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Study links SSRIs to violent crime in young adults

Pfizer loses UK patent for blockbuster pain drug after threats to doctors and pharmacists

Zosia Kmietowicz THE BMJ

The drug company Pfizer made unjustifiable threats when it said earlier this year that prescribing generic versions of pregabalin, which it markets as Lyrica, for pain control could leave doctors open to litigation, the High Court has ruled.

Mr Justice Richard Arnold said, in the course of a judgment in which he also overturned Pfizer's UK patent for pregabalin for pain control, that the company made "groundless claims" that its patent for Lyrica would be infringed if doctors did not specify Lyrica as opposed to a generic alternative when prescribing pregabalin for pain.

Pfizer has said that it will appeal against the ruling.

NHS England responded by saying that its current advice to doctors to prescribe Lyrica by brand name for use in pain control still stood and would not change until a court order giving effect to the judgment had been received.

Andrew Green, chairman of the BMA's clinical and prescribing subcommittee for GPs, said that Pfizer should refund what the NHS has spent on branded Lyrica for pain.

The patent for the use of Lyrica for epilepsy and generalised anxiety disorder expired in July 2014, and manufacturers of generic versions already have licences for these two indications. But the manufacturer, Warner-Lambert (a subsidiary of Pfizer), holds a "second medical use" patent for the use of pregabalin to treat peripheral and central neuropathic pain, which expires in July 2017. A second medical use patent is one that relates to a new medical use for a known compound.

The system of second medical use patents needs to be clearer, said the judge

Lyrica is one of Pfizer's most successful products, with global sales in 2013 of some $4.6bn (£3bn). In England sales of Lyrica rose by 53% between 2011 and 2013, and monthly sales were just under £18m last year.

In his 174 page ruling Mr Justice Arnold said, "Since late September 2014, Pfizer has taken extensive steps to try to ensure that generic pregabalin is neither prescribed nor dispensed for the treatment of pain." This included sending a letter to the BMA and pharmacists stating that doctors and pharmacists risked infringing the patent if they supplied generic pregabalin for the pain indication and that this would be an unlawful act.

A letter sent to clinical commissioning groups in December 2014 was described by Mr Justice Arnold as "calculated to have a chilling effect on the sales of Lecaent [the version of pregabalin made by Actavis]."

These letters would be seen by the recipients as a threat, said Mr Justice Arnold.

Pfizer said in a statement that the "unusual and complex situation" of a second medical use patent had led to mistakes in its communications with health professionals. The company said, "With the benefit of hindsight and having navigated particularly challenging and complex legal issues, we wish we had been able to explain this better and sooner."

In his ruling Mr Justice Arnold considered that a clearer system was needed for how second medical use patents operated in the UK.

The BMA's Green commented, "Pfizer has said throughout this process that they want to do the 'right thing for everyone,' so I trust that if they are shown to be incorrect in law they will refund the NHS all the money which will have been unnecessarily spent on branded Lyrica as a result of their threats of legal action."

CHRIS GALLAGHER/SPL

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IN BRIEF

Government defines seven day services: The government has responded to calls from the BMA for a definition of seven day services by confirming that the focus would be on the delivery of urgent and emergency care, rather than seven day elective care. More detail was still needed on how the service would be staffed and funded, said the BMA.

Top executives quit Addenbrooke's: Keith Neil, chief executive of Addenbrooke's Hospital in Cambridge since 2012, has resigned ahead of a report from the Care Quality Commission next week. The chief finance officer at the hospital, which is running a weekly deficit of £1.2m, has also resigned.

Shadow health team appointed: The UK Labour Party's new leader, Jeremy Corbyn, has appointed Heidi Alexander as shadow health secretary. The MP for Lewisham East has campaigned against the closure of the A&E at Lewisham Hospital and voted against the coalition government's health service reorganisations (see longer story doi:10.1136/bmj.h4930). Corbyn also appointed Luciana Berger to the new post of shadow mental health minister.

Plain soap is as effective as antibacterial soap: Antibacterial soap that contains triclosan is no more effective than ordinary soap at reducing bacterial contamination on the hands when used in real life situations, concludes a study in the *Journal of Antimicrobial Chemotherapy*. In two experiments plain and antibacterial soap each led to a significant reduction in bacterial populations (longer story doi:10.1136/bmj.h4944).

