.0-2.5 times that of the baseline time.

The frequency of major bleeding associated with therapeutic dose unfractionated heparin or low molecular weight heparin during pregnancy is about 2%. Bleeding is seen most commonly in relation to delivery, manifesting as wound haemorrhage or pelvic haematoma after caesarean section, or bleeding of the vulva or vaginal wall after vaginal delivery. Vitamin K antagonists (for example, warfarin) cross the placenta and can cause fetal microcephaly, nasal hypoplasia, and stippled epiphyses when given between the sixth and 12th weeks of gestation. They can be associated with fetal haemorrhage. Vitamin K antagonists are thus generally avoided in pregnancy since low molecular weight heparin is an effective and safe alternative for prophylaxis and treatment of venous thromboembolism in pregnancy. Use of warfarin in pregnancy is generally limited to the second and third trimesters in women with prosthetic heart valves, in whom there is uncertainty about the efficacy of low molecular weight heparin.

How is anticoagulant therapy managed at the time of delivery?
In women who have been treated with anticoagulant drugs, vaginal delivery and caesarean section increase the risk of bleeding, and use of regional anaesthesia is associated with a risk of epidural haemorrhage. Thus anticoagulants should be discontinued for a sufficient period before delivery to allow their effect to wear off. A safe interval between stopping anticoagulants and delivery can be achieved by scheduling elective induction of labour or caesarean section at least 12 hours after prophylactic dose low molecular weight heparin or 24 hours after therapeutic dose low molecular weight heparin.

Restarting anticoagulation using low molecular weight heparin or unfractionated heparin may be considered within 12 hours of delivery in women with an uncomplicated delivery and in whom haemostasis is secure. In the postpartum period, low molecular weight heparin is usually given concurrently with...
warfarin until the international normalised ratio reaches at least 2.0 on two consecutive days.

Are there any management issues in the postpartum period?

Since the absolute risk of venous thromboembolism in the postpartum period is higher than during the pregnancy and because bleeding is less of a concern after labour and delivery, postpartum thromboprophylaxis is recommended for women with known inherited thrombophilia and for women with a history of venous thromboembolism. Warfarin is usually given for 6-8 weeks, targeting an international normalised ratio of 2.0-3.0. Alternatively, therapeutic dose unfractionated heparin or low molecular weight heparin may be used for 2-3 weeks, targeting an international normalised ratio of 2.0 on two consecutive days.

Contributors: WL prepared the first draft of the manuscript. WL, JWE, and JSG jointly revised and finalised the manuscript. JWE is guarantor.

Competing interests: None declared.

Provenance and peer review: Commissioned; externally peer reviewed.


A memorable patient: Appendicitis in the Himalayas

In October 2006 a British echocardiographer, a senior house officer from Kathmandu, and myself were in Lobuje (4900 m above sea level), eight hours’ walk below the Everest base camp in the foothills of the Himalayas. We were there to help with the “high altitude pulmonary edema prevention trial 2006.”

One evening, when it was snowing outside and the dining hall of the teahouse was full of the trekkers on their way to or from Everest base camp and Kalapatarka, we were busy tabulating our research data. The owner of the teahouse approached us and said that one of the girls working for the teahouse had been complaining of severe abdominal pain for the past few hours. We hurried to her room and found a 15 year girl rolling from side to side in pain on her bed. When we had finished taking her history and examining her we had the impression that she could have acute appendicitis. We were worried that the nearest town with surgical facilities was Kathmandu, and eight day walk down the hills or a 45 minute flight from Lobuje—the latter being almost impossible for a poor maid girl without an inkling of insurance.

We had been using an echocardiography machine for our research, so we considered the possibility of getting an abdominal scan of the girl. However, doing an abdominal scan was as challenging for our echocardiographer colleague as it was for us.

We therefore made an announcement in the dining hall, asking if there was anyone who could do it. To our surprise, there were two British radiologists on their way to Everest base camp. They did the abdominal scan with the portable scanner normally used for echocardiography and found no evidence of acute appendicitis, ruptured ectopic pregnancy, or perforitonitis. We therefore decided to treat the girl symptomatically and gave her painkillers and antibiotics. With the drugs, her pain subsided to a great extent, and she slept the night. Early the next morning she left for Kathmandu.

