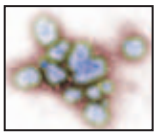

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# Medical student debts could rise to more than £70 000 under Browne proposals, BMA says

**Adrian O'Dowd** LONDON

The level of debt held by newly qualified doctors in England could rise sharply to between £70 000 (€80 000; $110 000) and £100 000 if the recommendations of a radical review of higher education funding are implemented.

In his independent review into funding of higher education and student finance, published on 12 October, the former BP chief executive John Browne called for the existing annual cap on the student tuition fee of £3290 to be abolished and for universities and colleges to be allowed to set their own fees up to a limit of around £12 000 a year.

The BMA has calculated that if universities were to set tuition fees for medicine courses to around £10 000, this would mean that a student would have an average debt of around £70 000 on qualifying—almost double the current average debt of £37 000. If tuition fees were set higher, it is possible that a new doctor's final debt could rise to around £100 000.

The Browne review proposes a new system, called the student finance plan, under which students would not pay anything until the student graduated and was working.

After graduating, successful students would begin repaying their debts only when they reach annual earnings of more than £21 000 a year, up from £15 000 under the current system.

Those students with higher earnings would pay an interest rate equal to the government's cost of borrowing (inflation plus 2.2%), while students earning below the repayment threshold would pay no real interest rate, and their loan balance would rise only in line with inflation.

MARTIN RICKETT/PA

**Student places would rise by 10% over the next three years under the new rules, said Lord Browne**

The review also says that although universities could set their own fees, those that charged more than £6000 a year would have a tapered levy placed on them to ensure that those that charge the most contribute more to supporting the poorest students.

Lord Browne said that, although students would be paying more for their education, his proposals would give them more power to choose where to study and would allow for a 10% rise in the number of student places over the next three years.

Launching the report, Lord Browne said, "Our higher education system is world renowned, but too often it enshrines the power of universities and not the power of students. These reforms will put students in the driving seat of a revolutionary new system.

"Under these plans universities can start to vary what they charge, but it will be up to students whether they choose the university. The money will follow the student, who will follow the quality."

Under the plans the amount of public funding for higher education could be removed from all but "priority" subjects, such as medicine, science, and engineering, says the report.

It says: "There is a critical role for public investment even if students are investing more.

"There are clinical and priority courses such as medicine, science and engineering that are important to the wellbeing of our society and to our economy. The costs of these courses are high and, if students were asked to meet all of the costs, there is a risk that they would choose to study cheaper courses instead."

***Securing a Sustainable Future for Higher Education in England*** **is at http://hereview.independent.gov.uk/hereview/report/.**

Cite this as: *BMJ* 2010;341:c5723

## Patient summary care records are to be scaled back in content

**Michael Cross** LONDON

The most clinically contentious element of Labour's £13bn (€15bn; $21bn) programme to computerise the NHS in England has received a new lease of life from the coalition government. Simon Burns, the health minister responsible for IT, indicated this week that electronic summaries of patients' health records would continue to be uploaded on to an NHS-wide computer system.

However, the minister endorsed the findings of two reviews that recommend limiting the ambitions of the summary care record and giving patients more information about their right to opt out of having their information shared.

The Department of Health said that the two reviews concluded that electronic summaries of core patient information "will prove valuable for patients needing emergency care."

Bruce Keogh, medical director of the NHS in England and chairman of the first review, told ministers, "It is reasonable for citizens to expect that when they arrive in an accident and emergency department or require treatment out of hours clinicians have access to the essential medical information they need to support safe treatment."

But he said that the core record should contain only a patient's demographic details (name, address, and NHS number), treatments received, allergies, and adverse reactions. These data should be copied from the GP's records and any further information added only with the patient's explicit consent.

A separate review recommended new efforts to inform patients of their right to opt out of the summary care record.

Cite this as: *BMJ* 2010;341:c5714

# NICE decision on dementia drugs was based on "common sense" not evidence, expert says

**Zosia Kmietowicz** LONDON

The claim by the National Institute for Health and Clinical Excellence that its decision to recommend three acetylcholinesterase inhibitors for people with mild Alzheimer's disease is based on new evidence of the drugs' effectiveness is a "red herring," an expert has said.

