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Self referral to therapy will prevent medical “merry-go-round”

Andrew Cole LONDON

Patients are to be allowed to bypass their GP and refer themselves directly to a physiotherapist or other therapist after a successful pilot programme for people with musculoskeletal problems.

The move, announced this week by the health secretary, Alan Johnson, was welcomed by Phil Gray, chief executive of the Chartered Society of Physiotherapy, who said it would end the current “merry-go-round” between GP, consultant, and physiotherapists endured by many patients. The economic argument for managing the problem at source was “irrefutable,” he said.

But the BMA questioned whether self referral would work without extra investment. A rise in demand in already overstretched areas could mean that patients who go through the normal referral routes may have trouble accessing services, warned Laurence Buckman, chairman of the BMA’s General Practitioners Committee.

Speaking at the conference of the Chief Health Professions Officers, Mr Johnson said that self referral would cut out the “additional unnecessary bureaucratic layer” of having to see a GP before being referred on to a physiotherapist. “There is no reason why more services cannot offer self referral where clinically appropriate,” he added.

It had been argued that self referral would “open the floodgates” and lead to therapy services being inundated. But evidence from the pilots across England indicated that self referral had not increased demand and that patients had to wait less time to be seen.

The six pilot studies, carried out by the Department of Health and the Chartered Society of Physiotherapy and involving 20 general practices, evaluated the effects of self referral for musculoskeletal physiotherapy. The results showed that self referring patients were more likely to complete their course of treatment and turn up for follow-up appointments.

See www.dh.gov.uk for more information.

Cite this as: *BMJ* 2008;337:a2239



Daniel James, who died with the help of Dignitas in Switzerland, with his parents

Police investigate parents’ role in assisted suicide

Clare Dyer *BMJ*

The parents of a 23 year old tetraplegic man who travelled to Switzerland from his home in England for an assisted suicide have been investigated by police and are waiting to hear whether they will be prosecuted in the United Kingdom.

The case of Daniel James, who was paralysed in a game of rugby in March 2007, has reignited last month’s debate over euthanasia and assisted suicide after Debbie Purdy, who has multiple sclerosis, took her case to the High Court (*BMJ* 2008;336:1394).

Ms Purdy, 45, who wants her husband to accompany her to Switzerland when the time comes, is awaiting a ruling on her challenge to a refusal by the director of public prosecutions, Ken Macdonald, to say what help a friend or relative may give without

risking a charge of aiding and abetting suicide.

Mr James is one of the youngest British people to have committed suicide with the aid of the non-profit organisation Dignitas in Zurich. Aiding and abetting a suicide is a crime punishable by up to 14 years in the UK, and more than 100 British people have taken their lives with the help of Dignitas.

So far no one has been prosecuted for helping a friend or family member to make the journey. Mr James’s parents, Mark and Julie, said that West Mercia police were alerted by someone “connected with social services” after they travelled to Zurich with their son in September.

Anti-euthanasia and disability rights campaigners have expressed concern that Mr James might have come to terms with his condition if given more time. But his

mother, from Sinton Green, near Worcester, wrote in a newspaper website discussion earlier this month (about the Debbie Purdy case) that her son had been in “unbearable” pain since the injury. She said it was “his right as a human being” to take his own life.

“Dan found his life so unbearable and had tried to commit suicide three times. Other than to starve himself, to travel to Switzerland was his only option,” she wrote. “Our son could not have been more loved, and had he felt he could live his life this way he would have been loved just the same, but this was his right as a human being.”

She said the person who reported the family to the police “gave no consideration for our younger daughters, who had seen their big brother suffer so much.”

Cite this as: *BMJ* 2008;337:a2195

Osteoporosis experts publish new guidelines to fill gaps left by NICE

Susan Mayor LONDON

A group of UK osteoporosis specialists have published national guidelines for the diagnosis and management of osteoporosis to provide evidence based recommendations on issues not dealt with by current guidance from the National Institute for Health and Clinical Excellence (NICE).

