



**bmj.com** UK cigarette makers challenge ban on displaying tobacco products  
**UK News** UK law firm starts action on “metal on metal” hip implants, p 994  
**World News** AstraZeneca pays \$520m fine for off-label marketing, p 999

For the full versions of articles in this section see [bmj.com](http://bmj.com)

## US anaesthetists are told not to give lethal injections

**Janice Hopkins Tanne** NEW YORK

The American Board of Anesthesiology, which certifies anaesthesiologists, has unanimously ruled that anaesthesiologists may not participate in capital punishment by lethal injection if they want to maintain their board certification.

Major hospitals and medical centres require anaesthesiologists to be certified by the board, so loss of certification would make it difficult for many anaesthesiologists to work. The board has about 42 000 members.

Mark Rockoff, the board’s secretary and spokesman, told the *BMJ* that the board issued its ruling in February after judges in some states suggested that they needed help from anaesthesiologists to prevent botched executions.

There is no way of knowing whether anaesthesiologists have taken part in executions by lethal injection, because executioners usually remain anonymous. Likewise there is no way of knowing who may have performed lethal injections if an anaesthesiologist did not.

“The board wanted to make it clear that [participating in an execution by lethal injection] was a violation of the anaesthesiologist’s responsibility as a physician to do no harm,” Dr Rockoff said. So far no doctors have been disciplined.

Dr Rockoff is also an anaesthesiologist at the Children’s Hospital of Boston and a faculty member at Harvard Medical School.

The board adopted the American Medical Association’s statement, which says, “A physician, as a member of a profession dedicated to preserving life when there is hope of doing so, should not be a participant in a legally authorized execution.”

It adds, “Physician participation in an execution includes . . . prescribing or administering tranquilizers and other psychotropic agents and medications that are part of the execution procedure; monitoring vital signs on site or remotely (including monitoring electrocardiograms); attending or observing an execution as a physician; and rendering of technical advice regarding execution.”

Cite this as: *BMJ* 2010;340:c2432

## Australia starts plain packs for cigarettes in new health move



LISA MAREE WILLIAMS/GETTY IMAGES

**Packaging will no longer be “mini-portable advertisements” acting as “silent salesmen”**

**Melissa Sweet** SYDNEY

Australia plans to become the first country in the world to mandate plain packaging of cigarettes as part of a raft of new tobacco control measures.

The Australian government also announced today a 25% hike in tobacco excise, which it predicts will cut the country’s total tobacco consumption by around 6%.

The move to plain packaging (right), to be introduced by mid-2012, will restrict or ban the use of tobacco industry logos, brand imagery, colours, and promotional text other than brand and product names in a standard colour, position, font style, and size.

The government plans to develop and test package design to make cigarettes less appealing, particularly to young people. It will also crack down on Australian internet advertising of tobacco products and increase spending on “hard hitting” advertising campaigns.

Public health and antismoking groups have applauded the measures, which were among recommendations made last year by the National Preventative Health Task Force with the aim of reducing smoking rates from the present 16%

to 10% or less ([www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/home-1](http://www.preventativehealth.org.au/internet/preventativehealth/publishing.nsf/Content/home-1)).

From 30 April, excise on cigarettes increased from \$A0.2622 (£0.16; €0.18; \$0.24) to \$0.32775 per stick and on loose leaf tobacco from \$327.77 to \$409.71 per kilogram of tobacco. The price of a pack of 30 cigarettes rose by around \$A2.16.

The government predicts that this measure alone will cut the number of smokers by 2-3%, or around 87 000 Australians.

The excise increase is expected to raise an extra \$A5bn over four years, and all tobacco revenues will be directly invested in the health system through the National Health and Hospitals Network Fund.

The Public Health Association of Australia (PHAA) expects the measures will lead to dramatic reductions in smoking. “This is outstanding news for tobacco control and for Australia’s health,” the association’s president, Professor Mike Daube, said in a statement.

“The government’s actions will over time prevent literally hundreds of thousands of premature deaths from cancer, heart disease, and many other conditions. Australia has become the world leader in tobacco control.”

Becky Freeman, a researcher at the University of Sydney who published an article last year calling for plain packaging (*Addiction* 2008;103:580-90), said that cigarette packs were a “mini-portable advertisement,” and acted as “silent salesmen.” She said, “This is a world first that will undoubtedly be rolled out in other countries who follow Australia’s lead.”

