NEWS

bmj.com
GPs and charity draw up plan to improve cancer diagnosis

Lack of warnings over flu may have led to more deaths after pandemic

Zosia Kmietowicz LONDON

The decision of the UK's coalition government to cancel the traditional publicity campaign about the dangers of flu the year after the H1N1 pandemic in 2009-10 is likely to have contributed to a rise in numbers of deaths and admissions to hospital in 2010-11, researchers say.

The only "notable difference" between the pandemic year of 2009-10 and the year immediately after was the action of the government, say investigators, one of whom is Liam Donaldson, the chief medical officer for England in the first year of the pandemic, who stepped down from the post when the coalition came to power in May 2010. They describe the government's approach to flu that year as "laissez-faire," particularly the cancellation of the public awareness campaign by the health secretary for England, Andrew Lansley.

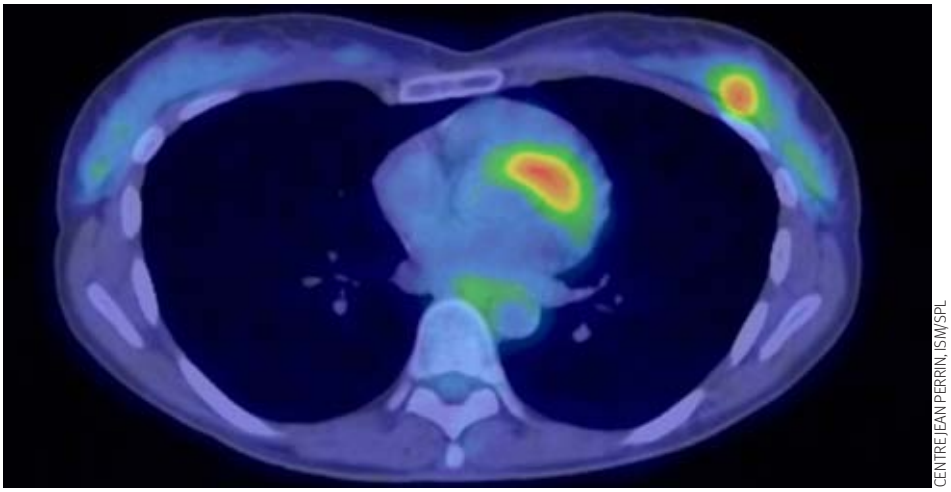
Their analysis of flu activity in England, published in *Eurosurveillance* (www.eurosurveillance.org), shows that during the winter of 2010-11 the burden of severe illness from flu was worse than in 2009-10, with 10% more hospital admissions (8797 versus 7879), 30% more deaths (474 versus 361), and 30% more admissions to critical care (2200 versus 1700).

In addition, there were fewer flu consultations with GPs in the year after the pandemic (370 000 versus 580 000 in 2009-10); a 30-fold reduction in the use of antivirals in 2010-11; and less public interest in flu, as shown by internet searches.

The authors say, "The most notable difference between the two years was the government response." They describe the public health response in the pandemic year as "highly assertive," with "strong public awareness and education campaigns," school closures, and wide use of antivirals.

"In contrast, in the influenza season that followed the pandemic year, the approach was laissez-faire. The traditional influenza public awareness campaign was cancelled. There was no attempt to warn about the likelihood that the pandemic virus would be circulating (thus affecting younger age groups)."

Cite this as: *BMJ* 2012;344:e2811



CENTRE JEAN PERRIN, IS M/SPL

New tests to better predict survival after breast cancer should be available in three to five years

Landmark study classifies breast cancer into 10 genetic types

Ingrid Torjesen LONDON

Scientists have reclassified breast cancer tumours into 10 categories according to genetic features that correlate with survival, in the largest global study of breast cancer tissue ever performed.

It is hoped that eventually doctors will be able to use these subtypes to predict more accurately a woman's likely survival and to better tailor treatment to patients. The first tests to identify which group a woman belongs to are expected to be available in the NHS in three to five years.

Scientists at Cancer Research UK in Cambridge and the BC Cancer Agency in Vancouver, British Columbia, analysed DNA and RNA samples taken from tumours in 2000 women who had been given a diagnosis of breast cancer between five and 10 years ago. They identified genetic markers, determined which genes were switched on and off, and ascertained numbers of copies of particular genes the chromosomes contained. By studying this genetic fingerprint they found that breast cancer could be classified into at least 10 subtypes.