Cite this as: *BMJ* 2015;351:h4936

IN BRIEF

London practices "beset by blockages in flow": General practices in London are unable to meet rising demand for appointments, the Londonwide Local Medical Committees have said in evidence to the House of Commons Health Committee's inquiry into the pressure on primary care. A poll found that 70% of 531 practices had at least one GP who planned to retire in the next five years and that 10% of GPs were thinking of quitting. Michelle Drage, chief executive officer of the committees, blamed a shortage of health visitors, mental health services, and social service leaders for GPs missing important illnesses and for longer waiting times.

New cancer diagnosis target set: Five hospitals in England are to pilot a new target to diagnose suspected cancer within 28 days, before the programme is rolled out across the country by 2020, the health secretary, Jeremy Hunt, has said. Other measures intended to be in place by 2020 include around 20000 more people a year having their cancers genetically tested, access to tests results online, and extra support for recovery, including help with depression. Giles Maskell, president of the Royal College of Radiologists, said that the NHS was "currently a million miles" from being able to deliver the targets "without more radiologists."

Larger portion sizes lead to overeating: Larger portions, packages, and tableware lead to higher consumption of food and drink, a Cochrane review has found.[3] The research said that eliminating larger portions from the diet could reduce energy intake by up to 16% (279 kilocalories a day) among UK adults or by up to 29% (527 kilocalories a day) among US adults.

Surgeons in Australia and New Zealand report bullying: Half of fellows and trainees in surgery in Australia and New Zealand said that they had been subjected to discrimination, bullying, or sexual harassment, an advisory group for the Royal Australasian College of Surgeons has found.[1] The problem crossed all surgical specialties, with senior surgeons and consultants the primary source of the problems. Rob Knowles, chair of the advisory group, said, "We have been shocked by what we have heard. The time for action has come."

Asthma admissions peak in September: More than 3550 children with uncontrolled asthma were admitted to hospital in England in September 2013, shows an analysis by the charity Asthma UK. This was an increase of 6.3% on the previous September, 73% more than the monthly average (2048), and a 293% rise from the previous month (903). It is thought that the "back to school" peak is caused by factors such as increases in colds and flu and a lower resilience to asthma triggers among children whose drug taking routine may have slipped over the summer.

Preparing cancer patients improves outcomes: Providing cancer patients who are in work with information about their disease, its treatment, and its likely effect on working life and education nearly doubles their chances of a positive treatment outcome (defined as completion of treatment with no further signs or symptoms of cancer), a study in *BMJ Supportive and Palliative Care* has found.[2] The study of nearly 3500 cancer patients in employment also found that patients who received information about treatment side effects had worse odds of a positive treatment outcome.

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Philippa Whitford, a surgeon and SNP health spokeswoman (left), opposed the bill, which was supported by Keir Starmer, MP

Assisted dying bill for terminally ill people is defeated by 330 to 118 votes

Clare Dyer BMJ

The United Kingdom's House of Commons has rejected a private member's bill that would have given terminally ill people in England and Wales the right to a doctor's help in ending their lives.

After an impassioned debate, MPs voted by 330 to 118 against a second reading for the Assisted Dying (No 2) Bill, introduced by the Labour MP Rob Marris.

The bill was almost identical to the Assisted Dying Bill, which made it through to committee stage in the House of Lords before running out of time in the last parliament. Largely based on a similar law in the state of Oregon, it would have allowed terminally ill people who were deemed to have less than six months to live the right to physician assisted suicide.

As an extra safeguard, a High Court judge as well as two doctors would have to be satisfied that the patient had a "voluntary, settled, clear and informed wish" to die.

The Labour MP Keir Starmer, a former director of public prosecutions for England and Wales and now a Labour MP, said that guidelines he had drawn up in his former role to guide decisions on whether to prosecute for assisting a suicide had an inherent limitation. The guidelines made it unlikely that relatives who acted from a compassionate motive would be prosecuted, but doctors were more likely to face prosecution. "That, to my mind, is an injustice we have trapped within our current arrangements," he said.

