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# Appeal court judges say scientific controversies must be settled by “methods of science” not law

Clare Dyer **BMJ**

The science writer Simon Singh has won a landmark victory at the Court of Appeal in London, giving stronger free speech protection to writers facing libel threats for raising issues of scientific controversy.

Three of the most senior judges in England and Wales have allowed his appeal against a High Court preliminary ruling that when he accused the British Chiropractic Association (BCA) of “happily promoting bogus treatments” he could not claim the defence of “fair comment” (*BMJ* 2009;338:b2127).

Lord Judge, the lord chief justice, said he and his fellow judges adopted a statement by Judge Easterbrook, now chief judge of the US Seventh Circuit Court of Appeals: “[Plaintiffs] cannot, by simply filing suit and crying ‘character assassination,’ silence those who hold divergent views, no matter how adverse those views may be to plaintiffs’ interests.

“Scientific controversies must be settled by the methods of science rather than by the methods of litigation . . . More papers, more discussion, better data, and more satisfactory models—not larger awards of damages—mark the path towards superior understanding of the world around us.”

Dr Singh was sued by the BCA over a comment piece in the *Guardian* newspaper on 19 April 2008, which argued that the association’s



Simon Singh, left, with supporter David Davis, MP, celebrate outside the High Court in London

claims that chiropractic could treat childhood conditions such as colic, ear infections, and feeding problems were made without “a jot of evidence.”

Lord Judge, master of the rolls Lord Neuberger, and Lord Justice Sedley said the litigation would have shut down debate on the issues raised, “which might otherwise have assisted potential patients to make informed choices.”

The judges ruled that High Court judge Mr Justice Eady had “erred” when he ruled that the meaning of Dr Singh’s article was that the

BCA “knowingly” promoted bogus treatments, and that his words were a statement of fact—requiring him to prove they were true to win the case—rather than comment. The natural meaning of the words, the appeal court judges said, was that the BCA was promoting what Dr Singh contended were bogus treatments.

Richard Brown, the BCA’s president, said the association had followed legal advice that to get a retraction it needed to issue a writ.

See **PERSONAL VIEW**, p 813

Cite this as: *BMJ* 2010;340:c1895

## Registering herbalists will improve patients’ safety, says Burnham

**Zosia Kmietowicz** **LONDON**  
Practitioners in the United Kingdom who supply unlicensed herbal products, including Chinese medicines, will have to register with the Complementary and Natural Healthcare Council under new plans from the Department of Health.

The health secretary for England, Andy Burnham, said that ensuring registration of herbal practitioners would help prevent unscrupulous practices in the sale of herbal

remedies to the public in high street shops and private clinics.

The move follows a consultation with the scientific community and the public in all four countries of the UK last year. It will become law as soon as parliamentary time allows.

Mr Burnham said, “Emerging evidence clearly demonstrates that the public needs better protection but in a way that is measured and does not place unreasonable extra burdens on practitioners.

“I believe that the introduction of such a register will increase public protection, but without the full trappings of professional recognition which are applied to practitioners of orthodox health care.”

Mr Burnham said he was in discussion with health ministers from Scotland, Wales, and Northern Ireland to agree a joint statement on legal regulation.

Edzard Ernst, professor of complementary medicine at the

University of Exeter’s Peninsula Medical School, said that the proposal to register herbalists would be a positive move only if it obliged herbalists to practise according to best practice.

“All other regulated professions do have such an obligation,” he said. If herbalists were allowed to practise without this provision it would be “a serious mistake and will endanger public health,” he added.

Cite this as: *BMJ* 2010;340:c1897

## BBC programme gave distorted facts about a major ADHD study

Clare Dyer **BMJ**

The BBC has been forced to broadcast an apology and correction after its independent watchdog, the BBC Trust, found it guilty of inaccurately reporting the results of a major US study on the treatment of attention deficit hyperactivity disorder (ADHD).



**William Pelham claimed that Ritalin had no long term benefits**

The BBC's flagship current affairs television programme *Panorama* included an interview with one of the study's authors, William Pelham, who claimed that methylphenidate (Ritalin) and similar drugs had no beneficial effects in the long term. In fact, the research found that the drug did have beneficial effects over time, although it was no better than behavioural therapy.