Carlos Caldas, senior group leader at Cancer Research UK's Cambridge Research Institute, said that the study, published in *Nature* this week (doi:10.1038/nature10983), made breast cancer an "umbrella term" for an even greater number of diseases and would mean that in the future patients with breast cancer could hope to receive treatment targeted to the genetic fingerprint of their tumour.

He said: "It is not going to change the management of women treated in the NHS tomorrow, but it is surely going to change the way in which we do clinical trials. We will be doing clinical trials that are much more targeted at each of these 10 subtypes. And finally, because we have discovered new breast cancer genes, this will give us new avenues to develop targeted treatments."

Before this study breast cancer was basically classified into four types according to whether the tumour was positive for receptors for oestrogen (Er+), human epidermal growth factor receptor 2 (Her2+), and progesterone (Pr+).

Seventy per cent of women have breast cancer that is Er+ and Her2−, and the researchers have now subdivided this group into seven subtypes. The likelihood that a woman with a high proliferation Er+ and Her2− tumour would be alive after 10 years is 75%, but when these tumours are subdivided into the seven new types the researchers found that survival varied from less than 40% to more than 80% after 15 years.

Of the other three new subtypes, one "robustly identifies" the Her2+ tumours, one contains most of the triple negative tumours, and another contains a subset of Er+ tumours, a subset of Er− tumours, and a subset of triple negative tumours.

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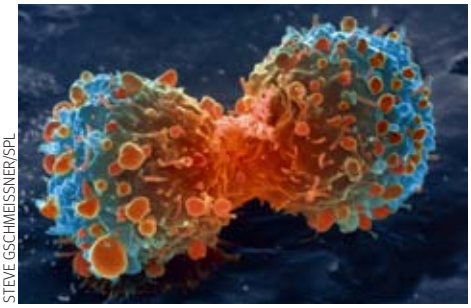


STEVE GSCHMEISSNER/SPL

Sharing information about processes in lung cancer care could drive up quality

Lung cancer teams pair up to review care processes and improve outcomes

Susan Mayor LONDON

Thirty lung cancer teams across England have observed how other services do things in a novel experiment to help them identify reasons for variations in lung cancer outcomes and to devise ways to improve the quality of care.

The Improving Lung Cancer Outcomes Project was set up to identify reasons for the variation in clinical outcomes and in patients' experiences shown in the NHS's national lung cancer audit.

Lung cancer teams in England have been submitting data to the national audit since 2005. Results have shown improvements in measures of processes and outcomes but also a large variation that is not wholly explained by differences in case mix (*BMJ* 2011;342:d3211). The latest audit, for 2010, showed that the proportion of lung cancer patients discussed at a multidisciplinary meeting ranged from 67% to 100% at different NHS trusts (www.ic.nhs.uk).

The Royal College of Physicians and eight partner organisations, including the national cancer action team and patients' organisations, invited all 156 lung cancer services in England to take part in the improvement project; 96 expressed an interest, of which 30 were randomly selected to participate.

Each of the 30 teams in the intervention group was paired with one of the other trusts, and each member of the pair visited the other's services for one full day, attending their lung cancer multidisciplinary meeting.

"The commonest areas for improvement were associated with efficiencies in how multidisciplinary team meetings operated," explained Ian Woolhouse, clinical director of the Improving Lung Cancer Outcomes Project. These included the amount of information available to the meeting, the way in which decisions were reached, and methods for capturing information and outcomes.

More details on the project are at http://bit.ly/IfopYU .

Cite this as: *BMJ* 2012;344:e2770

Special support is offered to dementia patients in Scotland

Bryan Christie EDINBURGH

Everyone newly diagnosed with dementia in Scotland is to be guaranteed at least a year's support in what is said to be one of the first commitments of its kind in the world.

It is part of a wider programme of improvements to dementia care which has seen 100 dementia champions trained to work in Scottish hospitals and the appointment of specialist dementia nurses across the country.