Clive Ballard, from King's College London and director of research at the Alzheimer's Society, said that the change in the guidance was more a result of a "constructive dialogue" with interested parties and a new interpretation of existing evidence than novel data becoming available.

NICE announced on 6 October that it was recommending that the three drugs—donepezil (marketed as Aricept), galantamine (Reminyl), and rivastigmine (Exelon)—be prescribed for people with mild forms of the disease in updated draft guidance on the treatment of Alzheimer's disease (*BMJ* 2010;341:c5562). Previous guidance issued in 2007 recommended withholding the drugs from this group of patients on the grounds that they were not cost effective.


Professor Ballard said that the evidence for the original guidance was "quite substantial," based as it was on 30 randomised controlled trials.

Although there is some new evidence on the drugs' long term effectiveness, he said, it is "a commonsense factor in the way the evidence is interpreted," in the cost benefit analysis, that has led to changes.

A spokeswoman said that NICE had expedited its review of the guidance on drugs for Alzheimer's disease. She denied that this was because of pressure from patients' groups and the media but was in the light of mounting evidence on the drugs' effectiveness. The *Daily Mail* claimed that the reversal of the advice was the result of a three year campaign by the paper.

Although no "landmark study" existed that

## The bear necessities

**Zosia Kmietowicz** LONDON

It's amazing what two to three days' worth of waste packaging from a kidney unit can make. Children from Great Ormond Street Hospital in London turned the waste packing from their unit into a polar bear with the help of artist Darcy Turner. They wanted to highlight how much waste the healthcare industry produces.

Rukshana Shroff, a nephrology consultant, said that although there was a need for medical equipment to be sterile, "products often come in excessive packaging that is oversized for the product and contain unnecessary extra bits of plastic that are simply discarded.

"The plastic is not recycled, and the manufacturers do not provide facilities for recycling the waste: this accounts for 72% of the carbon impact of kidney care, and the majority of emissions are attributable to pharmaceuticals, medical equipment, and waste services."

The unit has signed up to the green nephrology programme to support the transformation to sustainable kidney care (http://greenerhealthcare.org/green-nephrology).

Cite this as: *BMJ* 2010;341:c5705

# Demand for crack and cocaine addiction treatment drops

**Jacqui Wise** LONDON

The number of drug users seeking treatment for cocaine and crack addiction in England has fallen for the first time.

A National Treatment Agency for Substance Misuse report, *Drug Treatment in 2009-10*, shows that the fall occurred in all age groups but was particularly marked among 18-24 year olds.

The new figures show that the number of people having treatment for problems with powder cocaine fell from 8522 in 2008-9 to 7304 in 2009-10. The figures had steadily increased in the preceding five years.

For crack cocaine the number being treated rose steadily from 2005 to a peak of 5045 in 2008-9 and then dropped last year to 3686. For those being treated for crack and heroin together the number fell from 25 460 in 2008-9 to 21 341 in 2009-10.

Announcing the results, the agency's chief executive, Paul Hayes, said, "We now have five years of robust data from the national drug treatment monitoring system so we can show some reliable trends. It shows a reverse in the trend of steadily increasing demand." He added, "It can probably be linked with the decline in the quality of cocaine. It is welcome news, but there is no room for complacency."

For young adults the numbers seeking drug treatment fell for every drug except cannabis, which suggests this age group is turning away from class A drugs. Just over 4400 under 25s had cannabis as their main drug, accounting for 29% of all new treatment cases, compared with 18% four years earlier.

Mr Hayes said, "Cannabis use is falling, but the number of people accessing treatment for cannabis use is increasing. This is due to the stronger forms of cannabis available, which create problems for a small number of users, particularly those with mental health problems."

Last year's report showed a big drop in demand for heroin treatment among 18-24 year olds. This trend has continued and now affects the 25-29 year age group as well. However, the report shows an increase in the over 40 age group coming into the treatment system for heroin addiction for the first time.

The report is published alongside research from the University of Glasgow, which shows that the estimated number of heroin addicts in England fell by almost 11 000 between 2006-7 and 2008-9 to 262 428. Overall in 2008-9 there were an estimated 321 229 problem drug users in England, which corresponds to 9.4 per 1000 of the population aged 15 to 64.

