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## US consumer group asks FDA to ban drug for diabetes

**Janice Hopkins Tanne** NEW YORK

Public Citizen, a US national consumer advocacy group, has petitioned the US Food and Drug Administration to ban the drug rosiglitazone (sold as Avandia), which is prescribed for type 2 diabetes.

The group said that liver failure, often fatal, was a newly documented risk with the drug, which is made by GlaxoSmithKline. Previously the drug had been linked to an increased risk of heart attacks, heart failure, bone fractures, and eye problems, Public Citizen said.

The drug now carries a “black box” warning from the FDA, saying that it may cause heart attacks and congestive heart failure (*BMJ* 2007;334:1237).

GlaxoSmithKline issued a statement saying it believed there to be no issue of liver safety with rosiglitazone. The company said that an external safety board reviewed liver problems that might be related to rosiglitazone. “As recently as July 2008,” the statement said, “this panel of experts continued to endorse a favorable hepatic safety profile for Avandia.”

Meanwhile the US Centers for Disease Control and Prevention has said that the number of new cases of diabetes in the US has almost doubled in the past decade, rising from about five cases per 1000 people to about nine per 1000 ([www.cdc.gov/mmwr](http://www.cdc.gov/mmwr)). About 90% of cases of diabetes were type 2.

In its petition to the FDA, Public Citizen said that toxicity associated with rosiglitazone was not outweighed by its benefits. It said that a working group with representatives from the American Diabetes Association and the European Association for the Study of Diabetes had unanimously advised against the drug.

GlaxoSmithKline said that “Avandia has been shown to be a safe and highly effective treatment for type 2 diabetes for the appropriate patient.” The safety and effectiveness of rosiglitazone, it said, had been shown in one of the largest clinical trial programmes ever undertaken for any drug, which included 52 000 patients.

Cite this as: *BMJ* 2008;337:a2401

## Patients told they can combine private drugs with NHS care

**Zosia Kmietowicz** LONDON

Patients in England will be able to top up their treatment with drugs bought privately and yet continue to receive NHS care, provided that they have their top-up treatment administered in a non-NHS setting, the health secretary announced this week.

The change in rules on top-up drugs, which has immediate effect, is part of a package of 14 recommendations made by Mike Richards, England’s national clinical director for cancer, in his review of copayments, all of which the government has accepted.

Taken together the new plans will reduce the number of people seeking private drug treatment from the estimated 5000 patients a year currently to a few hundred people, predicted Professor Richards.

New guidance, which is being sent to all trusts and commissioners in England, says that patients may pay for additional private health care while continuing to receive care from the NHS but that there should be no risk of the NHS subsidising their private care. Patients who opt to buy drugs privately will need to pay for any predictable related costs, such as antiemetic drugs, heart scans, and pharmacy and nursing costs, although any unpredictable costs, such as from side effects of drugs, will be covered by the NHS.

The health secretary, Alan Johnson, asked Professor Richards in June to review the rule after increasing complaints from patients who were unable to access cancer drugs not approved by the National Institute for Health and Clinical Excellence (NICE) for use on the NHS and who were forced to pay for all of their care privately if they chose to buy additional drug treatments (*BMJ* 2008;336:1455).

The situation was aggravated by the fact that some trusts used a loophole in the rules to allow patients to buy the drugs while continuing to receive NHS care, leading to variable practices around the country (*BMJ* 2008;337:a2112).

Primary care trusts are also to be sent guidance to help them decide on exceptional



EDWARD HIRST/REX

**Health secretary Alan Johnson said the new measures will bring “greater clarity, greater fairness and . . . greater access to a wider range of drugs”**

cases, so that “if a patient is denied access to a particular treatment,” said Mr Johnson, “the reasoning behind that decision is both transparent and consistent.”

New proposals will see NICE set out a new timetable to speed up the appraisal of all new drugs. It is expected that in 2009 draft or final guidance will be available within six months of a drug being licensed for about half of the drugs being appraised through the fast track programme; by 2010 the six months deadline will apply to all new cancer drugs.

A new system for appraising expensive drugs designed to extend the end of life is also being put forward by NICE.