Scotland already outperforms other parts of the UK in diagnosing dementia. A report earlier this year from the Alzheimer's Society found that 64.5% of people with dementia in Scotland had been given a diagnosis in 2011, compared with 61.5% in Northern Ireland, 41.1% in England, and 37.4 % in Wales (www.alzheimers.org.uk/dementiamap).

Early diagnosis is important in providing access to care, treatment, and support. The *World Alzheimer's Report 2010* estimated that it can also save taxpayers around $10 000 (£6290; €7630) per person by delaying the need for care outside the home.

Scotland's health minister, Nicola Sturgeon, has said that her top priority is to improve the care of older people, including those with dementia. The one year post-diagnosis support will be delivered by a named and trained individual and will aim to help individuals and families understand the illness, manage its symptoms, connect with support networks, and plan for the future.

Henry Simmons, chief executive of Alzheimer Scotland, said: "Scotland has had tremendous success in facing one of the key challenges of dementia—encouraging people to come forward and making sure that they receive a prompt diagnosis. Recent statistics show we are leading the way in this regard compared to our counterparts in England and Wales.

"The new national commitment to a guarantee of one year's post-diagnostic support for everyone receiving a diagnosis of dementia, as well as their partners and families, is a perfect way to build on this."

The first 100 dementia champions have started work in Scottish hospitals, where they are helping to improve the frontline care of people with dementia as well as cascading information and education to other staff. By the end of next year 300 dementia champions will be in place across Scotland.

Sturgeon said: "Providing the very best care for every older person on every occasion, in care homes and in hospitals, continues to be a personal priority for me. Getting the right support in place at this (early) stage of the illness can greatly help improve the quality of care throughout the journey of the illness."

Cite this as: *BMJ* 2012;344:e2687

Cancer treatment in US is "costly but effective"

Bob Roehr WASHINGTON, DC

Cancer treatment in the United States is more expensive than in other developed countries but achieves better outcomes, a new study has shown.

The study looked at survival after cancer diagnosis in the US and 10 European Union countries and "looked at the value of any additional gains [in life expectancy] that might have occurred because of extra spending," said a coauthor, Dana Goldman, an economist and public policy analyst at the University of California.

Although cancer survival rose in both regions between 1983 and 1999, the gap between them widened over that period: survival in the US was two years longer than in the EU countries at the start of the period (nine years in the US versus seven in the EU) and rose to 2.7 years by the end (*Health Affairs* 2012;31:667-75).

The gap in spending also rose over that period. The US spent $8400 more (in terms of 2010 dollars) for each patient with cancer than did the EU countries in 1983, and that difference rose to $25 000 by 1999. The additional $17 000 in spending in the US purchased an additional 0.6 years of life, Goldman said.

The difference in the decline in the mortality rate between the EU countries and the US was particularly marked for prostate and breast cancer, but Europe achieved more cost effective outcomes in treating colon cancer.

Another study in the same issue of *Health Affairs* looked at the cost effectiveness of screening for lung cancer (2012;31:770-9). The authors looked at whether it made economic sense for insurance companies to cover their customers for the cost of computed tomography to detect lung cancer. They concluded that it did and would cost less than a dollar per member per month.

Cite this as: *BMJ* 2012;344:e2766

6000 patients are left in limbo as company fails to record radiograph results

Nigel Hawkes LONDON

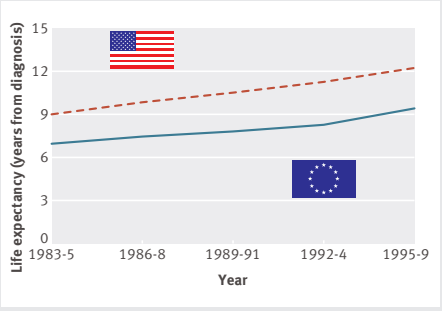
Six thousand patients sent for radiography by a 24 hour care centre in northwest London have been left in limbo, with no evidence that a specialist radiologist ever reviewed the radiographs to see if the patients had any serious conditions.

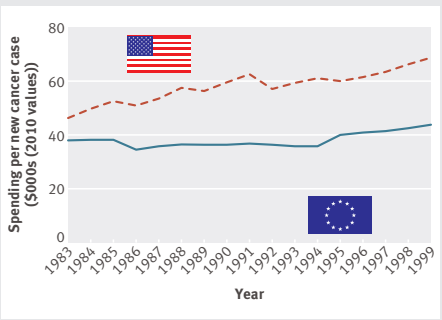
NHS Brent has logged the failures at Brent Urgent Care Centre as a serious incident and has launched a full investigation. A review of 5% of the cases has indicated that 2% had "missed pathology" because their radiographs had not been reviewed.

