bmj.com BMA warns against letting patients have access to their electronic records
UK news Lansley defends NHS preparations for this year's flu season, p 127
World news French drug journal is sued for criticising drug's licence extension, p 130
For the full versions of articles in this section see bmj.com

UK needs new health research agency to speed up approval process

Michael Rawlins: European directive has been "a disaster"

Luisa Dillner BMJ

Health research in the United Kingdom is being stifled by over-regulation and urgently needs a new single agency to reduce delays in launching trials, says a report from the Academy of Medical Sciences.

The work was commissioned in May 2010 by Andy Burnham, the then Labour health secretary for England, after a report earlier that year from the academy warned that the UK's global share of patients in clinical trials had fallen from 6% to 2% in the past decade. The new report was written by a working group from academia, industry, the NHS, medical research charities, and regulators and was chaired by Michael Rawlins, chairman of the National Institute for Health and Clinical Excellence.

Launching the report, Professor Rawlins said, "Medical research in the UK is over-regulated [and] over-governanced . . . Just as an example, Cancer UK calculated that the time it takes from the day they award a research grant for a particular trial to the time the first patient comes into the trial is 621 days, and there's another 179 before the last patient comes in. We cannot go on like this."

Professor Rawlins said that there was almost universal agreement among the more than 300 submissions to the working party on the causes of the bottlenecks in launching clinical trials. The first bottleneck is the European Clinical Trials Directive, introduced in 2001. The report says that it has been implemented more strictly in the UK than in other European Union member states.

"It has been a disaster," said Professor Rawlins. "All sorts of research that should come nowhere near the directive has been mopped up in it." He gave the example of a research team that had wanted to conduct a trial of the cognitive effects of high dose morphine in patients with advanced cancer. The trial involved a questionnaire for patients, which was counted as an extra test, thus bringing it under the directive. This required the team to keep the morphine at below 4°C, to take out indemnity insurance costing £4000 (€4800; $6220), and to report all serious adverse events.

"These poor patients are all patients with advanced cancer, so of course they are all going to get the ultimate adverse events," said Professor Rawlins. In the face of such bureaucracy the team abandoned the trial, he added.

The second bottleneck is getting ethics approval. The report praises the National Research Ethics Service, which provides general approval, but says that trials often need specialist ethical approval. The approval service operates sequentially, causing considerable delays.

The report recommends that general and ethical approval take place in parallel.

But the biggest delays are caused by research governance arrangements in NHS trusts. Many studies involve several trusts, all of which want to carry out their own governance checks—meaning, says the report, that each trust replicates what the others are doing. "They'll each want to look at patient information leaflets, and they will all want different modifications to be made," said Professor Rawlins. This means that it can take months to give approval. "Too many trusts regard it [research] as an add-on activity," he said.

The report recommends one single port of entry for researchers through a new body.

A New Pathway for the Regulation and Governance of Health Research **is at www.acmedsci.ac.uk/index.php?pid=99.**

Cite this as: *BMJ* 2011;342:d185

See FEATURE, p 143

Publishers withdraw free access to 2500 journals in Bangladesh

Zosia Kmietowicz LONDON

Five publishers have withdrawn free access to more than 2500 health and biomedical online journals from institutions in Bangladesh. One research leader has described the situation as "very discouraging."

From 4 January Elsevier Journals withdrew access in Bangladesh to 1610 of its publications, including the *Lancet* stable of journals, which had been available through the World Health Organization's Health Inter-Network for Access to Research Initiative (HINARI) programme. HINARI was set up in 2002 to enable not for profit institutions in developing countries to gain access online to more than 7000 biomedical and health titles free or at very low cost.

Springer has withdrawn 588 of its journals from the programme in Bangladesh and Lippincott Williams and Wilkins 299 journals. The American Association for the Advancement of Science and the American Society for Animal Science have withdrawn access to, respectively, two and three of their journals. Altogether 150 publishers take part in HINARI.

Tracey Koehlmoos, head of the health and family planning systems programme at the International Centre for Diarrhoeal Disease Research in Dhaka, said, "We are a little less than 300 scientists eking out world class research on a shoestring budget without the purchasing power capacity of a big university in the West. HINARI has been our lifeline. My colleagues publish in many of these journals, and now we won't even have access to our own papers." She described the situation as very discouraging and said it would make working in a challenging environment even harder.