British American Tobacco Australia said in a statement that it was surprised and disappointed by the new measures and warned that the excise increase and plain packaging requirement “will be welcomed by the illegal market.”

See **PERSONAL VIEW**, p 1035

**Competing interests:** MS holds an honorary appointment in the University of Sydney’s School of Public Health.

Cite this as: *BMJ* 2010;340:c2401

## IN BRIEF

### China lifts ban on visitors with HIV:

China's government has lifted its ban on foreigners with HIV entering the country in advance of the Shanghai Expo, which opened on 1 May. UNAIDS welcomed the change, and its executive director, Michel Sidibé, urged the 51 remaining countries and territories of the world with HIV related travel restrictions still in place to lift them.

### UK Biobank nears target of half a million recruits:

The UK Biobank, planned to be one of the largest databases linking genetic information to health, has recruited 458 106 people ([www.ukbiobank.ac.uk](http://www.ukbiobank.ac.uk)). The volunteers, aged 40 to 69 years, provide health information and samples of blood, urine, and saliva and are followed for up to 30 years.

### a rise of 48% from 2008

#### Alcohol poisonings rise in Netherlands:

Five hundred Dutch teenagers were admitted to hospital with alcoholic poisoning last year, a rise of 48%

from 2008, show figures from the Dutch Paediatric Surveillance Unit ([www.stap.nl/content/bestanden/alcoholintoxicaties-bij-jongeren-in-nederland-cijfers-2007-2008-en-2009.pdf](http://www.stap.nl/content/bestanden/alcoholintoxicaties-bij-jongeren-in-nederland-cijfers-2007-2008-en-2009.pdf)). Most had an alcoholic coma lasting three hours, on average. One in 10 needed intensive care.

#### Scotland publishes patients' views on general practices:

Information on the performance of every general practice in Scotland has been published to show how well they are meeting patients' needs ([at www.bettertogetherscotland.com](http://www.bettertogetherscotland.com)). The information is based on the views of 185 000 patients who were asked to rate practices on factors such as access and how well they were listened to.

#### Computerised prescription and test ordering system reduces mortality:

Implementing a computerised system for staff to prescribe drugs and request tests electronically was associated with a 20% fall in mortality over 18 months after the system was introduced, although the researchers cautioned that other factors may also have contributed, a US study showed (*Pediatrics* doi:10.1542/peds.2009-3271).

#### Canada has new guidelines to reduce opioid risks:

New guidelines have been published in Canada to reduce the risks of opioid treatment in patients with chronic non-cancer pain, after a major increase in their use led to a greater incidence of misuse and deaths from overdose (*CMAJ* doi:10.1503/cmaj.100187).

Cite this as: *BMJ* 2010;340:c2423



De Puy's metal on metal hip replacement system and in place (middle); MRI showing tissue damage that can be caused by metal debris from such systems and that can adversely affect revision surgery

## UK law firm starts action against "metal on metal" hip implant maker

Clare Dyer *BMJ*

A London law firm is preparing to launch a compensation claim against the makers of an artificial hip replacement component on behalf of patients who have had to undergo early revision procedures after developing complications.

Leigh Day & Co plans to issue proceedings in the English courts against De Puy International, the UK based division of US based De Puy Orthopaedics, a Johnson & Johnson company, which makes the articular surface replacement (ASR) metal on metal system.

The claim, to be brought under UK legislation covering defective products, follows a report from the National Joint Replacement Agency in Australia. It found that the ASR system had been failing early at a higher rate than that of some competitors' devices.

The product was voluntarily withdrawn from the market in Australia in December 2009.

The company announced late last year that it planned to phase out sales worldwide because of falling sales.

Although the ASR was not widely used in the United States, it has been implanted in thousands of patients worldwide.

Studies have raised concerns about metal debris from metal on metal implants that can give rise to inflammatory reactions and cause soft tissue damage in some patients.

The UK Medicines and Healthcare Products Regulatory Agency issued a medical device alert on 22 April covering all metal on metal hip replacement products, which noted: "A small number of patients implanted with these hips may . . . develop progressive soft tissue reactions to the wear debris associated with MoM [metal on metal] articulations. The debris can cause soft tissue necrosis and adversely affect the results of revision surgery."