The centre, which is located at Central Middlesex Hospital, is run by Care UK, a private company with many NHS contracts in primary and secondary care. It deals with minor illnesses and injuries that require urgent and immediate treatment, referring more serious cases to the emergency department at the hospital.

Care UK told NHS Brent on 30 March that it had identified 6000 patients who had not been discharged from its computer system. In a letter to GPs, Jo Ohlson, borough director for NHS Brent, said: "Upon investigation it became clear that many of these patients had been sent for x ray, and the provider cannot confirm that the radiology reports have been reviewed for missed pathology. In addition, discharge notifications will not have been issued to GPs."

Cite this as: *BMJ* 2012;344:e2713





ALEX SEGRE/ALAMY

Doctors think it's unlikely that companies that make money from selling high calories food, such as McDonald's, are going to persuade their customers to eat more healthily, Terence Stephenson said

Medical colleges and faculties unite to tackle obesity after "failure" of current strategies

Nigel Hawkes LONDON

The Academy of the Royal Medical Colleges has launched an inquiry into effective ways to reduce the prevalence of obesity. Supported by all 21 royal medical colleges and faculties, the academy says that the three month inquiry will be the springboard for campaigning activity that will continue into next year.

In an article in the *Observer* newspaper Terence Stephenson, president of the Royal College of Paediatrics and Child Health and chairman of the academy's steering group, criticised the government's "responsibility deals" with the food industry. He said that instead it must take on the major brands, which he likened to the tobacco companies of the last century blocking moves to save lives so as to protect their profits (http://bit.ly/HZ2LZJ).

"Doctors think it's inherently unlikely that huge companies that make money from selling high-calories food and drinks, like McDonald's and Coca-Cola, are going to persuade their customers to eat more healthily," he told the *Observer*. "It's like asking the petrol companies to say to people 'why not go on your bicycle?' It just does not seem likely that is going to happen."

The announcement of the inquiry on the academy's website is more circumspect. It does not blame anybody but says that it will seek the views of a wide range of people and consult research evidence over how best to prevent or reduce obesity, looking at five areas: action that can be taken by individuals; the environment; clinical interventions; fiscal measures; and education.

Under the environment would be included advertising, food labelling, sponsorship, the built environment, and local authority policies, while fiscal measures would include taxation, minimum pricing, and corporate or personal incentives.

The announcement quotes Stephenson as saying: "Our starting point is the collective desire to ensure the healthcare profession is doing all it can to detect, treat, manage—and ultimately prevent—obesity.

"It is unprecedented that the medical royal colleges and faculties have come together on such a high profile public health issue. But we've done so because we recognise the huge crisis waiting to happen and believe that current strategies to reduce obesity are failing to have a significant impact. Speaking with one voice we have a more of a chance of preventing generation after generation falling victim to obesity related illnesses and death."

Neil Douglas, chairman of the Academy of the Royal Medical Colleges, added: "This won't be just another report that sits on the shelf and gathers dust; it will form the bedrock of our ongoing campaigning activity. We are absolutely determined to push for whatever changes need to happen to make real progress—which is why we're casting the net wide to get input from a range of organisations and individuals."

Levels of overweight and obesity in children and adults in the United Kingdom are high by historical standards. Among children the national child measurement programme in England shows that 9.4% of children joining primary schools in 2010-11 were obese, down from 9.9% in 2006-7. But by year 6 19% were obese, against 17.5% in 2006-7. Some of this increase may be the result of better data collection.

Cite this as: *BMJ* 2012;344:e2775

IN BRIEF

Whooping cough rises in England and Wales: From January to March this year 665 confirmed cases of whooping cough were reported in England and Wales. In the whole of 2011 the number was 1040. The rise has continued from the second half of last year, with clusters in schools, universities, and healthcare settings.

