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MPs' report criticises influence of drugs industry

Zosia Kmietowicz LONDON

Too many GPs are influenced by the pharmaceutical industry, which spends £850m (€1130m; \$1670m) every year on marketing its products in primary care, says a report from the Public Accounts Committee, the government's spending watchdog.

And the NHS spends at least £200m more than it should on medicines because GPs do not heed official guidelines and continue to prescribe branded medicines rather than generics, says the report.

The committee's comments follow a survey by the National Audit Office which found that one in five GPs said their prescribing choices were swayed more by industry marketing that by official NHS advice.

"It's hard to doubt that the blandishments of the pharmaceutical industry are having an effect," said Edward Leigh, chairman of the Public Accounts Committee.

The Department of Health should set a minimum level above which gifts and hospitality to GPs from the pharmaceutical industry should be declared to trusts, says the report. It also says that despite increases in generic prescribing in recent years there is a wide variation between primary care trusts in the proportions of generics being prescribed for some conditions. For example, GPs in some trusts prescribe 86% generic versions of statins, but in other trusts the figure is just 28%.

GPs must concentrate more on following official guidelines, increasing the prescribing of generic drugs where clinically appropriate, said Mr Leigh. "The fact that primary care trusts vary hugely in the extent to which their GPs prescribe generic drugs for common conditions shows what can be achieved."

The committee calls on the Department of Health to develop better prescribing indicators to measure the proportion of generics dispensed and the potential savings that could be made by prescribing more effectively. It also says that the "medicines management" indicators in the Quality and Outcome Framework, on which nearly all GPs achieve maximum points, need to be set

higher and to include a reward for generic prescribing where appropriate.

The report calls for greater awareness among the public about the cost of drugs to reduce waste, perhaps by displaying the cost of items on the packaging. Most prescriptions—88%—are dispensed free and the standard charge for the rest does not reflect the cost of the items, says the report.

"Unused and wasted drugs cost the NHS at least £100m a year and almost certainly a lot more," said Mr Leigh. "The Department of Health must do more to find out why this is happening."

Trusts should be encouraged to pilot formularies which have been agreed between primary and secondary care to boost cost effective prescribing. And strategic health authorities should work with the National Prescribing Centre to promote agreed formularies across health sectors and trusts, recommends the report.

Department of Health: Prescribing Costs in Primary Care is at www.parliament.uk

UK government wants to increase number of donated organs

Caroline White LONDON
A single organ donation
organisation for the whole of
the United Kingdom should be
set up to ease the shortage of
donor organs, a government task
force has concluded in a report
published this week.

More than 8000 people in the UK are currently awaiting organ transplants—primarily kidneys—and the numbers are rising by about 8% every year, according to figures from UK Transplant.

Over 1000 people die every year waiting for a transplant.

The report, drawn up by representatives from specialist societies, MPs, and royal colleges, among others, nominates NHS Blood and Transplant (NHSBT) as the most

suitable candidate to take on the task.

The move would see a doubling in the numbers (to around 200) of donor transplant coordinators, whose role is to encourage consent to organ donation and support bereaved families through the process.

These coordinators would become part of a centrally coordinated network and would be employed by NHS Blood and Transport rather than local trusts.

This network, recommends the report, should be supported by boosted numbers of dedicated organ retrieval teams, available 24 hours a day and working closely with hospital critical care teams, to increase the supply of high quality organs for transplant.

Under the proposals, trusts would be officially monitored on their donation activity and rewarded financially accordingly.

The 14 proposals are intended to increase the number of donors by 50%, providing an additional 12 000 transplants every year in the next five years.

In an article "Organ donations help us make a difference" published in the *Sunday Telegraph* on 13 January
Prime Minister Gordon Brown signalled his support for presumed consent, which would require a change in the law, and called for a national debate on organ donation. *Organs for Transplants. A report from the Organ Donation Taskforce* is at www.dh.gov.uk



Heart transplant operation in progress

3EN EDWARDS/GETTYIM

IN BRIEF

Cancer patients should have equal access to fertility services: The UK should have a national policy on storing sperm, eggs, and embryos for patients having cancer treatment, says a report from the Royal Colleges of Physicians, Radiologists, and Obstetricians and Gynaecologists (order through www. rcplondon.ac.uk). Every year 11 000 people in the UK aged under 40 are diagnosed with cancer and they should have the same access to funded infertility treatment as everyone else, they say.