Mr Johnson also announced that he would be working closely with the drug industry on new and more flexible pricing arrangements that will increase patients’ access to new drugs.

Professor Richard’s report, *Improving Access to Medicines for NHS Patients*, is at [www.dh.gov.uk](http://www.dh.gov.uk).

Cite this as: *BMJ* 2008;337:a2418

## NICE publishes osteoporosis guidance after more than six

Zosia Kmietowicz LONDON

The UK National Institute for Health and Clinical Excellence (NICE) has published final guidance on the use of drugs for the primary and secondary prevention of osteoporotic fractures in postmenopausal women.

The guidance recommends a range of treatments, depending on a woman's age, her bone density, and how many indicators of fragile bones or risk factors for fracture she has.

It recommends alendronic acid as the first line treatment for primary prevention in women aged 70 or over who are given a diagnosis of osteoporosis and who have a clinical risk factor for the condition or an indicator of low bone density.

NICE defines a diagnosis as a T score of  $-2.5$  or below on dual energy x ray absorptiometry scanning, although it says that women aged over

75 with two or more risk factors for fracture or low bone density can be assumed without a scan to have osteoporosis.

Risk factors for osteoporosis are defined as a parental history of hip fracture, alcohol intake of four or more units per day, and rheumatoid arthritis. Indicators of low bone density include low body mass index ( $<22 \text{ kg/m}^2$ ), untreated menopause, and medical conditions such as ankylosing spondylitis, Crohn's disease, and conditions that result in prolonged immobility, says NICE.

If women cannot take alendronic acid, it recommends risedronate sodium and disodium etidronate as second line treatments, with strontium ranelate as a third line agent if these drugs are contraindicated or cannot be tolerated.

For women who have had a fracture and a diagnosis of osteoporosis, raloxifene is recommended along with strontium ranelate as a third line agent if first and second line treatment with alendronic acid and the other recommended bisphosphonates has failed or is unsuitable.

In addition, teriparatide is recommended if none of the other secondary prevention treatments can be tolerated. This drug is also a possible alternative treatment for women who have had another fracture while taking alendronic acid, risedronate, or etidronate for one year and who have further loss of bone mass.

Juliet Compston, professor of bone medicine at the University of Cambridge School of Clinical Medicine and Addenbrooke's Hospital, said that while "it was good that NICE had produced something on osteoporosis after six and a

## Only a minority of patient safety incidents are reported

Adrian O'Dowd MARGATE

Only 5-10% of serious incidents in the NHS with the potential to compromise patients' safety are actually reported, a Labour MP said last week.

Witnesses giving evidence to MPs on the parliamentary health select committee last week admitted that under-reporting of patient safety incidents was significant but defended the system.

Committee members, who were taking evidence for their inquiry into patient safety, asked witnesses from the Department of Health and the National Patient Safety Agency how much harm the NHS did to patients.

Martin Fletcher, the agency's chief executive, said that statistics from his organisation's national reporting and learning system (covering England and Wales) for 2007-8 showed that 796 142 patient safety incidents were reported by staff. Two thirds (66%) of the total number were reported as causing no actual harm to patients, and around 1%—or around 10 000 incidents—were associated with severe harm to patients or death.

But the committee member Howard Stoaite, Labour MP for Dartford, said that health department and safety agency estimates of the number of serious adverse events were much higher than those quoted by Mr Fletcher. Rather than the official 3200 deaths caused by a safety incident in 2007-8, the estimated

number was more like 72 000 deaths, he said.

"That isn't just under-reporting—that is an extraordinary figure," said Dr Stoaite. "I think if the public realised that only between 5% and 10% of preventable deaths are being reported, they might have something to say about that."

Mr Fletcher said, "If you look at the overall trend in reporting, it is upwards."

The committee's chairman, Kevin Barron, Labour MP for Rother Valley, asked why reporting of patient safety incidents was not mandatory.

Bruce Keogh, medical director of the NHS in England, also giving evidence, said that reporting "relies on an individual's personal moral and professional responsibility to report," adding that it tended to be from the two ends of the spectrum, with the very important events being reported as well as the "annoying and irritating trivia."