The report highlights a number of regional variations. London was the region with the highest estimated prevalence for problem drug use, followed by the north west and Yorkshire and the Humber. The north west had the highest estimate for opiate use, and London the highest figures for crack cocaine use.

The report also shows that for people coming into treatment in 2009-10, 74% of powder cocaine users and 60% of crack users either stopped or reduced their use within the first six months. And within six months of starting treatment more than a third of heroin users had stopped using the drug altogether.

**Both reports can be found at www.nta.nhs.uk.**

Cite this as: *BMJ* 2010;341:c5616

persuaded NICE's appraisal committee to reverse its original guidance, there was a "firming up of the evidence" on the effectiveness of the drugs that "enabled the committee to be more confident about the drugs in the mild stages [of the disease]," the spokeswoman said.

In 2009 NICE found that for people with mild Alzheimer's disease the best estimate of cost per quality adjusted life year (QALY) gained with the acetylcholinesterase inhibitors ranged from £56 000 (€64 000; $90 000) to £72 000. This ruled out the drugs for use in the NHS.

But using the updated model NICE estimated that acetylcholinesterase inhibitors cost around £30 000 per QALY gained, low enough to be recommended for NHS use. NICE also estimated that treatment with one of these drugs delayed the time to residential care by about six weeks, leading to savings of approximately £4500.

Cite this as: *BMJ* 2010;341:c5642

# Trusts warn that NHS reforms could lead to poorer patient care

**Adrian O'Dowd** LONDON

NHS trusts in England are concerned at the "significant risks and worrying uncertainties" of the proposed reforms to the health service, mirroring concerns raised by medical professional bodies.

The NHS Confederation, which represents 95% of NHS organisations, warns that the government's plan to make major structural changes to the NHS when money is being trimmed could lead to poorer patient care and loss of financial control.

The confederation, which published its response to the government's white paper, *Equity and Excellence: Liberating the NHS*, on 11 October, said its members had major concerns that GPs did not yet have enough capacity and capability to take over commissioning, as envisaged by the government.

In its response the confederation makes 40 suggestions for improving the new system.

Although confederation members supported the government's aim of empowering patients and involving clinicians more closely in decision making, there were "significant risks, worrying uncertainties, and unexploited opportunities" that had to be dealt with if the plans were to succeed.

One of the concerns that emerged is that the GP consortiums that will take control of much of the NHS budget from 2013 don't seem to be clearly accountable to patients and the public.

Cite this as: *BMJ* 2010;341:c5693

# Why don't scientists have the same visa exemptions as footballers, ask Nobel winners

**Adrian O'Dowd** LONDON

The government's plan to cap immigration to the United Kingdom poses a threat to the country's standing as a centre of scientific excellence, claim eight Nobel prize winning academics.

The group of experts has spoken out collectively in opposition to the coalition government's plans to restrict the number of migrants coming to the UK from outside the European Union.

In a letter to the *Times* (7 October) the laureates said, "The UK has long had a reputation as a global centre of research excellence."

The world's best scientists had long been attracted to the UK by its "world class institutions" and inclusive culture, which had produced many benefits for science and medicine, they argued.

The government's plan to cap migration to the UK, they warned, "would damage our ability to recruit the brightest young talent, as well as distinguished scientists, into our universities and industries."

The letter is signed by eight British or British based scientists who have all won a Nobel prize for medicine, physics, or chemistry since 1996, including Andre Geim and Konstantin Novoselov, from the University of Manchester, who were awarded the prize on 5 October.

The other signatories are Paul Nurse, Tim Hunt, Martin Evans, Harry Kroto, John Walker, and John Sulston.

The letter calls for the government to rethink its recently introduced visa policy.

An interim cap of 24 100 work visas for non-European Union citizens in 2010 was introduced in June, and the government plans to replace it with permanent measures next April.

Exceptions to the rules have already been made for sport, a development that the laureates commented on, saying, "The government has seen fit to introduce an exception to the rules for Premier League footballers.

"It is a sad reflection of our priorities as a nation if we cannot afford the same recognition for elite scientists and engineers."

Sir Harry Kroto, who won the Nobel prize for chemistry in 1996, speaking on the BBC Radio 4's *Today* programme, said, "It does seem a bit odd when footballers are allowed to break this [visa rule].