Twelve days later, when I was on my way back to Kathmandu, I met the girl returning to Lobuje. She told me that she had walked for four days down the hills with a friend and then took a flight from Lukla to Kathmandu. There, she was found to have an appendicular lump and was admitted and given some medications. She was also advised to have an elective appendicectomy after six weeks. She was also advised to have an elective appendicectomy after six weeks.

We explained the possible immediate complications of an acute appendicitis that she might have developed, and we agreed that it was her luck that she had avoided them. Otherwise, what would have happened to that poor girl from the Himalayas without basic healthcare facilities?

Ram Hari Ghimire, student, Institute of Medicine, Kathmandu, Nepal dr_rhg@yahoo.com
VIEWS & REVIEWS

Should doctors go to patients’ funerals?

Some years ago I (BA) decided to start attending the funerals of patients. This was in response to having had a positive experience of attending a funeral where the family was appreciative of my presence. Recently I attended the funerals of two patients who died within a few weeks of each other. Again, both funerals afforded me the opportunity to meet the extended family of the deceased and again, in both cases the family appreciated my attendance.

What stood out with the two recent funerals was that in both cases a close relative came to visit me in the clinic within a week. It was obvious these were not visits for any particular pressing medical problem but more of a social nature. The talk revolved around the funeral and, having been a participant, I felt I could make a meaningful contribution to the conversation.

I was left with the impression that my attendance at the funeral was contributing to the resolution of grief in those two people. This was particularly rewarding and made the small investment of a few hours of my time worthwhile.

These recent events piqued our interest in the area of doctors attending their patients’ funerals. It is not an area of much discussion (perhaps because doctors view death as a defeat?), but we had expected there to be literature on this topic to offer guidance.

A Medline search was fruitless. Searching on Google was more illuminating, offering up anecdotal experiences which highlighted the value of attending patients’ funerals, and provided some common themes of the value of doing this—namely, themes of appreciating the human and of ongoing caregiving.

Attending the funeral of a patient is a gesture of respect to the deceased and is generally interpreted as such by the patient’s family. It also allows the doctor to gain a complete picture of a patient’s life: often services are a real celebration of an individual’s life and this is a positive and affirming experience. Long term patients often become fond fixtures in a practice and can even be regarded as good friends. Attending a funeral shows this important connectedness and it also enables a personal expression of grief.

Traditional viewpoints often persist among the community of patients, and, to many, having a doctor attend a loved one’s funeral validates and emphasises the worth of that person. As Dame Cicely Saunders, a pioneer in the modern palliative care movement, once said: “How people die remains in the memories of those who live on.” This is true regarding the dignity of death that they are afforded, but also the celebration of life that they are given at the funeral service.

To many doctors—particularly those ascribing to the patient centred or family centred approach—a crucial point to emphasise is the recognition that in most cases our responsibility to the departed person extends to caring for their family in the wake of their death. As Elizabeth Kubler-Ross quite rightly emphasises, “Be available. The void and emptiness is felt after the funeral [when the busyness of preparations is over]. It is at this time that the family members may feel most grateful to have someone to talk to, especially if it is someone who had recent contact with the deceased. This may help the relative over the shock and the initial grief and prepare them for gradual acceptance.”

The doctor’s presence at a funeral service can pave the way for the family to have an opportunity to talk about their experiences surrounding the death. They may have questions about what happened in the last days or need reassurance or help with guilt.

The family (or attending) doctor is the appropriate person to “be available.”

Regular funeral attendance will not fit all doctors. Clearly, those in palliative care and some hospital disciplines may find this burdensome. It may be wise to avoid funerals when the family is unhappy with care, but asking the family for their permission to attend might facilitate reconciliation. Primary care providers usually have long term relationships with patients and their families, and we would argue that it is important to witness the end of the life journey of an individual. This is what we do for friends and family, and longstanding relationships with patients are in a similar category. Our experience indicates that there are personal and family benefits to be gained and little to be lost.