The National Osteoporosis Guideline Group has updated previous guidelines from the Royal College of Physicians after taking account of advances in the management of osteoporosis over the past few years, including new techniques for measuring bone mineral density, better methods for assessing the risk of fracture, and new treatments that reduce the risk of osteoporotic fractures.

The resulting guidance is supported by professional and patients' organisations in the field, including the Royal College of Physicians, the National Osteoporosis Society, and the British Society of Rheumatology.

Juliet Compston, professor of bone medicine at the University of Cambridge School of Clinical Medicine and Addenbrooke's Hospital, said, "Essentially we see the national osteoporosis guideline as filling a big gap that currently exists in management guidelines, particularly for primary care."

Guidelines on osteoporosis from NICE have been in development since 2002 but remain unpublished. The organisation lost an appeal against its initial appraisal after charities and drug companies said that it offered only limited treatment options for a small group of patients. The latest appraisal has also been appealed against, adding to the delay.

"All we have at the moment is very restricted, out of date guidance on the secondary prevention of fractures in postmenopausal women," explained Professor Compston. "This leaves out the primary prevention of fractures, men, steroid induced osteoporosis, and the newer treatments," she said.

The National Osteoporosis Group's new guidance aims to provide more comprehensive advice on the detection and management of osteoporosis in postmenopausal women and in men from the age of 50. It sets out evidence based recommendations on measuring bone mineral density to diagnose osteoporosis and on treatment algorithms that were developed from a health economics analysis of fracture in the United Kingdom.

The guidance on the diagnosis and management of osteoporosis can be seen at www.shef.ac.uk/NOGG.

Cite this as: *BMJ* 2008;337:a2204



Israel blocks

Lynn Eaton LONDON

Attempts to organise an international annual conference on mental health in Gaza later this month have been stymied by the Israeli authorities, which, the organisers say, have stopped delegates from overseas entering the territory.

Mahmoud Abu Aisha, who is organising the conference, the fifth such, said that the Israeli authorities had initially "promised to study this issue positively," although they hadn't actually given the go ahead. On 17 October the official decision came to deny the participants permission to attend.

The conference, entitled "Siege and Mental Health ... Walls vs Bridges" and which is partnered by the World Health Organization, was due to begin on 27 October to discuss

Giant figure represents 60 years of NHS



Zosia Kmiotowicz LONDON

Anyone looking for the embodiment of the NHS of the last 60 years need look no further than *Our Kid*, a steel sculpture more than 2 m tall that will shortly be on display in Manchester.

The figure is embedded with digital screens packed with information, interviews with experts, original public service broadcasts, and films made by local young people. It is part of an exhibition that charts changes in health care over the last 60 years, including some of the medical breakthroughs that came out of Manchester.

The project has been run by Nowgen, a centre for genetics in health care, and sponsored by the Central Manchester and Manchester Children's University Hospitals NHS Trust.

Alisa's Tale: A Short Story by the artist Al Davison, a new graphic novel about a woman's experience of dwarfism, is also on display.

The exhibition runs until 29 November at Central Library, Manchester, St Peter's Square, M2 5PD

Cite this as: *BMJ* 2008;337:a1958

All MI patients in

Lynn Eaton LONDON

Angioplasty is to become the treatment of choice in England for people who have a myocardial infarction, the Department of Health has announced, with 97% of patients expected to be having the procedure in specialist heart attack centres by 2011.

Results of a three year study involving 2400 patients treated in 10 hospitals across England show that primary angioplasty is feasible and cost effective.

Provided that the procedure is carried out within two hours of a heart attack, death rates are lower than with thrombolysis, the current standard treatment, and hospital stays are shorter, says a report of the study.



Living under siege may impact on people's mental health

ABID KATIB/GETTY IMAGES

access to conference in Gaza

the effects of siege situations on mental health and human rights. A total of 120 delegates from universities around the world were to attend the conference, 25 of whom were scheduled to present papers and original research.

