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Record number of fake drugs are seized in crackdown

Surgeon blames crude data for causing "debacle"

Zosia Kmietowicz BMJ
Krishna Chinthapalli BMJ

A surgeon who was wrongly identified as having the highest mortality rate for a specific operation in the United Kingdom has criticised the release of crude data to the general public.

Simon Payne, a surgeon at Portsmouth Hospitals, told the *BMJ* that he felt like he "had been kicked in the stomach" when a number of newspapers used the incorrect and unadjusted data from the Vascular Society to name surgeons with the highest mortality rates for infra-renal abdominal aortic aneurysm (AAA) surgery and carotid endarterectomy.[1 2] This was despite the fact that the report made it clear that none of the UK's vascular surgeons were "outliers," defined as performing outside the expected range.[3]

Payne had been recorded as having a crude mortality rate of 31% for infra-renal abdominal aortic aneurysm—compared with a national average of 2.2%—even though he had not done the operation since 2011. Two days after publishing the data the Vascular Society had to reissue them with Payne's figure corrected to 2%.

Asked whether mortality data that had not been adjusted for case mix should be in the public domain, Payne said, "I don't think it's helpful or informative, as illustrated by this whole debacle."

He added, "The general public are not able to interpret data correctly to make informed choices, and the media will misinterpret data and exaggerate to create a story. So it doesn't actually let the public make an informed decision."

ZEPHYR/SPL

Surgeon level outcomes of AAA operations are a "good thing," said Ben Bridgewater, who has championed data collection

Another problem with crude figures was that the data could make surgeons think about the risk of complications when assessing a patient for surgery—something that should "never be a consideration," he said.

Ben Bridgewater, a cardiac surgeon in south Manchester who leads the Healthcare Quality Improvement Partnership team that helps surgical specialties publish data on surgeons' performance, defended the Vascular Society's report. He told the *BMJ* that the six month deadline set by NHS England last December for individual level data to be made available for surgeons in 10 specialties was not too tight.[4]

"Our experience shows that unless we set tight deadlines then we could be waiting a long time for progress," he said.

It had taken 10 years after the discovery of excess deaths of children undergoing heart surgery at Bristol Royal Infirmary between 1991 and 1995 for cardiothoracic surgeons to become the first doctors in the UK to publish individual outcome data, in 2005. That was too long, said Bridgewater.

He said that although he stood by comments he made at the weekend that unadjusted figures were "virtually worthless," he believed that what the Vascular Society had done in publishing the data "was a good thing."

He added, "These data have never been seen before, and they should be heralded. Of course, there are lessons to be learnt. But this is a key cornerstone to governance of the NHS."

Peter McCollum, one of six vascular surgeons who opted out of allowing their data to be published, told BBC Radio 4 that he took the stance because the data were "inherently flawed."

He said, "Bad surgeons will not be picked up by this process—and it puts pressure on younger surgeons not to do any difficult surgery at all." He would prefer data to be analysed at a unit level, he said.

Cite this as: *BMJ* 2013;347:f4299

Large rise in consultants' pay has not improved productivity, say MPs

Adrian O'Dowd LONDON

Large pay rises of between 24% and 28% for consultants 10 years ago had failed to lead to more productivity for the NHS and had not been value for money, MPs said.

The public accounts committee published a report on 2 July on the management of consultants, in which it said that management of consultants' performance was poor.

Doctors' leaders, however, have rejected many of the report's claims, saying that the statistics used were inappropriate, did not reflect the quality of care, and unfairly criticised doctors for spending too much time with patients.

In October 2003 the Department of Health for England introduced a new consultant contract, which was designed to improve the management of NHS consultants. Most consultants are now on the contract, which increased their pay in 2003-04, with the bottom of the consultant pay band rising by 24% and the top by 28%.

MPs on the committee said the contract represented a "missed opportunity" to change consultants' performance and had provided poor value for money to the taxpayer.

Although most of the expected benefits of the contract—such as a new career structure for consultants, a stronger contract framework to allow managers to better plan consultants' work, and better arrangements for consultants' professional development—had been fully or partly realised, the health department had not been ambitious enough in setting targets, said MPs.

A particular concern was the fact that although the decline in consultants' productivity had slowed, this hadn't been followed by an increase in productivity.