Bruce Arroll is professor and Karen Falloon is academic registrar, Department of General Practice and Primary Health Care, University of Auckland, New Zealand.

b.arroll@auckland.ac.nz

Competing interests: BA is on the advisory board for the Pharmac educational seminars (Pharmac is the government funded pharmaceutical purchasing agency in New Zealand) and is on the primary care committee of the Future Forum, an educational foundation funded by AstraZeneca (UK).
Seeds of discontent

A chronicle of a couple’s epic attempt to have children questions whether modern reproductive technology is more trouble than it’s worth, finds Abi Berger

Caroline Gallup went through almost four years of unsuccessful infertility treatment before finally stopping. It’s clear from her book that reaching the decision to stop was a long and painful process and that her persistent hope of becoming a mother has never quite died.

Gallup tells the story of her initial desire to become a mother and the desperate gnawing that grows inside her as achieving her dream seems to slip away. It’s a story that makes essential reading for couples hell bent on producing a family and for doctors trying to support them. It’s also a useful eye opener for those who are not sure whether they are ready for the robust demands that infertility treatment can make on couples.

The book combines the story of a journey with a lay person’s digest of the biological aspects of infertility technology. It would have been hard to do the first without providing the second, although there’s a lot of repetition—just in case the reader has forgotten what’s involved.

Or perhaps, the sense of this simply reflects the repetitiveness of undergoing seemingly endless cycles of the same thing until someone says enough is enough. Reaching that point is undoubtedly a unique decision for everyone undergoing such treatment, and should be regarded as such.

What’s interesting in this couple’s story is that Gallup’s husband Bruce has been diagnosed with azoospermia, and therefore for him it’s apparently an open and shut case. He discovers that he cannot conceive children naturally through any intervention whatsoever. His hope truly dies. But Caroline can still hold out for a genetic child of her own if she is willing to accept a donation of another man’s sperm. And while this remains a possibility, the door never quite closes.

While the goal—pregnancy—is the same for both partners, if feels very different, and they become virtually estranged from each other. The book’s message is an important one that is often underplayed or even ignored by the medical profession: undergo infertility treatment without thinking through the emotional implications at your peril, or at least recognise that the emotional whirlwind may be far removed from the dream you were pursuing. Fortunately, this couple survived, but it’s not always the case.

Apart from addressing the arguably modern cultural assumption that having children is a right, this book provokes other more difficult questions. Is the conception of a non-genetic baby going so against nature’s intention that for women to conceive using donor sperm can feel like infidelity? And can couples who embark on such a journey ever truly come through it intact? Is modern technology causing more trouble than it’s worth?

Doubtless Gallup would conclude that the availability of the technology and her own personal resources allowed her hope to survive longer than would otherwise have been the case. Without them she may have felt more bereft at the point of the diagnosis, but I suspect she would have come through it. With more resolution and reached closure more quickly and more succinctly.

On the other hand, had she not been in this position she may have felt more bereft at the point of the diagnosis, but I suspect she would have come through it with more resolution and reached closure more quickly and more succinctly.

There are numerous references to the two of them undertaking different processes to get through the ordeal, but I would have loved to have read about their journeys in equal measure.

Abi Berger is associate editor, BMJ, and general practitioner, London aberger@bmj.com
Stubbled out

I went to the launderette fortnightly. It wasn’t that I had lots of clothes—I didn’t. But a wet sponge and steam iron works wonders. As I ironed, the steam billowed from my PolymixPubJob shirt, carrying the sweet smell of stale beer and cigarettes. The final touch to my shirt was aftershave. In the 1980s this was all produced in Middlesbrough by ICI to a classified cold war formula—a tiny splash of Brut Musk could conceal weeks of unwashed clothes. To this day it still seeps from my pores when I sweat. But the modern bartender will soon be spared the need to wear cheap aftershave, for England is to ban smoking in confined public spaces.

The risks of smoking have been clear for many decades, but when I grew up in the 1970s smoking was common—vast ornamental ash trays and coffee table lighters were the order of the day. People puffed away in sitcoms and in Hollywood’s blockbusters, and Formula One cars were cigarette packets on wheels. As an adult in the 1980s I smoked occasionally but regularly in a way that has become known as “social smoking”—on nights out and sometimes during the day. In the conformist sausage factory that is medicine it was my youthful (and stupid) act of defiance to stand outside the exam hall smoking one of those foreign brands that newsagents would sell only to card carrying students. The dire warnings printed on the packets were meaningless to risk obsessed youth. I am lucky, for I was able to resist the terrible pull into the tornado of addiction that smoking is.

