

NEWS

UK news Woman with gene for Huntington's disease fails in attempt to sue her father's trust, p 2

Research news Delayed cord clamping helps motor and social skills, p 3

▶ References and full versions of news stories are on thebmj.com



thebmj.com

▶ Use of coloured overlays and lenses is unlikely to help children with dyslexia, study finds

Start of cheaper technique for breast cancer is delayed in UK despite adoption elsewhere

EXCLUSIVE

Nigel Hawkes LONDON

A new technique that substantially reduces the burden of radiotherapy in women with early breast cancer and could save the NHS millions of pounds a year has been approved in Australia by the Medical Services Advisory Committee—the Australian equivalent of the UK National Institute for Health and Care Excellence (NICE)—ahead of its UK counterpart.

In July 2014 NICE published draft guidance recommending the use of intrabeam radiotherapy, which replaces a course of 15 postoperative radiotherapy sessions with a single dose, given at the time of surgery. A randomised controlled trial led by University College London (UCL), the TARGIT-A trial, was published in 2010,¹ and a five year follow-up in 2014 showed that the outcomes were not inferior to the established approach.²

At that time Carole Longson, director of health technology evaluation at NICE, said that the technique had the potential to be a much more efficient form of radiotherapy. “Unlike regular

radiotherapy, with the Intrabeam Radiotherapy System only one dose is required,” she said. “The single dose is given at the same time as surgery, eliminating the need for numerous hospital visits.”

But, after comments from what NICE referred to simply as professional organisations, the final recommendation has been delayed. This delay has blighted the use of the technique in the UK, where it was developed, but it continues to be enthusiastically employed elsewhere in the world.

“It’s a terrible and shameful situation,” said Jeffrey Tobias, consultant clinical oncologist at UCL and one of the original trialists. “It was invented here—we did the first case in 1998 at the Middlesex Hospital. Now it’s being done routinely in the US, Germany, Australia, France and elsewhere but not here. A number of our patients even have had to go abroad for this treatment.”

Jayant Vaidya, professor of surgery and oncology at UCL, said, “As professionals, we can’t give our patients the treatment that’s best for them. I had to send a patient to Italy last week to get

the treatment there. It’s very frustrating.” He calculated that use of the technique would save the NHS £12m to £60m a year.

The technique has been adopted worldwide. At the St Gallen Breast Cancer Conference in 2011 the consensus among more than 52 breast cancer expert panellists was that TARGIT alone could be used as the only radiation treatment in selected cases. At the Miami Breast Cancer Conference in 2012, 91% of the audience in the surgical oncology stream echoed that view.

Over 250 centres worldwide now use the technique for treating breast cancer in the United States, Europe, Australia, the Middle East, the Far East, and South America.

NICE told *The BMJ* that its decision to call for more evidence does not mean that the technique cannot be used in England and Wales, but Tobias and Vaidya both said that this has indeed been the effect of the ruling, except for patients enrolled in the National Institute for Health Research’s Health Technology Assessment TARGIT-B trial.

Cite this as: *BMJ* 2015;350:h2874

IN BRIEF

Foundation trusts face mounting pressure:

Foundation trusts ended 2014-15 in deficit (–£349m) for the first time, and many missed waiting time targets for emergency departments, routine operations, and some cancer treatments, a report by the healthcare regulator Monitor has found. The sector treated 574 000 more emergency inpatients last year, bringing the total to 10.7 million.

Medical care targeted in areas of unrest:

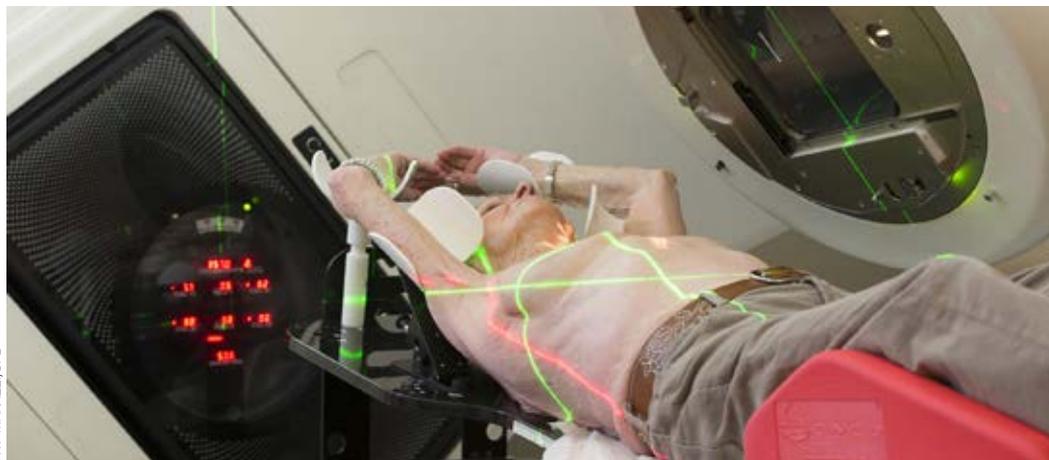
Attacks on medical facilities, health workers, and patients have occurred in at least 17 countries undergoing conflict and civil unrest in the past year, a report from Human Rights Watch and the Safeguarding Health in Conflict Coalition has found. Armed groups have killed over 45 health workers, primarily polio vaccinators, in Nigeria and Pakistan, while in eastern Ukraine around 30-70% of health workers have fled the region because of insecurity.

Nebraska votes to end the death penalty:

Lawmakers in the conservative US state of Nebraska voted 32 to 15 on 12 May to ban the death penalty. Moderate Republicans, citing moral and financial reasons, joined Democrats to pass the legislation. The state’s Republican governor has vowed to veto the bill.

Californian doctors’ leaders change tack on aid in dying bill:

The California Medical Association has dropped its opposition to a hotly contested bill in the state’s legislature that would allow doctors to prescribe lethal drugs to terminally ill patients. It is the first state medical association to take such action.



The new technique replaces a course of 15 radiotherapy sessions with a single dose given at the time of surgery

DRP MARAZZI/SPL

NICE plans new office to advise firms on how to speed up NHS adoption of their drugs

Nigel Hawkes LONDON

The UK National Institute for Health and Care Excellence (NICE) is to set up a new Office for Market Access to advise companies producing new drugs on how to speed up their adoption by the NHS.

The decision was outlined on 21 May at a Westminster Forum seminar on healthcare research by Carole Longson, NICE's director of health technology evaluation. Research was the key to generating new drugs, she said, and moves to accelerate the adoption of new products were being encouraged by regulators in the

form of early access schemes, where drugs may be approved on much less evidence than in the past.

In this new environment, she asked, "Is NICE sending the right signals to the research environment, and are we doing it in a way that can be picked up?" She answered her own question by admitting, "Well, I think we can do a little bit better."

The new office would be a visible "hub" for research and life science companies, she added, and a signal that NICE was really interested in using its experience and expertise to do things of real value for the healthcare

system. The implication, which she did not spell out, was that NICE's reputation for saying no to new drugs had overshadowed its wish to make worthwhile ones quickly available in the NHS.

"NICE needs to be involved as early as possible in discussions about new medicines, and we believe the new Office for Market Access will allow that to happen," she said.

Earlier the seminar had heard details of the government's life science strategy, including biomedical research centres. Graham Lord, director of the National Institute

for Health Research's Biomedical Research Centre at Guy's and St Thomas' Hospital in London, said that seven years after their introduction biomedical research centres had had a big effect.

Three recent successes were papers showing that peanut allergy might be prevented by exposing children to peanuts early in life (the reverse of existing advice to avoid such contact), research at Oxford on an Ebola vaccine, and research at University College London on cancer immunotherapy.

Cite this as: BMJ 2015;350:h2813



Irish health minister James Reilly and school students display standard packs in 2014 after Irish government decided to outlaw branded packaging

Four tobacco companies plan action against UK government over standard packaging

Clare Dyer THE BMJ

Tobacco companies have launched a multi-billion pound legal claim against the UK government for losses as a result of a law that will require them to sell their cigarettes in plain packaging.

The companies claim that forcing them to use unbranded packages amounts to deprivation of highly valuable intellectual property. They say that the law, which is expected to come into force in May 2016, amounts to illegal seizure of their trademarks by the state.

Philip Morris International and British American Tobacco have filed papers at the High Court in London, and Imperial Tobacco and Japan Tobacco International have signalled that they intend to follow suit.