## Court of Appeal quashes GMC decision to strike Southall off the medical register

Clare Dyer *BMJ*

The child protection paediatrician David Southall is free to practise again after the UK Court of Appeal quashed the General Medical Council's decision to strike him off the medical register for accusing a mother of drugging and murdering her son.

In an addendum to its judgment last month allowing his appeal and overturning a High Court judgment in the GMC's favour (*BMJ* 2010;340:c2195, 20 Apr), the three appeal court judges also quashed the finding that he had made the accusation.

He maintained—backed up by a social worker who was at the interview in 1998—that he had not accused the mother, Mandy Morris, of murder

and that her belief that she had been accused was a misperception.

The judges, who allowed the appeal on the ground that the GMC's fitness to practise panel had given inadequate reasons, sent the case back to be reheard by a different panel. They rejected an argument by the GMC that the same panel could just reconvene and give further reasons.

However, as the *BMJ* went to press it seemed likely that the GMC would discontinue the proceedings against Dr Southall after a strong indication from the judges that they think the case should be dropped.

Lord Justice Leveson said, "I am far from convinced that the public interest is truly served by a rehearing of the limited factual allegation that was

The alert advises NHS trusts to consider revision surgery if imaging shows soft tissue reactions, fluid collections, or tissue masses.

In March De Puy put out a safety alert advising doctors that the ASR device seemed to have a high early failure rate in some patients. Citing the Australian data, the letter cautioned against using it in patients of small stature—a group that typically includes women—and those with poor bone quality.

Bozena Michalowska, product liability solicitor at Leigh Day, said, “Replacement hip and knee implants are supposed to provide pain free mobility for at least 15 years. However, patients fitted with this device may have to undergo early revisions due to pain and inflammation caused by the defective component.

“In these circumstances patients may be entitled to claim compensation for the pain and suffering caused by the failure of the component and their consequent financial losses.”

In a statement De Puy said: “Based on ongoing and comprehensive reviews of multiple sources of data, our ASR platform has shown a revision rate consistent with other monoblock and resurfacing devices in their respective classes.

“We continue to closely monitor the performance of ASR and all implants as part of our post-market surveillance activities and to communicate with health authorities and physicians worldwide as performance and safety information dictate. Recent analysis of new data from these sources suggests a higher than expected revision rate for the ASR monoblock metal on metal system linked to usage of monoblock MoM cups with corresponding head sizes less than 50 mm in diameter.”

Cite this as: *BMJ* 2010;340:c2394

made in this case, turning on the precise language used 12 years ago.” The other two judges, Sir John Dyson and Lord Justice Waller, agreed.

They sent the case back to the GMC “to determine whether or not, in the light of all the circumstances and these observations, it is appropriate to pursue the complaint of Mrs M to a fresh panel.”

In their judgment last month the judges voiced fears that the panel’s whole approach may have been prejudiced by its belief that it was not Dr Southall’s responsibility, as an expert witness in care proceedings involving the boy’s younger brother, to investigate the circumstances of the boy’s death. The panel had formed this view without any expert evidence on the usual practice.

Dr Southall, an expert on fabricated or induced illness, said he was “delighted” by the decision and would be seeking a licence to practise from the GMC.

Cite this as: *BMJ* 2010;340:c2448

## Academics fight for Wellcome Trust medical history centre

Wendy Moore LONDON

A worldwide campaign has been launched to save the renowned Wellcome Trust Centre for the History of Medicine at University College London (UCL) from closure.

Staff at the centre have joined forces with emeritus academics in calling for a reversal of the decision, announced jointly by UCL and the Wellcome Trust earlier this month, to close the centre within two years. A petition against the closure was being launched this week and a blog on the centre’s website has attracted messages of support from academics at universities from Thailand to California.

The plan stems from a failure of UCL and the Wellcome Trust

to agree a five year grant due from the trust later this year. It follows an inquiry into allegations of mismanagement last October. The decision puts the jobs of 12 academic and 10 support staff in jeopardy and leaves the future of undergraduate and postgraduate students uncertain.

The campaign is being spearheaded by William Bynum and Vivian Nutton, two of the original founders of the centre who helped build its international reputation. Professor Nutton, who retired last October, said it was “disgraceful” that the closure had been agreed without a review or any input from historians.

“The centre has a tremendous reputation. It has taught thousands of undergraduates at UCL and has had the widest ranging programme in the history of medicine in the world.”