FDA demands clot warnings on US labels of drospirenone: Labels in the United States on contraceptive pills containing drospirenone (marketed as Yaz) will now state that the pills may cause as much as a threefold higher risk of blood clots than other birth control pills, the US Food and Drug Administration has said. The decision comes after a controversial advisory committee meeting at which experts, some with ties to the manufacturers, voted that the drug's benefits outweigh its risks.

Lung cancer continues to rise in women and fall in men: The prevalence of lung cancer in the UK rose to 39.3 cases for every 100 000 women in 2009, from 22.2 per 100 000 in 1975, show Cancer Research UK figures. Lung cancer is still more common in men but has fallen from 110 cases per 100 000 men in 1975 to 58.8. The numbers mirror smoking rates two to three decades earlier.

England to have consultation on plain packaging for cigarettes: England's health secretary has launched a consultation on whether plain packaging could drive down the appeal of tobacco to young people. He said that the Department of Health would not work in partnership with tobacco companies as he wants them to have "no business" in the UK because, unlike alcohol and fatty foods, there was "no harmless level" of smoking. Australia has already introduced a bill on plain packaging (*BMJ* 2011;342:d2801), but the legislation is not yet in place.

Cite this as: *BMJ* 2012;344:e2776

CORRECTION

Journals question integrity of almost 200 papers by Japanese anaesthetist

In the print version of this News article about Dr Yoshitaka Fujii of Toho University, Tokyo (*BMJ* 2012;344:e2490), we inadvertently used a picture of a different Dr Yoshitaka Fujii, who is not the person mentioned in the article. We apologise to Dr Fujii for our mistake.

Cite this as: *BMJ* 2012;344:e2830

GPs do not know whom to contact when patients have IBD relapse

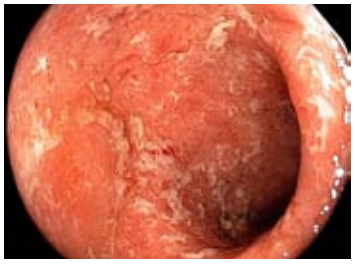
Ingrid Torjesen LONDON

Patients who experience a relapse of inflammatory bowel disease (IBD) are not being referred to hospital as quickly as they should be, according to a survey by the Royal College of Physicians.

GPs told researchers that they want patients who consult with renewed symptoms of ulcerative colitis or Crohn's disease to be seen in hospital within seven days, but 59% of the 1675 respondents admitted that such speedy access was not available.

Half of GPs indicated that they either did not know whom to contact in secondary care when they required help and advice on IBD or that the lines of communication were slow. Many GPs were unaware of the existence of IBD clinical nurse specialists, and these nurses were the first point of contact for fewer than 10% of GPs.

Ian Arnott, consultant gastroenterologist at Western General Hospital, Edinburgh, and clinical director for the UK IBD Audit, for which the survey was conducted, said the findings highlighted significant issues in communication between primary and secondary care services for patients with IBD and a number of educational issues surrounding the long term follow-up of patients.



Many GPs in the survey did not know of the existence of IBD nurse specialists

GASTROLAB/SPL

John O'Malley, secretary of the Primary Care Society for Gastroenterology, said: "This audit highlights the need for better working together between primary and secondary care with better recognition and treatment of flare ups in IBD needed on the primary care side and better provision of 'fast track' access to hospital care. It also shows that a greater awareness of the potentially valuable role that IBD nurses could play in primary care is needed."

A report from the UK IBD Audit Steering Group based on the survey findings recommends raising GPs' awareness of the role of IBD specialist nurses and the support they can offer to primary care. It also says that hospitals should provide GPs with management plans for patients that indicate a named individual to be contacted for advice in the event of a relapse and details of an IBD nurse specialist where there is one.

The survey found that three quarters of IBD patients are under hospital care for their long term follow-up, but some are not being seen by any clinical team, adversely affecting their healthcare needs.

Both UK IBD audit surveys can be found at www.rcplondon.ac.uk/resources/inflammatory-bowel-disease-audit.

Cite this as: *BMJ* 2012;344:e2675

US tops league table for salt content in fast food

Bob Roehr WASHINGTON, DC

The salt content of items sold by international fast food chains can vary substantially both between different food items and even for the same item sold in different countries, a new study published in *CMAJ*, the journal of the Canadian Medical Association, has found (doi:10.1503/cmaj.111895).