The conference's aim was to establish a forum to discuss issues concerning the Gaza siege and "to build bridges for dialogue, mutual acknowledgement and peace," says a statement from the Gaza Community Mental Health Programme, the group organising the conference. "The main themes of the conference are addressing professional, mental health and human rights matters," it adds.

The Israeli authorities' decision "represent a profound blow to the rights of academic freedom, free speech, education, and cultural

dialogue," said the organisers. "We view this action as an action to block communication [and to] distort the platform for mutual acknowledgement, understanding, and admitting the suffering of others. Once again, and unlike what is claimed, Israel—as an occupying power—is proving that it is controlling the Gaza Strip, preventing . . . entry or exit."

The conference organisers have said that the meeting will still go ahead. Delegates who have been denied access to the Gaza Strip will take part by video link from Ramallah in the West Bank.

The Israeli Embassy in London said it could not comment on the decision before the *BMJ* went to press as a two day holiday in Israel meant it was unable to contact officials.

Cite this as: *BMJ* 2008;337:a2225

NICE is to confer on taking more account of patients' views

Caroline White LONDON

The National Institute for Health and Clinical Excellence (NICE) is to invite patients and health economists to comment on the factors it uses to decide which drugs to recommend for use in the NHS. But it has denied suggestions in press reports that it will be radically overhauling its processes.

The move comes in the wake of research that proposes an alternative way of apportioning monetary value to drugs that is based on what patients would be prepared to pay in return for living longer (*Health Economics*, doi:10.1002/hec.1416).

In common with other public sector healthcare bodies NICE uses the quality adjusted life year (QALY) to calculate whether an intervention offers value for money. Its maximum threshold is currently set at £30 000 (€40 000; \$51 000).

But the *Health Economics* study, by researchers from the Institute of Health and Society at Newcastle University, found that patients believe this threshold should range from £35 000 to £70 000.

Peter Littlejohns, the clinical and public health director of NICE, welcomed the research but said that the evidence was not yet strong enough to justify major changes.

NICE would be asking its Citizens Council in November whether there are specific circumstances (such as advanced illness or rare disease) "in which we should deviate from our threshold," he said.

Cite this as: *BMJ* 2008;337:a2211

England are to have angioplasty

Roger Boyle, England's clinical director for heart disease and stroke, said that the 30 day mortality rate for thrombolysis is 7%, but this reduces to 5% for angioplasty if it is given within two hours. In some parts of the country, such as London, regional death rates have been reduced to 3-4%.

"Those two hours are absolutely crucial," said Professor Boyle. "Patients treated after that time have a higher death rate."

Currently in England around 25% of myocardial infarction patients have angioplasty, he said, but the number of centres offering it has been slowly growing: 54 hospitals now offer the procedure after a heart attack, up from 35 in 2006-7. In London in the past

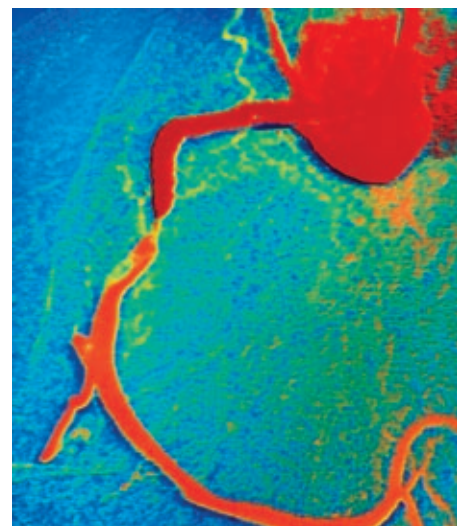
year only six patients had received thrombolysis.

Routine use of angioplasty after myocardial infarction will save around 240 more lives each year, reduce the recurrence of heart attacks, and prevent about 260 strokes a year, clinical evidence shows.

By 2011 the new centres should be able to cover 97% of the population of England. Some people living in more remote parts of the country, such as Cumbria and the east coast of Lincolnshire, will not be able to access a centre within the two hour time limit.

The report of the National Infarct Angioplasty Project can be seen at www.dh.gov.uk.