Cite this as: *BMJ* 2011;342:d196

IN BRIEF

Record numbers of Irish patients wait for hospital beds: Some 570 patients were waiting for hospital beds in Ireland's public hospital emergency departments on 5 January, the highest number since records began in 2004. Cuts to healthcare budgets and an outbreak of H1N1 flu are blamed. The Irish health budget for 2011 has been cut by 5.7% (€765m (£635m; $990m)).

Law will force Chinese to visit elderly relatives: A draft amendment of China's Law on the Protection of the Rights and Interests of the Elderly will require the adult offspring of elderly parents to pay them regular visits, take care of their spiritual needs, and not neglect or isolate them, say reports in China's media.

New team will investigate maternal and neonatal deaths: A new team based in Oxford University's National Perinatal Epidemiology Unit will lead the UK's maternal and newborn clinical outcomes review programme from April 2011. The programme will investigate the deaths of women and their babies during or after childbirth and cases where women and their offspring survive serious illness during pregnancy or after childbirth.

Sessional GPs suffer from isolation: Professional isolation remains a major issue for sessional GPs in the United Kingdom, shows research by the Royal Medical Benevolent Fund. Problems include limited access to information about education, clinical systems, and professional support structures. Opportunities for interaction with peers, including feedback, are lacking.

Confidential enquiry wins funding for further reviews: The National Confidential Enquiry into Patient Outcome and Death (NCEPOD) has won its funding bid to continue undertaking confidential case reviews into hospital care. Its chairman, Bertie Leigh, says that the reviews "enable the profession to examine its own work self critically." In 2011 NCEPOD will be publishing studies into surgery in children and perioperative care.

Former Royal College of Surgeons president supports assisted suicide: Terence English, who carried out Britain's first successful heart transplantation, has joined the right to die campaigning group Healthcare Professionals for Assisted Dying. Sir Terence said that he would be prepared to help a patient take their own life provided that "safeguards" were in place.

Cite this as: *BMJ* 2011;342:d133

Hospitals should offer bingo and art sessions, says BMA

Jacqui Wise LONDON

Hospital patients should have the opportunity to play bingo and card games and to take part in creative activities to overcome boredom and improve clinical outcomes, says a new report from the BMA's board of science.

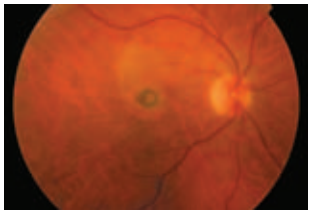
The report says that a patient's physical environment is also important: sunnier rooms, views of green spaces, and quieter wards can make patients happier and speed up their recovery. While many current buildings may not allow them, consideration of such changes should be paramount in new buildings and renovations.

The report says that the broader wellbeing of the patient can be lost in the traditional medical model of healthcare and that hospitals should place greater importance on the psychological and social needs of patients.

Vivienne Nathanson, the BMA's head of science and ethics, said, "People tend to think it's just frippery, but it can be cost saving in the long run. Having more light, less noise, and a more pleasant hospital environment can help people get better quicker and go home sooner, so there is a financial saving there."

She added: "With the government's emphasis on 'big society,' this could be something that volunteers could do—come and play cards with patients, for example."

The report, produced after a debate at the



Roche does not want bevacizumab (Avastin) licensed for age related macular degeneration (above right)

Health ministers may call for appraisal of unlicensed cancer drug for eye care

Nigel Hawkes LONDON

Health ministers in England are considering calling for a full technical appraisal of a cancer drug to treat eye conditions, even though it is unlicensed for the indication.

Bevacizumab (Avastin) has been widely used in the US and the UK to treat the wet form of age related macular degeneration, despite its lack of a licence, because it is much cheaper than the licensed product ranibizumab (Lucentis). Both were originally developed by Genentech, part of Roche, and ranibizumab has been approved for NHS use by the National Institute for Health and Clinical Excellence (NICE). Both share a common mode of action, inhibiting blood vessel growth.

Bevacizumab is around 15 times cheaper than ranibizumab, if it is bought as a cancer drug and then split into many separate doses for injection into the eye. But Roche has no desire to apply for a licence because it would be undercutting its own more expensive alternative, which is marketed in the UK by Novartis.