The report's authors admitted, however, that consultant productivity was difficult to measure precisely. This had been made worse when, in 2008, the health department withdrew its national toolkit to measure productivity levels.

Cite this as: *BMJ* 2013;347:f4267

IN BRIEF

UK's highest court hears first right to life case: The UK Supreme Court is to hear its first healthcare right to life case since it began work in October 2009. The family of David James, a former musician who is in a minimally conscious state, is appealing against a Court of Appeal ruling that doctors need not give him "burdensome" treatment,[1] in a hearing on 24 and 25 July.

Drug regulator suspends use of starch drips: The use of starch drips to treat critically ill patients and people undergoing surgery is to be suspended in the United Kingdom because their benefits no longer outweigh the risk of using them, the Medicines and Healthcare Products Regulatory Agency has said. The drips were used to treat and prevent low blood volume and steep drops in blood pressure and to maintain adequate circulation during surgical procedures.

Mental health nurses to join police on the beat: Mental health nurses will patrol with police officers in four new pilot sites to improve responses to mental health emergencies, England's care and support minister, Norman Lamb, has announced. The street triage scheme sees mental health nurses accompany officers to incidents where police believe people need immediate mental health support. The first four areas in the scheme are North Yorkshire, Devon and Cornwall, Sussex, and Derbyshire.

Ireland gets electronic patient record system: An electronic care record system has been launched to cover Northern Ireland's 1.8 million population. The web based portal system will enable the communication and sharing of patient data taken from several existing information systems across acute, community, primary, and social care. The system is provided by the e-health software provider Orion Health.

Group challenges closure of services in south London: A decision by England's health secretary to close some services at Lewisham Hospital in south London and downgrade others will be challenged at the High Court in a three day hearing starting on 2 July. The campaigning group Save Lewisham Hospital argues that the decision was unlawful and the court should quash it and ask Jeremy Hunt to reconsider.

Cite this as: *BMJ* 2013;347:f4234

Avoid diclofenac in people with heart problems, drug regulator has advised

Jacqui Wise LONDON

Diclofenac should not be prescribed to patients with serious underlying heart conditions because of a small increased risk of heart attack and stroke, the UK Medicines and Healthcare Products Regulatory Agency has warned.[1]

The advice comes after a recent meta-analysis found that the arterial thrombotic risk with diclofenac was similar to that with the selective cyclo-oxygenase-2 (COX-2) inhibitors.[2] The study found that, in comparison with placebo, the risk of major vascular events was increased by about a third by a COX-2 inhibitor (rate ratio 1.4 (95% confidence interval 1.1 to 1.7) or diclofenac (1.4 (1.1 to 1.8)).

Sarah Branch, deputy director of the MHRA's Division of Vigilance and Risk Management of Medicines, said, "Whilst this is a known risk, and warnings have been included in patient and healthcare information for some time, this advice is now being updated. For many patients diclofenac will continue to provide safe and effective pain relief, but [it] is no longer suitable for certain at-risk groups."

In line with COX-2 inhibitors, diclofenac is now contraindicated in people with ischaemic heart disease, peripheral arterial disease, cerebrovascular disease, and established congestive heart failure (New York Heart Association classification II-IV).

Patients with these conditions should be switched to an alternative treatment at their next routine appointment.

Diclofenac should be prescribed to patients with significant risk factors for cardiovascular events—such as hypertension, hyperlipidaemia, diabetes mellitus, and smoking—only after careful consideration.

The advice applies to tablets, capsules, suppositories, and injections available on prescription and over the counter from a pharmacy but does not apply to topical formulations. The MHRA said that naproxen and low dose ibuprofen were considered to have the most favourable thrombotic cardiovascular safety profiles of all the non-selective non-steroidal anti-inflammatory drugs.

The new safety advice comes after a review by the European Medicines Agency's Pharmacovigilence Risk Assessment Committee. The committee concluded that overall the benefits of diclofenac were greater than its risks but that there was a small risk of heart attack or stroke in patients taking systemic diclofenac regularly, particularly at high doses (150 mg a day) and for long periods.

Sotiris Antoniou, a consultant pharmacist at Barts Health NHS Trust and the London Heart Centre, said, "Diclofenac has similar COX-2 selectivity to celecoxib, and understandably the European Medicines Agency concluded that the risk of cardiovascular side effects was on par with that observed with other COX-2 inhibitors."