The trust's editorial standards committee found that the programme *What Next for Craig?* had distorted some of the facts about the US multimodal treatment study of children with ADHD (MTA study) (*US Arch Gen Psychiatry* 1999;56:1073-86; *Arch Gen Psychiatry* 1999;56:1088-96).

It had failed to point out that some of Professor Pelham's coauthors interpreted the results differently, "failed to be fair and open-minded when examining the evidence," and "distorted some of the known facts."

Responding to a complaint from a viewer of the programme, which aired in November 2007, the committee cleared the programme makers of deliberately broadcasting inaccuracies but said they had "either misunderstood the underlying material that the team had in its possession, or had chosen just one interpretation and failed to place it in context."

The committee also criticised the BBC's editorial standards unit, which dealt with the complaint before it went to the trust on appeal, for taking too long to issue a decision.

The incident comes 10 years after the now defunct Broadcasting Standards Commission partly upheld a complaint by a doctor who claimed that *Panorama* gave only a partial account of his views on Ritalin in the programme *Kids on Pills*, broadcast in April 2000.

Cite this as: *BMJ* 2010;340:c1894

## New rules say donors can name who will receive their organs

Lynn Eaton **LONDON**

People who want, on their death, to donate their organs to a relative or close friend can do so with immediate effect under new government guidance, which covers the United Kingdom.

Until now it has not been possible to name someone whom the donor specifically wants to receive their organs. This is because a fundamental principle of the UK donation programme is that organs are given freely, voluntarily, and unconditionally. Donation must not depend on the donor only wanting their organs to go to a specified relative or friend. Instead organs had to be donated on the understanding they would go to whoever was most in need—even though a complete stranger might be the recipient, rather than a family member who was also in need.

The change in the rules follows a case in 2008 when a mother, who needed a kidney replacement after developing complications from diabetes, could not use the organs from her daughter who had died in an asthma attack.

Rachel Leake, 39, had hoped that her 21 year old daughter's wishes for her kidneys to be given to her mother would be honoured, but instead they went to others on the transplant waiting list deemed to have a more urgent need.

At the time, Adrian McNeil, chief executive of the Human Tissue Authority, stood by the decision, saying: "The central principle of matching and allocating organs from the deceased is that they are allocated to the person on the UK

transplant waiting list who is most in need and who is the best match with the donor."

The new guidance will, potentially, allow for a named individual to receive the organs on the person's death—but it won't guarantee that will happen.

Health minister Ann Keen said, "This change is greatly welcomed. It will bring much needed clarity to what is a sad and difficult time for the family of a deceased donor and a family member or close friend who could benefit from donation.

"We hope these latest changes encourage more families and close friends to talk about their wishes before it is too late."

But she said that people on the super urgent heart or liver lists or those who will not live beyond 72 hours without a transplant will still have priority over any request to donate an organ to family or close friends.

But where there are no appropriate candidates on heart or liver urgent lists, then it will be possible for the organ to be given to a family member or close friend, as long as it is a clinical match.

Chris Rudge, national clinical director for transplantation, said, "A significant balance has been struck between the wishes of those who agree to donate their organs unconditionally and the need to allocate organs on the basis of clinical need."

Frontline staff who need additional advice on a case can refer it to the Requested Allocation



**Artefacts include an old anaesthetic kit**

## Doctors are asked to help identify old medical artefacts

Wendy Moore **LONDON**

Doctors are being invited to turn detective to help curators at University College London identify a hoard of mysterious medical artefacts that has accumulated in museum basements and cupboards over nearly two centuries.

The array of nearly 200 items includes a wheelchair and carbolic spray that may have belonged to Joseph Lister, medical apparatus once used by the pioneering physiologist Ernest Starling, and assorted bleeding bowls, surgical instruments, and apothecary jars. Although some of the items—such as Starling's defibrinating whip—are known to be historically

UCL MEDIA SERVICES

# Breast screening benefits twice as many women as it harms

**Zosia Kmietowicz** LONDON

For every woman treated for breast cancer unnecessarily on the basis of mammography results the deaths of two other women from the disease are prevented, a new analysis has found.