Cite this as: *BMJ* 2008;337:a2185



A blocked coronary artery before angioplasty

SIMON FRASER/SPSL

IN BRIEF

Surgeons call for limit on bed occupancy to reduce infections:

Hospital bed occupancy should not exceed 82%, and there should be enough staff on wards so that patients with infections can be cared for in isolation beds, says the Royal College of Surgeons of England (www.rcseng.ac.uk).

Rwanda's women MPs launch campaign to reduce maternal deaths:

Women MPs in Rwanda, who make up just over half the parliament, have launched a campaign to increase awareness of safe pregnancy and birth. The country has one of the world's highest rates of deaths during childbirth: 720 women die in every 100 000 giving birth.

Colour coding reduces medication errors:

A "significant proportion" of serious medical errors in hospital would be prevented by introducing a universal system of colour coding of intravenous drugs, concludes research presented at the 2008 annual meeting of the American Society of Anesthesiologists.

UK heart failure audit lacks input:

Data on only 6% (6299) of patients who leave hospitals in the UK with a diagnosis of heart failure were submitted to the national heart failure audit, shows a report on its first eight months (www.ic.nhs.uk). By March, 105 of 147 trusts providing services had registered with the audit, but more trusts need to enter data.

Study will look at stent and drug cotreatment:

Four stent makers and four drug companies have joined forces in a \$100m (£60m; €75m), four year study that will involve 20 000 patients. The study aims to provide evidence for a Food and Drug Administration inquiry into how long cardiac patients must take anticoagulants after receiving a drug coated stent.

Bottled water in US is no purer than tap water:

Leading brands of bottled water in the US contain as much as 35 parts per billion of chlorine byproducts known as trihalomethanes, which have been linked to cancer. The findings were reported by the Environmental Working Group, a research group who advocate stricter regulation. The industry's International Bottled Water Association advocates 10 parts per billion or less of the compounds in its voluntary guideline.

Cite this as: *BMJ* 2008;337:a2233



"Worrying" growth of drug resistant HIV is detected in China

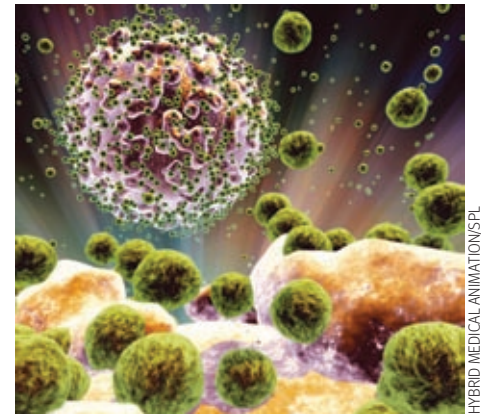
Jane Parry HONG KONG

Resistance of HIV to drugs is increasing in China, Zhiwei Chen, director of the University of Hong Kong's AIDS Institute, has said. Only seven of the more than 20 antiretroviral drugs on the market are available in China.

"The drug resistant mutations are not unique to Chinese people and therefore are consistent with those found in other countries," he said. "However, the frequency of drug resistance after two years of treatment is high. The unique feature is that a significant portion of treated patients have developed AIDS due to the drug resistant mutations and the lack of second line drugs."

At the same time, he said, the profile of China's epidemic was changing as infections are spreading beyond historically high risk groups and into the general population, including vertical transmission from mother to child.

Research published in *Nature* (doi:10.1038/455609a) by Professor Chen and colleagues from China and the United States describes critical changes in the pattern of infections in China as shown in data from the country's Ministry of Health and UNAIDS, the joint United Nations programme on HIV and AIDS. With 700 000 people in China infected with HIV as of October 2007, the



HYBRID MEDICAL ANIMATION/SP

Mutations of HIV are high after two years' treatment

prevalence remains low, at 0.04% to 0.07% of the population. But this represents an increase of 8% from 2006. In addition, the percentage of cases attributed to heterosexual transmission has more than tripled since 2005, from 11% to 38%. The proportion of cases in women has doubled in a decade, and 90% of these women are aged between 15 and 44, increasing the risk of vertical (mother to child) transmission. Furthermore, the number of infections among men who have sex with men rose from 0.4% of infections in 2005 to 3.3% in 2007.