More than half of Iraqis in some parts of the country have no health care:

A third of Iraq's 2.4 million displaced persons cannot access the medicines they need and 14% have no access at all to health services, says a report from the International Organization for Migration. In Kirkuk, 57% of the population have no access to health care.

Study shows scale of migraine in the

UK: A study based on 51688 UK patients with a first time diagnosis of migraine and the same number of matched controls shows that the incidence of migraine was 3.69 (95% confidence interval 3.66 to 3.73) cases per 1000 person years. It was about 2.5 times higher in women. Most chronic diseases were slightly more prevalent in those who experience migraines than in controls (Cephalalgia 2008;28:57-64).

German journal publishes English

translation: Deutsches Ärzteblatt, Germany's largest medical journal, which is co-owned by the German Medical Association, will publish an international online edition containing English translations of medical research papers from the German edition (www. aerzteblatt-international.de) from 21 Jan. The journal says that English is the "Lingua franca of medicine," noting that 90% of papers in the Medline database are in English, with only 2% in German.

GP leader warns extended hours could

damage elderly care: The BMA General Practitioners Committee has written to charities and groups representing older people to apologise that a package of measures aimed at improving the care of patients with osteoporosis, peripheral arterial disease, and other disease has been rejected by the government. Instead the government has chosen to put resources into longer opening hours, plans which were "incredibly short sighted," said Dr Laurence Buckman. See 'In the line of fire' page 114

Research body helps to boost the total

Susan Mayor LONDON
A shake-up in the way research is organised in the NHS has led to a massive increase in the numbers of patients taking part in clinical trials, according to a report published this week.
The National Institute for Health Research, set up in 2006 to oversee NHS research in England, says that setting up research networks has been

The networks are providing the framework needed to support clinical trials across the country, the report says.
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Dutch academics criticise suicide claims in American journal

Tony Sheldon UTRECHT

Claims in an influential scientific journal of a link between a leap in suicides among young people in the Netherlands and a fall in prescriptions for selective serotonin reuptake inhibitors (SSRIs) has been condemned as "astonishing" and "misleading."

Researchers led by Robert Gibbons, of Illinois University in Chicago, have reported

that, following warnings from regulatory authorities, SSRI prescriptions for Dutch youths decreased between 2003 and 2005 by approximately 22% (American Journal of Psychiatry 2007;164:1356-63; reported in BMJ 2007;335:531).

During the same period, Dutch youth sui-

cide rates increased by 49%. The findings are "preliminary" and show "no definitive causal relationship" but, the researchers claim, the increased suicide rate shows "a significant inverse association with SSRI prescriptions."

Last month's Geneesmiddelenbulletin (Dutch Drug Bulletin) pointed out that the absolute figures used-34 suicides in 2003, increasing to 51 in 2005-were so small that they were not statistically significant. Its editor, Dick Bijl, also pointed out that the 2006 figures now show a fall in youth suicides to 48.

Dr Bijl says the paper's conclusions were "astonishing" and "cannot be made from the data available." He believes the abstract in the American Journal of Psychiatry should have

"The numbers for the Netherlands are so small that you have to be very, very careful before you make a statement," he said. In an issue as important as childhood suicide he feels the authors were "reckless."

Dr Bijl has raised his concerns with the American Journal of Psychiatry, which is investigating the matter.

The Dutch investigative radio programme Argos has highlighted Dr Bijl's concerns, quoting experts in statistics, epidemiology, and child psychiatry, who warn of the "danger" in such "misleading" research. They empha-

> sise that there is no clear trend in suicides but large swings between years and age groups. For example, in the 10-15 age group, suicides fell from 13 in 2005 to four in 2006.

Responding to the criticisms, Professor Gibbons told the BMI that the paper tests the hypothesis that antide-

pressants increase youth suicide rates.

"Our paper is the first to illustrate that this hypothesis and corresponding regulatory actions are clearly not supported by the early data that are available both in the Netherlands and the US," he said. If anything, he argued, decreased use of antidepressants has led to increases in suicide rates in children.

He added that, as stated in the paper, the difference overall in Dutch suicide rates between 2003 and 2005 approaches statistical significance (at P<0.078) and is significant for boys under 15 (P<0.027). He maintains that from 1998 to 2005 there is a statistically significant inverse association between antidepressant prescriptions and youth suicides (P<0.04).