"It's the tranche in the middle that are poorly reported," Sir Bruce said, "for a variety of reasons, but mainly because people don't recognise the value of reporting incidents like that. If this sort of thing were made mandatory there is a risk that it could simply switch off a slow and growing tendency to report the mid-range events."

The inquiry continues.

Cite this as: *BMJ* 2008;337:a2384

See **FEATURE**, p 1082

## Treasure chest of medicine past

Zosia Kmietowicz LONDON

This medicine chest, which belonged to Sir Stuart Thriepland, the personal physician of Bonnie Prince Charlie, is among the artefacts on display at the library at the Royal College of Physicians of Edinburgh ([www.rcpe.ac.uk](http://www.rcpe.ac.uk)). The chest is part of the Sibbald Library project, named after Sir Robert Sibbald, whose donation of "three shelves of books" helped create the library in 1682. The aim of the project is to raise funds to improve access to the rare and historical collection.

Cite this as: *BMJ* 2008;337:a2415



## years of consultation

half years, there are a number of significant shortcomings with the guidance.”

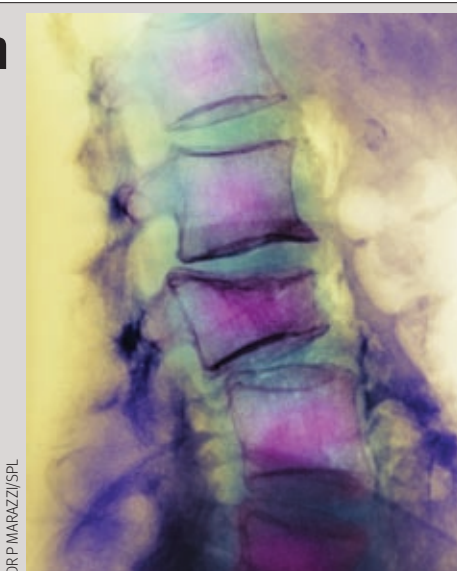
She said that men have been excluded from the guidance, which has also failed to include people whose bone density may be affected by taking steroids.

Professor Compston was part of an expert panel, the National Osteoporosis Guideline Group, that launched its own guidelines on managing the condition last month (*BMJ* 2008;337:a2204, 21 Oct).

The charity the National Osteoporosis Society criticised NICE's guidance for being overly complex, inflexible, and unethical and called for a completely fresh appraisal of osteoporosis treatments.

NICE's guidance can be seen at [www.nice.org.uk](http://www.nice.org.uk).

Cite this as: *BMJ* 2008;337:a2397



DR P. MARAZZI/SPL

Coloured x ray side view of the lumbar spine showing vertebral damage from osteoporosis

## Audit has lacked a national strategy and cooperation from GPs

Lisa Hitchen LONDON

Clinical audit in England has been neglected and under-resourced but should now move to centre stage, the chairman of the National Clinical Audit Advisory Group, an advisory body to the NHS, told auditors at a conference in London this week.

The group was set up to strengthen the existing programme of national clinical audits, to pull funding from those that do not work, and to support local staff involved in auditing. It will also guide the National Clinical Audit and Patient Outcomes Programme.

Nick Black, the group's chairman, said that current spending on education of healthcare professionals is £2.4bn (€3bn; \$3.8bn) and research expenditure by the National Institute of Health Research alone is £800m but that only £8m is spent nationally on clinical audit.

“If the main intention of all these activities is to improve quality of care,” he said, “I don't think that reflects the power and the ability of these different activities.”

Clinical audit has lacked a national strategy and a clear programme of activity, meaning that inconsistent practice has occurred across England at both a national and local level, added Professor Black, professor of health services research at the London School of Hygiene and Tropical Medicine.

A lack of representation “at the centre,”

mixed experiences of audit in trusts—with little discussion on the topic at board level—and a lack of funding, support, and understanding meant that clinical audit had been given lower priority than other core professional activities.