Cite this as: *BMJ* 2013;347:f4285

Survival rates after bowel surgery reach their highest ever level, audit shows

Jacqui Wise LONDON

Four in five patients who have major surgery for bowel cancer survive at least two years, show figures from the latest national bowel cancer audit.[1]

The audit of data from more than 50 000 bowel cancer patients in England and Wales also showed that survival was much poorer in those patients who didn't have surgery, with only two in five patients surviving for two years. Many of the patients who did not undergo a major resection were too frail, or the cancer was too advanced, but the report said that there needed to be more investigation to find out the reasons for not operating.

The audit, by the Association of Coloproctology of Great Britain and Ireland, the Health and Social Care Information Centre, and the Royal College of Surgeons of England, found that post-operative survival was at an all time high. Of 16 250 patients who underwent surgery, 95.5% were alive 90 days after their operation, up from 94.7% in 2010-11 and 93.9% in 2008-09.

Nigel Scott, clinical lead on the audit and a consultant colorectal surgeon at the Royal Preston Hospital, said, "Correct patient selection and postoperative care has delivered a fall in postoperative mortality of one third in just a few years. In addition, these better outcomes immediately after surgery are matched by 80% of patients surviving at least two years or more—a testimony to bowel cancer multidisciplinary working in England and Wales."

However, the audit also showed that the proportion of patients admitted to hospital as an emergency case had changed little in four years, remaining at 21%. One in seven patients

Health secretary promises crackdown on foreigners who misuse NHS

Nigel Hawkes LONDON

England's health secretary, Jeremy Hunt, has promised to crack down on the use of the NHS by people who are not entitled to it, including migrants from outside the European Union.

In a speech on Wednesday 3 July, after the *BMJ* went to press, he was expected to outline for consultation a package of measures designed to reduce "health tourism," the cost of which to the NHS is disputed—anywhere between £12m and £200m a year, depending on the source.

Reports suggest that Hunt will propose a tracking system that links people's NHS numbers with their immigration status. As things stand, anybody who claims to be ordinarily resident in the United Kingdom—which means, the courts have ruled, that they live here on a "lawful, properly settled basis"—can register with a GP and get an NHS number. There is no formal requirement when registering with a GP to prove identity or immigration status.

It is not clear whether Hunt proposes changes to GP registration, such as requiring evidence of entitlement, but if he does he will face opposition from doctors. At the BMA's annual representatives meeting in Edinburgh last week Richard Vautrey, a GP who sits on the BMA's governing council, declared such an idea "unworkable and unethical."

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undergoing emergency surgery in 2011-12 did not survive 90 days after the operation.

Graham Williams, president of the Association of Coloproctology of Great Britain and Ireland, said, "What is concerning is the stubbornly high proportion of patients who present as an emergency. This equates to 5000 patients, and these patients have a higher likelihood of dying in hospital after resection. Understanding why so many patients present as an emergency, despite the wide introduction of screening, should be a priority."

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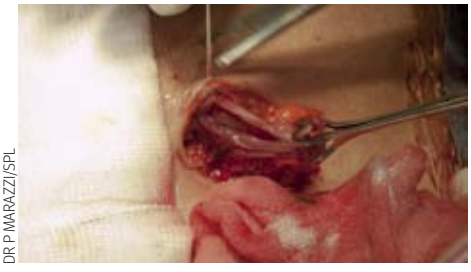


DR P MARAZZI/SPL

95.5% of patients live for 90 days after surgery

STEFAN ROUSSEAU/PA

Jeremy Hunt (left) opened a new dementia ward at the Royal Chelsea Hospital, London, in June

Dementia experts are optimistic because of government support

Nigel Hawkes LONDON

Patients with dementia and their families still face hurdles in getting support and care, a conference in London on 27 June heard. But despite the problems—and against a backdrop of recent disappointments in drug development—the mood was not downcast.

Advocates of people with dementia believe that at last they have the ear of government and that change is possible.

David Blunkett, MP, set the tone by welcoming what he called David Cameron's "continuing commitment" on dementia. "It matters that the prime minister is interested," said Blunkett, a former Labour cabinet minister whose speech gained force by its avoidance of political point scoring. Almost the only political point he made was against his own side, an acknowledgment that the £150m the Labour government put into dementia care when Alan Johnson was health secretary ought to have been ringfenced to ensure that it was spent as intended.