But by middle age, life matters—I don’t want to die. Half of all smokers die from their addiction, and on average smokers live 10 years less. But quitting is not easy. For me, smoking is bound to the extremes of my life—the good and the bad. Smoking is pernicious. I have witnessed too many men and women in their 40s die from the many manifestations of vascular disease and seen others consumed by lung cancer. But worse still is the decades spent on an oxygen mask, confined to your home. Smoking has left great wounds slashed into the lives of children, husbands, wives with the needlessly and prematurely death of their loved ones. It is harder still for families to accept the injustice of the loss of a victim of second-hand smoking.

My attitude towards smokers remains passive. If smokers choose to smoke, then so be it. In the cockpit of life the control panel is jammed with self destruct buttons—smoking is merely one among many. Smoking is in terminal decline, and banning smoking in public is long overdue. Whether we do likewise with 1980 aftershaves is another issue.

Des Spence is a general practitioner, Glasgow destwo@yahoo.co.uk

Back from Basra

When your son joins the Territorial Army it seems no big deal at first. Weekends on Salisbury Plain are healthy exercise for a lawyer. From time to time he helps to fire off a royal salute or invites you to a rather jolly mess dinner.

Then reality bites. Volunteers are wanted for a tour of duty “somewhere overseas.” Not you, son, surely? Tell them you’re an essential worker. Oh. OK. I suppose it’s a matter of honour. That and no loss of salary, he replies. The government is desperate, after all.

The farewell, last September, was a cliché repeated down the centuries but no less affecting for that. Mum holding back tears, handshake from dad, laconic smile and a wave from the young man. Mum now says she thought she’d never see him again.

You keep checking for email. Communication with Iraq is fitful but you begin to notice a pattern. A brief, unexpected phone call just to say hello. Then silence for a few days. Finally, a short item on the evening news. A British soldier has been killed and the next of kin have been informed.

What does “being informed” entail, now that telegrams have been abolished? An army car waiting when you get home from work? Mum sometimes thought she heard the doorbell in the night. Then, thank goodness, another email: “Day off, relaxing. Biggest danger is sunburn.”

Here, the biggest danger is losing friends in hospital management. They tell us we can’t afford more midwives because there’s no money. When I remind the meeting that we can afford £3m (€4.4m; $5.9m) a day for the prime minister’s war, everyone looks uncomfortable. Their silence implies: there’s nothing we can do, so why mention it? My silence implies: that’s democracy for you.

After six months the veteran returns, suntanned. He seems taller. Photos on his laptop show his comrades with camouflage Land Rovers. And son in battledress with his number and blood group in big letters on the chest.

I feel smaller. Did I protest against the war? No, I left that to others. My father, wounded in 1944, and my son have done things I’ll never achieve. My dad’s generation set up the NHS only three years after coming home. My generation, combat free, can’t even run it properly.

James Owen Drife is professor of obstetrics and gynaecology, Leeds j.o.drife@leeds.ac.uk

FROM THE FRONTLINE
Des Spence

IN AND OUT OF HOSPITAL
James Owen Drife

1324 | BMJ | 23 JUNE 2007 | VOLUME 334
Sheer delight in doing evil

In Sir Arthur Conan Doyle’s *The Resident Patient*, a doctor called Trevelyan comes to see Sherlock Holmes about a little problem. Dr Watson recognises him as the author of “a monograph on obscure nervous lesions.” Dr Trevelyan is delighted, naturally enough: “I so seldom hear of the work that I thought it was quite dead. My publishers give me a most discouraging account of its sale.”

This, the common lot of all authors, or at least the lot of all the authors known to me in person (though this, I admit, may be a reflection merely on the nature of my literary acquaintance and therefore indirectly on me), is not the problem about which Dr Trevelyan comes to consult Holmes.

Trevelyan is in an unusual situation. He has been set up in practice by a stranger called Blessington, on condition that he, Blessington, continues to live in Trevelyan’s house and takes three quarters of his fees. Trevelyan, who has no capital to start a practice of his own, agrees.