The researchers conclude “there is a worthwhile benefit of mammography in terms of lives saved, and that this significantly exceeds any harm in the form of overdiagnosis that may occur.”

The authors of the study, which was partly funded by Cancer Research UK, firstly looked at data from the Swedish two county trial, published in 1985. It was this trial that showed that screening reduced mortality from breast cancer by 30% and led to the UK national breast screening programme.

In that trial 80 000 Swedish women aged 50 to 69 were randomised to screening or no screening. From data on deaths in the two groups the researchers in the new study estimated that screening every two to three years over a period of 20 years would prevent 8.8 deaths for every 1000 women screened (*Journal of Medical Screening* 2010;17:25-30).

By extrapolating mortality data from before 1988 they then estimated the number of women who would have died from breast cancer in the United Kingdom between 1989 and 2003 if the screening programme had not been introduced. They found that an estimated 5.7 deaths from breast cancer would be prevented for every 1000 women screened for 20 years.

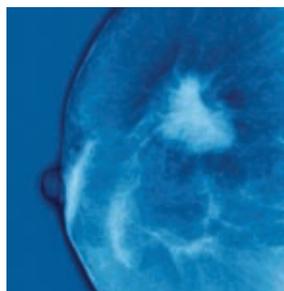
The estimated number of overdiagnoses—those cancers picked up and treated as a result of screening that would not have been diagnosed if screening had not taken place—were

4.3 per 1000 women in Sweden and 2.3 per 1000 in the United Kingdom over 20 years.

Stephen Duffy, Cancer Research UK's professor of cancer screening, who is based at Queen Mary, University of London, said, “This shows that the benefits of screening outweigh the harms.

“Unfortunately we haven't yet got a flawless screening test, and some cases that are picked up wouldn't have needed treatment. But for every case like this, screening saves two women who would have otherwise died from breast cancer.

“If a tumour is detected through screening it is important to consider a range of options before treatment begins.”



ZEPHYR/SPL

**Debate is increasing as to whether all cancers detected through screening need treating**

The latest results are in contrast to other analyses, say the authors. Other commentators have claimed that cases of overdiagnosis are 10 times more common than the number of deaths prevented (*BMJ* 2009;338:b86).

The authors of the present study say that the difference between their own and other analyses may be partly explained by the fact that other researchers have looked at women invited for screening and not just those who

underwent mammography. Another reason may be that other studies analysed data from 10 years of screening, whereas much of the benefit occurs over a longer period, say the authors.

The findings of one analysis of the first seven years of the UK screening programme (*BMJ* 2009;339:b2587) implied that almost all the tumours detected by screening would never have occurred during the patients' lifetime, a conclusion the present study authors describe, in their paper, as “absurd and frankly incredible.”

Cite this as: *BMJ* 2010;340:c1824

## UK minister announces “national care service”

**Clare Dyer** BMJ

Plans for a comprehensive personal care service for England that is free for all who need it have been unveiled by the UK government, creating what ministers trumpeted as “the biggest change to the welfare state since the creation of the NHS.”

A white paper unveiled by the health secretary, Andy Burnham, commits Labour to a national care service (NCS) for disabled people and elderly people, mirroring the free healthcare service pro-

vided by the NHS, which was set up in 1948.

But the reforms would not come into effect before 2015, by which time Labour may be out of office, after the general election on 6 May.

The white paper sees the comprehensive service as the final stage of a three stage process, with the first stage being the Personal Care at Home Bill, just finishing its parliamentary passage. This will provide free personal care in their own homes for people with the highest needs from 2011.

Cite this as: *BMJ* 2010;340:c1836



**Rachel Leake had hoped to receive a kidney from her daughter, Laura Ashworth, who died**

Oversight Group, which will provide expert guidance where needed.

This group will consist of 15 people drawn from several organisations, including NHS Blood and Transplant, the Human Tissue Authority, transplant clinicians, and patient groups. It will be chaired by the associate medical director for organ donation and transplantation at NHS Blood and Transplant. Many of these individuals have 24 hour on-call arrangements for advice in an emergency, but if one cannot be reached clinicians are advised to contact the associate medical director for organ donation and transplantation immediately.