Philip Morris argues that the

new regulations violate a core doctrine of English and European Union law, that there must be fair compensation for deprivation of property. The company also contends that the rules obstruct the free movement of goods and breach EU law, which states that European Community trademarks can be used by identical means throughout the EU.

"We respect the government's authority to regulate in the public interest, but wiping out trademarks simply goes too far," said Marc Firestone, senior vice president and general counsel for Philip Morris International. "Countries around the world have shown that effective tobacco control can co-exist with respect for consumer freedoms and private property."

Cite this as: BMJ 2015;350:h2865

Woman with gene for Huntington's disease fails in attempt to sue her father's trust

Clare Dyer THE BMJ

A woman whose father refused to let his doctors tell her that he had Huntington's disease, and who later found that she had the gene, has been barred from bringing a claim for negligence against the NHS trusts involved with his care. A High Court judge has ruled that her case had no chance of success and has struck it out.

The unnamed woman was pregnant at the time and says that she would have had an abortion had she known that her child might be at risk of the hereditary disease.

Her father was convicted of manslaughter on the grounds of diminished responsibility in 2007 after shooting her mother dead. He was sentenced to a hospital order and detained at Springfield University Hospital, run by South West London and St George's Mental Health NHS Trust.

Doctors at the hospital began to suspect that he had Huntington's disease and referred him to St George's Hospital. In November 2009 the diagnosis was confirmed.

The doctors treating him wanted to disclose his condition to the woman and her sister, but he refused his consent. His notes show that he "was concerned that his daughters should not be informed about the possibility

of HD [Huntington's disease] as he felt they might get upset, kill themselves or have an abortion."

The woman's baby was born in April 2010, and the next August she learnt accidentally from one of her father's doctors that he had the condition, which meant that she had a 50% chance of inheriting it. She discovered that she had the gene for it in January 2013. Her child will not be tested until she reaches adulthood.

The woman's lawyers cited a 2006 report from a joint committee of two royal colleges and the British Society of Human Genetics that said, "In special circumstances it may be justified to break confidence where the aversion of harm by the disclosure substantially outweighs the patient's claim to confidentiality.

"Examples may include a person declining to inform relatives of a genetic risk of which they may be unaware, or to allow the release of information to allow specific genetic testing to be undertaken."¹

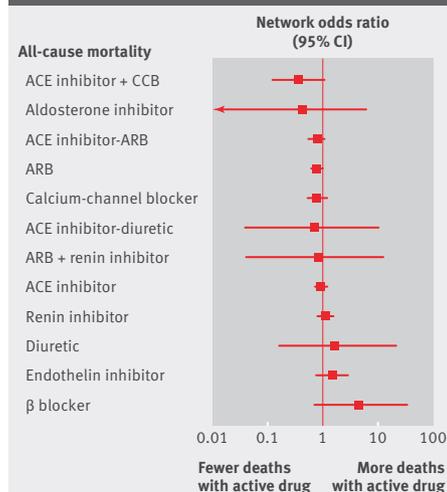
But to establish negligence the woman would have had to show that her father's doctors owed her a duty of care, although she was not their patient.

The judge, Justice Nicol, noted earlier cases where the courts had refused to find that doctors owed a duty of care to family members.

Cite this as: BMJ 2015;350:h2864

RESEARCH NEWS

Primary outcomes of blood pressure drugs in adults with diabetes and kidney disease



HYPERTENSION

Drugs fail to prolong diabetes and renal survival

No blood pressure lowering agents used either alone or in combination prolong survival in adults with diabetes and kidney disease, a meta-analysis in the *Lancet* has found.¹

Researchers analysed 157 studies comparing blood pressure lowering agents in a total of 43 256 patients with diabetic kidney disease.

Results showed that no drug regimen was more effective than placebo in reducing all cause mortality. Odds ratios ranged from 0.36 (95% confidence interval 0.12 to 1.05) with the highest ranked strategy (ACE inhibitor plus calcium channel blocker) to 5.13 (0.81 to 32.4) with the lowest ranked agent (beta blocker).

Progression to end stage renal disease was significantly less likely with a combination of an angiotensin receptor blocker (ARB) and an ACE (angiotensin converting enzyme) inhibitor than with placebo (0.62 (0.43 to 0.90)).