This arrangement works until one day Blessington seems to have been agitated by some news and becomes fearful for his safety. A little while later, Trevelyan is consulted by a man who is supposedly a Russian aristocrat, accompanied by his son; the man is suffering from catalepsy, a condition in which the main difference between the cases was this: that in the case in which I was involved the man was not motivated by revenge, but (as far as I could tell) by sheer unadulterated malignity. I thought it was quite dead.

The main difference between the cases was this: that in the case in which I was involved the man was not motivated by revenge, but (as far as I could tell) by sheer unadulterated malignity, by sheer delight in doing evil. This delight is one of the great puzzles of human nature.

Theodore Dalrymple is a writer and retired doctor.

**BETWEEN THE LINES**

**Theodore Dalrymple**

**In the case in which I was involved the man was not motivated by revenge, but (as far as I could tell) by sheer unadulterated malignity**

**MEDICAL CLASSICS**

**The Bell Jar** By Sylvia Plath

First published in 1963

Chiefly celebrated for her “confessional poetry,” Sylvia Plath (1932–1963) was also ambitious to break new ground with prose. Poignant, *The Bell Jar*, published under a pseudonym a month before her death, was her only attempt at the novel form. One of the compelling aspects of this increasingly respected novel is the degree of connection between the troubled life of its heroine, Esther Greenwood, and Plath herself. Inevitably, as we encounter Esther’s subtle mental breakdown and successive suicide attempts, we are drawn further into the now almost mythic events of Plath’s short life. Despite the inevitable curiosity about the autobiographical content, *The Bell Jar* is of lasting importance for further reasons.

First and foremost is its subject matter, which has increasing relevance 40 years on. The book examines a contemporary concern—how is it that privileged and educated young people (especially young women) increasingly turn to varied kinds of self-harm, as a way of coping and escape? Plath was one of the first writers to explore this area, and her description of Esther’s escalating suicidality is all the more realistic for being described so matter of factly.

Various themes spin out from this central idea, such as the restricted role of women in 1950s America, an emerging feminist viewpoint, and personal renewal through struggle.

Esther’s development of psychotic depression is Plath’s interpretation of the classic “rite of passage” journey. The bell jar of confusion that descends on Esther hampers her personal progress, yet it protects her from being overwhelmed by a highly competitive social world. Plath ushers us into the clinic of the subtly monstrous psychiatrist, Dr Gordon, and exposes us to the stunning brutality of Esther’s unanaesthetised electroconvulsive therapy. Psychiatry is redeemed when Esther is renewed under the care of a female consultant, Dr Nolan, who represents what Esther aspires for herself—independence and social respect as a professional woman.

In describing Esther’s recovery, Plath covers an aspect of mental illness that is not sufficiently publicised. Esther has undergone a life changing experience. Plath’s novel serves as an important reminder that our stigmatised psychiatric wards, sometimes places of misery and tragedy, can also nurture momentous personal change and a new beginning. As we finish the novel, we are drawn again into the author’s own life. Esther’s overriding concern, as she faces the grand round that will decide for or against her hospital discharge, is whether the bell jar “with its stifling distortions” might descend again. Tragically (for once, this word is not misplaced), Sylvia Plath did not escape the fate that Esther fears.

Iain McClure, consultant child and adolescent psychiatrist, Murray Royal Hospital, Perth imcclure@nhs.net

*Theodore Dalrymple is a writer and retired doctor.*

*In Sir Arthur Conan Doyle’s “The Resident Patient,” a doctor called Trevelyan comes to see Sherlock Holmes about a little problem. Dr. Watson recognises him as the author of “a monograph on obscure nervous lesions.” Dr. Trevelyan is delighted, naturally enough: “I so seldom hear of the work that I thought it was quite dead. My publishers give me a most discouraging account of its sale.”

This, the common lot of all authors, or at least the lot of all the authors known to me in person (though this, I admit, may be a reflection merely on the nature of my literary acquaintance and therefore indirectly on me), is not the problem about which Dr. Trevelyan comes to consult Holmes.

Trevelyan is in an unusual situation. He has been set up in practice by a stranger called Blessington, on condition that he, Blessington, continues to live in Trevelyan’s house and takes three quarters of his fees. Trevelyan, who has no capital to start a practice of his own, agrees.