"If one looks over the years, one quarter of the Nobel prizes that came to the UK were won by immigrants from outside."

Cite this as: *BMJ* 2010;341:c5622


MARK THOMAS

**More than 2000 people attended a "Science is vital" rally in London on Saturday 10 October**

TONY MARSHALL/EMPICS/PA

## How immigration to UK works for skilled workers

All skilled workers who want to emigrate to the UK can apply for a tier 1 (general) skilled migration visa. People on student or graduate visas, work visas, or work permits who want to extend their stay in the UK can also apply for this visa.

**To gain a visa the applicant has to score 100 points in the tier 1 points test. The points awarded are based on:**

**English language ability (10 points)**—this is mandatory

**Settlement funds (10 points)**—applicant must have earned £25 000 over a 12 month period in the past 15 months (also mandatory)

**Qualifications**—30 points for a bachelor's degree, 35 for a master's, and 45 for a doctorate

**Age**—ranging from 20 points for ‹29 years down to 0 points for ›40

**Past earnings in previous year**—ranging from 5 points for earnings between £25 000 and £29 999 to 80 points for £150 000 or above

**UK work experience (5 points for previous earnings in the UK)**

**UK qualifications (5 points for a UK qualification)**

# IN BRIEF

**Southern Sudan sees upsurge of kala-azar:** Recurrent outbreaks of visceral leishmaniasis (kala-azar) have been reported in the autonomous region of Southern Sudan. A total of 6363 cases and 303 deaths have been recorded since outbreaks began in September 2009. Most patients (70%) are children aged under 15 years who are also malnourished and have other illnesses. WHO is supporting the relief operation but says that another $0.7m (£0.4m; €0.5m) is needed.

**NICE has approved 73% of cancer drugs since 2002:** An analysis by the *Financial Times* has found that the UK National Institute for Health and Clinical Excellence (NICE) approved 73% of 102 uses of cancer drugs between 2002 and August 2010. Between March 2000 and July this year NICE approved 309 (83%) of the 372 drugs and treatments it assessed.

**Canadian doctors advise phasing out codeine:** Codeine's metabolism to morphine is not only unpredictable but also potentially dangerous, say doctors in Canada (*CMAJ*, doi:10.1503/cmaj.101411). Evidence indicates that codeine can cause death even at conventional doses, and infants and small children are at highest risk. Toronto's Hospital for Sick Children has removed codeine from its formulary, and other hospitals should follow, says the editorial.

**Mental health hospital launches online referral system:** The South London and Maudsley NHS Foundation Trust has launched an online referral system for health professionals. Health professionals can refer patients from anywhere in the UK to the trust's specialist mental health services (www.national.slam.nhs.uk).

**GPs "uncertain if NHS shake-up will benefit patients":** A BBC survey of 827 doctors has found that less than a quarter thought that putting GPs in charge of budgets would noticeably improve services for patients. Most believed that they were not trained to take on commissioning. Seven in 10 respondents said they thought the changes outlined in the government's health white paper would lead to a greater role for the private sector.

***BMJ* editor gets accolade:** The *BMJ*'s editor in chief, Fiona Godlee, was named the 80th most important figure in British science in the top 100 list compiled by the *Times*'s monthly science magazine *Eureka*. The Nobel prize winning geneticist Paul Nurse was named the most influential British scientist.

Cite this as: *BMJ* 2010;341:c5646

# GMC imposes conditions on surgeon's registration after the death of two babies

**Clare Dyer** BMJ

A doctor whose failings in obstetric emergencies may have contributed to the death of two babies has been found guilty of deficient professional performance by the General Medical Council.

Ashok Mohanty also left gauze swabs in two women's bodies within a single week. Last week a GMC fitness to practise panel imposed 15 conditions on his registration for a period of 18 months. These include working with a postgraduate dean to formulate a personal development plan to tackle deficiencies in his management of emergencies and working only in the NHS, where his work will be supervised.

Ashok Mohanty has 15 conditions on his GMC registration

CENTRAL NEWS.CO.UK

He was also found guilty of dishonesty in answering "no" on a job application form when asked whether there were any conditions on his registration, although a GMC interim orders panel had imposed conditions pending the full hearing.