"We did not expect to see rapid HIV spread into the general populations yet it is happening" said Professor Chen. "Preventive measures need to give priority to this new situation. Preventing HIV transmission should not just focus on high risk groups."

Cite this as: *BMJ* 2008;337:a2197

BMA chairman quizzed about public campaign to

Adrian O'Dowd MARGATE

The BMA has rejected accusations that its recent "Support Your Surgery" campaign concerning planned changes to general practice was "irresponsible" and alarmist.

The accusation was made by MPs on the parliamentary health select committee as part of its inquiry into the government's *NHS Next Stage Review*, published in June.

At an evidence session MPs asked Hamish Meldrum, chairman of the BMA Council, whether in its campaign the BMA was interested more in protecting the interests of its members than in improving care of patients, to which he replied no.

"It has been misconstrued in many areas that the BMA was totally against any change and against GP led health centres [sometimes known as polyclinics]. That was not the case," said Dr Meldrum. "What we were against was the way that we felt some

of the implementation was taking place and that there was a one size fits all approach."

Kevin Barron, Labour MP for Rother Valley and the committee's chairman, said he had had several letters from local constituents who as a result of the BMA's campaign feared that their general practice was under threat of closure or privatisation.

"Do you think that is an irresponsible position to have engineered?" asked Mr Barron, who said that some doctors had perhaps exaggerated the consequences of the proposed changes.

Dr Meldrum said, "That was not the main purpose. In the main, initially a lot of the contracts were very much geared towards the commercial sector. And if commercial GP premises are set up—in effect, in opposition to existing ones—then it could quickly put existing ones under threat."

The BMA's campaign lasted three weeks

US paediatricians update guidance on children's vitamin D intake to double previous levels

Bob Roehr WASHINGTON, DC

The American Academy of Pediatrics has recommended that children under the age of 18 consume 400 IU of vitamin D a day, double the amount previously recommended.

The guidance, published in *Pediatrics* (doi:10.1542/peds.2008-1862) and also available on the academy's website (www.aap.org/new/VitaminDreport.pdf), says that infants who consume at least a litre a day of formula milk fortified with vitamin D do not need supplementation. However, infants who are fully breast fed or who have mixed feeding and receive less than a litre of fortified milk a day should begin supplementation with 400 IU a day of vitamin D in the first few days after birth.

Children and adolescents can get the new recommended amounts of vitamin D by drinking four glasses of milk fortified with the vitamin each day and by eating eggs, oily fish such as salmon, and fortified cereals, but growing numbers of young people don't consume these. Those who are likely to consume less than the recommended amount should be given a supplement while continuing to eat fortified foods, the doctors advise.

Some children may need higher levels of supplementation because of problems with absorption or interactions between drugs

that affect the vitamin's bioavailability.

"We are doubling the recommended amount of vitamin D children need each day because evidence has shown this could have lifelong health benefits," said Frank Greer, chairman of the committee that wrote the report. "Supplementation is important, because most children will not get enough vitamin D through diet alone."

Exposure to sunlight in the summer months can generate important amounts of vitamin D in fair skinned children. But far from the tropics the sun's oblique angle during much of the year is insufficient to produce that activity. Even in San Diego, near the border with Mexico, serum concentrations of vitamin D fall into deficiency during the winter months.

The situation is worse for people with darker skin, which is less efficient at generating vitamin D from sunlight. Children with dark skin run a higher risk of developing rickets when they live away from the tropics.

The report discusses vitamin D deficiency in pregnant and nursing women, particularly among those with dark skin, and how this could affect development of the fetus and newborn child. However, the academy does not advise on maternal supplementation.