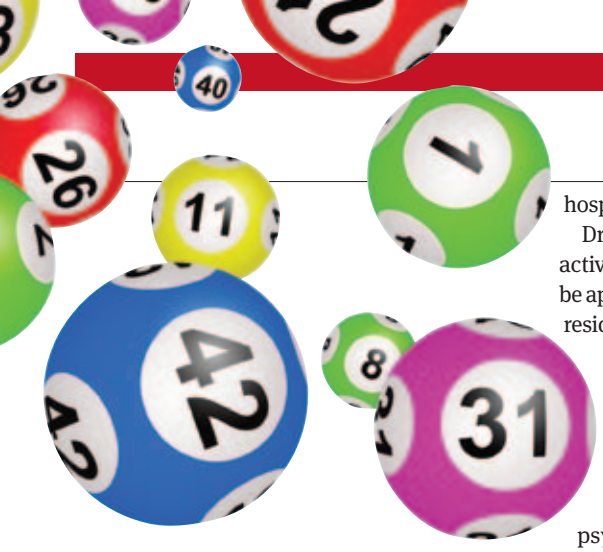
The last UK government asked NICE to examine the issues and provide advice. It published its findings early in December, concluding that there was support among interested parties for a full appraisal which would need to incorporate an assessment of the safety and quality of bevacizumab by a regulatory body, or through regulatory expertise. And since Roche would not be responsible for monitoring the use of the drug, special arrangements for safety monitoring would need to be implemented.

It is now up to ministers to decide if they want NICE to complete a full appraisal. A Department of Health spokeswoman said this week that the department was considering the issue with input from the Medicines and Healthcare products Regulatory Agency (MHRA).

Although it is not unprecedented for NICE to be asked to review unlicensed or off-label medicines, the MHRA generally sets its face against the use of such products when licensed alternatives are available.

Several clinical trials of bevacizumab in eye conditions have been carried out or are in progress, according to a report commissioned from Southampton Health Technology Assessments Centre.

Cite this as: *BMJ* 2011;342:d62



BMA's annual representative meeting in 2009, examines the evidence base for a number of different activities, such as playing board games, dancing, music, creative writing, and visual art. It says that art and humanities programmes do more than just help beat the boredom of a hospital stay; they can produce positive physiological and psychological changes in clinical outcomes, reduce drug consumption, shorten length of hospital stay, and improve mental health.

Dr Nathanson said, "There is a whole range of activities that can be offered, but these should be appropriate to the patient. Long term hospital residents may enjoy bingo, for example.

"There are lots of bits and pieces of good practice being done around the country, but nothing is being done systematically. We would like to hear more examples of what has worked so that these can be shared."

The report also states that meeting the psychological and social needs of patients should be a theme that runs through all medical undergraduate and postgraduate curriculums. And the acquisition of communication skills should be a key feature from the start of medical training.

The Psychological and Social Needs of Patients **is at www.bma.org.uk/health_promotion_ethics/psychologicalandsocialneedsofpatients.jsp.**

Cite this as: *BMJ* 2011;342:d172

End of free access to database will shrink body of UK generated research

Zosia Kmietowicz LONDON

The end of an agreement that allowed UK researchers direct access to a database of anonymised patient records from general practices will have a detrimental effect on research generated in the United Kingdom, a primary care expert has said.

Azeem Majeed, professor of primary care and head of the department of primary care and public health at Imperial College London, told the *BMJ* that the licence agreement between the Medical Research Council and the general practice research database (GPRD), the world's largest primary care database, was "very useful in allowing UK researchers to make greater use of the [database]." He described the end of the scheme as "disappointing."

He added, "The UK has one of the highest uses of electronic patient records in primary care, and these records [have been a] great resource for biomedical researchers."

The licence allowed 50 researchers a year to access the database from 1 December 2005 to 30 November 2010 on a first come, first served basis. The latest data show that 96 investigators used the licence up to 31 March 2010.

The database collects information on about five million patients from around 590 primary care practices throughout the UK. It is used worldwide for research by the drug industry, clinical research organisations, regulators, government departments, and academic institutions. Despite its popularity some people have criticised the database for generating different results from the same datasets (*BMJ* 2010;341:c5980).

Professor Majeed said that before the licence scheme was implemented the main users of the database were based in the United States, Spain, and Switzerland but that after it was set up this was no longer the case.

"We were starting to see research teams in the UK build up expertise in using GPRD, but it is likely that this will start to decrease because of difficulty in accessing GPRD data," he said.