Controversy over youth suicide notes continues

112

number of patients in clinical trials

in England having a greater percentage of cancer patients in clinical research trials than any other country, says the report.

The Stroke Research Network has doubled the number of patients entering trials. It recruited 905 patients to clinical trials during the first three months of 2007, compared with fewer than 450 in 2006, reported Professor Gary Ford,

director of the network.

"We aim to get 400 patients per network into trials each year," he said, explaining that the network is working in collaboration with similar networks in the rest of the UK. He added that the network is also improving collaboration between different professionals working in stroke.

The institute has also set up

the School for Primary Care Research in a £15m (€20m; \$30m) initiative based on five academic departments of primary care scoring highly in research.

To date the school has commissioned 38 studies.

Transforming Health Research—
The First Two Years is available at www.nihr.ac.uk.
See Editorial, p 106.

Iraqi healthcare still crippled five years after invasion

Owen Dyer LONDON

Iraq's health system is still crippled, nearly five years after the US led invasion of 2003, partly as a result of a disorganised and often incompetent reconstruction effort, concludes a report from the organisation Medact.

The report describes Iraq as "a failing state with a complex health emergency," with as few as 9000 doctors and 15 000 nurses serving a population of 28 million people. Around half of Iraq's doctors have fled the country, while many more are counted among the 2.2 million internal refugees.

The report follows the publication last week in the *New England Journal of Medicine* (doi: 10.1056/NEJMsa0707782) of the largest household survey to date, measuring mortality in Iraq after the invasion. The Iraq family health survey, led by the World Health Organization, found sharp rises in all

cause mortality as well as a heavy death toll from violence.

It estimates that 151000 Iraqis died from violence between March 2003 and June 2006, most of them men. Violence was the leading cause of death in men aged 15 to 59.

The findings are based on 9345 households in 971 clusters, a sample almost 10 times larger than in the most recent survey, published in the *Lancet* in October 2006 (368;1421-8), which estimated 601000 excess deaths from violence.

The latest survey shows a steep rise in all cause mortality, even in groups less affected by violence. Among children under 15, all cause mortality rose from 2.82 deaths per 1000 person years before the invasion to 4.37 in 2003-6.

Rehabilitation Under Fire: Health Care in Iraq 2003-7 is available at www.medact.org



Iraqis attempt to get into a US army health clinic because their own hospitals lack decent care

Healthcare reform is important to US voters, study shows

Bob Roehr WASHINGTON, DC

A large majority of Americans say that a presidential candidate's views on healthcare reform will be a very important or somewhat important factor in how they cast their vote, according to a survey by the Commonwealth Fund that was released on 15 January. It was accompanied by an analysis of the positions of presidential candidates on health reform.

Health expenditures surged to 16% of the US gross domestic product in 2006 and are



Hillary Clinton, potential Democrat candidate

projected to reach an unsustainable 20% within a decade said the fund's president, Karen Davis.

But the United States ranked last for preventable deaths in a recent study of 19 industrialised nations, most of whom spend about half as much as the US on health care. She said the American people have begun to realise that "the case for health reform is overwhelming."

Among Democrats, 77% said that health care was very important and 17% said it was somewhat important in deciding who to vote for; among Republicans the figures were 47% and 36% respectively, said Sara Collins, the author of the report.

Political affiliation made little difference when it came to financing health care; 67% of Democrats and 66% of Republicans said it should be a mix of individual, employer, and government contributions.

The Public's Views on Health Care Reform in the 2008 Presidential Election is available at www.commonwealthfund.org

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Cost of many common treatments varies widely across Europe

Janice Hopkins Tanne NEW YORK

The cost of common medical, surgical, and dental procedures varies widely across nine countries of the European Union, according to studies published in a supplement to Health Economics (2008;17:S8-103).

The studies, known as HealthBASKET (Health Benefits and Service Costs in Europe), looked at the costs of hip replacement, treatment of stroke, myocardial infarction, delivery of a child, appendicectomy, cataract surgery, and a single dental filling during 2005. The countries participating in the study were Denmark, England, France, Germany, Hungary, Italy, the Netherlands, Poland, and Spain.