Sometimes it was hard to get cooperation from GPs, some conference delegates said. Martin Ferris, head of clinical audit and effectiveness for Sheffield Primary Care Trust, said, “Independent contractors [general practitioners] have a contract, and it does not say they will audit what the PCT or what the NHS wants them to audit. If we want them to do a national diabetes audit, in my area I will get 5-10% of practices who will say: ‘I'm not doing that.’”

Bruce Keogh, medical director of the NHS, said that the time was ripe for a renewed focus on audit. Drivers for change included the health minister Ara Darzi's next stage review of the NHS and greater awareness among patients.

“There is no going back,” he said. “We have unleashed a series of changing attitudes among ourselves and the public.”

The Darzi review had shown that many different groups were involved in carrying out audit, Sir Bruce said, but standards did not always mean the same thing to them, so quality outcomes were not always aligned.

Changes to improve audit would include a new role for the National Institute for Health and Clinical Excellence (NICE).

More information on the National Clinical Audit Advisory Group is at [www.advisorybodies.doh.gov.uk/ncaag](http://www.advisorybodies.doh.gov.uk/ncaag).

Cite this as: *BMJ* 2008;337:a2422

## Delaying HIV treatment increases risk of mortality

Bob Roehr WASHINGTON, DC

Delaying the start of antiretroviral treatment in people with a CD4 T cell count of between 351 and 500 raises the risk of mortality by 70%, concludes an as yet unpublished analysis of data from 22 HIV cohort studies in the United States and Canada.

Opinions on when to start treatment for HIV have oscillated between “hit it early, hit it hard”—which came into vogue with the advent of highly active antiretroviral therapy (HAART) in the mid-1990s—and retrenchment to a more cautious approach as the side effects of HAART became more evident.

The pendulum began to swing back to more aggressive treatment with the approval of newer drugs that were more tolerable and carried fewer long term risks. The findings from this new study are likely to lead to earlier intervention.

The North American AIDS Cohort Collaboration on Research and Design focused on a group of patients with an intermediate CD4 T cell count of 351-500, where the controversy has been the fiercest. US and European

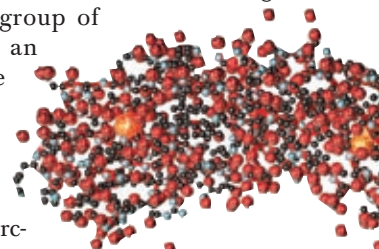
treatment guidelines strongly recommend that those with a count at 350 or below be started on a regimen.

The trial identified 2473 patients (8358 person years) who had begun treatment with HAART in the period 1996 to 2006 and an additional 5901 (16 636 person years) whose treatment was deferred in the same period, excluding those who had previously been on treatment or experienced an AIDS defining illness. The findings were clear: patients whose HAART was deferred had a mortality relative hazard 1.7 times that of patients whose treatment wasn't deferred.

“These data strongly support the use of antiretroviral treatment for patients at a CD4 count of 500 and below, regardless of the presence of symptoms,” said the lead author, Mari Kitahata, from the University of Washington Center for AIDS Research.

Cite this as: *BMJ* 2008;337:a2369

Molecular model of the CD4 glycoprotein found on the surface of T cells (above)



ANIMATE4.COM/SPL

## IN BRIEF

**NICE must reveal model used to assess drug for Alzheimer's:** The National Institute for Health and Clinical Excellence has lost the final stage of its legal fight against a court ruling that it must release a copy of the computer model used in its decision to restrict the use of donepezil for Alzheimer's disease. On 29 October the House of Lords refused to hear a last ditch appeal against a ruling from the Court of Appeal last May that NICE must supply the model to two drug companies that are challenging the refusal to recommend the £2.50 (€3.15; \$4) a day drug to NHS patients in the early stages of the disease.

**CDC recommends flu vaccine for all children over 6 months old:**

The US Academy of Pediatrics and the Centers for Disease Control and Prevention (CDC) say that children aged between 6 months and 18 years should be vaccinated against flu every year, because of their higher risk of complications. Children vaccinated for the first time need two jabs: one to prime the immune system and one to provide immunity, says the CDC.