This arrangement works until one day Blessington seems to have been agitated by some news and becomes fearful for his safety. A little while later, Trevelyan is consulted by a man who is supposedly a Russian aristocrat, accompanied by his son; the man is suffering from catalepsy, a condition in which—oddly enough, I was once involved the man was not motivated by revenge, but (as far as I could tell) by sheer unadulterated malignity, by sheer delight in doing evil. This delight is one of the great puzzles of human nature.*
Prudence Tunnadine played a key role in founding the Institute of Psychosexual Medicine in 1974, and was an authority on treating sexual problems.

She was born Lesley Prudence Dundas Bellam in a nursing home in Chiswick, head first into a commode, which she thought explained her very singular brain. Her father worked in the rag trade and was an army reservist. When war broke out he was commissioned into the royal tank regiment and the family moved to Sussex, where they had previously spent their holidays.

She was educated at Bedford Park High School for Girls and Chichester High School, where she excelled in everything except needlework, was embarrassed at having to stand on the stage wearing rosettes on prizegiving day, and was talkative and boisterous.

After the war her father was posted to India, and she remained with an aunt and uncle to do her A levels. She then went out to India, via Suez, on the troopship Britannic from Liverpool. She had a wonderful 18 months, visiting hill stations, doing voluntary work as a teacher and in her father’s office, and being courted by droves of young men. On her return—on another troopship, via Mombasa and Naples—she applied to Guy’s. She went to the interview in cocktail dress, heels, and a fur stole: the few other girl applicants were in school uniform.

She had a good time at medical school, living on coffee and cigarettes, and married a fellow student, David Tunnadine, in 1952. She did her house appointments and senior house officer jobs at Guy’s and its satellite hospitals in north Kent. Her husband went into general practice, and she, by now with children, abandoned her idea of a career in gynaecology and did locums and family planning sessions.

The only other part time work available for women doctors in the 1960s was child welfare clinics. But as the pill became more widely available, women patients wanting non-judgmental contraceptive advice, or who wanted to discuss a gynaecological problem, soon learnt that family planning doctors were very approachable, mostly female, and could be consulted without a referral from their general practitioner. Their male partners made the same discovery. Prue soon realised that patients brought their emotional and sexual distress to the family planning clinic as physical symptoms or contraceptive needs, often voicing these concerns during an intimate examination.

Psychoanalysis was then in the intellectual forefront and Michael Balint’s ideas were in the air. Prue and some like-minded colleagues turned to Tom Main, a psychoanalyst and follower of Balint, who had been running training seminars on the doctor-patient relationship. Main encouraged Prue and some others to lead the seminars. He then led groups of leaders, and the two developed the tiered training structure that still exists at the Institute of Psychosexual Medicine. They both discouraged the idea that they were gurus and that students should metaphorically sit at their feet.

Prue understood and taught the need to use all the skills of physical doctoring while never forgetting, or allowing her pupils to forget, à la Balint, that doctors should always ask themselves what is happening for the one troubled person in front of them and how they can best reflect it back to give the patient insight into the difficulty. She drew a clear distinction between this body-mind doctoring and other disciplines such as psychotherapy and sex therapy, the skills she used being specific to doctors and other professionals with a licence to examine the body.

The psychosexual clinics started by the Family Planning Association, probably with Prue’s involvement, were taken over by the NHS in 1974, when she and others started the Institute of Psychosexual Medicine. She also established a private practice in Harley Street around this time. She had already published her first book, Contraception and Sexual Life (1971).

She was scientific director of the institute from 1990 to 2000 and continued to hone the skills of psychosexual medicine and to teach them. She wrote three further books—Sense and Nonsense about Sex (1981), The Making of Love (1984) and Insights into Troubled Sexuality (1991). In The Making of Love she wrote, “This book is not about sexual performance. It is about people who … have not been able to rejoice in their own sexuality, or who have sought help to do so.”

She was terrified of public speaking but did it well. Her life was one of passion, and her heroes were George Best, Muhammed Ali, Franz Klammer, Nelson Mandela, Billy Beaumont, Gareth Edwards, and Seve Ballesteros. She played golf and bridge, and had a go at boogie-boarding when she was 75.

Two years ago she was diagnosed with bowel cancer. She took it well, apart from resenting the stolen time. Divorced in 1978, she leaves three sons and a daughter.