Professor Nutton said the campaign was seeking to ensure a “visible and discreet presence” for medical history within UCL, ideally

within a continued base at the Wellcome Trust’s headquarters in Euston Road, London, providing access to the Wellcome Library there.

He raised concerns that closing the centre could undermine the future of the library, which is one of the world’s largest and most important sources of manuscripts and books on the history of medicine.

The centre’s plight is expected to be raised at the annual meeting of the American Association for the History of Medicine, which opens on 29 April in Rochester, Minnesota. Outgoing president W Bruce Fye, speaking personally, described the decision as “very disappointing.”

The trust spokesperson said there would be no review of the decision, taken after discussion with senior staff and consideration by the trust’s governors. The trust remained “fully supportive” of the study of the history of medicine and the library.

Cite this as: *BMJ* 2010;340:c2364



Academics fear that closure of the centre could undermine the Wellcome Trust Library

## Artist behaving madly

Zosia Kmiotowicz LONDON

When she was told in 1996 by a consultant psychiatrist that she had borderline personality disorder the artist Bobby Baker firmly replied, “I beg your pardon, but speak for yourself.”

Over the next 11 years Ms Baker created over 700 watercolours of her journey towards full recovery, often with a witty and wry regard to attempts at treatment and society’s attitude to mental illness. A selection of 158 of these drawings has been

compiled in a new book, *Diary Drawings: Mental Illness and Me*. On day 403 of her illness she captured her feelings (figure) towards one of the dialectical behaviour therapy skills she was taught, which her team enthused over but which caused her extreme irritation and left her with “steam coming out of her ears.” Her drawing was her riposte, she says. The book is published by Profile Books ([www.profilebooks.com](http://www.profilebooks.com)), price £15.

Cite this as: *BMJ* 2010;340:c2308



# India's top education regulator is arrested on bribery charges

**Ganapati Mudur** DELHI

India's Central Bureau of Investigation has arrested Ketan Desai, the president of the Medical Council of India, on allegations of bribery in a fresh case that threatens to sully the image of the country's top agency involved in regulating medical education. Dr Desai is also president elect of the World Medical Association.

Investigators said last week that Dr Desai had sought 20 million rupees (£296 000; €350 000; \$450 000) as a bribe from a private medical college in the northern Indian town of Patiala for approving admissions of students in the college for the academic year 2010-11. The council has the responsibility of inspecting and approving colleges.

The arrest comes only months after the council led by Dr Desai released a code of conduct that prohibits doctors from accepting cash, gifts, or hospitality of any kind from the drug industry (*BMJ* 2010;340:c206).

Not all doctors are happy with the new rules. But some among even those who have welcomed the code of conduct have questioned the moral authority of Dr Desai in leading the initiative, given his own track record.

"This [investigation] is another opportunity for the government to clean up the mess in the council—in medical education," said Kunchala Michael Shyamprasad, a cardiothoracic surgeon, who was a member of a former government task force on medical education.

Sections of medical educationists have blamed India's health ministry for shielding Dr Desai and not trying to reform the council, an agency responsible for granting approvals to medical colleges after inspections to ensure that colleges have the stipulated infrastructure.

In 2001 the Delhi High Court had, on the basis of evidence collected by income tax investigators, observed that Dr Desai and his family had received two unexplained gifts of money totalling 6.5 million rupees. The court had ordered his removal as the council's president and asked the Central Bureau of Investigation to initiate prosecution against him.

An income tax officer had observed, in a report of December 2000, that the "alleged gifts" were "make believe arrangements and not genuine gifts." The report had said the earlier payments were "accommodation transactions in the form of gifts, and the alleged donors merely acted as conduits to channelise

the unaccounted money of Dr Ketan Desai into his accounts."

But in December 2005, the Central Bureau of Investigation said that it had not found any evidence that Dr Desai had extended any official favours to those who had paid him.

Two of the people who had paid him 5 million rupees told the investigators that "since Dr Desai is an influential person in medical circles, they gifted him the amount ... to earn his goodwill." The other payment of 1.5 million rupees was a gift from a friend of his family, the investigators concluded.

The 2005 report paved the way for the return of Dr Desai as president in 2009. The council has also come under a cloud of suspicion in the past amid allegations by medical academics that inspections of medical colleges were used to make money.