To compensate for the ending of the licence the Medical Research Council has said that it will continue to fund access to the database through its research grant application scheme. The council said that although the "licence arrangement has helped to build capacity in public health and primary care research . . . a more flexible approach is now required."

It added, "For instance, researchers may require access to datasets not covered under the licence or to databases other than GPRD. The new approach will allow researchers to determine what datasets are most suitable."

However, Professor Majeed said that because applying for the council's grants is highly competitive it is likely that most grant applications will be unsuccessful. "Hence, it is very likely that we will see a reduction in UK based research using the GPRD once current projects using data obtained under the old scheme end," he said.

Cite this as: *BMJ* 2011;342:c7455

Lansley defends preparations for this year's flu season

Zosia Kmietowicz LONDON

The health secretary for England, Andrew Lansley, has defended his actions during the current flu outbreak after being accused by Labour of making a "serious misjudgment" for failing to ensure that people at risk of developing serious illness were vaccinated in time.

Speaking in the House of Commons on 10 January the Labour MP Kevin Brennan said that Mr Lansley had "failed to act" by not running the usual advertising campaign last autumn to encourage people to get vaccinated.

However, Mr Lansley denied that he had cancelled the vaccination campaign, and said that he had implemented a flu hygiene campaign after Christmas. He said, "NHS is again well prepared to respond to the pressures that winter brings."

Clare Gerada, chair of the Royal College of General Practitioners, said that pharmacists could help doctors in their task of vaccinating people at higher risk of developing serious illness from flu by asking those presenting for the vaccine whether they fall into one of the at-risk groups. In the past pharmacists have acted as a back up when general practices run out of vaccine by filling out prescriptions for GPs. But this year many pharmacies have run out of vaccine after greater demand for private vaccinations from those not in at-risk groups.

Last week GPs in the UK were given access to 12.7 million doses of vaccine against the H1N1 strain of flu left over from the pandemic in 2009-10 to ensure that everyone in high risk groups can be vaccinated against the main circulating virus.

TOBY TALBOT/AP/PA

The flu outbreak may be beginning to plateau, said interim CMO Sally Davies

The pandemic vaccine, which became available in October 2009, does not expire until the end of this year.

The Health Protection Agency said that the number of people in England in critical care beds rose to 783 in the week ending 6 January, up from 738 the previous week. Another 11 people in the UK died in the same week, bringing the total number of confirmed deaths in the UK from flu this season to 50.

bmj.com for the latest flu figures

Cite this as: *BMJ* 2011;342:d203

Republicans act to repeal health reform as they take control of House of Representatives

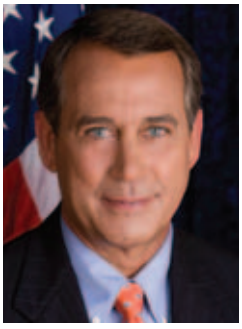
Janice Hopkins Tanne NEW YORK

The new speaker of the US House of Representatives, the Republican John Boehner of Ohio, said that his party's first priority was to repeal the health reform bill passed in March.

Republicans took control of the lower house of Congress after winning a majority of seats in the November elections. They want to repeal the health bill before President Barack Obama makes his State of the Union speech at the end of this month.

Although the house may pass the repeal bill the action is symbolic, as there is almost no chance that it will be enacted into law. To become law the repeal bill would have to be passed by the Senate, which Democrats still control, and signed by President Obama, a Democrat for whom passing the reform was a triumph.

The repeal bill has been posted on the website of the House of Representatives Committee on Rules (http://rules.house.gov). Its short title is "Repealing the Job-Killing Health Care Law Act." The bill's text says that its effect will be "as if such Act [health reform] had not been enacted." A vote on the bill was expected on 12 January, after the *BMJ* went to press.



Speaker John Boehner is promoting the bill called "Repealing the Job-Killing Health Care Law Act"

Repealing health reform and cutting government spending were key promises in the election campaigns of the Republicans and their Tea Party allies. They said that health reform was increasing taxes and paperwork and resulting in employers who don't provide health insurance being fined. Thus it would cut jobs and reduce entrepreneurship, they claimed. They said that it was a socialist over-reach of government that would lead to government rationing of healthcare. They also said it was unconstitutional to require Americans to buy health insurance; a challenge to the law on these grounds is before the courts and will not be resolved soon.