But Philippa Whitford, a breast cancer surgeon and the Scottish National Party's health spokesperson, said that with good palliative care "the journey can lead to a beautiful death." She urged MPs to vote for "life and dignity, not death."

Cite this as: *BMJ* 2015;351:h4917

Study supports more aggressive blood pressure treatment targets, US officials say

Michael McCarthy SEATTLE

US health officials have halted a large hypertension treatment trial ahead of schedule after finding strong evidence to support more aggressive treatment of high blood pressure. Initially, the trial, called the Systolic Blood Pressure Intervention Trial (SPRINT), was expected to be completed in 2017.

Officials said on 9 September that they decided to halt the study after an interim analysis of the data indicated that treating patients to achieve a target systolic blood pressure of 120 mm Hg, instead of the commonly recommended target of 140 mm Hg, cut the rate of cardiovascular events such as myocardial infarction, heart failure, and stroke by almost a third and the risk of death by almost a quarter, officials said.

The National Institute of Health officials said that they would publish the findings in the next several months.

The study, which began in 2009, enrolled more than 9300 participants aged 50 years or older with average baseline systolic blood pressure of 130 mm Hg or higher and who had at least one additional risk factor

NHS needs emergency injection of £1bn, says King's Fund as more trusts go into debt

Gareth Iacobucci THE BMJ

The NHS in England needs an emergency injection of money to the tune of around £1bn this year to cope with the huge deficits facing the service, a leading healthcare think tank has warned.

In its submission to the government's upcoming spending review,[1] the King's Fund said that even the best run NHS hospitals were now forecasting a deficit and that "emergency deficit funding is likely to be required this year."

The think tank added that the £8bn increase in real terms NHS funding by 2020 pledged by the government was "the absolute minimum requirement" to maintain current standards of care and would not be enough to pay for new commitments such as seven day services. It added that, contrary to some rumours that this £8bn would not be committed by the Treasury until later in this parliament, it should be "frontloaded" from 2016-17 to avoid "an accelerating decline in performance and quality."

Chris Ham, chief executive of the King's Fund, warned, "If more funding is not made available, the key turning point will be the arrival of the next NHS 'crisis,' most likely during the winter when many hospitals run out of money and all other budgets have been raided to the point of exhaustion."

The fund's warning came in the same week that two senior executives at one of the country's leading hospitals, Addenbrooke's in Cambridge, resigned because of the trust's financial deficit.

The fund said the government's aim should be to increase public spending on health and social care to 11-12% of gross GDP.

Cite this as: *BMJ* 2015;351:h4964

Government's move to cut red tape is impeding public health measures, say charities

Ingrid Torjesen LONDON

A government policy designed to reduce the regulatory burden on business is making it increasingly difficult to introduce measures to improve public health in the UK, a group of medical bodies and charities has warned.

To try to remove and simplify the regulations with which businesses must comply, the last coalition government introduced a "one in, one out" rule in 2010. This required government departments to assess the net cost to businesses of complying with any proposed regulation and to identify ways to cut regulation so as to save businesses the same amount. Proposed new regulations and corresponding deregulations then had to be approved by the Cabinet's Reducing Regulation Subcommittee before being implemented.[1] In 2012 the rule was toughened to "one in, two out."

For example, before legislation passed in March to bring in standardised packaging of tobacco products can be implemented, the Department of Health for England had to carry out an impact assessment that calculated that the new regulations would cost business an estimated £37m a year, which included lost cigarette sales. Partly to compensate tobacco companies for lower profits, government departments would therefore have to slash regulations costing business £74m a year.[2]

The Smokefree Action Coalition wants public health regulations to be made exempt from the rule.

Cite this as: *BMJ* 2015;351:h4925

Full seven day NHS service is unachievable with current state of services, conference hears

Matthew Limb LONDON

Providing full seven day services for every kind of service offered in the NHS looks "unachievable" in the near future, a leading NHS policy expert has said.

Saffron Cordery, director of policy and strategy for NHS Providers, the membership organisation for NHS service providers, said that the government had to be clearer about what it meant by its seven day service provision and questioned its affordability.

She also warned that patients could be misled by the policy and that their expectations would have to be managed well or the NHS risked "setting ourselves up to fail." She queried whether the plans could be implemented successfully, given major workforce shortages, other service priorities, and rising NHS deficits, set to reach £2bn this year.