Cite this as: *BMJ* 2008;337:a2133



Advice on vitamin D distinguishes between breast fed and bottle fed babies for the first time

PURESTOCK/GETTYIMAGES

defend general practice

and gathered 1.3 million signatures in support from patients (*BMJ* 2008;336:1399).

One committee member, Howard Stoate, Labour MP for Dartford, challenged Dr Meldrum, saying that the BMA had not done enough to explain to the public that the government was not proposing polyclinics for everywhere in the country.

"This comes back to the effectiveness of campaigning," said Dr Meldrum. "Campaigning is a bit of a blunt instrument, but there is an overall message you are trying to get out.

"I apologise and condemn people who misused the information we were giving them, but I think there was a feeling that there was a drive to set up clinics, not just in London, but everywhere that would be in some ways in opposition to existing services."

The inquiry continues.

Cite this as: *BMJ* 2008;337:a2176

Value of foundation trusts needs to be proved

Adrian O'Dowd MARGATE

NHS foundation trusts should be independently evaluated to judge their real performance to date, says a report by a cross party group of MPs.

The report, by the parliamentary health select committee, which looked at foundation trusts and their regulator, Monitor, also calls for the trusts to work more closely with other NHS organisations.

Foundation trusts, of which there are now 107, were introduced in England in 2004 as a new type of NHS organisation with a greater degree of financial and management freedom from central government.

For their short inquiry MPs took oral and written evidence from a number of witnesses, including Monitor, academic commentators, and representatives of trusts and other NHS organisations that work with them.

In their report the MPs said that they were

surprised by the lack of objective evidence and evaluation of foundations trusts' performance, including their achievements in promoting innovation and involving the public.

Foundation trusts have some "proven strengths," says the report: they have performed well financially and generated surpluses and are among the highest performers in quality measures of routine NHS processes. This performance, however, was tempered by uncertainties, said the MPs. For example, it was unclear whether their high performance was the result of their changed status or simply a continuation of previous trends, as the best trusts had become foundation trusts.

The trusts had contributed little towards the government's aim of delivering more NHS care outside hospitals, with the exception of mental health trusts, the MPs said.

The report is at www.publications.parliament.uk.

Cite this as: *BMJ* 2008;337:a2188

Thai doctors say they won't treat police who use violence

Ben Bland SINGAPORE

The Medical Council of Thailand has launched an investigation after a group of doctors at Bangkok's leading university hospital said they would not treat police officers hurt in violent clashes with antigovernment protesters last week.

The group of around 50 doctors at Chulalongkorn Hospital said that as a protest against the government's use of violence on demonstrators they would deny treatment to injured police.

But Suthep Kolchanwit, the group's leader, later apologised for having announced the boycott, insisting that he had not, in practice, denied treatment to anyone.

Two people were killed and hundreds injured earlier this month in the worst street violence that Thailand has seen in more than 15 years. The bloodshed began when police fired tear gas at supporters of the antigovernment People's Alliance for Democracy to prevent them gaining access to the parliament building.

The alliance accused the police of using excessive force, claiming that the severity of injuries sustained by the protesters could not have been caused by the use of tear gas alone.

"No one was refused treatment," said Somsak Lohlekha, chairman of the medical council. "According to medical ethics, you cannot refuse

emergency treatment, and we warned the doctors of this."

A spokeswoman for the Thai government said, "It was just a symbolic gesture, and in the end everyone received the treatment they needed. This action was a personal stance of the individual doctors and not the hospital."

Despite the insistence that no police officers were actually denied treatment, the council said it would still investigate the incident following some complaints.

"Our ethics committee is now looking into this," Dr Lohlekha said. "We should not use the medical profession to influence this conflict. We need to separate our political

views from our professional role."

However, he added that doctors could legitimately refuse non-emergency treatment if they believed this to be in the best interests of the patient. "If there is some conflict between a doctor and the patient, it is safer for the patient to be treated by someone else," he explained.

The political crisis in Thailand has been escalating since August, when the People's Alliance for Democracy occupied the prime minister's offices, claiming that the elected People's Power Party is merely a front for former premier Thaksin Shinawatra, whom they accuse of corruption and nepotism.