On 5 January the secretary of health and human services, Kathleen Sebelius, the secretary of labour, Hilda Solis, and the secretary of the Treasury, Timothy Geithner, sent a joint letter to Mr Boehner and members of Congress noting that when President Obama took office 50 million Americans—one in six—had no health insurance (www.healthcare.gov/center/letters/repealcosts.pdf).

They wrote, "We urge you to consider all that this law has already done to improve the health and financial security of so many Americans—and what it will mean to hundreds of millions or more in the next several years—as you evaluate any proposal that will set the nation back on a path to higher costs and skyrocketing premiums, less competition, and fewer consumer protections against industry abuses."

They described reform provisions already in effect: allowing young people up to age 26 to remain covered by their parents' health insurance scheme; tax credits to help small businesses buy health insurance for their employees; and prohibiting insurance companies from denying insurance to people with pre-existing conditions, cancelling policies because of a technical error in the application or when someone becomes ill, and applying a lifetime limit to benefits.

From this month insurance companies must provide policyholders with preventive services—such as mammography, colonoscopies, vaccinations, prenatal care, and care for new babies—without additional fees. A website (www.healthcare.gov) lets consumers compare health insurance plans.

In their letter the secretaries noted important changes to take place in 2014: individuals and small businesses will be able to buy health insurance through state based insurance exchanges; greater tax credits for small businesses will make health insurance more affordable for their employees; and transparency and accountability in the health insurance market will increase.

The non-partisan Congressional Budget Office said that the health reform act would reduce US budget deficits by about $145bn (£94bn; €112bn) by 2019. Repealing the legislation would increase costs in a similar but not identical way.

Cite this as: *BMJ* 2011;342:d114

International response threatens Haiti's health system

Peter Moszynski LONDON

Despite one of the largest aid operations in recent years Haiti still faces a serious health and humanitarian crisis one year after it was devastated by an earthquake. In a new report on the lessons learnt from the emergency the medical relief agency Merlin calls for a "more coordinated, collaborative approach" to future disaster responses.

Merlin says that how the humanitarian community works with national health systems needs to be rethought, because "one unintended consequence of this international goodwill has been to undermine the capacity of local health workers."

The 7.0 magnitude earthquake in January 2010 was the biggest urban disaster in modern history. An estimated 230 000 people were killed and more than 1.5 million were left homeless in the capital.

The report says that the sheer scale of the earthquake "would have challenged any government, let alone one of the poorest countries in the Western Hemisphere." Haiti's "fragile and underfunded health system," its "chronic shortage" of trained health workers, and the "systemic lack of emergency planning" meant that the country was simply overwhelmed and unable to respond effectively, "undoubtedly costing many thousands of lives."

Yet few of the aid agencies that flocked to help made use of local doctors and nurses and the extensive healthcare facilities in Port-au-Prince. "Instead of finding themselves working alongside incoming international teams, local NGOs [non-governmental organisations] and health workers were bypassed and sidelined by the wave of international NGOs and clinical teams sweeping into their city," the report says. Having been at the forefront of saving lives in the initial aftermath, local healthcare workers "found themselves sidelined and undermined in the chaos."

The report says that although it was "welcome and vital," the international response—with 600 international organisations becoming involved in the health sector—"failed to support the existing health capacity, staging a 'take-over' and undermining Haiti's capacity to respond and coordinate."

***Is Haiti's Health System Any Better?* is available at www.merlin.org.uk.**

Cite this as: *BMJ* 2011;342:d182

US health spending jumped to $2.5 trillion—17.6% of GDP

Bob Roehr WASHINGTON, DC

Healthcare spending in the United States jumped by 1% to 17.6% of the gross domestic product (GDP) between 2008 and 2009, the largest increase in the 50 year history of the National Health Expenditures Accounts report.

The rise came despite the fact that overall healthcare spending grew by 4% during this time, the slowest rate ever recorded. This comes on top of a 4.7% increase in health spending in 2008, the second slowest rate of growth in annual expenditures, says the report.

Total healthcare spending topped $2.5 trillion (£1.6 trillion; €1.9 trillion). That averages out to $8086 for every US citizen. Highlights of the report are published in the journal *Health Affairs* (doi:10.1377/hlthaff.2010.1032).

Anne Martin, an economist at the Centers for Medicare and Medicaid Services and senior author of the report, said that the main contributors to the slowdown include slower growth in private health insurance expenditures and consumer out of pocket spending and a fall in spending on structures and equipment.