The authors believe that there are no technical reasons for salt to be added at high levels and therefore that it should be possible to significantly reduce the overall use of salt in fast food.

Hypertension and related health problems are associated with high consumption of salt in the Western diet. About three quarters of that salt comes from processed foods, particularly fast foods.

The study surveyed the salt content of menu items from six of the largest international fast food chains—Burger King (known as Hungry Jack's in Australia), Kentucky Fried Chicken, McDonald's, Pizza Hut, and Subway—in Australia, Canada, France, New Zealand, the United Kingdom, and the United States. Data on a total of 2124 items were gathered from company websites in each country in April 2010.

One of the greatest transnational differences was found in McDonald's Chicken McNuggets. The US version had two and a half times the salt content of the UK version (1.6 versus 0.6 g per 100 g of food). As a group, all chicken products in the UK had a significantly lower salt content than in the US (1.1 versus 1.8 g salt/100 g).

Levels of salt in savoury breakfast items were lower in the UK (1.4 g), Australia (1.3 g), and New Zealand (1.1 g) than in the US (1.8 g per 100 g).

The study also found "much greater variability when salt levels were reported per serving rather than per 100 g, which reflected non-standard serving sizes between countries and

No clear benefit is seen from proton therapy for prostate cancer

Keith Epstein WASHINGTON, DC

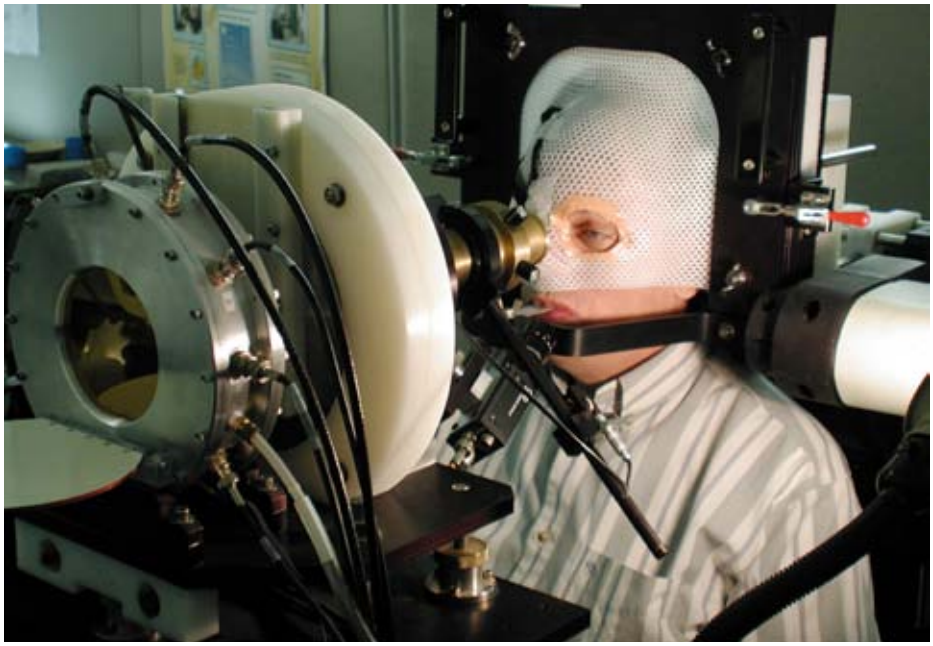
A study that used patients' records to compare outcomes and morbidity from the three most common radiation treatments for prostate cancer showed no clear clinical benefit from the increasingly popular and expensive use of proton beams. Those patients had more complications.

The study of 12 000 patient records, financed by the US Department of Health and Human Services and the National Institutes of Health, adds to questions in the United States not only about the relative merits of expensive breakthrough technologies but whether the government and insurers should pay more for treatments that are less effective.

No other study is thought to have examined the records of such a large number of patients treated with proton therapy.

Specifically the study, published on 18 April in *JAMA* (2012;307:1611-20), examined records of a surveillance and epidemiological database of the primary US government health insurance programme, Medicare, which pays for treatment of a large segment of the US population, to compare traditional radiation therapy with intensity modulated radiation therapy (IMRT) and, separately, IMRT with proton beam therapy. Patient records covered the years 2000-9.