However, this combination was associated with increased risks of hyperkalaemia and acute kidney injury. Treating 1000 patients with dual ACE inhibitor and ARB treatment for a year would prevent three additional cases of end stage kidney failure but would also lead to 38 more patients having acute kidney injury and would cause 65 more cases of hyperkalaemia, the study estimated.

Treatment with an ACE inhibitor alone also reduced the risk of end stage renal disease (0.71 (0.51 to 1.01)), as did ARB monotherapy (0.77 (0.65 to 0.92)) and endothelin inhibitors (0.71 (0.44 to 1.14)).

Chronic kidney disease occurs in 25-40% of patients who have diabetes for 20-25 years.

Cite this as: *BMJ* 2015;350:h2824

ANTIPLATELET THERAPY

Optimal length of dual therapy is still unclear

The optimal duration of dual antiplatelet therapy after having a drug eluting stent implanted remains unclear after a systematic review¹ found that longer duration therapy is associated with fewer myocardial infarctions but more major bleeding than treating for a shorter period.

Current recommendations suggest giving patients six or 12 months' treatment with aspirin plus a P2Y12 inhibitor (clopidogrel, ticagrelor, or prasugrel) to reduce their risk of stent thrombosis, but the optimal duration of therapy is controversial. To investigate this, researchers searched for randomised controlled trials comparing longer with shorter dual antiplatelet therapy after drug eluting stent placement. They identified nine trials including 29 531 patients.

The systematic review, reported in *Annals of Internal Medicine*, showed moderate quality evidence that longer duration dual antiplatelet therapy reduced the risk of myocardial infarction by 27% (risk ratio 0.73 (95% confidence interval 0.58 to 0.92)).

But longer dual antiplatelet treatment was associated with increased mortality (1.19 (1.04 to 1.36)), with 279 deaths, compared with 231 with shorter treatment.

Longer therapy also increased the risk for major bleeding by 63% (1.63 (1.34 to 1.99)).

Cite this as: *BMJ* 2015;350:2841



OBSTETRICS

Delayed cord clamping helps motor and social skills

Delaying clamping of the umbilical cord for around three minutes is associated with better fine motor function and social skills in children aged 4 years, a controlled trial has found.¹

Delaying umbilical cord clamping by two to three minutes is known to produce higher haemoglobin concentrations after birth and increased iron stores until 6 months of age.

Many clinicians delay cord clamping, but there has been hesitation in including the practice in guidelines because of a lack of evidence on its long term safety and benefits.

The new study in *JAMA Pediatrics* involved 382 full term infants born after a low risk pregnancy at a Swedish hospital, two thirds of whom returned for assessment with a psychologist at age 4.

The study found no difference between the two groups in full scale IQ or behavioural difficulties. However, children in the delayed cord clamping group showed improvements in the personal-social scale (adjusted mean difference 2.8 (95% confidence interval 0.8 to 4.7)) and in fine motor skills (2.1 (0.2 to 4.0)). Boys, who are generally more prone to iron deficiency, were shown to have the biggest differences, particularly in fine motor skills.

Cite this as: *BMJ* 2015;350:h2828

OBESITY

Teenage male obesity is linked to bowel cancer

Being obese as a teenager may increase the risk of developing bowel cancer later in life, research published in the journal *Gut* has shown.¹

The large observational study followed almost 240 000 Swedish men who had been conscripted into the army from the ages of 16 to 20 in 1969-76. At the time of conscription nearly 12% were underweight, 5% were moderately overweight, 1.5% were very overweight, and 1% were obese. After an average of 35 years' follow-up 885 men had developed bowel cancer, including 501 colon cancers and 384 rectal cancers.

Those who were obese, classed as a body mass index (BMI) of 30 or over, had a 2.38 times higher risk of colorectal cancer (95% confidence interval 1.51 to 3.76) than those in the normal range. Those who were overweight, with a BMI of 27.5 to 30, were twice as likely (1.40 to 3.07) to develop bowel cancer as those in the normal range.

Systemic inflammation during adolescence was also associated with an increased risk of colon cancer in later life. Among men without known inflammatory bowel disease, those with a high erythrocyte sedimentation rate of 15+ mm/h had a 63% higher risk of colon cancer than those with a rate lower than 10 mm/h (hazard ratio 1.63 (1.08 to 2.45)).

The researchers said that the findings showed that BMI and inflammation during adolescence may both have a role in the development of bowel cancer.