Often healthcare spending does not begin to slow until a year or two after the overall economy begins to slow, but Ms Martin noted that the US GDP fell by 1.7% in 2009, "which is the largest decline since 1938. Because of the severity of this recession, healthcare spending responded much more quickly than it has in past recessions."

The full report is available at www.cms.gov.

Cite this as: *BMJ* 2011;342:d65

JACQUELINE KOCH/MERLIN

Geralda, who was injured in the quake, is treated in a Merlin field hospital in Port-au-Prince

UN urges Nigeria to prevent further cases of lead poisoning

BLOOMBERG/GETTY IMAGES

Members of a lead removal team break up contaminated soil in the village of Sunke, northern Nigeria

John Zarocostas GENEVA

Nigerian authorities need to take more steps to prevent further cases of acute lead poisoning in the northern state of Zamfara, a United Nations report says. Already more than 18 000 people have been affected, and hundreds of children have died, it warns.

Investigations have shown that the cause of the high rates of death and illness among children since the beginning of 2010 was acute lead poisoning from the processing of rich lead ore for gold extraction inside houses and compounds. At least 2400 children, located in seven affected villages, needed immediate emergency treatment, the report says.

The problem was first reported by the aid group Médecins Sans Frontières (MSF) Holland to state authorities last March after investigations triggered by an unusually high number of deaths of children showed acute lead poisoning to be the cause (*BMJ* 2010;341:c4031).

The UN says that 207 children have reportedly died as a result of the poisoning, but MSF puts the figure closer to 400.

If poisoning is not detected early, children with high concentrations can develop learning and hearing problems, slowed growth, and headaches.

UN investigators found that amounts of lead in drinking wells in some of the affected villages were up to 10-15 times above the World Health Organization guideline limit of 10 micrograms per litre and that the soil was often polluted.

So far MSF has treated about 800 children with chelation therapy in its clinics, Joana Tempowski, a WHO scientific officer, told the *BMJ*. She said that WHO helped secure a donation of the chelating agent dimercaptosuccinic acid (succimer) from the US drug company Lundbeck. The donation, valued at $400 000 (£260 000; €310 000), included 900 bottles containing 100 capsules each. A single course of treatment (four weeks) requires 42 capsules. Some children, however, need several courses.

WHO says that chelating agents should not be given to people who are continuing to be exposed and notes that treatment so far has focused on children whose home compounds have been decontaminated.

About 12 villages have been confirmed as contaminated, UN officials said, and more remain unconfirmed but suspected.

Thousands more people are at risk, the report says. "More rapid and coordinated intervention is imperative by authorities, with the support of the international community, in making mining safer, cleaning up polluted villages, and treating those affected by poisoning."

The report also urges authorities to close wells with high lead concentrations and install alternative water supply systems. They also need to ensure that children are not allowed to play on former processing sites.

Lead Pollution and Poisoning Crisis: Environmental Emergency Response Mission, Zamfara State, Nigeria September/October 2010 **is available at http://ochaonline.un.org.**

Cite this as: *BMJ* 2011;342:d179

ARIS MESSINIS/AFP/GETTY IMAGES

Austerity measures imposed by the Greek government to reduce its debt provoked riots last year

Greek health charges could cut access to care, charity warns

John Zarocostas GENEVA

Concern is growing in Greece that the rise in user fees announced by the minister of health last week could reduce access of many cash strapped and vulnerable groups to public hospitals and primary care clinics.

"Measures like this are no way to facilitate access to health," said Rebecca Papadopoulos, head of Médecins Sans Frontières in Greece. "The population is already in crisis because of the tough austerity measures."

On 4 January Andreas Loverdos, the minister of health and social solidarity, announced that the charge for morning visits to public hospitals and health centres would rise to €5 (£4.2; $6.5) from €3, with immediate effect.

However, the directive stipulates that some people will be exempted from the fee, including people needing urgent care, severely disabled people, people with AIDS, asylum seekers, and very poor welfare recipients.

Mr Loverdos also announced that public hospitals and clinics would have to ensure that at least 50% of the drugs they buy in future are generic rather than branded, up from about 30% at present.

The government estimates that lower drug prices and renegotiation of prices with suppliers will result in savings of about €1.4bn for the heavily indebted nation.