The group will monitor the number of requests and circumstances in which donations are given to family members or close friends.

The government has also published advice to coroners and transplant teams on people donating an organ to a family member.

To learn more see *Requested Allocation of a Deceased Donor Organ* [www.dh.gov.uk](http://www.dh.gov.uk).

Cite this as: *BMJ* 2010;340:c1843

important, others have baffled curators.

“Some might be important and some we don't even have any idea what they are,” said UCL's cultural property adviser, Subhadra Das. Museum staff are uncertain whether Lord Lister ever used the wheelchair labelled as his because he attended UCL only as a student and junior surgeon. For other items, such as surgical instruments, it has proved impossible to pinpoint a date, past ownership, or even a purpose.

The medical items have been drawn from four museums and 14 collections within UCL as part of a wide ranging review of the use and fate of the university's total 380 000 artefacts.

UCL is inviting expert help to view the items and have a say in their future use between 10 am and 6 pm on 21 and 22 April in the Haldane Room, Wilkins Building. For more information email Jayne Dunn at [j.dunn@ucl.ac.uk](mailto:j.dunn@ucl.ac.uk).

Cite this as: *BMJ* 2010;340:c1868

## IN BRIEF

**More than 700 people executed in 2009:** At least 714 people were executed in 18 countries in 2009 and a further 2001 people were sentenced to death in 56 countries, says Amnesty International. However, the estimates exclude the thousands of executions that were likely to have taken place in China—where such information remains a state secret. The worst offenders were Iran (at least 388 executions), Iraq (120), Saudi Arabia (69), and the United States (52).

**Broadmoor psychiatrist wins appeal over dismissal:** Sameer Sarkar, a consultant psychiatrist at Broadmoor high security hospital who was sacked for gross misconduct after allegations of bullying and harassment, was unfairly dismissed, the Court of Appeal has ruled. Dr Sarkar originally won his case at an employment tribunal then saw the decision overturned by the employment appeal tribunal, but has now succeeded in the appeal court.

### Banned Chinese medicine is circulating in the UK:

More than 900 packs of Jingzhi Kesou Tan Chuan—a potentially dangerous traditional Chinese medicine—are currently on the UK market despite warnings

from the Medicines and Healthcare Products Regulatory Agency. The product label hides the fact the product contains aristolochia, a banned toxic and carcinogenic plant derivative, which can result in kidney failure and cancer. Anyone taking it is advised to stop.

**Breast implant banned:** French health regulator AFSSAPS has banned the marketing, distribution, and export of breast implants produced by French firm Poly Implant Prothese after learning the implants contain an unauthorised silicone gel different from the originally approved material. The UK's Medicine and Healthcare Products Regulatory Agency is investigating the implants and advising doctors not to use them. Other EU member states are taking similar steps.

### Obama names patient safety expert to head Medicare and Medicaid:

Donald Berwick, a Harvard paediatrician and head of the Institute for Healthcare Improvement, was named as head of the Centers for Medicare and Medicaid Services. The centres oversee medical care for more than 100 million US citizens. The office has been vacant since 2006. Dr Berwick's appointment needs approval by the Senate.

Cite this as: *BMJ* 2010;340:c1852

## NHS Global hopes to repeat success of BBC Worldwide

Donald Asprey *BMJ*

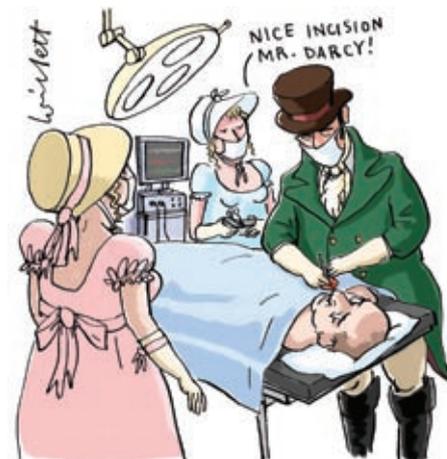
The NHS will sell its ideas and skills abroad and plough the profits back into frontline services, England's health secretary, Andy Burnham, announced last week. NHS Global aims to repeat the success of BBC Worldwide, which markets programmes abroad and invests money back into the BBC.