The clinical incidents happened between September 2006 and October 2007, when Dr Mohanty was a year 5 specialist registrar and then a locum senior specialist registrar at King's College Hospital, Denmark Hill, south London.

Both women who had swabs left in their bodies developed infections, the panel heard. Dr Mohanty had written in their notes that the swabs were all accounted for after the operation. In his evidence to the GMC he blamed the midwives for not counting the swabs accurately and removing the instrument trays before he had a chance to check them.

In the cases of three patients in labour the panel concluded that his performance fell below the standard of a competent specialist registrar. In the two cases in which babies died "fast and effective action was required, and the lack of it may have contributed to the tragic and unnecessary death of the baby," said Tom Kark, counsel for the GMC.

One was the case of Patient D. Dr Mohanty failed to take adequate steps to get her to theatre quickly and then attempted a forceps delivery although he had been told not to by a senior consultant. The baby was born by emergency caesarean section but died.

In the case of Patient F, whose baby also died, Dr Mohanty failed to appreciate the urgency of the situation, despite a "suspicious to pathological CTG [cardiotocogram]" recorded by another doctor. When, according to expert evidence to the panel, the baby had 10 minutes to live and he should have advised immediate transfer to theatre, he gave a direction to increase the oxytocin infusion, a move that a GMC expert witness described as "absolutely contraindicated."

In Patient E's case the panel found that Dr Mohanty failed to take immediate action to perform an emergency caesarean section, as he should have done, given the significantly abnormal cardiotocogram.

The panel heard Dr Mohanty had undergone training to improve his skills. Testimonials from colleagues at Barnet and Chase Farm Hospitals NHS Trust, where he worked after King's, and the Conquest Hospital, East Sussex Hospitals NHS Trust, where he has worked since June 2010 as a staff grade doctor in obstetrics and gynaecology, described him as "a doctor with good clinical skills who has handled patients' management well," said the panel chairman, Michael Whitehouse.

Taking these into account, the panel was satisfied that suspension would be disproportionate and that imposing conditions would be "sufficient and proportionate for the protection of patients and the public interest."

Cite this as: *BMJ* 2010;341:c5663

# Experts criticise proposed new German law for favouring drug companies

**Annette Tuffs** HEIDELBERG

A new law on approving drugs for reimbursement by German insurance companies currently being debated in parliament could put the safety of patients at risk, experts have warned.

The law would substantially weaken the role of the German Institute for Quality and Efficiency in Health Care (IQWiG), the German equivalent of the UK National Institute for Health and Clinical Excellence, and lead to inefficient and dangerous drugs being approved, say experts.

An amendment to the law proposed by the governing coalition of the Christian Democrats and the liberal Free Democratic Party says that all new drugs admitted to the market should be reimbursed by health insurance companies

# Boehringer Ingelheim halts further development of its libido drug for women after negative FDA review


**Jeanne Lenzer** NEW YORK

The German drug firm Boehringer Ingelheim announced that it is withdrawing from development its drug to increase female sexual desire.

The drug, flibanserin, which reduces serotonin concentrations while raising those of dopamine and noradrenaline (norepinephrine), was originally intended to be an antidepressant.

The company made the announcement after negative reviews by an advisory panel of the US Food and Drug Administration in June (*BMJ* 2010;341:c3339) and a letter issued by the agency in August in response to the company's new drug application.

Boehringer Ingelheim conducted several studies of the drug, measuring two co-primary end points: satisfactory sexual encounters and sexual desire. Although pooled data showed a rise in the number of satisfactory sexual encounters among women treated with flibanserin, there was no difference in sexual desire between women treated with placebo and those treated with flibanserin.

The FDA said the failure to show benefit in one of two co-primary end points meant that the studies failed to fulfil the specified outcome. Flibanserin is the third failure in a series of drugs aimed at treating hypoactive sexual desire disorder.

Cite this as: *BMJ* 2010;341:c5701

# Online sale of drugs and medical health checks should be better regulated, says Nuffield report

**Ann McGauran** LONDON

Doctors should be trained in how to advise people who search online for health information and to buy drugs, says a new report from the Nuffield Council on Bioethics.

The report says that although online health information and services are convenient to use and extend choice, they could mislead, confuse, or create unnecessary anxiety.