Cordery was speaking at a seminar on the future of seven day services, held by the Westminster Health Forum on 10 September.

Trusts in rural areas in particular were already struggling with recruitment, she said.

Liz McInnes, a Labour MP and member of the House of Commons Health Committee, said that the committee would soon be questioning the health secretary for England, Jeremy Hunt, about "what is the issue he is trying to address, and are the measures he's proposing the right way to address those issues?"

Cite this as: *BMJ* 2015;351:h4903

for cardiovascular disease, such as chronic kidney disease, or evidence of cardiovascular disease. The primary outcomes were first occurrence of a myocardial infarction, acute coronary syndrome, stroke, heart failure, or cardiovascular death.

Participants were randomly divided into two groups. One group, the standard therapy group, received blood pressure drugs to achieve a target systolic blood pressure of <140 mm Hg. On average, these patients took two blood pressure drugs. In the second group the treatment target was 120 mm Hg. On average, these patients took three drugs.

Cite this as: *BMJ* 2015;351:h4920

National Institute of Health officials say they will publish the full results in the next few months

ROBYN BECK/AFP/GETTY IMAGES

MPs propose inquiry into safety of using antimalarial mefloquine in armed forces

DAVID BRAUCHLI/SYGMA/CORBIS

CHRIS ISON/PA

Major-general Alastair Duncan (left), who commanded British forces in Bosnia, and Baroness Margaret Jay, a former health spokeswoman for Labour, have both experienced serious side effects from mefloquine (Lariam)

Adrian O'Dowd LONDON

Pressure is building to end the practice of routinely giving the antimalarial drug mefloquine (Lariam) to UK military personnel and to investigate the drug's safety.

MPs on the parliamentary defence select committee sent a letter to the defence secretary, Michael Fallon, asking whether he had plans to reassess the drug's safety in the light of recent concerns raised by the military.[1]

Mefloquine is licensed in the UK by the Medicines and Health Products Regulatory Agency, on the basis of expert guidance from Public Health England's advisory committee for malaria prevention.

Possible side effects of the drug, which is given to military personnel serving overseas, include "depression and suicidal ideation, anxiety, panic, confusion, hallucinations, paranoid delusions, and convulsions."

In the defence committee's new letter, its chairman, Julian Lewis, the Conservative MP for New Forest East, said, "The use of Lariam has come under increasing scrutiny and it is clear that the drug does not command the universal support of members of our Armed Forces.

"The number of cases of military personnel reporting serious side-effects after taking Lariam is deeply disturbing and, as a consequence, the defence committee is minded to conduct an investigation into its use."

The committee, which is seeking a response by 22 September, asked the defence secretary:

- When the Ministry of Defence last assessed the drug's safety and whether any health risks were highlighted
- What plans the ministry had to reassess the drug's safety, and
- How many complaints the ministry had received from military personnel about side effects after taking it.

Last month Johnny Mercer, the Conservative MP for Plymouth Moor View, a former army officer and member of the defence select committee, called on the government to stop prescribing the drug until more research was carried out into its safety.

Mercer said that, since 2008, 994 service personnel had been treated for mental health problems after taking the drug.

Cite this as: *BMJ* 2015;351:h4868

Charging £500 for work experience in hospital is "completely unfair," says charity

Zosia Kmietowicz THE BMJ

A charity that provides careers advice to children from disadvantaged backgrounds has condemned a private care provider for charging £500 a week for work experience at its facilities.

Deborah Streatfield, from MyBigCareer, told *The BMJ* that some of the children she worked with could not afford their school uniform and that many came to school hungry. Yet for pupils in the private school sector the £500 placements offered by the Chartwell Trust "was nothing," she said. "It is not a level playing field," said Streatfield.

Chartwell Trust runs a private hospital in Essex and several care homes. Its "Work Experience for Medical School Applicants" scheme offers pupils the chance to gain an "in-depth insight into working in a hospital and care environment with valuable supervision from motivated staff."

The "valuable medical work experience," which includes shadowing staff, can be used to support an application to medical school, it says. The brochure says that the work placement would help pupils "learn many valuable medical interview techniques."