A panel of doctors appointed by India's Supreme Court in 2004 to oversee the council said it did not find evidence of corruption. "We searched, but except for one case in which another official of the council [not Dr Desai] was caught redhanded taking a bribe, we did not find anything to prove corruption," said Prakash Tandon, former head of neurosurgery at the All India Institute of Medical Sciences, New Delhi, and a member of the panel.

But Dr Tandon said that there were instances where the council's executive committee had rejected applications of some medical colleges because of infrastructure deficiencies, but the government had overruled the objections and approved the colleges. "We did find deficiencies in the numbers of faculty in some medical colleges—we brought this to the notice of authorities, but nothing has been done about it," Dr Tandon said.

Amar Jesani, a doctor and ethics expert at the Centre for Studies in Ethics and Rights, Mumbai, said, "The health ministry could have played a much stronger role to try correct things—but it has remained largely a passive observer."

Dr Shyamprasad wrote to the health ministry in February 2009 seeking its intervention to prevent the return of Dr Desai as the president of the council. "But there has been no response from the ministry," Dr Shyamprasad said.

Investigators probing the new case are currently probing Dr Desai's assets and questioning other officials.

Cite this as: *BMJ* 2010;340:c2355



**Dr Ketan Desai is said to have sought £296 000 in bribes**

# Head of European disease centre backs its H1N1 response

**Rory Watson** BRUSSELS

Marc Sprenger, the new director of the Stockholm based European Centre for Disease Prevention and Control (ECDC), has made it clear that he will not be pushing for the centre's mandate to be extended to include non-communicable diseases.

In his first major public appearance since being appointed director, Dr Sprenger told members of the European parliament's public health committee on 28 April that, despite calls in some quarters for the centre's role to be extended, he believed it should concentrate on consolidating existing achievements.

He said that the organisation was entering "adolescence," which, he admitted, could be "a difficult period."

Dr Sprenger took over the role of directing the centre from Zsuzsanna Jakab, who developed the centre from its beginnings and who became director of the World Health Organization's Europe region at the beginning of February.

Dr Sprenger, 47, a specialist in medical microbiology, moved to the centre from the Netherlands' National Institute for Public Health and the Environment, where he was also director.

He strongly defended the advice that the centre promulgated the dangers of the H1N1 virus. Pointing to the report that his predecessor delivered to European institutions last September, he said, "It was very well balanced. She did not announce a disaster. Some people did, but not the ECDC."

Cite this as: *BMJ* 2010;340:c2430

# EU prepares to tackle sales of counterfeit drugs



**European Union agencies seized 2.5 million counterfeit medicinal products in 2007**

THERRY ROGEE/REUTERS



At least a million Chinese workers are thought to have pneumoconiosis; few can afford to seek compensation

## Workers behind China's economic miracle are paying a heavy price

Jane Parry HONG KONG

A conservative estimate of the number of workers in China with occupation related pneumoconiosis puts the figure at one million, many of whom are migrant workers, and who are routinely denied access to compensation, says a report by the Hong Kong based non-government organisation China Labour Bulletin.

The report used official figures and press reports from state media to estimate the number of workers in China with pneumoconiosis, including black lung disease among coal workers and silicosis caused by prolonged exposure to mineral and metal dust in the construction and jewellery industries.

Together the two conditions account for nearly 90% of new reported cases of pneumoconiosis. Many of the official data, however, exclude migrant workers, who are often employed without formal contracts.

Workers who try to pursue claims for compensation face considerable hurdles, and these are exacerbated for migrant workers, explains China Labour Bureau's communications director, Geoffrey Crothall.

"In most cases a migrant worker will go home if they are ill and will try to solve the problem with traditional Chinese medicine or over the counter medication. Many will not even bother to go back to where they got the disease because

they can't afford to make the journey," he said.

"Even if they do, they are met with huge obstacles getting their foot in the door because the hospital diagnostic centres want to see a contract, and a diagnosis from another district cannot be used to initiate administrative proceedings for compensation."

Many of the workers who spoke to researchers from the bulletin were convinced that the local hospitals were bought off by employers to give an inconclusive or even false diagnosis, which prevented them from pursuing compensation, Mr Crothall says.

A case in point is a worker at an abrasive metals factory, in Xinmi, Henan province. When he developed severe respiratory symptoms he was diagnosed with pneumoconiosis by hospitals in the provincial capital, Zhengzhou, and Beijing, but was diagnosed with tuberculosis by the clinic where he was sent by his employer. In July 2009 the worker took the drastic step of voluntarily undergoing open chest surgery, which proved he had pneumoconiosis.