Blunkett also disclosed that "someone very close to me," a member of his family, had recently developed dementia. He did not name the person but said the experience had made him understand the issues better. As vice chairman of the All-Party Parliamentary Group on Dementia, he said he hoped that in the past he had used the right words, "but now I really do understand what those families are suffering."

The conference, sponsored as one of a series by the magazine *Public Servant*, heard a compelling account of a carer's life from Kate Harwood, who looked after her husband, Marco, for the eight years between his diagnosis of dementia and his death earlier this year. Initially, she said, diagnosis was delayed because her husband, a former university lecturer, had "sailed through" cognitive tests. She was also critical of the difficulty she had had in being heard as a carer. Life would have been easier, she said, if she had had a single point of contact, "someone who was there for us." She added, "So much time is taken in fighting for support and ending up exhausted—it can't be right."

Although the number of diagnoses of dementia was rising, hopes of effective drug treatment to prevent or control the disease had fallen, admitted Eric Karran, director of research at Alzheimer's Research UK.

Since 2010 all but one of seven drugs then in phase III trials had failed, and some phase II candidates had been dropped too, he said. "The old model of drug development has failed," he said. "It's a significant concern for everyone. The last new drug was approved in 2003."

But the situation was not hopeless, he added. The existence of genetic mutations that protect against the disease shows that effective drugs might be possible if they could mimic the same action. More research spending was needed, he said: although cancer research has £600m a year to spend, dementia research has only £50m. The total costs of the disease to individuals, the NHS, and the economy are 450 times what is spent researching it, Karran said.

Cite this as: *BMJ* 2013;347:f4265

Ravi Sondhi was out of reach at his home in Fakenham when he was meant to be in London

Tribunal hears GP who ran out of hours service provided inadequate care

Clare Dyer BMJ

A GP earning £230 000 a year was 225 km away at his home in Norfolk when he should have been on call in Croydon in south London, the Medical Practitioners Tribunal Service has been told.

Ravi Sondhi, 52, is also accused of abusing his position as financial director of Croydon Doctors on Call (Croydoc) and taking unauthorised financial advances from the service without the board's agreement.

A fitness to practise panel at the tribunal in Manchester heard that he took the advances for himself and his wife, Salma Uddin, who also worked for the service, against their salaries. By 2009 he had taken £100 000 more than the couple were entitled to at that point.

Paul Ozin, counsel for the General Medical Council, told the panel, "Dr Sondhi had plenty of time to bring it to the attention of the board. We invite you to draw the inference he chose not to do so as he knew they would take a dim view of his actions, as indeed they did." He added, "Dr Sondhi got through getting on for two years without anybody knowing about it. By any ordinary standards of behaviour his conduct was dishonest, and he must have known that." A sum of £41 910 was never recovered and had to be written off.

Croydoc, a GP cooperative set up in 1995, won contracts to provide overnight and weekend services to patients in the London boroughs of Croydon, Kingston, Sutton, and Merton. A report commissioned by NHS Croydon concluded in 2011 that Sondhi had personally controlled the out of hours service.[1]

At one time he was simultaneously chairman, medical director, operations director, and financial director and was responsible for allocating doctors to on-call rotas.

The GMC alleged that he failed to ensure an adequate level of cover and misled other directors about the cover provided. After 2006 there was only one doctor on the rota, covering a population of 950 000, the NHS Croydon report found.

Ozin said that Sondhi was out of reach at his home in Fakenham, Norfolk, when he was expected to be at the surgery in south London. "This led to the creation of a system which amounted to the provision of inadequate care," he said.

Sondhi is accused of repeatedly failing to respond to calls, arriving late for shifts, and sometimes failing to turn up at all. On one occasion he is said to have missed 144 calls overnight, and the GMC alleged that he would take between 1.5 and three hours to respond to urgent calls, against a target of 20 minutes.

The GMC also accused him of acting in a "verbally aggressive, intimidating, and abusive" manner to colleagues and referring to coworkers in inappropriate and racist terms.

Sondhi, who denies the misconduct charges, was suspended from practice by the GMC pending the hearing, which is due to last until 26 July.

Cite this as: *BMJ* 2013;346:f4217

GP is suspended for failing to provide shared care for child over nine year period

Clare Dyer BMJ

A GP has been suspended for 12 months by the Medical Practitioners Tribunal Service (MPTS) after he failed to take active steps to safeguard the health of a child cancer survivor who was missing appointments and growth targets.