The total cost of care for each procedure was lower than the average in Hungary, Poland, and Spain. The probable reason was lower wage levels, the studies say.

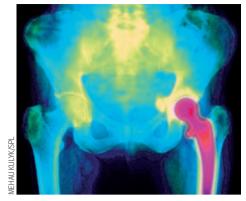
Cost of a hip replacement ranged from €1290 (£975; \$1905) in Hungary to €8739 in the Netherlands. Treatment of stroke ranged from €1043 in Hungary to €6533 in the Netherlands. Treating a myocardial inf-

TOTAL COST (IN EUROS) OF HIP REPLACEMENT, AND COST OF OPERATION ALONE

Country	Total cost (adjusted by purchasing power parity)	Costs of operation* (not adjusted)		
		Anaesthetist/ surgeon	Other staff	Other costs
Denmark	4401	202	179	4774
England	5274	535	123	2970
France	5680	728	216	4279
Germany	6047	596	417	3067
Hungary	2147	93	19†	684
Italy	6795	229	111	6142
Netherlands	5328	669	378	3732
Poland	3861	52	10	1509
Spain	3965	400	109	2507

*Does not include diagnostic procedures or care on the ward †Non-nursing staff subsumed in overheads

Source: Health Economics 2008; 17:S15



X ray of a prosthetic hip joint in place

arction in Germany cost €3114, compared with €8722 in the neighbouring Netherlands. The cost of normal childbirth varied from €342 in Hungary to €2365 in Germany. Cataract extraction and lens implantation varied from €318 in Hungary to €1087 in Italy, and a single dental filling cost from €8 in Hungary to €156 in England.

The reason for variation in reimbursements in all procedures except normal delivery "most often was the use of particular technologies or procedures," the authors write.

In an accompanying editorial, Reinhard Busse and Jonas Schreyogg from the department of health care management at Berlin Technical University and Peter Smith from the Centre for Health Economics at the University of York say the study will help EU member states form policies on patient mobility, let patients know about opportunities in the emerging EU healthcare market, and permit international comparisons to learn from the best practices in each country.

The HealthBASKET study used a "case vignette" approach to explore resource use, costs, and prices. The vignettes depicted "typical" patients, including specified age, sex, and relevant comorbidity. They included inpatient and outpatient settings, primary and secondary care, and elective and emergency care.

Adrian O'Dowd MARGATE
Could the increasingly public dispute about general practice opening hours backfire?

The latest battleground between doctors and the government is the issue of extended opening hours in general practices—and the battle seems no closer to an end, despite talks last week.

Tempers on both sides are frayed. The government has launched a consultation on a second, tougher proposal to change the GP contract from April if most GPs vote

GP contract from April if most GPs vote against the original negotiated offer. This has prompted the BMA to accuse the Department of Health of putting a "gun to our head."

The government's approach, called "antagonistic" by some, has, in combination with the BMA's refusal to budge, resulted in a very public dispute—one that is potentially damaging to the reputation of GPs, not least because of the way it is playing out in the media.

Neither of the two options on the table (see box) is acceptable to the BMA, whose main objection is what it calls the government's bullying approach. Although the extended hours are voluntary, the BMA says that an average practice that chooses not to provide them could lose around £36000 (€48000; \$71000) a year. It argues that the government's agenda is to introduce alternative private sector providers to compete with GPs.

Richard Vautrey, deputy chairman of the BMA's General Practitioners Committee, said, "We see [the move to extend opening hours] as being a symptom of a far bigger picture. The more important issue is the way government currently does not value quality of care and is prepared to take money away from

Spanish abortion clinics close amid safety fears for women and doctors

Jane Burgermeister VIENNA Only emergency abortions were performed in Spain last week after clinic staff went on strike, demanding greater legal protection for women and doctors.

More than 2000 women were affected when private clinics, which carry out 98% of all abortions in Spain, closed their doors,

according to a report in El Pais (8 January; www.elpais.com/ articulo/sociedad/Paro/historico/ centros/aborto/elpepisoc/ 20080108elpepisoc_3/Tes).

In Andalusia, where state clinics do not carry out abortions, only emergency abortions were available at private clinics between 8 and 12 January.

"We will take care of women sent to us by public health bodies, but only if they are at the 22 week limit or if there is a great risk to their physical health, such as hypertension or a heart problem," said a spokesman for the GineGranada clinic in Andalusia.