Among patients with non-metastatic prostate cancer, IMRT was associated with less gastrointestinal morbidity and fewer hip fractures than traditional radiation therapy but more erectile dysfunction. IMRT, when compared with proton therapy, was associated with fewer gastrointestinal effects.



SPL

Proton beam therapy has been shown to be useful for certain uncommon brain tumours, such as childhood medulloblastoma. Here it is being used for a carcinoma within the eye

"Overall, our results do not clearly demonstrate a clinical benefit to support the recent increase in proton therapy use for prostate cancer," the authors noted. "We found no significant differences among patients treated with proton therapy vs IMRT in morbidity or receipt of additional cancer therapy, except an association with increased gastrointestinal morbidity in proton therapy patients."

One of the study's authors, Ronald Chen, a radiation oncologist at the University of North Carolina, told the *BMJ*, "We did not find a significant benefit in patient outcomes from proton compared to IMRT.

"I think our results call for additional comparative effectiveness research on this issue. More broadly, I think it is important to perform studies that directly compare newer versus older treatments [and that these] demonstrate benefit before adopting the newer treatment as standard."

FEATURE, p 20

Cite this as: *BMJ* 2012;344:e2767

between companies." One of the greatest ranges in salt content per "serving" was found in pizzas, ranging from less than 1 g to more than 10 g per serving.

The study is part of an ongoing effort by the Global Food Monitoring Group, composed of representatives from about 25 countries.

"We aim to collect nutrition information for processed and fast food products around the world in an effort to monitor changes over time and identify where reformulation efforts will be most effective," the paper's lead author, Elizabeth Dunford, a researcher at the George Institute for Global Health in Sydney, told the *BMJ*.

She said that the lower levels of salt found in fast food in the UK were the result of efforts by the Food Standards Agency and the industry.

Cite this as: *BMJ* 2012;344:e2769

Study found faults in hip implants a year before UK ban

Deborah Cohen BMJ

An unpublished trial of a metal-on-metal total hip replacement, funded by the US medical device company Stryker, was stopped early more than a year before the UK regulator told surgeons not to use the implant, the *BMJ* has learnt.

Earlier this month the Medicines and Healthcare Products Regulatory Agency (MHRA) told surgeons to stop using the MITCH TRH cup/heads, made by Finsbury Orthopaedics (now Depuy), in combination with Accolade femoral stems made by Stryker Orthopaedics.

The instruction came after the National Joint Registry for England and Wales showed a higher than acceptable revision rate of 10.7% at four years among 271 patients. However, a Stryker funded trial conducted at the Freeman Hospital in Newcastle upon Tyne was stopped more than a year earlier after it showed that the hip prosthesis was failing two years after being implanted.

The trial recruited 73 participants from December 2007, 37 of whom were implanted with a metal-on-polyethylene total hip replacement and 36 with the metal-on-metal MITCH TRH total hip prosthesis.

The trial's chief investigator, Nigel Brewster, an orthopaedic surgeon at the Freeman, told the *BMJ* that within two to three years 9% of patients in the MITCH TRH arm needed to have their hip revised. He scanned them after they came back to him with pain and found that tissue around the joint was inflamed and necrotic. He is currently following up the patients and publishing the results.

Stryker declined to say whether it had conducted any studies on the implant, saying it was the responsibility of Depuy (which bought Finsbury Orthopaedics in 2009) to oversee its safety—even though Stryker marketed it across Europe.

Cite this as: *BMJ* 2012;344:e2698

Use of branded version of cholesterol drug costs US healthcare system $700m a year, study shows

Michael Day MILAN

Doctors are too easily persuaded to continue prescribing branded drugs by marketing strategies designed to ensure that they do not switch to cheaper generic versions, a new study says.

New formulations extended the drug's patent from 2002 to 2011

Yale University researchers cite Abbott's marketing of its blockbuster cholesterol lowering drug fenofibrate as a key example of a company's techniques to extend a drug patent. The first formulation of the drug, which is marketed in the United States as TriCor, came off patent in 2002, but the introduction of new formulations allowed a version of it to remain on patent until 2011.