Streatfield said that selling work experience in the manner of the Chartwell Trust would create a barrier to pupils who could not afford the price. "Many of the pupils we work with at MyBigCareer can't afford the UCAS [Universities and Colleges Admissions Service application] fee of £23 let alone £500. This is exploiting youngsters," she said.

The Medical Schools Council, which represents UK medical schools, emphasised that work experience in a clinical environment was not an essential component of an application to medical school.

Cite this as: *BMJ* 2015;351:h4895

More doctors charged with manslaughter are being convicted, shows analysis

Philip White WINCHESTER

More doctors in the UK who are charged with medical manslaughter and whose cases reach court are being convicted and sent to jail, data indicate, though overall numbers are too small for statistical analysis.

Searches of news, legal, and medical databases, together with a request to the General Medical Council made under freedom of information legislation, found that 11 doctors had been charged with medical (gross negligence) manslaughter in the UK between 2006 and the end of 2013. Of these, six (55%) were convicted.

The last three doctors convicted in 2012-13 all received custodial sentences rather than the usual suspended sentence (box on bmj.com). Before that the previous doctor to get a custodial sentence for medical manslaughter was in 2004.[1] Since December 2014 four more doctors have been charged with medical manslaughter and are awaiting trial.

The 55% conviction rate was higher than the 30% found by a review of medical manslaughter cases in the 10 years up to 2006 and the 38% in a separate review covering cases up to 2012.[2 3]

But although the data indicate that the conviction rate is rising, the number of doctors charged with medical manslaughter seems to be falling. In the 10 years from 1995 to 2005 a total of 28 doctors were charged with medical manslaughter, whereas 15 were charged in the past decade.

The new research was undertaken as part of a master of law degree at Cardiff Law School. Because of the low number of cases the identification of trends needs to be treated cautiously. But the data do provide a useful snapshot at a time when cases such as that of David Sellu (see box on bmj.com) have focused attention on the issue of medical manslaughter. Sellu, who is now out of prison, is appealing aganst his conviction this month.

Cite this as: *BMJ* 2015;351:h4402

Jane Dacre

Heavily indebted to Barty

PETER LOCKE

JANE DACRE, 59, was elected president of the Royal College of Physicians in April 2014 and took office three months later. She is director of University College London Medical School and a consultant in rheumatology at the Whittington Hospital in north London. She sees her mission as empowering physicians by restating the care values of the profession and encouraging positive leadership. She wants to bring more young people from minority backgrounds into medicine and fears that too much whingeing about how awful the job is may be putting them off. "It's actually a brilliant profession," she says.

What single unheralded change has made the most difference in your field in your lifetime?
"Biologic therapies for inflammatory conditions transform people's lives: they get back to work, and they go on holiday for the first time in years"

What was your earliest ambition?
I decided to become a doctor at age 12 because I liked biology and people, and it seemed to fit. I was hugely influenced by my late father, who was an anaesthetist and was very wise.

Who has been your biggest inspiration?
The first women doctors, who were extraordinarily dedicated to medicine. We think that we struggle with our careers, but it pales into insignificance when we look at the steps these remarkable women took to become doctors . . . including pretending to be men. Also, the two previous female presidents of the Royal College of Physicians, Margaret Turner-Warwick and Carol Black.

What was the worst mistake in your career?
I like to follow Eleanor Roosevelt's advice that nothing in life is wasted, even if it was a mistake—so I try to always learn when things have gone wrong. Several things could have gone better, and my biggest mistakes have been when I didn't learn from past experience.

What was your best career move?
Being true to myself, deciding to focus my career on education and bringing on the next generation of doctors, even though it was considered risky at the time because it was an untested career track. I decided to do something a bit different, and I've never looked back.

Bevan or Lansley? Who has been the best and the worst health secretary in your lifetime?
I think that the jury's out on this one. It would be difficult to beat Bevan for vision, but I hope that I have many years yet to judge the best and worst in my own lifetime.

Who is the person you would most like to thank and why?
My husband, Nigel, for coping with the ups and downs of my career and his own, over many years.

To whom would you most like to apologise?
The poor old dog, Barty, who never got enough walks and remained unstintingly loyal for 14 years.