Reform of the health sector to generate efficiency gains and transparency, including strengthened procurement practices, was part of the conditions imposed by the International Monetary Fund and the European Central Bank for bailing out Greece with a €110bn loan.

The terms, agreed by Greece last May, also stipulate that Greece's public healthcare system, "where there have been major expenditure overruns, will be overhauled through management accounting and financing systems."

Ms Papadopoulos and Ilias Sioras, a cardiologist and president of the workers' union at the Evangelismos Hospital, Athens, said that many in the health sector objected to the fee rises and that some hospitals are refusing to implement the new measures.

Critics point to experience in African countries that rises in user fees greatly reduce access to healthcare.

Ms Papadopoulos said that many people in Greece were facing cuts in income of up to 30%, which meant that they had to contend with "many new barriers either to access public hospitals or to medicines."

Mr Loverdos, in an interview with the radio station Real FM on 7 January, said that a key objective was to make the cuts "without denying services." He also noted that Greece spent about 10% of its gross domestic product on public and private healthcare but that the quality of its healthcare service didn't reflect that amount of spending. He also indicated that he intends to press ahead with reforms of the Greek hospital system in the coming months.

Cite this as: *BMJ* 2011;342:d200

Germany reverses decision on very low birthweight babies

Annette Tuffs HEIDELBERG

The German healthcare system has decided to temporarily lift the recently announced ban on some small hospitals caring for babies with a very low birth weight.

The ban, which was announced in June 2010 and was due to come into force on 1 January, would have allowed only 70 hospitals to care for the 8000 very low birthweight babies born in Germany every year. Hospitals that cared for fewer than 30 cases a year would have been affected by the ban (*BMJ* 2010;341:c6881, 30 Nov).

After the ban was announced by the Federal Joint Committee, the regulator of Germany's statutory

French journal is sued for criticising drug's licence extension

Paul Benkimoun PARIS

An independent French drug review journal is being sued for calling for the tacrolimus based ointment Protopic (made by Astellas) to be banned and for criticising the European Medicines Agency and French authorities for approving a recent extension of its licensed indications.

Astellas France claims that the journal, *Prescrire* (*Prescribe*), was "malicious" in its interpretation of the safety data on Protopic. *Prescrire* denies the charges. The drug company's complaint was heard by the 17th section of the Paris civil court, which specialises in libel cases involving newspapers, on 5 January. The ruling is expected on 16 February.

Prescrire has faced several similar challenges in its 30 year history but has never lost a case.

In a review published in September 2009 *Prescrire* claimed that the balance of benefits and risks for Protopic was unfavourable and criticised the regulatory authorities for extending the drug's licence in early 2009 to include "maintenance treatment" to prevent flare ups of atopic dermatitis (*Prescrire* 2009;29:653).

The review referred particularly to side effects, including itching and skin infections, and claimed that some patients using the drug had developed skin cancer or lymphoma. It concluded that Protopic "should be banned as a short term [treatment] and more importantly as a long term treatment."

The European Medicines Agency says on its website: "A very small number of patients using

health insurance companies, several German states issued special allowances to hospitals that fell below the 30 case threshold. Fourteen hospitals in Brandenburg, Bavaria, and Baden-Württemberg were exempted from the ban.

The committee announced on 16 December that it would suspend its decision until the end of February, to allow more time for discussion and consideration.

The decision to reduce the number of approved hospitals on the basis of insufficient experience has been controversial since it was first proposed.

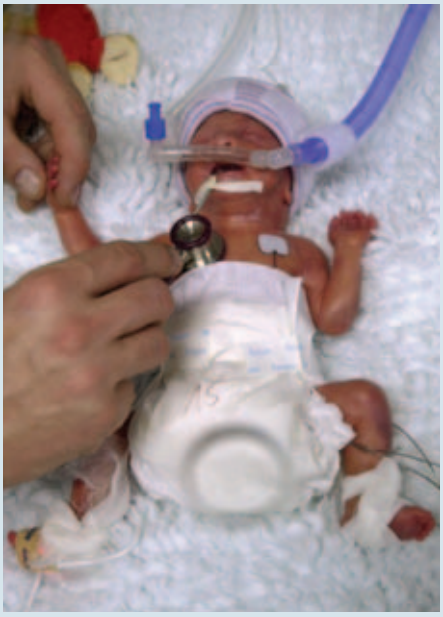
The Institute for Quality and Efficiency in Health Care (IQWIG, Germany's equivalent of the UK National Institute for Health and Clinical Excellence) had suggested a relation between the quality of care of very premature babies and the number of cases a hospital dealt with. But the German Medical Association and the German Hospital Association argued that there was not enough evidence to introduce such a strict regulation.