"We want the right of women to have an abortion and the safety of the professionals who perform them to be guaranteed," Francisca Garcia Gallego, regional director of the Association of Accredited Abortion Clinics, told El Pais.



The government believes that longer evening opening could make it easier for commuters to see their GP

quality of provision to fund access targets."

Dr Vautrey rejects the suggestion that matters have been made worse by the BMA bringing attention to the clash of opinion and says: "One of the reasons we voted not to accept the current proposals is because of the bullying stance taken by government and the way they have approached these negotiations and their overt threats."

NHS Employers' director of operations Alastair Henderson says that negotiation over changes to the general medical services (GMS) contract has effectively finished and that it is now up to the profession to decide whether it wants to agree to the negotiated proposal or else accept the government's imposed one.

Mr Henderson said he hoped that once GPs saw the government proposal they would see it provided improvements for patients and for them.

But some believe that the continuing clash between the two sides is damaging the profession.

Martin Marshall, former deputy chief medical officer at the Department of Health and now director of clinical quality of the Health Foundation (an independent organisation that aims to improve health care in the United Kingdom), said, "My concern is that both sides are sparring for a fight and digging their heels in, and I don't think that's going to be healthy for the public.

"There is evidence that some patients rate access highly and think general practice is inaccessible. There is also a perception within government that GPs did extremely well out of the new contract negotiations, perhaps too well, and government wants to get more back from them than they are getting at the moment."

Dr Marshall, who is also a practising GP, believes that the BMA would be wiser to choose another issue to battle on.

"I personally have some doubts as to whether this is the right battle to fight. There are some other battles that need to be fought: the importance of the generalist at the front line of the health service, fragmentation of care, patient lists.

"Picking a battle over access is going to look pretty bad to the public and will make general practice look like it's digging its heels in."

About 10 years ago Saturday morning surgeries with a skeleton staff were common and well attended but were not always used as the emergency service they were designed to be.

Kieran Sweeney, a GP in Exeter, said,

"Most practices had them as open surgeries to be used only in emergencies.

"They were reasonably well attended, and about 10-13% of our consultations took place on a Saturday morning. I think it would be a good idea to reintroduce them."

The current problems over agreeing extended hours are not doing anyone any favours, Dr Sweeney says. "I think the government is being antagonistic and is very anxious to shake up the way health services have been provided historically.

"I am not sure the BMA's line on this is doing the profession harm, but it's not doing it any good either. It's a matter of great regret that 'greedy' and 'lazy' are adjectives that are being applied to GPs. I feel aggrieved about that."

The BMA's letter for GPs is at www.bma.org.uk/ap.nsf/Content/LBletter080108.

The two proposals for extending GPs' hours

A negotiated proposal from NHS Employers to change the general medical services (GMS) contract so as to open general practices for three more hours a week and until 8 pm once a week was rejected by the BMA, which said that it would need to consult with its membership. Under this original offer:

- An average practice with 6000 patients would offer three extra hours a week, funded by a £158m cash incentive pot of money
- A total of 58.5 points under the quality and outcomes framework (QOF) would be reallocated from clinical to access targets
- GPs would be guaranteed a 1.5% pay rise for next year.

If GPs reject this offer the government will impose an alternative settlement, meaning that:

- The potential 1000 QOF points that practices can currently earn would be cut by 135
- QOF thresholds would be increased
- Primary care trusts would decide where to invest access money locally (possibly with private providers)
- There would be no guaranteed pay rise.

Mr Garcia said that abortion clinics had been subjected to protests from anti-abortion campaigners and raids by local authorities. On 26 December, five protesters threw stones and other objects at a clinic in Madrid; four days earlier a doctor and a nurse had been attacked as they left their clinic.

Four clinics in Barcelona were raided in November and their director, Carlos Morin, was arrested

on suspicion of performing illegal, late term abortions. Files on 40 patients have been opened after a Danish news team filmed Dr Morin offering to perform an abortion on a Danish journalist who was 26 weeks pregnant.

State prosecutor Elisabeth Castellon is also investigating four gynaecologists, a manager (the wife of Dr Morin), and the clinics' administrative head. Women from France, Great Britain, the Netherlands, Germany, and Australia are reported to have travelled to Barcelona to have late terminations. According to Spanish health officials, only 95 British women have had abortions in Catalonia between 1994 and 2005.