Published after a two year inquiry, the report also calls on the government to provide high quality health information on the internet or to ensure that such information is available. Healthcare professionals should draw their patients' attention to these sites, says the council.

The report recommends that UK organisations such as medical schools, royal colleges, and the General Medical Council should be responsible for training and advising healthcare professionals on caring for patients who are increasingly using the internet to access health information.

It says that UK governments should set up an accreditation scheme for providers of online health records. The report also calls for better regulation of services sold directly to consumers such as personal DNA testing.

The commercial sale of whole body scans as a health check for people without symptoms of illness should be banned, says the report. It says that any potential benefits do not justify the potential harm caused by the radiation. But the council does not consider that there is enough evidence to prohibit part body computed tomography scanning of people without symptoms.

MARK THOMAS

**Christopher Hood said that health websites need to specify where they get their information**

Claims that personal genetic profiling services are leading to a new era of "personalised health care" are overstated and should be treated with caution, says the report. It recommends that regulators of these services should request evidence for the clinical claims made by companies.

With regard to the online purchase of drugs the council calls on governments to monitor and assess the incidence and extent of harm caused.

Christopher Hood, chairman of the report's working party, said that websites offering health information and advice should state "where the information originates and what it is based upon, who wrote it, and how the author or organisation is funded."

***Medical Profiling and Online Medicine*** **is at www.nuffieldbioethics.org/personalised-healthcare-0.**

Cite this as: *BMJ* 2010;341:c5710

unless they are proved to be inefficient.

Under current regulations new drugs are excluded from reimbursement if they have severe side effects or no additional advantages over drugs already on the market. These requirements would disappear under the new law.

Opposition MPs have criticised the government, claiming that it has given way to lobbying from the drug industry.

Drugs are presently admitted on the German market if they fulfil certain standards of efficiency and safety. However, IQWiG focuses solely on pharmacological criteria, such as reduction of hypertension or blood glucose concentrations. It is down to the Federal Joint Committee of the German healthcare system to decide whether a drug improves outcomes and quality of life, has no major side effects, and should be refunded by the health insurance companies. The committee asks IQWiG to analyse and prepare the scientific evidence for its decision.

Under the new law the committee will have to base its decision to reject reimbursement of a drug's cost on proved inefficiency.

But Jürgen Windeler, the director of IQWiG, said, "We cannot prove that inefficiency is there. There are no studies, least of all by the pharmaceutical industry."

Reiner Hess, the head of the joint committee, told *Der Spiegel* magazine on 4 October, "This reversal of the burden of proof jeopardises patient safety." He criticised the fact that in future the health ministry, not the joint committee, will set the criteria for reimbursement of drug costs. He also condemned the new regulation, which would automatically certify all drugs for rare diseases as they came on the market.

Cite this as: *BMJ* 2010;341:c5650

**See ANALYSIS, p 809**

# Doctor who spoke out about atrocities in Darfur wins award

**Peter Moszynski** LONDON

Halima Bashir (not her real name), a doctor who was gang raped by soldiers after speaking out about atrocities in Darfur in western Sudan (*BMJ* 2008;337:a951, doi:10.1136/bmj.a951), has won the Anna Politkovskaya award for female human rights defenders. The annual prize, in memory of the campaigning Russian journalist murdered in 2006, was awarded by the charity Reach All Women in War, which says that "violence against women during conflict has reached epidemic proportions."

Dr Bashir was unable to attend the ceremony in London because of last minute security concerns, but in a statement she said, "My own life is testimony to the one conflict that has caused more death and suffering than any other today."

Last month the Sudanese government accused her of being part of a conspiracy between Darfur rebels, Western governments, and the International Criminal Court and revealed her real name, leading to threats against her. The organisers of the award had to take the threats seriously, as another recipient, Natalia Estemirova, was murdered in Russia last year. Sudan's security services have threatened to kill anyone cooperating with the court.

JENNY MATTHEWS

**Dr Bashir (a pseudonym) has to keep her identity secret because of death threats**

Dr Bashir said she had to speak out because, "as a trained medical doctor, I treated the victims of the child rapes in Darfur. Imagine it. Imagine a country where grown men and leaders drew up a policy of child rape as a weapon of waging war. This is what happened in my country. The world failed to stop the horror, and still the refugee camps are not secure."