Mr Burnham said there is increasing demand abroad for NHS knowledge and innovations and even to replicate parts of the NHS. "There is great potential to benefit from the exceptional knowledge and intelligence within the NHS. We know that BBC Worldwide has already had success in this area, and now the NHS must make the most of these international opportunities," he said.

"The reason [that] now is the right time is because the NHS has faced challenges over the last 10 years and dealt with the challenges of the last 10 years."

Mr Burnham gave several examples of innovations that could be exported, including the NHS's reduction in the incidence of hospital acquired infections, the National Institute for Health and Clinical Excellence, NHS Direct software, and the Quality and Outcomes Framework in managing primary care. Potential customers were health-care officials from Australia, New Zealand, South Africa, Canada, and the United States.

An NHS Innovation Expo held in October



generated more than £27m (€30m; \$40m), with £20m more expected over the next 12 to 18 months. NHS Global will support NHS organisations to try to build on that success by tapping into the global market for healthcare services, estimated at around \$4.1 trillion in 2007.

NHS Global will act as a central contact point for foreign countries interested in doing business with the NHS. It will identify commercial opportunities in the NHS, generate demand in international markets, broker partnerships between NHS organisations and customers, advise on intellectual property, identify legal risks, and facilitate marketing and communications.

The Department of Health has begun preliminary work with NHS organisations to bring products to the market and will consult with NHS staff and stakeholders in the coming months on a proposed operating model for NHS Global.

Cite this as: *BMJ* 2010;340:c1823

## US judge overturns patents on breast cancer genes because they are products of nature

Clare Dyer *BMJ*

A United States federal judge in New York has overturned US patents covering genes linked to breast and ovarian cancer, in a decision that has rocked the biotech industry.

US district judge Robert Sweet held that claims in seven patents on BRCA1 and BRCA2 held by Myriad Genetics and the University of Utah were invalid because the genes are products of nature, which cannot be patented.

The lawsuit challenging the patents was filed by the American Civil Liberties Union with the Public Patent Foundation at Benjamin N Cardozo School of Law and doctors' groups. They argued that the patents were unconstitutional as well as unlawful, but the judge held there was no need to rule on the constitutional issue, having found that the patents were unlawful.

He stated in a 152 page opinion, "It is concluded that DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes.

"Therefore, the patents at issue directed to 'isolated DNA' containing sequences found in nature are unsustainable as a matter of law and are deemed unpatentable subject matter."

He added that many critics of gene patents considered the idea that isolating a gene made it patentable a "lawyer's trick" to circumvent the ban on the direct patenting of the DNA in the body.

Myriad Genetics announced that it would appeal against the ruling, which covers seven of its 23 patents relating to BRCA1 and BRCA2. Peter Meldrum, its president and chief executive

# Poverty, corruption, and armed conflict hinder Afghans' access to health care, says UN

John Zarocostas GENEVA

An estimated nine million Afghans, about 36% of the population, are living in absolute poverty, and the situation is exacerbated daily by widespread corruption and insecurity because of the armed conflict, a United Nations report says. The problems are impeding efforts to meet basic needs and to provide services, including access to health care, it adds.

The study, published by the Office of the UN High Commissioner for Human Rights, says that despite the injection of about \$35bn (£23bn; €26bn) in international aid by donors since 2002, key indicators of development show that a reduction in the level of poverty has had little effect on the daily life of most Afghans.

"Afghanistan has the second highest maternal mortality rate in the world . . . and the third worst global ranking for child mortality. Drinking water supplies reach only 23% of Afghans, and only 24% of the population 15 years and older can read and write," the report says.

In 2009 maternal mortality was 1600 deaths per 100 000 live births, it says. The problem is partly caused by social pressure: "Men hesitate to bring their wives for medical care as the nature of delivery is connected with intimacy and personal privacy which is seen as shameful to bring this into the public sphere."

The report concludes that the "abuse of power is a key driver of poverty in Afghanistan" and

notes that widespread corruption limits access to services.

Corrupt practices, it says, are entrenched, and even poor people, where they are able, use bribes to get a service, it says.