**Man dies after inhaling anthrax:** A drum maker has died in hospital in east London after inhaling anthrax spores from imported animal skins he had been handling. Fernando Gomez, aged 35, had been in the intensive care unit of Homerton Hospital for over a week. The Health Protection Agency said it was trying to trace the origin of the infected skins.

**Immunisation saves 3.4 million lives in poor countries:** A progress report by the Global Alliance for Vaccines and Immunisation (GAVI), which includes the World Health Organization and Unicef, says that 3.4 million premature deaths will be averted in poor nations as a result of immunisation programmes funded between 2000 and 2008. By the end of 2008 a cumulative 213 million children will have been reached by its programmes in 76 countries.

**NICE is to decide details of pay scheme for GPs:** England's health department has launched a consultation exercise on the GP quality incentive scheme, which determines about a third of GPs' income. Under the new proposals the National Institute for Health and Clinical Excellence would oversee the annual process of reviewing clinical indicators known as the quality and outcomes framework (QOF).

Cite this as: *BMJ* 2008;337:a2411



US senators Chuck Grassley (left) and Herb Kohl (right) are investigating links between doctors and industry

## US senators inquire into ties between cardiac device makers and doctors

Janice Hopkins Tanne NEW YORK

Two US senators have asked the non-profit Cardiovascular Research Foundation and Columbia University to clarify their financial relations with manufacturers of cardiac devices such as stents.

Chuck Grassley, senior Republican member of the Senate Committee on Finance, and Herb Kohl, chairman of the Senate Special Committee on Aging, have been investigating links between the medical drug and device industry and influential doctors for several years (*BMJ* 2008;337:a2088, 16 Oct).

The senators sent letters to Lee Bollinger, president of Columbia University, and Gregg Stone, chairman of the Cardiovascular Research Foundation, who is also a professor at Columbia. They asked for information by 30 October.

The senators asked Mr Bollinger for information about payments to 22 doctors affiliated to the university's medical centre. They asked for the source of each payment, what it was for (such as continuing medical education, honorariums, or research support), the amount, and the annual total each doctor received from 2003 to the present.

In their letter to the foundation the senators wrote, "Our Committees have been investigating various aspects of the

pharmaceutical and medical device industries, including consulting arrangements and industry funding for Continuing Medical Education (CME)."

The letter also said that both senators sponsored the Physician Payments Sunshine Act, which calls for disclosure of financial relations between drug and device manufacturers and doctors.

The senators asked the foundation how much it had received from device companies or foundations set up by the companies from 2003 to the present.

The foundation's 2006 tax return (available at [www.guidestar.org](http://www.guidestar.org)) lists 2006 revenue of \$47.2m (£29m; €37m).

The university said it would respond to the senators' letter. "It is important to note that Columbia University and its Medical Center have conflict of interest policies and procedures in place and we expect that they are followed by all members of the faculty," the university's statement said.

In its statement the foundation also said it would comply with the senators' request. It said, "CRF is an independent, non-profit organization dedicated to improving the survival and quality of life for people with heart disease.

Cite this as: *BMJ* 2008;337:a2363

## FDA warns Bayer about illegally marketing

Zosia Kmietowicz LONDON

The German drug giant Bayer has been sent warning letters by the US Food and Drug Administration for illegally marketing and "misbranding" two of its products.

Bayer Women's Low Dose Aspirin with Calcium and Bayer Aspirin with Heart Advantage contain aspirin with either calcium or phytosterols in single tablets. They

are sold over the counter and labelled as helping to reduce the risk of heart disease and "fight" osteoporosis, but neither product has been approved by the FDA for these uses in the United States. The only approval they have is for use as an analgesic.

Because both products are labelled as a combination of a drug and dietary supplement in a single tablet the FDA requires

# Patient fails to get law on aiding suicide abroad clarified

Clare Dyer **BMJ**

A woman with multiple sclerosis has failed in a bid to force the director of public prosecutions for England and Wales to issue guidance clarifying whether her husband would face prosecution if he helped her travel to Switzerland for an assisted suicide.

Two senior judges at the High Court in London acknowledged that many people would regard such help as “something that the law should permit” but said that only parliament could change the law.