The lack of protection for workers, particularly migrants, has been recognised by the authorities. In the same week that the bulletin's report came out, China's Ministry of Health also reported that migrant workers bore the brunt of occupational diseases facing workers.

In 2009 there were 14 495 new cases of pneumoconiosis diagnosed, with more than half coming from the coal mining, metal alloy, and metallurgy industries, said a report in the state run *China Daily* newspaper.

Yang Zhiming, vice minister of human resources and social security, was reported as recommending safety training for migrant workers in high risk industries.

The report is at [www.china-labour.org.hk/en/](http://www.china-labour.org.hk/en/).

Cite this as: *BMJ* 2010;340:c2396

Rory Watson BRUSSELS

European legislators are preparing new measures to clamp down on the sale of counterfeit drugs and to warn the public of the dangers of buying unauthorised drugs on the internet.

The European parliament's environment and public health committee has given overwhelming backing (51 members for, none against, and three abstentions) to moves to tackle the network of criminals exploiting gaps in existing controls.

Marisa Matias, the European United Left member from Portugal who is steering the draft legislation through the parliament, described the

counterfeiting of drugs as "a form of pharmaceutical crime which does not stop at borders of regions or states." Such drugs, she added, "are silent killers because they can seriously harm patients through either lack of therapeutic effect or inherent toxicity."

The new measures are almost certain to be approved by the full parliament in July and will then need to be endorsed by the 27 European Union governments before becoming law. They provide a uniform definition for the first time of what in EU terminology is termed "falsified medicines."

The category covers any medicinal product that contains false or

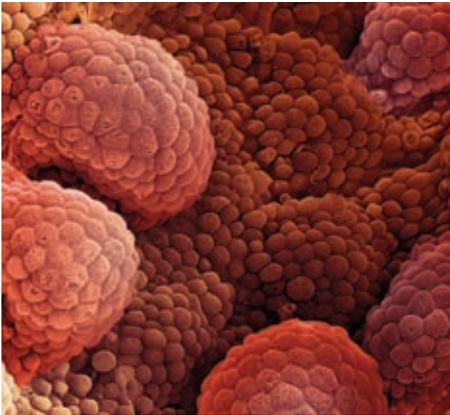
misleading details on data such as its identity, packaging, name, composition, source, and history. The MEPs want national authorities to carry out frequent and unannounced inspections of premises of manufacturers, distributors, and importers of active substances used as starting materials with the aim of preventing counterfeit drugs entering the European Union or leaving for other countries.

Penalties for any crimes would be based on sanctions contained in the new draft convention of the Council of Europe on counterfeiting of medicinal products and similar crimes involving threats to public health.

The parliament is specifically looking at the issue of sales through the internet, which, while legal in some European countries, are a major source of counterfeit drugs.

Legal internet pharmacies would need to be authorised by national authorities and display an official EU logo guaranteeing their authenticity, whose validity the public could check in a centralised national website. Only drugs bought from such sites would be eligible for reimbursement. In addition, the MEPs are calling for wide ranging awareness campaigns highlighting the dangers of internet purchases from unauthorised sites.

Cite this as: *BMJ* 2010;340:c2425



STEVE GSCHEISSNER/SPL

The treatment, which costs \$93 000, might increase life expectancy by four months

## FDA approves prostate cancer “vaccine” treatment

Janice Hopkins Tanne NEW YORK

The US Food and Drug Administration last week approved the first therapeutic “vaccine” against cancer.

Provenge (sipuleucel-T), made by Dendreon, a company in Seattle, Washington, does not prevent cancer. The individualised treatment is designed to induce a patient’s own cells to attack metastatic prostate cancer that is causing few or no symptoms but that no longer responds to hormone therapy.

Trial results show that Provenge extended men’s lives by an average of 4.1 months, in comparison with a control group, and reduced the risk of death by 22% (hazard ratio 0.78 (95% confidence interval 0.61 to 0.98)).

Each year in the United States about 192 000

cases of prostate cancer are diagnosed and about 27 000 men die from the disease.

The treatment costs \$93 000 (£60 000; €70 000) for the three doses, given about two weeks apart.