Earlier this year a study by the UN Office against Drugs and Crime estimated that one in every two Afghans had to pay at least one bribe to a public official. This amounted to an average of \$158 paid per person in a country where the annual gross domestic product per person was

around \$425. It was a "crippling tax on people already among the world's poorest."

The armed conflict, which has inflicted a heavy toll in deaths, injuries, and disabilities among civilians and destruction of homes and livelihoods, has worsened the high level of poverty and inhibited access to health care.

*Human Rights Dimension of Poverty in Afghanistan* is at [www.ohchr.org/EN/Countries/AsiaRegion/Pages/HRReports.aspx](http://www.ohchr.org/EN/Countries/AsiaRegion/Pages/HRReports.aspx).

Cite this as: *BMJ* 2010;340:c1902



MUSTAFA QURANISH/AP/PA

Even poor people use bribes to access services when they can afford it, the UN report says

officer, said, "While we are disappointed that Judge Sweet did not follow prior judicial precedent or Congress's intent that the Patent Act be broadly construed and applied, we are very confident that the Court of Appeals for the Federal Circuit will reverse this decision and uphold the patent claims being challenged."

If Judge Sweet's ruling is upheld on appeal, it will have wide implications for other gene patents based on isolated DNA. Around 20% of the human genome has already been patented.

Judge Sweet made it clear that if his ruling is upheld the US Patent and Trademark Office will have to "avoid issuing patents related to isolated DNA or the comparison or analysis of DNA sequences."

Myriad's patents have given it a monopoly in the United States on the test to determine if women have mutations in the genes which put them at high risk of developing breast and ovarian cancer.

Cite this as: *BMJ* 2010;340:c1870

## Home Office has failed to monitor effect of England's drug strategy, says watchdog

Zosia Kmietowicz LONDON

It is "unacceptable" that the Home Office in England does not know the overall effect of the drug strategy it introduced in 2008, says the public spending watchdog.

The 10 year strategy, which aims to "reduce the harm that drugs cause to society, to communities, individuals, and their families," costs the country £1.2bn (€1.4bn; \$1.8bn) a year. But the House of Commons Public Accounts Committee criticised the Home Office for not evaluating its work rigorously enough.

Edward Leigh, the committee's chairman, said, "Central and local government spends around £1.2bn a year on activities to tackle problem drug use. Given the amount of public money being spent, it is unacceptable that the Home Office does not know what overall effect

this spending is having. It does not carry out enough evaluation of its work and does not know if its drug strategy is directly reducing the overall cost of drug related crimes."

Mr Leigh added that the Home Office had agreed to produce an overall framework to evaluate and report on the value for money achieved from the government's drug strategy, with initial results from late 2011.

Estimates covering 2003-4 put the number of problem drug users in England at 330 000. They cost society more than £15bn a year, including £13.9bn from drug related crime. Problem drug use is defined as the use of opiates (mainly heroin) or crack cocaine, which are responsible for most drug related crime.

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

Cite this as: *BMJ* 2010;340:c1911

## Primary care must have greater role in China, says OECD

John Zarocostas GENEVA

China's spectacular economic growth in recent years has helped improve some health outcomes, such as deaths from infectious diseases, but has been accompanied by an increase in chronic diseases, an analysis by the Organisation for Economic Cooperation and Development says.

Despite the country's increased wealth, serious problems remain in access to treatment, quality of care, and costs to people in poorer areas, the OECD's report says.

"Improving health outcomes will require addressing a number of imbalances and incentive problems plaguing the healthcare system, in a context of rapidly rising demand," it says.

At present the Chinese health system is not oriented to preventing chronic diseases, the report says, even though the trend worldwide has been to increase care at the primary level.



Hospitals are the dominant suppliers of primary ambulatory care in urban areas in China

In China patients prefer to go to hospitals, it says, as doctors in primary care are less qualified than their hospital colleagues.

"It will be important to ensure primary care plays a greater role in healthcare delivery to reduce inappropriate high demands on hospitals," the report says.

Overall, hospitals produce nearly 80% of the value of all first level medical consultations, and this is reflected in the number of outpatient visits per hospital bed, which in 2008 stood at 1048, whereas in English hospitals the number was 313.