Cite this as: *BMJ* 2008;337:a2132

Death rates from cancer in the UK are predicted to fall further

Rebecca Coombes LONDON

The risk of dying from cancer before the age of 84 in the United Kingdom will continue to fall for most types of the disease for the next two decades, a new study predicts.

Researchers from the charity Cancer Research UK looked at data on the numbers of people dying from 21 of the commonest cancers and have predicted a 17% fall in the death rate in men and 16% in that in women from 2003 to 2023 (*British Journal of Cancer*, doi:10.1038/sj.bjc.6604710).

They used trends in mortality from 1970 to 2005 to project what cancer death rates are likely to be in the next 20 years.

In men the largest projected fall in the risk of dying was for stomach cancer (a 43% drop over the next 20 years). In women the risk of death from cervical cancer is predicted to fall by 57% over the same period.

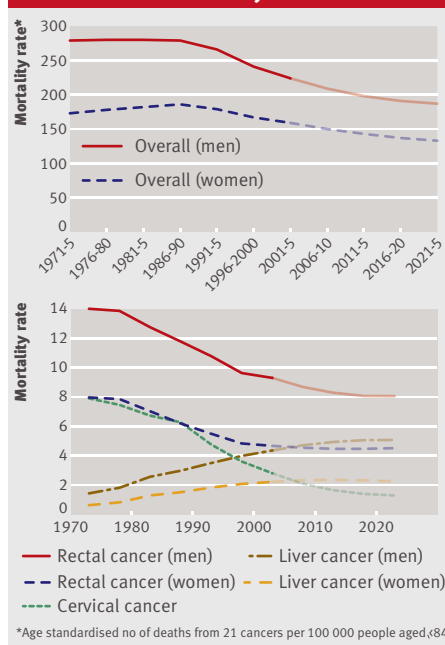
Peter Sasieni, an epidemiologist and one of the authors of the study, said, "There are two reasons why we have seen a fall in cancer death rates. Firstly, the chance of developing cancer is getting lower as a result of lifestyle changes. Secondly, more people are surviving cancer because there are better treatments and more effective screening programmes.

"Our study provides a benchmark against which we can measure the effect of new screening programmes and cancer treatments."

There were some exceptions to the overall trend. In men, mortality from cancers of the oral cavity, oesophagus, and skin (melanoma) are predicted to rise slightly, while the death rate from liver cancer is likely to rise by 14%. In women, the only projected increase in mortality was for cancer of the uterus.

Cite this as: *BMJ* 2008;337:a2198

CANCER MORTALITY PROJECTIONS IN THE UK



Advertisements for atorvastatin were misleading to women

Roger Dobson ABERGAVENNY

Advertising of the world's best selling drug failed to disclose the absence of benefits for women, who should be entitled to compensation to recoup the costs of treatment, claim experts in epidemiology and law in a new analysis.

They argue that unqualified claims of protection against heart attacks made in advertisements for the lipid lowering drug atorvastatin (which is made by Pfizer and sold as Lipitor) may be misleading and that the advertising raises concerns about the way the US Food and Drug Administration regulates drugs (*Journal of Empirical Legal Studies* 2008;5:507-50).

The authors, Theodore Eisenberg, a professor of law at Cornell Law School, and Martin Wells, professor of clinical epidemiology at Cornell University Weill Medical College, claim that a substantial portion of the multibillion dollar market in statins may be made up of users for whom the drugs offer no benefit.

They add that remedies to recover costs should exist for consumers who have not been properly informed about statins. "If we are correct about omissions from Pfizer's advertising, then neither market forces nor FDA regulation has effectively regulated the mass marketing of Lipitor."



Political deadlock in Thailand has left society divided

CHUMSAK KANOKNAN/GETTY IMAGES

“The progression from the underlying scientific study of Lipitor, expressly reporting no benefit for women, to Pfizer’s advertising of the world’s best selling drug while failing to disclose the absence of benefit for women raises grave concern about the FDA’s regulation of drugs and drug company candor.”