If you were given £1m what would you spend it on?
I'd be tempted to give it to my three children, because it would help them establish their careers and lives in a time of unprecedented austerity—but my conscience would make me set up a foundation to support research in medical education.

Where are or were you happiest?
In the countryside, with my family, preferably in a place teeming with wildlife and blessed by sunny weather.

What single unheralded change has made the most difference in your field in your lifetime?
As a rheumatologist, it's undoubtedly the introduction of biologic therapies for inflammatory conditions. It's remarkable to see how these drugs transform people's lives: they get back to work, and they go on holiday for the first time in years.

What book should every doctor read?
Atul Gawande's *Being Mortal*: a wonderful and thought provoking read that makes you think about life, death, and doing the right thing in partnership with your patients.

What poem, song, or passage of prose would you like mourners at your funeral to hear?
Elgar's *Nimrod*. A beautiful piece, which reminds me of my family, especially as my father's youngest brother was a Nimrod pilot in the RAF. The music was played at the funeral of both of my parents.

What is your guiltiest pleasure?
Sneaking off to sit quietly, think, and listen to birds and other wildlife, when no one knows where I am.

If you could be invisible for a day what would you do?
I'd go and watch wildlife, without disturbing the animals, and get really close to them without scaring them off.

What television programmes do you like?
I don't watch much telly, but I really like *Borgen* and the Nordic noir genre, especially the strong female role models.

What is your most treasured possession?
My Kindle Fire. I don't go anywhere without it.

What, if anything, are you doing to reduce your carbon footprint?
I try to walk everywhere between meetings. From the Royal College of Physicians building (a beautiful Lasdun masterpiece) in Regent's Park, you can get to most places in London, including stations, in around half an hour.

What personal ambition do you still have?
There's still a lot to do to improve the service we provide for our patients and the training we provide for our doctors.

Summarise your personality in three words
Cheerful, conscientious, resilient.

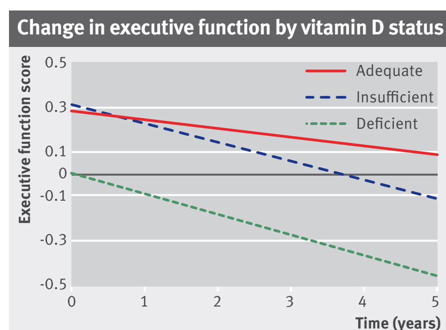
Where does alcohol fit into your life?
Evenings only, and in moderation.

What is your pet hate?
Arrogance, in anyone.

Cite this as: *BMJ* 2015;351:h4862

RESEARCH NEWS

Change in executive function by vitamin D status



DEMENTIA

Low vitamin D is linked to faster cognitive decline

A low vitamin D concentration is associated with a more rapid decline in cognitive function among older adults, concludes a multiethnic cohort study published in *JAMA Neurology* (doi:10.1001/jamaneurol.2015.2115).

The US study enrolled 382 people with an average age of 75.5 years who had their cognitive function and vitamin D levels assessed at baseline and then annually for an average of 4.8 years. At the start of the study 17.5% had a diagnosis of dementia, 32.7% had mild cognitive impairment, and 49.5% were assessed as cognitively normal.

The mean serum 25-hydroxyvitamin D concentration at baseline was 19.2 ng/mL. A quarter of participants were categorised as being deficient in vitamin D (below 12 ng/mL) and 35.1% as having insufficient vitamin D (between 12 and 20 ng/mL). Mean vitamin D concentrations were significantly lower in African American participants (17.9 ng/mL) and Hispanic participants (17.2 ng/mL) than in their white counterparts (21.7 ng/mL).

Mean vitamin D concentration was significantly lower in the dementia group (16.2 ng/mL) than in participants who had mild cognitive impairment (20.0 ng/mL) and those who were cognitively normal (19.7 ng/mL).

The researchers found the rates of decline in episodic memory and executive function among participants who were vitamin D deficient or insufficient to be greater than rates of decline among participants with an adequate vitamin D status, after they had controlled for other factors (P=0.049 and P=0.01, respectively). Over five years of follow-up, in vitamin D deficient participants episodic memory declined by 0.30 of a standard deviation and executive function by 0.46, while in those with normal vitamin D levels episodic memory declined by 0.10 and executive function by 0.20.