Cite this as: *BMJ* 2015;350:h2838

David Nutt

Fights establishment orthodoxy



DAVID NUTT has a short name but a long title: Edmond J Safra professor of neuropsychopharmacology at Imperial College London. He is famous for claiming that riding horses is riskier than taking ecstasy and for losing his job as a government adviser after his public criticism of drug policy. Many sprang to his defence, and he established the Independent Scientific Committee on Drugs, now called DrugScience, which he chairs. He supports a public health approach to drug addiction and an end to the criminalisation of users, and he has written a book arguing this case, *Drugs Without the Hot Air*.

Bevan or Lansley? Who has been the best and the worst health secretary in your lifetime?

"I consider the deceitful privatisation of the NHS that has taken place over my professional career to be one of the most damning legacies of our generation"

What was your earliest ambition?

I decided that I wanted to be a scientist when, in junior school, my teacher showed how atmospheric pressure could crush a large tin can—amazing proof of something you'd never imagine without scientific inquiry.

Who has been your biggest inspiration?

Ignaz Semmelweis. He collected data on maternal deaths from different practitioners and concluded that puerperal sepsis was caused by doctors transferring something from mortuaries to birthing suites. This predated the discovery of bacteria, so he was ridiculed by the medical profession—yet he was ultimately proved right. A lesson to us all not to let establishment orthodoxy get in the way of facts. I found his example very helpful.

What was the worst mistake in your career?

Joking at a senior house officer interview that, as a doctor, I was the black sheep in my family. I got the job, but it was apparently a very close thing.

Bevan or Lansley? Who has been the best and the worst health secretary in your lifetime?

Correct analysis—I'm a passionate fan of the NHS. This dates back to the 1960s, when I discovered that my father had had to give up his ambition to go to university: he had to leave school at 16 to pay for the private treatment of his younger brother, who had polio. I consider the deceitful privatisation of the NHS that has taken place over my professional career to be one of the most damning legacies of our generation. Most addiction services are now privatised, and I see the rest of psychiatry going the same way.

What was your best career move?

Getting a research fellow position at the MRC Clinical Pharmacology Unit in Oxford, where my enthusiasm for research was encouraged and supported. From then on my career flourished.

Who is the person you would most like to thank and why?

David Grahame-Smith (director of the MRC Clinical Pharmacology Unit in Oxford), who gave me my first opportunity to do research, from which I've never looked back.

If you were given £1m what would you spend it on?

Developing "alcosynth"—my safe alternative to alcohol. It would lead to a massive health gain as people switched from alcohol to this; alcohol currently causes over four million premature deaths a year worldwide. Some variants of alcosynth would also have antidotes—so you could go to a party, get intoxicated, and then rapidly sober up to drive home safely.

Where are or were you happiest?

With my children and grandchildren on our annual summer beach holiday in north Devon.

What single unheralded change has made the most difference in your field in your lifetime?

The growing limitations on prescribing medicines that are "off licence" and thus not evidence based. I see the ever increasing control by formulary committees and treatment algorithms as something that de-skills doctors: it limits their ability to understand and use drug treatments.

Do you support doctor assisted suicide?

Yes, if you mean euthanasia. People have as much right to a peaceful and pain-free death as they do to life prolonging treatments.

What book should every doctor read?

Awakenings by Oliver Sacks. This is a magnificent account of applying science to revolutionise the medical treatment of Parkinson's disease and is a paradigm case of the value of experimental medicine.

What poem, song, or passage of prose would you like mourners at your funeral to hear?

The Water is Wide, sung by Renée Fleming. As a west country folk song this reflects my origins as a Somerset boy, but it is also a haunting melody about love and hope. What more could you want at a funeral?

What is your guiltiest pleasure?

A (small) single malt at bedtime.

If you could be invisible for a day what would you do?

Explore the *Daily Mail* offices to see whether they really believe what they write or whether it's all a sophisticated parody of the worst of the English.

What is your most treasured possession?

My 1960 Austin-Healey 3000 Mark 1.

What personal ambition do you still have?

To get United Nations drug conventions rewritten and based on underpinning principles. Currently—unlike the newer conventions, such as the rights of people with disabilities—the drug conventions are not based on any principles other than that drug use is unacceptable.

Summarise your personality in three words

Enthusiastic, caring, humorous.

Cite this as: *BMJ* 2015;350:h2808