Jaffar Shah, a partner at Darlaston Health Centre near Walsall, West Midlands, admitted repeatedly breaching the shared care protocol agreed between him and Birmingham Children's Hospital in the case of patient "X" and failing to immunise her despite direct requests from her specialists.

X, now in her late teens, was diagnosed with acute myeloid leukemia at age 2 in 1996 and underwent a bone marrow transplant in 1997 after a relapse. From October 2001 to 2010, her care was divided between Birmingham Children's Hospital and Shah, her GP. His responsibilities included immunisation, administering growth hormone, and tracking her growth.

In 2010, X made a complaint to the police alleging parental abuse and neglect. Evidence of shortcomings in her medical care led to an investigation by Walsall Healthcare NHS Trust, which showed not only systemic failures but also personal failings by her GP.

Shah did not attend the MPTS hearing but admitted the factual charges against him in a solicitor's letter. The charges included failure to adequately record the growth hormone administered to X, failing to properly monitor her growth and to comply with dose changes and immunisations requested by the hospital, and failing to act on her non-attendance at appointments.

Shah's overall treatment of X amounted to serious misconduct, said the panel.

Cite this as: *BMJ* 2013;347:f4238

Peers call for UK to harness cell science

Adrian O'Dowd LONDON

Regenerative medicine has "enormous" potential to help people with chronic disease, but the United Kingdom is currently unprepared to harness its possibilities, peers have claimed.

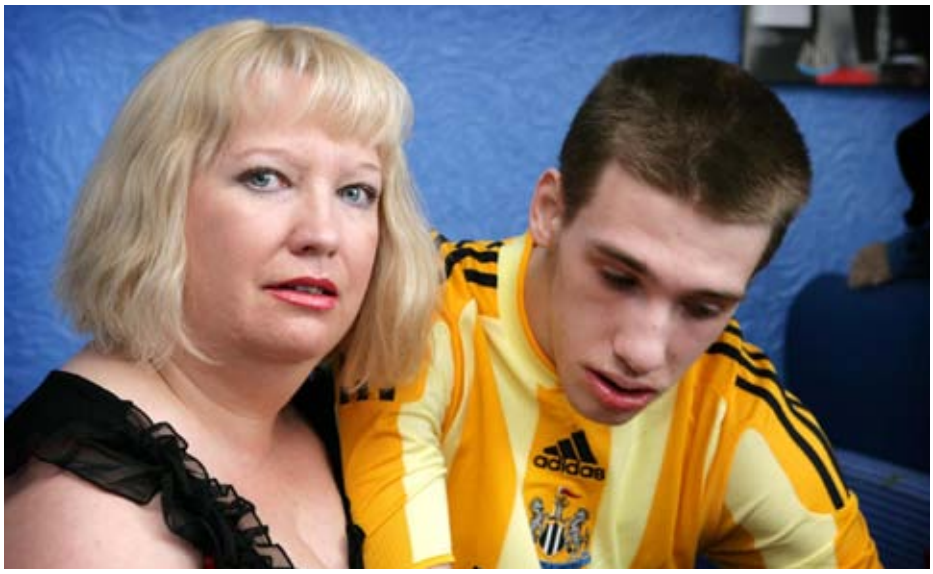
Regenerative medicine, which involves replacing or regenerating cells, tissues, or organs in the human body to restore or establish normal function, includes cell therapy, gene therapy, and tissue engineering.

A report published on 1 July by the House of Lords Science and Technology Committee said that the UK was a potentially attractive location for international investment in regenerative medicine.[1] This area of medicine, it argued, offered significant hope for innovative treatments for many chronic diseases, such as Parkinson's disease, cardiovascular disease, and diabetes, which together account for around 75% of all UK healthcare costs.

"The UK has many strengths in regenerative medicine, including: an excellent basic science base, potential access to hundreds

A synthetic windpipe created in 2011 using nanotechology to replace a cancerous trachea

Allow mitochondrial replacement to prevent disease, says CMO



Sharon Bernardi, with her son Edward, who died in 2011, lost seven children to mitochondrial disease

Susan Mayor LONDON

England's chief medical officer is recommending that the UK government introduce regulations to enable couples at high risk of having a child with severe mitochondrial disease to undergo in vitro fertilisation (IVF) to replace the mother's faulty mitochondria with those from a healthy donor.