Drug industry analysts said that the drug may be a “blockbuster,” with potential sales of \$4.3bn by 2020.

The technique is being used in other possible cancer vaccines in development.

Men participating in the trial had immune system cells collected by leukapheresis about three days before each scheduled infusion of Provenge. Their cells were then sent to a Dendreon facility where they were processed with a recombinant protein found in most prostate cancers. The company says that exposure to the protein “helps to activate the immune system and functions as a prostate cancer associated antigen, which may make it possible for the immune system to recognise and attack prostate cancer cells in the body. It also functions as an immune cell activator. Once processed, the activated cells are infused into the patient. Inside the body, Provenge is designed to stimulate an immune response to prostate cancer.”

The “vaccine” is then infused in three doses about two weeks apart. Each infusion takes about an hour.

Side effects included chills, fever, fatigue, back pain, nausea, joint ache, and headache.

However, because the therapy is individualised, Dendreon said it would be able to provide treatment to only about 2000 patients during the next year, at centres that had participated in trials.

Dendreon had applied to the FDA for approval three years ago but was asked to conduct further trials, which it did, gaining approval.

Cite this as: *BMJ* 2010;340:c2431

## Australia suspends flu vaccination of young children

Melissa Sweet SYDNEY

Australia has extended a suspension of vaccination of children aged 5 years and under against seasonal flu, pending further investigations into an apparent spike in febrile convulsions associated with the vaccine.

A temporary suspension was first announced on 23 April, after concerns emerged in Western Australia about an increase in the number of young children presenting to hospitals with febrile convulsion after receiving the trivalent seasonal flu vaccine.

The federal government’s chief medical officer, Jim Bishop, announced on 30 April that more time was needed to complete epidemiological and scientific investigations.

“Given the ongoing and incomplete scientific and clinical case review, the moratorium on the use of seasonal influenza vaccine in children 5 years and less will continue,” he said.

Figures released by the national Department of Health and Ageing show that 77 cases of febrile convulsion in children aged 5 or under and associated with the vaccination have recently been reported to the Therapeutic Goods Administration.

Of these, 57 were in Western Australia, the only Australian state to provide free seasonal flu vaccination for all children aged 6 months to 4 years. It introduced the vaccination programme in 2008 after the deaths of three young children with flu and because of the high hospitalisation rates of children aged under 4.

Cite this as: *BMJ* 2010;340:c2419

## More women health workers would save millions of lives

Peter Moszynski LONDON

Investing in more frontline women health workers could help save the lives of millions of mothers and children across the developing world every year, says a report from Save the Children.

The *State of the World’s Mothers 2010* report, which ranks 160 countries in terms of their maternal and child health indicators, points out that 99% of child and maternal deaths occur in developing countries “where mothers and children lack access to basic healthcare services.” Norway tops the ranking, and Afghanistan comes last.

The charity estimates that 250 000 women’s lives and 5.5 million children’s lives could be saved each year if all women and children had access to a full package of essential health care.

Yet 57 countries have “critical shortages” of health workers—36 of them in Africa. It estimates there is a global shortfall of 4.3 million health workers.

The charity says that countries that have trained women to deliver care within their communities have seen the “most dramatic drops” in child and maternal mortality rates. Bangladesh, for example, has reduced its child mortality rate by 64% since 1990 “thanks—in part—to the recruitment of thousands of women health workers.”

The report says that employing more women community health workers would be a major contribution to the achievement of the United Nations’ fourth millennium development goal, which includes reducing childhood mortality by two thirds by 2015, and the fifth goal, to reduce

the maternal mortality ratio by three quarters.

To solve the “interconnected problems” of maternal and newborn mortality, “we must do a better job of reaching these mothers and babies with skilled care during pregnancy and childbirth in the minutes, days and weeks following birth.”

For a variety of reasons, in many parts of the world pregnant women and young children will not receive health care unless there is a female health worker nearby to provide it. A quarter of women questioned in 41 developing countries who currently have no health services said they go without medical help because they have no access to a woman health worker.

The report is at [www.savethechildren.org.uk](http://www.savethechildren.org.uk).

Cite this as: *BMJ* 2010;340:c2379

# Public will see department closures, leading doctors warn

Zosia Kmietowicz LONDON

The public must be prepared for certain facilities in local hospitals to close and to have to travel further to specialist centres for treatment if the NHS is to survive the level of cuts that have to take place under the next government, warns a group of eminent clinicians and academics.