They add, “At a minimum, the FDA should use its authority to address massive questionable marketing. Our review suggests the need for modified labelling, marketing, and information for physicians.”

The authors say that atorvastatin is now the world’s top selling drug, with more than \$12bn (£7bn; €9bn) in annual sales.

Advertisements for the drug claim that it is clinically established to reduce heart attacks, without any indication of qualification by sex, their paper says. The authors say that they were unable to find high quality clinical proof of a lessened risk of heart attack for women who take the drug. Studies of atorvastatin show a significant benefit for men but not for women, the authors say.

They add that Pfizer’s advertising omits label information relevant to women and that neither the label nor the advertising disclose that the key clinical trial of atorvastatin found a moderately raised risk of heart problems in women.

“Not one of the studies that include women with a mixture of risk factors for heart attacks provides statistically significant support for prescribing Lipitor or other statins to protect against our cardiovascular end points,” they wrote. “Pfizer’s claims of clinical proof that Lipitor reduces ‘risk of heart attack . . . in

patients with multiple risk factors for heart disease, including family history, high blood pressure, age, low HDL (‘good’ cholesterol) or smoking” does not appear to be scientifically supported for large segments of the female population.

They add: “Pfizer’s advertising also does not disclose critical portions of the Lipitor FDA-approved label, which acknowledges the absence of evidence with respect to women.”

They say that the study’s findings also have implications for the costs of health care. “Our findings indicate that each year reasonably healthy women spend billions of dollars on drugs in the hope of preventing heart attacks but that scientific evidence supporting their hope does not exist.”

In a statement responding to the article Pfizer said, “The statin class has extensive data supporting a reduction in CV [cardiovascular] risk burden and Lipitor’s ability to reduce cardiovascular morbidity and mortality has been demonstrated in 12 CV outcomes trials.

“Cardiovascular disease is a major cause of death in women as well as men and it ultimately kills as many women as men. However, onset of disease is delayed by some 10-15 years in women compared to men; thus the National Institutes for Health (NIH) ATP III guidelines define age as a risk factor in women at age 55, compared to age 45 for men. In addition, the AHA CVD Guidelines for Women were updated in 2007 and recommend that healthcare professionals should focus on women’s lifetime heart disease risk, not just short-term risk.”

Cite this as: *BMJ* 2008;337:a2209

US university plans to set up new conflict of interest office

Janice Hopkins Tanne NEW YORK

Emory University in Atlanta, Georgia, said that it was setting up a new office to oversee conflict of interest issues.

The US Senate Finance Committee is investigating Charles Nemeroff, chairman of the university’s department of psychiatry and behavioural sciences, for allegedly not reporting payments from drug companies (*BMJ* 2008;337:a2088, 16 Oct).

The university said that the new central office “will help us ensure strong conflict of interest policies and procedures university-wide.”

The National Institutes of Health froze a \$9.3m (£5.4m; €6.9m), five year grant to Dr Nemeroff on 15 August. Dr Nemeroff temporarily stepped down as department chairman, although he remains a professor.

Emory University received \$411m in research funding last year, of which \$251m came from the National Institutes of Health (NIH), said a university spokesman, Jeffrey Molter.

The university told its researchers about new rules on financial disclosure for those working under new and pending grants from NIH. The university’s new office to oversee conflict of interest administration and policies will centralise reporting.

Previously, most sponsored research had been at Emory’s School of Medicine, but now more studies are being done at other colleges, the university said.

NIH imposed strict rules on Emory investigators, requiring them to disclose information about those who had received grants, subcontractors, collaborators, financial interests, and what Emory has done to manage, reduce, or eliminate conflicts of interest.

An NIH statement said, “Results from NIH funded research must not be biased by any conflicting financial interests. Officials at Emory are investigating the concerns. Failure to follow NIH standards on conflict of interest is very serious, and NIH will take all appropriate action to ensure compliance.”

Cite this as: *BMJ* 2008;337:a2200



Charles Nemeroff is being investigated