The decision is likely to make the United Kingdom the first country in the world to provide mitochondrial replacement to prevent serious mitochondrial disease. The technique is considered controversial because it adds new DNA to the resulting embryo, by combining nuclear DNA from both parents with a tiny amount of mitochondrial DNA from a donor.

"This is not a decision to take lightly," said the chief medical officer, Sally Davies. "There are clearly some sensitive issues here, but it is clear that, overall, there is general support for allowing these treatment techniques to be used, subject to strict safeguards."

Her recommendation came after a public consultation and science review led by the Human Fertilisation and Embryology Authority, the independent regulator overseeing fertility treatment and research, showed general support for use of the technique.[1] The authority concluded that the benefits outweighed the risks.

A report from the Nuffield Council on Bioethics found that it would be ethical for families affected by mitochondrial disease to use these techniques, after confirming their safety and efficacy.[2]

"So we are going to move forward, and I have advised the government that we should," said Davies. Regulations on mitochondrial replacement will now be developed and will be for open consultation during the autumn. These will be put before parliament for debate. If passed, they will then be added to the Human Fertilisation and Embryology Act, which makes allowance in its current wording for the addition of regulations on mitochondrial replacement.

Ted Webb, deputy director for health science and bioethics at the Department of Health for England, said, "Where we are now is part of a process. There has been a public dialogue—the public has said, 'Yes, move forward'—and now regulations will go to parliament."

Davies predicted that it would take at least a year before the procedure became available to patients. "We would then be the first country to allow this in practice," she said, adding that it would be provided by the NHS to couples meeting the criteria set out in the regulations.

"It provides a safe way for five to 10 babies each year to be born healthy," she predicted. All children born after use of mitochondrial replacement will be followed up to collect information on long term safety and effects.

Webb acknowledged that details of the criteria by which patients would be selected for mitochondrial replacement were still to be worked out, but he suggested that they would be likely to include having had a child who had died from mitochondrial disease.

Mitochondrial DNA is passed from mother to child, and mutations can lead to serious and potentially fatal mitochondrial diseases, with symptoms including poor growth, muscle weakness and loss of coordination, blindness, liver disease, and heart failure. They affect around one in 6500 people in the UK, making them more common than childhood cancers.

> "There has been a public dialogue—the public has said, 'Yes, move forward'—and now regulations will go to parliament"

The mitochondrial replacement technique being researched in humans in the UK is pronuclear transfer. It involves fertilising the mother's egg and then transferring the two pronuclei containing the DNA from both parents—which later fuse to code for the child's complete genetic blueprint—into a fertilised donor embryo that has had its pronucleus removed.

Davies argued that nuclear replacement did not result in a major change in genetic makeup. "The majority of the DNA is in the nucleus—it's the germline, it's what makes us what we are, and there is no intention of looking at doing anything involving [replacement of] the nuclear DNA."

Cite this as: *BMJ* 2013;346:f4211

of thousands of patients in a unified healthcare system, and experienced blood and transfusion services, clinicians, and scientists," the report said.

However, opportunities to develop this area of medicine were being hindered because of problems in regulatory arrangements and a lack of coordinated leadership.

Peers on the committee made several recommendations, including that the Health Research Authority take steps to streamline the overall regulatory system for regenerative medicine. They also said that the National Institute for Health Research should set up a regenerative medicine stream in its clinical research network to help design clinical trials, identify patients, and find interested clinicians.

The Department of Health for England should develop a strategy to ensure that the NHS was ready to provide regenerative treatments, and the National Institute for Health and Care Excellence should also review its evaluation processes, the peers argued.

John Krebs, a crossbench peer and the committee's chairman, said, "Regenerative medicine has the potential to be good for public health and the health of the UK economy, but we must take steps now to ensure we realise that potential."

Cite this as: *BMJ* 2013;346:f4248

GRAHAM TURNER/GUARDIAN NEWS & MEDIA LTD

Hilary Cass said management culture determines whether staff feel able to raise safety issues

Great Ormond Street Hospital gagged doctor who raised concerns

Clare Dyer BMJ

A senior consultant who left Great Ormond Street Hospital after a dispute with management, which began when she raised concerns about cuts in the numbers of junior doctors, was subjected to a gagging clause banning her from speaking about the circumstances in which her employment ended.