**More information is at www.rawinwar.org/content/view/117/197/.**

Cite this as: *BMJ* 2010;341:c5629

# New US institute for outcomes research officially starts work

**Bob Roehr** WASHINGTON, DC

The United States ratcheted up its commitment to research on comparative effectiveness in health care when the Patient-Centered Outcomes Research Institute officially began operations on 1 October.

The journal *Health Affairs* used the occasion to publish an issue on comparative effectiveness, which it unveiled at a 5 October briefing in Washington, DC.

The institute differs significantly from the United Kingdom's National Institute for Health and Clinical Excellence in that it doesn't have the authority to approve treatment for use in the US healthcare system. Criticisms by Republicans that such an institute would lead to the establishment of "death panels" ensured that the final legislation barred Medicare from using the institute's work in deciding whether and how much to pay for a given intervention.

The field of comparative effectiveness research received a $1.1bn (£0.7bn; €0.8bn) boost under the 2009 economic stimulus package, allocated by the end of September 2010.

**bmj.com** Analysis: "US moves to improve health decisions" (*BMJ* 2010;341:c3615)

Cite this as: *BMJ* 2010;341:c5652

# First patient enters trial to test stem cells in spinal injury

**Susan Mayor** LONDON

The first patient has been recruited to a clinical trial to assess the safety of oligodendrocyte progenitor cells derived from human embryonic stem cells to treat complete spinal cord injury, a US company, Geron, reported on Monday 11 October.

The phase I study is investigating the safety and tolerability of stem cell derived oligodendrocyte progenitor cells. The aim is to recruit a group of patients with injuries graded as A on the American Spinal Injury Association impairment scale, which means that they have complete loss of sensory and motor function, with the last fully preserved neurological level from the T3 to T10 thoracic vertebrae.

Patients who meet these criteria are being recruited at seven US medical centres. Two million of the cells will be injected into the site of each patient's spinal cord lesion at a single time point between seven and 14 days after the injury occurs.

The trial's primary end point is safety, measured by the frequency and severity of adverse events related to the injected stem cells, to the injection procedure, or to the concomitant immunosuppression administered during the first year after treatment. Neurological function will also be assessed as a secondary end point.

The stem cells being used in the trials have been developed by Geron. These cells are precursors to oligodendrocytes, which have several functions in the nervous system, including producing myelin that enables efficient conduction of nerve impulses.

Oligodendrocytes are lost in spinal cord injury, resulting in loss of myelin and neurones, which disrupts transmission of nerve impulses and results in paralysis.

Preclinical studies in which oligodendrocyte progenitor cells were injected into the site of spinal cord injuries in animals showed that the cells migrated throughout the lesion site. They then matured into functional oligodendrocytes that remyelinated axons and produced neurotrophic factors, resulting in improved locomotion in the treated animals.

The ultimate goal for the use of these cells in humans is to repair spinal cord injuries by injecting the cells directly into the spinal cord lesion.

Chris Mason, professor of regenerative medicine bioprocessing at the Advanced Centre for Biochemical Engineering, University College London, said, "This first in man study marks the dawn of the 'stem cell age.' The essential transition, from bench to bedside, is a critical step change in the progression of embryonic stem cells towards eventual cures."

He added, "There are still many years of rigorous testing ahead, and no doubt there will be setbacks and failures before we have safe and effective cell based therapies. This pivotal clinical trial is a major morale boost for scientists, clinicians, and, most of all, patients by finally commencing the transformation of stem cells from a scientific curiosity into advanced health care."

Thomas Okarma, president and chief executive office of Geron, said, "When we started working with human embryonic stem cells in 1999, many predicted that it would be a number of decades before a cell therapy would be approved for human


CHARLES PLATIAU/REUTERS

French health minister Roselyne Bachelot-Narquin had support from the UK, Finland, and Spain

# Patients won't get reimbursed for care abroad without prior approval

**Rory Watson** BRUSSELS

National health authorities are entitled to insist that patients wishing to be reimbursed for specialised medical treatment outside a hospital setting in another European Union country must first receive prior authorisation, says the European Court of Justice in a new ruling.