A spokesperson for the Association of Accredited Abortion Clinics said that 90% of abortions are carried out within 12 weeks.

The association says that inspections of its abortion clinics have increased since the arrests in Barcelona, with the five abortion clinics in Madrid inspected an average of six times in 2007, up from an average of two in 2006. Madrid also closed two clinics last month for alleged administrative irregularities.

Altogether, 101 592 abortions were carried out in Spain last year.

Hormone replacement therapy quadruples risk of breast cancers

Susan Mayor LONDON

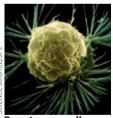
Postmenopausal women taking combined oestrogen and progestin hormone replacement therapy for three years or longer run four times the risk of developing lobular breast cancer, finds US research. This is shorter than the time associated with an increased risk of other types of breast cancer (Cancer Epidemiology, Biomarkers Prev 2008;17:43-50).

The study included 1044 women between the ages of 55 and 74 who had been diagnosed as having invasive breast cancer between 2000 and 2004 and entered into the cancer surveillance system in Washington state. They were compared with 469 age matched controls without cancer.

A third of the women with breast cancer had lobular cancers, which occur in the chambers of the breast that contain milk producing glands. They are hormonally sensitive, so are more treatable than the more common ductal cancers, but they are more difficult to detect.

Women using combined hormone replacement had a 2.7-fold higher risk of lobular cancer (95% CI 1.7 to 4.2) and a 3.3-fold (2.0 to 5.7) higher risk of ductal-lobular cancer.

The higher risk was seen only in those who used hormone replacement therapy for three or more years. In women with mixed



ductal-lobular cancers, hormone replacement increased the risk of predominantly lobular tumours.

The incidence of invasive lobular breast cancers in the United States increased by 52% between 1987 and 1999.

The rate of ductal-lobular cancers increased by 96% but ductal cancers increased by only 3% during this time.

Christopher Li, associate member at the Fred Hutchinson Cancer Research Center in Seattle and lead author of the study, said that the specific use of combined oestrogen plus progestin therapy "may be contributing to this increase."

"The results provide further evidence that combined hormone therapy use increases the risk of invasive lobular carcinoma, and they indicate that current use for as little as three years may increase risk of these tumours substantially," he said.



Black women in Hackney, East London, where the study was carried out

Black women have a higher risk of breast cancer than white women

Roger Dobson ABERGAVENNY

Black women in Britain develop breast cancer up to 21 years earlier than white women. They are seen at a median age of 46-four years before routine NHS screening for the disease starts—compared with 67 for white women, according to the first published data on breast cancer presentation in black women (British Journal of Cancer, doi: 10.1038/sj.bjc.6604174).

Among women with smaller tumours (less than 2 cm), black women were nearly three times as likely to die of their disease (hazard ratio 2.90, 95% CI 0.98 to 8.60, P=0.05).

"Our findings could have major implications for the biology of breast cancer and the detection and treatment of the disease in black women," say the authors. "It is crucial to target this group of women to raise their awareness regarding the risks of breast cancer, the likelihood of early age at presentation, and the importance of self-examination."

The authors, from Barts and The London, Queen Mary's School of Medicine and Dentistry, and Wolfson Institute of Preventive Medicine, say that until now there have been no data on the patterns of breast cancer in British black women.

"Since there are no published data on breast cancer in British black women, we sought to determine whether, like African-American women, they present at a younger age with biologically distinct disease patterns," they say.

For the study, the authors looked at women presenting at the Homerton University Hospital, Hackney, between 1994 and 2005 with a diagnosis of invasive breast cancer. Of the 445 patients with a new diagnosis of breast cancer between 1994 and 2005, 102 were black and 191 white British women.

Results show big differences in age at diagnosis. Black patients were significantly younger (median 46 v 67 years, P=0.001). No other common cancer in the same population of black women was as common in younger women.

A higher proportion of black women had grade 3 tumours, lymph node positive disease, negative oestrogen receptor and progesterone receptor status, and basal-like (triple negative status) tumours. Some 62% of black women had grade 3 tumours, compared with 42% of white patients.

The authors say there is no evidence that the results are due to late presentation or inequalities in the receipt of therapy. A data review showed that black women received more adjuvant therapy-chemotherapy, radiotherapy, and hormone therapy-than their white counterparts.