Debbie Purdy, 45, wanted Ken Macdonald, the director of public prosecutions, to outline the circumstances in which a helper might risk prosecution for aiding or abetting suicide in a country where assisted suicide is lawful. Assisting a suicide is a crime in the United Kingdom, carrying a possible prison sentence; but although around 100 people have travelled from the UK to Switzerland to end their lives, no relative or friend assisting them has so far been prosecuted.

Ms Purdy claimed that she would have to go to Switzerland earlier than she wanted to, while she was still able to make all the arrangements herself, unless she could be certain that her husband, Omar Puente,

would escape prosecution on his return to the UK after helping her.

Her barrister, David Pannick QC, argued that Sir Ken’s refusal to issue guidance breached Ms Purdy’s right to respect for her private and family life under article 8 of the European Convention on Human Rights. But Lord Justice Scott Baker and Mr Justice Aikens ruled that article 8 did not apply to Ms Purdy’s case. As the House of Lords decided in the earlier case of Diane Pretty, who had motor neurone disease, it covers a person’s life but not the way that life is ended.

In any event, they said, the convention lays down a right for the state to infringe an individual’s rights under article 8 if this is done “in accordance with the law.” Even if the law against assisted suicide had infringed Ms Purdy’s rights under article 8, the scope of prosecutors’ discretion as to whether to prosecute, and the manner of exercising it, could be regarded as being “in accordance with the law,” the judges said.

They concluded: “We cannot leave this case without expressing great sympathy for Ms Purdy, her husband, and others in a similar position who wish to know in advance whether they will face prosecution for . . .



BEN STANSALL/GETTY IMAGES

**Debbie Purdy has said the lack of clarity in the law may force her to end her life sooner than she wants**

[helping] a loved one to go abroad to end their suffering when they are unable to do it on their own.

The judges granted Ms Purdy permission to take her case to the Court of Appeal, but her chances of success on appeal are slim, and the case is likely to go eventually to the European Court of Human Rights in Strasbourg.

Cite this as: *BMJ* 2008;337:a2368



## Exhibition captures the power of humanitarian action and the human spirit

Zosia Kmietowicz **LONDON**

Richard Ofei (left) and Richard Opentil fight for the ball during football practice in Accra, Ghana. The photograph, by the Canadian Olivier Asselin, can be seen in an exhibition organised by Médecins du Monde UK.

The UK arm of the international

humanitarian aid organisation is running the 11th Luis Valtueña awards for photographs that capture the horror and desolation of war but also the beauty and power of humanitarian action. Listings for the exhibition can be seen at [www.medicinsdumonde.org.uk](http://www.medicinsdumonde.org.uk).

Cite this as: *BMJ* 2008;337:a2419

## two over the counter combination products containing aspirin

them to be regulated as a drug. In addition, because heart disease and osteoporosis need to be diagnosed and supervised by a health-care professional, the FDA says that the drugs cannot be sold over the counter.

“The FDA considers these products new drugs, and thus they must undergo the FDA’s drug approval process,” said Mike Chappell, the agency’s acting associate commissioner

for regulatory affairs.

“The FDA will take enforcement action against manufacturers found to be violating the law or attempting to circumvent the drug approval process,” he said.

The FDA has also ruled that the two products are misbranded, because their labels do not carry adequate warnings about safety. In letters to Bayer the FDA describes the labelling

as sending consumers “a mixed message about the purpose of the product.”

Helmut Schaefer, head of communications at Bayer, said that the company is reviewing the letters and will respond to the FDA by the 17 November deadline. He added, “The company stands behind the products and the claims made in them.”

Cite this as: *BMJ* 2008;337:a2402

# Doctor is sued for comments on potential migraine device

Clare Dyer *BMJ*

A leading British interventional cardiologist who was a joint principal investigator in a clinical trial of a device made in the United States is being sued for libel and slander in the English courts by the manufacturer. The case concerns comments attributed to him about the trial that were posted on a US based news website for heart specialists.

NMT Medical, which is based in Boston, Massachusetts, makes the STARFlex septal repair implant. The company has launched the legal action against Peter Wilmshurst, a consultant cardiologist at the Royal Shrewsbury Hospital. Dr Wilmshurst and a headache specialist from King's College London, Andrew Dowson, led the Migraine Intervention with STARFlex Technology (MIST) trial in the United Kingdom to study the effect of the device on migraine (*Circulation* 2008;117:1397-404).