Caroline Richmond
Lesley Prudence Dundas Bellam, consultant in psychosexual medicine (b 1928; q Guy’s Hospital 1953), d 15 December 2006.
Charles Alan Blake Clemeton

Professor emeritus Tulane University School of Medicine, New Orleans (b 1923; q Oxford 1948; FRCOG, FRCS, FACOG), died from heart failure after a heart attack on 30 August 2006. Charles Alan Blake Clemeton (“Alan”) moved to Saskatoon, Canada, in 1958 as assistant professor of obstetrics and gynaecology, where he started his work on vitamin C in studying the capillary strength of the Inuit. After appointments in San Francisco and Brooklyn, New York, he was professor of obstetrics and gynaecology at Tulane University 1981-90. An original thinker and not afraid of controversy, Alan wrote on the role of vitamin C in the shaken baby syndrome when he was professor emeritus. In a work of three volumes he also noted that subclinical vitamin C deficiency is comparatively common and often associated with raised blood histamine concentrations. He leaves three children and six grandchildren.

Michael Innis
F Edward Yazbak

Ian Thomas Twistington Higgins

Professor emeritus of epidemiology and environmental and industrial health University of Michigan (b 1919; q London Hospital 1942; MD, FRCP), d 26 March 2006. Ian Higgins was an international expert on the epidemiology of chronic respiratory diseases, cancer, coronary heart disease, and other diseases resulting from occupational and environmental exposures to hazardous materials. A member of the scientific staff of the Medical Research Council during 1953-63 at the Pneumoconiosis Research Unit in Wales, Ian emigrated to the United States in 1963 to a professorship at the University of Pittsburgh. In 1967 he joined the University of Michigan until his retirement in 1985. He was elected to the fellowship of many distinguished organisations and served on many committees, including the National Academy of Sciences and the National Institutes of Health. He leaves a wife, Millicent; two sons; and a granddaughter. Millicent Higgins

Frank Ian Lee

Former consultant physician Blackpool, Wyre, and Fylde district (b 1930; q London Hospital 1957; MD, FRCP), died from pancreatic cancer on 13 May 2007. Frank Ian Lee planned to study at the London School of Economics but changed his mind in the army. He was appointed consultant physician with an interest in gastroenterology in 1967. Undergraduate and then postgraduate tutor for students who came to the hospital from Manchester in the early 1970s, he was also tutor when the medical education centre was developed at Blackpool. He developed the first sizeable gastroenterology investigation centre outside a teaching hospital in the United Kingdom. He published and lectured widely, and was president of the North of England Gastroenterology Society in 1985. Frank had a lifelong interest in sport and natural history and was active in his local Methodist church. He leaves a wife, Pamela; four children; and seven grandchildren.

Pamela Lee

Margaret Lauretta Mabel Manford

Former consultant anaesthetist Queen Mary’s Hospital for Children Carshalton (b 1914; q Royal Free 1947; FFARCS), died from bronchopneumonia on 25 February 2007. Margaret Manford taught physical education for four years before taking up medicine and then, from the outset, pursued a career entirely in paediatric anaesthesia. Paediatric surgery in the 1950s and 1960s embraced all surgical specialties and needed equally versatile anaesthetists. Margaret responded to each new challenge with notable dedication. She always involved her trainees in research, publishing many papers with them on a wide variety of subjects. In 1969 she visited Vietnam and later Bangladesh to work there. After retirement, Margaret spent several years working with the blood transfusion service and subsequently with disadvantaged families in the Kent family scheme. Her husband, Jim, predeceased her. There were no children.

Dai Davies

Barry Windsor Roper

Former consultant radiologist Neath General, Port Talbot, and Ystradgynlais Hospitals (b 1934; q Birmingham 1957; MRCP, DMRD), died from perforation of diverticular disease on 22 April 2007.

Neil Somerville

ADVICE
We will be pleased to receive obituary notices of around 250 words. In most cases we will be able to publish only about 100 words in the printed journal, but we can run a fuller version on our website. We will take responsibility for shortening. We do not send proofs. Please give a contact telephone number and, where possible, supply the obituary by email to obituaries@bmj.com
MINERVA

There are three categories of complainants according to the Medical Protection Society. Vexatious ones (who are rare), those who have been harmed by a doctor’s negligence and should be compensated, and, the largest group, those who think they’ve been harmed by a doctor but who are usually just experiencing the natural course of their disease or who have recognised complications. It’s the last group who could be kept out of the arms of lawyers if sufficient time is taken to explain things to them (Casebook 2007;15(2):8-9).