Hilary Cass, now a consultant at Guy's and St Thomas' NHS Foundation Trust and president of the Royal College of Paediatrics and Child Health, lost her roles as deputy medical director and director of medical education at Great Ormond Street in 2007 after she objected to a proposed reduction in the numbers of junior doctors.

She filed a grievance about the behaviour of senior management over the concerns she had raised and her treatment by the Great Ormond Street trust, then launched a claim for constructive dismissal and left in 2009 to take up her new job. But in 2010, she accepted a settlement of her constructive dismissal claim that would allow her to train in palliative care at Great Ormond Street, to enable her to set up a service for terminally ill children at her new hospital.

The settlement made the training conditional on her accepting the gagging clause, which also forbade her making "any statements derogatory of GOSH [Great Ormond Street Hospital]."

Private Eye magazine obtained the compromise agreement under the Freedom of Information Act.

Great Ormond Street said in a statement: "The trust recognises that Dr Cass's continued clinical training at Great Ormond Street Hospital should not have been referenced in the agreement."

Cass said: "The lesson of the Francis inquiry is that it is the management culture which directly creates the environment in which professionals feel able to raise concerns about clinical care and patient safety."

Cite this as: *BMJ* 2013;347:f4253

US hospitals adopt "tobacco-free" hiring policy

Michael McCarthy SEATTLE

The University of Pennsylvania Health System has become the latest in a growing number of US health systems that will no longer hire smokers.

The University of Pennsylvania Health System includes the Hospital of the University of Pennsylvania and the Children's Hospital of Philadelphia, both located in Philadelphia.

Civil libertarians have denounced similar tobacco-free hiring policies, saying that employers should have no say over what their employees do on their own time. And health policy analysts are concerned that such polices would make smokers conceal their smoking, making it harder to enrol them in smoking cessation programmes. Under the new policy the University of Pennsylvania Health System stopped hiring tobacco users "to improve the overall health of our workforce while reducing healthcare benefit costs."

Holly Auer, the system's spokeswoman, said, "Since the University of Pennsylvania Health System began collecting information about applicants' tobacco use this spring, only a small number of prospective employees have indicated they use tobacco."

Cite this as: *BMJ* 2013;347:f4294

US court ruling gives free speech protection to scientific articles

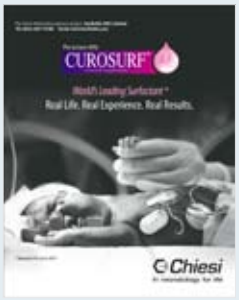
Michael McCarthy SEATTLE

Citing free speech protections guaranteed by the First Amendment of the US Constitution and New York state law, a US federal court has ruled that researchers cannot be sued for scientific conclusions made in journal articles about matters of scientific debate.

In addition, companies that cite excerpts from such articles in their advertising and promotional efforts are also protected, "so long as the excerpts do not mislead a reader about the conclusions of the article," the court ruled.

The case involved a lawsuit over false advertising brought by the company ONY of Amherst, New York, maker of the lung surfactant product calfactant (which it markets as Infasurf), against Cornerstone Therapeutics, in North Carolina, which markets a competing product, poractant alfa (Curosurf), under contract for Chiesi Farmaceutici of Parma, Italy.

In the lawsuit ONY alleged that Chiesi and Cornerstone paid for research designed to show that the Chiesi product was superior and then disseminated the false and deceptive findings through an article published in the *Journal of Perinatology* and through promotional material citing the article's conclusions.



ONY alleged the findings about Curosurf were false

The research compared the efficacy of three lung surfactant products for the treatment of respiratory distress syndrome in newborns: poractant alfa, calfactant, and beractant, marketed as Survanta by Abbott Pharmaceuticals.

The article in the *Journal of Perinatology* concluded that infants treated with poractant alfa had lower mortality than was seen in infants treated with the other two products.

Shortly after the paper appeared ONY sued in the US District Court for the Western District of New York, claiming that the article was intentionally misleading. In its decision the higher court, the second US Circuit Court of Appeals, ruled that the question hung on whether a researcher's conclusion was a statement of fact or opinion.

It said that scientific conclusions "are more closely akin to matters of opinion."

Cite this as: *BMJ* 2013;347:f4259