The company is suing over an article published in October 2007 by Heartwire, an online cardiology news service ([www.the-heart.org](http://www.the-heart.org)). Dr Wilmshurst gave an interview



Dr Wilmshurst had a "moral duty" to make the information public

to a Heartwire journalist, Shelley Wood, at the transcatheter cardiovascular therapeutics meeting in Washington, DC, in 2007.

The MIST trial was launched in early 2005 to study whether using the STARFlex device to close a hole between the right and left atriums of the heart—patent foramen ovale—would reduce the incidence of migraine, particularly migraine with aura.

Migraine is relatively common among people who have right to left shunts, which allow blood to

flow from the right to the left atrium; and those who have had shunts closed for other reasons have reported a reduction in the frequency and intensity of migraines.

The published results of the trial were negative. Dr Wilmshurst, who supported the idea that closing such shunts might affect migraine, later put forward several ideas why the results were negative, with which the company disagreed.

He suggested that in some cases the device might not have sealed off the shunts and that some of the patients might not have been properly screened, with the result that they

were included in the trial, even though they did not actually have patent foramen ovale.

Two members of the steering committee, Dr Wilmshurst and Simon Nightingale, also of the Royal Shrewsbury Hospital, were not listed as authors of the study. They had been offered coauthorship but refused because they were not allowed access to the whole data set.

In his 90 page defence to the libel action, filed at the High Court in London, Dr Wilmshurst admits making some, though not all, of the comments attributed to him but says that his statements were true and made in the public interest.

NMT Medical's solicitor, Robert Barry, told the *BMJ* that the company disagreed with Dr Wilmshurst's statements but did not want to comment and would be producing a detailed answer by 25 November, the date fixed by the High Court. The company is also seeking an injunction to restrain Dr Wilmshurst from repeating his comments.

Dr Wilmshurst admits telling Ms Wood that some of the data he had seen were "internally inconsistent and mathematically impossible." He says he also told her that one theory for the MIST trial's failure was the possibility that a high rate of residual shunts remained among patients who had supposedly had their patent foramen ovale closed.

He admits saying that his review of the echocardiograms suggested that the rate of residual shunts was approximately one

## "Humanitarian corridor" for medical aid, food, and water is

Peter Moszynski *LONDON*

United Nations peacekeepers are escorting a convoy of urgent medical supplies across the frontline in the east of the Democratic Republic of Congo, in an attempt to prevent mass outbreaks of disease among hundreds of thousands of people displaced by recent fighting.

Paul Garwood, of the World Health Organization's department for health action in crises, said that up to a million people were affected by the crisis and that WHO was "reacting aggressively" by intervening with emergency supplies in a response to the immediate healthcare needs of the affected people.

He said, "This region of DRC [Democratic Republic of Congo] is endemic for a range of illnesses, and the fear is that the massive displacement of people could exacerbate these health risks." Thus an immediate priority was to strengthen surveillance and monitoring activities, he said.

Medical aid has been prioritised ahead of food aid because widespread outbreaks of cholera and malaria have already occurred, and the health authorities fear that worse is to come. The World Food Programme is also sending an emergency assessment team.

After a fact finding mission to the region alongside the French foreign minister, Bernard Kouchner, the UK foreign secretary, David Miliband, said, "There is no excuse for turning away.

"The immediate needs are obvious. We saw them yesterday. The ceasefire last Wednesday needs to be bolstered. The humanitarian needs for food, shelter, water, and health care must be met through universal provision and secure routes for delivery. This requires local and international cooperation."

The region, on the border of the Democratic Republic of Congo and Rwanda, has been beleaguered by fighting and ethnic tension since the mass influx of Hutu



third of the total, although Dr Dowson told the Washington conference that the residual shunt rate was only 6%. It was possible, Dr Wilmshurst alleged, that some of the patients enrolled in the trial may not have been properly screened and may not have had a patent foramen ovale.