"This continued use of branded formulations, which cost twice as much as generic versions of fenofibrate, imposes an annual cost of approximately $700m [£440m; €540m] on the US healthcare system," said one of the Yale team, Nicholas Downing. "The example of fenofibrate highlights a system-wide opportunity for improvement."

The team's report, published in the *Archives of Internal Medicine* (doi:10.1001/archinternmed.2012.187), says that Abbott Laboratories maintained its dominance of the fenofibrate market through "a complex switching strategy" that involved frequent launches of branded reformulations that the authors claim had not been shown to be superior to the first generation product—combined with aggressive use of patent litigation to delay the approval of rival generic formulations.

The slight differences in dose of the newer branded formulations were enough to prevent their substitution with the generic competitors. And as soon as rival products were due to appear at the same dose, Abbott would launch another reformulation, and the cycle would repeat.

The researchers note that Abbott's strategy for preserving its share of the fenofibrate market, which was 77% in 2009, was entirely legal. This indicates, they say, that greater awareness by prescribers and changes in government policy are needed to save money for health services.

In a statement Abbott insisted that its new formulations of the drug had benefited patients. It said, "Enhanced formulations of TriCor have brought important benefits to patients, including lower doses, fewer pills, new indications, and the ability to take the medicine without food, which improves patient compliance and ensures that patients are getting its full therapeutic benefit."

The company's claims are disputed by the Yale researchers, who say that the new formulations "showed no improvement in surrogate markers or patient outcomes."

But one of the authors, Harlan Krumholz, a professor of cardiology, told the *BMJ* that it was not just the company that could be criticised. He thought that doctors were "complicit" in the problem. He asked, "Why didn't we prescribe the bioequivalent generics for our patients? What was the advantage to our patients of the more expensive proprietary drug? Did we let down our patients and society? Why didn't we think about whether the higher cost, brand drug was providing any additional benefit?"

Cite this as: *BMJ* 2012;344:e2736

US judge fines Johnson & Johnson $1.1bn for misleading marketing of risperidone

Janice Hopkins Tanne NEW YORK

Judge Tim Fox of the Arkansas Circuit Court fined the Johnson & Johnson subsidiary Janssen Pharmaceuticals $1.1bn (£0.7bn; €0.84bn) for promotional information about the antipsychotic drug risperidone that misled the state into spending Medicaid funds for the drug. He also fined the company $11m for violating the state's law on deceptive practices. Medicaid is a joint federal and state health insurance scheme for people on low incomes.

The Arkansas attorney general, Dustin McDaniel, charged that Johnson & Johnson and Janssen had not clearly described the risks of risperidone (which is marketed as Risperdal), had marketed the drug for unapproved uses, including for problems in children and elderly people, and had marketed it as safer and better than its competitors.

A jury decided that Johnson & Johnson had defrauded the Medicaid programme. Fox fined the company for 238 000 violations of the state's Medicaid fraud laws over nearly four years since 2002. He set a fine of $5000 for each violation.

Johnson & Johnson said in a statement that it was disappointed by the judge's decision on penalties. "If our motion for a new trial is denied, we will appeal," the statement said.

Johnson & Johnson also said, "During the nearly three week trial, Janssen presented abundant evidence showing the company acted responsibly and fully complied with all laws and regulations regarding its antipsychotic medication Risperdal. In contrast, the state did not show any Arkansas patient was ever harmed by using Risperdal, that any Arkansas physician or Arkansas Medicaid was ever misled by the drug's label or package insert, or that the state ever paid for a Risperdal prescription that was not properly written and eligible for reimbursement. In fact, during the entire period at question in the trial, Arkansas Medicaid paid a total of $8.1m on prescriptions for Risperdal. Risperdal continues to help patients around the world who suffer from the debilitating effects of schizophrenia and bipolar mania."

DANIEL HULSHIZER/AP/PA

The company was fined $5000 for each of 238 000 violations of Arkansas Medicaid fraud laws

Johnson & Johnson and Janssen and the related company Ortho-McNeil-Janssen have had other problems with the promotion of risperidone.

In January 2012 Johnson & Johnson settled a Texas case alleging that Janssen had defrauded the state's Medicaid programme. The company settled for $158m.

Last year a South Carolina judge fined the company $327m after a jury found that it had promoted the drug as more effective than its competitors, which it considered unfair.

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