To tackle the problems, in 2003 China ushered in new urban and rural insurance schemes, which have boosted the proportion of the population with some coverage, from less than 10% to around 90% in 2008. The schemes have also increased the use of medical facilities, except among migrants from the countryside, says the report.

Moreover, catastrophic and chronic illnesses continue to push people into poverty.

A second OECD paper argues that the rise in spending on catastrophic illnesses is perhaps the result of people being drawn into hospital care initially and then being faced with expensive treatments that they would not have become aware of without insurance coverage.

The paper says that reimbursement rates are low for catastrophic illness, which the World Health Organization defines as illness resulting in expenditure of 40% of annual income less subsistence expenditure.

*China in the 2010s: Balancing Growth and Strengthening Social Safety Nets* is at [www.oecd.org/china](http://www.oecd.org/china), and *Improving China's Health Care system* is at [www.oecd.org/eco/working\\_papers](http://www.oecd.org/eco/working_papers).

Cite this as: *BMJ* 2010;340:c1903

## US maternal mortality rates double in 20 years, Amnesty report says

Peter Moszynski LONDON

As the US administration struggles to push controversial health reforms through Congress, a new report by Amnesty International claims that exclusion and discrimination have led to a mounting crisis in maternal health care, with mortality rates doubling in 20 years.

The report says that at least two women die each day from complications of pregnancy and childbirth and maintains that half of these deaths could be prevented "if maternal healthcare were available, accessible and of good quality for all women."

The report indicates that maternal mortality ratios have increased from 6.6 deaths per 100 000 live births in 1987 to 13.3 deaths per 100 000 live births in 2006. Although some of the recorded increase is due to improved data collection, "the fact remains that maternal mortality ratios have risen significantly."

Amnesty points out that

the United States spends more than any other country on health care, and more on maternal health than any other type of hospital care. "Despite this, women in the USA have a higher risk of dying of pregnancy-related complications than those in 40 other countries.

"For example, the likelihood of a woman dying in childbirth in the USA is five times greater than in Greece, four times greater than in Germany, and three times greater than in Spain."

The report also indicates that not only are African American women nearly four times more likely to die of pregnancy related complications than white women but that "these rates and disparities have not improved in more than 20 years."

It says that "discrimination profoundly affects a woman's chances of being healthy in the first place. Women of color are less likely to go into pregnancy in good health because they are more likely to lack access to primary health care services. Despite representing only 32% of women, women of color make up 51% of women without insurance."

Amnesty says: "This is not just a public health emergency—it is a human rights crisis."

Women in the US "face a range of obstacles in obtaining the services they need." The healthcare system "suffers from multiple failures," including discrimination; financial, bureaucratic, and language barriers to care; lack of information about maternal care and family planning options; . . . inadequate staffing and quality protocols; and a lack of accountability and oversight.

*Deadly Delivery: The Maternal Healthcare Crisis in the USA* is available at [www.amnestyusa.org/dignity/pdf/DeadlyDelivery.pdf](http://www.amnestyusa.org/dignity/pdf/DeadlyDelivery.pdf).

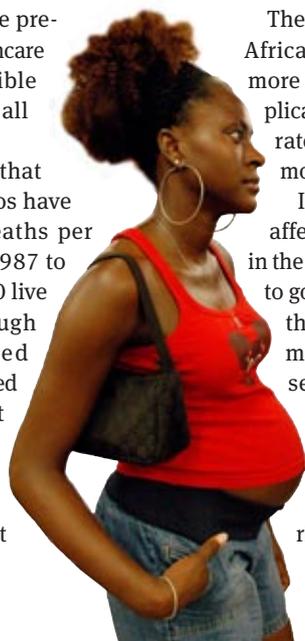
Cite this as: *BMJ* 2010;340:c1856

## Safety events in over 65s cost US hospitals \$9bn over two years

Janice Hopkins Tanne NEW YORK

The safety of patients aged more than 65 years in US hospitals has not improved in the past five years, according to results of the annual study by HealthGrades, an independent healthcare ratings organisation.