Further investigation could have determined whether residual shunting was in fact a problem with STARFlex, he told her, but he had not been allowed access to the full data set. If it was a problem, he said, “that information needs to be in the public domain” and would have “much larger implications for STARFlex, a device already marketed in Europe for the treatment of cryptogenic stroke.”

His solicitor, Mark Lewis of the law firm George Davies, argues in Dr Wilmshurst’s defence that he was “under a social, moral, and ethical duty” to make the information public and that the cardiologists and other healthcare professionals who read the Heartwire article had a legitimate interest in receiving the information.

The defence alleges that the libel action is “highly oppressive and unconscionable” and intended to “bully” him into silence.

Richard Davis, NMT Medical’s vice president and chief financial officer, said that the company did not want to comment on pending litigation. “He’s making these comments, they’re not new, and we believe they’re inaccurate and inappropriate.”

Cite this as: *BMJ* 2008;337:a2412

## Rape victim is stoned to death as violence sweeps Somalia

Peter Moszynski LONDON

A 13 year old girl was publicly stoned to death last week in Somalia, as a new upsurge in violence and piracy threaten to disrupt humanitarian assistance to hundreds of thousands displaced by fighting in the country.

Aisha Ibrahim Duhulow was killed on 27 October by a group of 50 men who stoned her to death in a stadium in the southern port of Kismaayo, an area recently recaptured by Islamist insurgents, in front of around 1000 spectators.

She was accused of adultery, in breach of Islamic law, but her father and other sources told Amnesty International that she had in fact been raped by three men.

After the rape her family attempted to report it to the al-Shabab militia, who control Kismaayo, and it was this act that resulted in her being accused of adultery. None of the men she accused of rape was arrested.

David Copeman, Amnesty International’s Somalia campaigner, said: “This was not justice, nor was it an execution. This child suffered an horrendous death at the behest of the armed opposition groups who currently control Kismaayo.”

“This killing is yet another human rights abuse committed by the combatants to the

conflict in Somalia,” said Mr Copeman, “and again demonstrates the importance of international action to investigate and document such abuses, through an international commission of inquiry.”

Amnesty International reports that “an escalating wave of attacks on humanitarian workers, peace activists, and human rights defenders” has been sweeping the country.

The news of the stoning came just before the publication this week by Amnesty of a new report on Somalia, which says that at least 40 Somali human rights defenders and humanitarian workers were killed between 1 January and 10 September this year.

The report warns that this violence has resulted in “the further deterioration of human rights and humanitarian conditions for the majority of the population.”

It says: “The restrictions on the freedom of humanitarian agencies to deliver emergency humanitarian services—food, shelter and essential medical services—form one of the leading factors contributing to widespread malnutrition and death from starvation or preventable diseases throughout the area.”

*Attacks on Aid Workers and Rights Defenders in Somalia* is available at [www.amnesty.org.uk](http://www.amnesty.org.uk).

Amnesty International is holding an event to discuss human rights in Somalia on 11 November at 7 pm at the Amnesty International UK Human Rights Action Centre, 17-25 New Inn Yard, London EC2A 3EA. To book a seat email [jennifer.scott-taggart@amnesty.org.uk](mailto:jennifer.scott-taggart@amnesty.org.uk).

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## vital in Congo, says UK foreign secretary David Miliband

Displaced people walk through a field as they return home in Kibumba, north of Goma in eastern Congo



refugees in the aftermath of the 1994 genocide in Rwanda. The latest insurgency by some 10 000 rebels led by General Laurent Nkunda is backed by a large number of Tutsis in the region, who are intimidated by the continuing activities of the Hutu militias and looting by the Congolese armed forces.

“Our message was that the world is watching,” Mr Miliband said. “Everyone is haunted by the memories of the 1990s. All sides have to live up to their stated responsibilities. It is vital we maintain the ceasefire and get a humanitarian corridor open.”

Hospitals and clinics in the area have been looted, and the UN believes that a number of camps for internally displaced people have been deliberately targeted by the rebels, creating tens of thousands of additional refugees. The UN has appealed for all sides to respect the camps and the humanitarian assistance.

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