There is a “wealth of clinical evidence” that shutting certain departments in local hospitals, such as stroke, trauma, and heart surgery, and concentrating these services in fewer centres with the latest equipment and expert clinicians improves patient safety and care, they write in a letter to the *Guardian* ([www.guardian.co.uk/society/2010/apr/29/nhs-change-clinical-evidence](http://www.guardian.co.uk/society/2010/apr/29/nhs-change-clinical-evidence)).

The group of 14 medical leaders, led by Neil Douglas, chairman of the UK Academy of Medical Royal Colleges and Faculties, accuses politicians discussing the need for the NHS to make efficiency savings of overlooking “the cogent arguments for service change that will bring long-term benefits for patients.”

Other signatories include Ian Gilmore, president of the Royal College of Physicians, Steve Field, chair of the Royal College of General Practitioners, and Sabaratnam Arulkumaran, president of the Royal College of Obstetricians and Gynaecologists.

The Labour government has said the NHS can deliver efficiency savings of £15-20bn (€17-€23bn; \$23-30bn) by 2013-14. The Conservatives and Liberal Democrats have also talked about the need for savings in the NHS, although

they have not put a figure on the level of spending cuts required.

In the letter the doctors say, “If the NHS is to cope with the financial pressures it is going to face under any government without resorting to indiscriminate and damaging service and staffing cuts, large-scale planned service redesign and reconfiguration based on clinical evidence will have to be at the heart of the strategy.”

This may mean that emergency departments, children’s services, and surgical units in local hospitals will have to close and patients will have to travel further for specialist care.

There is also “strong evidence” that patient care can be improved and costs reduced by GPs providing “a large amount” of more routine care in the community rather than by consultants in hospitals.

But the group warns, “Delivering this requires strong leadership and brave decision-making from doctors, managers and politicians.” They add, “Simply condemning change as bad and defending the status quo as ideal is not serving the interests of patients.”

To be managed smoothly and deliver the desired outcomes such changes in services must involve doctors, other healthcare staff, and patients, say the doctors. They conclude, “This involvement should include a voice in the planning and strategy development for such services, thereby ensuring appropriate service reconfiguration driven by clinical evidence and not simply the need for financial savings.”

Cite this as: *BMJ* 2010;340:c2393



JB REED/BLOOMBERG/GETTY IMAGES

**AstraZeneca was charged with promoting Seroquel for 11 conditions outside its licence**

## AstraZeneca pays \$520m fine for off-label marketing

Janice Hopkins Tanne NEW YORK

AstraZeneca agreed to pay a \$520m (£340m; €391m) fine to settle allegations it had marketed the antipsychotic drug quetiapine fumarate (Seroquel) for unapproved off-label uses, the US Department of Justice announced on 27 April.

The drug was a bestseller for AstraZeneca in 2009, with sales of \$4.9bn. Eric Holder, the US attorney general, unusually announced the settlement at a news conference. He said that illegal acts by drug companies and false claims for government health programmes “can put the public health at risk, corrupt medical decisions by health care providers, and take billions of dollars directly out of taxpayers’ pockets.”

The Department of Justice said that by promoting off-label uses AstraZeneca caused “false claims for payment to be submitted to federal insurance programmes including Medicaid, Medicare,” and other government programmes.

The federal government will receive about \$302 000 in the settlement, and Medicaid programmes for the poor in the states and the District of Columbia will share about \$218 000.

AstraZeneca denied wrongdoing but signed the civil settlement with the Department of Justice and other federal agencies and whistleblowers. The company also entered into a corporate integrity agreement with the US Department of Health and Human Services for five years.

Quetiapine is approved in the US only for the treatment of psychotic disorders, schizophrenia, and manic episodes of bipolar disorder.

AstraZeneca was charged with off-label promotion of the drug to psychiatrists and general physicians for aggression, Alzheimer’s disease, anger management, anxiety, attention deficit hyperactivity disorder, bipolar maintenance, dementia, depression, mood disorder, post-traumatic stress disorder, and sleeplessness.

See Review of the Week, *BMJ* 2010;340:c604.

Cite this as: *BMJ* 2010;340:c2380



AUBREY WADE

**Adama, a maternal and child aide in Freetown, Sierra Leone, checks a pregnant woman’s belly**