Patient safety has been a high profile issue in America since the US Institute of Medicine issued *To Err Is Human: Building a Safer Health System*, in 1999. That report said nearly 100 000 patients died every year from errors



# WHO is accused of “crying wolf” over its decision to declare the H1N1 virus a pandemic



ITSUO INOUE/AP/PA

The warnings over swine flu went well beyond the effects of the virus, said Paul Flynn

## Rory Watson BRUSSELS

Three separate international inquiries will soon be investigating the World Health Organization's decision to declare the H1N1 virus a pandemic. The most advanced, being conducted by the Council of Europe, began in January.

Also, support is growing inside the European parliament for members to conduct their own investigation, and WHO itself will set up an independent review committee later this month.

Paul Flynn, the British Labour MP who is drafting the report of the Council of Europe's

investigation into the pandemic, believes that the discrepancy between the scale of the warnings and the actual effect of the virus has badly dented public confidence in WHO and many public health institutions.

“The next time someone cries wolf over a pandemic, the overwhelming majority will not take it seriously. A pandemic cannot be whatever the WHO declares it is,” he told a public hearing on the handling of the H1N1 pandemic (the second organised by the Council of Europe) in Paris on 29 March.

He warned that if it transpired that the pan-

demical label had been attached to the virus to help the drug industry to make bigger profits, “this might turn out to be one of the biggest health scandals ever.”

Poland's health minister, Ewa Kopacz, explained to the hearing why her government had refused to launch a vaccination campaign after the WHO alert. The country's experts had concluded that the situation was not as serious as portrayed, and the government had refused to accept the drug companies' conditions that it, rather than the manufacturers, should bear full responsibility for any undesirable side effects of the vaccines.

While the Council of Europe is trying to shed light on whether undue industry influence or conflicts of interest were involved in WHO's decision, the European parliament is approaching the issue from a different angle. A French Green MEP, Michèle Rivasi, is leading a move to establish a special committee of inquiry. This would investigate why European Union institutions such as the European Medicines Agency and the European Centre for Disease Prevention and Control uncritically followed WHO's decision without carrying out their own independent evaluation of the threats involved.

This led, she points out, to the European Medicines Agency giving fast track approval to vaccines whose impact on pregnant women and children had not been fully assessed. Ms Rivasi is confident that she will win the backing of the 183 MEPs she requires for the committee of inquiry to be created.

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while undergoing treatment in US hospitals.

The latest report from HealthGrades found that between 2006 and 2008 there were almost a million patient safety events affecting 908 401 patients in the 39.5 million Medicare hospitalisations.

The safety events were 2.29% of the admissions, and resulted in \$8.9bn (£6bn; €6.5bn) in excess costs. About one in 10 patients who experienced a safety problem died: 99 180 people between 2006 and 2008.

The figures are unchanged since the last HealthGrades report, which looked at safety in people over 65 in US hospitals between 2005 and 2007.

Rick May, a HealthGrades vice president and coauthor of the study, said, “It is disheartening

to see that the numbers [in HealthGrades study] have not changed since last year's study and, in fact, certain patient safety incidents, such as postoperative sepsis, are on the rise.” He said the study aimed to document the status of patient safety and to provide people with information about top performing hospitals.

HealthGrades' website lists the best performing hospitals: 111 teaching hospitals and 177 non-teaching hospitals. Few are big name medical centres—only the Cleveland Clinic in Florida and Brigham and Women's and Massachusetts General in Boston are listed among the familiar names. Some hospitals that do well may be affiliated with teaching centres but their names do not reflect this.

Patients treated in the top 5% of hospitals

identified in the study had 43% fewer patient safety incidents compared with those treated in poorly performing hospitals. If all hospitals performed at the top level, 218 572 patient safety incidents would not have occurred and 22 590 people would not have died, the study says.

The most common safety incidents were failure to rescue (not diagnosing and correcting an acute problem in time), bed sores, postoperative respiratory failure, and postoperative sepsis.

Since October 2008 the Center for Medicare and Medicaid Services has refused to reimburse hospitals treating Medicare patients for “never events,” events that should not have occurred, such as bed sores.

The study is at [www.healthgrades.com/research](http://www.healthgrades.com/research).

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