Members of the UK reserve armed forces who were sent to Iraq in 2003 experienced high rates of mental health problems compared with the regulars. An investigation into the reasons for this points to higher exposure to traumatic events, lower unit cohesion, more problems adjusting to coming home, and lower marital satisfaction. Interestingly, higher rates of post-traumatic stress disorder symptoms were most powerfully associated with problems at home rather than events in Iraq (British Journal of Psychiatry 2007;190:484-9).

People under 55 who undergo knee replacement surgery for osteoarthritis apparently have increased long term mortality compared with the general population. For the first 12 years after surgery, this group enjoys a reduced overall mortality, but then the trend reverses and there’s an inverse correlation between age and mortality. The specific causes of death were chiefly cardiovascular, gastrointestinal, and urogenital diseases. The authors say their observations call for increased awareness of potential health problems in these patients (Journal of Bone and Joint Surgery (Br) 2007;89-B:599-603).

Between 1993 and 2004, 175 patients in New Zealand died in hospital from meningitis. Of the 140 deaths for which records remained, 70% occurred within 24 hours of admission. In 29% of the deaths, a delay of more than two hours was noted between arrival and antibiotics being administered. The chief cause of delay was a failure to include meningococcal disease in the original differential diagnosis (Journal of Infection 2007;54:551-7).

Here’s a controversial suggestion in a letter published in Medical Education. The term “learning style” is commonly bandied about, and some researchers have suggested that such styles not only influence how we learn but also our attitude to work. However, there are apparently 71 different and competing learning styles theories, many of them contradictory. And the controversial idea? Perhaps we don’t have learning styles at all, just personalities (2007;41:618-20).

Another controversial issue is raised by researchers in the Journal of Laryngology and Otology. Is rhinitis due to food allergies fact or fiction? The view of many parents, possibly informed by what they read on the internet, is that food allergies often cause rhinitis. In fact, the incidence of food allergy in children is 2-8% and usually presents with multi-system symptoms, which the vast majority outgrow. Isolated rhinitis due to food allergy is “extremely rare,” and treatment is rarely indicated (2007;121:526-9).

Marketing costs are said to exceed 30% of revenues for the pharmaceutical industry, and more than 90% of the marketing effort is aimed at doctors. Despite the “unprecedented numbers of regulatory activities focusing on relationships” between the medical profession and the industry, such legislation is often “unrecognised or flouted.” The bottom line is that a re-evaluation of responsibilities towards both patients and shareholders alike is critically needed (Journal of Surgical Research 2007;140:1-5).

One might hypothesise that there’s a direct relationship between exposure to road noise at home and hypertension. But a careful analysis of noise exposure and self reported use of antihypertensive drugs shows that the strongest link between the two is in middle aged people (45-55 years) and specifically at the higher noise levels. Minerva surmises that, as we get beyond middle age, we become more accepting of those irritations which are beyond our control (Journal of Occupational and Environmental Medicine 2007;49:484-92).

A 34 year old drug misuser attended the hospital emergency department with a week-long history of progressive ptosis, dysphagia, dysphonia, and unsteady gait. Examination revealed chronic abscesses on each thigh. Her weakness progressed rapidly, and she ultimately required ventilatory support. Botulinum poisoning was diagnosed, and the patient was treated with antitoxin and intravenous antibiotics and by excision of the abscess cavities. Tissue culture confirmed the diagnosis. The patient received ventilatory support for 21 days and eventually made a full recovery. Although uncommon, Clostridium botulinum type-A sepsis is associated with subcutaneous heroin injection “skin popping” and should be considered in such cases.

J E Tomlinson, senior house officer, R I S Winterton, specialist registrar (wintertonris@hotmail.com), H Peach, consultant Department of plastic and reconstructive surgery, Leeds General Infirmary, Leeds LS1 3EX
J Dunbar, specialist registrar Department of infectious and tropical diseases, St James’s University Hospital, Leeds LS9 7TF