A parents' group called the decision to allow more hospitals to treat very premature babies a "shocking setback," saying that the risk of very low birthweight babies dying was 80% higher in smaller centres

The decision to restrict care to a limited number of hospitals was welcomed by parents' groups, neonatologists, and health insurance companies, all of whom had been campaigning for a concentration of services in a smaller number of neonatal centres of excellence.

The suspension of the ban was criticised by Hans-Jürgen Wirthl, the chairman of Das Frühgeborene Kind (The Premature Child), an umbrella organisation of groups for parents of premature or ill newborns. In the weekly magazine *Der Spiegel* he called it a "shocking setback," noting that the risk of very low birthweight babies dying was 80% higher in smaller centres.

Cite this as: *BMJ* 2011;342:d156



DPA/PA

REUTERS

"Malicious" data interpretation or freedom of the press? A French court will decide on 16 February

the drug have developed cancer (skin cancer or lymphoma). A link to Protopic has not been shown. However, doctors must ensure that the medicine is used appropriately."

Hervé Chemouli, the solicitor acting for Astellas France, claims that *Prescrire*'s views are based on "no valid and recognised scientific data." He said the comments were "particularly shocking" in the case of a drug that has been "granted a strictly conforming marketing authorisation."

Mr Chemouli raised objections to the *Prescrire* article's subtitle ("Beware of cancers, especially with long term use") and the fact that it linked Protopic with a 0.007% risk of cancer. Astellas France is arguing that *Prescrire* should be required to publish a statement agreed by the court in which it admits to libel and to pay €10 000 in damages and another €5000 to cover expenses.

A lawyer for *Prescrire* claimed that the journal acted in accordance with legislation on the freedom of the press.

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Australian doctors report high rates of job satisfaction

Melissa Sweet SYDNEY

More than 80% of Australian doctors are moderately or very satisfied with their jobs, a national survey has found.

Doctors who had a good support network, whose household had a high income, and who believed that their patients had realistic expectations were most likely to report high satisfaction.

Other factors associated with professional satisfaction were being able to take time off, being younger or close to retirement, and having good self reported health. However, the researchers noted that "the direction of causality in these relationships is unknown."

The survey findings, published in the 3 January edition of the *Medical Journal of Australia* (2011;194:30-3), come from an ongoing longitudinal study by researchers from Melbourne and Monash universities that is investigating the professional and personal drivers of satisfaction in the Australian medical workforce.

The survey, of 10 498 doctors, 19% of those who were contacted and eligible, found that 86% were moderately or very satisfied with their jobs, with no significant differences between GPs, specialists, and specialists in training. Hospital non-specialists were less satisfied.

Less than 2% of doctors in each group were very dissatisfied, but 12% of hospital non-specialists were moderately dissatisfied, whereas in the other groups this proportion was 7-8%.

No significant difference was seen in the proportions of male and female doctors with very good job satisfaction. The findings also suggested "that overseas-trained doctors have the same level of satisfaction as Australian-trained doctors," the researchers wrote.

With Australia in the throes of national health reform, the researchers said that their findings set an important baseline for examining the effects of policy changes on doctors' job satisfaction.

The survey was conducted between June and November 2008, before the Australian government announced its national health reform agenda, which includes the establishment of primary healthcare organisations and the Australian National Preventive Health Agency and changes to the financing and governance of public hospitals.

The researchers said that doctors' satisfaction is an important issue as it affects their decisions to reduce working hours or quit the workforce and is also associated with patients' satisfaction and quality of care.

Previous results from the study showed that female GPs earn an average 25% less than their male counterparts and that GPs on average earn 32% less than specialists. The average annual pretax personal earnings of GPs and specialists were $A177 883 (£114 400; €137 000; $US180 000) and $316 570, respectively.

Commenting on the latest findings, Peter Brooks, director of the Australian Health Workforce Institute at the University of Melbourne, who was not involved in the study, said that the results were unsurprising, given that Australian doctors were relatively well paid. The findings might help lure UK doctors to Australia, he added.

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