Cite this as: *BMJ* 2015;351:h4916

HIP SURGERY

More deaths with hip fracture surgery than hip replacement

Patients who undergo surgery for a hip fracture have a higher risk of mortality and of developing major complications than do patients who undergo an elective total hip replacement, a large cohort study has found.

The research, published in *JAMA* (doi:10.1001/jama.2015.10842), looked at 690 995 patients who underwent hip surgery at 864 centres in France. Those undergoing elective total hip replacement were younger, more commonly men, and had less comorbidity than patients undergoing surgery for hip fracture.

Of the 319 804 patients who had hip fracture surgery, 10 931 (3.24%) died before discharge from hospital. Of the 371 191 patients who had an elective total hip replacement, 669 (0.18%) died before discharge.

The researchers then compared a population of 234 314 patients who were matched for age, sex, and preoperative medical conditions. Patients who underwent hip fracture surgery had a higher risk of death (1.8%, versus 0.3% of patients who underwent elective total hip replacement) and an increase in the incidence of major postoperative complications (5.9% versus 2.3%). The absolute increase in risk of death from hip fracture surgery was 1.51% (95% confidence interval 1.46% to 1.55%), while the increase in risk of major postoperative complications was 3.54% (3.5% to 3.59%).

The researchers said that further studies were needed to examine the causes of these differences.

Cite this as: *BMJ* 2015;351:h4929

BREAST CANCER

Med diet with added olive oil may prevent breast cancer

A Mediterranean diet that is supplemented with extra virgin olive oil may help prevent breast cancer, a randomised trial published in *JAMA Internal Medicine* indicates. The research was carried out as part of the PREDIMED study, which was designed to test the effects of a Mediterranean diet on the primary prevention of cardiovascular disease.

The study, which was conducted at primary health centres in Spain, involved 4282 women aged 60 to 80 years who were at high risk of developing cardiovascular disease (doi:10.1001/jamainternmed.2015.4838). They were randomly assigned to a Mediterranean diet supplemented with extra virgin olive oil, a Mediterranean diet supplemented with 30 g of mixed nuts daily, or to a control group who were advised to follow a low fat diet.

During the median follow-up period of five years there were 35 confirmed new cases of breast cancer (17 in the control diet group, 10 in the nuts group, and eight in the olive oil group). Women eating the Mediterranean diet supplemented with olive oil showed a 68% relatively lower risk of malignant breast cancer than women in the control group (multiple adjusted hazard ratio 0.32 (95% confidence interval 0.13 to 0.79)). The incidence rates per 1000 person years were 1.1 for the Mediterranean diet with olive oil group, 1.8 for the Mediterranean diet with nuts group, and 2.9 for the control group.

Cite this as: *BMJ* 2015;351:h4911

HIV PREVENTION

Daily PrEP prevents HIV in high risk gay men

Daily HIV medicine is highly effective in preventing new HIV infections in gay men who are at high risk of becoming infected, a study has shown. The open label study enrolled 544 HIV negative men who have sex with men who had had anal intercourse without a condom in the previous 90 days.

Study participants were randomly assigned to daily HIV prophylaxis with combined tenofovir disoproxil fumarate (245 mg) and emtricitabine (200 mg) either immediately or after a deferral period of one year. They were followed up every three months. The results showed early evidence of effectiveness, so in October 2014 the trial steering committee recommended that all participants in the deferred group should be offered pre-exposure prophylaxis (PrEP).

Final results, reported in the *Lancet* (doi:10.1016/S0140-6736(15)00056-2), showed that three HIV infections occurred in men randomised to immediate use of PrEP (1.2 HIV infections per 100 person years), compared with 20 HIV infections in the deferred group (9.0 HIV infections per 100 person years), despite 174 prescriptions of PrEP in this group.

PrEP was associated with an 86% relative reduction in HIV infection (90% confidence interval 64% to 96%; P=0.0001). The absolute difference in HIV infections between men given PrEP and the deferred group was 7.8 per 100 person years (4.3 to 11.3).

Cite this as: *BMJ* 2015;351:h4860