The judgment is a setback for the European Commission, which had taken France to court, arguing that the authorisation requirement violated European law and one of the EU's basic principles: the freedom to provide services. The French government, supported by the United Kingdom, Finland, and Spain, successfully contested the commission's interpretation of European rules.

The ruling by the Luxembourg based judges is the latest in a series of cases involving the right of patients to be treated in another member state and be reimbursed for the costs.

Under France's social security code, patients must get formal authorisation before going abroad for treatment requiring the use of major medical equipment. They submit their application to the health fund to which they are affiliated and must receive a reply within two weeks. If no reply is given, authorisation is deemed to have been given.

The treatment includes nuclear magnetic resonance imaging and spectrometry apparatus used to detect and treat cancer.

In its ruling the European court pointed out that existing case law states that patients should not be hampered by any restrictions if they wish to receive medical services and be reimbursed for treatment in another EU country, whether this is in a hospital or not. It noted that the prior authorisation required by France could be considered as a deterrent that might prevent people using this right.

However, it also said that it should be possible for the purchase of sophisticated medical equipment to be subject to planning policy to ensure a rational, stable, balanced, and accessible supply of up to date treatment throughout the whole country and to avoid, as far as possible, any waste of financial, technical, and human resources.

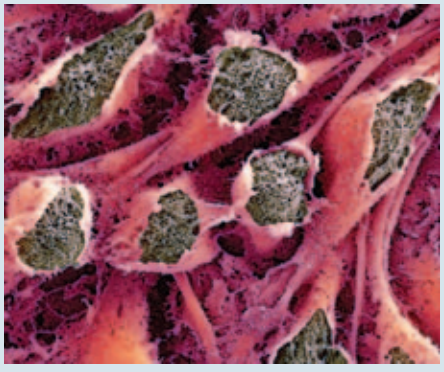
Therefore it ruled that, given the possible dangers to the organisation of public health policy and to the financial balance of the social security system, the requirement of prior authorisation for this kind of treatment was a justified restriction.

Cite this as: *BMJ* 2010;341:c5657

clinical trials. This accomplishment results from a succession of inventive steps to enable production of master cell banks [to the necessary standard for use in humans] and preclinical studies in vitro and in animal models of spinal cord injury, leading to [authorisation] by the FDA to initiate the clinical trial."

The study is planned to be completed by October 2012.

Cite this as: *BMJ* 2010;341:c5724



PROFESSOR MODRAG STOJKOVIC/SPL

**The study has been described by a British scientist as "the dawn of the stem cell age"**

# Dutch doctors warn that the overuse of antibiotics in farming is increasing resistance

**Tony Sheldon** UTRECHT

Public health experts in the Netherlands are calling for an urgent reduction in the use of antibiotics in farming as evidence mounts of transmission of antimicrobial resistance to humans through the food chain.

Dutch agriculture tops a European league table of the use of antibacterial agents per weight of slaughtered animal (*Journal of Antimicrobial Chemotherapy* 2010;65:2037-40). Amid concerns that this has caused a rise in numbers of bacteria producing extended spectrum ß lactamase (ESBL)—an enzyme that confers resistance to modern antibiotics, including cephalosporins—the government this year ordered a 50% cut in antibiotic use by farmers within four years.

This followed a call by Roel Coutinho, director of the Centre for Infectious Disease Control of the Dutch Institute for Public Health and the Environment, for drastic short term action. Professor Coutinho told the *BMJ* that the evidence of transmission was now even stronger.

Details have recently emerged of the first documented case of a death in the Netherlands resulting from infection by multidrug resistant *Escherichia coli* bacteria that produce ESBL, which appeared to be indistinguishable from the type of ESBL found in poultry.

Maurine Leverstein-van Hall, a medical microbiologist and project leader for antibiotic resistance at the institute, explained that in January an 85 year old woman died from urosepsis soon after being admitted to hospital. She failed to respond to the recommended treatment, cephalosporins.

The woman had not recently visited a hospital, nor had she been prescribed antibiotics, so was not considered at risk of antibiotic resistance. However, her blood culture strain showed ESBL-producing *E coli* bacteria that carried a CTX-M-1 gene, the same as the predominant ESBL strain found in poultry meat.

Cite this as: *BMJ* 2010;341:c5677