"Breast cancers arising in young black women appear to be biologically different, an effect not attributable simply to the young age of affected individuals," say the authors, who add that tumours in younger black women are considerably more aggressive.

The authors point out that the NHS breast screening programme is offered to all women up to age 70, starting at 50, four years later than the median age for presentation of the black women in the study.

US drugs regulator issues severe pain alert on bisphosphonates

Jeanne Lenzer NEW YORK

Bisphosphonate drugs, which are used to reduce bone fractures in patients with osteoporosis, may cause severe and even "incapacitating" musculoskeletal pain, says the US Food and Drug Administration in an alert issued on 7 January.

The pain can occur within days or years after starting treatment, says the agency. Severe musculoskeletal pain is mentioned in the prescribing information for all bisphosphonates, but the agency issued the alert because of "a sizable number of additional reports of severe bone, joint, and/or muscle pain in patients taking a variety of bisphosphonates" since a 2005 report on the problem.

The agency cautions that "the association between bisphosphonates and severe musculoskeletal pain may be overlooked, delaying diagnosis, prolonging pain and/or impairment, and necessitating the use of analgesics."

In the 2005 report of 112 patients who developed pain described as "extreme" and "disabling," the connection to bisphospho-

nates was not made as doctors attributed the symptoms to underlying osteoporosis (*Archives of Internal Medicine* 2005;165:346).

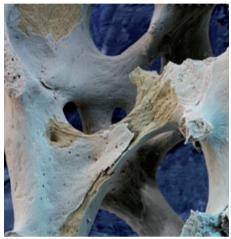
In most patients, pain resolved when treatment was stopped, but others obtained only partial or delayed relief. The risk factors for developing pain are unknown.

The agency distinguished severe musculoskeletal pain from a spontaneously resolving acute phase reaction "characterized by fever, chills, bone pain, myalgias, and arthralgias," which can occur initially with intravenous bisphosphonates or with once weekly or once monthly doses of oral formulations.

The agency recommends that healthcare professionals consider "temporary or permanent discontinuation of the drug" in patients who develop pain, adding that it will issue further recommendations in six months.

In a statement to the *BMJ*, the agency said that the reports number in the "hundreds" while "hundreds of thousands" of patients take bisphosphonates. But it continued: "The absence of a significant increase in . . .

pain in subjects treated with bisphosphonates *vs* placebo in controlled trials does not exclude the possibility that bisphosphonates are associated with these symptoms [since] clinical trials included highly screened, relatively healthy patients who are treated for limited durations."



Osteoporotic bone showing reduction in bone mass

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BMA says inadequate sanitation is a global crisis

Peter Mozynski LONDON

Lack of adequate sanitation is a global crisis that is undermining all development efforts—and particularly efforts to reduce the number of children who die before their fifth birthday. That is the message from the BMA, which has dubbed sanitation

"the silent emergency."

It was described as "the last taboo of international development" and "the missing link in international health" at a briefing held this week.

BMA chairman Hamish Meldrum said: "In developing countries, thousands of children are dying every day due to lack of adequate sanitation and basic hygiene. Governments must take action now on this vital area of international development."

The United Nations declared 2008 as the International Year of Sanitation to accelerate progress for 2.6 billion people worldwide who lack access to proper sanitary facilities.

"Access to sanitation is deeply connected to virtually all the millennium development goals, in particular those involving the environment, education, gender equality, and the reduction of child mortality and poverty," according to UN secretary general Ban Ki-moon. "42,000 people die every week from diseases related to low water quality and an absence of adequate sanitation. This situation is unacceptable."

The World Health

Organization estimates that each year 1.6 million children die of diarrhoea, and 88% of these deaths could be prevented by providing access to sanitation, safe water, and hygiene. Malnutrition caused by diarrhoea is an underlying factor in three million child deaths every year. Children in households with no toilet are twice as likely to get diarrhoea as those with such access.

Furthermore, 1.8 million children die every year of pneumonia, and half of these deaths could be prevented by the simple act of handwashing.

At any one time, people with diarrhoea and other water related diseases fill half the hospital beds in developing countries.

WaterAid, the charity leading the End Water Poverty campaign, points out that five times more children die every day from bad sanitation than from HIV/AIDS.



The World Bank says 21% of communicable diseases in India are water related

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